THE CSTE WASHINGTON REPORT

Marcia S. Mabee, MPH, PhD
Editor
11479 Waterview
Reston, Virginia 20190
mmabee@ix.netcom.com
703-709-3001

April 13, 2006 Volume 10, Number 8

INSIDE THIS ISSUE

EDITOR'S NOTE: The Agency for Healthcare Research and Quality (AHRQ) released a report April 11 acknowledging that while health information technology has been shown to improve quality of care for patients, most health care providers need more information about how to implement these technologies successfully. AHRQ is helping to fill this gap with findings from more than 100 projects across the country. These projects make up AHRQ's $166 million health IT initiative ---– 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 FAILS TO ACT ON BUDGET – The U.S. House of Representatives failed to take up its version of the FY 2007 Budget Resolution before adjourning for the two week Easter recess because leadership could not muster enough votes to pass it. The Committee-passed measure includes $1 billion in cuts to health programs. This follows over $1 billion in cuts in FY 2006. Public health advocacy groups, working together with education groups, have been urging House Members to vote against the Budget Resolution unless it includes $7 billion in additional funding for health, education and training programs. The Senate successfully adopted an amendment to its Budget Resolution last month, on a vote of 73-27, to add $7 billion for these activities. Advocacy groups are working with Moderate Republicans in the House, led by Rep. Mike Castle (R-DE), to add the $7 billion in funding through a substitute amendment. The House returns on April 25th.

CSTE PARTICIPATES IN SENATE ROUNDTABLE – On April 5th, Secretary-Treasurer of the CSTE Executive Committee, Eddy Bresnitz, MD, participated in a Senate Bioterrorism and Public Health Preparedness roundtable discussion on the topic: All-Hazards Medical Preparedness and Response. A brief summary of the roundtable is provided below:

Participants:
Panel I –
John Agwunobi, MD; Assistant Secretary for Health, DHHS
Ellen Embrey; Deputy Assistant Secretary for Defense for Force Health Protection and Readiness; Director, Deployment Health Support
Lawrence Deyton, MSPH, MD; Chief, Public Health & Environmental Hazards Officer, U.S. Department of Veterans Affairs

Panel II –
Thomas Inglesby, MD; Chief Operating Officer and Deputy Director, Center for BioSecurity, University of Pittsburgh Medical Center
Richard Serino; Chief of Department, Boston Emergency Medical Services
Eddy Bresnitz, MD, MS; Deputy Commissioner/State Epidemiologist, Public Health Services Branch, New Jersey Department of Health and Senior Services
Rob Gougelet, MD; Director of Emergency Preparedness, Dartmouth-Hitchcock Medical Center

General description: Subcommittee Chairman Richard Burr (R-NC) presided and conducted most of the questioning. He was joined briefly during the first panel of federal witnesses by Sen. Orrin Hatch (R-UT) and Sen. Tom Harkin (D-IA). Both Senators Hatch and Harkin tended to focus on how volunteer physicians, nurses, and others could be better utilized in regional or national disasters and received witness comments on the need for a credentialing process, more coordination, etc. Sen. Harkin would like to create a training program for non-working nurses and nurses aides, etc. so they can be ready to be enlisted in the case of a flu pandemic.

Sen. Burr focused on the capacities of the federal system to assist state and local jurisdictions with surge capacity needs. Dr. Agwunobi stressed that disasters are local in

nature, communities are organized differently and the federal government really cannot dictate, but rather can merely assist. Sen. Burr countered that there has to be some underlying standard of public health preparedness/readiness for every locality. Ms. Embrey described the effort that the DoD makes to be ready to assist state and local jurisdictions if asked to help and Dr. Deyton described the on-going interaction the VA system, which is in virtually every major community, has with local medical/health systems. He said the VA routinely plans to make 500 staffed beds available to the private sector health system in the case of a disaster or for military needs. Dr. Deyton also said that DHHS, DHS, DoD, and the VA are currently working together on what they could do collectively to provide surge capacity in the event of a flu pandemic.

Sen. Burr said the Subcommittee is interested in accountability for the dollars being spent on preparedness as well as effectiveness. The Subcommittee is planning a tour of the Gulf Coast area to assess lessons learned from Katrina. He said that the focus of Louisiana's preparedness had been on developing surge capacity, while the focus of Mississippi's preparedness funding had been on emergency response and exercising that response with strikingly different results when disaster (Katrina) hit. He said choice may not be appropriate, we may know enough to require that a certain approach to readiness be adopted.

Ms. Embry commented at one point that one area where the Subcommittee and the federal government could impose standards was disease surveillance. She then said surveillance in states was not uniform, not timely, no standards, etc. Sen. Burr responded that the Subcommittee had heard a lot about surveillance in a recent roundtable discussion and they were going to re-think their approach.

During the second panel Eddy Bresnitz summarized his prepared statement and provided additional information about the 2001 anthrax attack in New Jersey and how the state health department worked with the CDC swat team to address the incident even though at that time state resources for that kind of an investigation and response were minimal. He then said that TOPOFF-3 in 2005, although virtual, had not gone as well in some regards. He described the scenario that resulted in an expectation that the state would provide antibiotics for plague exposure to the entire population of the state in a 24 hour timeframe using local post offices and postal employees as the distribution mechanism. He concurred with the federal panel that communities differ and incidents differ and each requires a different approach – one size does not fit all. Since surveillance had been brought up, Eddy also said that CSTE and public health epidemiologists feel that disease surveillance is best and most appropriately done at the state and local level. Sen. Burr repeated that the Subcommittee had heard a great deal about surveillance and that they were taking several steps back in their approach to drafting provisions.

During questioning, Sen. Burr talked about a vision for public health and asked to what standards should local public health be held. Dr. Bresnitz said that public health practice standards already exist and many local health departments were doing assessments to identify strengths and weaknesses, but not all were equally proficient or resourced. Dr. Bresnitz also indicated that once local health departments identified deficiencies, there

was the question of what resources would be provided to bridge the gaps and raise practices to, or above, a minimal floor of standards.

Sen. Burr also seemed to praise the idea of using the postal service as a way to distribute antibiotics. Dr. Bresnitz said he had learned from the anthrax experience that the U.S. Postal Service has very sticky management/labor relations and despite postal leadership assurances, postal employees might not be willing to deliver antibiotics. Sen. Burr replied that the Subcommittee had really "drilled down" about distribution and felt they understood the issues involved.

SURVEILLANCE AND LEGISLATIVE ISSUES – In response to repeated questions from both House and Senate Committees and Subcommittees with jurisdiction over homeland security and bioterrorism preparedness, CSTE has developed a Q and A on Surveillance and the way the current Nationally Notifiable Infectious Diseases system works. The fact sheet and an accompanying letter expressing CSTE's concerns about interest by some Members of Congress in federalizing and mandating the current system, has been provided to Senators Hagel (R-NE), Burr (R-NC) and Kennedy (D-MA) and Representative Terry (R-NE).

H5N1 AVIAN FLU VIRUS VACCINE INDUCES IMMUNE RESPONSES IN HEALTHY ADULTS -- Results from a clinical trial demonstrate that high doses of an experimental H5N1 avian influenza vaccine can induce immune responses in healthy adults. Approximately half of those volunteers who received an initial and a booster dose of the highest dosage of the vaccine tested in the trial developed levels of infection-fighting antibodies that current tests predict would neutralize the virus. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, funded the study, published in the current issue of *The New England Journal of Medicine*. Preliminary results from this trial were first disclosed late last summer.

"These findings represent an important step forward in the nation's efforts to prepare for the possible emergence of a human pandemic of H5N1 avian influenza," notes NIH Director Elias A. Zerhouni, M.D.

"We are working hard to address the many challenges that remain with regard to the development of an H5N1 vaccine," adds NIAID Director Anthony S. Fauci, M.D. "For example, potentially protective immune responses were seen most frequently at the highest dose of this vaccine. We are investigating other options that may allow us to reduce the dosage — for example, adding an immune booster, or adjuvant, to the vaccine — so we can achieve a more practical immunization strategy." In addition, the U.S. Department of Health and Human Services is pursuing other approaches to an H5N1 vaccine, including vaccines made in cell cultures rather than grown in eggs.

H5N1 avian influenza viruses are of enormous concern to public health officials worldwide. The potential for a human avian flu pandemic looms large, say experts, as daily reports indicate an increasing spread of infection in bird populations in Southeast Asia, Europe, the Middle East and Africa. According to the World Health Organization,

as of March 24, 2006, 186 people had been infected with avian flu viruses, and more than half of them had died.

Generally, flu viruses are easily transmitted from person to person, but so far, the H5N1 avian influenza viruses have not demonstrated this characteristic. In the worst-case scenario, if an avian flu virus became easily transmissible from person to person, it could trigger an influenza pandemic because humans have no pre-existing immunity to these viruses.

The trial, conducted between March and July 2005, was carried out at three NIAID-supported Vaccine and Treatment Evaluation Units located at the University of Rochester Medical Center in Rochester, NY; the University of Maryland School of Medicine Center for Vaccine Development in Baltimore; and the Los Angeles Biomedical Research Institute at Harbor–University of California Los Angeles Medical Center. John Treanor, M.D., of the University of Rochester, led the group.

The study was conducted in two stages. In the first stage, the research team enrolled 118 healthy adults ages 18 to 64 years old. Each participant was assigned at random to one of five groups. Volunteers in each group received an initial dose of vaccine (7.5 micrograms [mcg], 15 mcg, 45 mcg or 90 mcg) or saline placebo into the upper arm muscle; about one month later, they received a booster shot of the same vaccine dosage or the placebo. The research team collected blood samples before each vaccination and one month after the second vaccination.

Before the study could be expanded, an independent Data and Safety Monitoring Board assessed the vaccine's safety by reviewing data collected through day 7 after the second vaccination; no safety concerns were found. The investigators then began stage two of the study, eventually enrolling an additional 333 healthy adult volunteers into the trial according to the same protocol design as in stage one.

The *NEJM* article describes an analysis of data on the safety and immune responses to the vaccine. In general, the higher the dosage of vaccine, the greater the antibody response produced. Of the 99 people evaluated in the 90-mcg, high-dose group, 54 percent achieved a neutralizing antibody response to the vaccine at serum dilutions of 1:40 or greater, whereas only 22 percent of the 100 people evaluated who received the 15-mcg dose developed a similar response to the vaccine.

Generally, all dosages of the vaccine appeared to be well tolerated:

* Almost all reported side effects were mild
* The second dose of vaccine did not cause more local or systemic symptoms than the first
* Systemic complaints of fever, malaise, muscle aches, headaches and nausea occurred with the same frequency in all dosage groups as in the placebo group
* Lab tests did not reveal any clinically significant abnormalities

The vaccine, made from an inactivated H5N1 virus isolated in Southeast Asia in 2004, was manufactured by sanofi pasteur, Swiftwater, PA, under contract to NIAID. Because there are no manufacturers licensed in the United States to use adjuvants in inactivated influenza vaccines, NIAID's first step was to test an H5N1 influenza vaccine made in a way that mimics the process used to make conventional flu vaccines. The clinical data collected in this study are now available to support the potential use of this vaccine should it be needed for an emerging pandemic.

NEW INFORMATION WILL HELP HEALTH CARE PROVIDERS ADOPT HEALTH IT -- The Agency for Healthcare Research and Quality (AHRQ) released a report April 11 acknowledging that while health information technology has been shown to improve quality of care for patients, most health care providers need more information about how to implement these technologies successfully. AHRQ is helping to fill this gap with findings from more than 100 projects across the country. These projects make up AHRQ's $166 million health IT initiative.

The report, *Costs and Benefits of Health Information Technology*, is a synthesis of studies that have examined the quality impact of health IT as well as the costs and organizational changes needed to implement health IT systems. This report reviews scientific data about the implementation of health IT to date, as documented in studies published through 2003. It does not project future health care benefits or savings, in contrast to other reports.

The authors conclude that scientific reviews have shown significant improvements in the quality of health care utilizing health IT systems. However, these successes have occurred primarily within large health care systems that created their own health IT systems and devoted substantial commitment and resources to these efforts. AHRQ's initiative is developing data needed about how to put health IT to work in more common health care settings such as physicians' offices and hospitals.

"HIT has the potential to enable a dramatic transformation in the delivery of health care, making it safer, more effective, and more efficient," the report concludes. "However, widespread implementation of HIT has been limited by a lack of generalizable knowledge about what types of HIT and implementation methods will improve care and manage costs for specific health organizations."

Large health care organizations and health plans have been leaders in health IT. The report points out that, by contrast, the smaller medical practices and hospitals that constitute the majority of the nation's health care providers have limited technological expertise and must depend on the purchase of commercial systems. Data about health IT implementation in these settings has been very limited, according to the report.

As a result, a predominant portion of health care providers in America have not had the information they need to calculate the impact of health IT implementation on their organizations.

"Health care providers need reliable information that tells them what they can expect when they implement health IT systems," said AHRQ Director Carolyn M. Clancy, M.D. "Leading institutions in health IT have shown that these systems can produce improved quality and patient safety. But smaller practices and hospitals need to know how these improvements can be achieved in settings like theirs, using the kinds of commercial systems they are likely to employ. AHRQ's health IT initiative is designed to generate and share the kind of information providers need."

Dr. Clancy said AHRQ's health IT initiative will help deliver this kind of information. The $166 million initiative includes more than 100 projects where health IT systems are being implemented, with an emphasis on systems in community-based health care settings, using commercially available systems. The AHRQ initiative was launched in September 2004, and most projects have 3-year duration.

The AHRQ-sponsored research will yield scientifically valid information that will share the experiences of typical providers in implementing health IT systems. This includes both the impact on quality and safety of care as well as the organizational impact of implementing health IT systems.

"AHRQ's initiative is a real-world laboratory, showing how health IT can be used successfully in typical health care settings," Dr. Clancy said. "The experiences of our grantees will be shared broadly to help all health care providers more successfully adopt health IT."

Findings from the AHRQ projects are being made available through the AHRQ National Resource Center for Health Information Technology, at http://www.healthit.ahrq.gov.

The report released April 11 was prepared by the Southern California Evidence-based Practice Center-RAND Corporation, one of 13 evidence-based practice centers supported by AHRQ. Another study released last year by a separate group of RAND researchers estimated that wide adoption of electronic medical records and other health IT could save more than $81 billion annually and improve the quality of care.

The report was requested and funded by AHRQ and the Office of the Assistant Secretary for Planning and Evaluation. The Office of Disease Prevention and Health Promotion also provided financial support. Others requesting the report were HHS' Centers for Medicare & Medicaid Services and the Leapfrog Group, an organization of health care purchasers.

The report is available at http://www.ahrq.gov/downloads/pub/evidence/pdf/hitsyscosts/hitsys.pdf (PDF file, 570 KB; PDF Help). In addition, an interactive database providing access to the studies reviewed as part of the report will be available at http://healthit.ahrq.gov/tools/rand.

An article summarizing the report will be published in the May 16 edition of *Annals of Internal Medicine*. It also will be available starting April 11 at http://www.annals.org/cgi/content/full/0000605-200605160-00125v1.

ELDERLY HAVE HIGHER RISK FOR CARDIOVASCULAR, RESPIRATORY DISEASE FROM FINE PARTICLE POLLUTION -- New data from a four-year study of 11.5 million Medicare enrollees show that short-term exposure to fine particle air pollution from such sources as motor vehicle exhaust and power plant emissions significantly increases the risk for cardiovascular and respiratory disease among people over 65 years of age. The study, funded by the National Institute of Environmental Health Sciences, a component of the National Institutes of Health, is the largest ever conducted on the link between fine particle air pollution and hospital admissions for heart- and lung-related illnesses.

The study results show that small increases in fine particle air pollution resulted in increased hospital admissions for heart and vascular disease, heart failure, chronic obstructive pulmonary disease, and respiratory infection. "The data show that study participants over 75 years of age experienced even greater increases in admissions for heart problems and chronic obstructive pulmonary disease than those between 65 and 74 years of age," said National Institutes of Health Director Elias A. Zerhouni, M.D.

The National Institute of Environmental Health Sciences and the U.S. Environmental Protection Agency provided funding to researchers at the Johns Hopkins Bloomberg School of Public Health for the study. The study results are published in the March 8, 2006 issue of the Journal of the American Medical Association.

According to the study, these findings document an ongoing threat from airborne particles to the health of the elderly, and provide a strong rationale for setting a national air quality standard that is as protective of their health as possible.

"These findings provide compelling evidence that fine particle concentrations well below the national standard are harmful to the cardiovascular and respiratory health of our elderly citizens," said NIEHS Director David A. Schwartz, M.D. "Now that the link between inhaled particles and adverse health effects has been established, we must focus our efforts on understanding why these particles are harmful, and how these effects can be prevented."

Fine particle air pollution consists of microscopic particles of dust and soot less than 2.5 microns in diameter - about thirty times smaller than the width of a human hair. These tiny particles primarily come from motor vehicle exhaust, power plant emissions, and other operations that involve the burning of fossil fuels. Fine particles can travel deep into the respiratory tract, reducing lung function and worsening conditions such as asthma and bronchitis.

The researchers based their fine particle analysis on 11.5 million Medicare enrollees who lived in 204 U.S. counties with populations larger than 200,000. Using billing records for

1999 to 2002, they tracked daily counts of hospital admissions for eight major outcomes - heart failure, heart rhythm disturbances, cerebrovascular events such as stroke or brain hemorrhage, coronary heart disease, peripheral vascular disease or narrowing of the blood vessels, chronic obstructive pulmonary disease, respiratory infection, and injury.

The investigators obtained daily measurements of fine particle concentrations from a network of air monitoring stations provided by the Environmental Protection Agency's Aerometric Information Retrieval Service. The average fine particle concentration for the 204 counties over the three-year period was 13.4 micrograms per cubic meter of air, slightly below the national air quality standard of 15 micrograms per cubic meter for an annual average.

"When we analyzed the data for heart failure, we observed a 1.28 percent increase in admissions for each 10 microgram per cubic meter increase in fine particle pollution," said Francesca Dominici, Ph.D., an associate professor of biostatistics with the Johns Hopkins Bloomberg School of Public Health and lead author on the study. "Most of these admissions increases occurred the same day as the rise in fine particle concentration, which suggests a short lag time between the change in pollution and the subjects' response."

The data also showed that the risk for air pollution-related cardiovascular disease was highest in counties located in the Eastern United States. "Identifying the various factors that might contribute to these differences between eastern and western regions is a very complex question that we must address," said Dominici.

According to Dominici, fine particles pose a significant health problem because they penetrate deep into the lungs, and some may even get into the bloodstream. "Now that we know that inhaled particles can affect cardiovascular and respiratory health, we must identify the specific characteristics of fine particles that produce these adverse health effects," she said. "In the meantime, these findings underscore the need for a national air quality standard that adequately protects the respiratory health of our citizens."