THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE:.When the President signed an executive order last Friday giving public health officials authority to quarantine SARS patients if necessary to halt spread of the potentially deadly disease, the role of public health in protecting the nation from spread of dangerous infectious diseases was underscored. Although SARS cases in the United States have not produced the same casualties as those in Asia and Canada, the President's action brought home the need to be fully prepared. Public health

professionals across the country are key players in establishing and maintaining front line defenses against new and unexpected disease outbreaks, and the President's action reinforces that role as the nation comes to terms with the disease risks in a global economy.

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 RECONCILE BUDGET DIFFERENCES – The House and Senate are expected to finalize and pass the conference report reconciling their widely differing Budget Resolutions today. The Senate BR contains $350 billion in tax cuts while the House contains the full tax cut amount requested by President Bush: $726 billion. Since Senate, and some House, Moderates refuse to support any conference report with more than $350 billion in tax cuts, and House conservatives refuse to accept much less than $626 billion, one likely outcome is separate reconciliation instructions to the respective tax writing committees who will then be forced to compromise differences without the protections of a 60 vote margin afforded in the Budget Resolution process. Meanwhile, the discretionary portion of the Budget Resolution must also be reconciled. Budget experts expect the President's number of $784 billion will prevail along with the various function allocations. Health discretionary spending received a $2.8 billion boost over FY 2003 levels on the Senate floor, but with the House coming in $1.4 billion below FY 2003, the compromise is likely to be the President's request level, which provides zero increase over FY 2003 for public health programs.

HOUSE AND SENATE RECONCILE SUPPLEMENTAL APPROPRIATIONS – The House and Senate are also working on reconciling differences in the just passed FY 2003 supplemental appropriations bills (H.R. 1559/S. 762) prior to the start of the Easter recess which begins tomorrow, April 11th. At stake is funding for smallpox compensation in the event authorizing legislation is passed. The House bill provides $50 million in funding while the House provides $35 million. The authorizing legislation, based largely on the Administration's proposal, with some compromises on overall caps for temporary disability, is making slow progress with a greased House floor vote failing badly, and a Senate HELP Committee effort winning only on a party-line vote spelling probable doom for a Senate floor vote without additional compromises. A key difference between the Republican and Democratic bills is mandatory versus appropriated funding for the compensation fund. Other items in the supplemental appropriations bill: assistance to state and local health departments for incurred smallpox vaccination costs – the House includes $94 million and the Senate $105 million. CDC is provided in both bills with an additional $16 million to address the costs/needs associated with SARS.

PATIENT SAFETY BILL INTRODUCED -- A Senate Patient Safety and Quality Improvement Act (S. 720) was introduced March 26th by Senator Jeffords, with Senators Frist, Breaux and Gregg as original co-sponsors. The bill has been referred to the Senate HELP

Committee. Two similar bills have made good progress in the House: H.R. 663 passed the House on March 12th and H.R. 877 has been voted out of the Ways and Means Committee and has been placed on the Union Calendar, a legislative mechanism for quick passage of non-controversial bills. The two House bills are largely complimentary and reflect the jurisdictions of the House Energy and Commerce and Ways and Means Committees. All three bills have provisions that require the HHS Secretary to develop or adopt voluntary national standards promoting the interoperability of information technology systems involved with health care delivery. A summary of S. 720 bill is as follows:

Patient Safety and Quality Improvement Act - Amends the Public Health Service Act to make patient safety data privileged and confidential. Excludes such data from subpoena, discovery, disclosure under the Freedom of Information Act (FOIA), evidentiary use, or any credentialing or licensing situation. Permits disclosures necessary to the proper management and administration of the patient safety organization, including maintenance of a patient's medical record, in a disciplinary proceeding relating to a provider, or as needed by the Food and Drug Administration for regulatory purposes.

Authorizes the establishment of a database for non-identifiable patient safety data, consistent, if practicable, with the administrative simplification provisions of the Social Security Act.

Authorizes technical assistance, including annual meetings for patient safety organizations.

Requires the Secretary of Health and Human Services to develop or adopt voluntary national standards promoting the integration of health care information technology systems.

Requires the Secretary to contract for and report to Congress on a study assessing the impact of medical technologies and therapies on patient safety and benefit, health care quality and costs, as well as productivity growth.

Directs the Attorney General to survey and report to Congress on State laws and their interpretation as they relate to patient safety data peer review systems.

SECRETARY OF HEALTH AND HUMAN SERVICES COMMENTS ON EXECUTIVE ORDER ON QUARANTINABLE DISEASES –"The President on April 4 signed an executive order adding SARS to the list of quarantinable communicable diseases under the Public Health Service Act. The president signed the order after he received a detailed briefing on SARS from myself, Dr. Julie Gerberding of the Centers for Disease Control and Prevention (CDC) and Dr. Anthony Fauci of the National Institutes of Allergy and Infectious Diseases.

"By amending the list, we are simply taking the pragmatic step of readying all options as we continue to tackle this disease. This authority would only be used if someone posed a threat to public health and refused to cooperate with a voluntary request. We're working to be prepared for any eventuality.

"The Department of Health and Human Services, particularly the scientists at the CDC, remains pro-active in addressing SARS. We continue to monitor those coming into the

United States from Asia, isolating those who are showing symptoms of SARS and providing them with medical care, informing those who may have been exposed to SARS what to do if they get symptoms, and personally following up with those who may have been exposed.

“Symptoms include coughing, fever and shortness of breath. Individuals with these symptoms who have recently returned from travel to mainland China, Hong Kong, Vietnam or Singapore should see a health care provider and inform them of their travel history. Clinicians should continue to report such cases to their state health department or the CDC.”

CDC ACCEPTS ACIP'S RECOMMENDATIONS FOR ADDITIONAL EXCLUSION CRITERIA FOR SMALLPOX VACCINATION PROGRAM --The Advisory Committee on Immunization Practices (ACIP) held a special meeting by conference call on Friday, March 28, 2003, to make recommendations to the Centers for Disease Control and Prevention (CDC) regarding cases of cardiac adverse events that have been reported following smallpox vaccination.

The ACIP recommended that persons be excluded from the pre-event smallpox vaccination program who have known underlying heart disease, with or without symptoms, or if they have three or more known major cardiac risk factors -- hypertension, diabetes, hypercholesterolemia (high cholesterol) and smoking.
Today, CDC informed states that the agency has accepted the ACIP’s recommendations and that the vaccination program will continue. CDC has distributed revised pre-vaccination clinic education materials which reflect the new exclusion criteria.

THE MAGNITUDE OF MATERNAL MORBIDITY DURING LABOR AND DELIVERY, UNITED STATES, 1993-1997 – In the April issue of the American Journal of Public Health the first report of maternal morbidity during labor and delivery was released with the following findings:

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* During the study period (1993-1997), almost 4 million women annually gave birth. About 43 percent of these women had some kind of maternal morbidity, which is defined as a condition that has an adverse impact on a woman’s physical health during childbirth, beyond what would be expected in a normal delivery.

* Maternal morbidity is a serious public health problem affecting nearly 1.7 million women annually. It can have an impact on fetal and infant health and can lead to maternal death.

* Much maternal morbidity is preventable, and many conditions can be managed to prevent death.

Methodology

* Data for this study came from the National Hospital Discharge Survey, the major source of data on inpatient use of short-stay hospitals in the United States.
* This study examined a total of 154,001 records of vaginal and cesarean deliveries, representing 19,081,038 deliveries during 1993-1997.
* The study analyzed three categories of maternal morbidity:

1. obstetric condition—a condition caused by the pregnancy itself or by its management
2. preexisting medical condition—an underlying condition that may be aggravated by the pregnancy
3. cesarean delivery—a major surgical procedure

Key Findings

* Overall, 30.7 percent of women who gave birth (nearly 1.2 million women annually) had an obstetric complication, a preexisting medical condition, or both.
* Overall, 43 percent of women (nearly 1.7 million women annually) had some kind of maternal morbidity—this includes the conditions mentioned above plus cesarean delivery.
* Of the 1 million women who had at least one obstetric complication, the most common problems were third- and fourth-degree lacerations, other obstetric trauma including cervical lacerations and pelvic trauma, preeclampsia and eclampsia, gestational diabetes, genitourinary infection, postpartum hemorrhage, and amnionitis.
* The most common preexisting medical condition was chronic hypertension.
* Even though some conditions were relatively rare, they nonetheless affected thousands of women. For example, only 0.1 percent of women experienced eclampsia during childbirth. However, that translated into nearly 4,000 women who had this life-threatening condition every year.

Implications and Potential for Prevention

* The magnitude of the problem of maternal morbidity during labor and delivery is greater than has been recognized previously. This is the first study to describe the extent of the problem.
* Even though the prevalence of any specific problem may be low, the overall burden of morbidity is high. Only 57 percent of women had a delivery with no maternal morbidity.
* Primary prevention is possible for some complications. For others, the goal is appropriate management to prevent them from becoming severe or even life-threatening.
* Continued monitoring of this problem is important. For example, as the average age of women who give birth rises, it will be helpful to track complications associated with preexisting medical conditions
* National, state, and local policies should address the needs of women during pregnancy, including the gaps in prevention programs and research.

To request a copy of the article, call Kelly Carr at 770-488-5131.

HHS TO TEST USE OF HANDHELD DEVICE NETWORK FOR TRANSMITTING URGENT INFORMATION ABOUT BIOLOGICAL AGENTS TO CLINICIANS -- HHS Secretary Tommy G. Thompson March 21 announced that HHS will begin testing a system using handheld personal digital assistants (PDAs) for transmitting urgent information about biological agents to clinicians. The three-month pilot test of the PDA network is designed to gauge the best ways for federal officials to communicate effectively with front-line clinicians in the event of a bioterrorist attack. The project will evaluate how and when clinicians download this urgent information and whether they find it useful to receive it via their PDAs.

"This important new project will allow us to harness the power of technology to communicate with many of the doctors, nurses, and other clinicians who will be called on to diagnose and treat patients quickly in the event of a bioterrorist attack," Secretary Thompson said. "This will literally allow them to have critical information at their fingertips when they need it most."

The project will evaluate the use of a system created by ePocrates, the nation's largest physicians' handheld network, for sending an urgent "Doc Alert" message to more than 700,000 front-line clinicians, including more than 250,000 physicians—more than 40 percent of the practicing physicians in the United States. The test message will contain a special memo on the highest threat (category A) biological diseases/agents, which include anthrax, botulism, plague, smallpox, tularemia and viral hemorrhagic fevers, including Ebola. The message will also include Web links for clinicians to go to for additional information about diagnosing and treating the conditions caused by the biological agents. Clinicians will be able to save this information to their PDAs for future reference.
The pilot project will be managed by HHS' Agency for Healthcare Research and Quality (AHRQ) and is designed to complement the Centers for Disease Control and Prevention's existing Health Alert Network, which was created in 1998 and is used by the Department to communicate directly with more than 25,000 public health officials in the 50 states, eight U.S. territories and seven large cities.

The ePocrates pilot project is being conducted under the auspices of the Council on Private Sector Initiatives to Improve the Security, Safety, and Quality of Health Care (http://www.cpsi.ahrq.gov), which was established in 2002 to ensure that HHS responds systematically and consistently to technological products or ideas proposed by private organizations or individuals that could improve public health/bioterrorism preparedness. This project is the first one to have been accepted and funded through this new initiative. The Council is staffed by AHRQ.

EPA ISSUES GUIDELINES FOR WATER UTILITIES ON GUARDING AGAINST TERRORIST AND SECURITY THREATS --The Environmental Protection Agency's Office of Water April 4 announced that suggested measures for drinking water and wastewater systems to guard against terrorist and security threats have

been issued. These measures are consistent with the Department of Homeland Security's color-coded advisory system beginning with green, which denotes low risk of terrorist/security threats and increasing in seriousness through blue, yellow, orange (current level) and red.

Water utilities are included in the 13 critical sectors identified by the Department of Homeland Security as potential targets of attack. The Agency took a two-pronged approach in disseminating these precautionary measures. First, through the Association of State Drinking Water Administrators each state's drinking water program managers and staff will receive these guidelines and will determine how best to coordinate these measures with other instructions developed by the state. This EPA document is intended to be complementary and does not override or replace the states' guidance.

The states will distribute these water-related measures to the water utilities within their jurisdiction, either in the original form developed by EPA or revised to be consistent with states' system. Second, these guidelines have been posted on the Internet at a secure, password-protected site, available to drinking water utilities only, that provides information to water utilities on a variety of critical water infrastructure protection activities.

FDA APPROVES EXPANDED USE OF HPV TEST -- The Food and Drug Administration (FDA) March 31 approved expanded use of a laboratory test to detect the presence in women of human papillomavirus (HPV), one of the most common sexually transmitted infections**.**

There are more than 100 types of HPVs. The test, the HC2 High-Risk HPV DNA Test, manufactured by Digene Corp., of Gaithersburg, Md., can identify 13 of the high-risk types associated with the development of cervical cancer. The HPV DNA test does not test for cancer, but for the HPV viruses that can cause cell changes in the cervix. If left untreated, these changes can eventually lead to cancer in some women.

FDA initially approved the HPV DNA test in March 2000 for testing women who had abnormal Pap test results to determine whether they needed to be referred for further examination. The new indication allows the test to be used for screening, in conjunction with the Pap test, of women over age 30 for HPV infection. It should be used along with the Pap test, a complete medical history and an evaluation of other risk factors to help physicians determine what kind of follow-up is necessary.

“Knowing whether or not a woman is infected with high-risk HPV is added information that will help physicians detect and treat early cell changes that might eventually lead to cervical cancer,” said FDA Commissioner Mark B. McClellan, M.D., Ph.D. “FDA is committed to bringing safe and effective new technologies to the market quickly.”
Up to 20 percent of the sexually active U.S. population is believed to be infected with HPV at any one time. Most women who become infected with HPV are able to eradicate the virus and suffer no apparent long-term consequences to their health. But a few women

develop a persistent infection that can eventually lead to pre-cancerous changes in the cervix.

The HPV DNA test, like the Pap test, is performed by collecting cells from the cervix and then sending them to a laboratory for analysis. The test detects high-risk types of HPV in cell DNA even before there are any conclusive visible changes to the cervical cells. Women who have normal Pap test results and no HPV infection are at very low risk (0.2%) for developing cervical cancer. Women who have an abnormal Pap test and a positive HPV test are at higher risk (6%-7% or greater) of developing cervical cancer if not treated.

FDA approved the expanded use of the test based on published literature describing studies of a cross section of women with normal and abnormal Pap test results who tested positive or negative for high-risk types of HPV. FDA also took into account additional input from professional societies, FDA advisory panel members and other interested parties in arriving at a decision.

The HPV DNA test is not intended to substitute for regular Pap screening. Nor is it intended to screen women under 30 who have normal Pap tests. Although the rate of HPV infection in this group is high, most infections are short-lived and not associated with cervical cancer.

Some 50 million women get Pap tests annually in the United States. According to the American Cancer Society, in 2003, 12,200 women will be diagnosed with cervical cancer and 4,100 will die from the disease. With proper screening, cervical cancer is avoidable and, if caught early, curable.