THE CSTE WASHINGTON REPORT

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

July 29, 2004 Volume 8, Number 15

INSIDE THIS ISSUE

EDITOR'S NOTE: The National Institute of Allergy and Infectious Diseases, one of the National Institutes of Health, has expanded its clinical trial of an experimental West Nile virus (WNV) treatment to about 60 sites throughout the United States and Canada. The multicenter trial, which opened at 36 sites last September, is expected to add about 24 new sites this summer, pending internal approval at each institution. The study is testing the safety and preliminary effectiveness of using a product containing WNV infection-fighting proteins, or antibodies, to treat people whose infection has reached or threatens to reach the brain -- 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

LEGISLATIVE UPDATE – Heath Information Technology -- In response to the Bush Administration's announcement on July 21st of a 10 year plan to transform the delivery of health care by building a new health information infrastructure (see story

below) Congress held hearings and Senators Gregg (R-NH), Sessions (R-AL) and Frist (R-TN) introduced friendly legislation (S. 2710). At a July 14 hearing of the House Subcommittee on Technology, Information Policy, Intergovernmental Relations and the Census entitled ``Health Informatics: What is the Prescription for Success in Intergovernmental Information Sharing?,'' Claire V. Broome, M.D., Senior Advisor to the Director for Integrated Health Information Systems, Centers for Disease Control and Prevention, Department of Health and Human Services testified along with former Speaker of the House of Representatives Newt Gingrich of Georgia. Mr. Gingrich is a strong proponent of speeding up development of widespread use of the electronic medical record and other health information technology improvements. **BioShield –** President Bush signed Project BioShield 2004 into law on July 21. The law amends the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures. **Youth Suicide** – On July 8th, in a surprisingly swift process, a bipartisan group of Senators, led by Senator Dodd (D-CT) introduced and then passed a bill to support planning, implementation, and evaluation of organized activities involving statewide youth suicide early intervention and prevention strategies. The bill provides a modest amount of grant money to the Substance Abuse and Mental Health Services Administration ($3 million in FY 2005, $4 million in FY 2006 and $5 million in FY 2007) to be provided to eligible states and private entities with preference given to those states with the highest rates of youth suicide. A companion bill, with bipartisan support, was introduced in the House on July 9th (H.R. 4799). **Public Health Workforce –** On July 7th, Senators Hagel (R-NE) and Durbin (D-IL) introduced the Public Health Preparedness Workforce Development Act of 2004. The bill establishes a scholarship and loan repayment program for public health preparedness workforce development to eliminate critical public health preparedness workforce shortages in Federal, State, and local public health agencies. ASTHO, NACCHO, the Association of Schools of Public Health, and CSTE have endorsed the bill. The sponsors do not expect activity on the legislation in the 108th Congress, but plan to reintroduce the bill in the 109th Congress. Below is Sen. Durbin's statement in the Congressional Record on the bill's introduction:

Mr. DURBIN. Mr. President, today I am introducing, along with my colleague Senator *Hagel*, legislation that will help to address the severe workforce shortages within public health agencies throughout the United States. This bill, known as the Public Health Preparedness Workforce Development Act of 2004, provides financial help to both full and part-time students who are interested in pursuing a career in public health at Federal, State and local public health agencies.

Our Nation faces myriad public health threats and challenges, ranging from emerging diseases such as West Nile virus and SARS to the special needs of an aging population, from bio-terrorism to obesity, tobacco use and environmental hazards. The ability of the public health system to prevent, respond to, and recover from these challenges depends

on adequate numbers of well-trained public health professionals in Federal, State, and local public health departments.

However, our public health system has an aging staff nearing retirement and there are not enough students graduating with training in public health disciplines to provide a consistent source of skilled employees to fill the void. The average age of the public health workforce is 47, 7 years older than the average age of the Nation's workforce. The ratio of public health workers to overall population has dropped from 219/100,000 in 1980 to 158/100,000 in 2000. There are already shortages of public health nurses, epidemiologists, environmental health workers, health educators and other public health professionals at Federal, State and local public health agencies. In my home State of Illinois, the Illinois Department of Public Health estimates that they are in need of at least 15 epidemiologists and are having trouble filling those positions.

Further evidence suggests that as much as 50 percent of the current public health workforce at the State level will be retiring in the next 5 years. Losing so many experienced public health workers at a time when the public health workforce should be expanding to meet increased needs presents a clear argument in favor of encouraging more students to enter the many academic fields related to public health such as epidemiology, health education, nursing and environmental health.

To continue to improve the health of our people, we must have a well-trained and dedicated public health workforce. But developing and maintaining the necessary human capital is already a challenge and promises to continue to be a challenge in the future. Our bill would help alleviate this dangerous shortfall of public health professionals by providing scholarships or loan repayments for full and part-time students in public health and for workers with previous public health training who agree to serve at the Federal, State and local level.

The scholarship program will provide scholarships to eligible graduate, undergraduate and community college students to pursue a course of study to prepare to serve in the public health workforce.

The loan repayment program is designed to help pay for education loans incurred by individuals currently employed or about to be employed in a Federal, State or local public health agency.

The grants for the loan repayment program to political jurisdictions at the State and local level will provide funds to the appropriate agencies to operate the loan repayment program.

The bill is supported by the Association of State and Territorial Health Officials, the National Association of City and County Health Officials, the American Public Health Association, and the Council of State and Territorial Epidemiologists.

HHS LAUNCHES "DECADE OF HEALTH INFORMATION TECHNOLOGY" -- HHS Secretary Tommy G. Thompson July 21 released the first outline of a 10-year plan to transform the delivery of health care by building a new health information

infrastructure, including electronic health records and a new network to link health records nationwide. At the same time, he announced a number of new action steps to help advance health information technology immediately

"America needs to move much faster to adopt information technology in our health care system," Secretary Thompson said as he released the action report ordered by President Bush. "Electronic health information will provide a quantum leap in patient power, doctor power, and effective health care. We can't wait any longer."

The plan, prepared by the new National Coordinator for Health Information Technology, David J. Brailer, M.D., Ph.D., lays out the broad steps needed to achieve always-current, always-available electronic health records (EHR) for Americans. EHR systems would also enable physicians and other health professionals to electronically tap into a wealth of treatment information as they care for patients. The report was released in Washington, D.C., at a Secretarial Summit on Health Information Technology bringing together the nation's technology and health leaders.

"Health information technology can improve quality of care and reduce medical errors, even as it lowers administrative costs," Secretary Thompson said. "It has the potential to produce savings of 10 percent of our total annual spending on health care, even as it improves care for patients and provides new support for health care professionals." At the same time, security and privacy of electronic medical records would be improved over protections of paper-based records, Secretary Thompson said. And health information technology also offers much greater access and control of health records by consumers themselves.

Secretary Thompson announced he would appoint a special Leadership Panel to assess total costs and benefits of health information technology and report to him by fall. He also announced efforts underway to develop private sector certification for health information technology products. And he said HHS will begin reviewing the feasibility of a private sector consortium to plan and develop a new nationwide network for health information.

In addition, Secretary Thompson announced Medicare plans to create an Internet portal allowing beneficiaries to access their personal Medicare information. And he said Medicare will accelerate regulations for e-prescribing of drugs in order to quickly disseminate common standards. He also announced new grants to help develop information exchanges in nine communities, adding that $50 million more in seed funding will be provided to five states this fall, with plans doubling the investment in 2005.
President Bush in April called for electronic health records for most Americans within 10 years. In an executive order, he created the new Office of the National Coordinator for Health Information Technology, and in May, David J. Brailer, M.D., Ph.D., was appointed to the new position.

Goals and Strategies

The report, *"The Decade of Health Information Technology: Delivering Consumer-centric and Information-Rich Health Care,"* says federal leadership can help hasten efforts to be carried out by the private sector. The report identifies four major goals, with strategic action areas for each:

* Goal 1 - "Inform Clinical Practice:" Bringing information tools to the point of care, especially by investing in EHR systems in physician offices and hospitals.
* Goal 2 - "Interconnect Clinicians:" Building an interoperable health information infrastructure, so that records follow the patient and clinicians have access to critical health care information when treatment decisions are being made.
* Goal 3 - "Personalize Care:" Using health information technology to give consumers more access and involvement in health decisions.
* Goal 4 - "Improve Population Health:" Expanding capacity for public health monitoring, quality of care measurement, and bringing research advances more quickly into medical practice.

In addition, the report identifies potential policy options for providing incentives for EHR adoption. The health sector has been slow to invest in EHRs, with only 13 percent of hospitals reporting they had the systems in 2002, and 14 to 28 percent of physicians' practices. Some incentive options to be reviewed include:

* regional grants and contracts to stimulate EHRs and community information exchange systems;
* improving availability of low-rate loans for EHR adoption;
* updating federal rules on physician self-referral that may unintentionally restrict investment and networks;
* using Medicare reimbursement to reward use of EHRs;
* using demonstration projects to test new concepts in Medicare of "paying for performance" -- linking payments to quality of care rather than volume of services only.

The *Decade of Health Information Technology* report has been published and is available online the HHS Web site at www.hhs.gov.

NIAID EXPANDS WEST NILE VIRUS TREATMENT TRIAL -- The National Institute of Allergy and Infectious Diseases, one of the National Institutes of Health, has expanded its clinical trial of an experimental West Nile virus (WNV) treatment to about 60 sites throughout the United States and Canada. The multicenter trial, which opened at 36 sites last September, is expected to add about 24 new sites this summer, pending internal approval at each institution. A listing of all sites is available at http://www.casg.uab.edu/adult/act%20210WNV.htm.

The study is testing the safety and preliminary effectiveness of using a product containing WNV infection-fighting proteins, or antibodies, to treat people whose infection has reached or threatens to reach the brain.

"As West Nile virus disease continues to spread across our country, it is critical that we develop specific treatments for its most severe symptoms," says Anthony S. Fauci, M.D., NIAID director. "At present, clinicians have few options besides supportive care for treating people with WNV illness. By expanding this study, we hope to accelerate NIAID's efforts to understand, develop treatments for and eventually prevent this disease."

Until recently, human infection with West Nile virus, which is spread by mosquitoes, was limited to Africa, Asia and the Middle East. Since its arrival in the New York City area in 1999, human WNV infection has increased in scope and severity in the United States each year. In 2003, the U.S. Centers for Disease Control and Prevention reported more than 9,860 cases of WNV disease, which included 264 deaths. Thus far in 2004, 78 cases of WNV, including 1 death, have been reported in eight states.
The main goal of this study, notes Walla Dempsey, Ph.D., who oversees NIAID's WNV clinical trial contracts, is to assess the safety of a blood plasma-derived substance containing WNV antibodies when given intravenously to patients with WNV infection. Secondarily, she adds, the study seeks preliminary data about the treatment's effectiveness against encephalitis, a brain inflammation caused by WNV infection. "Information from this study will enable us to better characterize the clinical course of West Nile virus infection," Dr. Dempsey says, "which in turn will allow us to design more meaningful clinical trials in the future."

The Israeli company Omrix is providing its product, Omr-IgG-am ™, for use in the trial. West Nile virus has circulated in Israel for decades, and many Israeli blood donors have antibodies to the virus. The company's product is based on WNV antibodies derived from Israeli donors who have high levels of these antibodies.

The trial can enroll up to 110 patients 18 years old and older who have WNV-related encephalitis or are who at risk of developing this severe neurological complication. Participants will receive a single dose of Omr-IgG-am™ or a dose of one of two placebos.
Participants are being recruited through NIAID's Collaborative Antiviral Study Group (CASG), headed by Richard Whitley, M.D., of the University of Alabama at Birmingham. Information about the trial is located both at CASG's Web site (www.casg.uab.edu) and at clinicaltrials.gov (http://www.clinicaltrials.gov/show/NCT00068055).

NEW DATABASE FOCUSES ON GENETIC POLICY AND LAWS -- The National Human Genome Research Institute (NHGRI), part of the National Institutes of Health (NIH), today unveiled a new Web-based resource that will enable researchers, health professionals and the general public to more easily locate information on laws and policies related to a wide array of genetic issues.

The NHGRI Policy and Legislation Database is located on NHGRI's Web site at www.genome.gov/LegislativeDatabase. The free, searchable database currently focuses on the following subject areas: genetic testing and counseling; insurance and employment

discrimination, newborn screening; privacy of genetic information and confidentiality; informed consent; and commercialization and patenting.

"This is a tremendous resource for anyone interested in learning more about the laws, regulations and policies pertaining to genetics and genomics. It will serve as a valuable tool for all Americans, from academic researchers seeking to patent genetic technologies to average citizens trying to determine what protections exist in their states against genetic discrimination," said NHGRI Director Francis S. Collins, M.D., Ph.D.

The resource features a convenient, interactive map of the United States that enables users to view state legislation and laws for any of the 50 states and the District of Columbia by simply clicking on that jurisdiction. Users also can search the database by keyword, content type, topic and/or source, and can also sort the information by date or citation.

The database, which will be updated on a regular basis, contains links to full-text copies of federal and state laws/statutes; federal legislative materials; and federal administrative and executive materials, including regulations, institutional policies and executive orders. Abstracts are also provided that summarize the government materials in lay language. The new database is managed by NHGRI's Office of Policy, Communications, and Education (OPCE), which develops policy related to the societal implications of human genome research. "This database fills a long-standing need in the genetic policy arena. It is literally a one-stop shop for anyone with an interest in this rapidly developing field," said OPCE Director Alan E. Guttmacher, M.D. "We think it will be of interest to a broad array of users, including legislators and policymakers at the local, state and federal levels."

In addition to federal and state laws, the database includes materials from these current and former federal agencies and advisory panels: Department of Health and Human Services (HHS), the Department of Health, Education and Welfare, the Equal Employment Opportunity Commission, the U.S. Patent and Trademark Office, the Secretary's Advisory Committee on Genetics, Health and Society and the President's Council on Bioethics.

This fall, NHGRI plans to add more categories of content to the database, primarily in the areas of foreign statutes and laws, foreign policy, treaty and international agreements, and policy material from international organizations.

UP TO $500 MILLION NEEDED ANNUALLY FOR SUBSIDY TO MAKE ARTEMISININ COMBINATION THERAPY THE FIRST-LINE TREATMENT FOR MALARIA WORLDWIDE -- Within the next five years, international organizations and world leaders should begin collectively to contribute $300 million to $500 million annually to create a global subsidy that would make new combination malaria treatments available to the world's poor for as little as 10 cents per treatment course, says a new report from the Institute of Medicine of the National Academies. Without significant investments in these new treatments -- called "artemisinin-based

combination therapies" (ACTs) -- the malaria mortality rate in Africa and Asia could double in a few decades as the drug now used most frequently is rendered useless by rapidly spreading resistance.

A centralized procurement agency should be established to buy ACTs from drug manufacturers at competitive prices using the subsidy funds and then resell them at substantially lower prices to public and private distribution organizations within countries where malaria occurs. The procurement agency could be either a new entity or a branch within an established organization, but initially procurement should be done by an existing organization with sufficient capacity, such as UNICEF. Conditions for participation should be placed on countries and drug manufacturers to ensure that the subsidized price actually reaches consumers and that use of single-drug therapies is discouraged. Combination therapies that contain both an artemisinin and one of several other antimalarial drugs should replace monotherapies as the first-line treatment for malaria, which is a leading killer of the poor, particularly in Africa, the report emphasizes.

"The widely used drug chloroquine likely will be useless within a relatively short time, making it all the more urgent that the global community provide significant subsidies to get ACTs into widespread use everywhere that malaria is endemic," said Kenneth J. Arrow, professor of economics, Stanford University, Stanford, Calif., and chair of the committee that wrote the report. "Artemisinins are extremely effective and apparently safe, and so far the malaria parasites have not developed resistance to them. No other currently available therapy has all the advantages of these drugs. Worldwide use of ACTs will enable us to halt and even reverse the rising death toll from malaria, while development of new and perhaps more effective remedies continues. But until ACTs are as affordable as chloroquine, impoverished people will continue to rely on cheaper, less effective drugs and on single-drug therapies. It is crucial that the world switches to combination therapies to prolong each individual drug's effectiveness and delay resistance."

The Case for a Global Subsidy

Over more than 50 years, low-cost chloroquine has saved millions of lives and cured billions of debilitating infections. Even in the poorest nations -- including many in Africa, where individuals frequently purchase their medicines themselves rather than receive them through public programs -- most people can afford chloroquine at its retail price of 10 cents per course of treatment. But because of rampant chloroquine resistance among the parasites that cause the disease, the death rates from malaria are increasing in Africa for the first time in decades. In sub-Saharan Africa alone, about 1 million children die from malaria each year.

Artemisinins, which are derived from a plant used in Chinese herbal medicine, have proved highly effective in treating malaria in Asia over the last 25 years, and resistance to these new drugs has not appeared so far, the report notes. In addition to quickly curing patients, artemisinins have reduced malaria transmission where they have been widely

used. However, ACTs currently cost about $2 per treatment course, which is beyond the financial reach of many developing nations and impoverished people, especially families of poor rural children, who are most likely to die from malaria.

The recommended $300 million to $500 million annual subsidy should put the price of ACTs in the range of 10 cents to 20 cents per course, providing enough medicine for several hundred million people around the world. The cost of ACTs should be no higher than the least expensive single-drug therapy, the report says; otherwise, individuals who buy their own medications will choose the cheaper option and perpetuate drug-resistance problems. Even at the subsidized prices, however, the poorest members of many societies still will need additional help to access the drugs.

Not all of the money for ACT subsidies would have to be "new," the report notes. For example, some of it could come from funds that organizations such as the World Bank's International Development Association already have earmarked for activities such as global health, poverty reduction, or other developmental programs, but have yet to spend. At the same time, money for subsidies should not be diverted from budgets for national or local initiatives to control the mosquitoes that transmit malaria.

The committee's proposed centralized procurement system would help keep prices low and production high by tapping multiple manufacturers. By creating a reliable market, the subsidy would spur more drug makers to begin producing ACTs. In addition, the procurement agency should monitor quality control in the drug-production process; create incentives for countries to follow prudent malaria-treatment policies; and provide technical assistance, such as helping countries to set up monitoring and evaluation systems and train regulators.

The procurement system should discourage use of single-drug therapies by requiring participating countries and drug distributors to avoid production of artemisinin-only treatments or any other single-drug treatment involving drugs that are or could be used in combination with artemisinins. The parasites that cause malaria eventually will develop resistance to any single therapy, even highly effective artemisinins, but they are much less likely to survive if a second effective antimalarial drug is simultaneously used. The use of artemisinins alone in the treatment of malaria is common in parts of Asia. If resistance to this class of drugs develops, mutated strains of malaria parasites will likely spread across national borders. Officials from the World Health Organization and the Global Fund to Fight AIDS, Tuberculosis, and Malaria also have embraced the combination approach in malaria control programs.

Evaluation and Research

Under the committee's proposal, countries that receive subsidized antimalarials through the procurement system would be expected to monitor how well public and private drug-distribution channels deliver the drugs to the people who need them. Information should be collected on such things as retail prices and whether products are in the original packaging when they reach consumers. Countries also should be required to track the

emergence of drug resistance, the report says. And nations that receive subsidized ACTs should be expected to educate the public about the new drugs and their proper use. To encourage ongoing development of new antimalarials, the committee added, governments and other organizations that support malaria-control activities should offer financial assistance to major research initiatives in this area -- such as the Medicines for Malaria Venture (MMV), WHO's Special Programme for Research and Training in Tropical Diseases, and the efforts of the Walter Reed Army Institute of Research (WRAIR). The global investment in research and development for new antimalarial agents should rise quickly to $60 million to $80 million a year, half of which should be provided by the U.S. government to WRAIR and its partners; the other half should go to MMV from its regular funders.

Combining effective antimalarial treatment with other malaria-control measures in well-designed programs can reduce sickness and deaths from the disease. For example, insecticide-treated bed netting can substantially reduce child mortality from malaria. Countries should carry out intensive, integrated programs of malaria control in areas where transmission can be dramatically reduced or eliminated within a few years.

The study was sponsored by the U.S. Agency for International Development and the Bill & Melinda Gates Foundation. The Institute of Medicine is a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences.