THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: Two new oversight groups are needed to ensure that the policies and procedures of the Vaccine Safety Datalink (VSD) and its data sharing program -- which is intended to give researchers access to patient data that will help them study vaccine safety issues -- are implemented as fairly and openly as possible, says a new report from the Institute of Medicine of the National Academies. The Centers for Disease Control and Prevention, which oversees VSD and the data sharing program, should create a new, independent committee to review researchers' proposals to use VSD data, monitor adherence to protocols, and advise the agency and its partners on when and how to release preliminary findings based on the data, the report says. In addition, CDC should create a new subcommittee of the National Vaccine Advisory Committee (NVAC), or tap an existing one, to enable stakeholders to review and provide input on the VSD research plan every year – 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

SECOND NATIONAL REPORTS ON QUALITY AND DISPARITIES FIND IMPROVEMENTS IN HEALTH CARE QUALITY, ALTHOUGH DISPARITIES REMAIN -- HHS' Agency for Healthcare Research and Quality (AHRQ) Ferbruary 22 released its second annual reports on the quality of and disparities in health care in America. The 2004 *National Healthcare Quality Report* finds both evidence of improving quality as well as specific areas in which major improvements can be made. The 2004 *National Healthcare Disparities Report* indicates that there are disparities related to race, ethnicity, and socioeconomic status in the American health care system. Both reports extend the baseline data on quality and disparities within health care delivery provided in AHRQ's 2003 reports.

The reports measure quality and disparities in four key areas of health care: effectiveness, patient safety, timeliness, and patient centeredness. They also present data on the quality of and differences in access to services for clinical conditions, including cancer, diabetes, end-stage renal disease, heart disease, and respiratory diseases; and for nursing home and home health care.

"The 2004 *National Healthcare Quality Report* and its companion 2004 *National Healthcare Disparities Report* provide a benchmark on the quality of care and health disparities in our country, and they also track the progress we are making," said AHRQ Director Carolyn M. Clancy, M.D. "This is important information for those who wish to improve health care quality and access to services for all individuals."

The Quality Report identifies three key themes important to policymakers, clinicians, health system administrators, community leaders and others who work in health care services. The report finds that:

* Quality is improving in many areas, but change takes time.
* The gap between the best possible care and actual care remains large. Quality of care remains highly variable across the country.
* Further improvement in health care is possible. Best practices have been identified, and collaborative, focused efforts among key stakeholders have produced impressive and inspiring gains.

In comparison to data reported in the 2003 Quality Report, modest improvement has been noted in many of the report's quality measures. Across the entire set of Quality Report measures, quality has improved by approximately 3 percent versus data reported in the 2003 report. These include selected measures used by HHS' Centers for Medicare & Medicaid Services, the Joint Commission on Accreditation of Healthcare Organizations, the National Committee for Quality Assurance, and others for quality reporting on hospitals, nursing homes, home health agencies and other settings. In addition, since the 2003 Quality Report, improvements have been made in specific measures related to health care delivery.

The greatest changes were in the following:

* A decrease of 37 percent from 2002 to 2003 in the percentage of nursing home patients who have moderate or severe pain.
* A decrease of 34 percent from 1994 to 2001 in the hospital admission rate for uncontrolled diabetes.
* A decrease of 34 percent from 1996 to 2000 in the percentage of elderly patients who were given potentially inappropriate medications.

Quality remains variable across the country. However, improvements were seen in many areas at the State level. Some of these notable improvements are:

* Minnesota—Largest improvement in State rank for mammogram testing rates.
* Alabama—Only State to significantly increase screening rates for two recommended tests for colorectal cancer.

Data for all States are available in the report's Tables Appendix and Measure Specifications Appendix.

The 2004 *National Healthcare Disparities Report* presents data on the same clinical conditions and other measures as the Quality Report but focuses on priority populations, including women, children, the elderly, racial and ethnic minority groups, low-income groups, residents of rural areas, and individuals with special health care needs, specifically children with special needs, people in need of long-term care and people requiring end-of-life care.

The 2004 Disparities Report identifies three key themes:

* Disparities are pervasive.
* Improvement is possible.
* Gaps in information exist, especially for specific conditions and populations.

A subset of measures with the comparable data for 2000 and 2001 is highlighted in the 2004 Disparities Report. In both years:

* Blacks received poorer quality of care than whites for about two-thirds of quality measures and had worse access to care than whites for about 40 percent of access measures.
* Asians received poorer quality of care than whites for about 10 percent of quality measures and had worse access to care than whites for about a third of access measures.
* American Indians and Alaska Natives received poorer quality of care than whites for about a third of quality measures and had worse access to care than whites for about half of access measures.

* Hispanics received lower quality of care than non-Hispanic whites for half of quality measures and had worse access to care than non-Hispanic whites for about 90 percent of access measures.
* Poor people received lower quality of care for about 60 percent of quality measures and had worse access to care for about 80 percent of access measures than those with high incomes.

The 2004 Disparities Report found improvement in care provided to the nation's poor, uninsured and minorities through federally supported health centers. These centers, administered by HHS' Health Resources and Services Administration, focus specifically on providing care to vulnerable populations. In 2004, over 3,600 health centers sites delivered primary and preventive care to 13.2 million people. The FY 2006 budget will complete the President's commitment to create 1,200 new or expanded health center sites resulting in the delivery of primary and preventive health care services to 6.1 million additional people, many of whom face multiple barriers to receiving health care. In addition, the President has established a new goal to help every poor county in America in need that lacks a health center and can support one. Forty new health center sites will be funded in FY 2006 for this new effort.

In addition, AHRQ has recently announced a new partnership designed to help reduce disparities in health care for people with diabetes and other conditions. "The National Health Plan Learning Collaborative To Reduce Disparities and Improve Quality" is the first national effort of its kind to go beyond research and actively tackle racial and ethnic inequities in health care service delivery. Over the next 3 years, the collaborative will test ways to improve the collection and analysis of data on race and ethnicity, match those data to existing Health Plan Employer Data and Information Set quality measures, develop quality improvement interventions that close the gaps in care and produce results that can be replicated by other health insurers and providers serving Medicare, Medicaid and commercial populations.

The *National Healthcare Quality Report* and *National Healthcare Disparities Report* are available on AHRQ's QualityTools Web site at http://www.qualitytools.ahrq.gov. The site serves as a Web-based clearinghouse to make it easier for health care providers, policymakers, purchasers, patients and consumers to take effective steps to improve quality.

INDEPENDENT OVERSIGHT OF VACCINE SAFETY DATA PROGRAM NEEDED TO ENSURE GREATER TRANSPARENCY AND ENHANCE PUBLIC TRUST -- Two new oversight groups are needed to ensure that the policies and procedures of the Vaccine Safety Datalink (VSD) and its data sharing program -- which is intended to give researchers access to patient data that will help them study vaccine safety issues -- are implemented as fairly and openly as possible, says a new report from the Institute of Medicine of the National Academies. The Centers for Disease Control and Prevention, which oversees VSD and the data sharing program, should create a new, independent committee to review researchers' proposals to use VSD data, monitor adherence to protocols, and advise the agency and its partners on when and how to

release preliminary findings based on the data, the report says. In addition, CDC should create a new subcommittee of the National Vaccine Advisory Committee (NVAC), or tap an existing one, to enable stakeholders to review and provide input on the VSD research plan every year.

"Concerns about access and transparency have accompanied the development and functioning of the Vaccine Safety Datalink data sharing program, and consequently some people's trust in the reliability of findings from VSD studies has eroded," explained John C. Bailar III, chair of the committee that wrote the report and emeritus professor of health studies at the University of Chicago. "Taking steps to improve the independence, transparency, and fairness of VSD procedures will help enhance confidence in the data sharing program and in research based on this important tool for evaluating vaccine safety."

The Vaccine Safety Datalink is a large, linked database of patient information that was developed jointly by CDC and several private managed care organizations in 1991. It includes data on vaccination histories, health outcomes, and characteristics of more than 7 million patients of eight participating health organizations. Researchers from CDC and the managed care groups have used VSD information to study whether health problems are associated with vaccinations. The subsequent VSD data sharing program was launched in 2002 to allow independent, external researchers access to information in the database. Four successive versions of guidelines for external researchers who wish to use VSD data have been released; the most recent draft is posted in the Federal Register with a March 1 deadline for public comment.

Because of certain unique characteristics, the VSD data sharing program does not function in the same way that other data sharing programs do. In addition to the protections accorded to patient information by privacy laws, the participating managed care organizations maintain proprietary control over data they have supplied from 2001 onward. This means that these data are not available to external researchers working independently on most types of studies. Even so, because the VSD is a tax-supported public resource used to inform health policy decisions, the public deserves access to the data that influence such decisions, the report says; the public also is entitled to transparency and independence in the processes that permit or restrict access. The committee concluded that it is possible to facilitate public access and transparency while also protecting patient privacy.

The public should be involved in setting priorities for VSD research, given the controls placed on information available through the VSD data sharing program, the report says. To that end, a subcommittee of NVAC with representation from a wide variety of stakeholders -- from vaccine manufacturers to federal agencies to advocacy groups -- should provide feedback and input on the program's research plan each year. Although such a group would inevitably have biases and conflicts of interest, it is important that VSD officials hear from all interested individuals. To promote transparency, the subcommittee's deliberations should take place in open meetings.

A separate, independent committee should review research proposals to use VSD data to ensure that they meet the criteria for access. In the interest of fairness and openness, CDC needs to spell out more clearly these criteria, among which the technical feasibility of the proposal should be paramount, the report added. The committee also should oversee changes in research protocols for VSD studies conducted by researchers from CDC or the managed care groups. Members of this independent review committee should be chosen on the basis of their scientific and technical expertise and their lack of conflicts of interest or biases, or CDC's ability to balance these.

Another key function of the independent review committee should be to counsel VSD scientists and officials on when and how to release preliminary findings from studies based on VSD data. In some instances, public disclosure of preliminary findings based on incomplete data or analyses that have not undergone external peer review may be necessary to protect the public's health and safety. But early release can lessen people's confidence in the final results of a study if further data collection and analysis lead to different final conclusions. In nearly all situations, preliminary findings should undergo independent, external peer review before they are shared with the public or used as the basis of policy decisions, the report says.

Given that the managed care organizations maintain proprietary control over data collected beginning in 2001, independent, external researchers will have to collaborate with a partner from CDC or one of the health groups to gain access to these data. Although it is impossible to make collaboration mandatory, CDC should require each participating managed care group to designate an individual whose role is to facilitate and encourage partnerships.

Because any breach of patient data confidentiality could discourage the managed care groups from participating, CDC should make certain that its rules for addressing confidentiality violations are clearly spelled out in the program guidelines and agreement forms, the report says. In addition, the committee concluded that it is reasonable to expect independent, outside researchers to provide VSD officials with status reports on their studies. When scientists have findings ready for public release, they should be required to provide CDC copies of any manuscripts at least 30 days before submission for publication and copies of presentations to be given at public events at least 15 days in advance.

The study was sponsored by Centers for Disease Control and Prevention. 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.

MOTHERS' EXPOSURE TO AIR POLLUTANTS LINKED TO CHROMOSOME DAMAGE IN BABIES -- A new study of 60 newborns in New York City reveals that exposure of expectant mothers to combustion-related urban air pollution may alter the structure of babies' chromosomes while in the womb. While previous experiments have linked such genetic alterations to an increased risk of leukemia and other cancers, much

larger studies would be required to determine the precise increase in risk as these children reach adulthood.

The air pollutants considered in this study include emissions from cars, trucks, bus engines, residential heating, power generation and tobacco smoking. These pollutants can cross the placenta and reach the fetus.

The study was funded by the National Institute of Environmental Health Sciences, part of the National Institutes of Health, the U.S. Environmental Protection Agency, and other private foundations. The research was conducted by scientists from the Columbia University Center for Children's Environmental Health. Study results will be published in the February issue of Cancer Epidemiology Biomarkers and Prevention, and are available online at **http://cebp.aacrjournals.org**.

"This is the first study to show that environmental exposures to specific combustion pollutants during pregnancy can result in chromosomal abnormalities in fetal tissues," said Kenneth Olden, Ph.D., the director of NIEHS. "These findings may lead to new approaches for the prevention of certain cancers."

Researchers monitored exposure to airborne pollutants, known as polycyclic aromatic hydrocarbons (PAHs), among non-smoking African-American and Dominican mothers residing in three low-income neighborhoods of New York City -- Harlem, Washington Heights and the South Bronx.

"Although the study was conducted in Manhattan neighborhoods, exhaust pollutants are prevalent in all urban areas, and therefore the study results are relevant to populations in other urban areas," said Dr. Frederica P. Perera, director of the Columbia Center for Children's Environmental Health and senior author of the study.

Exposure to combustion pollutants was assessed through personal questionnaires and portable air monitors worn by the mothers during the third trimester of their pregnancies. Researchers then calculated the concentration of air pollution to which each pregnant woman and her baby were exposed. Study participants exposed to air pollution levels below the average were designated as having "low exposure," while those exposed to pollution levels above the average were designated as having "high exposure."

"We observed 4.7 chromosome abnormalities per thousand white blood cells in newborns from mothers in the low exposure group, and 7.2 abnormalities per thousand white blood cells in newborns from the high exposure mothers," said Perera. "In particular, stable alterations were increased, which are of greatest concern for potential risk of cancer, since cells with this type of abnormality can persist in the body for long periods of time."

Chromosomal abnormalities were measured in umbilical cord blood by a "chromosome painting" technique called fluorescence in situ hybridization, one that enabled researchers to observe the structural changes within the chromosome. Chromosomes are the threadlike packages in the nucleus of the cell that contain the cell's genetic information.

"This evidence that air pollutants can alter chromosomes in utero is troubling since other studies have validated this type of genetic alteration as a biomarker of cancer risk," said Perera. "While we can't estimate the precise increase in cancer risk, these findings underscore the need for policymakers at the federal, state, and local levels to take appropriate steps to protect children from these avoidable exposures."

Previous studies conducted by Perera and colleagues showed that combustion-related air pollutants significantly reduce fetal growth, which may affect cognitive development during childhood.

The study is part of a broader, multi-year research project, "The Mothers & Children Study in New York City," started in 1998, which examines the health effects of exposure of pregnant women and babies to air pollutants from vehicle exhaust, the commercial burning of fuels, and tobacco smoking, as well as from residential use of pesticides and allergens.

The National Institute of Environmental Health Sciences is a federal agency that conducts and funds basic research on the health effects of exposure to environmental agents.

REFORMS WILL IMPROVE OVERSIGHT AND OPENNESS AT FDA -- In a meeting February 15 with employees, HHS Secretary Mike Leavitt shared an emboldened vision for the Food and Drug Administration (FDA) that included a new culture of openness, improved oversight and enhanced independence. In keeping with this vision, the FDA will create a new independent Drug Safety Oversight Board to oversee the management of drug safety issues, and will provide emerging information to doctors and patients about the risks and benefits of medicines.

"The public has spoken and they want more oversight and openness," Secretary Leavitt said during a meeting with FDA employees at the Parklawn Headquarters in Rockville, Md. "They want to know what we know, what we do with the information and why we do it. We will address their concerns by cultivating openness and enhanced independence."

The independent Drug Safety Oversight Board will oversee the management of important safety issues such as recommending information and updates for placement on the Drug Watch; resolving disagreements over approaches to drug safety issues; assessing the need for MedGuides and overseeing development and implementation of Center-wide drug safety policies. The board will be comprised of members from FDA and medical experts from other HHS agencies and government departments (e.g., Department of Veterans Affairs) and will consult with outside medical experts and representatives of patient and consumer groups.

As a complement to the board's oversight, FDA will improve transparency by sharing drug safety information sooner and more broadly and conveniently. FDA will launch a

new Drug Watch Web Page and proactively share tailored drug safety information sheets with healthcare professionals and patients. These new and direct communication channels will significantly enhance public knowledge and understanding of safety issues by discussing emerging or potential safety problems even before FDA has reached conclusions that would prompt a regulatory action.

Acting FDA Commissioner Dr. Lester M. Crawford accompanied Secretary Leavitt at today's announcement. "FDA understands that the public expects better and more prompt information about the medicines they take everyday," Dr. Crawford said. "Our goal is to prepare the agency for these new demands by improving the way we monitor and respond to possible adverse health consequences that may arise regarding drugs that have been approved for sale to U.S. consumers."

The new communication channels include:

* The Drug Watch Web Page. At the direction of the new Drug Safety Oversight Board, this page will include emerging information for both previously and newly approved drugs about possible serious side effects or other safety risks that have the potential to alter the benefit/risk analysis of a drug, affect patient selection or monitoring decisions, or that can be avoided through measures taken to prevent or mitigate harm. The agency will enhance access to this information and call for assistance in prioritizing and further evaluating potential adverse health concerns.

* Healthcare Professional Information Sheets. One-page information sheets for healthcare professionals for all drugs on FDA's Drug Watch and all drugs with Medication Guides (FDA-approved patient labeling) containing the most important new information for safe and effective product use, such as known and potential safety issues based on reports of adverse events, new information that may affect prescribing of the drug, and the approved indications and benefits of the drug.

* Patient Information Sheets. One-page information sheets for patients containing new safety information as well as basic information about how to use the drug in a consumer friendly format for all products on Drug Watch.

"The FDA is an icon of trust, a certifier of safety, an enabler of innovation and a repository of information," Secretary Leavitt said. "We will keep the promise of the FDA brand by putting in place more rigorous oversight and collecting and sharing important and emerging information about drug safety and effectiveness."