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PHYSICIAN NEWSLETTER

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MANUFACTURER'S RECALL OF HUMAN RABIES VACCINE

On April 2, 2004, CDC announced that they and the FDA had been notified that a recent quality-assurance test of IMOVAX® Rabies Vaccine (Aventis Pasteur, Swiftwater, Pennsylvania) identified the presence of non-inactivated Pitman-Moore virus (the attenuated vaccine strain) in a single product lot. IMOVAX® is an inactivated viral vaccine and should not contain live virus. The vaccine lot containing non-inactivated virus was not distributed.

As a precautionary measure, Aventis Pasteur initiated a voluntary recall of lot numbers X0667-2, X0667-3, W1419-2, and W1419-3, which were produced during the same period as the lot that contained non-inactivated Pitman-Moore virus. These four lots, which were distributed in the United States from September 23, 2003 through April 2, 2004, passed all FDA-approved release tests, including testing to confirm the absence of live virus. These test results suggest that any potential risk to those vaccinated with recalled vaccine is likely to be low. No unusual adverse events associated with the recalled vaccine have been reported.

Aventis Pasteur is providing additional detailed information to all distributors and providers. Health-care providers should contact persons who received recalled vaccine to implement the recommendations outlined in the official CDC notice regarding this voluntary recall (see the section

entitled Recommendations for Persons Who Received Recalled Vaccine (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm53d402a1.htm>). Health-care providers who have any remaining doses of the recalled lots should not use them and should contact Aventis Pasteur regarding their disposition. Information about this recall is available from the Aventis Pasteur Medical Information Services Department, telephone 800-835-3587, or at <http://www.vaccineshoppe.com>.

CDC GUIDELINES ON CONFIRMATORY TESTING FOR POSITIVE RAPID HIV TESTS

In addition to the OraQuick Rapid HIV-1 Antibody test, the FDA has recently approved two more HIV rapid tests for diagnostic use, the Reveal Rapid HIV-1 Antibody Test and the Uni-Gold Recombigen HIV Test. The CDC issued specific quality assurance testing guidelines after the approval of OraQuick that must be followed when performing any HIV rapid test. The following is excerpted from the CDC guidelines and specifically addresses confirmatory testing:

Whenever a rapid HIV test is reactive (preliminary positive), a confirmatory test must be performed to verify whether the person being tested is infected with HIV. Therefore, all reactive (preliminary positive) rapid tests must be followed up with either a Western blot or immunofluorescent assay (IFA) for confirmation. With blood samples, enzyme immunoassay (EIA) screening tests prior to the Western blot or IFA confirmatory test are optional. However, if an EIA is performed, even if it is non-reactive, the specimen must proceed to Western blot or IFA for confirmatory testing. (Reactive EIA specimens will automatically be tested by Western blot or IFA.) For oral fluid testing, both EIA and Western blot testing should be performed to confirm results.

If the laboratory providing confirmatory testing after a reactive rapid test performed an EIA test only and reported a non-reactive or negative result, the rapid testing site needs to contact the laboratory and request a Western blot or IFA. If the original specimen is not available, a new specimen will need to be collected for confirmatory testing”.

Follow-up testing for a negative confirmatory test result:

- Most confirmatory test results will be positive, however, some may be negative or indeterminate.
- If the confirmatory test result is negative, specimen mix-up needs to be ruled out versus a false positive rapid test result.
- If the Western blot or IFA test is negative, it is recommended that:
 - For blood specimens, a confirmatory test should be repeated with a new specimen to rule out specimen mix-up.
 - For oral fluid specimens, a repeat confirmatory test with a blood specimen should be done, since the oral fluid test is less sensitive than the blood test.
 - Follow-up testing for an indeterminate confirmatory test result:
- If the Western blot or IFA confirmatory test is indeterminate, it is recommended that:
 - For blood specimens, the person should be advised to return for repeat testing in one month
 - For oral fluid specimens, the Western blot or IFA test should be repeated using a blood specimen.

The complete guidance can be found on CDC's website at:

http://www.cdc.gov/hiv/rapid_testing/materials/QA_Guidelines_OraQuick.pdf.

Specific information about confirmatory testing is on pages 14-16. If there are any questions about the HIV rapid testing algorithm guidelines, please contact Tony Tran, atran@aphl.org or Dr. Bernard Branson, bbranson@cdc.gov.

ACPM LAUNCHES WEB SITE ON RADIATION EXPOSURE AND IODINE 131

The American College of Preventive Medicine (ACPM) has launched a new web site, www.iodine131.org, which provides scientific information on what physicians and other health professionals should know about radiation exposure from iodine 131 (I-131). The web site is a gateway to medical and public health information and resources about I-131 radiation exposure and the related health effects. On the web site physicians can find answers to such questions as: Why should I be concerned about I-131? What do I need to know about I-131? Where do people get exposed in the United States? How can I help my patients and community? Where can I go for more in-depth information?

PNEUMOCOCCAL CONJUGATE VACCINE IN A SETTING OF VACCINE SHORTAGE

CDC is recommending a reduced schedule of PCV7 vaccine for healthy children due to vaccine shortages. On March 2, CDC released an MMWR article discussing the most recent recommendations on the use of pneumococcal conjugate vaccine. This article may be found at the following link: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm53d302a1.htm>

CDC has also posted a Q & A, dosage facts for parents, a press release, a schedule alert, and the MMWR article. These tools may be found at the following website: <http://www.cdc.gov/nip/news/shortages/default.htm>

MDCH has developed a PCV7 shortage assessment tool that providers may want to post in their offices. A copy of the assessment tool can be obtained by contacting the Health Department at (906) 779-7210 or (906) 265-4156. We hope that these documents and additional information will be helpful during this challenging time.

The MDCH supply of PCV7 is currently less than 3,000 doses. The average statewide demand of this vaccine is between 27,000-30,000 doses per month. It is unclear when MDCH will receive additional supplies of PCV7 vaccine. Any available doses of vaccine will be rationed to local health departments based on the vaccine inventories available at each department. Thank you for your patience during this challenging time.

MICHIGAN INFLUENZA UPDATE

During the month of February 2004, influenza-like illness (ILI) activity in Michigan returned to low (baseline) levels of 1.5% of patient visits to sentinel surveillance sites. Influenza activity peaked in Michigan during the latter half of December 2003 and the first week of 2004, accentuated by abrupt increases seen just prior to the holiday season. During the peak, ILI levels reached the season high of 10% and there were widespread outbreaks noted. As the month of January progressed, ILI activity began to rapidly subside throughout most of the state. It remains possible that we could still see another small resurgence in flu activity later this spring season, called a secondary peak. There are 40 sentinel physician sites established throughout Michigan that provide weekly information on influenza-like illnesses among their patient populations.

Nationally, the Centers for Disease Control and Prevention (CDC) has reported that the percentage of patient visits for influenza-like illness (ILI) remained below the national baseline (2.5%) for all consecutive weeks since mid-January 2004. Based on antigenic characterization of influenza isolates submitted to the CDC during the 2003-04 season, the A/Fujian (H3N2) strain has dominated throughout all of the season so far. The A/Fujian strain is an antigenically drifted variant of the (H3N2) A/Panama/2007/99-like strain contained in the 2003-04 vaccine.

To view real-time information on influenza activity in Michigan, please visit the Michigan Department of Community Health website at www.michigan.gov/mdch. This information is updated regularly throughout the flu season. National influenza surveillance summary information for the current week is available at the CDC website www.cdc.gov/ncidod/diseases/flu/weekly.htm

SARS UPDATE

In China, there have been three confirmed, and one probable SARS case reported since December 16, 2003. All of the cases have recovered and contacts have not reported any SARS-like illness. Although the source of infection has not yet been determined, there is no known community transmission thought to be occurring. Also, there are no cases in the United States or other countries so far. The CDC issued the second version of the **Public Health Guidance for Community-Level Preparedness and Response to Severe Acute Respiratory Syndrome (SARS)** on January 8, 2004 (<http://www.cdc.gov/ncidod/sars/updatedguidance.htm>). Based on the new CDC version, MDCH is currently updating the *Michigan Guidance to SARS* document. The current version may be viewed by clicking the SARS link on the MDCH homepage (<http://www.michigan.gov/mdch>).

HEALTH PROMOTION CLEARINGHOUSE

The Health Promotion Clearinghouse provides access to a wide variety of brochures and other educational materials produced by the Michigan Department of Community Health to promote healthier lifestyles for a healthier Michigan. These materials are suitable for distribution in a physician's waiting room. Materials can be ordered in quantity and are free of charge. For more information visit the Clearinghouse website at <http://www.hpclearinghouse.org>.

OBESITY CLOSES GAP ON TOBACCO AS LEADING CAUSE OF DEATH

A new study from the CDC shows poor diet and inactivity may soon become the leading preventable cause of death among Americans—causing an estimated 400,000 deaths in 2000. *Actual Causes of Death in the United States, 2000*, published in the March 10 issue of JAMA, sought to identify and quantify the leading causes of death in the United States attributable to modifiable behavioral risk factors, the first update of the groundbreaking work of McGinnis and Foege more than a decade ago. The researchers found that the leading causes of death in 2000 were tobacco (435,000 deaths; 18.1 percent of total U.S. deaths), poor diet and physical inactivity (400,000 deaths; 16.6 %), and alcohol consumption (85,000 deaths; 3.5 %).

In response to the growing obesity epidemic, HHS Secretary Thompson recently unveiled a new national education campaign in conjunction with the Ad Council to encourage Americans to take small steps to fight obesity and announced a new obesity research strategy at the NIH. The Secretary also released a new FDA report outlining another element in HHS' strategy for combating obesity. The report highlights actions that the FDA, which regulates many foods and their labels, plans to take to enable consumers to make smart choices about their diet and maintain a healthy weight. The report is available at <http://www.fda.gov/oc/initiatives/obesity/>.