Availability of Hepatitis B Vaccine That Does Not Contain Thimerosal as a Preservative

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ON AUGUST 27, 1999, MERCK VACCINE DIVISION* (Merck & Co., Inc., West Point, Pennsylvania) received approval from the Food and Drug Administration (FDA) of a supplement to Merck’s license application to include the manufacture of single-antigen preservative-free hepatitis B vaccine (Recomvax HB®, Pediatric); distribution is expected to begin September 13, 1999. In addition, SmithKline Beecham Biologicals (SmithKline Beecham, Philadelphia, Pennsylvania), expects to make single-antigen preservative-free hepatitis B vaccine (Engerix-B®, Pediatric) available in the near future. Further product information will be provided when it becomes available. Product packaging and labels will indicate that these vaccines do not contain preservative.

To prevent shortages because of limited supplies of single-antigen hepatitis B vaccines that do not contain thimerosal as a preservative and to assure prevention of perinatal and early childhood hepatitis B virus (HBV) infection during the transition when both vaccines that contain and do not contain thimerosal as a preservative are available, the following three steps should be taken:

1. Newborn infants. The priority for use of single-antigen hepatitis B vaccines that do not contain thimerosal as a preservative should be to vaccinate newborn infants. Routine hepatitis B vaccination policies for all newborn infants should be reintroduced immediately in hospitals in which these policies and practices have been discontinued. All hospitals should ensure that newborn infants of hepatitis B surface antigen (HBsAg)-positive mothers and of mothers whose HBsAg status is unknown receive their first dose of hepatitis B vaccine within 12 hours of birth. If hepatitis B vaccine that does not contain thimerosal as a preservative is not available, then thimerosal preservative-containing vaccine should be used for these infants.

2. Infants aged <6 months. When available, hepatitis B vaccines that do not contain thimerosal as a preservative should be used to vaccinate infants aged <6 months (single-antigen hepatitis B vaccine for infants aged <6 weeks and either single-antigen or combination products for infants aged greater than or equal to 6 weeks). Infants in groups at high risk for perinatal and early childhood HBV infections should complete the three-dose hepatitis B vaccine series by age 6 months. When vaccines that do not contain thimerosal as a preservative are not available, these groups should be vaccinated with thimerosal preservative-containing vaccine. For infants born to HBsAg-negative mothers who are not in high-risk groups, existing recommendations should be used for administering thimerosal preservative-containing hepatitis B vaccines if vaccine that does not contain thimerosal as a preservative is not available.1-4 These groups should complete the three-dose hepatitis B vaccine series by age 18 months.

3. Children aged ≥6 months, adolescents, and adults. Thimerosal preservative-containing hepatitis B vaccines can continue to be used for vaccinating children aged ≥6 months, adolescents, and adults as is recommended.1-6

Reported by: National Center for Infectious Diseases; National Immunization Program; Agency for Toxic Substances and Disease Registry; National Center for Environmental Health, CDC.

CDC Editorial Note: On July 8, 1999, the American Academy of Pediatrics (AAP) and the Public Health Service (PHS) released a joint statement about thimerosal in vaccines, and the American Academy of Family Physicians (AAFP) released a comparable statement.1-3 Thimerosal is a mercury-containing preservative that has been used as an additive to biologics and vaccines since the 1930s because it is effective in preventing bacterial and fungal contamination, particularly in open multidose containers. Vaccine manufacturers, FDA, and other PHS agencies are working together to replace expeditiously thimerosal preservative-containing vaccines whenever possible with vaccines that do not contain thimerosal as a preservative while ensuring maintenance of high vaccination coverage levels and prevention of disease.

Previous recommendations for using thimerosal-containing vaccines indicated that clinicians and parents could take advantage of the flexibility in the immunization schedule to delay hepatitis B vaccination from birth until age 2-6 months for infants born to mothers who are HBsAg negative.1-4 No changes were made in recommendations for immunization at birth of infants of HBsAg-positive mothers or infants of mothers with an unknown HBsAg status.

After the joint AAP/PHS statement on thimerosal, the AAP and CDC provided additional implementation guidance.3-4 CDC guidance included hepatitis B vaccination should be continued at birth for infants born to HBsAg-negative mothers belonging to populations or groups that have a high risk for early childhood HBV infection, including Asian/Pacific Islanders, immigrant populations from countries in which HBV infection is of high or intermediate endemicity,7 and households with persons with chronic HBV infection. To ensure the prevention of perinatal HBV transmission, hospitals should con-
continue policies to vaccinate all infants at birth until procedures are in place to guarantee that (1) the HBsAg status of every pregnant woman is reviewed at delivery, (2) appropriate passive-active immunophrophylaxis (hepatitis B immune globulin and hepatitis B vaccine) is provided for infants of HBsAg-positive women within 12 hours of birth, and (3) appropriate active immunophrophylaxis (hepatitis B vaccine) is provided for infants of women with an unknown HBsAg status.

After the statements on thimerosal in vaccines were published, changes occurred in newborn hepatitis B vaccination policies and practices in some hospitals, including unintended changes affecting immunization of infants at risk for perinatal HBV transmission. In August 1999, state and territorial health department hepatitis coordinators conducted surveys of selected birthing hospitals in their project areas. Of 977 hospitals surveyed in 48 project areas, 773 (79%) were aware of the joint AAP/PHS statement on thimerosal. Of 574 hospitals that were aware of the statement and had existing policies or standing orders to vaccinate all newborns, 262 (46%) reported a policy change to no longer routinely vaccinate newborns of HBsAg-negative mothers. In addition, 52 (9%) reported they no longer routinely vaccinate any newborn (CDC, unpublished data, 1999). Such a policy usually requires a physician’s order to vaccinate infants of HBsAg-positive mothers and infants of mothers whose HBsAg status is unknown. CDC also has received anecdotal reports of hospitals in which policies were changed, and infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status were not vaccinated within 12 hours of birth (CDC, unpublished data, 1999). Chronic HBV infection develops in approximately 90% of infants infected perinatally; among chronically infected infants, the risk for premature death from HBV-related liver cancer or cirrhosis is approximately 25%.8 The availability of hepatitis B vaccine that does not contain thimerosal as a preservative should alert medical facilities to review their policies to ensure the vaccination of newborns as recommended by the Advisory Committee on Immunization Practices, AAP, and AAP.

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*Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

State-Specific Maternal Mortality Among Black and White Women—United States, 1987-1996

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1 table omitted

ONE OF THE NATIONAL HEALTH OBJECTIVES for 2000 is to reduce the overall maternal mortality ratio (MMMR) i.e., number of maternal deaths per 100,000 live-born infants) to no more than 3.3 (objective 14.3); however, during 1982-1996, the MMR remained at approximately 7.5. In addition, the risk for maternal mortality consistently has been higher among black women than white women. This report presents state-specific MMRs for 1987-1996, focusing on persistent disparities in maternal mortality between black and white women. The findings indicate that in every state where MMRs could be reliably calculated, black women were more likely than white women to die from complications of pregnancy and that the 2000 objective will not be met; however, for white women, it has been met in three states.

MMRs were calculated using information from birth and death certificates filed in state vital statistics offices and compiled by CDC’s National Center for Health Statistics. Maternal deaths were defined as deaths that occurred during pregnancy or within 42 days after pregnancy termination, regardless of pregnancy duration and site, from any cause related to or aggravated by the pregnancy, but not from accidental or incidental causes. Cause of death is recorded on the death certificate by the attending physician, medical examiner, or coroner. For the denominator (live-born infants), maternal race as indicated on the birth certificate was used; for the numerator (maternal deaths), maternal race as indicated on the death certificate was used. Data for racial groups other than black and white are not presented separately because numbers were too small to provide reliable estimates; however, data for other races were included in the totals for each state. Data for Hispanic women were not available from all states and were not analyzed.

Data from states with fewer than seven maternal deaths for black and white women were considered unreliable and were not reported (relative standard error [RSE]: >38%). Data for states with seven-19 maternal deaths for black and white women were reported. RSE for these maternal deaths was 23%-38%; however, data were not considered as reliable as those for states...
with at least 20 maternal deaths. Total MMRs were presented for all states, regardless of the total number of deaths. During 1987-1996, for black women, MMRs in 26 states ranged from 8.7 (Massachusetts) to 28.7 (New York); for white women, MMRs in 41 states ranged from 2.7 (Massachusetts) to 9.2 (Vermont). The MMR for black women was higher than for white women in every state where ratios could be calculated. The black:white ratio of MMRs ranged from 2.6 (Iowa, Maryland, and South Carolina) to 6.3 (Michigan).

Total MMRs ranged from 1.9 (New Hampshire) to 22.8 (District of Columbia). Eight states and the District of Columbia had significantly higher MMRs than the national MMR. Because the MMR for black women was 3-6 times higher than for white women, states with higher percentages of births to black women tended to have higher total MMRs.

To discern possible trends in maternal mortality, data were divided into two 5-year periods (1987-1991 and 1992-1996). The national MMR was 7.7 for each time period. The MMR did not differ significantly between these periods for black women (18.8 and 20.3, respectively) or for white women (5.5 and 5.0, respectively). The difference in MMRs for the two time periods was not significant in 48 states and the District of Columbia.

Reported by: Div of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion; Div of Vital Statistics, National Center for Health Statistics, CDC.

CDC Editorial Note: Although no progress has been made in achieving the 2000 objective to reduce maternal mortality, the findings in this report indicate that for white women, the goal has been achieved in three states (Massachusetts, Nebraska, and Washington) and has almost been met in eight other states (MMRs of <4). Therefore, in the United States, lower levels of maternal mortality can be achieved.

The proposed 2010 objective for maternal mortality using vital statistics data remains at 3.3 per 100,000 live-born infants. A focus for the 2010 objectives is to eliminate racial disparities in maternal mortality. The fourfold increase nationally in risk for maternal death among black women compared with white women is one of the largest racial disparities among major public health indicators; no improvement has occurred during 1987-1996. Race and ethnicity are not risk factors for maternal mortality but instead may be markers of social, economic, cultural, health-care access and quality, and other interrelated factors that may increase the risk for death among pregnant women.

Black women have a higher risk than white women for dying from every pregnancy-related cause of death reported, including the three leading causes (i.e., hemorrhage, pregnancy-induced hypertension, and embolism). Although prenatal care reduces the risk for maternal mortality, health-care access and use do not explain fully the disproportionate risk for maternal death for black women. Other factors, such as quality of prenatal, delivery, and postpartum care, and interaction between health-seeking behaviors and satisfaction with care, may explain part of this difference. Epidemiologic, sociologic, health-care delivery, and program research are needed to identify key factors that may contribute to the disparity between black and white women in maternal health whether at the individual, clinic, community, or health systems level.

The wide disparity that exists among states for both black and white MMRs is not attributable solely to small numbers. However, vital statistics data do not include information necessary to assess risk factors and case-fatality rates that may have contributed to these state-to-state disparities.

The findings in this report are subject to at least two limitations. First, although U.S. vital statistics data during 1987-1996 indicated that 3080 women died because of pregnancy complications, these data are underestimates because of misclassification on death certificates. Misclassification occurs when the cause of death on the death certificate does not reflect the relation between a woman’s pregnancy and her death. The estimated number of maternal deaths is 1.3-3.0 times higher than that reported in vital statistics records. If a maternal mortality review discovers that the cause of death on the death certificate is reported incorrectly, the certifying physician should be contacted to file an amended record. Second, misclassification of race on death certificates may vary among the states and are not known.

To identify interventions that may reduce maternal mortality, 25 states have reestablished maternal mortality review committees. These committees review factors that may have contributed to maternal deaths, including the quality of medical care and problems in the health-care delivery system. All states should implement such review mechanisms to help identify and investigate maternal deaths, discuss each case in a multidisciplinary process, disseminate findings, and provide recommendations for preventing future deaths. Both public health surveillance and prevention research are needed to understand the underlying causes of maternal mortality and the disparity between black and white women and to guide appropriate interventions and improvements in maternal health care.

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*CDC’s National Center for Health Statistics uses the term “rate” when reporting this indicator of maternal mortality. The term “ratio” is used instead of rate in this report because the numerator includes some maternal deaths that were not related to live-born infants and thus were not included in the denominator.
† When a death occurs under “accidental” circumstances, the preferred term within the public health community is “unintentional injury.”
§International Classification of Diseases, Ninth Revision, codes 630-676.

Satellite Broadcast on Diagnostic and Therapeutic Dilemmas for Gonococcal and Chlamydial Infections

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The CDC-sponsored National Network of STD/HIV Prevention Training Centers (PTC) will broadcast STD Diagnostic and Therapeutic Dilemmas: Gonococcal and Chlamydial Infections, an interactive satellite broadcast, in English and Spanish on October 14, 1999, from 1 PM to 2:30 PM eastern daylight time. The broadcast is intended for primary-care and managed-care providers and health-care clinicians caring for patients exposed to or infected with gonococcal and chlamydial infections. The broadcast will cover state-of-the-art screening and diagnostic interpretations of chlamydial and gonococcal technologies. Continuing medical education credit is available.

Additional information is available from the STD/HIV PTC, Dallas County Health and Human Services, 2377 N. Stemmons Fwy., #430, Dallas, TX 75207-2710; telephone (214) 819-1947; or from the World-Wide Web, http://www.stdptc.uc.edu.*

*References to sites of nonfederal organizations on the World-Wide Web are provided as a service to MMWR readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites.

Multiple Human Exposures to a Rabid Bear Cub at a Petting Zoo and Barnwarming—Iowa, August 1999

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On August 27, 1999, a black bear cub, approximately 5-6 months old, died after several hours of acute central nervous system symptoms; preliminary test results available on August 28 indicated the bear had rabies. The bear was part of the Swenson’s Wild Midwest Exotic Petting Zoo in Clermont, Iowa (northeastern Iowa). At the petting zoo, visitors fed, wrestled, and may have been nipped by the bear. The bear also was taken to an August 14 barnwarming at the Tharp barn in Holy Cross, Iowa (eastern Iowa), where it reportedly nipped people. An estimated 400 people from 10 states (Arizona, California, Florida, Illinois, Iowa, Minnesota, New Mexico, New York, Ohio, and Wisconsin) and Australia had contact with the bear cub at either the petting zoo or the barnwarming during the 28 days before its death, during which the bear may have transmitted rabies virus.

On the basis of telephone calls to petting zoo visitors who signed the guest register and provided contact information, approximately 150 of the 400 persons were exposed to the bear’s saliva and need to obtain vaccine and rabies immune globulin. Public health authorities are attempting to contact petting zoo visitors by telephone and the Internet. However, because not all petting zoo visitors signed the register or provided sufficient information to enable health authorities to locate them, state and local health departments are encouraged to ensure local media coverage to alert persons who had contact with the bear after July 30 to the need for exposure assessment. Persons who attended the barnwarming also need to be assessed for prophylaxis.

Information is available from the emergency telephone number of the Iowa Department of Public Health: (515) 323-4360.

Reported by: Center for Acute Disease Epidemiology, Iowa Dept of Public Health.

Epidemiology in Action

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CDC and Emory University’s Rollins School of Public Health will co-sponsor a course, “Epidemiology in Action,” during November 8-19, 1999, in Atlanta. The course is designed for state and local public health professionals.

The course emphasizes the practical application of epidemiology to public health problems and will consist of lectures, workshops, classroom exercises (including actual epidemiologic problems), and roundtable discussions. Topics covered include descriptive epidemiology and biostatistics, analytic epidemiology, epidemic investigations, public health surveillance, surveys and sampling, Epi Info software training, and discussions of selected prevalent diseases. There is a tuition charge.

Deadline for application is October 8, 1999. Additional information and applications are available from Emory University, International Health, Dept. (PIA), 1518 Clifton Rd., N.E., Room 742, Atlanta, GA 30322; telephone (404) 727-3485; fax (404) 727-4390; or on the World-Wide Web, http://www.sph.emory.edu/EPICOURS; or e-mail pvaleri@sph.emory.edu.