Unintentional Administration of Varicella Virus Vaccine - United States, 1996

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Since June 1995, seven separate cases of unintentional administration of varicella virus vaccine (Varivax{Registered} *) to pregnant women have been reported in the United States to the Varivax{Registered} Pregnancy Registry **. All seven women had household exposure to varicella, and varicella zoster immune globulin (VZIG) prophylaxis was indicated. However, Varivax{Registered} was administered unintentionally instead of VZIG to these women. One of the women received five times the recommended dose of vaccine. All had negative histories for varicella, and the status of their immunity to varicella before receiving the vaccine was not reported to the registry. Gestational age at vaccination ranged from 6 to 31 weeks; four of the seven pregnancies were less than 20 weeks' gestation. Two of these women have since delivered healthy infants; pregnancy outcomes are pending for five women.

Reported by: JM Manson, PhD, RG Sharrar, MD, Merck Research Laboratories, Worldwide Product Safety and Epidemiology Div, West Point, Pennsylvania. Vaccine Safety and Development Activity, Child Vaccine Preventable Diseases Br, Epidemiology and Surveillance Div, National Immunization Program, CDC.

Editorial Note: The use of Varivax{Registered} is contraindicated during pregnancy (1) because its effects on the fetus are unknown and because infection with wild varicella zoster virus during the first half of pregnancy may result in congenital varicella syndrome (2). The Advisory Committee on Immunization Practices recommends that VZIG be used for postexposure prophylaxis in susceptible persons at high risk for varicella complications, including women exposed to varicella at any stage of pregnancy (1). The risk for congenital varicella syndrome after natural infection with wild varicella zoster virus is 1%-2%; because the virulence of the attenuated virus used in the vaccine is less than that of the wild-type virus, the risk to the fetus, if any, should be lower (1).

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Two potential reasons these incidents occurred are 1) use of the wrong vial by mistake and 2) a lack of understanding of the appropriate indications for the use of these two products. These cases underscore the need for health-care providers and pharmacists to carefully check product labels before administering any drug and to read the package inserts for any drug if they are uncertain of the appropriate indications for its use. VZIG is shipped as a liquid in 2-mL or 10-mL vials and must be stored at 36 F-46 F (2 C-8 C). In contrast, Varivax{Registered} is shipped as a lyophilized powder for suspension in 0.7-mL vials, must be reconstituted with diluent before use, and must be stored at 5 F (-15 C).

Before a vaccine or any drug is administered to a woman of childbearing age, a health-care provider should be careful to obtain a history of pregnancy or intended pregnancy from the patient. Health-care providers are strongly encouraged to enroll any women who were unintentionally vaccinated with varicella virus vaccine 3 months before or at any time during pregnancy in the Varivax{Registered} Pregnancy Registry, telephone (800) 986-8999.

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

** This registry is maintained jointly by Merck and Company and by CDC; Merck and Company is responsible for daily management and operation of the registry. The registry was established to determine the risk for congenital varicella syndrome or other birth defects following vaccination with Varivax{Registered} 3 months before or at any time during pregnancy.

References available on request.
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DISEASES OF LOW FREQUENCY

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<th>DISEASE</th>
<th>1996 YTD</th>
<th>1995 YTD</th>
<th>1995 ANNUAL TOTAL</th>
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<td>Diphtheria</td>
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<td>Encephalitis</td>
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<td>Legionellosis</td>
<td>8</td>
<td>10</td>
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<tr>
<td>Lyme Disease</td>
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<td>Pertussis</td>
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<tr>
<td>RMSF</td>
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<td>16</td>
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<td>Rubella</td>
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<td>Tetanus</td>
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<td>Typhoid</td>
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</table>

Disease numbers reflect only those cases which meet the surveillance definition.
Program Phone Numbers

Division Office 502-564-7243
Communicable Disease Branch 502-564-3261
Adult Health Branch 502-564-7996
AIDS/HIV Program 502-564-6539
Surveillance & Investigations Branch 502-564-3418

Let us know how we can better serve you in the new year.

ALL Staff of the Division of Epidemiology join me in wishing you a very

HAPPY
NEW YEAR

and Many Thanks for your Support of Public Health in Kentucky.

Reginald Finger, M.D., M.P.H., Director, State Epidemiologist