

ACIP SUPPLEMENTARY STATEMENT OF CONTRAINDICATIONS TO RECEIPT OF PERTUSSIS VACCINE

This article first appeared in the Centers for Disease Control (CDC) publication, Morbidity and Mortality Weekly Report, Vol. 33/No. 13, April 6, 1984.

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The following statement updates some of the previous recommendations regarding pertussis vaccine. The Immunization Practices Advisory Committee (ACIP) reviewed the available data concerning the risks of pertussis disease and pertussis vaccine to infants and children with personal or family histories of convulsions. Based on available evidence, the ACIP does not consider a family history of convulsion to be a ... contraindication to receipt of pertussis vaccine. However, a personal history of a prior convulsion should be evaluated before initiating or continuing immunization with vaccines containing a pertussis component (ie, diphtheria and tetanus toxoids with pertussis vaccine [DTP]).

#### ... DEFERRAL OF DTP FOR INFANTS AND CHILDREN WITH PERSONAL HISTORIES OF CONVULSION(S)

> . Although there are uncertainties in the reported studies, recent data suggest that infants and young children who have previously had convulsions (whether febrile or nonfebrile) are more likely to have seizures following pertussis vaccination than those without such histories. Available data do not indicate that seizures . . temporally associated with vaccine administration predispose to permanent brain damage or exacerbate existing conditions. The incidence of pertussis in most areas + 4 of the United States is presently quite low. Consequently, for infants and young children who have histories of seizures before initiation of DTP immunization or who develop seizures before the four-dose primary series is completed, initiating or continuing pertussis immunization should be deferred until it can be determined that there is not an evolving neurologic disorder present. If such disorders are found, the infants or children should be given diphtheria and tetanus toxoids (DT) instead > . of DTP. If DT is used, three doses at least 4 weeks apart, followed by a fourth dose 6 to 12 months later, are recommended for infants. For children 1 year of age or older, two doses of DT at least 4 weeks apart, followed by a third dose 6 to 12 months later, are recommended.

### RECOMMENDATIONS FOR BEGINNING OR CONTINUING DTP AFTER DEFERRAL

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For infants and children whose DTP immunizations are deferred because of histories of convulsion(s), the decision whether or not to proceed with DTP immunization can usually be made within the next few months. For infants who have received fewer than three doses of DTP, such a decision in most instances should be made no later than at 1 year of age. Following individual assessment, it may be decided to proceed with DTP, because infants and young children with convulsive disorders also appear to be at higher risk of adverse outcomes if they contract pertussis disease. Further, if unimmunized infants attend day-care centers, special clinics, and residential-care

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settings where other children may be unimmunized or if they travel to, or reside in, areas where the disease is endemic, they may be at increased risk of exposure to pertussis.

For infants and children with stable neurologic conditions, including well-controlled seizures, the benefits of pertussis immunization outweigh the risks, and such children may be vaccinated. The occurrence of single seizures (temporally unassociated with DTP) in infants and young chidren, while necessitating evaluation, need not contraindicate DTP immunization, particularly if the seizures can be satisfactorily explained. An example might be a febrile seizure in the course of exanthem subitum in a 14-month-old child. As with all infants or children with one or more febrile seizures, consideration of continuous anticonvulsant prophylaxis may be warranted.

Parents should be fully informed of the benefits and risks of immunization with DTP. Parents of infants and children with histories of convulsions should particularly be made aware of the slightly increased chance of post-immunization seizures. A minimum of three doses of DTP given at intervals of at least 4 weeks is necessary to provide adequate protection against pertussis. A fourth dose 6 to 12 months later is also recommended.

# CONTRAINDICATIONS TO PERTUSSIS VACCINE

Hypersensitivity to vaccine components, presence of an evolving neurologic disorder, or a history of a severe reaction (usually within 48 hours) following a previous dose all remain definitive contraindications to the receipt of pertussis vaccine. Severe reactions include collapse or shock, persistent screaming episode, temperature  $40.5^{\circ}C$  ( $105^{\circ}F$ ) or greater, convulsion(s) with or without accompanying fever, severe alterations of consciousness, generalized and/or local neurologic signs, or systemic allergic reactions. Although hemolytic anemia and thrombocytopenic purpura have previously been considered contraindications by the ACIP, the evidence of a causal link between these conditions and pertussis vaccination is not sufficient to retain them as contraindications.

# OTHER IMMUNIZATIONS FOR INFANTS AND CHILDREN FOR WHOM PERTUSSIS VACCINE IS CONTRAINDICATED

Immunization with DT and/or oral polio vaccine is not known to be associated with an increased risk of convulsions. Therefore, a history of prior convulsions is not a contraindication to receipt of these toxoids and vaccine. In addition, a history of prior convulsion(s) is not a contraindication for measles-mumps-rubella (MMR) vaccine. Further details concerning DTP vaccine or DT toxoids can be found in the 1981 ACIP statement.

<u>PDN Editorial Note:</u> The ACIP recommends the use of pediatric diphtheria and tetanus toxoid, <u>DT</u>, instead of diphtheria and tetanus toxoids with pertussis vaccine, <u>DTP</u>, for infants and young children in two situations: 1. when the child has had a seizure within 48 hours of receiving DTP vaccine, and 2. when the child has had a seizure in the last six months and medical evaluation indicates an <u>evolving</u> neurologic disorder.

In children under one year of age who meet these criteria, the TDH recommends completing immunization with DT such that the infant receives TWO doses of these antigens at least 4 weeks apart, followed by a dose 6-12 months later. This is consistent with the <u>1982 Report of the Committee of Infectious Diseases</u> of the American Academy of Pediatrics and the DT package insert. However, the ACIP recommends completing the series with <u>THREE</u> doses at least 4 weeks apart, followed by a fourth dose 6-12 months later. 1 -

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According to CDC, the ACIP recommendation, a total of four DT doses, is intended to assure high vaccination levels against diphtheria and tetanus among the population of infants and young children. There is evidence which supports adequate immunologic protection with only three DT doses, and, because Texas has achieved high vaccination levels, TDH suggests this three-dose schedule for vaccination of infants. However, physicians may use either schedule with confidence.

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## SYSTEMIC ALLERGIC REACTIONS FOLLOWING IMMUNIZATION WITH HUMAN DIPLOID CELL RABIES VACCINE

The following article was adapted from the Centers for Disease Control (CDC) publication, Morbidity and Mortality Weekly Report, Vol. 33/No. 14, April 13, 1984.

Human diploid cell rabies vaccine (HDCV) has been licensed for use since June 9, 1980. Approximately 400,000 doses have been administered to an estimated 100,000 persons in the United States since that time. The majority of these were for post-exposure treatments. Information on possible adverse reactions to HDCV has been collected by CDC from individual physicians and from medical personnel in charge of providing rabies pre-exposure and post-exposure prophylaxis to large cohorts of persons, such as veterinary students and animal-control workers. During the past 46 months, 108 clinical reports of systemic allergic reactions ranging from hives to anaphylaxis were reported to CDC (11 per 10,000 vaccinees). Few patients required hospitalization, and no deaths secondary to the reactions were reported.

The reports of systemic allergic reactions included nine cases of presumed Type I immediate hypersensitivity (1/10,000), 87 cases of presumed Type III hypersensitivity reactions (9/10,000), and 12 cases of allergic reactions of indeterminate type. These reactions were classified on the basis of clinical observations only. Type I hypersensitivity reactions refer to immunoglobulin E (IgE)-mediated immediate reactions, such as anaphylaxis and atopy, whereas Type III hypersensitivity refers to immunoglobulin G (IgG)- or immunoglobulin M (IgM)-mediated immune complex disease characterized by antigen-antibody complex deposition in tissues, complement activation, and inflammation.

Hypersensitivity reactions presumed to be Type III occurred 2 to 21 days after a dose or doses of HDCV; patients presented with a generalized or pruritic rash or urticaria, sometimes accompanied by arthralgias, angioedema, fever, nausea, vomiting, and malaise. All nine of the presumed immediate hypersensitivity reactions occurred during either primary pre-exposure immunization (vaccine administered on days 0, 7, and 21 or 28) or post-exposure immunization (vaccine on days 0, 3, 7, 14, and 28 and rabies immune globulin on day 0). However, 81% (93%) of 87 of the presumed Type III hypersensitivity reactions were observed following booster immunization. Although the presumed Type III reactions occurred in six persons during primary immunization series, none were observed following the first dose of the primary series.

Routine boosters of HDCV at two-year intervals have been recommended for persons with continuing risks of exposure. As increasing numbers of persons received their first routine two-year boosters, reports of presumed Type III hypersensitivity reactions increased in frequency. In approximately half of known cohorts who received booster immunizations between January 1982 and March 1984, some recipients had presumed Type III hypersensitivity reactions. Sixty-seven (7%) of 962 persons in these cohorts fit the above case description for presumed Type III hypersensivity reactions.

Clinical features [have been studied] in three of the cohorts reporting presumed Type III reactions following booster immunization with HDCV. When performed, urinalyses, blood urea nitrogen (BUN), and serum creatinine determinations were normal. Elevated white blood cell counts ranging from 14,000 to 24,000 (predominantly polymorphonu-

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clear leukocytes) were reported in two cases. Serum complement levels (C-3, C-4, and CH-50) were depressed in two patients when serum was drawn at the time of most active clinical symptoms; one of these also had detectable cryoglobulins. Serum-complement levels were normal in five other patients whose sera were collected at other times. Respiratory distress was infrequently seen. Most patients' symptoms improved within 2 to 3 days when treated with antihistamines, but a few required systemic corticosteroids and epinephrine.

Preliminary analysis of epidemiologic features of the illness in several cohorts revealed a male/female relative risk of 2.3 (95% confidence limits, 1.2 to 4.4). No significant associations have been demonstrated between persons who reported presumed Type III hypersensitivity reactions and age, route of primary or booster immunization (intramuscular or intradermal), timing of booster after primary immunization, history or other allergies, or history of previous immunization with rabies vacines other than HDCV. HDCV produced by both Merieux Institute and Wyeth Laboratories has been associated with reactions. In two groups for which serologic data were available, no difference was shown in pre-booster antibody titers between reactors and nonreactors, but post-booster titers were significantly higher in those who developed reactions. Most presumed type III reactions were reported to have occurred following booster doses, but six occurred following two or more doses of HDCV given for primary immunization.

MMWR Editorial Note: Primary immunization with HDCV appears to sensitize some recipients to an as yet unidentified component of the vaccine. When booster doses of HDCV are then administered, these persons develop a hypersensitivity reaction clinically consistent with Type III immune complex disease. Until this reaction problem can be resolved, it would be prudent to carefully assess each use of rabies vaccine for routine booster immunization. Persons who have experienced Type III hypersensitivity reactions should receive no further doses of HDCV unless: (1) they are exposed to rabies\*, or (2) they are truly likely to be inapparently and/or unavoidably exposed to rabies virus and have unsatisfactory antibody titers. The routine use of booster immunization in persons without histories of hypersensitivity reactions is clearly indicated only in those subjected to apparent and/or unavoidable exposures to rabies virus. All available data suggest an anamnestic antibody response will occur in any person who previously received primary pre-exposure immunization with HDCV, even when the antibody titer at the time of the booster was low or undetectable.

Individuals with histories of presumed Type III hypersensitivity to HDCV may be at higher risk of subsequent hypersensitivity reactions, and vaccine should be administered under appropriate medical supervision.

\*Post-exposure prophylaxis in previously immunized persons consists of two 1-ml intramuscular doses of HDCV, one each on days 0 and 3.

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