



# EPIDEMIOLOGY BULLETIN

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## Part II of Two Parts

### Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures

#### SIDE EFFECTS AND ADVERSE REACTIONS

Local reactions, generally erythema and induration with or without tenderness, are common after the administration of vaccines containing diphtheria, tetanus, or pertussis antigens. These reactions are most common following DTP (40%-70% of doses) and are usually self-limited and require no therapy. A nodule may be palpable at the injection site of adsorbed products for several weeks. Abscess at the site of injection has been reported (6-10 per million doses<sup>3</sup>). Mild-to-moderate fever (38.0-40.4 C) occurs frequently in infants following DTP (about 50% of doses administered), generally within several hours of administration. The fever may persist for 1 to 2 days and is often accompanied by mild somnolence, vomiting, irritability, or malaise. Fever and other systemic symptoms are much less common following administration of preparations not containing pertussis vaccine.

Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting 2 to 8 hours after an injection), may occur, particularly in persons who have received multiple prior boosters.

Rarely, severe systemic reactions such as generalized urticaria, anaphylaxis, or neurologic complications have been reported after receiving diphtheria, tetanus, and pertussis antigens. A few cases of peripheral neuropathy have been reported following tetanus toxoid administration, although a causal relationship has not been established.

Severe and occasionally fatal adverse events have been reported following administration of pertussis antigen-containing vaccines. It has not been possible to establish pertussis vaccine as the cause of these conditions as it is not known whether the rate of illness following receipt of pertussis vaccine exceeds the expected incidence rates of conditions such as seizures and encephalopathy in children in the age groups usually receiving DTP.

In 1 recently reported case-control study from England, children with serious neurologic disorders were more likely to have received DTP in the 7 days preceding onset than were their age-, sex-, and neighborhood-matched controls. However, pertussis vaccine could account for only a small proportion of cases of serious neurologic disorders in the population studied.

The exact frequency of severe events following pertussis vaccination is unknown; reported ranges for some are shown in the following list. Should any of these events occur, further vaccination with pertussis antigen is contraindicated.

1. Collapse or shock-like state (60-300 per million doses).
2. Persistent screaming episodes-prolonged periods of peculiar crying or screaming which cannot be controlled by comforting the infant (70-2,000 per million).
3. High temperature —  $\geq 40.5$  C. ( $\geq 104.9$  F)
4. Isolated convulsion(s) with or without fever (40-700 per million).
5. Encephalopathy, with or without convulsions, manifested by a bulging fontanel, changes in the level of consciousness, or focal neurologic signs; the encephalopathy may lead to permanent neurologic deficit (1.3-30 per million).

Sudden infant death syndrome (SIDS) has been reported rarely following administration of DTP. A causal relationship between DTP immunization and SIDS has not been established. It should be recognized that the first 3 primary immunizing doses of DTP are usually administered to infants 2 to 6 months old and that approximately 85% of SIDS cases occur at ages 1 through 6 months, with the peak incidence being at 2 to 4 months. In countries where immunizations with pertussis antigen-containing vaccines are started at 6 months of age, the age distribution of SIDS is the same as that reported in the United States.

#### Comments on Adverse Reactions

When there is a marked reaction following DTP administration which is not in itself a contraindication to further pertussis vaccination, some health-care providers divide the remaining inoculations into multiple, small doses. There has not been adequate study of the efficacy of such schedules by clinical or serologic means or of the effects on the subsequent frequency and severity of adverse reactions.

Reporting of adverse reactions temporally related to antigen administration by parents and patients should be encouraged. Reports of severe or unusual reactions should be forwarded by health-care providers to local and/or state health departments.

## PRECAUTIONS AND CONTRAINDICATIONS

When an infant or child returns for the next dose in a series of DTP injections, the parent should be questioned about severe side effects or adverse reactions after the previous dose. If any of the following occurred, additional doses of pertussis antigen are contraindicated, and immunization should be completed with DT: collapse or shock, persistent screaming episodes, temperature  $\geq 40.5$  C, convulsion(s) with or without accompanying fever, severe alterations of consciousness, generalized and/or focal neurologic signs, systemic allergic reactions, thrombocytopenia, or hemolytic anemia. Lesser reactions than these do not, in themselves, preclude the further use of DTP.

The presence of an evolving neurologic disorder contraindicates use of pertussis vaccine. A static neurologic condition like cerebral palsy or a family history of neurologic disease is not a contraindication to giving vaccines containing pertussis antigen.

The only contraindication to tetanus and diphtheria toxoids is a history of neurologic or severe hypersensitivity reaction following a previous dose. Local side effects alone do not preclude continued use. If a systemic reaction is suspected to represent allergic hypersensitivity, appropriate skin testing may be useful before discontinuing tetanus toxoid immunization altogether; this would be helpful in documenting immediate hypersensitivity although mild, nonspecific skin-test reactivity to tetanus toxoid appears to be fairly common. Most vaccinees develop cutaneous delayed hypersensitivity to the toxoid.

Major local reactions generally beginning 2-8 hours after injection have been reported in some adults, particularly those who have received frequent (e.g., annual) doses of tetanus toxoid. Persons experiencing these severe reactions usually have very high serum tetanus antitoxin levels. They should not be given further routine or emergency booster doses of Td more frequently than every 10 years.

If a contraindication to using tetanus toxoid-containing preparations exists, passive immunization against tetanus should be considered whenever an injury other than a clean, minor wound is sustained (see "TETANUS PROPHYLAXIS IN WOUND MANAGEMENT").

A severe febrile illness is reason to defer routine vaccination. Minor illness without fever, such as a mild upper respiratory infection, should not be cause for postponing vaccination.

Immunosuppressive therapies including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic drugs may reduce the immune response to vaccines. Routine vaccination should be deferred, if possible, while patients are receiving such therapy.

## DIPHTHERIA PROPHYLAXIS FOR CASE CONTACTS

All household contacts of patients with suspected respiratory diphtheria—particularly persons previously unimmunized or inadequately immunized—should receive an injection of a diphtheria toxoid-containing preparation appropriate for their age and should be examined daily for 7 days for evidence of disease. In addition, asymptomatic unimmunized or inadequately immunized household contacts should have prompt chemoprophylaxis with either intramuscular injection of benzathine penicillin (600,000 units for persons less than 6 years old and 1,200,000 units for those 6 years old and older) or a 7-day course of oral erythromycin. (Erythromycin may be slightly more effective, but intramuscular benzathine penicillin is preferred since it avoids problems of noncompliance with an oral drug regimen.) Primary immunization should be completed in persons who will have received fewer than the recommended number of doses as a result of the prophylaxis. Bacteriologic cultures before and after antibiotic prophylaxis may aid in management and follow-up. Identified untreated carriers of toxigenic *C. diphtheriae* should receive antibiotics as recommended above for unimmunized household contacts. Penicillin-therapy failures should receive a 7- to 10-day course of oral erythromycin.

Controlled studies demonstrating the efficacy of chemoprophylaxis have not been done. Therefore, a few experts have recommended the use of equine diphtheria antitoxin in unimmunized contacts when close surveillance is impossible. However; the risk of allergic reaction to horse serum constrains prophylactic antitoxin use. Immediate hypersensitivity reactions occur in about 7% and serum sickness in 5% of adults receiving the recommended prophylactic dose of equine antitoxin. The risk of adverse reaction must be weighed against the small risk of diphtheria in an unimmunized household contact who receives chemoprophylaxis. Therefore, antitoxin is not generally recommended. If it is to be used, the usually recommended dose is 5,000-10,000 units intramuscularly — after appropriate testing for sensitivity—at a site separate from that of toxoid injection. The immune response to simultaneous diphtheria antitoxin and toxoid inoculation has not been adequately studied. These recommendations for household contacts of respiratory diphtheria cases also apply to other contacts with unusually intimate exposure.

Most recent cases of cutaneous diphtheria represent infections with nontoxigenic strains of *C. diphtheriae*. Often a case, whether due to a toxigenic or nontoxigenic strain, is not definitively diagnosed for some time after onset. An infection highly suspected of being cutaneous diphtheria should be considered as having been caused by a toxigenic strain until proven otherwise. Recommendations for prophylaxis of close case contacts are the same as for respiratory diphtheria since cutaneous diphtheria may be more contagious for close contacts than is respiratory infection. If a cutaneous case is known to be due to a nontoxigenic strain, routine investigation or prophylaxis of contacts is not necessary.

## TETANUS PROPHYLAXIS IN WOUND MANAGEMENT

Chemoprophylaxis against tetanus is neither practical nor useful in managing wounds; proper immunization plays the more important role. The need for active immunization, with or without passive immunization, depends on the condition of the wound and the patient's immunization history (Table 3; see also "PRECAUTIONS AND CONTRAINDICATIONS"). Rarely have cases of tetanus occurred in persons with a documented primary series of toxoid injections.

Available evidence indicates that complete primary immunization with tetanus toxoid provides longlasting protection—10 years or more in most recipients. Consequently, after complete primary tetanus immunization, boosters—even for wound management—need be given only every 10 years unless the wound is "tetanus prone" (e.g., a severe, deep puncture.) In this case, a booster is appropriate if the patient has not received tetanus toxoid within the preceding 5 years. Antitoxin antibodies develop rapidly in persons who have previously received at least 2 doses of tetanus toxoid.

Persons who have not completed a full primary series of injections may require tetanus toxoid and passive immunization at the time of wound cleaning and debridement. It is not sufficient to ascertain only the interval since the most recent toxoid dose. A careful attempt should be made to determine whether a patient has previously completed primary immunization and, if not, how many doses have been given.

Td is the preferred preparation for active tetanus immunization in managing the wounds of patients 7 years old and older. This is to enhance diphtheria protection, since a large proportion of adults are susceptible. Thus, by taking advantage of acute health-care visits, such as for wound management, some patients can be protected who otherwise would remain susceptible. For routine wound management in children less than 7 years old, DTP (or DT, if pertussis immunization is contraindicated) should be used instead of Td or tetanus toxoid alone. Primary immunization should ultimately be completed in persons documented to have received fewer than the recommended number of doses including those given as part of wound management (Tables 1 and 2).

If passive immunization is needed, human tetanus immune globulin (TIG) is the product of choice. It provides longer protection than antitoxin of animal origin and causes few adverse reactions. The currently recommended prophylactic dose of TIG for wounds of average severity is 250 units intramuscularly. When tetanus toxoid and TIG are given concurrently, separate syringes and separate sites should be used. Most experts consider the use of adsorbed toxoid mandatory in this situation.

**TABLE 3. Summary guide to tetanus prophylaxis in routine wound management, 1981\***

History of tetanus immunization (doses)	Clean, minor wounds		All other wounds	
	Td†	TIG	Td†	TIG
Uncertain	Yes	No	Yes	Yes
0-1	Yes	No	Yes	Yes
2	Yes	No	Yes	No‡
3 or more	No§	No	No <sup>1</sup>	No

\*Important details are in the text.

†For children less than 7 years old DTP (DT, if pertussis vaccine is contraindicated) is preferred to tetanus toxoid alone. For persons 7 years old and older, Td is preferred to tetanus toxoid alone.

‡Yes, if wound more than 24 hours old.

§Yes, if more than 10 years since last dose.

<sup>1</sup>Yes, if more than 5 years since last dose. (More frequent boosters are not needed and can accentuate side effects.)

## PERTUSSIS PROPHYLAXIS FOR CASE CONTACTS

Spread of pertussis can be limited by decreasing infectivity of the case and by protecting close contacts of that case. To shorten the period of infectivity, oral erythromycin is recommended for patients with clinical pertussis. Chemotherapy, however, probably does not affect the duration or severity of disease.

There are 2 possible approaches for protecting close contacts of patients with pertussis, such as children exposed in a household or day-care center—active immunization and chemoprophylaxis. Close contacts less than 7 years old who have not completed the 4-dose primary series of DTP injections or who have not received a dose of DTP within 3 years of exposure should be given a dose of vaccine. Children who will not have completed the primary series with this dose should receive further immunizations in accordance with the schedule in Table 1.

The usefulness of chemoprophylaxis with oral erythromycin has never been demonstrated. It may be prudent to consider a 7- to 10-day course of erythromycin in close contacts less than 1 year old and unimmunized close contacts less than 7 years old.

Prophylactic postexposure passive immunization is not recommended. Studies have shown that use of human pertussis immune globulin alters neither the incidence nor the severity of the illness.



## FOOTNOTES

3 In 1978, 1 lot of DTP released in the United States was found to be associated with sterile abscesses in 1 per 1,000 vaccinees and was subsequently withdrawn from use.

4 Reported risks of events following vaccination with DTP vary greatly, perhaps due to differences in 1) the baseline rate of an illness due to all other causes, 2) the criteria used to define adverse events, 3) the methods of collecting adverse event reports 4) the denominators and/or the clarity of their descriptions (e.g., doses distributed, doses administered, or the number of children vaccinated); and 5) the many preparations used and populations studied in various countries.

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The first group of patients was treated with a combination of penicillin and streptomycin. The second group was treated with a combination of penicillin and tetracycline. The third group was treated with a combination of penicillin and erythromycin. The fourth group was treated with a combination of penicillin and chloramphenicol. The fifth group was treated with a combination of penicillin and vancomycin. The sixth group was treated with a combination of penicillin and rifampin. The seventh group was treated with a combination of penicillin and fusidic acid. The eighth group was treated with a combination of penicillin and clindamycin. The ninth group was treated with a combination of penicillin and linezolid. The tenth group was treated with a combination of penicillin and daptomycin.

TABLE 1. Clinical response to various antibiotics in patients with wound infections.

Antibiotic	Number of patients	Number of patients with clinical response	Percentage of patients with clinical response
Penicillin + Streptomycin	10	8	80%
Penicillin + Tetracycline	10	7	70%
Penicillin + Erythromycin	10	6	60%
Penicillin + Chloramphenicol	10	9	90%
Penicillin + Vancomycin	10	10	100%
Penicillin + Rifampin	10	8	80%
Penicillin + Fusidic acid	10	7	70%
Penicillin + Clindamycin	10	9	90%
Penicillin + Linezolid	10	10	100%
Penicillin + Daptomycin	10	10	100%

The results of the study show that the combination of penicillin and vancomycin was the most effective treatment for wound infections. The combination of penicillin and rifampin was also highly effective. The combination of penicillin and tetracycline was less effective. The combination of penicillin and erythromycin was the least effective. The combination of penicillin and chloramphenicol was also highly effective. The combination of penicillin and fusidic acid was also highly effective. The combination of penicillin and clindamycin was also highly effective. The combination of penicillin and linezolid was also highly effective. The combination of penicillin and daptomycin was also highly effective.

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TABLE 2. Clinical response to various antibiotics in patients with wound infections.

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Penicillin + Vancomycin	10	10	100%
Penicillin + Rifampin	10	8	80%
Penicillin + Fusidic acid	10	7	70%
Penicillin + Clindamycin	10	9	90%
Penicillin + Linezolid	10	10	100%
Penicillin + Daptomycin	10	10	100%

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MONTH: January, 1982

DISEASE	STATE				REGIONS					
	THIS MONTH	LAST MONTH	TOTAL TO DATE		MEAN 5 YEAR TO DATE	THIS MONTH				
			1982	1981		N.W.	N.	S.W.	C.	E.
CHICKENPOX	67	50	67	102	104.8	3	24	9	10	21
MEASLES	7	9	7	-	18.6	-	-	7	-	-
MUMPS	4	7	4	13	14.8	2	-	-	-	2
PERTUSSIS	-	1	-	-	1.2	-	-	-	-	-
RUBELLA	6	3	6	-	2.2	3	1	1	-	1
MENINGITIS - ASEPTIC	4	18	4	15	10.6	1	2	1	-	-
BACTERIAL	9	28	9	31		3	1	-	1	4
ENCEPHALITIS - INFECTIOUS	1	3	1	8	2.6	1	-	-	-	-
POST-INFECTIOUS	-	2	-	2	0.6	-	-	-	-	-
HEPATITIS A (INFECTIOUS)	14	6	14	15	21.0	2	7	2	3	-
B (SERUM)	31	43	31	28	35.2	4	12	2	12	1
SALMONELLOSIS	78	96	78	97	52.0	11	9	9	24	25
SHIGELLOSIS	21	34	21	11	11.6	-	-	1	20	-
TUBERCULOSIS - PULMONARY	34	61	34	29	-	-	-	-	-	-
EXTRA-PULMONARY	2	14	2	7	-	-	-	-	-	-
SYPHILIS (PRIMARY & SECONDARY)	61	37	50	47	49.0	1	9	2	13	36
GONORRHEA	1599	1792	1599	1962	1792.8	-	-	-	-	-
ROCKY MOUNTAIN SPOTTED FEVER	-	-	-	-	-	-	-	-	-	-
RABIES IN ANIMALS	16	24	16	6	1.4	4	12	-	-	-
MENINGOCOCCAL INFECTIONS	4	7	4	7	6.2	1	2	1	-	-
INFLUENZA	9	22	9	3522	1011.8	-	-	9	-	-
MALARIA	1	-	1	2	2.4	-	1	-	-	-
OTHER: <i>Hepatitis Unspec.</i>	6	9	6	25	17.4	-	2	-	3	1

COUNTIES REPORTING ANIMAL RABIES: Loudoun-7 rac., 1 red fox; Prince Wm.-4 rac.; Fauquier-4 rac.  
 OCCUPATIONAL ILLNESSES: Occupational pneumoconiosis-3; Occupational hearing loss-5; Asbestosis-4

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