





**Table of Reportable Events  
Following Vaccination (RET)**



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**Call VAERS at  
1-800-822-7967**

Vaccine/Toxoid (click on link for CDC VIS)	Event (click on link for definitions)	Interval from Vaccination (click on link for inserts)
<b>Tetanus</b> in any combination; DTaP, DTP, DTP-HiB, DT, Td, or TT)	A. <u>Anaphylaxis or anaphylactic shock</u>	7 days
	B. <u>Brachial neuritis</u>	28 days
	C. Any <u>sequelae</u> (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Pertussis</b> in any combination; DTaP, DTP, DTP-HiB, P	A. <u>Anaphylaxis or anaphylactic shock</u>	7 days
	B. <u>Encephalopathy (or encephalitis)</u>	7 days
	C. Any <u>sequelae</u> (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Measles, mumps and rubella</b> in any combination; MMR, MR, M, or R	A. <u>Anaphylaxis or anaphylactic shock</u>	7 days
	B. <u>Encephalopathy (or encephalitis)</u>	15 days
	C. Any <u>sequelae</u> (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert

<b>Rubella</b> in any combination; MMR, MR, R	A. Chronic arthritis	42 days
	B. Any <u>sequelae</u> (including death) of above event	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Measles</b> in any combination; MMR, MR, M	A. Thrombocytopenic purpura	7-30 days
	B. Vaccine-strain measles viral infection in an immunodeficient recipient	6 months
	C. Any <u>sequelae</u> (including death) of above event	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
Oral <b>Polio</b> (OPV)	A. Paralytic polio	30 days/ 6 months
	B. Vaccine-strain polio viral infection	30 days/ 6 months
	C. Any <u>sequelae</u> (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
Inactivated <b>Polio</b> (IPV)	A. <u>Anaphylaxis or anaphylactic shock</u>	7 days
	B. Any <u>sequelae</u> (including death) of the above event	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Hepatitis B</b>	A. <u>Anaphylaxis or anaphylactic shock</u>	7 days
	B. Any <u>sequelae</u> (including death) of the above event	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
	A. Events described in	

<b>Hemophilus influenzae</b> , Type b, (conjugate)	manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Varicella</b>	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Rotavirus</b>	A. Intussusception	30 days
	B. Any sequela (including death) of the above event	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
<b>Pneumococcal conjugate</b>	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert

\*Effective date: August 26,2002.

The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert. In addition, individuals are encouraged to report **any** clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for **any** vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.

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### Reportable Events Table Definitions

**Anaphylaxis and anaphylactic shock.** Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. (Return to Table)

**Brachial neuritis** is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, division, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. (Return to Table)

**Encephalopathy.** For purposes of the Reportable Events Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the

description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

1. An **acute encephalopathy** is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
    - a. For **children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.
    - b. For adults and **children 18 months of age** or older, an acute encephalopathy is one that persists for at least 24 hours and is characterized by at least two of the following:
      - i. A significant change in mental status that is not medication related: specifically a confusional state, or a delirium, or a psychosis;
      - ii. A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and
      - iii. A seizure associated with loss of consciousness.
  3. **Increased intracranial pressure** may be a clinical feature of acute encephalopathy in any age group.
2. A "**significantly decreased level of consciousness**" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater:
    - a. Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
    - b. Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
    - c. Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

3. **Chronic Encephalopathy** occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

An encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). ([Return to Table](#))

**Chronic Arthritis.** For purposes of the Reportable Events Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

1. Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and
2. Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination.
3. Medical documentation of an antibody response to the rubella virus.

The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

**Arthralgia** (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis. ([Return to Table](#))

**Early-onset Hib disease** is defined as invasive bacterial illness associated with the presence of Hemophilus influenzae b (Hib) organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic findings consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered an adverse event only if the vaccine was the first Hib immunization received by the child. ([Return to Table](#))

**Sequela.** The term "sequela" means a condition or event, which was actually caused by a condition listed in the Reportable Events Table. ([Return to Table](#))

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## Links to Package Inserts

### Tetanus Vaccine Combinations

Diphtheria, Tetanus Toxoids, and acellular Pertussis Pertussis Vaccine, Adsorbed (DTaP)

- **ACEL-IMUNE®** by [Lederle Laboratories](#)
- **Certiva** by [Abbott Laboratories](#)
- **Infanrix®** by [GlaxoSmithKline](#)

- **Tripedia®** by Aventis Pasteur

Diphtheria, Tetanus, Pertussis (DTP)

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed and Hemophilus b Conjugate Vaccine (DTP-Hib)

- **TETRAMUNE®** by Lederle (no longer marketed)
- **ActHIB®** by Aventis Pasteur

Diphtheria and Tetanus Toxoids, Adsorbed for Pediatric Use (DT)

- **PUROGENATED®** by Lederle Laboratories

Tetanus and Diphtheria Toxoids Adsorbed for Adult Use (Td)

- Td by Mass Public Health Biologic Laboratories
- **Td** by Aventis Pasteur
- **Td PUROGENATED®** by Lederle

Tetanus Toxoids (TT) Adsorbed,

- **TTox PUROGENATED** by Lederle Laboratories

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### **Pertussis**

Pertussis (P)

- No non-combination pertussis vaccines are currently licensed in the U.S.

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### **Measles, Mumps and Rubella**

Measles, Mumps and Rubella (MMR) Vaccine, Live

- **M-M-R® II** by Merck & Co., Inc.

Mumps and Rubella (MR) Vaccine, Live

- **M-R-VAX® II** by Merck & Co., Inc.

Mumps (M) Vaccine

- **MUMPSVAX®** by Merck

Rubella (R) Virus Vaccine, Live

- **Meruvax® II**, by Merck & Co., Inc.

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**Polio**

Polio Virus Vaccine, Inactivated

- **IPOL**® by Aventis Pasteur

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**Hepatitis B Vaccines**

Recombinant vaccines

- **Engerix-B**® by GlaxoSmithKline
- **RECOMBIVAX HB**® by Merck & Co, Inc.

Combination Hepatitis B (Recombinant) and Hib Vaccine

- **COMVAX**® by Merck & Co., Inc.

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**Hemophilus influenzae, Type b**

Polysaccharide Vaccines

Conjugate Vaccines

- Tetanus Toxoid Conjugates
  - **ActHIB**® by Aventis Pasteur
  - **OmniHIB**® is identical to Aventis' ActHIB but is distributed by SmithKline
- Diphtheria CRM197 Protein Conjugate
  - **HibTITER**® by Lederle Laboratories
  - **ProHIBIT**® by Connaught Laboratories
- Meningococcal Protein Conjugate
  - **PedvaxHIB**® by Merck & Co., Inc.
  - Hib and Hepatitis B (Recombinant), **COMVAX**® by Merck & Co., Inc.

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**Varicella**

Varicella Vaccine Live (Oka)

- **VARIVAX**® by Merck & Co., Inc.

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**Rotavirus**

Rotavirus Vaccine, Live, Oral, Tetravalent

- **RotaShield**® by Wyeth Laboratories (withdrawn from production October 15, 1999)

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**Pneumococcal Conjugate**

Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein Conjugate)

- **Prevnar** by Lederle Laboratories

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