VAERS Table of Reportable Events Following Vaccination*

Vaccine/Toxoid	Event	Interval from Vaccination
Tetanus in any combination; DTaP, DTP, DTP-HiB, DT, Td, TT, Tdap	A. Anaphylaxis or anaphylactic shock B. Brachial neuritis C. Any acute complications or sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days 28 days Not applicable See package insert
Pertussis in any combination; DTaP, DTP, DTP-HiB, P, Tdap	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complications or sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days 7 days Not applicable See package insert
Measles, mumps and rubella in any combination; MMR, MR, M, MMRV, R	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complications or sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days 15 days Not applicable See package insert
Rubella in any combination; MMR, MMRV, MR, R	A. Chronic arthritis B. Any acute complications or sequela (including death) of above event C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	42 days Not applicable See package insert
Measles in any combination; MMR, MMRV, MR, M	A. Thrombocytopenic purpura B. Vaccine-strain measles viral infection in an immunodeficient recipient C. Any acute complications or sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7-30 days 6 months Not applicable See package insert
Oral Polio (OPV)	A. Paralytic polio – in a non-immunodeficient recipient – in an immunodeficient recipient – in a vaccine associated community case B. Vaccine-strain polio viral infection – in a non-immunodeficient recipient – in an immunodeficient recipient – in a vaccine associated community case C. Any sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	 30 days 6 months Not applicable 30 days 6 months Not applicable Not applicable See package insert
Inactivated Polio (IPV)	A. Anaphylaxis or anaphylactic shock B. Any sequela (including death) of the above event C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days Not applicable See package insert
Hepatitis B	A. Anaphylaxis or anaphylactic shock B. Any acute complications or sequela (including death) of the above event C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days Not applicable See package insert
Hemophilus influenzae type b (conjugate)	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
Varicella	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
Rotavirus	A. Intussusception B. Any acute complications or sequela (including death) of the above event C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	30 days Not applicable See package insert
Pneumococcal conjugate	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
Hepatitis A	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert
Influenza	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert

* **Effective date: July 01, 2005.** 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.

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.

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.

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.
    c. 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).

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:

a. 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
b. 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.
c. 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.

Sequela. The term "sequela" means a condition or event, which was actually caused by a condition listed in the Reportable Events Table.