**Appendix 6: Definitions of adverse events following immunisation**

**Notify any events that the reporter considers serious and which may be related**

**to the vaccine or vaccines administered. See Section 1.5.2, *Adverse events***

***following immunisation*.**

**Abscess**

Occurrence of a fluctuant or draining fluid-filled lesion at the site of injection,

with or without fever.

• Bacterial: purulent collection.

• Sterile abscess: no evidence of bacterial infection.

**Acute flaccid paralysis [diagnosis must be made by a physician]**

Acute onset of flaccid paralysis of one or more limbs following any vaccine.

**Allergic reaction (generalised)**

A non-anaphylactic, generalised reaction characterised by 1 or more symptoms

or signs of skin and/or gastrointestinal tract involvement WITHOUT respiratory

or cardiovascular involvement.

(NB. See also ‘Anaphylaxis’).

**Anaphylaxis**

A rapidly evolving generalised multi-system allergic reaction characterised by

1 or more symptoms or signs of respiratory and/or cardiovascular involvement

AND involvement of other systems such as the skin or gastrointestinal tract.

• Respiratory: difficulty/noisy breathing, swelling of the tongue, swelling/

tightness in the throat, difficulty talking/hoarse voice, wheeze or

persistent cough.

• Cardiac: loss of consciousness, collapse, pale and floppy (babies),

hypotension.

**Arthralgia**

Joint pain without redness or swelling.

**Arthritis**

Joint pain with redness and/or swelling.

**Brachial neuritis**

Pain in arm causing persisting weakness of limb on side of vaccination.

**Death**

Any death of a vaccine recipient temporally linked to vaccination, where no

other clear cause of death can be established.

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**Disseminated BCG**

Disseminated infection occurring after BCG vaccination and confirmed by

isolation of *Mycobacterium bovis* BCG strain.

**Encephalopathy [diagnosis must be made by a physician]**

Encephalopathy is an acute onset of major neurological illness temporally

linked with vaccination and characterised by any 2 or more of the following 3

conditions:

• seizures,

• severe alteration in level of consciousness or mental status (behaviour and/or

personality) lasting for 1 day or more, and/or

• focal neurological signs which persist for 1 day or more.

**Encephalitis [diagnosis must be made by a physician]**

Encephalitis is characterised by the above-mentioned symptoms and signs

of cerebral inflammation and, in many cases, CSF pleocytosis and/or virus

isolation.

**Extensive limb swelling**

Swelling of the limb, with or without redness, which:

• extends from the joint above to the joint below the injection site, or beyond a

joint (above or below the injection site), orAppendix 6 361

**Injection site reaction (severe)**

Reaction (redness and/or swelling) at site of injection which:

• persists for more than 3 days AND is associated with ongoing symptoms

such as pain or an inability to use the limb (see ‘Brachial neuritis’ above), and

• does not fulfil the case definition for extensive limb swelling (see ‘Extensive

limb swelling’ above), or

• requires hospitalisation.

**Intussusception [diagnosis must be made by a hospital physician]**

The invagination of a proximal segment of bowel into the distal bowel lumen.

**Lymphadenitis (includes suppurative lymphadenitis)**

Occurrence of either:

• at least 1 lymph node, 1.5 cm in diameter or larger, or

• a draining sinus over a lymph node.

**Meningitis [diagnosis must be made by a physician]**

Acute onset of major illness with fever and often neck stiffness/positive

meningeal signs (Kernig, Brudzinski) and with CSF pleocytosis.

**Nodule**

A discrete or well demarcated soft tissue mass or lump that is firm and is at the

injection site in the absence of abscess formation, warmth and erythema.

**Orchitis**

Swelling with pain and/or tenderness of testes.

**Osteitis**

Inflammation of the bone due to BCG vaccination.

**Osteomyelitis**

Proven bacterial infection of bone.

**Parotitis**

Swelling and/or tenderness of parotid gland or glands.

**Rash**

Severe or unusual rash.

**Screaming (persistent)**

The presence of crying which is continuous and unaltered for longer than 3 hours.

**Seizure**

Witnessed sudden loss of consciousness and generalised, tonic, clonic, tonicclonic,

or atonic motor manifestations.

• febrile seizures: with fever ≥38.5°C,

• afebrile seizures: without fever,

• syncopal seizures: syncope/vasovagal episode followed by seizure(s).

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**Sepsis**

Acute onset of severe, generalised illness due to bacterial infection and confirmed

by positive blood culture.

**Subacute sclerosing panencephalitis [diagnosis must be made by a physician]**

Degenerative central nervous system (CNS) condition with laboratory

confirmation of abnormal serum and CSF measles antibodies.

**Syncope**

See ‘Vasovagal episode’.

**Thrombocytopenia**

Platelet count <50 x 109/L.

**Toxic shock syndrome [diagnosis must be made by a physician]**

Abrupt onset of fever, vomiting, watery diarrhoea and shock within a few hours

of vaccination as can be associated with other conditions listed here.

**Vaccine-associated paralytic poliomyelitis**

See ‘Acute flaccid paralysis’.

**Vasovagal episode (syncope, faint)**

Episode of pallor and unresponsiveness or reduced responsiveness or feeling

light headed AND

• occurring while vaccine being administered or shortly after (usually within

5 minutes), AND

• bradycardia, AND

• resolution of symptoms with change in position (supine position or head

between knees or limbs elevated).

(See Table 1.5.1 to distinguish from anaphylaxis).

**Other severe or unusual events**

Any unusual event that does not fit into any of the categories listed above, but

is of medical or epidemiological interest, should be reported with a detailed

description of the clinical features.

Report by telephone to State or Territory Health Department or notify by the blue

card to ADRAC (see Section 1.5.2, *Adverse events following immunisation*).

Note: The Brighton Collaboration is an international group considering definitions of adverse

events following immunisation. Its website is: http://www.brightoncollaboration.org.