

– Appendix I –

Definitions Used For Reportable Adverse Events

Consult the facsimile of the reporting form included in this Guide for definitions. The following notes are clarifications and amplifications, where necessary, of the definitions or notations on the reporting form.

Adenopathy

Report severe or unusual enlargement or drainage of the lymphatic nodes.

Allergic Reaction

Indicate whether therapy with antihistamines was found clinically necessary and/or useful.

Anaphylaxis

Should be distinguished from vaso-vagal episodes. If unsure whether it was true anaphylaxis (epinephrine given rapidly), describe the episode as completely as possible while noting the uncertainty. True anaphylaxis is rare.

Anesthesia/Paresthesia

Describe patient symptoms and course of illness in detail.

Arthralgia/Arthritis

Note any pre-existing history of arthritis, as well as any diagnostic testing done, and persistence of symptoms if follow-up information available.

Convulsion/Seizure

Episodes shortly after vaccination are more likely secondary to the act of vaccinating (i.e., features of a vaso-vagal episode). Note if this is the suspected etiology. Otherwise, carefully note the presence or absence of fever, as well as any antipyretic use.

Encephalopathy

Describe symptom onset and clinical course.

Fever

Report temperatures 39° C or above (rectal equivalent) or believed high with accompanying systemic symptoms.

Guillain-Barré Syndrome

Indicate if the patient had any other recent illnesses (GBS may have an antecedent viral etiology).

Hypotonic-Hyporesponsive Episode

This condition is non-specific. Follow definition carefully but report any possible cases. Tends to be related to pertussis-containing vaccines.

Infected Abscess

If antibiotics have been prescribed for a possible cellulitis, and signs and symptoms appear to have responded to the treatment, code this definition.

Meningitis and/or Encephalitis

Describe symptom onset and clinical course.

Paralysis

Differentiate from weakness or immobility due to pain (which may be seen in children).

Parotitis

Swelling and/or tenderness of the parotid glands.

Rashes

No need to code those that are part of an allergic reaction, but descriptions of all rashes should be made.

Screaming Episode/Persistent Crying

The key is the persistence and abnormal character (for that infant). Should be differentiated from a dramatic pain response if possible.

Severe Pain and/or Severe Swelling

Lasting for at least 4 days, or requiring hospitalization.

Severe Vomiting and/or Diarrhea

Note the possibility of any co-existing illness that may be responsible.

Sterile Abscess/Nodule

Since small nodules are common, report those that are significant; usually this means that they persist for > 1 month and are > 2.5 cm in diameter.

Thrombocytopenia

Please indicate laboratory values and/or basis for the diagnosis.

Other Severe or Unusual Events

Describe any other reaction that is significant enough to warrant reporting. Please include reason for reporting (of medical/epidemiologic interest, dramatic, not listed in product information, unexpected, patient very concerned, etc.). Indicate a specific diagnosis in addition to clinical description.