

Appendix 5.0 : Summary of Reporting Criteria

*The length of time between vaccine administration and onset of symptoms is an important consideration in causality assessment. Temporal criteria listed below are approximate timelines of which an applicable AEFI could occur.

| AEFI | Reporting criteria | *Vaccines (temporal criteria) | |
|---|---|-------------------------------|-----------------|
| | | Inactivated | Live attenuated |
| LOCAL REACTION AT INJECTION SITE | | | |
| Minor reactions | <ul style="list-style-type: none"> · Redness or swelling or pain extends past the nearest joint AND/OR · Redness or swelling or pain persists for 10 days or more | 0-48 hours | 0-48 hours |
| Major reactions: Arthus reaction | <ul style="list-style-type: none"> · Onset within 48 hours of immunization AND · Swelling extends past the nearest joint | 0-48 hours | 0-48 hours |
| Infected abscess | <ul style="list-style-type: none"> · Physician diagnosed AND · Material from the abscess is purulent (positive gram stain or culture) OR · Signs of localized inflammation (erythema, pain to touch, warmth) AND · Evidence of improvement with antimicrobial therapy | 0-7 days | 0-7 days |
| Sterile abscess | <ul style="list-style-type: none"> · Persists for >1 month, is >2.5cm in diameter and/or drainage is evident AND · Material from the mass is non-purulent AND · Absence of localized inflammation OR · Failure to improve on antimicrobial therapy | 0-7 days | 0-7 days |
| Nodule | <ul style="list-style-type: none"> · Is >2.5cm in diameter · Persists for >1 month | 0-7 days | 0-7 days |
| Cellulitis | <ul style="list-style-type: none"> · Physician diagnosed AND · Characterized by at least 3 local signs or symptoms: pain or tenderness to touch, erythema, induration or swelling, warmth to touch | 0-7 days | 0-7 days |

| SYSTEMIC EVENTS | | | |
|---------------------------------|--|--------------------------|------------|
| Fever | · Fever that occurs in conjunction with another reportable event | 0-72 hours | 0-42 days |
| Rash | · Generalized rash for which urgent medical attention is sought and believed to be related to vaccine · Any rash requiring hospitalization or treatment in ER | 0-7 days | 5-26 days |
| Adenopathy/ lymphadenopathy | · Enlargement of one or more lymph nodes, ≥ 1.5 cm in diameter AND/OR · Draining sinus over a lymph node | 0-6 days | 1-6 months |
| HHE | · Physician diagnosed AND · Reduced muscle tone AND · Hyporesponsiveness AND · Pallor or cyanosis AND · Child <2 years of age | 0-48 hours | 0-48 hours |
| Screaming/ Persistent crying | · Continuous, unaltered crying lasting for 3 or more hours | 0-72 hours | 0-72 hours |
| Parotitis/ Orchitis | · Physician diagnosed following immunization with mumps-containing vaccine | | 5-30 days |
| Vomiting/ Diarrhea | · 3 or more episodes in 24-hour period AND · Severe (i.e. projectile vomiting or explosive, watery diarrhea) | 0-72 hours | 0-72 hours |
| ALLERGIC REACTIONS | | | |
| Allergic reactions | · Any allergic reaction (hives, bronchospasm, edema) occurring within 72 hours of immunization | 0-48 hours | 0-48 hours |
| Anaphylaxis | · All adverse events managed as anaphylaxis at the time of occurrence | 0-24 hours | 0-24 hours |
| ORS | · Bilateral red eyes and respiratory symptoms with onset within 24 hours of Influenza vaccine receipt | Influenza: 0-24 hours | |

| NEUROLOGIC EVENTS | | | |
|---------------------------------|---|----------------|----------------|
| Convulsion/ seizure | · Seizures (febrile or afebrile) if they meet the temporal criteria | 0-3 days | 5-42 days |
| Encephalopathy/ encephalitis | · Physician diagnosed encephalopathy or encephalitis | 0-15 days | 2-42 days |
| Meningitis | · Physician diagnosed meningitis for which no other cause was identified | 0-15 days | 2-42 days |
| Anesthesia/ paresthesia | · Physician diagnosed anesthesia or paresthesia lasting 24 hours or more | 0-7 days | 0-7 days |
| Paralysis | · Physician diagnosed paralysis lasting 24 hours or more | 0-15 days | 0-42 days |
| GBS | · Physician diagnosed GBS | 0-8 weeks | 0-3 months |
| Bell's palsy | · Physician diagnosed Bell's palsy | 0-8 weeks | 0-3 months |
| SSPE | · Physician diagnosed SSPE | | |
| MISCELLANEOUS | | | |
| Thrombocytopenia | · Physician diagnosed occurring within 30 days post-immunization | 0-30 days | 0-30 days |
| Arthralgia/Arthritis | · Any arthralgia or arthritis that follows the receipt of rubella-containing vaccine and lasting at least 24 hours | | 0-42 days |
| Intussusception | · Intussusception or Hematochezia following rotavirus vaccine receipt | | 0-42 days |
| Syncope with injury | · Any syncope with injury following immunization | 0-24 hours | 0-24 hours |
| Death | · Any death of a vaccine recipient temporally linked to immunization where no other clear cause of death can be established | Within 1 month | Within 1 month |
| Fetal death or abnormality | · Any fetal death or abnormality that follows immunization of a pregnant woman | | |