Serious AEFI

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunisation:

- results in death – requires rapid escalation
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time.

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury
- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis.

Category 4: AESI related to TGA clinical evaluation – individual vaccine candidates and safety profile

- Pregnancy and birth outcomes.