Suggested list of core COVID-19 adverse events of special interest (AESIs) for safety monitoring in low- and middle-income countries

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The list is adapted from the Brighton Collaboration's Safety Platform for Emergency vACcines (SPEAC) list (https://brightoncollaboration.us/wp-content/uploads/2021/01/COVID-19-updated-AESI-list.pdf), and expanded to include conditions that have concern related to immunization errors.

The core AESIs are further prioritized in two tiers for consideration by countries. AESIs are categorized as **Tier One** because they (1) are serious; and (2) have been observed or associated with a COVID-19 or other coronavirus vaccine in animal models, clinical trials, or postintroduction pharmacovigilance, or are specific to immunization errors. Most **Tier One** AESIs would be hospitalized and can be included in hospital-based sentinel site surveillance.

AESIs that are seen with COVID-19 disease as theoretical concerns, nonserious, or relatively common are categorized as **Tier Two** and can be assessed in cohort event monitoring or outpatient settings.

Tier One
Vaccine associated enhanced disease
Multisystem inflammatory syndrome in children and adults (MIS-C/A)
Myocarditis
Pericarditis
Thrombosis with thrombocytopenia syndrome (TTS)
Thrombosis
Thrombocytopenia
Acute disseminated encephalomyelitis (ADEM)
Encephalitis
Myelitis
Acute respiratory distress syndrome (ARDS)
Anaphylaxis*
Toxic shock syndrome (TSS)
Injection site cellulitis/abscess*

*Cases of anaphylaxis and infection site cellulitis/abscess may not be hospitalized.

Tier Two
Acute kidney injury
Acute liver injury
Anosmia/ageusia
Bell's palsy
Chilblain like lesions
Erythema multiforme
Acute pancreatitis
Rhabdomyolysis
Subacute thyroiditis