Notification Form for Adverse Events Following Immunization (AEFI) with COVID Vaccines

Patient information

Name:		RDHS area - MOH Division:
Age:	Sex: Male ☐ Female ☐ Pregnant- Y/N	Telephone:
Address:		Guardian/contact details:

Information on the Vaccine

Location of vaccine administration: | Vaccination date: D D/M M/Y Y Y Y

Vaccine administered by: Doctor ☐ PHNS/Nurse ☐ PHM ☐ PHI ☐ | Vaccination time: a.m./p.m.

Vaccine	Dose (1st, 2nd, 3rd, or booster)	Route	Batch/lot number	Expiry date (DD/MM/YYYY)	VVM status (I, II, III, IV)
ChAdOx1nCoV-19 Corona Virus Vaccine-☐ (Oxford-Astra Zeneca/ Covishield/.....) Sputnik V ☐ Sinopharm ☐ Sinovac ☐ Pfizer-BioNTech ☐ Moderna ☐ Other:.....					

Diluent used: Yes ☐ No ☐ If yes, diluent batch/lot number: Expiry date of diluent: DD/MM/YYYY

Adverse events (AE)

Instruction: Before reporting an AEFI, please refer to the definition for the relevant AEFI given overleaf and make sure that the reported event agrees with the criteria stipulated in the definition

Neurological AE requiring investigation	CVT with TTS ☐ CVT without TTS ☐ Ischaemic stroke/TIA ☐ ICH ☐ Meningoencephalitis ☐ ADEM ☐ Myelitis ☐ GBS ☐ Encephalopathy ☐ Seizure ☐ Bell's palsy ☐ Myocarditis ☐ Sensorineural hearing loss ☐ Other (specify):
Other AE requiring investigation	Anaphylaxis ☐ ACS ☐ DVT/PE ☐ TTP ☐ Pneumonia ☐ Respiratory failure ☐ TTS elsewhere (specify site) ☐: Other (specify):
AE not requiring investigation	Isolated thrombocytopaenia ☐ Allergic reaction ☐ Arthralgia ☐ Nodule at injection site ☐ High fever (>39^{0}C/102^{0}F) ☐ Ecchymoses ☐ Other (specify):
Details of this AE	Date, time of onset of AE: DD/MM/YYYY, TT:TT Date, time of presentation to the Institution DD/MM/YYYY, TT:TT Short history of AE & treatment given: Thrombocytopaenia: Yes ☐ No ☐ If yes, lowest PLT count: Relevant investigations (PLT count, Fibrinogen, D-dimer, NS1 Ag etc.):

Medical history

Past Covid-19 infection: Yes ☐ No ☐ If yes, confirmed by: PCR ☐ RAT ☐ Date of diagnosis: DD/MM/YYYY
Severity: Asymptomatic ☐ Mild ☐ Moderate ☐ Severe - Yes ☐ No ☐ HDU/ICU ☐
Treatment details:

Past Covid-19 vaccinations: Yes ☐ No ☐ Completed ☐ If yes/completed,
Vaccine name: Dose (1st, 2nd, 3rd, or booster): Route: Date: DD/MM/YYYY

Past thrombotic illnesses: Yes ☐ No ☐ If yes: CVA ☐ ACS ☐ PE ☐ Other venous thrombosis ☐ (specify):

Relevant drug history (aspirin/heparin/warfarin/other):

Comorbidities :DM ☐ HTN ☐ BA ☐ CKD ☐ CLD ☐ Neoplasm ☐ Autoimmune/inflammatory disease ☐
Acute Infections ☐ Other details:

Outcome and grading of this AEFI

Hospitalized: Yes ☐ No ☐ If yes, hospital: BHT: Still in-ward ☐ Discharged ☐

Grading: Mild ☐ Moderate ☐ Severe ☐ | Complete recovery ☐ Partial recovery ☐ No recovery ☐ Death ☐

Reporting source

Name of the notifying Officer: Designation: Telephone:
Institution: Signature: Date of notification:

(Medical Officers who attend any patient suffering from Adverse Effects Following Immunization with COVID vaccine shall notify the AEFI using this form to the Epidemiology Unit,231 Seram Place, Colombo 10. Email: epidunit@sltnet.lk. Tel:+94-11-2695112/2681548.Fax: 011 -2696583)

Acute Encephalitis
Brain histopathology with acute inflammation of CNS parenchyma
OR clinical evidence of encephalopathy *WITH* Focal central nervous system (CNS) abnormal symptoms and signs
AND Evidence for inflammation (fever, CSF pleocytosis, EEG and neuroimaging changes suggestive of inflammation)
Exclusion criterion – alternative diagnosis for CNS abnormalities (neoplastic, vascular, or metabolic disorder, infection, toxin)

Acute Myelitis
Spinal cord histopathology with evidence of acute spinal cord inflammation
OR clinical evidence of myelopathy (limb weakness with typically upper motor neuron signs, sensory level, or autonomic dysfunction)
AND evidence of spinal cord inflammation (fever, evidence of CSF pleocytosis, CT/MRI evidence of inflammation)
Exclusion criterion – presence of alternative diagnosis for findings

ADEM – Acute Disseminated Encephalomyelitis
Multifocal clinical CNS events with alteration in consciousness or behaviour *AND* abnormal brain MRI with typical diffuse, poorly demarcated inflammatory lesions >1cm.

Anaphylaxis
Sudden onset OR rapid progression of signs & symptoms
WITH involvement of >2 of the following
Skin – generalized urticaria, erythema, angioedema, pruritus with skin rash.
Respiratory – bilateral wheeze, stridor, upper airway swelling, indicators of respiratory distress – e.g.: tachypnoea, cyanosis, grunting, chest wall retractions, increased use of accessory muscles
CV – measured hypotension, signs of uncompensated shock – e.g.: tachycardia, CRFT >3s, reduced central pulse volume, decreased level or loss of consciousness

ARDS – Acute Respiratory Distress Syndrome
Hypoxaemia- P/F ratio ≤ 300
AND positive pressure requirement: - PEEP/CPAP ≥ 5 cmH_20
AND imaging: chest imaging with bilateral chest opacities not explained by other process
AND origin of oedema: not related to fluid overload or cardiogenic oedema
AND timing: within 1 week of known clinical insult

Aseptic Meningitis
Clinical evidence of acute meningitis
AND CSF pleocytosis, with NO evidence of infection on CSF gram stain, culture, or other investigations (antigen/antibody/PCR tests)
antibiotic therapy - not given *OR* not started until after CSF collected for culture

Bell's Palsy
Peripheral facial nerve palsy
AND disease onset abrupt, course rapidly progressive and some or complete resolution
AND not attributed to other aetiology

CVT – Cerebral Venous Thrombosis
Relevant clinical features (e.g.headache, visual disturbance, focal neurological deficits, impaired consciousness, seizures) with evidence of cerebral venous sinus or cortical vein thrombosis on neuroimaging (CT/MR venogram).

Encephalopathy
Acute or subacute (<4 weeks) alteration in consciousness, cognition, personality, or behavior, persisting for >24 hours, with no evidence of CNS inflammation and absence of alternative diagnosis.

GBS – Guillain-Barré syndrome
Flaccid paralysis of limbs
AND decreased/absent deep tendon reflexes
AND monophasic illness pattern with weakness nadir 12h – 28 days
AND absence of alternative cause for weakness
AND electrophysiologic findings typical for GBS
OR CSF WBC <50/uL with elevated/normal protein

Generalized Seizure
Sudden loss of consciousness
AND motor manifestations (generalized, tonic, clonic, tonic-clonic, atonic or other)
AND not attributed to other aetiology

Stroke/ICH
Rapidly developing disturbance of cerebral function
AND vascular origin (haemorrhagic/thrombotic)
AND not attributed to other aetiology

Thrombocytopenia
Platelet count < 150 x 10^9/ L
AND Low platelets confirmed on peripheral blood smear
OR clinical symptoms and/or signs of spontaneous bleeding

TTP – Thrombotic Thrombocytopaenic Purpura
Associated thrombocytopenia <150 × 109/L
AND haemolytic anaemia
AND fever
AND neurological abnormalities
AND renal disease

TTS - Thrombosis Thrombocytopaenia Syndrome
A platelet count of less than 150,000/ ul of new onset without history of receipt of heparin within 100 days
AND imaging study, surgical
Or pathology findings consistent with thrombosis/thromboembolism

Abbreviations

ACS - Acute Coronary Syndrome
AE - Adverse Effects
CKD - Chronic Kidney Disease
CLD - Chronic Liver Disease
CNS - Central Nervous System
CSF - Cerebrospinal Fluid
CVA - Cerebrovascular Accident
DM - Diabetes Mellitus
GBS - Guillain-Barre Syndrome
HTN - Hypertension
MOH - Medical Officer of Health
PAD - Peripheral Arterial Disease
PCR - Polymerase Chain Reaction
PHI - Public Health Inspector
PHM - Public Health Midwife
PHNS - Public Health Nursing Sister
PLT - Platelet
RAT - Rapid Antigen Tests
VVM - Vaccine Vial Monitoring
NS1- Nonstructural protein 1
PE- Pulmonary Embolism