

Annex 1

Updated (October 2022) COVID-19 AESI including status of associated Brighton case definitions

TABLE 1. Updated (October 2022) COVID-19 AESI including status of associated Brighton case definitions

| BLE 1. Updated (October 2022) COVID-19 AESI including status of a | |
|---|---|
| AESI | Brighton Case Definition Status |
| Acute respiratory distress syndrome | Published |
| Multisystem inflammatory syndrome (children & adults) 3.4 | Published |
| Myocarditis / pericarditis Other forms of acute cardiac injury including arrhythmias, heart failure, coronary artery disease, myocardial infarction, stress cardiomyopathy | Published No Brighton case definition to be developed but companion guide to myocarditis/pericarditis includes background rates and ICD/MedDRA codes |
| Thrombosis and Thromboembolism | Published |
| Hemorrhagic disorders including DIC | Not yet started |
| • Anosmia ^{3,4} | • To be submitted to Vaccine by Oct 31, 2022 |
| • Ageusia ^{3,4} | No case definition to be developed |
| Chilblain – like lesions | Not yet started |
| Erythema multiforme | Not yet started |
| Single Organ Cutaneous Vasculitis | Published |
| Acute kidney injury | Published lab-based criteria (see *) |
| Acute liver injury | Published lab-based criteria (see #) |
| Acute pancreatitis | Not yet started |
| Rhabdomyolysis | Not yet started |
| Subacute thyroiditis | Not yet started |
| Anaphylaxis ^{1,2} | Published |
| Thrombocytopenia ^{1,2,3,4} | Published |
| Generalized convulsion ^{1,2} | Published |
| Acute disseminated encephalomyelitis ⁴ | Published |
| Guillain Barré Syndrome ^{3,4} | Published |
| Acute aseptic arthritis r-VSV | Published |
| Aseptic meningitis Live vaccines | Published |
| Encephalitis / Encephalomyelitis Live vaccines | Published |
| Bell's Palsy Intranasal EColi Heat Labile Toxin Adjuvanted Vaccine | Published |
| $\label{lem:Vaccine} \begin{tabular}{ll} Vaccine associated enhanced disease 1(Formalin inactivated measles/RSV; HIV),} \\ 2(Chimeric YF Dengue), 5 (SARS / MERS-CoVs) \\ \end{tabular}$ | Published |
| Thrombocytopenia and Thrombosis Syndrome ⁶ | Proposed case definition posted online; Working group to be formed by end of 2022 |
| Immune Thrombocytyopenia (ITP) ⁶ | Thrombocytopenia published; revision needed |
| Capillary Leak Syndrome ⁶ (Flare up in individuals with prior history of capillary leak syndrome) | Not yet started |
| Delayed hypersensitivity reaction ⁶ | Not yet started |
| Extensive limb swelling ⁶ | Not yet started |



| Facial swelling in individuals with dermal fillers ⁶ | Not yet started |
|---|-----------------|
| Dizziness and tinnitus ⁶ | Not yet started |

¹ Proven association with immunization encompassing several different vaccines

- Increase in serum creatinine by ≥ 0.3 mg/dl (≥26 μmol/l) within 48 hours; OR
- \bullet Increase in serum creatinine to ≥ 1.5 times baseline, known or presumed to have occurred within prior 7 days OR
- Urine volume ≤0.5 ml/ kg/ hour for 6 hours

Acute liver injury – definition as used in majority of COVID-19 publications (but no international consensus):

- > 3-fold elevation above the upper normal limit for ALT or AST OR
- > 2-fold elevation above the upper normal limit for total serum bilirubin or GGT or ALP
- Case Definition and resources available at: https://docs.google.com/spreadsheets/d/1QgF35nYcsaFN3DZTOtV IPOTYqQzsDMUQBAd5M9brrM/edit#gid=1666959
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² Proven association with vaccine that could theoretically be true for novel COVID-19 vaccines

³ Theoretical concern based on wild type disease immunopathogenesis

⁴Theoretical concern related to viral replication during wild type disease

⁵ Theoretical concern because it has been demonstrated in an animal model with ≥ 1 vaccine platform

⁶ Signal recognized and validated during COVID-19 mass campaigns or regaultor(s) required update to product information

^{*} Acute kidney injury–consensus definition of Kidney Disease Improving Global Outcomes expert consensus group www.kdigo.org