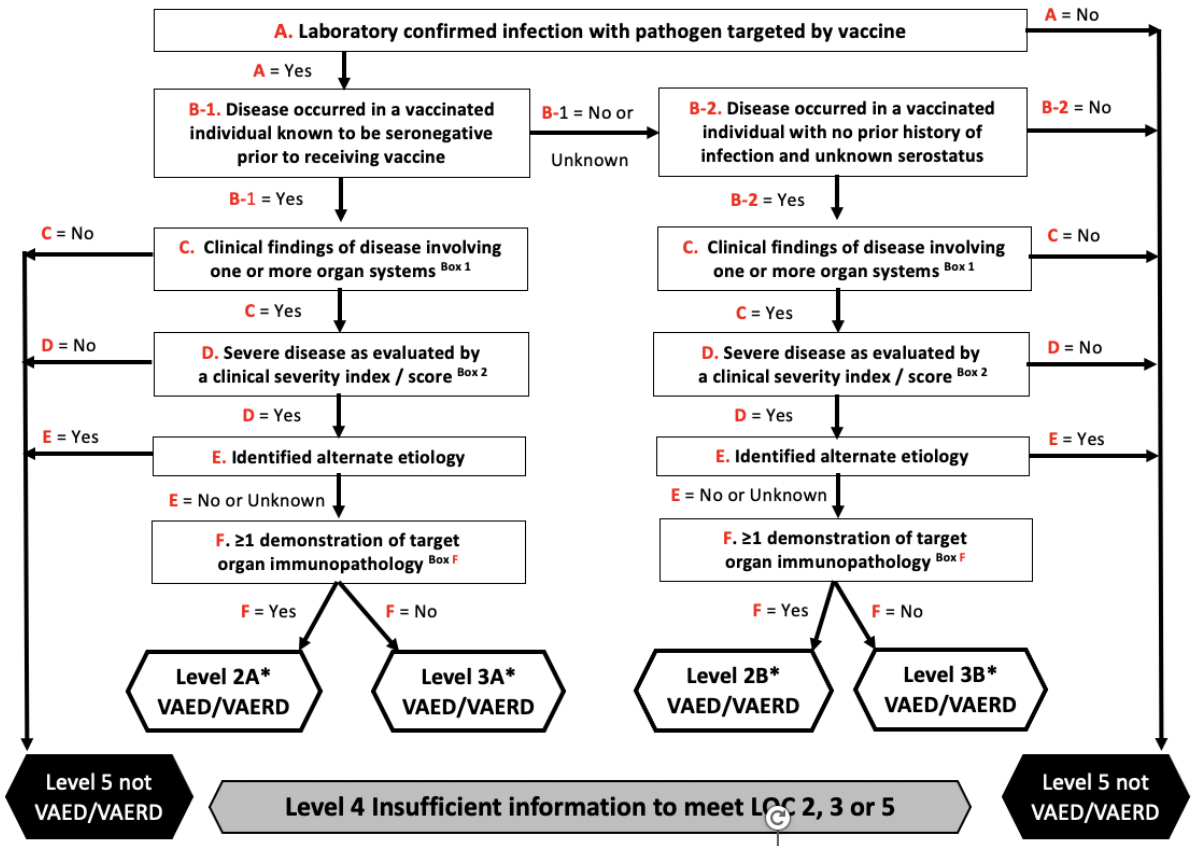
SPEAC

FIGURE 1. PICTORIAL ALGORITHM FOR DETERMINING VAED LEVEL OF CERTAINTY IN ADULTS



C.. Organ system involvement (guide only; not exhaustive)

i. Respiratory (VAERD) ≥1 :
- ❑ Clinical - respiratory distress / failure; Lower respiratory tract disease; pulmonary hemorrhage; Radiolographic abnormalities
- ❑ Lab – hypoxemia, oxygen requirement; PaO2; Aa gradient; PaO2/FiO2 ratio

ii. Cardiovascular ≥1:
- ❑ Clinical: tachycardia; hypotension; heart failure; myocarditis; vasculitis/vasculopathy; cardiogenic shock
- ❑ Lab – elevated NTproBNP or Troponin; abnormal EKG; abnormal echocardiogram

iii Hematopoietic & Immune system - ≥1:
- ❑ Clinical: coagulopathy; DIC; bleeding/thrombotic events
- ❑ Lab – leukopenia; lymphopenia; thrombocytopenia; B and t cell functioin assays; altered coagulation parameters (PT, PTT, D-Dimer, INR); elevated inflammatory markers (CRP, procalcitonin, ferritin, LDH); elevated cytokines

iv. Renal - ≥1:
- ❑ Clinical: renal dysfunction; acute kidney injury; need for renal replacement therapy
- ❑ Lab – decreased urine output; elevated serum creatinine; decreased GFR

v. Gastrointestinal and Hepatic systems - ≥1:
- ❑ Clinical: emesis/diarrhea; abdominal pain; hematochezia/Melena; hepatitis; acute liver failure
- ❑ Lab – electrolyte abnormalities; elevated liver enzymes / bilirubin

vi. Central Nervous System
- ❑ Clinical: altered mental status, seizures; cranial nerve palsies; loss of consciousness
- ❑ Lab: elevated ICP; abnormal CSF parameters

vii. Other
- ❑ Clinical: fatigue; myalgia/myositis/myonecrosis;arthralgia / arthritis; multiorgan failure; death
- ❑ Lab – viral load (PCR Ct value); antibody titers

NOTE: There is no Level 1 for VAED/VAERD due to lack of evidence for establishing a definite case

***G. Increased frequency of severe outcomes (including severe disease, hospitalization and mortality) when compared to a non-vaccinated population (control group or background rates)**

Criteria A, B-1, B-2, C, D, E and F must be applied to individuals. However, to meet the case definition of VAED/VAERD at any level of certainty , it is necessary to confirm that the frequency of identified cases exceeds that in a control group or the background rate of severe outcomes following infection in unvaccinated persons

F. Evidence of immunopathology in target organs - ≥1:
- ❑ Present or elevated eosinophils in tissue
- ❑ Elevated pro-inflammatory Th2 cytokines in tissue (IL4, IL5, IL10, IL13)
- ❑ C4d tissue deposition (evidence of immune complex deposition)
- ❑ C1q assessments of immune complexes in fluids
- ❑ Low C3 levels (evidence of complement consumption)