# VAD Adverse Events

*A Summarized Clinician Reference Guide*

action
ADVANCED CARDIAC THERAPIES IMPROVING OUTCOMES NETWORK

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# Hematologic Events

## 1. Neurological Dysfunction

**TIMING**

Anytime during VAD support

**TYPES**

- Ischemic stroke
- Intracerebral hemorrhage (in brain/spinal cord)
- Extra-axial hemorrhage (around brain/spinal cord)
- Undefined type
- Hypoxic ischemic encephalopathy
- Encephalopathy (other)
- Neuropathy

**PRESENTATION**

- Overt: With neurological symptoms
- Covert: No exam findings; injury detected on imaging

**GRADES**

***2:*** No change in management

***3:*** Requires any of the following:
- New antiepileptic medication,
- Discontinuation of antithrombotic therapy >24 hrs
- Change in transplant listing

***4:*** Requires neurosurgical or interventional procedure

## 2. Bleeding

**TIMING**

- Grade 4: Any time after index procedure
- Grades 2–3: Identified ≥72 hrs after leaving OR/cath lab

Report each event with location and grade

**LOCATIONS**

- GI
- Nasal/Oral
- Pleural/Mediastinal
- Pericardial
- Pulmonary
- Genitourinary
- Cannula/Driveline/Percutaneous
- Retroperitoneal
- Other

**GRADES**

***2:*** Local intervention only (packing, superficial cautery, topical hemostatic agent)

***3:*** Any of the following:
- PRBC transfusion due to bleed.
- New surgical/percutaneous drain placement.
- All anticoagulation held >24 hrs (if started).

***4:*** Invasive procedure (e.g., surgical exploration or embolization)

## 3. Hemolysis

**TIMING**

Anytime during VAD support

**LAB CRITERIA**

Any of the following on 2 separate draws:
- Plasma Free Hgb > 50 mg/dL (clean draw)
- LDH > 3× upper limit of normal (no other cause; provider judgment)
- Moderate or greater hemolyzed cells on smear

**GRADES**

***2:*** Isolated lab criteria without other clinical findings

***3:*** Lab criteria plus:
- PRBC transfusion (hemolysis main reason), or
- External pump/component exchange (hemolysis main reason)

***4:*** Lab criteria plus:
- Surgical intracorporeal pump exchange, or
- AKI from hemolysis requiring RRT

*Grade 5 (death related to the adverse event) is applicable to all adverse events listed in this document, even if not explicitly stated under each definition.*

# Device Related Events

## 1. Pump Thrombosis

**TIMING**
Anytime during VAD support

**TYPES**
***Note:*** *Applies only if pump is functioning appropriately. If the device is not functioning appropriately, the exchange will qualify as a device malfunction AE.*

*Paracorporeal/Transcatheter Devices:*
- Criteria met if device/component is exchanged due to thrombus/fibrin
- Multiple components exchanged in one procedure due to or related to thrombosis = one AE

*Intracorporeal Devices:*
- Criteria met if 2 or more of the following are present, attributed to thrombus:
  - Abnormal device function or parameter changes
  - Inadequate cardiovascular support or embolic event
  - Hemolysis
  - Confirmed thrombus (on imaging or after explant)

**GRADES**
- ***2:*** No embolization; external component replaced
- ***3:*** Embolization (e.g., stroke); external component replaced
- ***4:*** Any embolization status; surgical or transcatheter replacement of internal component

***Note:*** *Multiple AE definitions may be met; for example, if hemolysis leads to concern for pump thrombosis and pump exchange, the criteria for hemolysis may also apply. Another example: If the patient has a stroke with evidence of pump thrombosis, complete the Neurological Event form as well.*

## 2. Device Malfunction (includes all components)

**TIMING**
Anytime during VAD support

**DEFINITION**
Device not functioning per manufacturer specifications (excludes routine maintenance). Report even if due to user error or non-FDA accessories.

**TYPES**
- Mechanical failure: e.g., controller overheating
- Structural failure: e.g., membrane/cannula rupture
- Dysfunction: e.g., battery not charging
- None: Device working but replaced due to concern

**GRADES**
- ***2:*** Device functioning properly, requires:
  - Non-routine Reset/alarm response or power source change (e.g., battery swap), or
  - Non-routine replacement/repair of an external paracorporeal pump or component (e.g., sound, abnormal appearance)
- ***3:*** Device not working, no clinical symptoms, requires:
  - Non-routine replacement/repair of paracorporeal/percutaneous component (e.g., tubing tear), or
  - Repair of external intracorporeal device's external component (e.g., driveline repair)
- ***4:*** Device not working and either:
  - Symptoms + vasoactive meds; treatment includes replacement/repair of paracorporeal/intracorporeal component, or
  - Surgical replacement of internal component (symptoms may or may not be present)

# Infection Events

## 1. Device-Specific Infections

**TIMING**
Anytime during VAD support

**REPORTING**
Each event includes a type and grade

**TYPES**

- Superficial driveline/cannula/peripheral site infection:
  - Negative blood culture and
  - At least one of: purulence, pain, erythema, or induration at the site
- Deep percutaneous site infection:
  - Meets superficial criteria plus at least two of:
    - Fluid collection at site
    - Imaging consistent with deep infection
    - Fever, leukocytosis, tachycardia, or systemic inflammatory response
- Device-specific bloodstream infection:
  - Positive blood culture plus one of:
    - Deep site infection
    - Culture from device circuit
    - Persistent culture with same organism >72 hrs apart
    - Imaging evidence of vegetation/thrombus
- Sternal wound infection with mediastinal extension:
  - Involves external device components and
  - Positive culture from surrounding tissue/fluid
  - Systemic signs of infection (e.g. fever, leukocytosis)

**GRADES**

***1:*** Superficial infection managed with:
- Dressing changes
- Topical antimicrobials or
- < 24 hrs systemic antimicrobials

***2:*** Superficial infection, no systemic signs, treated with >72 hrs of enteral antimicrobials

***3:*** Either:
- Superficial infection with systemic signs, treated with >72 hrs of IV/IM antimicrobials
- Superficial infection (± systemic signs) requiring:
  - External component exchange
  - I&D at site
  - Long-term (>4 weeks) oral or IV therapy

***4:*** Deep infection with any of:
- Internal device component exchange
- Surgical/invasive procedure (e.g. chest tube, washout)
- ≥3 positive cultures with same organism over ≥7 days, requiring long-term IV therapy

## 2. Non-Device Related Infections

**TIMING**
Anytime during VAD support

**REPORTING**
Each event includes a type and grade

**TYPES**

- Viral upper/lower respiratory infection
- Viral gastroenteritis
- Sternal wound infection (no mediastinal extension)
- Pneumonia (with radiographic + clinical findings)
- UTI (clinical + positive culture)
- Other

**GRADES**

***1:*** Observation or antimicrobials <72 hrs

***2:*** Admission or oral antibiotics ≥72 hrs

***3:*** IV/IM antibiotics >72 hrs or fluids <40 mL/kg

***4:*** IV/IM antibiotics + ≥40 mL/kg fluids, vasoactives, or surgery

# End-Organ Failure Events

## 1. Right Heart Dysfunction (Biventricular Circulation Only)

**TIMING**

- Additional of RVAD or transition to ECMO anytime post VAD placement
- Medical management for right heart dysfunction >10 days post-op

**DIAGNOSTIC CRITERIA**

- Requires a functioning LVAD and one finding from both categories, ≥10 days post-index operation:

**HEMODYNAMICS** *(one of)*

- Right-sided/systemic venous pressure >14 mmHg
- Clinical signs of elevated CVP (e.g., effusions, ascites, hepatomegaly) with inadequate LVAD preload (CO <50% expected and not responsive to pump changes)

**IMAGING** *(one of)*

- Moderate/severe tricuspid regurgitation
- Moderate/severe RV systolic dysfunction (documented)

**OR, AT ANY TIME POST-OP**

- Transition to ECMO (for RV failure)
- RVAD implantation

**GRADES**

***3:*** Medical management requiring vasoactives, invasive drainage, or prolonged drain use due to RV failure

***4:*** ECMO or RVAD placement for RV failure

## 2. Renal Dysfunction

**TIMING**

Anytime during VAD support

**DIAGNOSTIC CRITERIA**

- Requires abnormal creatinine or eGFR (via Cystatin C, modified Schwartz, or CKiD) on 2 consecutive lab draws

**GRADES**

***2:*** Creatinine 2–3× baseline* or eGFR 35–60 ml/min/1.73 m²

***3:*** Creatinine ≥3× baseline* or eGFR <35 ml/min/1.73 m²

***4:*** New need for renal replacement therapy (RRT)

**Baseline = last lab draw before VAD placement*

## 3. Hepatic Dysfunction

**TIMING**

Anytime during VAD support

**DIAGNOSIS**

Requires ≥2 of the following, confirmed on two consecutive labs:

- Total bilirubin >3x upper limit of normal or >3x baseline if elevated pre-implant
- INR >3 (not from anticoagulants, dilution, or vitamin K deficiency)
- AST/ALT >3x upper limit of normal or >3x baseline (not due to hemolysis, myositis, rhabdo)
- Hepatic encephalopathy diagnosed by neurology

**Baseline = last lab draw before VAD placement*

**GRADES**

***2:*** Meets lab criteria

***3:*** Labs + hepatic encephalopathy and/or coagulopathy needing FFP, cryo, or clotting factor products

***4:*** Encephalopathy requiring mechanical ventilation or hepatic replacement therapy (MARS)

## 4. Respiratory Dysfunction

**TIMING**

Escalation in respiratory support >10 days post VAD placement or transition to ECMO, oxygenator addition, or tracheostomy placement at any time post VAD

**DEFINITION**

New need for PPV (invasive or non-invasive) or MCS (e.g., ECMO, oxygenator) due to impaired respiratory function unrelated to diagnostic/therapeutic procedures

**GRADES**

***2:*** New non-invasive PPV (e.g., CPAP, BiPAP) not prescribed pre-VAD

***3:*** >10 days post VAD, requirement of PPV via ETT or tracheostomy for >24 hours (not procedure-related)

***4:*** ECMO, oxygenator addition, or new tracheostomy

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## 5. Vasoplegia

**TIMING**
Within 72 hours post VAD implant

**DEFINITION**
- Low SVR with hypotension and normal/elevated device flow (CI >2.4 L/min/m2) with no alternative cause
- End organ hypoperfusion with new kidney/liver dysfunction

**GRADES**
***3:*** ≥3 vasoconstrictors required
***4:*** >3 vasoconstrictors + one of the following:
- ECMO
- Distal extremity necrosis requiring treatment

# Gastrointestinal Events

## 1. Feeding Intolerance

**TIMING**
Identified >10 days post VAD implant

**DEFINITION**
Inability to meet caloric goals enterally. Excludes intolerance due to pre-existing GI abnormalities or other AEs.

**GRADES**
***2:*** Caloric goal met via enteral + TPN/IL
***3:*** TPN/IL dependent, no enteral intake
***4:*** TPN/IL dependent with TPN cholestasis (conjugated bili >2x upper limit of normal or no route meets caloric needs

## 2. Chylothorax

**TIMING**
Anytime during VAD support

**DEFINITION**
- Effusion (pleural/peritoneal) with:
  - Triglycerides >110 mg/dL, or
  - Pleural triglyceride > serum triglyceride, or
  - >80% lymphocytes in pleural fluid

**GRADES**
***2:*** NPO >72 hrs for chylothorax
***3:*** NPO + medical therapy (e.g., Octreotide) and/or new chest tube placement to treat chylothorax
***4:*** Requires surgical or transcatheter intervention

## 3. Necrotizing Enterocolitis (NEC)

**TIMING**
Anytime during VAD support

**DEFINITION**
- Meets Modified Bell Criteria:
  - Imaging: Intestinal dilation, pneumatosis, pneumoperitoneum, or portal gas
  - ≥2 clinical signs: Temp instability, apnea/bradycardia, bloody stool, thrombocytopenia/DIC (abdominal), or distension

**GRADES**
***3:*** Medical management only (e.g., antibiotics, and/or NPO >72 hrs)
***4:*** Requires surgical treatment

# Inadequate Support

## 1. Inadequate Hemodynamics After VAD

**TIMING**

>10 days post-implant or patient death before 10 days

**DEFINITION**

- Inadequate systemic perfusion or ongoing congestion despite a functioning VAD, evidenced by:
  - Continued vasoactive support and lack of improvement in ≥2 end-organ systems (Respiratory, Hepatic, Renal, Feeding intolerance)

**GRADES**

***3:*** Lab-based organ dysfunction managed with vasoactive drugs

***4:*** Organ replacement therapy (e.g., dialysis, TPN, ventilation) due to inadequate support

## 2. Fontan Venous Failure After SVAD

**TIMING**

- Identified anytime post VAD procedure requiring placement of Fontan venous VAD (right-sided VAD) or transition to ECMO
- Worsening clinical evidence of high venous pressure >equal to 10 days post VAD placement

**DIAGNOSTIC CRITERIA**

- Inadequate SVAD preload (no response to VAD changes):
  - Worsening signs of high venous pressure (e.g., effusions, ascites, lymphatic dysfunction) >10 days post op
  - Transition to ECMO (for right-sided failure) anytime
  - Right-sided VAD ("Fontan" VAD) implantation anytime

**GRADES**

***2:*** ≥10 days post-op, persistent effusion output <25 mL/kg/day for >3 days

***3:*** ≥10 days post-op, high output effusions >25 mL/kg/day for >3 days

***4:*** ECMO use or Fontan VAD placed as a separate procedure

# Other Events

## 1. Arrhythmia

**TIMING**

Anytime during VAD support

**DEFINITION**

Abnormal rhythm resulting in a new IV medical treatment and/or invasive therapy

**GRADES**

- ***3:*** Requires IV therapy
- ***4:*** Requires cardioversion, ICD, permanent pacemaker, or ablation

## 2. Vascular Injury

**TIMING**

Anytime during VAD support

**DEFINITION**

Injury related to percutaneous cannulation

**TYPES**

- Perforation
- Pneumothorax
- Pseudoaneurysm
- AV fistula
- Thrombosis
- Dissection
- Stenosis
- Bleeding at cannulation site *(may need Bleeding AE if meets criteria)*
- Limb hypoperfusion/ischemia

**GRADES**

- ***3:*** Injury not requiring surgery/intervention
- ***4:*** Requires surgery/intervention or results in loss of limb/digit