Severity Grading Tool for Blood Donor Adverse Events

Advancing Transfusion and Cellular Therapies Worldwide

International Society of Blood Transfusion

International Haemovigilance Network

European Blood Alliance

A User Brochure

Introduction:

The severity assignment tool is designed to be used with the Standard for Surveillance of Complications Related to Blood Donation published in 2014 by ISBT/AABB/IHN. Severity assignment can be hampered by subjectivity; this tool was created to enhance objective assignment of severity. The Severity assignment is patterned after an established clinical severity scale, Common Terminology Criteria for Adverse Events (CTCAE1) v 5.0, which rates severity by Grades 1 -5 with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death. Definitions and general considerations for severity grading include:

Severity Grade	General factors to consider in assigning severity Donor Adverse Event (DAE) Severity Tool	(DAE) Examples
Grade 1	No Outside Medical Care (OMC) ***AND*** Short duration ≤ 2 weeks ***AND*** No limitation on Activities of Daily Living (ADL) ***AND*** Resolved with no or minimal intervention	Arterial puncture, pressure bandage applied, resolved without intervention or sequelae Vasovagal event that resolves with comfort care and/or oral hydration Citrate reaction resolved with oral calcium or reduction in infusion rate
Grade 2	OMC, no hospitalization ***OR*** Duration >2 weeks- ≤ 6 months ***OR*** Limitations on ADL for ≤2 weeks	Superficial thrombophlebitis resolved with oral antibiotics, no sequelae Vasovagal event that requires transport to ER for IV hydration Lacerations requiring sutures
Grade 3	Not life-threatening ***AND any of the following*** Hospitalization ***OR*** Duration >6 months ***OR*** Limitations on ADL >2 weeks ***OR*** Require surgery ***OR*** Other serious complications (Category E)	Arteriovenous fistula requiring surgical repair Fracture, dental injury, or concussion TIA and other cardiovascular events , which are not life-threatening
Grade 4*	Immediate medical intervention required to prevent death	LOC with fall and intracranial bleed Anaphylaxis requiring intubation or tracheostomy
Grade 5*	Death	Death

* Grade 4 and Grade 5 are not shown in the Severity Grading Tool of Blood Donor Adverse Events .

AABB Donor Hemovigilance Working Group

CTCAE v 5: Common Terminology for Adverse Events Version 5.0; published November 27, 2017; US Department of Health and Human Services, National Institutes of Health, National Cancer Institute

Please refer to Standard for Surveillance of Complications Related to Blood Donation, December 2014 for complete Donor Adverse Event Definition

Instructions for Use

- Determine category of Donor Adverse Event (DAE) using ISBT/AABB/ IHN Standard for Surveillance of Complications Related to Blood Donation, December 2014.
- For Grade 1, the reaction must satisfy all criteria listed
- Select the highest applicable grade of severity; for example, if a vasovagal reaction resulted in a fall and the donor was seen in the emergency room where she required sutures (Grade 2) to repair a laceration on her arm and was also diagnosed with a concussion (Grade 3), the final severity assignment would be **Grade 3.**
- Occasionally a donor may experience multiple adverse events. Assigning a severity grade in such cases requires judgement.
    - If the reactions are distinct, with more than one type DAE classification, assign each DAE a separate Severity Score based on the Grading Tool. (Example, citrate reaction that resolves with oral calcium [**Gr1**] plus a nerve injury that impacts ADL for more than 2 weeks [**Gr3**]).
    - If the DAEs are related or difficult to distinguish , then assign a single Severity Grade based on the highest applicable Severity Grade.
- Not all Grades are applicable for all DAE; for instance, all DAE involving major blood vessel injury, cardiac and cerebrovascular incidents are graded at least Grade 3 ; no option for Grade 1 or 2 is given. Likewise, DAEs involving arm pain are not life-threatening and are limited to Grades 1, 2 or 3.
- Grades 4 (Life-threatening) and 5 (Death) are very rare. **Neither Grade 4 nor Grade 5 is shown in the Severity Assessment Table/Tool,** and should only be selected when the final diagnosis is confirmed in consultation with appropriate medical personnel. (See definition of Life-threatening).
- Death due to a blood donation or if donation was a contributing factor should be reported to the competent authority as required by law.
- Imputability: This grading tool is developed to assist with assignment of severity. Imputability must be assessed separately for determination of the relationship of the donation to severe DAEs, as required for fatality reporting. Please refer to Standard for Surveillance of Complications Related to Blood Donation 2014 -- ISBT/AABB/IHN.

Working Definitions and Abbreviations for Use in Grading Reactions:

- ***Outside Medical Care (OMC):*** donor is evaluated and/or treated by Emergency Medical Response (EMR), Health Care Professional (HCP), urgent care, hospital emergency room (ER) without admission to the hospital. Please note that if EMR is called (an ambulance) and the donor is evaluated but not transported, then it is still considered OMC.
- ***Hospitalization*****:** admission to the hospital; does NOT include being seen and discharged from urgent care or hospital emergency department.
- ***Life-threatening***: any adverse event that places the subject at ***immediate*** risk of death without intervention.
    - A DAE should be graded as life-threatening, ***Grade 4***, only if the situation required immediate action to prevent death. For instance, the following interventions would suggest a life-threatening DAE: intubation or tracheostomy for stridor, wheezing, bronchospasm or laryngeal edema (anaphylactic shock).
    - A situation that is ***potentially*** life-threatening should NOT be given a ***Grade 4***; ***Grade 4*** is reserved for only those DAE that actually required intervention to prevent death.
- ***Surgery***: Any procedure that required regional (spinal, block), inhalation or general anesthesia. The following are NOT considered surgery: simple sutures, staples, butterfly closure.
- ***Activities of Daily Living (ADL):*** Include everyday household chores, doing necessary business, shopping, going to work or school, or getting around for other purposes. ADL are impacted if the donor
    - Needs the help of other persons with bathing or showering, dressing, eating, getting in or out of bed or chairs, using the toilet, and getting around the home (Self-care ADL)
    - Cannot work, attend school or manage routine personal/family activities because of the Donor Adverse Event (Instrumental ADL).

Severity Grading Tool of Blood Donor Adverse Events

Category	Grade 1	Grade 2	Grade 3
A.1. Blood outside vessel **--Haematoma** **--Arterial puncture** **--Delayed bleeding**	• No OMC • Localized to venipuncture site	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • ADL ≤2 weeks, or • Generalized beyond venipuncture site	• Hospitalization, or • ADL >2 weeks, or • Severe sequelae, or • Surgical intervention
A.2. Arm Pain **--Nerve injury/irritation** **--Other arm pain**	• No OMC • Duration ≤2 weeks	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • Duration >2 weeks to ≤6 months, or • ADL ≤2 weeks	• Duration > 6 months, or • ADL >2 weeks
A.3. Localized infection/inflammation of vein or soft tissue **--Superficial thrombophlebitis** **--Cellulitis**	• No OMC	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • ADL ≤2 weeks, or • Resolved with oral antibiotics	• Hospitalization, or • ADL >2 weeks, or • Resolved with IV treatment
A.4. Other major blood vessel injury **--Deep venous thrombosis** **--Arteriovenous fistula** **--Compartment syndrome** **--Brachial artery pseudoaneurysm**			• Diagnoses medically confirmed, or • Treated with anticoagulant therapy, or • Required surgical intervention
B. Vasovagal reactions **--Vasovagal reaction, no loss of consciousness (LOC)** **--Vasovagal reaction, loss of consciousness (LOC)**	• No OMC	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • ADL ≤2 weeks, or • Suture of laceration(s), or • IV rehydration	• Hospitalization, or • ADL >2 weeks, or • Fracture(s), medically confirmed concussion, dental injury requiring dental procedure, e.g. cap/crown, dental implant, bridge, tooth extraction, dentures
C. Related to apheresis **--Citrate reaction** **--Haemolysis** **--Air embolism** **--Infiltration**	• No OMC • Citrate toxicity (including carpopedal spasm) resolved with or without oral calcium	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • ADL ≤2 weeks, or • Citrate toxicity requiring intravenous calcium	• Hospitalization, or • ADL >2 weeks, or • Abnormal cardiac rhythm medically diagnosed
D. Allergic Reaction **--Local allergic reaction** **--Generalized (anaphylactic) reaction**	• No OMC • Managed with over- the- counter medications—topical steroids, antihistamine	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • Generalized reaction including bronchospasm, laryngospasm managed with inhalation or oral bronchodilator and/or auto -injector (EpiPen)	• Hospitalization, or • Generalized reaction, including bronchospasm, laryngospasm or anaphylaxis, requiring management with intravenous steroids and/or epinephrine, but NOT intubation or tracheostomy
E. Other serious complication **--Acute cardiac symptoms** **--Myocardial infarction** **--Cardiac arrest** **--Transient ischemic attack** **--Cerebrovascular accident (Stroke)**			• Diagnoses medically confirmed
F. Other	• No OMC • No injury	• OMC (EMR, ER, PCP, Urgent care), no hospitalization, or • Duration >2 weeks to ≤6 months, or • ADL ≤2 weeks	• Hospitalization, or • Duration > 6 months, or • ADL >2 weeks, or • Surgical intervention