

Organization/Nationality:

Participant Name:

2016 AABB, IHN, and ISBT Donor Haemovigilance Case Validation
Answer Scheme

Case number	Likely Diagnosis (at least one)	Optional Information	Severity	Imputability	Comments (optional)
S1.	<i>A2.1 Nerve injury/irritation</i>	<i>Duration <12months</i>	<i>Moderate</i>	<i>Definite</i>	<i>Donor with ongoing pain after two months and reports reduced physical working capacity.</i>
S2.	<i>B.1</i>	<i>w/o inj OFFSITE</i>	<i>Mild</i>	<i>Probable</i>	<i>Unable to definitely if donor had loss of consciousness. Unsure if donor's blood pressure meds played a role in symptoms</i>
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
Case	Likely Diagnosis (at least one)		Severity	Imputability	Comments (optional)

Organization/Nationality:

Participant Name:

2016 AABB, IHN, and ISBT Donor Haemovigilance Case Validation
Answer Scheme

Number				
15.				
16.				
17.				
18.				
19.				
20.				
21.				
22.				
23.				
24.				
25.				
26.				
27.				
28.				
29.				
30.				

Abbreviations of the complications of donation:

Organization/Nationality:

Participant Name:

2016 AABB, IHN, and ISBT Donor Haemovigilance Case Validation Answer Scheme

A1 Blood outside vessel

- A1.1 Haematoma
- A1.2 Arterial puncture
- A1.3 Delayed bleeding

A2 Arm pain

- A2.1 Nerve injury/irritation
 - D<12m: duration < 12 months*
 - D>12m: duration > 12 months*
- A2.2 Other arm pain

A3 Localized infection/inflammation of vein or soft tissues

- A3.1 Superficial thrombophlebitis
- A3.2 Cellulitis

A4 Other major blood vessel injury

- A4.1 Deep Venous Thrombosis (DVT)
- A4.2 Arteriovenous fistula
- A4.3 Compartment syndrome
- A4.4 Brachial artery pseudoaneurysm

B. Generalized symptoms – Vasovagal Reactions

- B.1 Vasovagal Reaction, no loss of consciousness (LOC)
- B.2 Vasovagal Reaction, loss of consciousness
 - <60s: < 60 seconds, no complications*
 - ≥60s: ≥ 60 seconds, and/or convulsions or incontinence*

Additional Information:

- w/ inj: With injury*
- w/o inj: Without injury*
- ONSITE: on collection site*
- OFFSITE: off collection site*

C. Related to apheresis

- C.1 Citrate reactions
- C.2 Haemolysis
- C.3 Air embolism
- C.4 Infiltration

D. Allergic reactions

- D1 Local allergic reaction
- D2 Generalized (anaphylactic) reaction

E. Other serious complications

- E.1 Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).
- E.2 Myocardial infarction
- E.3 Cardiac arrest
- E.4 Transient Ischemic Attack (TIA)
- E.5 Cerebrovascular accident
- E.6 Death

F. Other (give diagnosis)

Severity Grading: To be classified as **severe**, the adverse event should be life-threatening or leading to hospitalisation, incapacity, chronic morbidity or death. Otherwise, the case can be classified more subjectively as **mild** or **moderate**.

Imputability:

- Definite:** Conclusive evidence donation caused adverse event
- Probable:** Clearly leans toward donation as cause of adverse event
- Possible:** Could be caused by donation or alternative reason
- Unlikely:** Clearly leans toward other causes for the adverse event
- Excluded:** Conclusive evidence something else caused even

Organization/Nationality:
Participant Name:

2016 AABB, IHN, and ISBT Donor Haemovigilance Case Validation
Answer Scheme