

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)

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Number				
15.				
16.				
17.				
18.				
19.				
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21.				
22.				
23.				
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25.				
26.				
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29.				
30.				

Abbreviations of the complications of donation:

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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

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