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.	A2.1 Nerve injury/irritation	Duration <12months	Moderate	Definite	Donor with ongoing pain after two months and reports reduced physical working capacity.
S2.	B.1	w/o inj OFFSITE	Mild	Probable	Unable to definitely if donor had loss of consciousness. Unsure if donor's blood pressure meds played a role in symptoms
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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	1		
Number			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			
26.			
27.			
28.			
29.			
30.			
			I.

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 injuryw/o inj: Without injuryONSITE: on collection siteOFFSITE: 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:

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