

Rationale for changes from 2008 to 2014 classification of adverse donor events

Tables 1 to 4 provide a comparison of the 2008 to 2014 categories for donor reactions. Additional explanations for the changes are detailed below.

Local complications

No changes have been made to the haematoma and arterial puncture categories. Delayed bleeding has been made an optional category, since it is not captured by all blood centers, is a minor occurrence and is not included in the donorHART software. Pain syndromes have been considerably simplified in the new classification with injury of a nerve by a haematoma, injury of a nerve, and tendon injury being combined into one category of nerve injury/irritation. Tendon injury is a very rare category. It is very difficult to distinguish injury of a nerve by a hematoma from injury of a nerve. Distinguishing symptoms mentioned in the 2008 document included the time of onset of pain. However, many donors call the blood centre days after phlebotomy to report this symptom and do not necessarily remember exactly when the pain started. There is no requirement for medical personnel to make this diagnosis, since in many countries, there is no specialized investigation that is available or performed. Blood centres could always split this category more finely, and report globally on nerve injury/irritation for international comparisons. DonorHART classifies this pain syndrome as nerve injury/irritation. A category of painful arm already existed in 2008, and has been maintained as an optional category. This is usually a minor reaction, not necessarily captured by all blood centres, and not included in the first version of donorHART. However, it may be useful to some blood centres and may be added to donorHART in the future. Finally, localized inflammation of vein or soft tissues have been grouped together as localized infection/inflammation. These are rare events that may be difficult to distinguish when the donor calls the blood centre and reports a swollen red arm with fever. Optionally, the blood center may split this category into cellulitis and superficial thrombophlebitis. These two categories are available in donorHART. There have been no changes to the other major blood vessel injury categories.

Generalized symptoms – vasovagal reactions

This category has been split into reactions with no loss of consciousness and reactions with loss of consciousness. There was extensive discussion of this category at the Amsterdam ISBT Hemovigilance Working Group meeting. The participants agreed that this would be a more practical, useful categorization of the reactions. The 2008 classification of reactions as mild vs. moderate depending on subjective vs. objective symptoms was not practical or based on any physiologic difference in mechanism. Loss of consciousness can be optionally split into <60 seconds with no complications, or >60 seconds or accompanied by complications of convulsions or incontinence. These attributes are available in donorHART. The location of the reactions (on or off the collection site) and the presence or absence of injury were present in the 2008 categories and are maintained as optional categories in 2014. They can easily be mapped to donorHART.

Complications related to apheresis

No changes have been made to this group of reactions, except that infiltration has been added as an optional category; it is not noted in all blood centers and is of minor importance.

Allergic reactions, other complications

No change has been made to local allergic reactions. Generalized allergic reactions are renamed generalized (anaphylactic) reactions since this is an extremely rare category, and it is hard to distinguish severe generalized reactions from anaphylactic reactions. There have been no changes to the major cardiovascular events categories.

Grading of complication severity

At the ISBT meeting in Amsterdam, again, the necessity for a grading system was discussed. The grading of severity used for adverse reactions in recipients is poorly adapted to donor reactions. It was therefore decided that grading of reactions for severity would be optional. The notion of severity will also be captured by the types and definitions of reactions. For example, by their nature, deep venous thrombosis, arteriovenous fistula, and compartment syndrome are severe reactions. Anaphylactic reactions and all major cardiovascular events are clearly severe reactions. Additionally, blood centres would report in their basic data, if they are including reactions that they consider to be mild, moderate, or severe, or only a subset of moderate and severe reactions, or only what they consider the most severe reactions.

Imputability

Most local reactions are clearly attributable to the venipuncture. Similarly, most vasovagal and apheresis reactions are clearly at least in part related to the phlebotomy. The section where imputability is specifically relevant is for cardiovascular events or death occurring within 24 hours post donation. In many cases, these events may be coincident with no causal link to blood donation.

Summary tables, changes in definitions, 2008 vs. 2014, *optional categories in italics*

Table 1A Local symptoms		
2008 Category	2014 Category	Comments
A1 Blood outside vessels		
Haematoma	Haematoma	No change
Arterial puncture	Arterial puncture	No change
Delayed bleeding	<i>Delayed bleeding</i>	Optional, not in donorHART, minor reaction
A2 Pain syndromes		
Injury of a nerve by a hematoma	Nerve injury/irritation	First 2-3 categories combined into 1: all fairly rare, hard to distinguish, align with donorHART Optional, not in donorHART, minor reaction
Injury of a nerve	Nerve injury/irritation	
Tendon injury	<i>According to symptoms</i>	
Painful arm	<i>Other painful arm</i>	
A3 Localised inflammation of vein or soft tissues		
Infection	Localised infection/inflammation, <i>cellulitis</i>	Rare events, may be difficult to distinguish
Thrombophlebitis	Localised infection/inflammation, <i>superficial thrombophlebitis</i>	Deep venous thrombosis separate category
A4 Other major blood vessel injury		
Axillary vein thrombosis	Deep vein thrombosis	Harmonize terminology with donorHART
Arteriovenous fistula	Arteriovenous fistula	No change
Compartment syndrome	Compartment syndrome	No change
Brachial artery pseudoaneurysm	Brachial artery pseudoaneurysm	No change

Table 2B Generalized symptoms-vasovagal reactions		
2008 Category	2014 Category	Comments
Vasovagal reaction	Vasovagal reaction	Simplification, aligned on donorHART
Mild-subjective symptoms	- no loss of consciousness	
Moderate-objective symptoms	- loss of consciousness	
Severe – hospitalization or significant disability	<60 seconds, >60 seconds or complications	
Immediate (on collection site)	<i>On collection site</i> <i>Off collection site</i>	Location optional
Immediate with injury		
Delayed (off collection site)	<i>With injury</i> <i>Without injury</i>	Injury optional
Delayed with injury		

Table 3C Complications related to apheresis		
2008 Category	2014 Category	Comments
Citrate reaction	Citrate reaction	No change
Haemolysis	Haemolysis	No change
Air embolism	Air embolism	No change
Infiltration	<i>Infiltration</i>	Optional, not noted in all systems

Table 4D, E Allergic reactions, other complications		
2008 Category	2014 Category	Comments
Local allergic reaction	Local allergic reaction	No change
Generalized allergic reaction	Generalized (anaphylactic) reaction	Combination of allergic (systemic) and anaphylaxis, both extremely rare and hard to distinguish
Major cardiovascular event		
Myocardial infarction	Myocardial infarction	No change
Cardiac arrest	Cardiac arrest	No change
Transient Ischemic Attack	Transient Ischemic Attack	No change
Cerebrovascular accidents	Cerebrovascular accident	No change
Death <24 hours post-donation	Death <24 hours	No change
	Acute cardiac symptoms (other than myocardial infarction or cardiac arrest)	Additional subcategory

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