

**Standard for Surveillance of
Complications Related to Blood Donation**

Working Group on Complications Related to Blood Donation

*International Society of Blood Transfusion
Working Party on Haemovigilance*

European Haemovigilance Network

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Introduction

In 2004 the *International Society of Blood Transfusion* (ISBT) and the *European Haemovigilance Network* (EHN) set up a *Common Working Group on Complications Related to Blood Donation* (DOCO). The task was to create a set of definitions of issues in this new field, definitions which could be used internationally, and thereby facilitate international benchmarking. The aim is to contribute to efforts to increase safety of blood donors world wide.

The DOCO group has consisted of the following members: Elisabeth Caffrey (UK, 2004 -2007), Jo Wiersum (The Netherlands, TRIP, since 2007), Hitoshi Okazaki (Japan, Japanese Red Cross Blood Service, since 2008), Peter Tomasulo (US, Blood Systems, writing member since 2008) and Jan Jorgensen (Denmark, chair, since 2004).

The intention of this standard is to present an internationally accepted description of the complications, including severity and imputability grades, which can be used for benchmarking and international presentations. The present version results from critical review of the Madrid 2007 version by a large international panel. This led to regrouping of the categories and some adjustments to the descriptors of the severity levels.

A total of 18 categories have been defined. They are grouped according to the localization of the symptoms (local or general), complications especially related to apheresis and a final group of "others". A description of a complication category is only given for the most common complications (occurrence >1% of all complications) and not for the rare events associated with blood donation (<1% of all complications). Some of the rare complications are of a serious nature and will often be diagnosed by medical professionals outside the blood service. Medical terms used in categories are defined as indicated in common medical dictionaries. Severity and imputability are graded as shown in annex 2. Definitions of other issues used for the description of the categories are given in annex 3.

This Standard deals, as stated above, with common complications (adverse reactions or incidents) related in time to a blood donation (whole blood or apheresis). The complications related to apheresis are included as categories only, but definitions may be developed in the future. In the present version there are no categories or definitions for complications related to donation of more than one unit, long term effects following several donations or adverse events related to the donation process as such. If these prove necessary these will be addressed in a future edition of the Standard.

Jan Jorgensen, MD
Chair of Working Group

Description of Categories

A. Complications mainly with local symptoms.

These complications are directly caused by the insertion of the needle. Some of these are mainly characterized by occurrence of blood outside vessels, whereas others are mainly characterized by pain

A 1. Complications mainly characterized by the occurrence of blood outside the vessels.

Haematoma

A haematoma is an accumulation of blood in the tissues outside the vessels. Symptoms are bruising, discolouration, swelling and local pain.

Haematoma is the second most common acute complication which occur related to blood donation.

The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. As the volume of the haematoma increases, swelling will occur. The swelling will put pressure on the surrounding tissues. The strength of the pressure will depend on size of the swelling and softness of the surrounding tissue.

Pressure on nerves will result in neurologic symptoms like pain radiating down in forearm and hand, and of peripheral tingling.

If blood accumulates in the frontal deep layers of the forearm between muscles and tendons swelling is hard to recognize, but the pressure increases very easily. Therefore, complications like injury of a nerve and even a compartment syndrome occurs more often related to a haematoma with this localization.

Arterial puncture

Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding of donor.

Symptoms: There may be weak pain localized to the elbow region. Objectively a lighter red colour than usual of the collected blood can be seen and perhaps some movements of the needle caused by arterial pulsation; the bag fills very quickly. In uncomplicated cases there may be no haematoma.

Complications: The risk of a large haematoma is increased and thereby risks such as Compartment Syndrome in the forearm, Brachial Artery Pseudo Aneurysm and arterio-venous Fistula.

Delayed bleeding

Delayed bleeding is spontaneous recommencement of bleeding from the venipuncture site, which occurs after donor has left the donation site.

A 2. Complications mainly characterized by pain

Nerve irritation

Irritation of a nerve by pressure from a haematoma.

Symptoms are nerve type as radiating pain and/or paraesthesiae in association with a haematoma. The haematoma may not always be apparent at the time. Symptoms do not occur immediately on insertion of the needle but start when the haematoma has reached a sufficient size, some time after insertion of the needle.

Nerve injury

Injury of a nerve by the needle at insertion or withdrawal.

Symptoms are pain often associated with paraesthesiae. The pain is severe and radiating. It arises immediately when the needle is inserted or withdrawn.

Tendon injury

Injury of a tendon by the needle.

Symptoms are very severe local non-radiating pain initiating immediately when the needle is inserted.

Painful arm

Cases characterized mainly by severe local and radiating pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above.

A 3 Other kinds of categories with local symptoms

Thrombophlebitis

Inflammation in a vein associated with a thrombus

Symptoms are warmth, tenderness, local pain, redness and swelling.

Thrombophlebitis in a superficial vein gives rise to a subcutaneous red, hard and tender cord.

Thrombophlebitis in a deep vein gives more severe symptoms and may be associated with fever.

Allergy (local)

Allergic type skin reaction at the venipuncture site caused by allergens in solutions used for disinfection of the arm or allergens from the needle.

Symptoms are rash, swelling and itching at venipuncture site

B. Complications mainly with generalized symptoms.

Vasovagal reaction

A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). Most give only minor symptoms, but a few have a more severe course with symptoms like loss of consciousness and convulsions or incontinence.

Symptoms are discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions, and loss of consciousness.

The reaction is generated by the autonomic nervous system and further stimulated by psychological factors, and the volume of blood removed relative to the donor's total blood volume.

It is the most common acute complication related to blood donation.

Some of the most severe complications seen in relation to blood donation are accidents in donors who lose consciousness after leaving the donation site. In order to register these properly the vasovagal reactions have been grouped in

Immediate Vasovagal reaction

Symptoms occurred before donor has left the donation site

Immediate Vasovagal Reaction with injury

Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before donor has left the donation site

Delayed Vasovagal Reaction

Symptoms occurred after donor has left the donation site.

Delayed Vasovagal Reaction with injury

Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness after donor has left the donation site.

C. Complications related to apheresis

Citrate reaction

Haemolysis

Generalised allergic reaction

Air embolism

D. Other complications related to blood donation

Annex 1.

Categories of complications related to blood donation (overview)

Local symptoms	Blood outside vessels		Haematoma
			Arterial puncture
			Delayed bleeding
	Pain	Specified as	Nerve irritation
			Nerve injury
			Tendon injury
		or not specified	Painful arm
	Others		Thrombophlebitis
Allergy (local)			
Generalised symptoms	Vasovagal reaction		Immediate
			Immediate with injury
			Delayed
			Delayed with injury
Related to apheresis			Citrate reaction
			Haemolysis
			Generalised allergic reaction
			Air embolism
Other			

Annex 2 Grading of complication severity and imputability

Grading of severity

Severity is graded in two main levels severe and non-severe, based on requirements for treatment and on outcome, in a way which corresponds to other systems in use internationally (i.e. ISBT for grading of adverse reactions to blood transfusion, European Commission for grading of transfusion reactions, FDA for grading of drug adverse events).

Severe complications

Conditions which define a case as severe are:

Hospitalization:	If it was attributable to the complication.
Intervention:	To preclude permanent damage or impairment of a body function To prevent death (life- threatening)
Symptoms:	Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity)
Death:	If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

Non-severe complications

The non-severe complications are complications which do not satisfy any of the requirements for being severe.

The non-severe level may be subdivided in mild and moderate complications as for instance for the following categories

Haematoma

Mild:	Local discomfort during phlebotomy only minor pain or functional Impairment
Moderate:	As mild but with major discomfort during normal activities

Arterial puncture

Mild:	No symptoms or local discomfort during phlebotomy and/or haematoma
Moderate:	Local discomfort continuing after the collection was terminated

Painful arm (subcategory specified or not)

Mild:	Symptoms for less than two weeks
Moderate:	Symptoms for more than two weeks but less than 1 year

Vasovagal reaction

Mild:	Subjective symptoms only
Moderate:	Objective symptoms

At the border between mild and no complication there will be a gradual transition of severity of the symptoms. It is likely that this border will not be placed at the same level in different settings and the number of mild cases may vary considerably from region to region. It is hoped that international sharing of data will gradually lead to improved uniformity.

Grading of imputability

The strength of relation between donation and complication is

- Definite or certain: when there is conclusive evidence beyond reasonable doubt for the relation
- Probable or likely: when the evidence is clearly in favor of a relation
- Possible: when the evidence is indeterminate for attributing the complication to the donation or an alternative cause
- Unlikely or doubtful: when the evidence is clearly in favor of attributing the complication to other causes
- Excluded: when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.

It is recommended that for international comparison of data on complications related to blood donation only cases with imputability of possible, probable or definite be captured.

Annex 3. Definitions and remarks concerning issues used for the description of categories

Donation site is the area within which staff can observe donor and be responsible for care of donors with complications.

Complications related to blood donation are adverse reactions and adverse events with a temporal relation to a blood donation.

An immediate complication is a complication which occurs before donor has left the donation site.

A delayed complication is a complication which occurs after donor has left the donation site.

The relation of a delayed complication to the actual blood donation should be critically assessed (see grading of imputability).

Bruises and haematomas

Bruises can be very extensive but without any measurable swelling, whereas when the name a haematoma is used there would generally be swelling. However, as there is no physiological difference between bruises and haematomas except for the thickness, large skin discolouration can still be registered as a haematoma.

Annex 4. Scheme for registration of collected data

Category	Number of cases				Total
	Mild	Mode rate	Severe		
			Sympt >1 y	All severe	
Haematoma					
Arterial puncture					
Delayed bleeding					
Nerve irritation					
Nerve injury					
Tendon injury					
Painful arm					
Total number local sympt.					
VVR Immediate type					
VVR Immediate , accident					
VVR Delayed type					
VVR Delayed, accident					
Total number VV R					
Citrate reaction					
Haemolysis					
Generalised allergic reaction					
Air embolism					
Total					