



**CENTRO  
NAZIONALE  
SANGUE**

Istituto Superiore di Sanità



# **Adverse reactions and adverse events in Italian blood donors**

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**Roma 28 marzo 2019**

# Conflitto di interessi

Il sottoscritto, in qualità di Relatore,

dichiara che

- nell'esercizio della sua funzione e per l'evento in oggetto, **NON È** in alcun modo portatore di interessi commerciali propri o di terzi;
- dichiara inoltre che gli eventuali rapporti avuti negli ultimi due anni con soggetti portatori di interessi commerciali **non sono tali da permettere a tali soggetti di influenzare** le sue funzioni al fine di trarne vantaggio.



# HAEMOVIGILANCE: DEFINITION

## What is haemovigilance?

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Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.

**World Health Organization 2016**  
**A guide to establishing a national haemovigilance system.**





## GOAL OF HAEMOVIGILANCE

The goal of haemovigilance is continuous quality improvement of the transfusion chain through corrective and preventive actions to:

- improve donor and patient safety,
- improve transfusion appropriateness,
- reduce wastage.

World Health Organization 2016  
A guide to establishing a national haemovigilance system.



# Paradigm shift in haemovigilance



Directorate-General for Health & Consumers

Screening

**SUBSIDIARITY**  
Clinical Follow-up

Collection    Testing    Processing    Storage    Distribution    Issue    Transfusion



Transfusion Chain

Donor

Def. SAR (art. 3.h Dir. 2002/98)

Recipient

**Reportable SAR** (art. 5 Dir. 2005/61)

Attributed to the **QUALITY** and **SAFETY** of blood

**SAR in DONOR**

Def. SAE (art. 3.g Dir 2002/98): « associated with... »

**Reportable SAE** (art. 6 Dir 2005/61)



**COMMON APPROACH  
FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS  
AS LAID DOWN IN THE TISSUES AND CELLS DIRECTIVE 2004/23/EC  
AND COMMISSION DIRECTIVE 2006/86/EC**

**VERSION 2.6 (2017)**

This Common Approach document comprises recommendations for the completion of the electronic reporting template for Serious Adverse Reaction(s) and Event(s) Tissues and Cells - Directive 2006/86/EC and has no legally binding status for Member States.

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# HAEMOVIGILANCE IN ITALY

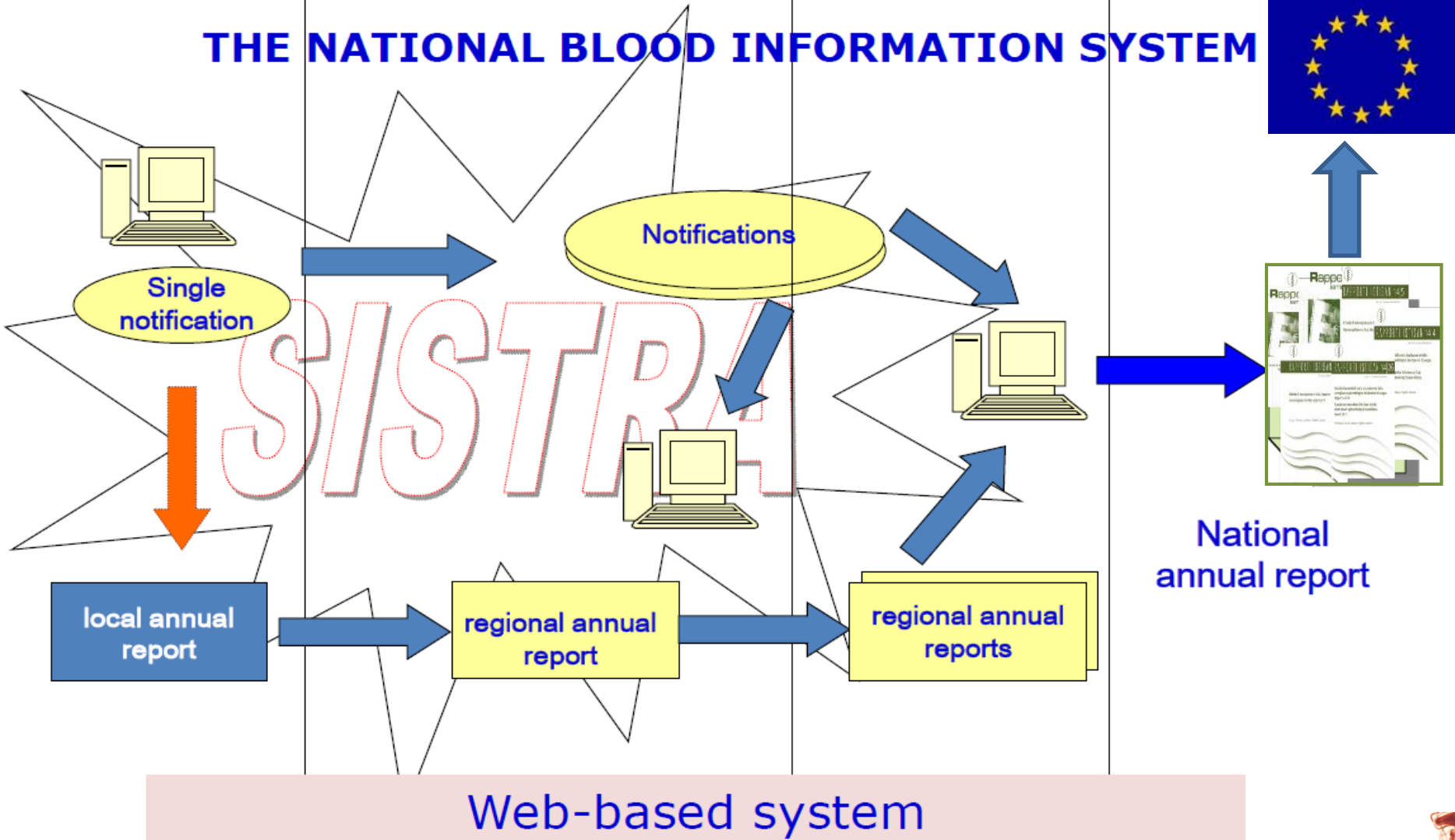
Blood Transfusion Centres

Regional Blood Centres

National Blood Centre



## THE NATIONAL BLOOD INFORMATION SYSTEM




# Haemovigilance

**Serious adverse reactions in donors**

**Epidemiological surveillance of donors**

**Serious adverse reactions in recipients**

**Serious adverse events**

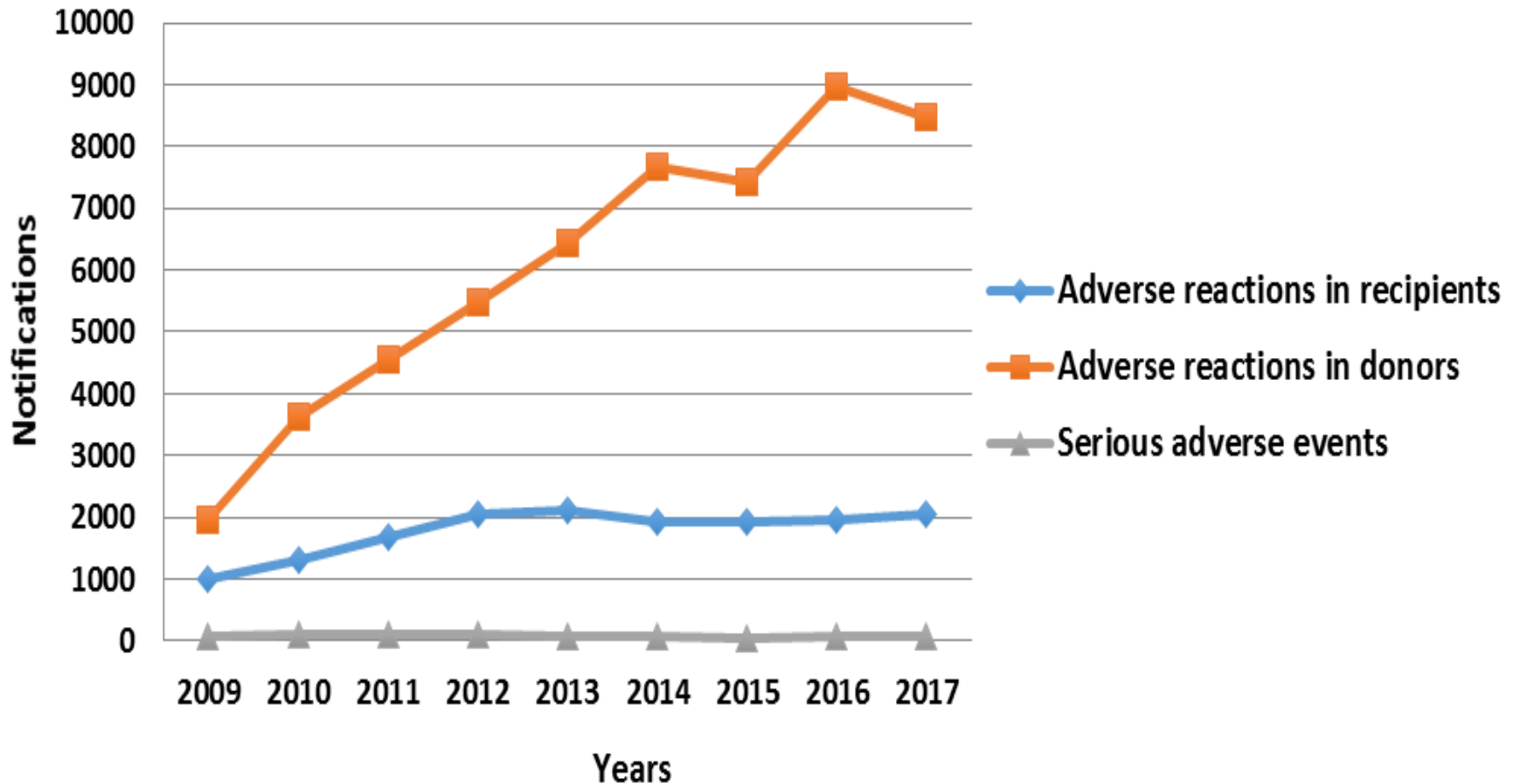


Any unintended response in donors associated with the collection of blood or blood components.





# Number of haemovigilance notifications per year (2009-2017)



# Adverse reactions in donors (2017)

In 2017, **8,484** adverse reactions to allogeneic donation were notified  
(**1 every 354 donations**)

Adverse reaction	n.	%
Immediate vasovagal reaction	6,373	75.12
Delayed vasovagal reaction	959	11.3
Haematoma	622	7.33
Citrate paraesthesia/tingling	235	2.77
Arterial puncture	32	0.38
Cold/shivers	16	0.19
Thrombophlebitis	11	0.13
Local allergic reaction	9	0.11
Incidents tied to vasovagal syndrome	8	0.2
Nerve injury	7	0.08
Citrate tetany	7	0.08
Haemolysis	7	0.08
Nerve injury due to a haematoma	3	0.04
Tightness in the chest	3	0.04
Systemic allergic reaction	1	0.01
Axillary Vein Thrombosis	1	0.01
Other incidents	19	0.22
Other reactions	175	2.06
<b>Total</b>	<b>8,484</b>	<b>100</b>



# Adverse reactions to donations classified per severity level (2017)

Adverse reaction	Mild	%	Moderate	%	Severe	%
Immediate vasovagal reaction	5,061	59.7	1,085	12.8	227	2.7
Delayed vasovagal reaction	636	7.5	260	3.1	63	0.7
Haematoma		0.0		0.0	622	7.3
Citrate paraesthesia/tingling	187	2.2		0.0	48	0.6
Arterial puncture		0.0	23	0.3	4	0.0
Thrombophlebitis		0.0		0.0	11	0.1
Local allergic reaction		0.0		0.0	9	0.1
Incidents tied to vasovagal syndrome		0.0		0.0	8	0.1
Nerve injury	6	0.1	1	0.0	0	0.0
Citrate tetany		0.0		0.0	7	0.1
Haemolysis		0.0		0.0	3	0.0
Nerve injury due to a haematoma	2	0.0	1	0.0	0	0.0
Tightness in the chest	3	0.0		0.0	1	0.0
Systemic allergic reaction		0.0		0.0	1	0.0
Axillary Vein Thrombosis		0.0		0.0	1	0.0
Other incidents	14	87.1	3	12.9	2	0.0
Other	134	1.6	26	0.3	15	0.2
<b>Total</b>	<b>6,055</b>	<b>71.4</b>	<b>1,404</b>	<b>16.5</b>	<b>1,025</b>	<b>12.1</b>

1,025 (12%) of these reactions were severe  
(1 every 2,933 donations)



# Donors with adverse reactions to donations classified per donation procedure (2017)

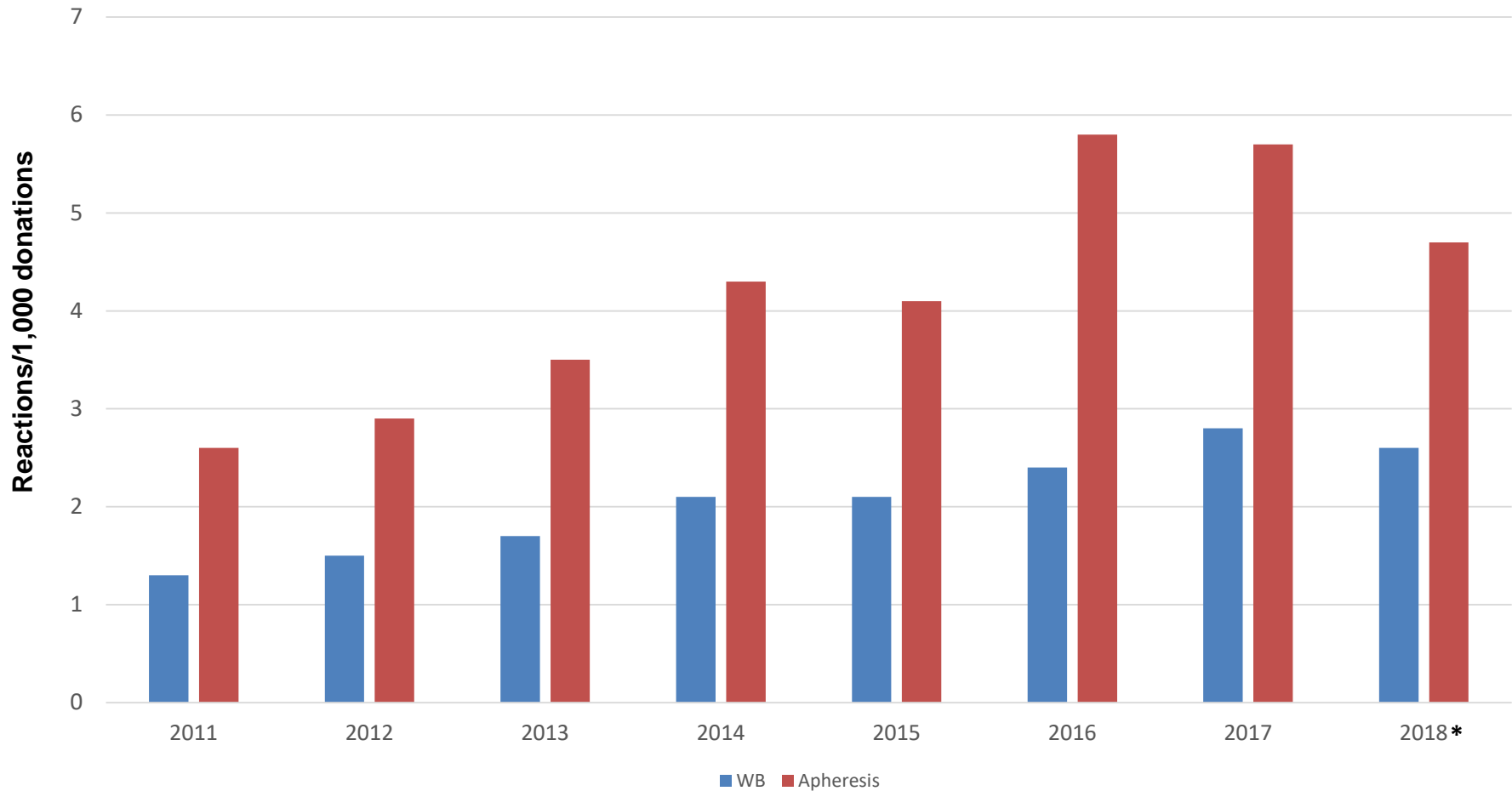
If the absolute number of adverse reactions are compared to the total number of donation procedures, there are more adverse reactions related to whole blood donations than to apheresis donations (6,028 against 2,456).

Donors with adverse reactions			Donation procedure			Donors with adverse reactions/1,000 donation procedures		
Whole blood	Apheresis	Total	Whole blood	Apheresis	Total	Whole blood	Apheresis	Total
2,579,438	427,288	3,006,726	6,028	2,456	8,484	2.3	5.7	2.8

Nevertheless, if we normalise the figures to 1,000 donation procedures, the highest incidence is linked to apheresis donation (2.3 against 5.7/1,000 donations)



# Adverse reactions per 1,000 donations classified per donation procedure (2011-2018)



\* Preliminary data

# Adverse reactions to plasmapheresis donation (2017)

<b>Adverse reaction</b>	<b>n.</b>	<b>%</b>
Immediate vasovagal reaction	1399	65,1
Delayed vasovagal reaction	183	8,5
Haematoma	387	18
Citrate paraesthesia/tingling	91	4,2
Arterial puncture	4	0,2
Cold/shivers	7	0,2
Thrombophlebitis	3	0,2
Local allergic reaction	6	0,2
Incidents tied to vasovagal syndrome	1	0,1
Nerve injury	1	0,1
Citrate tetany	9	0,4
Haemolysis	3	0,2
Tightness in the chest	1	0,1
Systemic allergic reaction	1	0,1
Other incidents	8	0,3
Other reactions	46	2,1
<b>Total</b>	<b>2,150</b>	<b>100</b>

# Donor adverse reaction classified per donation site (2017)



Donation site	n.	%
BE related peripheral organisational sites	1,119	13.2
In Itinere	179	2.1
BE	4,777	56.3
BCU	2,490	28.4
<b>Total</b>	<b>8,484</b>	<b>100</b>

BE Blood establishment/s; BCU Blood Collection Unit/s.



# CNS WORKING GROUP



Ministero della Salute  
Istituto Superiore di Sanità

*Centro Nazionale Sangue*

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Roma, 27 aprile 2015


Gruppo di Lavoro (GDL) nazionale Emovigilanza, istituito con Decreto del Direttore del CNS - Prot. n. 0629.CNS.2015


**Standardisation at national level of the  
severity level classification of adverse  
events/reactions in donors**




# Sources

## Standard for Surveillance of Complications Related to Blood Donation

 International Society of Blood Transfusion

 International Haemovigilance Network

 Advancing Transfusion and Cellular Therapies Worldwide

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

Working Group on Donor Vigilance  
of the  
International Society of Blood Transfusion  
Working Party on Haemovigilance

in collaboration with



The International Haemovigilance Network  
The AABB Donor Haemovigilance Working Group

December 11, 2014

These definitions have been formally endorsed by

The Alliance of Blood Operators

The European Blood Alliance



## Scientific references



# Grading Severity of Blood Donor Adverse Reactions Tool (Example 1 - Haematoma)

**A.1.1  
EMATOMA**

## **Factors to consider:**

- **DIAMETER**
- **LIMITATIONS ON ACTIVITIES OF DAILY LIVING**
- **TREATMENT**
- **HOSPITALISATION**



# Grading Severity of Blood Donor

## Adverse Reactions Tool

(Example 2 – Immediate Vasovagal Reaction)

<b>B.</b> <b>COMPLICANZE CON SINTOMI GENERALIZZATI: REAZIONI VASO VAGALI</b>	
<b>B.1</b> <b>REAZIONE</b> <b>VASOVAGALE DI</b> <b>TIPO IMMEDIATO</b>	<b>Factors to consider:</b> <ul style="list-style-type: none"><li>- <b>SIGNS AND SYMPTOMS</b></li><li>- <b>LOC</b> (&lt;60 seconds vs ≥60 seconds)</li><li>- <b>TREATMENT</b> (confort care and/or oral hydration vs IV hydration)</li><li>- <b>HOSPITALISATION</b></li><li>- <b>TIED FALL AND/OR BLEED</b></li></ul>
<b>B.1.1</b> <b>REAZIONE</b> <b>VASOVAGALE DI</b> <b>TIPO IMMEDIATO</b> <b>CON</b> <b>COMPLICAZIONI</b>	

# SISTRA SCREENSHOT



Ministero della Salute

**SISTRA** Sistema Informativo dei Servizi Trasfusionali  
Coordinato a livello nazionale dal Centro Nazionale Sangue



Emovigilanza

Utente: I

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## Reazioni Indesiderate Donatori - Inserimento Notifica

Dati Generali    Informazioni Cliniche

### INSERIMENTO NOTIFICA

Servizio Trasfusionale	-	Seleziona	
Codice Regionale Notifica	<input type="text"/>		
Data reazione	<input type="text"/>	Data notifica al S.T.	<input type="text"/>
Codice Donatore	<input type="text"/>	Sesso	<input checked="" type="radio"/> M <input type="radio"/> F
Data di nascita	<input type="text"/>	Peso	<input type="text"/>
Donazione	<input checked="" type="radio"/> Omologa <input type="radio"/> Autologa		
Tipologia donazione	Selezionare... <input type="text"/>		
Donazione completata	<input checked="" type="radio"/> Si <input type="radio"/> No	N. Donazioni pregresse	<input type="text"/>
Luogo della donazione	Selezionare... <input type="text"/>		
Luogo della reazione	Selezionare... <input type="text"/>		
	Reazioni/Sintomi		Grado di severità
	Reazione da citrato		Selezionare... <input type="text"/>



#### DESCRIZIONE

Tossicità da citrato che causa iperattività neuromuscolare per riduzione dei livelli ematici di calcio ionizzato. Può precedere/associarsi a reazione vasovagale senza PdC. Fattori di rischio: sesso femminile, età più avanzata, ridotto volume ematico totale.

#### GRADING

**LIEVE:** parestesia isolata che interessa un solo distretto corporeo (ad es. intorpidimento e/o formicolii delle labbra e delle dita, sensazione di vibrazione, sapore metallico) con risoluzione spontanea.  
**MODERATO:** parestesie che interessano più distretti corporei. Intorpidimento e/o formicolii delle labbra e delle dita, sensazione di vibrazione, sapore metallico, brividi, tremori, sensazione di costrizione; tali sintomi possono precedere contratture muscolari, tachibradicardia, respiro corto.  
I sintomi possono progredire a spasmi carpo-podali e vomito con necessità di trattamento.  
**SEVERO:** come moderato ma con evoluzione verso reazioni generalizzate di contrazione muscolare (tetania), shock, polso irregolare ed arresto cardiaco. Necessità di trattamento e/o visita specialistica.

Notifica completa

# Conclusions (I)

**The increased number of notifications in 2017 were not related to a higher incidence of severe reactions.**

**Immediate vasovagal reactions** were the **most frequently notified (71.4%)** of which only **2.7% severe**.

**Standard definitions are essential** in order to improve data collection at national level but also to facilitate the comparisons of data from different haemovigilance systems.



# Conclusions (II)

**More accurate monitoring of the donation processes**, starting from donor selection criteria and the assessment of their physical and personal characteristics, such as venous access, haematological parameters and degree of individual compliance with the procedure is needed.

**Adequate training and continuing education of the operators** responsible for donation (especially for apheresis donation) is necessary in order to:

- detect the donors at “high risk” of adverse reactions and adopt suitable preventive measures;
- promptly recognise, diagnose, classify and treat reactions;
- minimise the number of individual errors and prevent whenever possible all adverse events potentially tied to equipment, sampling kits and possible usage of fluid balance, by constantly checking both materials and instruments.







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*Thanks for your  
attention!*

