PATIENT BLOOD MANAGEMENT ITALY

PLASMA ITALIA

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.

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HAEMOVIGILANCE: DEFINITION

What is haemovigilance?

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.

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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.

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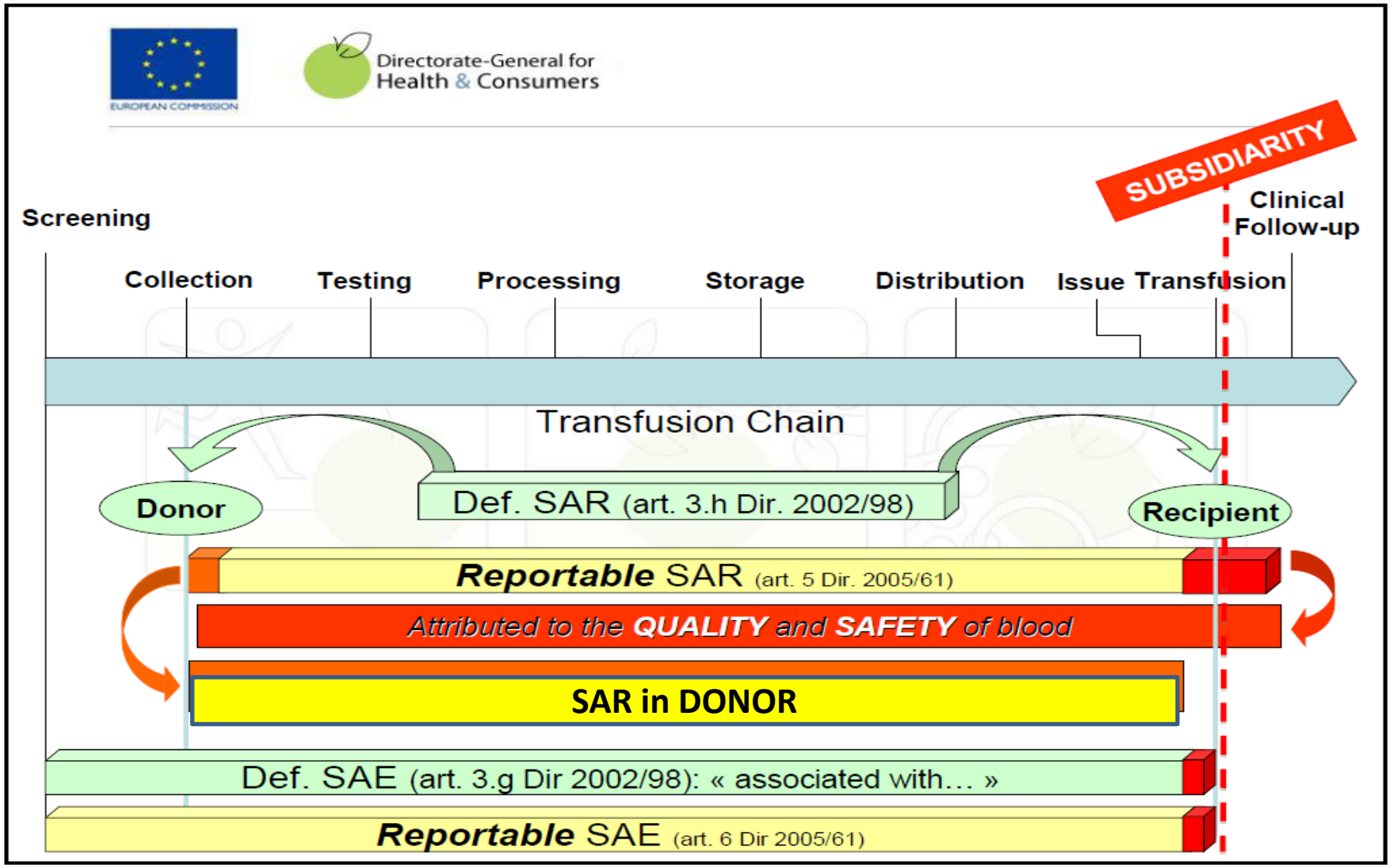
Paradigm shift in haemovigilance



EUROPEAN COMMISSION
HEALTH AND FOOD DIRECTORATE-GENERAL

Directorate B: Health systems, medical products and innovation
B4 - Medical Products : quality, safety, innovation

Brussels, SANTE B4/2017

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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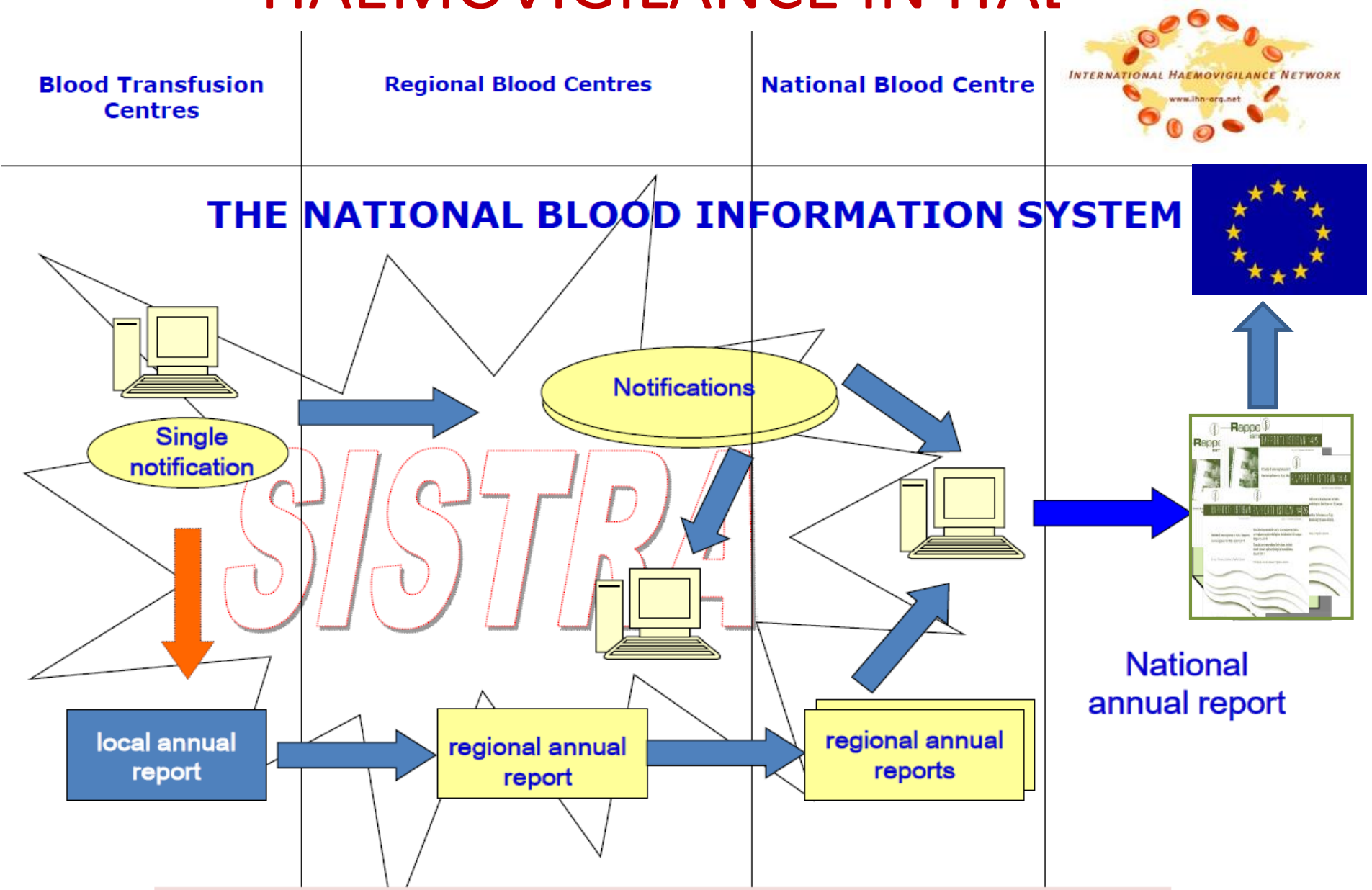


SANGUE

Haemovigilance

Serious adverse reactions in donors

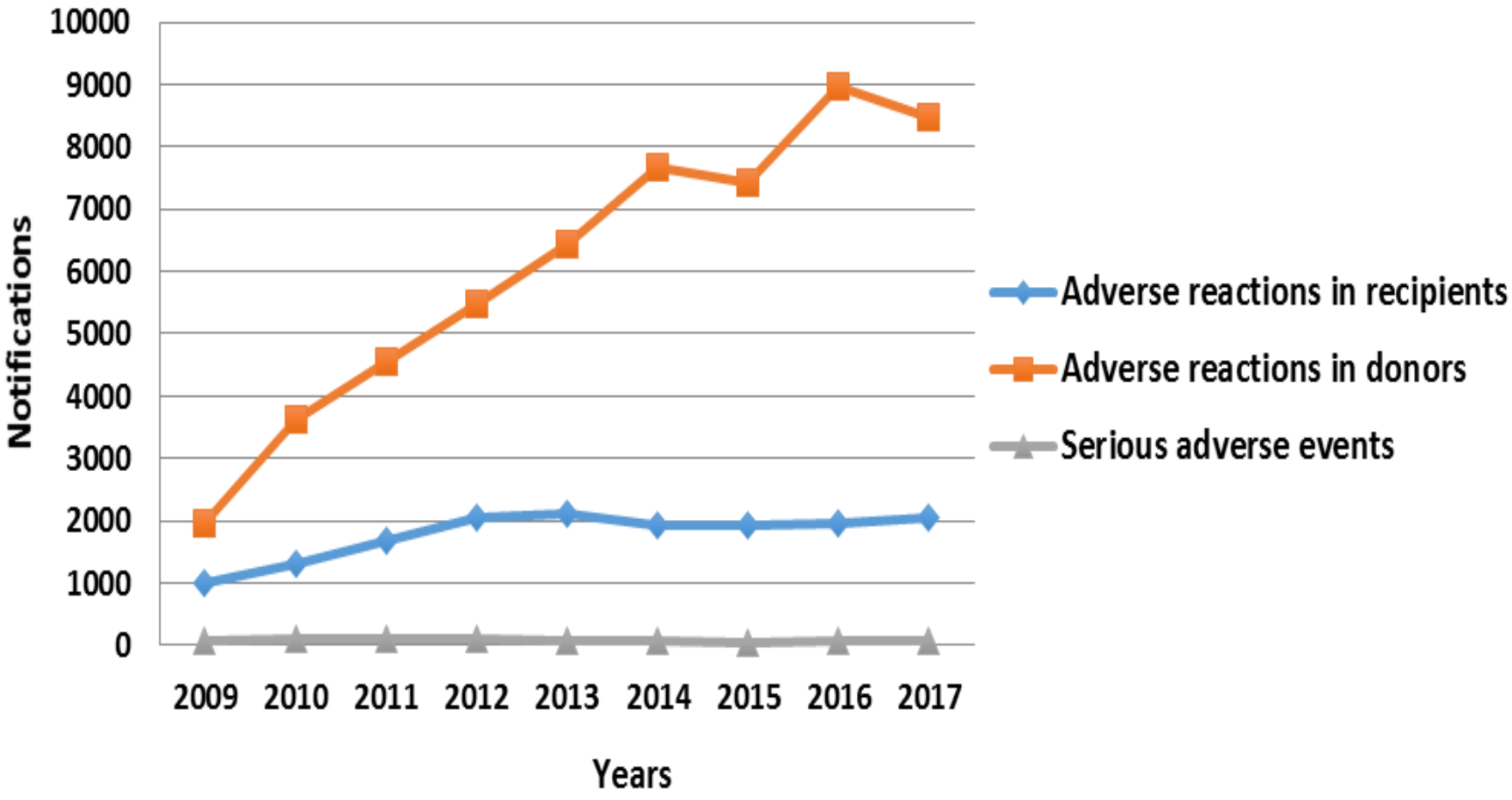
Epidemiological surveillance of donors

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)



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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
Haemolisis	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
Total	**8,484**	**100**

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 punture		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
Haemolisis		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
Total	**6,055**	**71.4**	**1,404**	**16.5**	**1,025**	**12.1**

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

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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)

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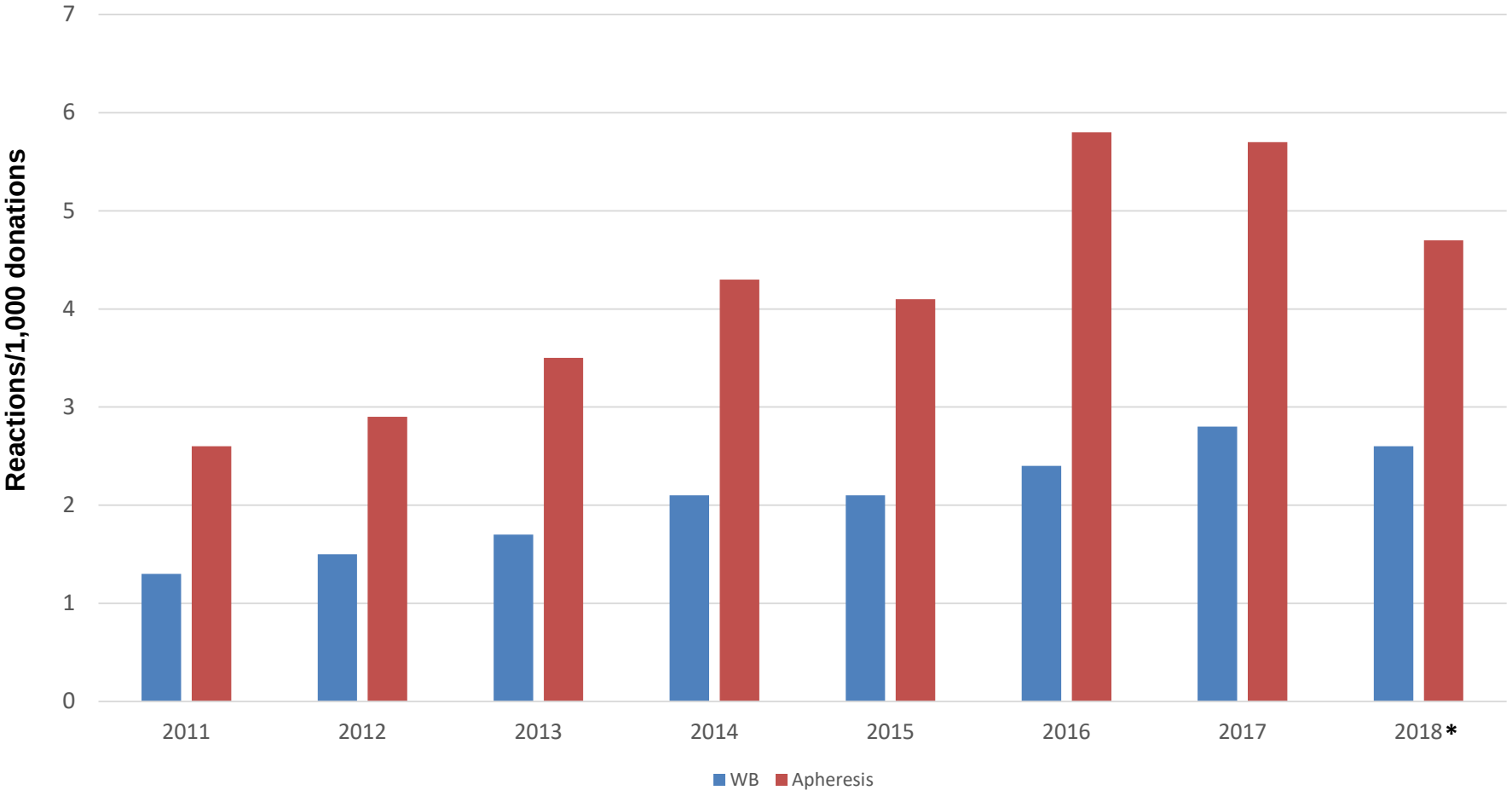
Adverse reactions per 1,000 donations classified per donation procedure (2011-2018)



*** Preliminary data**

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Adverse reactions to plasmapheresis donation (2017)

Adverse reaction	n.	%
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
Haemolisis	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
Total	**2,150**	**100**

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
Total	**8,484**	**100**

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

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CNS WORKING GROUP

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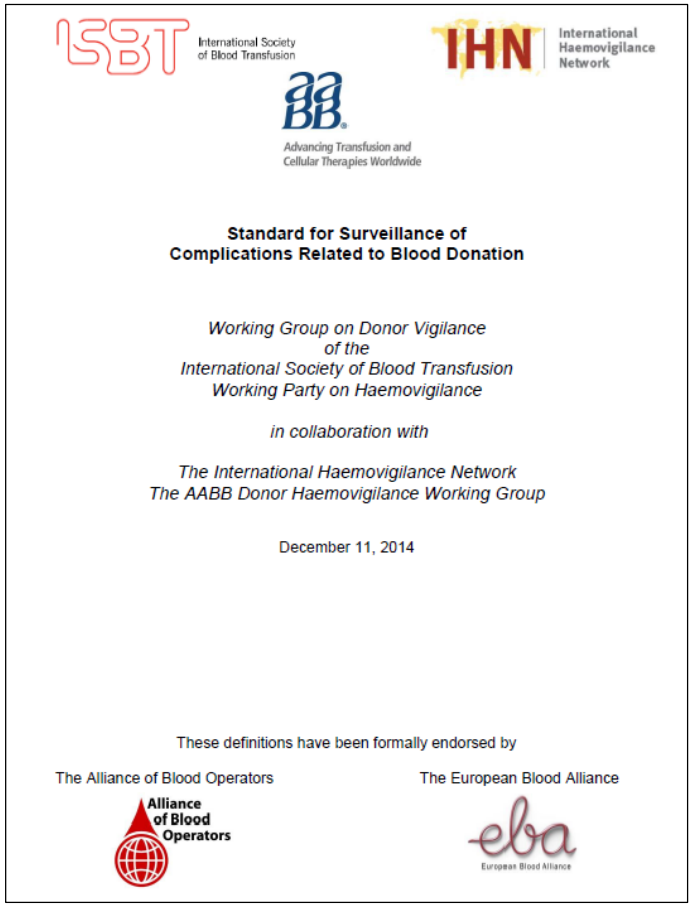
Roma, 27 aprile 2015

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

Alliance of Blood Operators

The European Blood Alliance

eba
European Blood Alliance

Scientific references

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

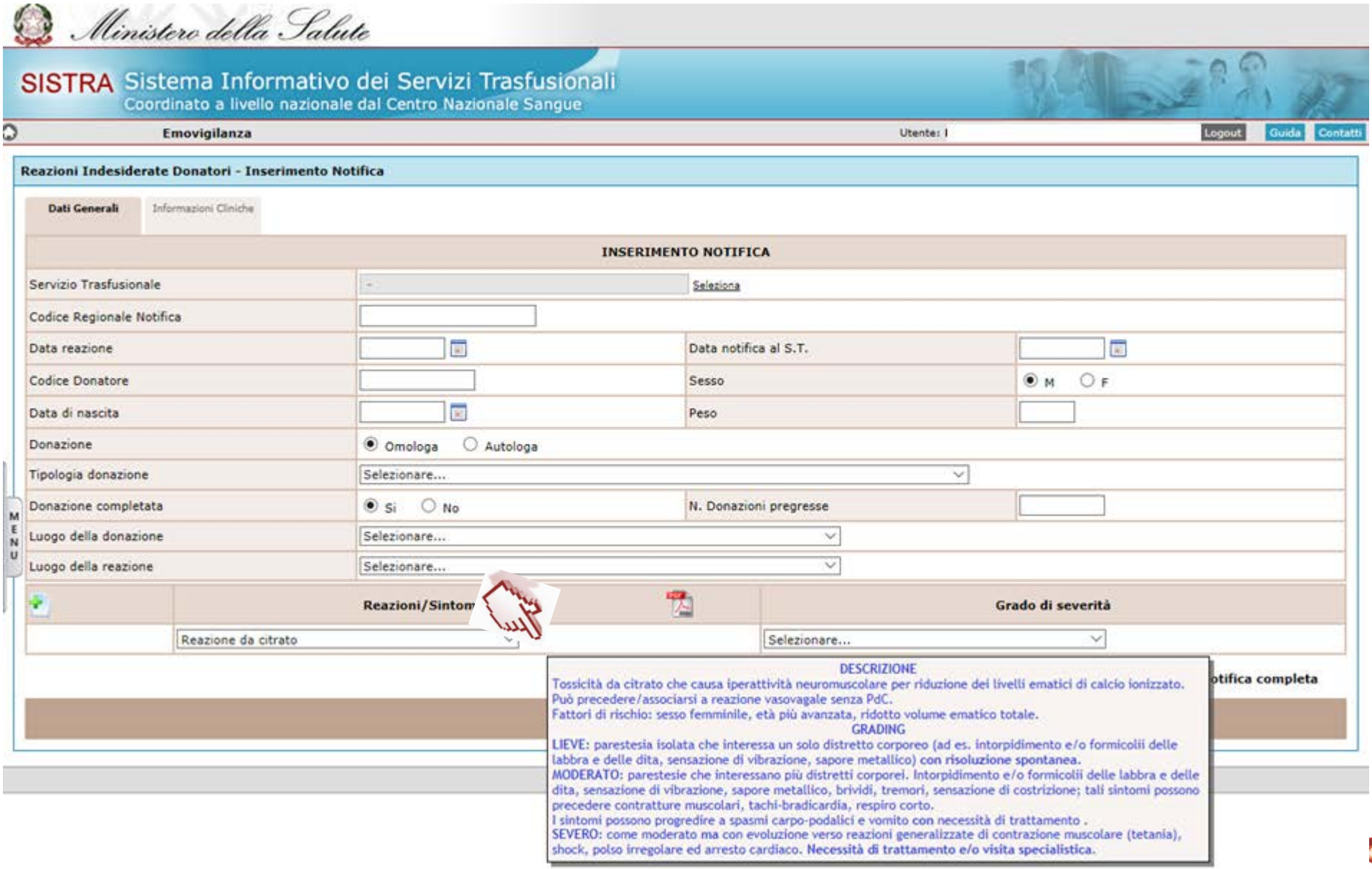
A.1.1 EMATOMA	**Factors to consider:** - **DIAMETER** - **LIMITATIONS ON ACTIVITIES OF DAILY LIVING** - **TREATMENT** - **HOSPITALISATION**

Grading Severity of Blood Donor Adverse Reactions Tool

(Example 2 – Immediate Vasovagal Reaction)

B. COMPLICANZE CON SINTOMI GENERALIZZATI: REAZIONI VASO VAGALI	
B.1 **REAZIONE VASOVAGALE DI TIPO IMMEDIATO**	**Factors to consider:** - **SIGNS AND SYMPTOMS** - **LOC** (<60 seconds vs ≥60 seconds) - **TREATMENT** (confort care and/or oral hydration vs IV hydration) - **HOSPTALISATION** - **TIED FALL AND/OR BLEED**
B.1.1 **REAZIONE VASOVAGALE DI TIPO IMMEDIATO CON COMPLICAZIONI**	

SISTRA SCREENSHOT



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.

ONLY ONE

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Thanks for your attention!