CENTRO NAZIONALE SANGUE

Istituto Superiore di Sanità

Webinar

Aggiornamenti in Emovigilanza

Emovigilanza: dati nazionali e internazionali *a confronto*

Vanessa Piccinini
Centro Nazionale Sangue
Istituto Superiore di Sanità, Roma

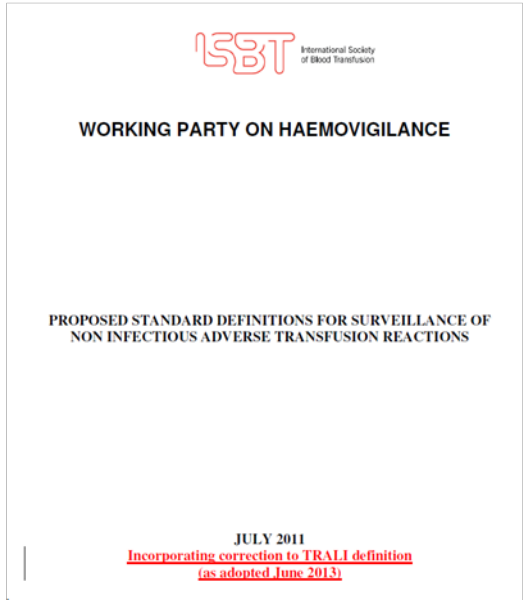
Roma, 5 dicembre 2023

Italian haemovigilance system: laws and definitions

Europe. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. Official Journal of the European Union L 033. 08/02/2003.

Europe. Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events. *Official Journal of the European Union* L 256/32. 01/10/2005

Italia. Decreto Legislativo 9 novembre 2007. n. 207. Attuazione della direttiva 2005/61/CE. che applica la direttiva 2002/98/CE per quanto riguarda la prescrizione in tema di rintracciabilità del sangue e degli emocomponenti destinati a trasfusioni e la notifica di effetti indesiderati ed incidenti gravi. *Gazzetta Ufficiale della Repubblica Italiana* n. 261 - Suppl. Ordinario n. 228. 9/11/2007.


ISBT International Society of Blood Transfusion

WORKING PARTY ON HAEMOVIGILANCE

PROPOSED STANDARD DEFINITIONS FOR SURVEILLANCE OF NON INFECTIOUS ADVERSE TRANSFUSION REACTIONS

JULY 2011
Incorporating correction to TRALI definition
(as adopted June 2013)


ISBT International Society of Blood Transfusion
IHN International Haemovigilance Network
AABB 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

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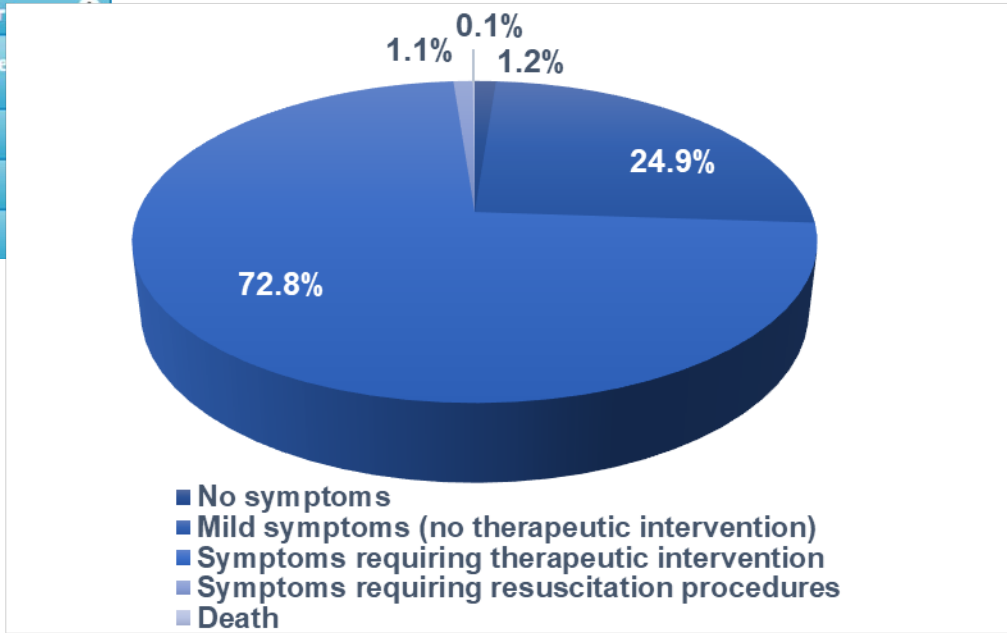
SISTRA Sistema Informativo dei Servizi Trasfusionali
Coordinato a livello nazionale dal Centro Nazionale Sangue

Emovigilanza

- Effetti Indesiderati Riceventi
- Near Miss
- Sorveglianza Donator
- Reazioni Indesiderate Donatori
- Incidenti Gravi
- Monitoraggio
- Gestione

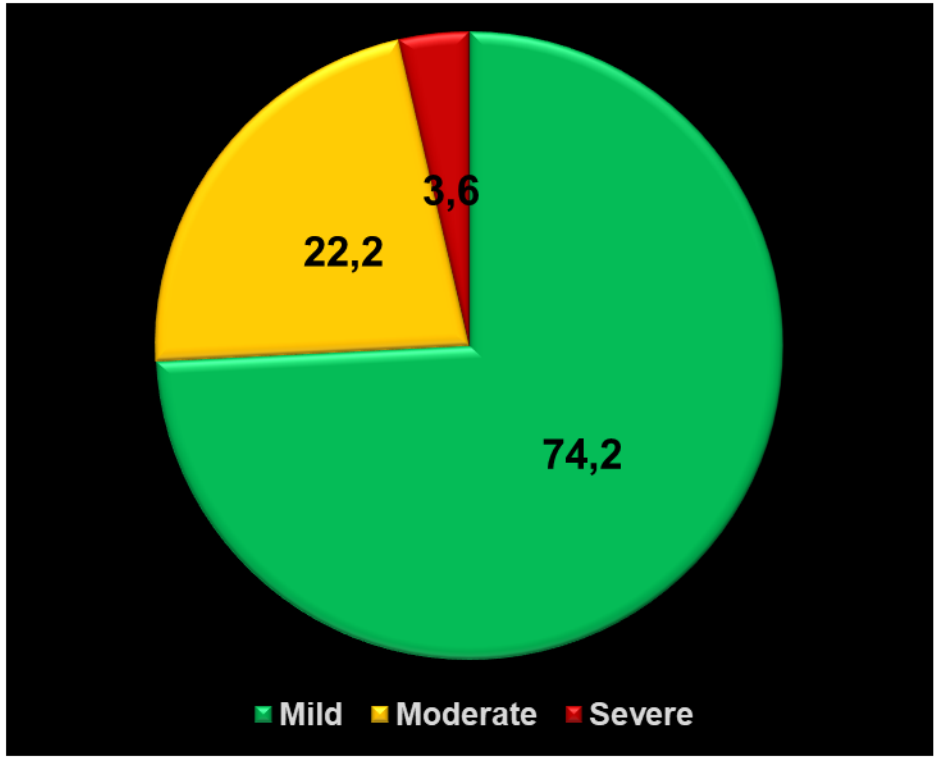
Adverse reactions in recipients and donors (2022)



Severity level of adverse reactions in recipients (2022)

Table 16. Adverse reactions in recipients by imputability level (2022)

Level	Imputability	n.	%
0	Excluded/Improbable	223	10.7
1	Possible	952	45.8
2	Probable	679	32.7
3	Certain	114	5.5
N.A.	Not assessable	111	5.3
	Total	**2,079**	**100**



Severity level of adverse reactions in donors (2022)

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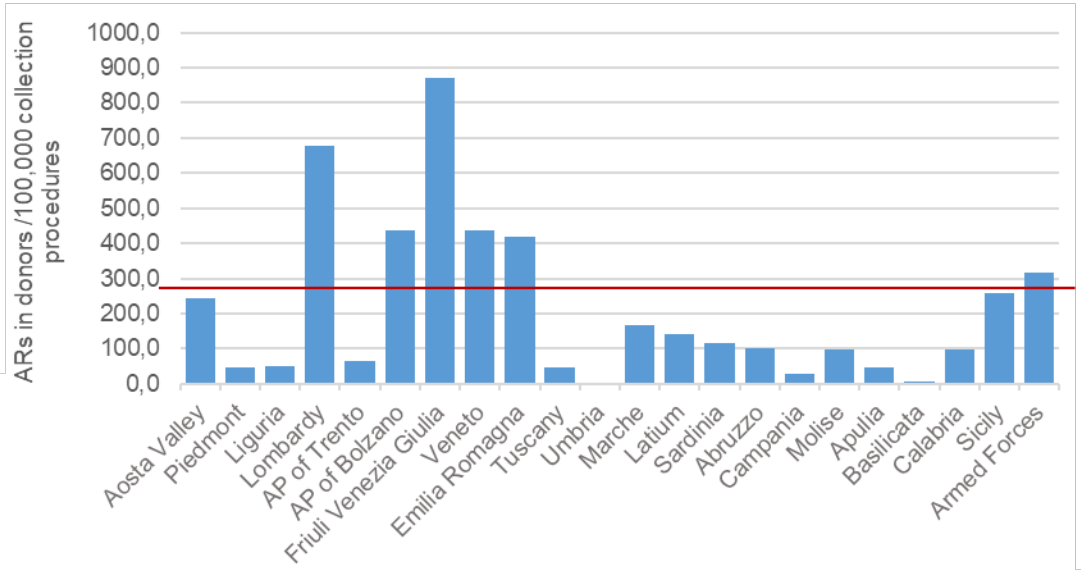
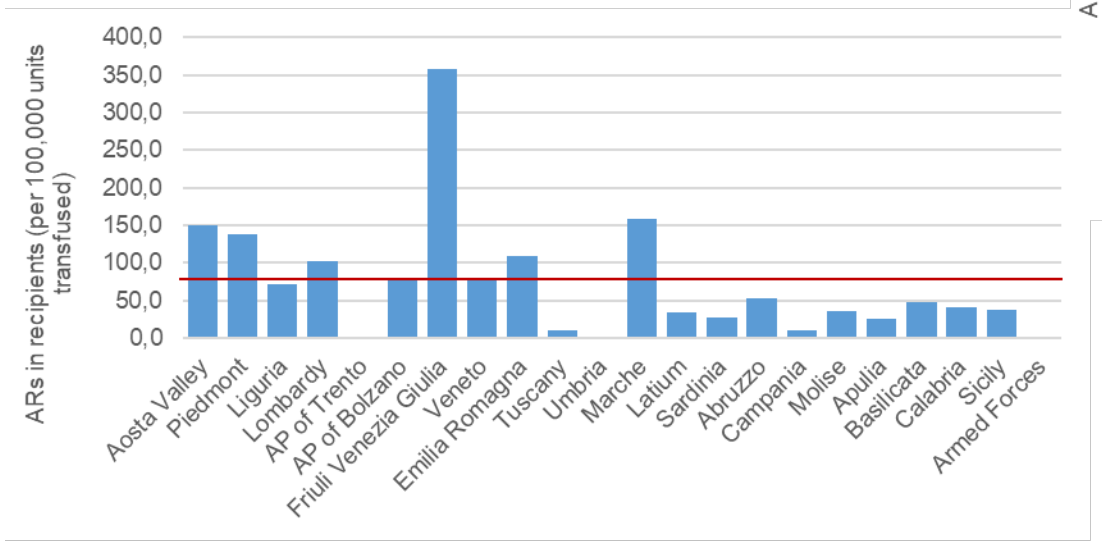
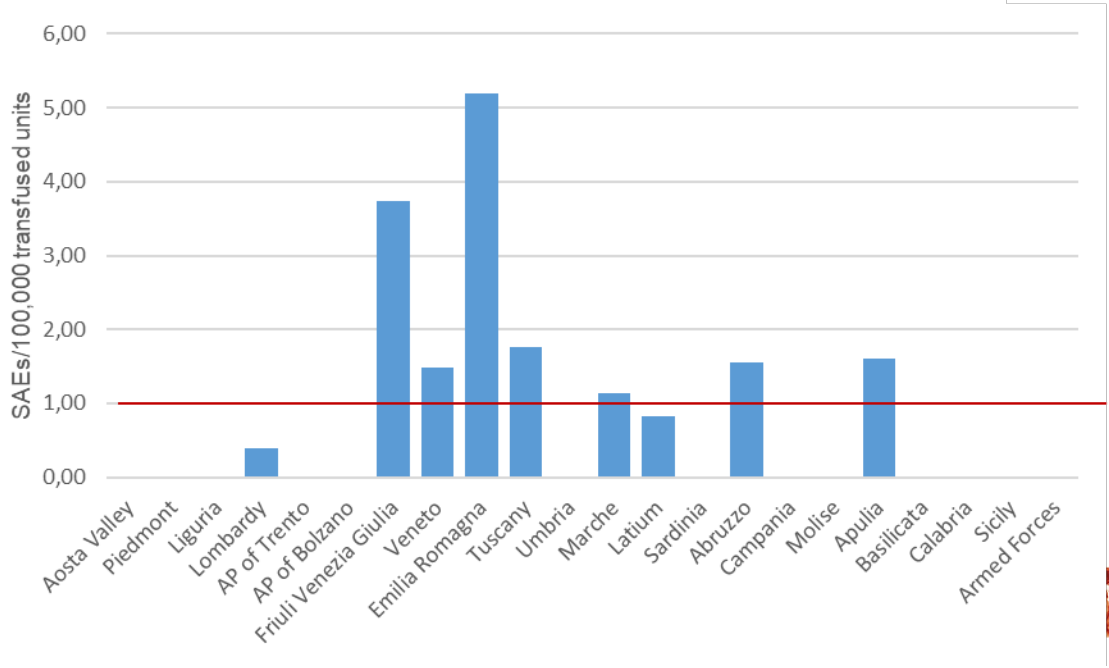
- Gestione

Haemovigilance notifications (per 100,000) per region (2022)







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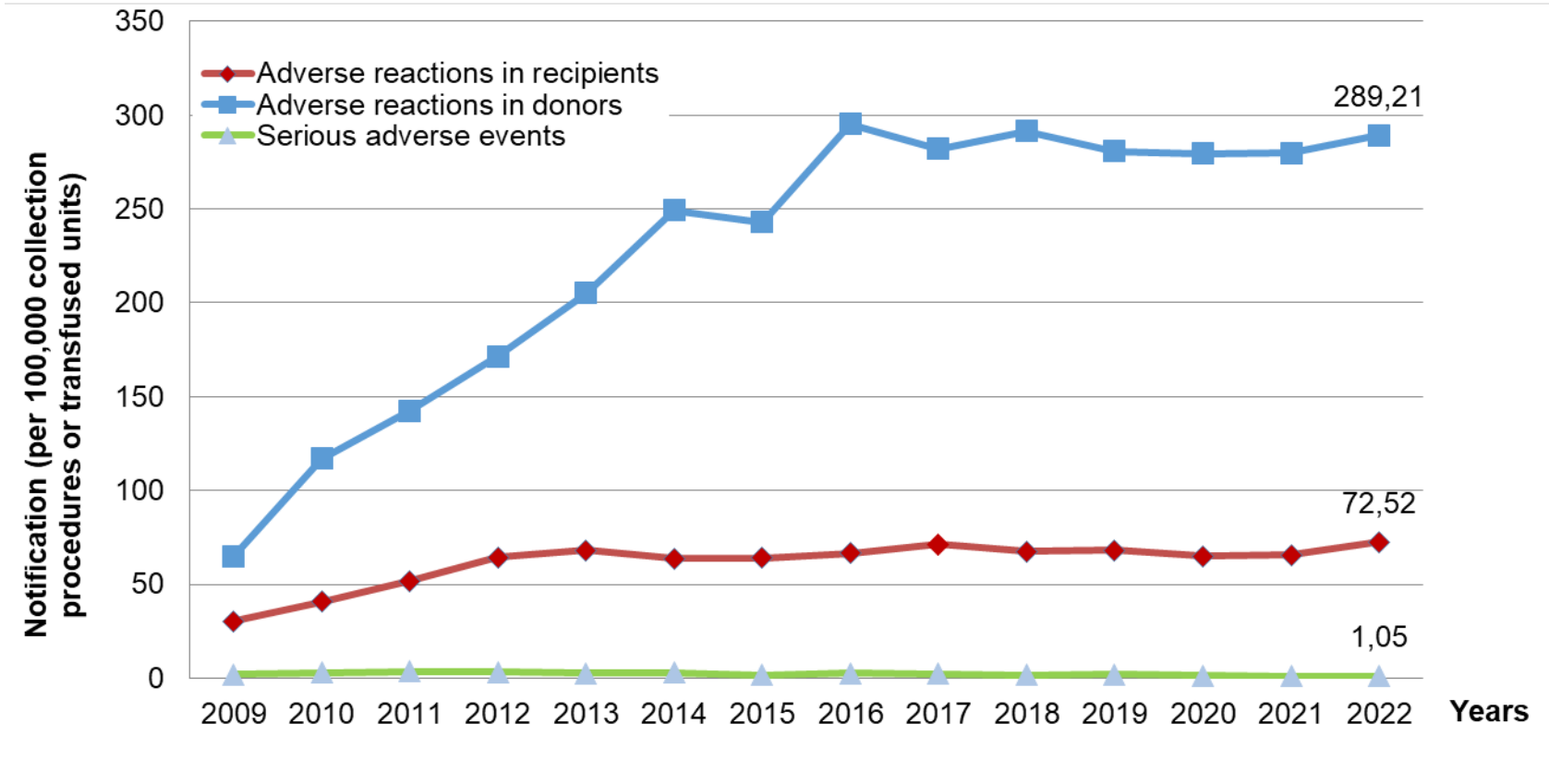
- Gestione

Haemovigilance notifications (per 100,000) (2009-2022)



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COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS AS LAID DOWN IN THE BLOOD DIRECTIVE 2002/98/EC AND COMMISSION DIRECTIVE 2005/61/EC

Ref. Ares(2021)2472560 - 12/04/2021

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Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels, SANTE.DDG1.B.4/MA

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VERSION 2021

The common approach aims to facilitate comparisons between data sent to the Commission from Member States, and associated countries.

The guidelines are meant to clarifying issues before data collection is undertaken each year.


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COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS

SCOPE OF REPORTING

EU legislation on blood states that reportable information concerns:

- "any **serious** adverse reactions (SAR) observed in recipients during or after transfusion which may be attributable to the quality and safety of blood and blood components (Directive 2005/61/EC Article 5(1))",

- "any **serious** adverse events (SAE) which may affect the quality or safety of blood and blood components (Directive 2005/61/EC Article 6(1)."

GOALS

Measuring general trends on the safety of blood transfusion (proportion of the total number of SAR during the reported year which are related to unsafe and/or bad quality blood components) for identifying areas where adaptations or improvements to EU blood legislation may be required.

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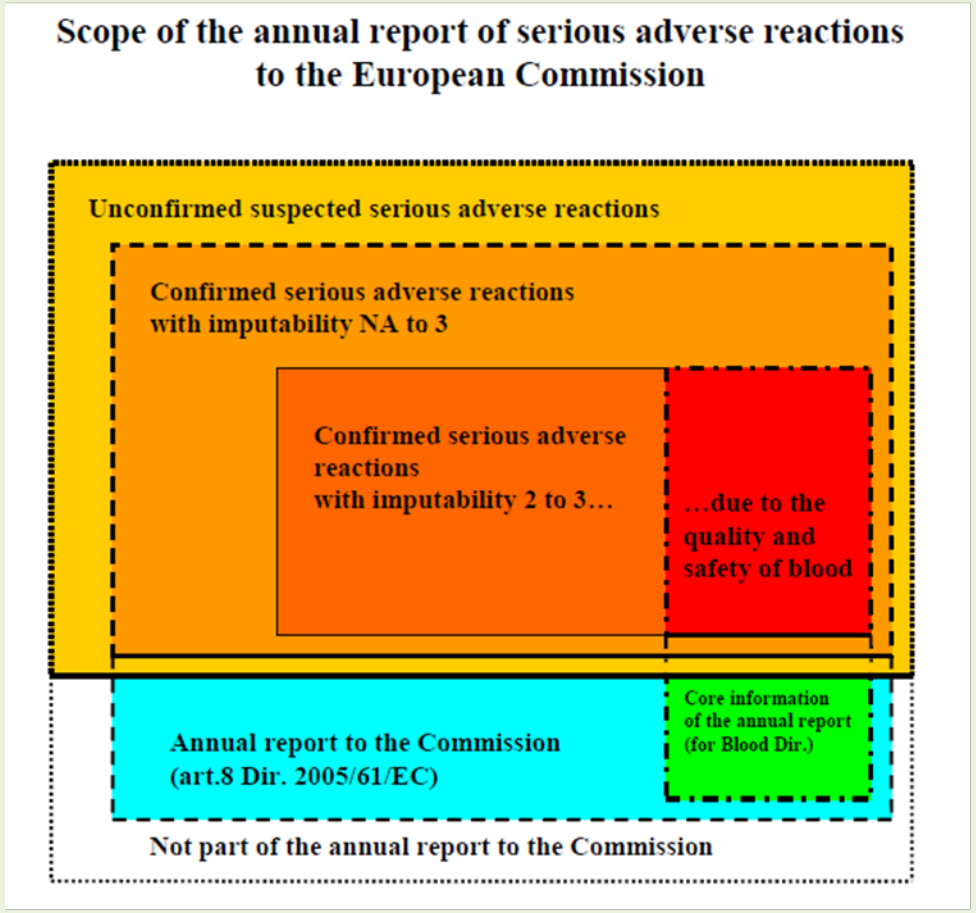

Reportable SAR

Confirmed SAR

- likely, probable or certain (imputability 2 to 3)

and

- attributable to a problem in quality and safety of the blood component

Imputability levels are defined by Annex II part B of the Directive as follows:

PART B

Serious adverse reactions — imputability levels

Imputability levels to assess serious adverse reactions.

Imputability level		Explanation
NA	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

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COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS

Member States shall submit to the Commission an annual report**, by 30 June of the following year,** on the notification of serious adverse reactions and events received by the competent authority using the formats in Part D of Annex II and Part C of Annex III.

Tables in the legally-mandated format should be filled in by **reporting establishments on an annual basis and sent to the national competent authorities**.

The competent authorities should then collate this information and complete the reporting template (sent by the Commission) with the aggregated data of confirmed cases per category over the previous year. The competent authorities should not forward individual forms sent by reporting establishments to the Commission.

Member States shall ensure that reporting establishments notify to the competent authority all relevant information about **serious adverse reactions of imputability level 2 or 3**, as referred to in Part B of Annex II, **attributable to the quality and safety of blood and blood components.**"

Reporting establishment submit a complete report on SAR to the competent authorities on an annual basis using the format set out in part D of Annex II of the Directive. **This format requires reporting of SAR with imputability levels NA to 3.**

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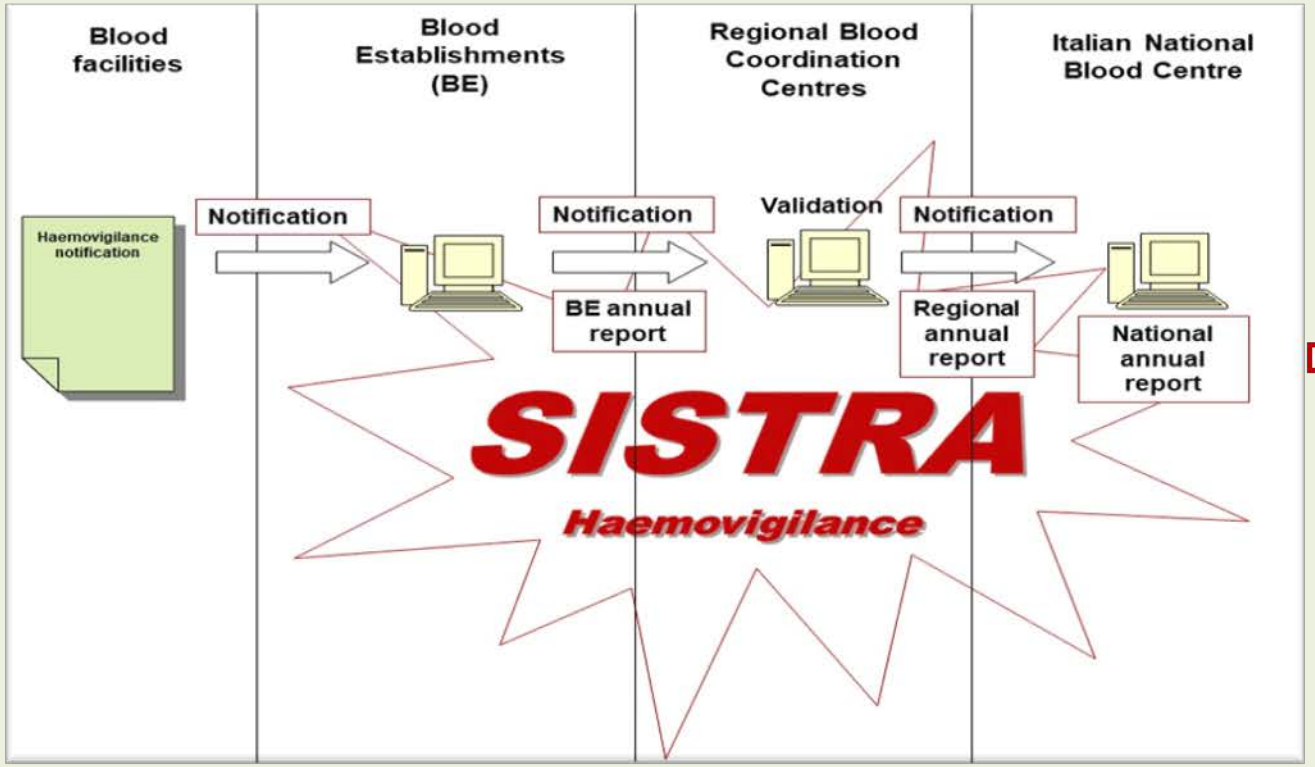
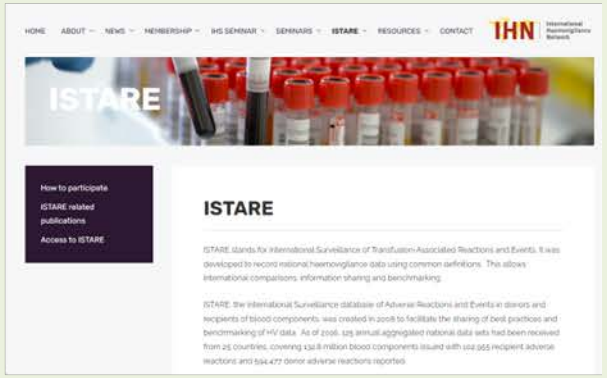
Italian Haemovigilance flow





serious adverse reactions of imputability level 2 or 3

SARE

European Commission

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COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS

SAR in recipient

Imputability level after confirmation of the Serious Adverse Reaction(s)			Level 1	Level 2	Level 3	Total
Immunological Haemolysis	Due to ABO incompatibility	Total no death				0
		Total deaths				0
	Due to other allo-antibody	Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Non-immunological Haemolysis		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted bacterial infection		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted fungal infection		Total no death				0
		Total deaths				0


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COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS

SAE

Component defect

- blood or a blood component that does not meet the quality and safety requirements

Equipment failure

- material, instruments or machinery that did not function as required

Materials

- any material (bags, preservation solutions, etc.) caused SAE, from collection to distribution of blood or blood components

System failure

- quality management system fails
- insufficient training or education
- high workload or pressure, incompetent staffing or insufficient skill-mixes of staffing
- inadequate processes, procedures or documentation

Human error

- incorrect decision or omission following the correct procedure
- following the wrong procedure
- inaccurate human handling of materials
- equipment failures due to inappropriate use or incorrect human action be
- slips and lapses

Other (specify)

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VERSION 2021

COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS

SAR in donor

SAR in donor

A SAR is "an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity."

Annual notification for Serious Adverse REACTION(S)

Total number of serious adverse reactions in donors of blood and blood components:(See section 2.1 of the Common approach)

Please provide additional detail about any reported death in a donor of blood or blood components (NB please also include any deaths in the total numbers of donor SAR above.)

	Specifications	*Nr*
Whole Blood	Nerve injury/irritation	
	Vasovagal reaction	
	Major cardiovascular event or death up to 24 hours after donation (include imputability assessment in comment box below)	
	Other	
Apheresis	Nerve injury/irritation	
	Vasovagal reaction	
	Citrate reaction	
	Allergic reaction	
	Major cardiovascular event or death up to 24 hours after donation (include imputability assessment in comment box below)	
	Other	

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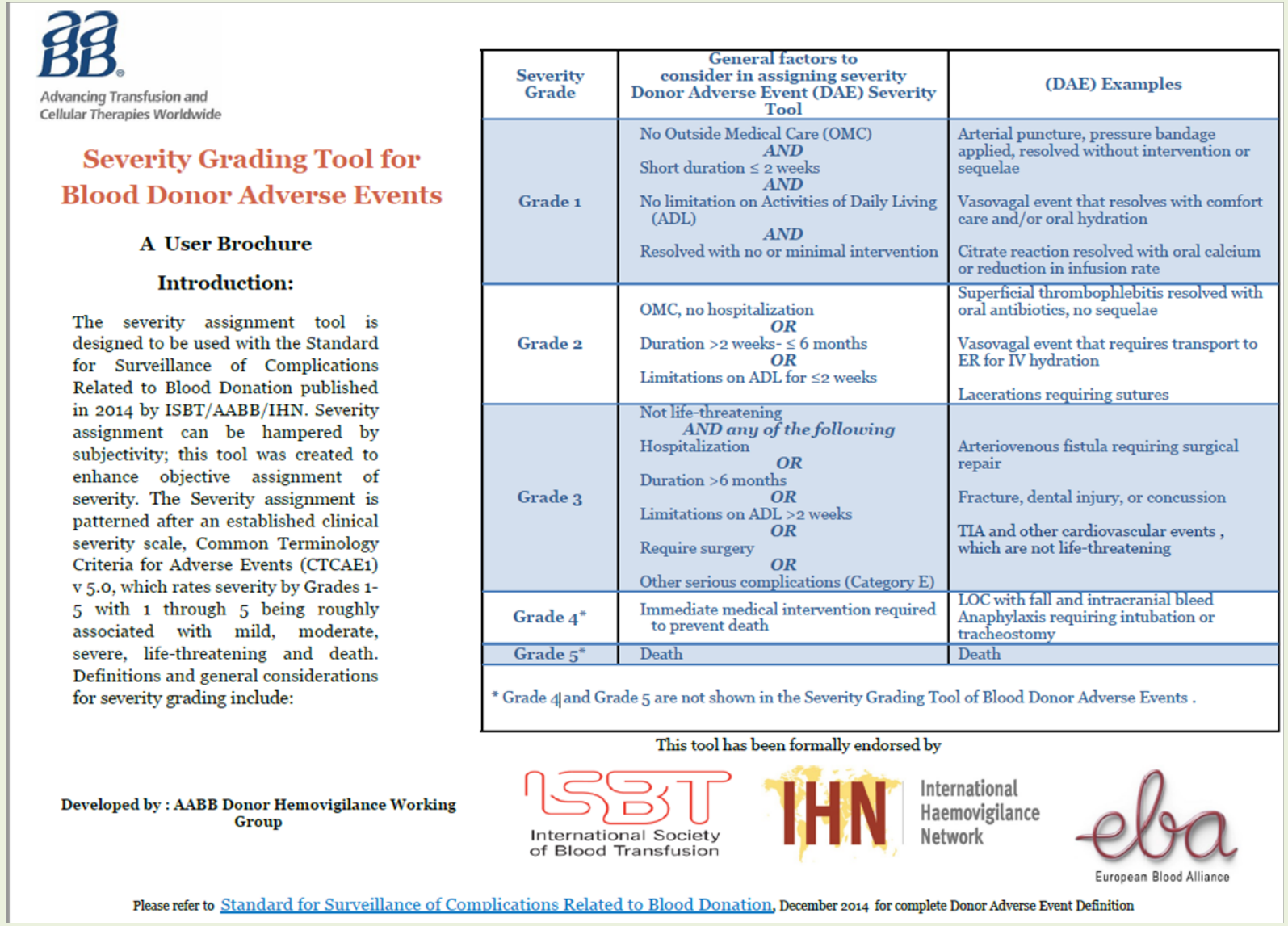
SEVERITY GRADING TOOL FOR BLOOD DONOR ADVERSE EVENTS



Advancing Transfusion and Cellular Therapies Worldwide

Severity Grading Tool for Blood Donor Adverse Events

A User Brochure

Introduction:

The severity assignment tool is designed to be used with the Standard for Surveillance of Complications Related to Blood Donation published in 2014 by ISBT/AABB/IHN. Severity assignment can be hampered by subjectivity; this tool was created to enhance objective assignment of severity. The Severity assignment is patterned after an established clinical severity scale, Common Terminology Criteria for Adverse Events (CTCAE1) v 5.0, which rates severity by Grades 1-5 with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death. Definitions and general considerations for severity grading include:

Developed by : AABB Donor Hemovigilance Working Group

Severity Grade	General factors to consider in assigning severity Donor Adverse Event (DAE) Severity Tool	(DAE) Examples
Grade 1	No Outside Medical Care (OMC) *AND* Short duration ≤ 2 weeks *AND* No limitation on Activities of Daily Living (ADL) *AND* Resolved with no or minimal intervention	Arterial puncture, pressure bandage applied, resolved without intervention or sequelae Vasovagal event that resolves with comfort care and/or oral hydration Citrate reaction resolved with oral calcium or reduction in infusion rate
Grade 2	OMC, no hospitalization *OR* Duration >2 weeks- ≤ 6 months *OR* Limitations on ADL for ≤2 weeks	Superficial thrombophlebitis resolved with oral antibiotics, no sequelae Vasovagal event that requires transport to ER for IV hydration Lacerations requiring sutures
Grade 3	Not life-threatening *AND any of the following* Hospitalization *OR* Duration >6 months *OR* Limitations on ADL >2 weeks *OR* Require surgery *OR* Other serious complications (Category E)	Arteriovenous fistula requiring surgical repair Fracture, dental injury, or concussion TIA and other cardiovascular events , which are not life-threatening
Grade 4*	Immediate medical intervention required to prevent death	LOC with fall and intracranial bleed Anaphylaxis requiring intubation or tracheostomy
Grade 5*	Death	Death

* Grade 4 and Grade 5 are not shown in the Severity Grading Tool of Blood Donor Adverse Events .

This tool has been formally endorsed by

ISBT International Society of Blood Transfusion

IHN International Haemovigilance Network

eba European Blood Alliance

Please refer to Standard for Surveillance of Complications Related to Blood Donation, December 2014 for complete Donor Adverse Event Definition

Studio pilota SGT sulle

SAR donatori in SISTRA di:

- grado SEVERO
- anno 2023

per determinare, a livello europeo, l'applicabilità e l'omogeneità del grading secondo i nuovi criteri

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SEVERITY GRADING TOOL
FOR BLOOD DONOR ADVERSE EVENTS

Severity Grade	General factors to consider in assigning severity Donor Adverse Event (DAE) Severity Tool	(DAE) Examples
Grade 1	No Outside Medical Care (OMC) *AND* Short duration ≤ 2 weeks *AND* No limitation on Activities of Daily Living (ADL) *AND* Resolved with no or minimal intervention	Arterial puncture, pressure bandage applied, resolved without intervention or sequelae Vasovagal event that resolves with comfort care and/or oral hydration Citrate reaction resolved with oral calcium or reduction in infusion rate
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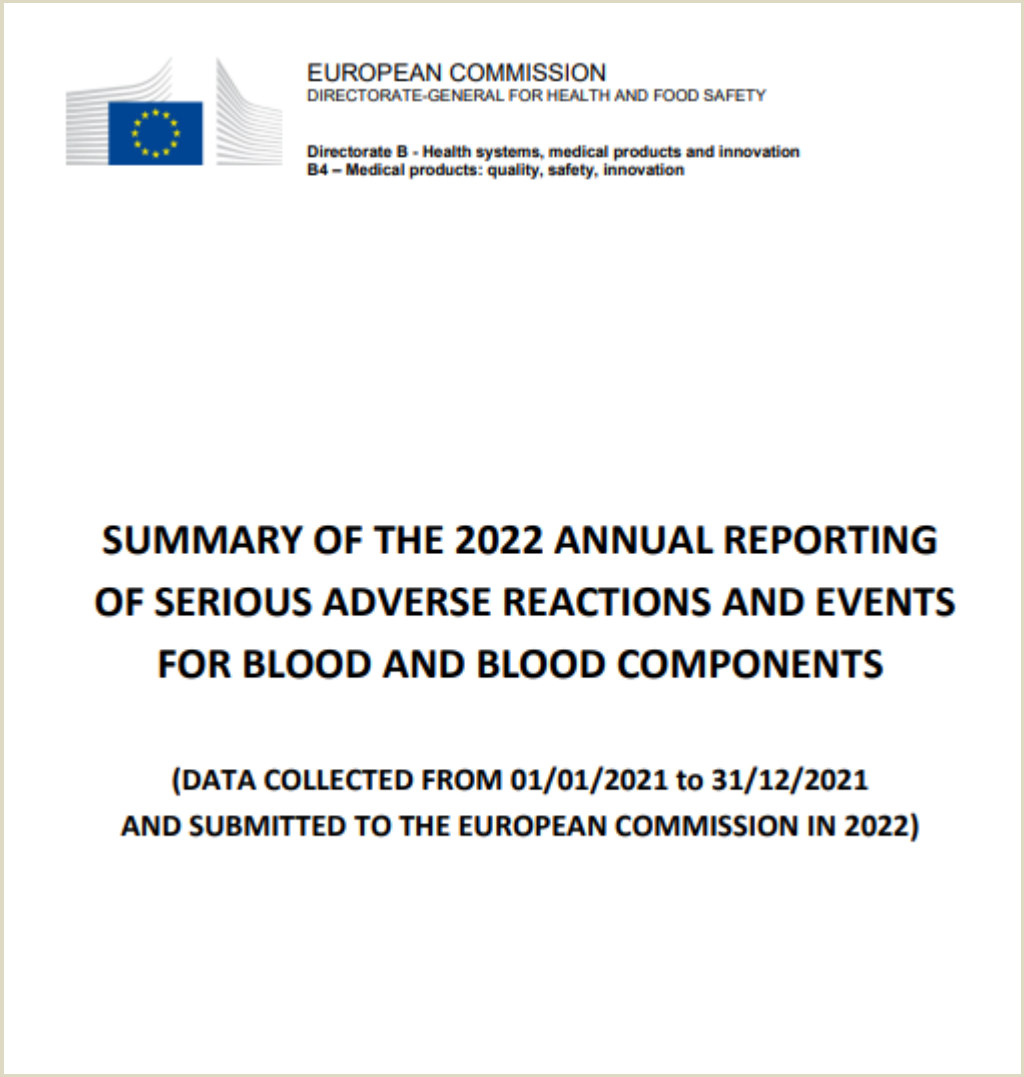
* Grade 4 and Grade 5 are not shown in the Severity Grading Tool of Blood Donor Adverse Events .

Integrazione voci in **SISTRA** non obbligatorie di tipo SI / NO

- Cure mediche esterne
- Limitazione delle attività di vita quotidiana <= / > 2 settimane
- Intervento chirurgico

Reazioni indesiderate donatori con necessità di ricovero 2022

SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)



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SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS

(DATA COLLECTED FROM 01/01/2021 to 31/12/2021 AND SUBMITTED TO THE EUROPEAN COMMISSION IN 2022)

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(DATA COLLECTED FROM 01/01/2021 to 31/12/2021 AND SUBMITTED TO THE EUROPEAN COMMISSION IN 2022)

SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)

EU Member States SARE Exercise Blood/Blood Components 2021 data of 25 Countries		ITALY SISTRA – Haemovigilance 2021 data
22.0 million units of blood or blood components **collected**	13%	**3.0 million** units of blood or blood components **collected** by Italy
17.8 million units of blood or blood components **transfused**	16%	**2.9 million** units of blood or blood components **transfused** by Italy

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SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)

SAR in recipient
Imputability level 2 or 3

EU Member States
SARE Exercise Blood/Blood Components
2021 data

1379 SAR

- Febrile non-haemolytic transfusion reaction (FNHTR) (24.2%)
- Anaphylaxis/hypersensitivity (15.7%)
- Transfusion-associated circulatory overload (TACO) (13.4%).

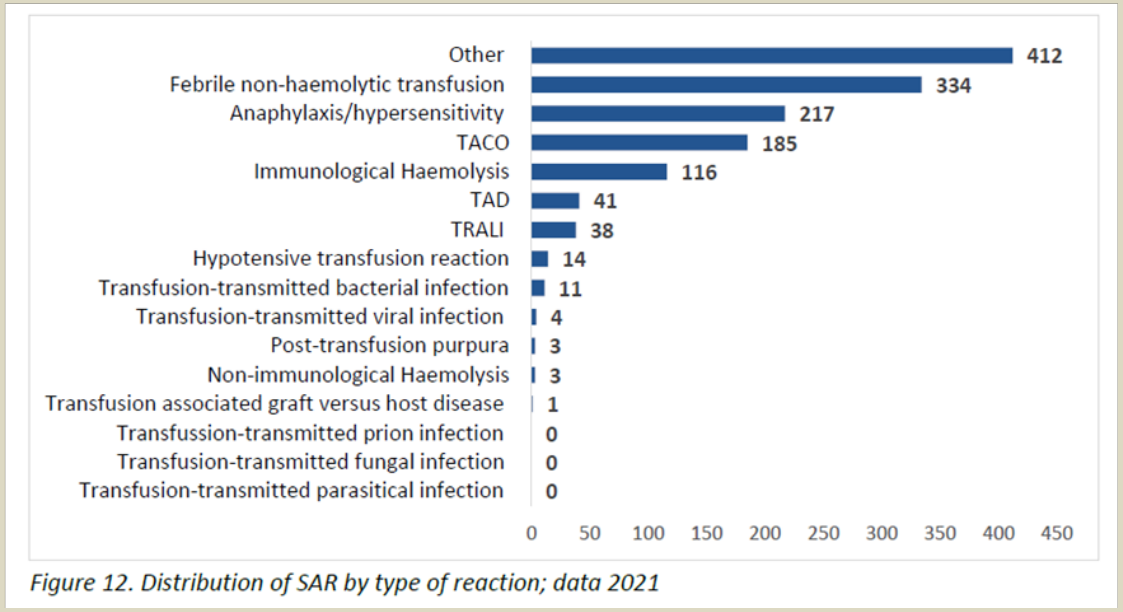

Figure 12. Distribution of SAR by type of reaction; data 2021

37%

ITALY
SISTRA – Haemovigilance
2021 data

Symptoms requiring therapeutic intervention
Symptoms requiring resuscitation procedures
Death

Reaction	Probable	Certain	Total	%
Allergic manifestations with only mucosal and cutaneous symptoms	217	36	253	43,5
Febrile non-haemolytic reaction (FNHTR)	181	16	197	33,9
Other	37	5	42	7,2
Allergic reactions involving the respiratory and/or cardiovascular system	26	9	35	6,0
Transfusion associated dyspnoea (TAD)	17	1	18	3,1
Transfusion-associated circulatory overload (TACO)	12	4	16	2,8
Haemolytic transfusion reactions due to autoantibodies	8		8	1,4
Hypotensive transfusion reaction	6	1	7	1,2
Transfusion-related acute lung injury (TRALI)	1		1	0,2
Non-immunological haemolysis - mecchanic cause	1		1	0,2
Post-transfusion purpura	1		1	0,2
Acute haemolytic reaction due to ABO incompatible transfusion		1	1	0,2
Anaphylactic shock	1		1	0,2
Total	**508**	**73**	**581**	**100,0**

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SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)

SAR in recipient

Imputability level 2 or 3

Other

EU Member States
SARE Exercise Blood/Blood Components
2021 data

Unclassified SAR remains the most prevalent group (30%).
Greater clarification is required here in order to address the potential issue of classification accuracy.

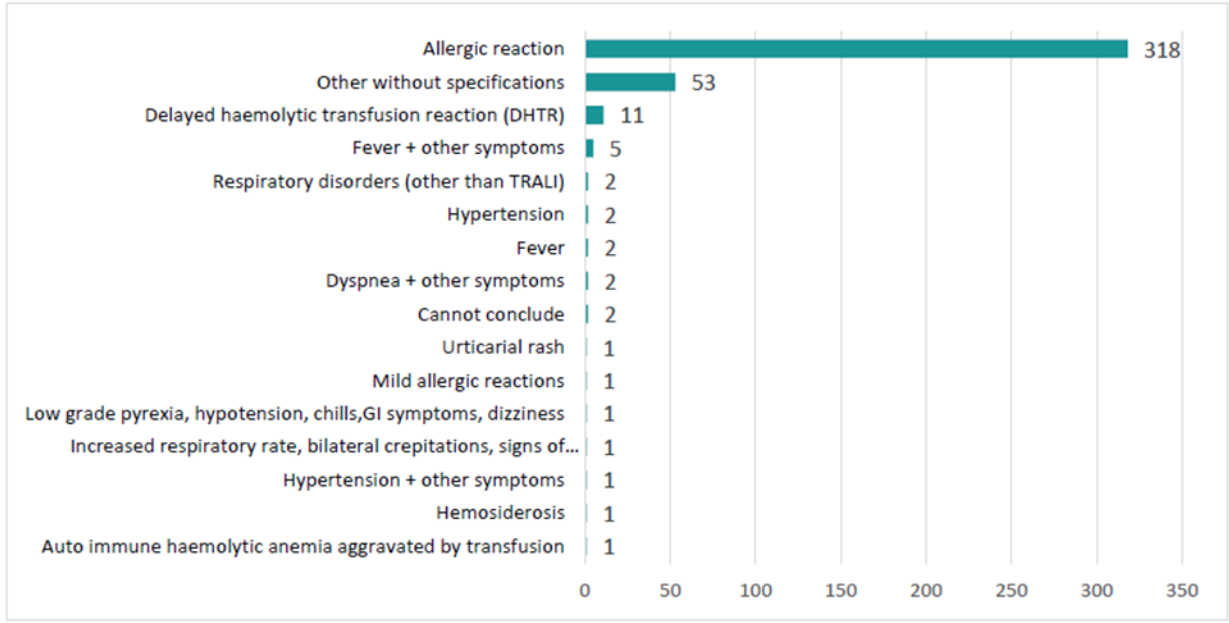

Figure 13. Distribution of SAR classified as "Others", by subtype of other reaction; data 2021

ITALY
SISTRA – Haemovigilance
2021 data

Symptoms requiring therapeutic intervention
Symptoms requiring resuscitation procedures
Death

10%

Other: 42 (7.2%)

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B4 – Medical products: quality, safety, innovation

SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS

(DATA COLLECTED FROM 01/01/2021 to 31/12/2021 AND SUBMITTED TO THE EUROPEAN COMMISSION IN 2022)

SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2020 DATA)

SAR in recipient
Imputability level 2 or 3

EU Member States
SARE Exercise Blood/Blood Components
2021 data

Incidence per 100 000 units transfused:

- platelets **17.3**
- plasma **7.2**
- RBC **5.4**
- **Total** **7.3**

ITALY
SISTRA – Haemovigilance
2021 data

Symptoms requiring therapeutic intervention
Symptoms requiring resuscitation procedures
Death

Incidence per 100 000 units transfused:

- platelets **86.5**
- plasma **44.7**
- RBC **11.3**
- **Total** **20.2**

As some participating countries reported partial data, the interpretation of these results should take into consideration this limitation

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SAR in recipient
Imputability level 2 or 3
Death

EU Member States
SARE Exercise Blood/Blood Components
2021 data

25 transfusion-related deaths

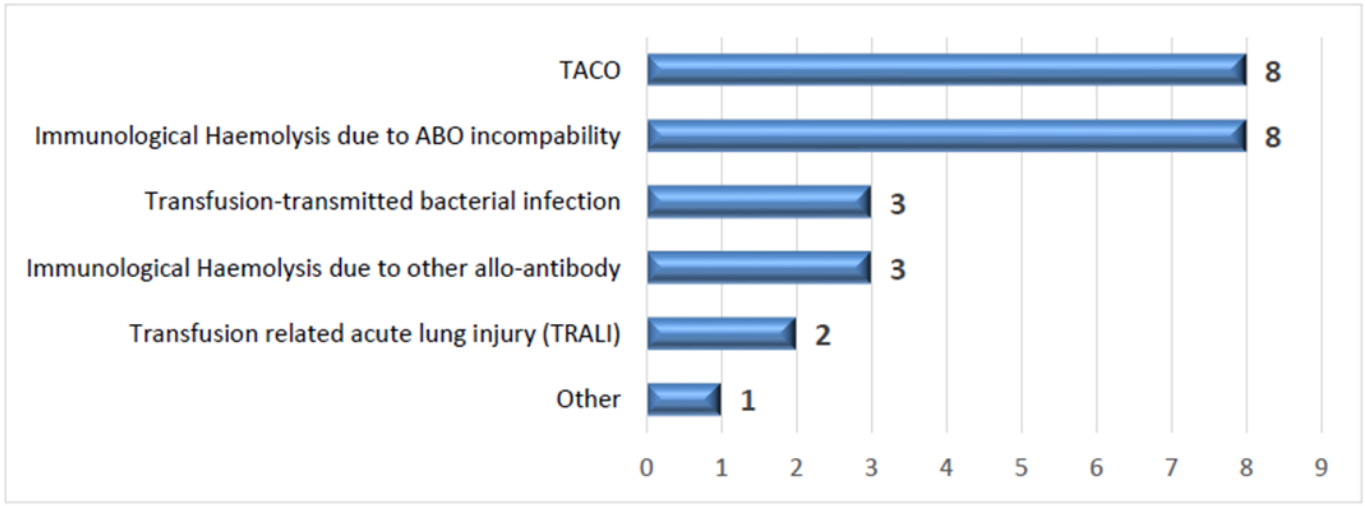

Figure 14. Deaths by SAR type (imputability level 2-3) in absolute values and percentages; data 2021

ITALY
SISTRA – Haemovigilance
2021 data

Symptoms requiring therapeutic intervention
Symptoms requiring resuscitation procedures
Death

No deaths

(3 cases of death
with excluded/unlikely and not assessable
imputability)

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(DATA COLLECTED FROM 01/01/2021 to 31/12/2021 AND SUBMITTED TO THE EUROPEAN COMMISSION IN 2022)

SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)

SAE

EU Member States
SARE Exercise Blood/Blood Components
2021 data

In total, **2734 Serious Adverse Events (SAE)** were reported by **24 Countries.**

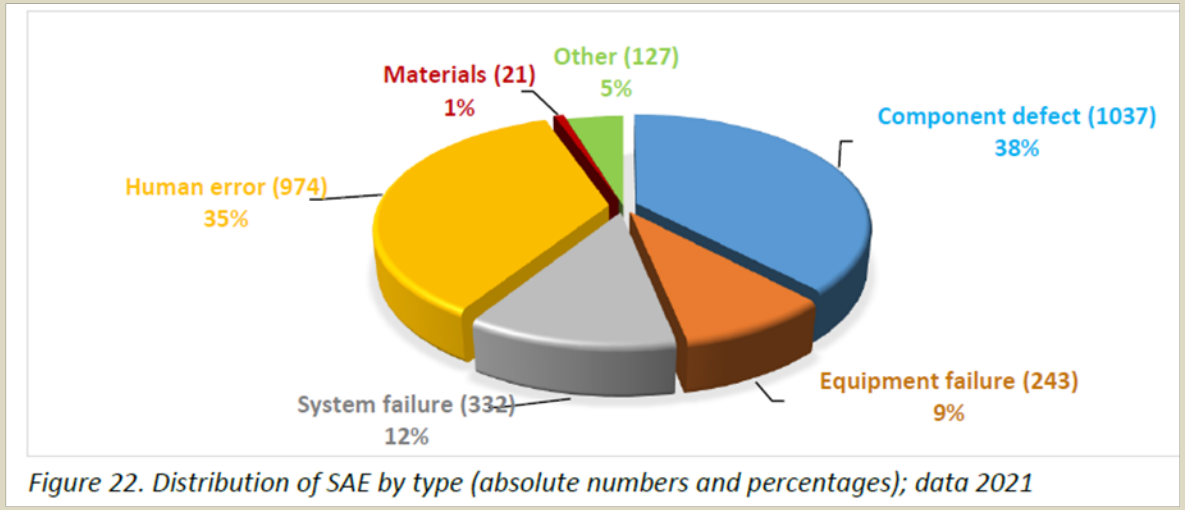


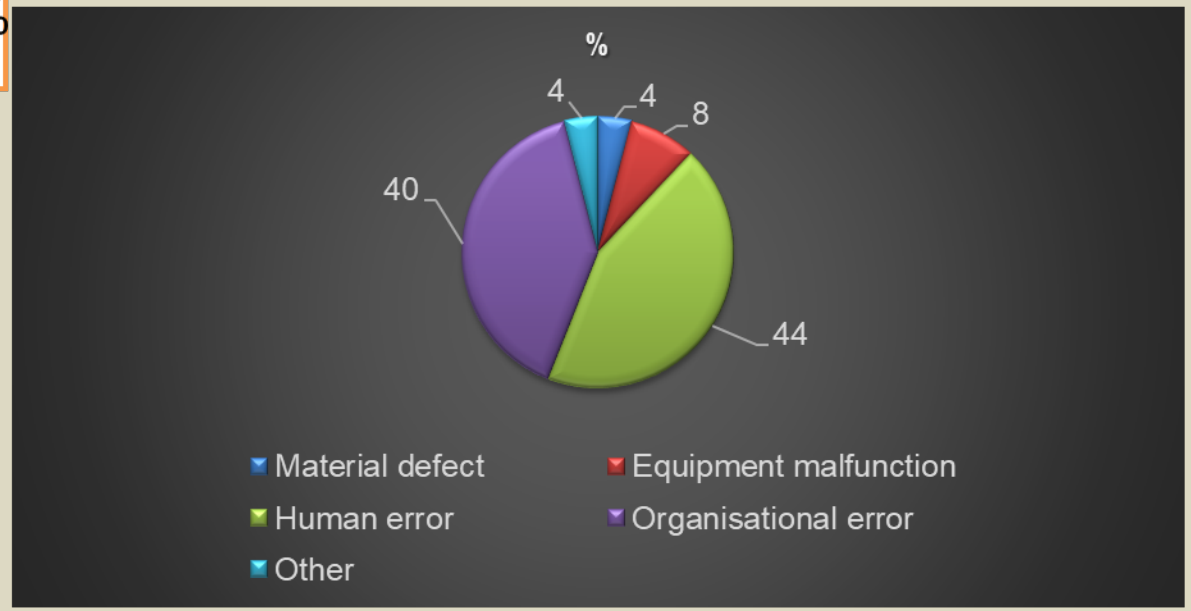
Figure 22. Distribution of SAE by type (absolute numbers and percentages); data 2021

Incidence per 100 000 units processed: **11.4**

0.9%

ITALY
SISTRA – Haemovigilance
2021 data

In 2021, **25 SAE** were notified



Incidence per 100 000 units processed: **0.3**

It is recommended to exercise caution when drawing conclusions from these data as 75% of SAE were reported by only 4 countries

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SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)

SAR in donor

EU Member States
SARE Exercise Blood/Blood Components
2020 data

In addition, **23 countries voluntarily** contributed to the reporting of SAR in blood donors. A total of **2946 SAR** were reported among **blood donors**,

	Adverse reactions/100,000 donation procedures
Whole blood	13.9
Apheresis	11.4
Total	13,4

11%

ITALY
SISTRA – EMOVIGILANZA
2021 data

Severity level: Severe

	Donation procedure	Adverse reactions	Adverse reactions/100,000 donation procedures
Whole blood	2566235	247	9,6
Apheresis	454908	96	21,1
Total	**3021143**	**343**	11,4

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SUMMARY OF THE 2022 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (2021 DATA)

EU Member States
SARE Exercise Blood/Blood Components

2020 data

- there is still a significant degree of **under-reporting, or even over-reporting, reflecting difficulties and inconsistency among countries in data collection and classification**

2021 data

- **gradual improvement** in the quality and accuracy of the data reported.
- there is still **a significant degree of inconsistency between countries in terms of data reporting rates, data completeness, classification and management of events**
- not all countries were able to provide complete data on all denominators, which affected the analysis and reliability of results. **Therefore, this report provides a partial insight into SARE related to blood/blood components, rather than a comprehensive view of the safety and quality of European transfusion services.**

In general, the major findings in this report indicate that European haemovigilance data are consistent with known effects and expected trends, with **no new safety concerns regarding blood and blood components identified from national vigilance and surveillance programmes**. However, it should be noted that, for the reasons mentioned above, **the results of analysis presented in this report should be interpreted with caution**.

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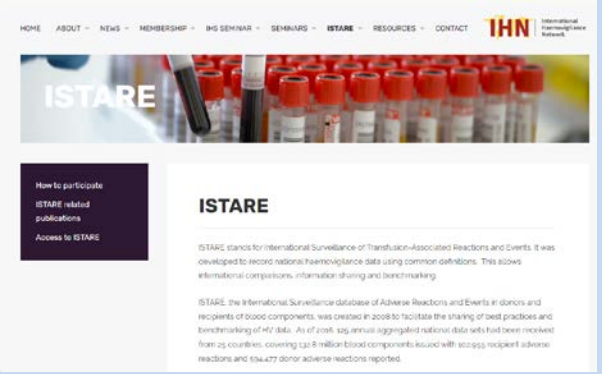

ISTARE

International Surveillance of Transfusion-Associated Reactions and Events

ISTARE was developed to record national haemovigilance data using common definitions. This allows international comparisons, information sharing and benchmarking.

As of 2016, 125 annual aggregated national data sets had been received from 25 countries, covering 132.8 million blood components issued with 102,955 recipient adverse reactions and 594,477 donor adverse reactions reported.

Despite the success of ISTARE, **the collected data have limitations which include inconsistent application of definitions and insufficient granularity of the (aggregate) data**. A 2019 membership survey endorsed and supported continuing collection of haemovigilance data by IHN. **Data collection into ISTARE was frozen** and a Task Force was convened to direct **redevelopment of an "ISTARE 2" database**.

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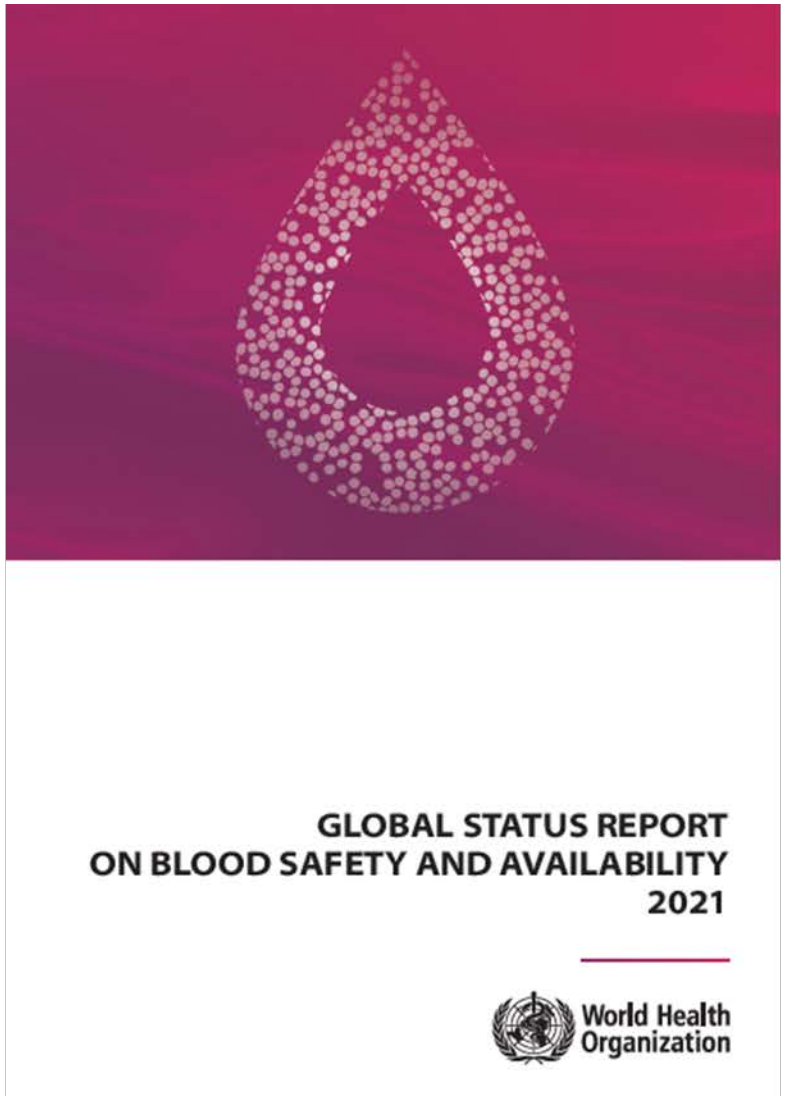
The **Global Database on Blood Safety (GDBS)** reports important data from many countries on a range of **indicators** covering the transfusion chain from donor to recipient, as a basis for more informed discussion on the **provision and governance of blood transfusion services**



An important component of a **blood safety system** is the establishment of **haemovigilance**, which is a set of **surveillance procedures** covering the entire transfusion chain. It includes efforts to **monitor and evaluate adverse events** associated with the blood supply and transfusion service, and **to use the findings to improve blood safety and transfusion outcomes.**

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GLOBAL STATUS REPORT ON BLOOD SAFETY AND AVAILABILITY 2021

Haemovigilance system

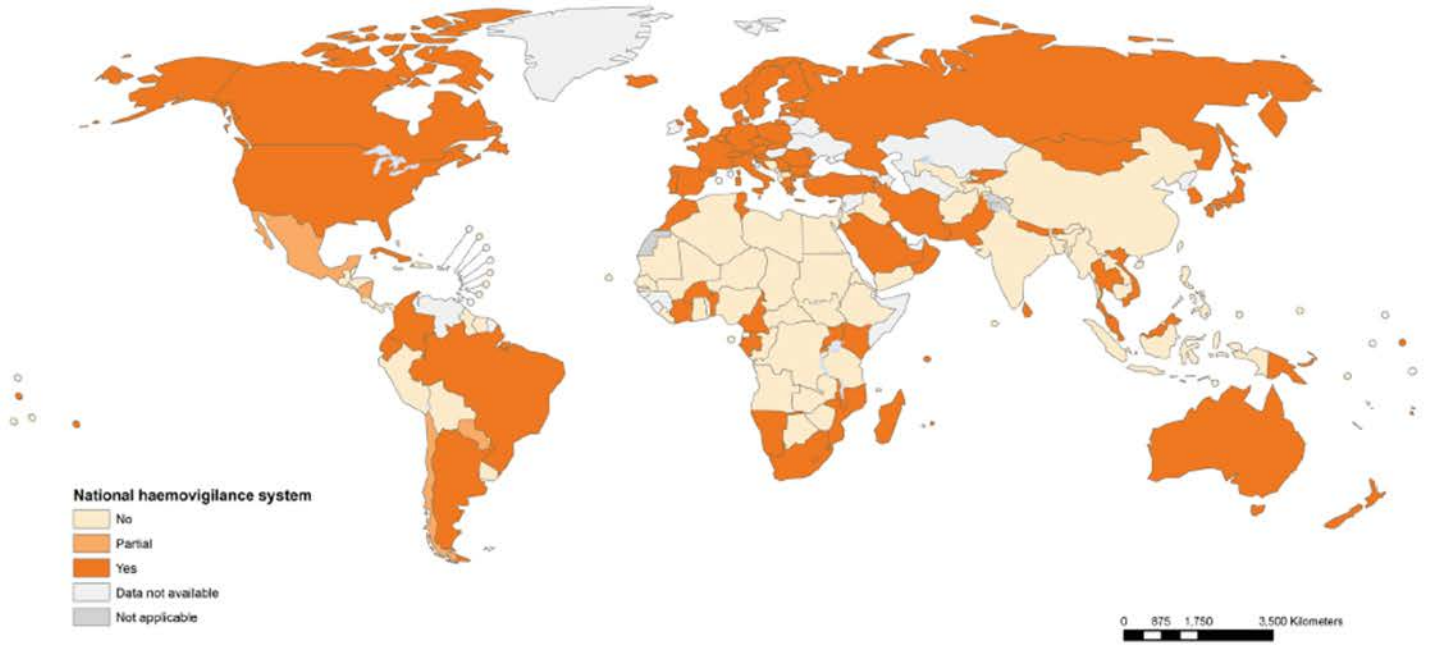
GLOBAL STATUS REPORT
ON BLOOD SAFETY AND AVAILABILITY
2021

World Health Organization

GDBS **2018** indicates that **49%** (84 of 171) countries reported having a national haemovigilance system.

Across WHO regions, Europe had the highest percentage, with 81% (34 of 42) of reporting countries having such a system.

Figure 19. Distribution of countries reporting the existence of national haemovigilance systems, 2018



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GLOBAL STATUS REPORT ON BLOOD SAFETY AND AVAILABILITY 2021

Adverse reactions in recipients

GLOBAL STATUS REPORT
ON BLOOD SAFETY AND AVAILABILITY
2021

World Health Organization

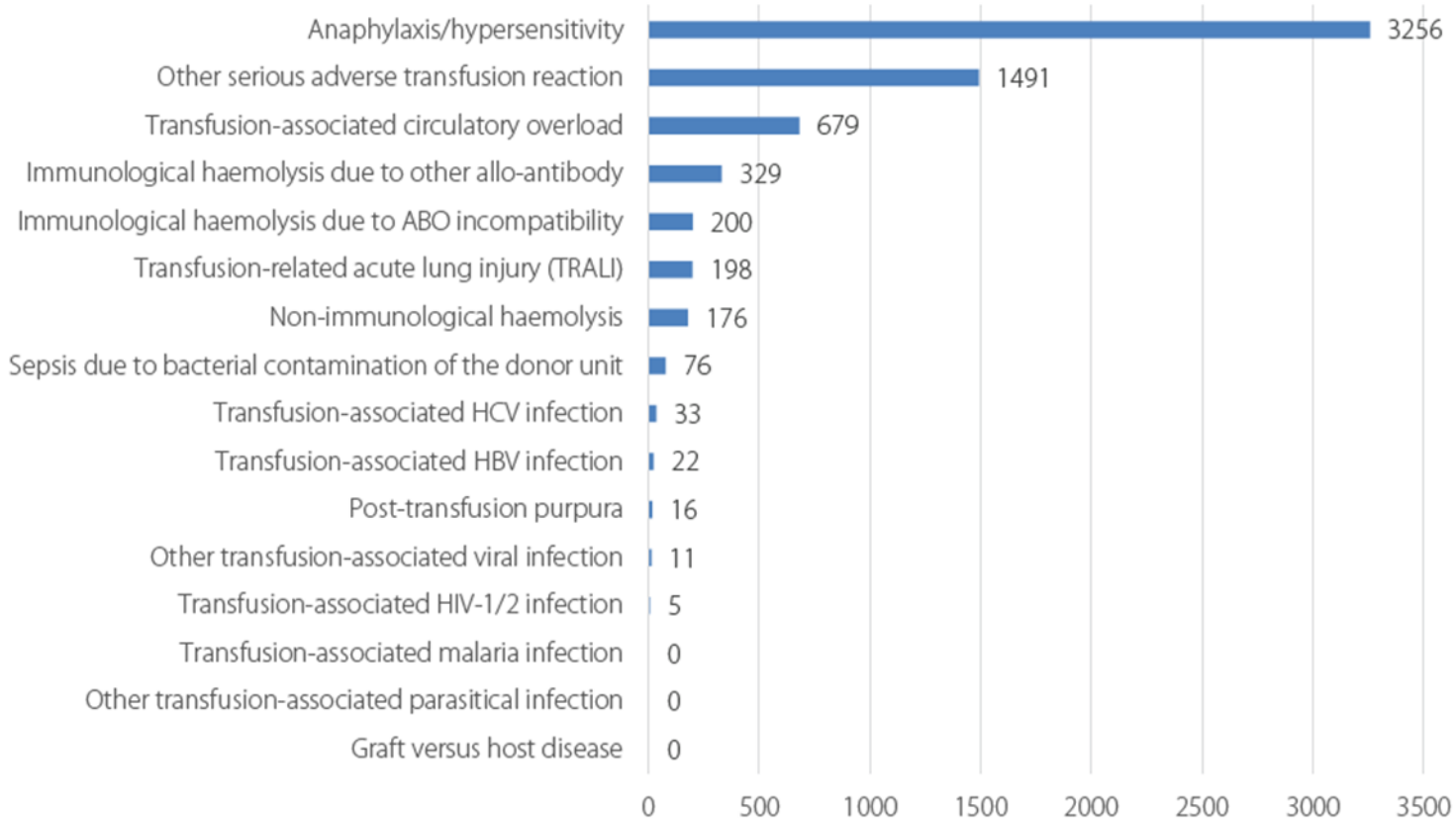
62 reporting countries

- Anaphylaxis and hypersensitivity (50%)
- Other serious adverse reaction (23%)
- Transfusion-associated circulatory overload (10%)

Category "**other**": many countries indicated that the main cases in this category were **febrile non-haemolytic transfusion reactions**.

Since cases of **febrile non-haemolytic transfusion reactions** are not always serious, the "other" category may represent **overreporting** of serious adverse reaction cases.

Figure 20. Serious adverse transfusion reactions reported



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GLOBAL STATUS REPORT ON BLOOD SAFETY AND AVAILABILITY 2021

Incidence

GLOBAL STATUS REPORT
ON BLOOD SAFETY AND AVAILABILITY
2021

World Health Organization

Table 31. Incidence of serious adverse reaction (per 100 000 units of components transfused) by WHO region

	Serious adverse reaction	Total number of components transfused/issued	Incidence
Africa (n=5)	214	1 457 280	14.7
Americas (n=7)	1 045	5 654 075	18.5
South-East Asia (n=3)	1 395	2 722 070	51.2
Europe (n=31)	2 634	27 238 559	9.7
Eastern Mediterranean (n=4)	409	4 070 358	10.0
Western Pacific (n=12)	795	11 892 266	6.7
Total (n=62)	6492	53 034 608	12.2

The European Region reported both the largest number of case and denominator.

Some of the reported adverse transfusion reactions might include both serious and non-serious transfusion reactions, accounting for higher serious adverse reaction rates in some countries. It may also be possible that not all countries followed the internationally recognized definitions promoted by WHO.

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Review Article

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Haemovigilance: current practices and future developments

Layla L. de Jonge[1], Johanna C. Wiersum-Osselton[1,2], Arlinke G. Bokhorst[1,2], Martin R. Schipperus[1,3], Jaap Jan Zwaginga[1,4]

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Contributions: (I) Conception and design: All authors; (II) Administrative support: LL de Jonge; (III) Provision of study materials or patients: AG Bokhorst, LL de Jonge, JC Wiersum-Osselton; (IV) Collection and assembly of data: AG Bokhorst, LL de Jonge, JC Wiersum-Osselton; (V) Data analysis and interpretation: AG Bokhorst, LL de Jonge, JC Wiersum-Osselton; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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HAEMOVIGILANCE: CURRENT PRACTICES AND FUTURE DEVELOPMENTS

Layla L. de Jonge[1], Johanna C. Wiersum-Osselton[1,2], Arlinke G. Bokhorst[1,2], Martin R. Schipperus[1,3], Jaap Jan Zwaginga[1,4]

Annals of Blood 2022 - doi: 10.21037/aob-22-2

Haemovigilance programs, including well-established systems, are challenged by **underreporting** of adverse reactions and incidents. Symptoms of transfusion reactions are often non-specific and delayed symptoms of adverse events in intrinsically sick patients may be difficult to recognize. **Underreporting decreases the accuracy of the data and leads to underestimation of the true incidence of transfusion reactions.**

It is well recognized that **active reporting**, characterized by the evaluation of the response to a transfusion regardless of the outcome, **leads to increased reporting rates.** In a large retrospective study in tertiary care hospitals discrepancies were found in the number of cardiopulmonary reactions identified through the active surveillance in the study versus the number of reactions reported to the transfusion medicine service. Most haemovigilance systems however, rely on passive reporting. Incorporating elements of active surveillance in passive systems, for example through the application of **wearable devices (75), may improve reporting.**

(75) wearable electronic biosensors during and post treatment may improve the safety of these treatments and make remote data collection in an outpatient care setting possible.

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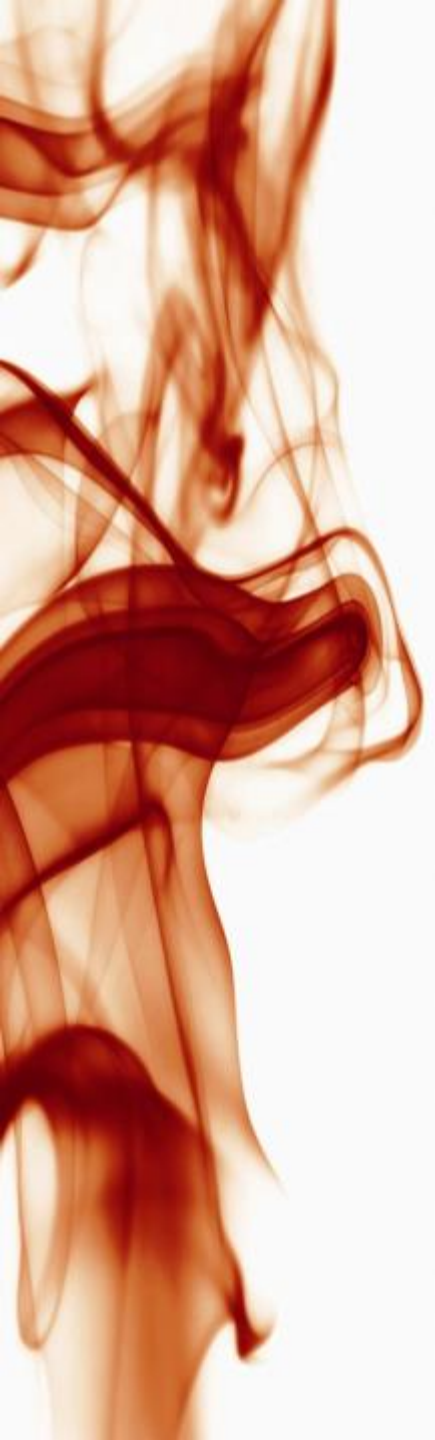

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Grazie per l'attenzione!