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Italian Blood System 2023: activity data, haemovigilance and epidemiological surveillance

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EPIDEMIOLOGIA
E SANITÀ PUBBLICA

ISTITUTO SUPERIORE DI SANITÀ

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2024, iii, 88 p. Rapporti ISTISAN 24/26

Since 2009 the collection of data regarding the activities of the Italian Blood System has been carried out through the Italian national blood information system (*Sistema Informativo dei Servizi TRAsfusionali,* SISTRA). The data collected at national level are reported to international health authorities. The data in this report are relevant to the year 2023.

Key words: Blood, Red cells; Plasma; Platelets; Blood donation; Blood donors; Self-sufficiency; Transfusion; Haemovigilance; Transfusion transmissible infections; Incidence; Prevalence; Risk factors

Istituto Superiore di Sanità
Sistema trasfusionale italiano 2023: dati di attività, emovigilanza e sorveglianza epidemiologica.
Liviana Catalano, Vanessa Piccinini, Ilaria Pati, Francesca Masiello, Simonetta Pupella, Vincenzo De Angelis
2024, iii, 88 p. Rapporti ISTISAN 24/26 (in English)

La rilevazione dei dati di attività del sistema trasfusionale italiano avviene, dal 2009, mediante il Sistema Informativo dei Servizi TRAsfusionali (SISTRA). I dati raccolti su base nazionale rispondono anche al debito informativo internazionale. Nel presente rapporto sono forniti i dati di attività del sistema trasfusionale italiano per l'anno 2023.

Parole chiave: Sangue; Globuli rossi; Plasma; Piastrine; Donazioni di sangue; Donatori; Autosufficienza; Trasfusione; Reazioni avverse; Emovigilanza; Infezioni trasmissibili; Incidenza; Prevalenza; Fattori di rischio

Si ringraziano i Direttori dei Centri Regionali di Coordinamento Sangue e i Responsabili dell'Emovigilanza per la preziosa collaborazione, e la Dott.ssa Livia Cannata per il supporto nella revisione linguistica.

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ACRONYMS

AP	Autonomous Province
AR	Adverse Reaction
AVIS	*Associazione Volontari Italiani del Sangue* (Association of Voluntary Italian Blood Donors)
BCS	Blood Collection Site
BE	Blood Establishment
BSS	Blood System Service
CIVIS	*Comitato Interassociativo del Volontariato Italiano del Sangue* (Inter-associative Committee of Voluntary Italian Blood Donors Associations/Federations)
CMV	Cytomegalovirus
CNS	*Centro Nazionale Sangue* (Italian National Blood Centre)
CT	Computed Tomography
ECG	ElectroCardioGram
FT	First-time tested (donor)
FTE	Full-Time Equivalent
FIDAS	*Federazione Italiana Associazioni Donatori di Sangue* (Italian Federation of Voluntary Blood Donors Associations)
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
GDBS	Global Database on Blood Safety
HAV	Hepatitis A virus
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HLA	Human leukocyte antigen
HSC	Haematopoietic stem cells
IRC	Italian Red Cross
ISTAT	*Istituto Nazionale di Statistica* (National Institute of Statistics)
NAT	Nucleic Acid Amplification Technology
NSIS	*Nuovo Sistema Informativo Sanitario* (New Health Information System)
PDMP	Plasma-Derived Medicinal Product
PTP	Post Transfusion Purpura
RBCC	Regional Blood Coordinating Centre
RT	Repeat tested (donor)
SAE	Serious Adverse Event
SISTRA	*Sistema Informativo dei Servizi TRAsfusionali* (National Blood Information System)
TACO	Transfusion Associated Circulatory Overload
TAD	Transfusion Associated Dyspnoea
TP	*Treponema pallidum*
TRALI	Transfusion-Related Acute Lung Injury
WHO	World Health Organization
XML	Extensible Markup Language

INTRODUCTION

The Italian National Blood Centre (*Centro Nazionale Sangue*, CNS) coordinates the National Blood Information System (*Sistema Informativo dei Servizi TRAsfusionali,* SISTRA), which was established by specific Ministerial Decree (1) and operates in the Ministry of Health's New Health Information System (NSIS). SISTRA collects data related to the activities of the Italian Blood System and ensures that, after their validation by the Regional Blood Coordinating Centres (RBCCs), the information from the Blood Establishments (BEs) is sent to the CNS for a final verification before being published.

The above-mentioned data are crucial to evaluate the capacity of the Italian National Healthcare System to respond to the needs of patients in different clinical settings and they are an indispensable tool for the strategic planning and coordination of the blood system.

For the purpose of this report, the blood activity and haemovigilance SISTRA's macro areas were taken into account. The first section supports planning at regional and national level to achieve self-sufficiency in blood components and plasma-derived medicinal products (PDMPs); the second section includes four modules based on the following notifications: adverse reactions in recipients, adverse reactions in donors, serious adverse events, and epidemiological surveillance of donors.

In this report, the data are relevant to the year 2023.

SISTRA is compliant with both technical regulations and security policies of the Public Connectivity System (PCS) (2-4). All information is encoded according to product standards established by the UNI (*Ente Italiano di Normazione*, the Italian organization for standardization) 10529 (5), which enables the unequivocal identification and traceability of every unit of blood and blood components collected, produced, and transfused. Information can be sent to SISTRA through the regional blood transfusion information systems – by exchanging XML files (eXtensible Markup Language) – or directly through the Blood System Services (BSSs), if an IT system of Regions/Autonomous Provinces (APs) does not exist or if the Regions/APs have authorised the BEs to entry the data directly into SISTRA.

ACTIVITIES OF THE ITALIAN BLOOD SYSTEM

Introduction

Through the descriptive data of BEs and Blood Collection Sites (BCSs) and their respective peripheral organizational sites, SISTRA gives a timely picture of the national transfusion network, which is in constant evolution due to the continuous redistribution of the production activities and rationalisation of resources.

This section of the report shows 2023 national data on blood donors and blood components collection, production, and use, including plasma intended for the manufacturing of PDMPs, against the data of the previous year (6).

In order to facilitate the network's benchmarking, the Appendix A reports the quantitative activity indicators at both Regional/APs and national level.

Methods

For the analysis related to this section of the report, only quantitative indicators were used. The data regarding transfused patients were analysed according to the blood components administered.

The above-mentioned indicators are presented in graphs and according to the geographic classification specified by the UNI 10529 standard (5).

The data processing was carried out with the utilisation of "SAP Business Objects", which is the business intelligence system made available by the Ministry of Health on the NSIS. The reference population for the calculation of the relative indicators is that provided by the Italian National Institute of Statistics (*Istituto Nazionale di Statistica*, ISTAT) as of 1st January, 2023, available at https://demo.istat.it/ (last accessed September 2023).

The data supplied by the Italian Regions/APs were mainly from single BEs. In some cases, the data, from two or more BEs, were incorporated in a single figure as specified below:

- Veneto Region that supplied 7 figures from 21 operating BEs;
- Friuli Venezia Giulia Region that supplied 1 figure from 5 operating BEs;
- Latium Region that supplied 22 figures from 23 operating BEs;
- Sicily Region that supplied 24 figures from 33 operating BEs.

National data

In 2023, 248 blood transfusion activity records, which include data from 276 BEs, were validated by the RBCCs on SISTRA. Compared to 2022, two BEs peripheral organisational sites were closed (Table 1).

Male donors are more prevalent in the 36-55 age group (Figure 1), while female donors are more prevalent in the younger 18-35 age group (Figure 2).

Table 1. BEs and BCSs and their respective peripheral organisational sites (2022-2023)

Blood facilities and population	2022	2023	Δ%
BEs	276	276	0.00
BEs peripheral organisational sites	827	829	0.24
BCSs	186	186	0.00
BCSs peripheral organisational sites	1,290	1,290	0.00
Population	58,983,122	58,850,717	-0.22

BEs Blood Establishments, BCSs Blood Collection Sites (in Italy all BCSs are run by Voluntary Blood Donor Associations and Federations).

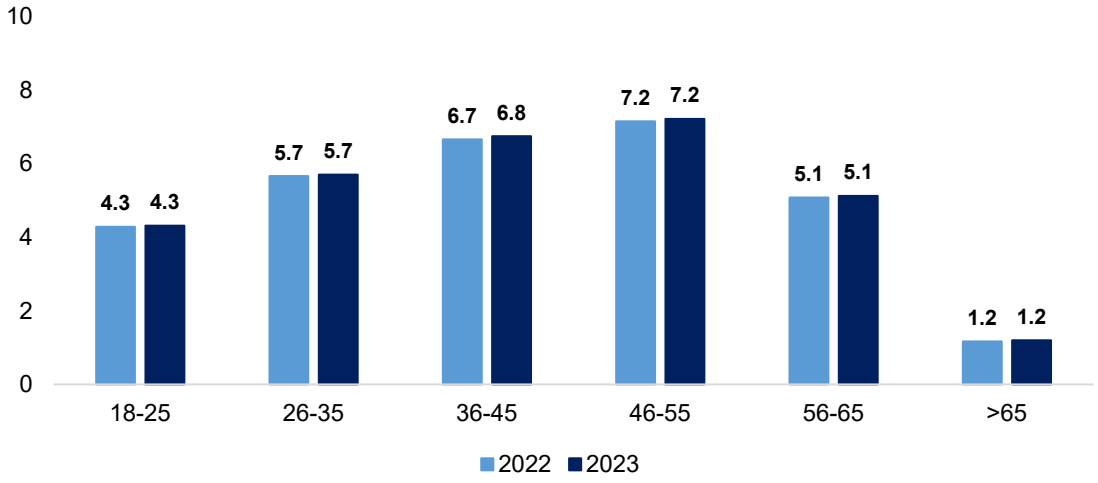

Figure 1. Percentage of male donors out of the resident population eligible for donation (2023)

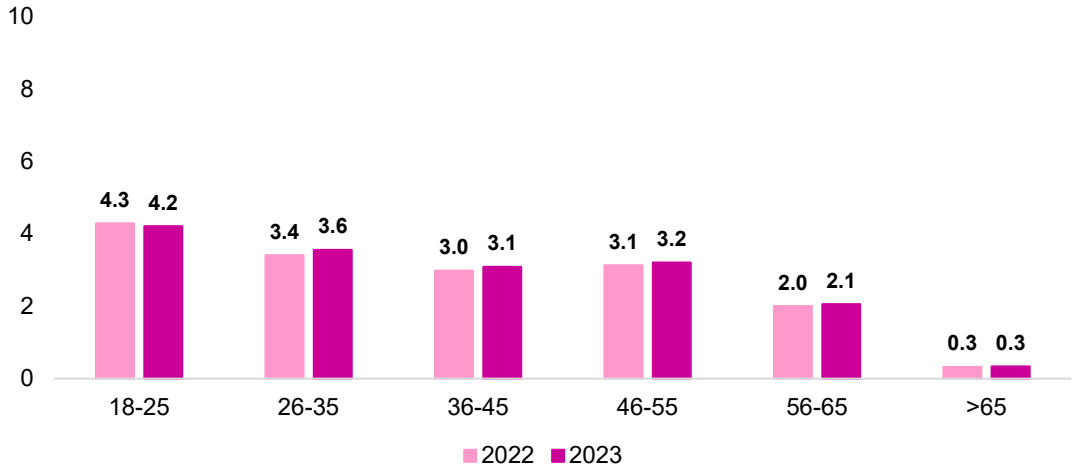

Figure 2. Percentage of female donors out of the resident population eligible for donation (2023)

Table 2 shows data concerning donors of blood and blood components per type of donation. Compared to 2022, there was an increase of 1.57% in the total number of first-time donors and of 7.32% in the total number of those who re-donated in the period under examination. Apheresis donors increased (9.19%), as well as the total (1.25%) and regular donors (1.49%).

Table 2. Donors of blood and blood components (2022-2023)

Donors	2022	2023	Δ%
First-time	**354,750**	**360,303**	1.57
Those who re-donated in the period under examination	*73,929*	*79,339*	*7.32*
Regular	**1,376,212**	**1,396,734**	1.49
Those who re-donated at least once a year in the last 5 years	*605,861*	*616,995*	*1.84*
Total	**1,657,033**	**1,677,698**	1.25
Apheresis	201,601	220,941	9.19
Those who donated only in apheresis	*106,781*	*113,211*	*6.02*
Permanently deferred	45,172	45,812	1.42
Members of VBDAs	**1,510,602**	**1,537,237**	1.76

VBDAs: Voluntary Blood Donors Associations/Federations.

Table 3 shows the total number of collection procedures (carried out by both BEs and BCSs) per type.

Table 3. Collection procedures (2022-2023)

Collection procedures	2022	2023	Δ%
Whole blood	**2,555,886**	**2,563,717**	0.32
Apheresis	**426,738**	**455,754**	6.86
Monocomponent apheresis	*372,209*	*401,798*	*7.9*
Multicomponent apheresis	*54,529*	*53,956*	*-1.05*
Total	**2,982,624**	**3,019,471**	1.25
Type			
Plasmapheresis	362,694	393,974	8.69
Plateletpheresis	7,632	5,349	-29.91
Stem Cells apheresis	1,487	1,894	27.37
Granulocytapheresis	54	115	112.96
Lymphocytapheresis	342	466	36.26
Red Blood Cell/Platelet apheresis	3,239	2,219	-31.49
Double Red Blood Cell unit apheresis	174	205	17.82
Plasma/Platelet apheresis	42,137	44,606	5.86
Red Blood Cell/Plasma apheresis	8,313	5,062	-29.76
Double Platelet unit apheresis	1,192	1,308	12.86
Red Blood Cell/Platelet/Plasma apheresis	814	556	-9.30

Table 4 shows the number of collections carried out by BCSs (total and by Association/Federation); 95% were carried out by the four Associations/Federations that form the national Inter-associative Committee of Voluntary Italian Blood Donors Associations/Federations (CIVIS).

Table 4. Number of collections carried out by blood collection sites (2022-2023)

Association/Federation	2022	2023	Δ%
AVIS	886,358	864,415	-2.48
FIDAS	101,020	102,838	1.80
FRATRES	20,188	18,831	-6.72
CRI	12,618	13,897	10.14
Other	62,103	66,060	6.37
Total	**1,082,287**	**1,066,041**	**-1.50**

AVIS Association of Voluntary Italian Blood Donors; FIDAS Italian Federation of Voluntary Blood Donors Associations; FRATRES National Consociation of Blood Donors Groups of "Misericordie d'Italia"; CRI Italian Red Cross.

Table 5 shows the production of blood components. Compared to 2022, there was an increase (1.50%) in the total number of units of blood components produced.

Table 5. Blood component production (2022-2023)

Blood component	2022	2023	Δ%
Red Blood Cells	**2,485,068**	**2,506,415**	0.86
Red Blood Cells from whole blood	*2,473,806*	*2,498,237*	0.99
Red Blood Cells by apheresis	*11,262*	*8,178*	-27.38
Platelets from single donors	13,673	7,058	-48.38
Platelet pools	228,881	236,348	3.26
Platelets by apheresis	55,912	57,728	3.25
Plasma	**2,905,083**	**2,966,653**	2.12
Recovered Plasma	*2,471,627*	*2,498,147*	1.07
Source Plasma	*382,363*	*417.276*	9.13
Source Plasma from multiple apheresis	*51,093*	*51,230*	0.27
Total	**5,688,617**	**5,774,202**	**1.50**

In 2023, 7,774 units of blood components were transfused per day. Compared to the previous year, there was a slight decrease (-0.10%) (Table 6).

Table 6. Transfused units of blood components (2022-2023)

Blood component	2022	2023	Δ%
Red Blood Cells	**2,393,798**	**2,392,289**	-0.06
Red Blood Cells from whole blood	*2,383,058*	*2,384,659*	-0.07
Red Blood Cells by apheresis	*10,740*	*7,630*	-28.96
Platelets from single donors	934	113	-87.90
Platelets Pools	193,041	201,316	4.29
Platelets by apheresis	47,305	47,292	-0.13
Plasma	**205,552**	**196,795**	-4.26
Recovered Plasma	*68,893*	*67,762*	-1.64
Source Plasma	*24,141*	*23,615*	-2.18
Source Plasma from multiple apheresis	*4,873*	*3,900*	-19.97
Plasma pooled and treated for virus inactivation	*107,645*	*101,518*	-5.69
Total	**2,840,630**	**2,837,805**	-0.10

Moreover, compared to 2022, there was:

a) an overall increase in the total number of units of blood components and plasma units discarded (Table 7);
b) an increase in the quantity of plasma for fractionation (Table 8);
c) an increase in the production and use of allogeneic fibrin glue and an increase of allogeneic platelets gel not intended for transfusion (Table 9);
d) an increase in the production and use of autologous fibrin glue and a decrease of platelet gel not intended for transfusion (Table 10);
e) an increase in the number of patients who pre-deposited blood components for autologous transfusion (Table 11);
f) a slight decrease in the number of transfused patients, including those transfused in BEs (day hospital) (Table 12).

Table 7. Blood components discarded for reasons linked to health, technical issues, quality control and expiry dates (2022-2023)

Blood component	2022	2023	Δ%
Red Blood Cells	**68,189**	**91,235**	33.82
Platelets from single donors	10,934	4,948	-54.75
Platelet Pools	32,684	32,720	0.11
Platelets by apheresis	5,932	7,159	20.68
Plasma	**124,453**	**124,449**	0.00
Recovered Plasma	*105,591*	*105,532*	-0.06
Source Plasma	*15,981*	*16,329*	2.18
Source Plasma from multiple apheresis	*2,881*	*2,588*	-10.17
Total	**242,192**	**260,511**	7.56

Table 8. Plasma for fractionation (2022-2023)

Blood component	2022	2023	Δ%
Plasma for fractionation (kg)	844,263	880,193	4.26

Data source: Pharmaceutical industry - year 2022 data updated to December 2023.

Table 9. Production and use of allogeneic blood components for non-transfusion use (2022-2023)

Blood component	2022	2023	Δ%
Platelet Gel			
Produced	28,238	30,366	7.54
- Used	*21,148*	*18,892*	-10.67
- Not used	*7,090*	*11,474*	61.83
Fibrin Glue			
Produced	91	162	78.02
- Used	*85*	*154*	81.18
- Not used	*6*	*8*	33.33

Table 10. Production and use of autologous blood components for non-transfusion use (2022-2023)

Blood component	2022	2023	Δ%
Platelet Gel			
Produced	*14,036*	7,824	-44.26
- Used	*13,090*	*7,812*	-40.32
- Not used	*946*	*12*	-98.73
Fibrin Glue			
Produced	476	689	44.75
- Used	*471*	*677*	43.74
- Not used	*5*	*12*	140

Table 11. Autologous donation and transfusion (2022-2023)

Patients and autologous donation activities	2022	2023	Δ%
Patients who pre-deposited blood components for autologous transfusion	13,622	14,815	8.76
Patients who underwent an autologous transfusion	11,178	12,570	12.5

Table 12. Transfused patients (2022-2023)

Patients* transfused with:	2022	2023	Δ%
Whole Blood^	32	23	-28.13
Red Blood Cells	604,761	603,125	-0.27
Plasma	46,426	43,415	-6.49
Platelets	54,512	55,431	1.69
Other	5,472	5,445	-0.49
Total**	**639,003**	**638,046**	-0.15

* Patients transfused once or more than once during the year under examination were counted only once.

** Patients transfused more than once during the year under examination with blood components of the same type were counted only once; patients transfused with more than one type of blood component were included in the count of each type.

^ Includes reconstituted whole blood.

Indicators

The five classes of quantitative indicators identified for the 2023 year are:
A. Donors,
B. Donations,
C. Produced blood components,
D. Discarded blood components,
E. Transfused blood components.

There are 36 indicators presented at national level (Table 13, next page) and regional level (Appendix A).

Table 13. Quantitative indicators for transfusion activities in Italy (2023)

Indicators		Index
A. Donors		
A1	N. of donors/1,000 RP	28.51
A2	M/F ratio: female donors (%)	33.79
A3	N. of donors/1,000 RP in the 18-65 age class	46.13
A4	N. of donors in the 18-65 age class/1,000 RP	3.40
A5	N. of donors in the 18-25 age class /1,000 RP in the 18-65 age class	5.51
A6	N. of donors/1,000 RP	23.73
A7	N. of first-time donors/1,000 RP	6.12
A8	N. of "regular" donors/1,000 RP	10.48
B. Donations		
B1	N. of donations (WB + apheresis)/1,000 RP	51.31
B2	N. of donations (WB + apheresis)/Total N. of donors (excluding prospective donors)	1.80
B3	N. of donations WB/1,000 RP	43.56
B4	N. of donations WB/N. of WB donors	1.64
B5	N. of donations in apheresis/1,000 RP	7.74
B6	N. of donations in apheresis/N. of apheresis donors	2.06
C. Production of blood components		
C1	N. of RBC units produced/1,000 RP	42.59
C2	N. of plasma units produced from WB and by apheresis/1,000 RP	50.41
C3	N. of plasma units produced from WB/1,000 RP	42.45
C4	N. of plasma units produced by apheresis (monocomponent or multicomponent)/1,000 RP	7.96
C5	Plasma for fractionation (kg)/1,000 RP	14.83
C6	Plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%)	30.06
C7	N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 RP	0.98
C8	N. of platelet units produced from buffy-coat pools/1,000 RP	4.02
C9	N. of "adult platelet doses"/1,000 RP	5.02
D. Discarded blood components		
D1	N. of discarded RBC units/N. of "usable" RBC units (produced + acquired - released) (%)	3.64
D2	N. of expired RBC units discarded/N. of discarded RBC units (%)	38.51
D3	N. of RBC units discarded for technical reasons/N. of discarded RBC units (%)	26.72
D4	N. of RBC units discarded for health reasons/N. of discarded RBC units (%)	29.66
D5	N. of RBC units discarded for reasons linked to QC/ N. of discarded RBC units (%)	5.12
D6	N. of platelet units by apheresis discarded /N. of platelet units by apheresis produced (%)	12.40
D7	N. of platelet units from buffy-coat pools discarded /N. of platelet units from buffy-coat pools produced (%)	13.84
E. Transfused blood components		
E1	N. of transfused RBC units/1,000 RP	40.65
E2	N. of transfused plasma units (from WB + by apheresis + PIP)/1,000 RP	3.34
E3	N. of transfused WB plasma units/Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	34.43
E4	N. of transfused apheresis plasma units/N. of transfused plasma units (from WB + by apheresis + PIP) (%)	13.99
E5	N. of transfused PIP units/Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	51.58
E6	N. of "adult platelet doses"/1,000 RP	4.23

WB: whole blood; **RP**: resident population; **IP:** Plasma pooled and treated for virus inactivation: **QC:** quality control.

* "Adult platelet dose" ≥ $2x10^{11}$ platelets. The "adult platelet dose" from single units of whole blood (plasma rich platelets, single buffy-coat, buffy-coat pools) is conventionally composed of 5 units. Each unit of apheresis platelets is equal to an "adult platelet dose". Each double platelet from apheresis is equal to 2 "adult platelet doses". All platelet units produced are expressed as "adult platelet dose".

Conclusions

Compared to 2022, the number of total donors increased in 2023 due to the increase of the number of new donors.

Data showed a slight increased (1.25%) in the overall collection of blood components: in particular, monocomponent apheresis procedures increased (7.9%), on the contrary multicomponent apheresis procedures decreased (-1.05%).

In 2023, there is a decrease in the number of units of blood components transfused (-0.10%) compared to 2022. The decrease of the use of RBCs shows that the Patient Blood Management strategies and techniques, first specified in the Italian national blood and blood products self-sufficiency plans dating back to 2012 (see the latest Italian self-sufficiency plan 2023 (7)), have been applied quite uniformly nationwide.

In 2023, there was an overall increase in the production of allogeneic platelet gel and in the production of allogeneic fibrin glue.

HAEMOVIGILANCE IN ITALY

Haemovigilance is a set of surveillance procedures covering the monitoring, reporting, investigation and analysis of the Adverse Reactions (ARs) in recipients and donors, Serious Adverse Events (SAE), including the surveillance of events caused by a medical device failure in the transfusion process, as well as the epidemiological surveillance of donors (8).

Haemovigilance systems are regulated by specific national laws and by European Directives (9, 10), transposed into national laws (11, 12), which state the procedures that must be adopted for the reporting of ARs in recipients during or after transfusion, including the reporting of every case of transfusion transmitted infection.

Haemovigilance also includes ARs in donors defined as any unintended response in donors associated with the collection of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity. The aim of SISTRA is to promote the standardisation and comparability of data at national level through the simplification of their aggregation and processing to produce national reports.

In Italy, BEs are responsible for the collection of haemovigilance data; BEs register and report adverse events occurring in their organisation and must collect data from the related clinical facilities and BCSs. By means of pre-defined forms, the RBCCs are responsible for communicating to the National Competent Authority annual reports concerning ARs in recipients and in donors and adverse events occurred in related BEs. The same flow of information is in place also for the epidemiological surveillance of donors (Figure 3).

In each organisation (BEs, RBCCs and the CNS) there is a responsible person for haemovigilance.

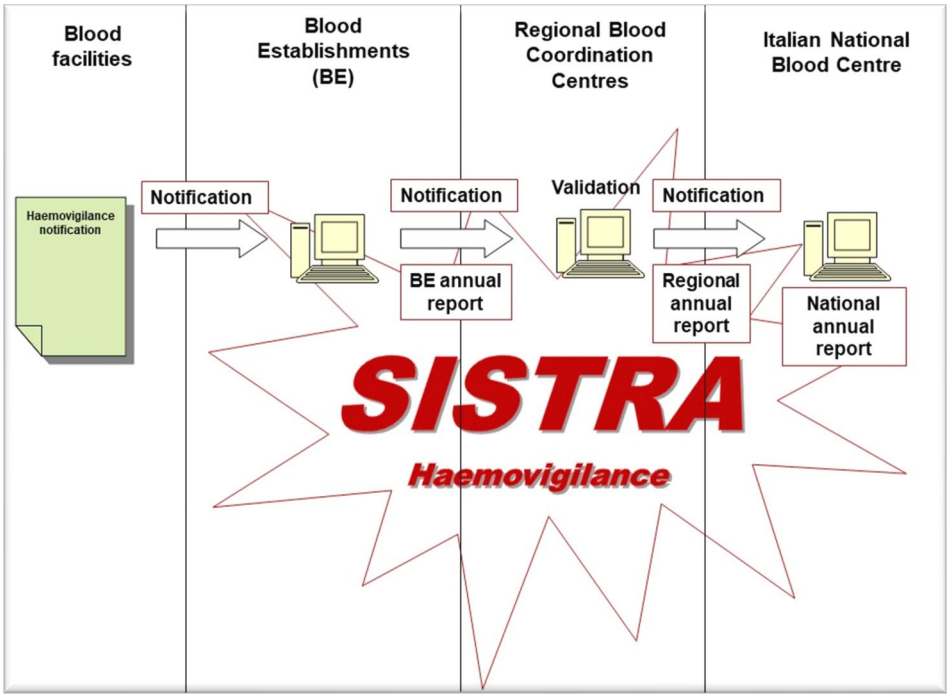

Figure 3. Haemovigilance information flow in SISTRA

The specific section of SISTRA dedicated to the haemovigilance includes:
– ARs in recipients;
– ARs in donors;
– SAEs;
– near miss events;
– epidemiological surveillance of donors.

Adverse reactions in recipients and in donors and serious adverse events

Definitions

For the purpose of this report, also in compliance with the Ministry of Health Decree of 2nd November, 2015 (8), donors are classified in:

– *First time donor*
  People who have never donated either blood or plasma. They can be:
  - first-time pre-qualified donors (newly-registered donors who are screened during their first (pre-donation) visit and who donate during their second visit);
  - first-time not pre-qualified donors (newly-registered donors who are screened and donate during their first visit).
– *Regular donor*
  People who routinely donate blood/plasma (i.e., within the last 2 years) in the same BCS/BE (Blood Collection Site/Blood Establishment).

The levels of severity and imputability of adverse reactions in recipients, adopted in accordance with the European Directives and reported in the Legislative Decree n. 207/2007 (12), are classified as follows:

– *Severity level*
  Level 0 - No symptoms.
  Level 1 - Mild symptoms (no therapeutic intervention).
  Level 2 - Symptoms requiring therapeutic intervention.
  Level 3 - Severe symptoms requiring resuscitation procedures.
  Level 4 - Death.
– *Imputability level*

NA *Non-Assessable*	→	when there are insufficient data to evaluate the imputability.
Level 0 *Excluded/unlikely*	→	when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to alternative causes.
Level 1 *Possible*	→	when the evidence is not such as to allow the attribution of the adverse event either to the blood/blood component or to alternative causes.
Level 2 *Probable*	→	when the available evidence is clearly in favour of attributing the adverse event to the blood or blood component.
Level 3 *Certain*	→	when there is conclusive evidence beyond reasonable doubt that the adverse reaction can be attributed to the blood or blood component.

General data

In 2023, the notified adverse events concerned 2,862,208 units of blood components transfused, 3,019,471 procedures of blood donation and 3,037,008 issued units. The notification to the haemovigilance system consists of the number of notifications of the ARs in recipients per 100,000 transfused units, the number of notifications of the ARs in donors per 100,000 collection procedures and the number of notifications of the SAEs per 100,000 issued units.

In 2023, 1,880 ARs in recipients (65.7 per 100,000 transfused units) and 8,791 ARs in blood donors (291.1 per 100,000 collection procedures) were reported. The notified SAEs were 28 (0.92 per 100,000 issued units).

As shown in Figure 4, the notification system improved over the years, recording a significant increase in ARs in both donors and recipients, from 2009 to 2016. Since 2016, the number of notifications has been almost constant. SAE notifications do not show significant variations over the years.

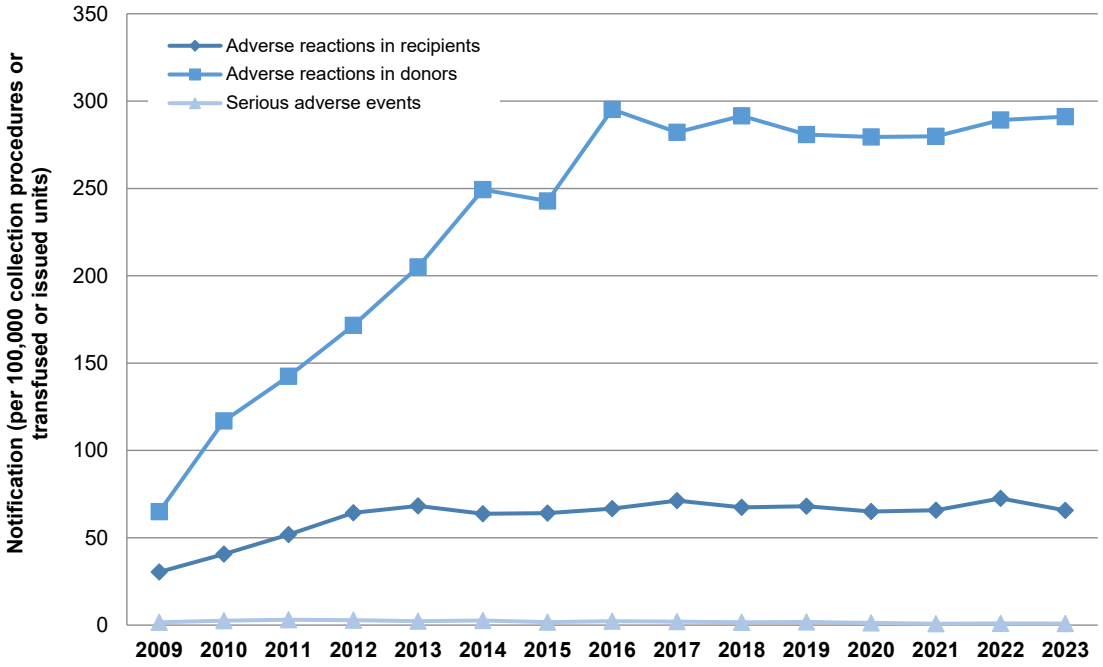

Figure 4. Number of haemovigilance notifications (per 100,000), per year (2009-2023)

Adverse reactions in recipients

From January 1st to December 31st 2023, 1,880 ARs were notified in blood components recipients. The ARs related to the transfusion of autologous blood units were excluded from the analysis.

As in the previous year (7), the notifications show a significant regional variability with a national average of 65.7 per 100,000 transfused units. Friuli Venezia Giulia (149.5 per 100,000 transfused units) and Piedmont (148.2 per 100,000 transfused units) recorded the highest values (Figure 5).

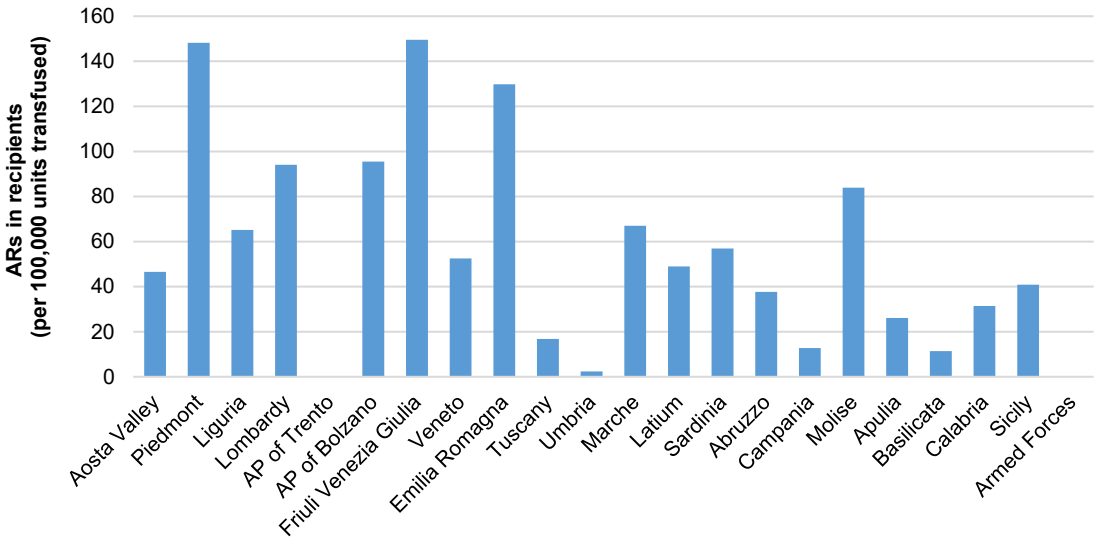

Figure 5. Adverse reactions in recipients by Region, per 100,000 units transfused (2023)

Table 14 reports all ARs notified in blood transfusion recipients in 2023. The most frequently notified reactions were febrile non-haemolytic reactions (FNHTR) (28.96 per 100,000 transfused units) and allergic reactions with only mucosal and cutaneous symptoms (17.92 per 100,000 transfused units): these reactions represent 71.4% of all ARs notified in recipients.

Table 14. Adverse reactions in recipients (2023)

ARs	n.	%	ARs/100,000 transfused units
Acute haemolytic reaction - ABO incompatible	5	0.3	0.17
Acute haemolytic reaction - other blood groups	3	0.2	0.10
Allergic manifestations - only mucosal and cutaneous symptoms	513	27.3	17.92
Allergic reactions - respiratory and/or cardiovascular system	109	5.8	3.81
Alloimmunisation	2	0.1	0.07
Anaphylactic shock	1	0.1	0.03
Delayed haemolytic reaction - other blood groups	2	0.1	0.07
FNHTR - Febrile non-haemolytic reaction	829	44.1	28.96
Haemolytic transfusion reaction - autoantibodies	4	0.2	0.14
Hyperkalaemia	1	0.1	0.03
Hypotensive transfusion reaction	38	2.0	1.33
IBCT - Incorrect Blood Component Transfused	2	0.1	0.07
IBCT - Incorrect Blood Component Transfused (wrong patient)	11	0.6	0.38
Non-immunological haemolysis - chemical cause	2	0.1	0.07
Non-immunological haemolysis - physic cause	1	0.1	0.03
Other	226	12.0	7.90
Post-transfusion purpura	7	0.4	0.24
TACO - Transfusion-associated circulatory overload	37	2.0	1.29
TAD - Transfusion associated dyspnoea	84	4.5	2.93
TRALI - Transfusion-related acute lung injury	2	0.1	0.07
TTI - Viral infection*	1	0.1	0.03
Total	**1,880**	**100.0**	**65.68**

* Viral infection referred to Parvovirus B19
ARs, adverse reactions.

The reactions with cardiac and/or respiratory symptoms were: 109 allergic reactions (3.81 per 100,000 transfused units), 84 TADs (2.93 per 100,000 transfused units), 37 TACOs (1.29 per 100,000 transfused units) and 2 TRALIs (0.07 per 100,000 transfused units).

Table 15 shows the notified ARs by imputability level: 54.6% were associated with a low imputability level (45.1% possible and 9.5% excluded/improbable) and 39.2% to high imputability level (32.1% probable and 7.1% certain). For 6.2% of ARs, the level of imputability was "not assessable".

Table 15. Adverse reactions in recipients by imputability level (2023)

ARs	Imputability level*					
	0	1	2	3	NA	Total
Acute haemolytic reaction - ABO incompatible			1	4		**5**
Acute haemolytic reaction - other blood groups		2	1			**3**
Allergic manifestations - only mucosal and cutaneous symptoms	23	197	209	63	21	**513**
Allergic reactions - respiratory and/or cardiovascular system	5	40	43	15	6	**109**
Alloimmunisation		2				**2**
Anaphylactic shock		1				**1**
Delayed haemolytic reaction - other blood groups	1	1				**2**
FNHTR	77	422	255	26	49	**829**
Haemolytic transfusion reaction - autoantibodies		2	2			**4**
Hyperkalemia			1			**1**
Hypotensive transfusion reaction	8	19	5	3	3	**38**
IBCT					2	**2**
IBCT (wrong patient)				9	2	**11**
Non-immunological haemolysis - chemical cause	1		1			**2**
Non-immunological haemolysis - physic cause		1				**1**
Other	53	96	44	4	29	**226**
Post-transfusion purpura		4	1	2		**7**
TACO	3	11	18	5		**37**
TAD	6	50	21	3	4	**84**
TRALI	1		1			**2**
TTI - Viral infection		1				**1**
Total	**178**	**849**	**603**	**134**	**116**	**1,880**
(%)	(9.5)	(45.1)	(32.1)	(7.1)	(6.2)	(100.0)

ARs, Adverse Reactions;
FNHTR, Febrile Non-Haemolytic Reaction;
IBCT, Incorrect Blood Component Transfused;
TACO, Transfusion-Associated Circulatory Overload;
TAD, Transfusion Associated Dyspnoea;
TRALI, Transfusion-Related Acute Lung Injury;
TTI, Transfusion Transmitted Infections.

* 0 Excluded/Improbable; 1 Possible; 2 Probable; 3 Certain; NA Not Assessable.

In 2023, the frequency of ARs in blood component recipients was 1 in 1,522 transfused units. As reported in Table 16, most of the 1,880 notified ARs were related to platelets transfusion (165.76 per 100,000 units transfused). For the 10 ARs related to multi-component transfusions, it was not possible to assign the AR to a specific blood component.

Table 17 shows 737 ARs with a probable and certain imputability level.

Table 16. Adverse reactions in recipients by blood component transfused (2023)

Blood component transfused	ARs	Transfused units	ARs/100,000 transfused units
Red blood cells	1,256	2,392,289	52.50
Platelets	413	249,156	165.76
Plasma*	191	196,721	97.09
Other	10	24,042	41.59
More than one blood component transfused**	10	NA	NA
Total	**1,880**	**2,862,208**	**65.68**

* Includes plasma pooled and treated for virus inactivation (29 ARs).
** ARs not ascribable to specific blood component.
ARs, adverse reactions; NA, not assessable.

Table 17. Adverse reactions in recipients with imputability level 2-3 regardless of severity levels (2023)

ARs	Total	%	ARs/100,000 transfused units
Acute haemolytic reaction - ABO incompatible	5	0.68	0.17
Acute haemolytic reaction - other blood groups	1	0.14	0.03
Allergic manifestations - only mucosal and cutaneous symptoms	272	36.91	9.50
Allergic reactions - respiratory and/or cardiovascular system	58	7.87	2.03
FNHTR	281	38.13	9.82
Haemolytic transfusion reaction - autoantibodies	2	0.27	0.07
Hyperkalemia	1	0.14	0.03
Hypotensive transfusion reaction	8	1.09	0.28
IBCT (wrong patient)	9	1.22	0.31
Non-immunological haemolysis - chemical cause	1	0.14	0.03
Other	48	6.51	1.68
Post-transfusion purpura	3	0.41	0.10
TACO	23	3.12	0.80
TAD	24	3.26	0.84
TRALI	1	0.14	0.03
Total ARs	**737**	**100.00**	**25.75**

ARs, Adverse Reactions;
FNHTR, Febrile Non-Haemolytic Reaction
IBCT, Incorrect Blood Component Transfused
TACO, Transfusion-Associated Circulatory Overload
TAD, Transfusion Associated Dyspnoea
TRALI, Transfusion-Related Acute Lung Injury.

The frequency of the ARs with a high imputability level is 1 every 3,883 transfused units. As reported in Table 18, the frequency distribution of ARs, per 100,000 transfused units, is 16.8 for red blood cells (RBCs), 101.9 for plasma, 86.7 for platelets, 10.8 for virus-inactivated plasma and 29.1 for other type of blood component.

The most frequent ARs related to the transfusion of RBCs was the febrile non-haemolytic reaction (8.6 per 100,000 transfused units); the allergic manifestation with only mucosal and cutaneous symptoms was the most frequent AR related to plasma (81.9 per 100,000 transfused units), platelets (43.3 per 100,000 transfused units) and virus-inactivated plasma (6.9 per 100,000 transfused units).

Table 18. Adverse reactions in recipients with imputability level 2-3 regardless of severity levels, by blood component transfused (2023)

Blood component transfused	ARs	n.	ARs/100,000 transfused units
RBCs	Acute haemolytic reaction - ABO incompatible	5	0.21
	Acute haemolytic reaction - other blood groups	1	0.04
	Allergic manifestations - only mucosal and cutaneous symptoms	75	3.14
	Allergic reactions - respiratory and/or cardiovascular system	18	0.75
	FNHTR - Febrile non-haemolytic reaction	206	8.61
	Haemolytic transfusion reaction - autoantibodies	1	0.04
	Hyperkalemia	1	0.04
	Hypotensive transfusion reaction	7	0.29
	IBCT - Incorrect Blood Component Transfused (wrong patient)	9	0.38
	Post-transfusion purpura	2	0.08
	TACO - Transfusion-associated circulatory overload	21	0.88
	TAD - Transfusion associated dyspnoea	18	0.75
	Other	37	1.55
Total		*401*	*16.76*
Plasma	Allergic manifestations - only mucosal and cutaneous symptoms	78	81.93
	Allergic reactions - respiratory and/or cardiovascular system	8	8.40
	FNHTR - Febrile non-haemolytic reaction	8	8.40
	Post-transfusion purpura	1	1.05
	Other	2	2.10
Total		*97*	*101.89*
Platelets	Allergic manifestations - only mucosal and cutaneous symptoms	108	43.35
	Allergic reactions - respiratory and/or cardiovascular system	31	12.44
	FNHTR - Febrile non-haemolytic reaction	61	24.48
	Haemolytic transfusion reaction - autoantibodies	1	0.40
	Hypotensive transfusion reaction	1	0.40
	TAD - Transfusion associated dyspnoea	6	2.41
	Other	8	3.21
Total		*216*	*86.69*
Virus-inactivated plasma	Allergic manifestations - only mucosal and cutaneous symptoms	7	6.90
	Allergic reactions - respiratory and/or cardiovascular system	1	0.99
	FNHTR - Febrile non-haemolytic reaction	2	1.97
	Other	1	0.99
Total		*11*	*10.84*
Other type of blood components	Allergic manifestations - only mucosal and cutaneous symptoms	2	8.32
	FNHTR - Febrile non-haemolytic reaction	2	8.32
	Non-immunological haemolysis - chemical cause	1	4.16
	TACO - Transfusion-associated circulatory overload	2	8.32
Total		*7*	*29.12*
More than one blood component transfused**	Allergic manifestations - only mucosal and cutaneous symptoms	2	NA
	FNHTR - Febrile non-haemolytic reaction	2	NA
	TRALI - Transfusion-related acute lung injury	1	NA
Total		*5*	*NA*
Total ARs		**737**	

ARs, adverse reactions; NA, not assessable; RBCs, red blood cells;
**ARs not ascribable to specific blood component.

Table 19 shows 8 ARs with imputability level 2-3 and severity level 3-4 (severe symptoms requiring resuscitation procedures or death) by blood component transfused. In 2023, the frequency of these ARs was 1 every 357,776 transfused units.

Table 19. Adverse reactions to transfusion with imputability level 2-3 and severity level 3-4, by blood component transfused (2023)

Blood component transfused	ARs	n.	ARs/100.000 transfused units
RBCs	Acute haemolytic reaction - ABO incompatible TACO - Transfusion-associated circulatory overload TAD - Transfusion associated dyspnoea	1 4 2	
Total		*7*	*0.29*
Platelets	Allergic reactions - respiratory and/or cardiovascular system	1	0.40
Total ARs		**8**	**0.28**

ARs, adverse reactions; RBCs, red blood cells.

Considering the severity of the total notified ARs to blood transfusion, 74.4% required therapeutic intervention, 1.1% required resuscitation procedures and 0.2% led to death (Figure 6). For the 4 deaths, the imputability of the transfusion was various (not assessable, excluded/unlikely, possible and probable).

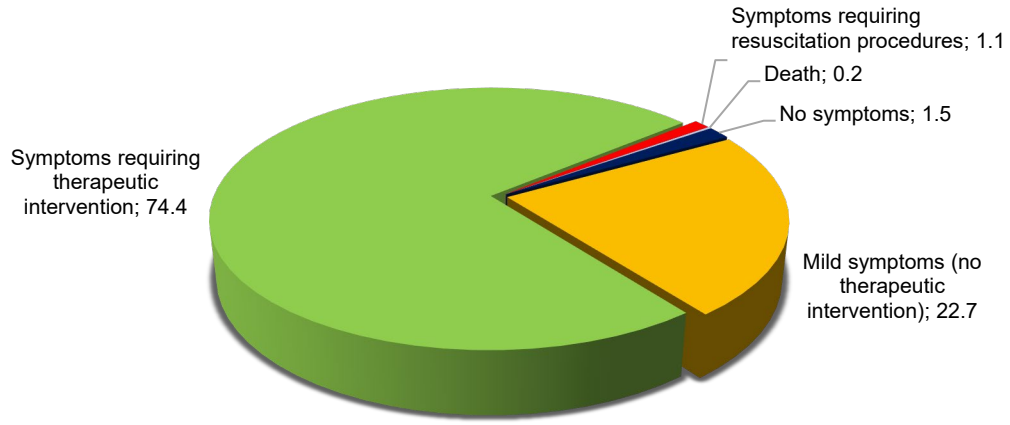

Figure 6. Severity level of adverse reactions in recipients (%) (2023)

In 91.8% of ARs, the clinical resolution was observed within a few hours and, in 1.5%, within a few days (Figure 7).

The majority of the ARs occurred in hospital ward (74.5%) and in day-hospital (12.9%) (outpatient clinics (8.9%) and BEs (4%)) (Table 20 and Figure 8).

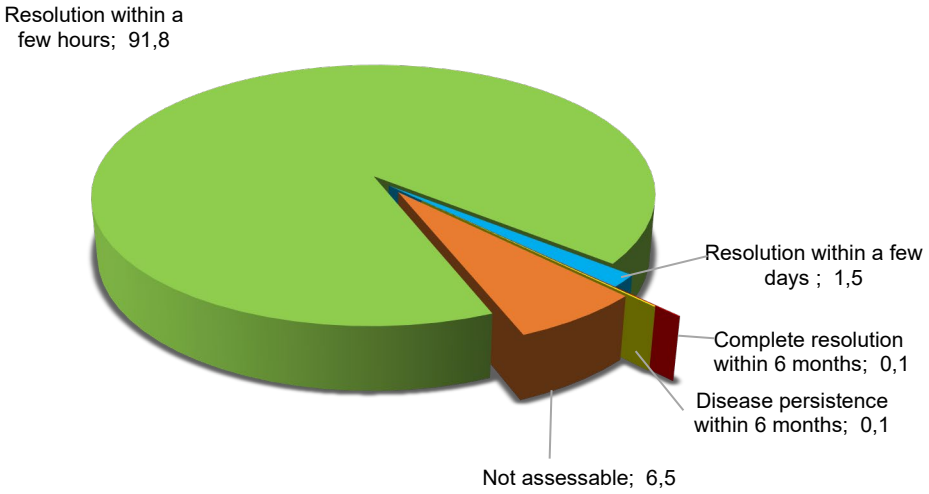

Figure 7. Adverse reactions in recipients by outcome (2023)

Table 20. Transfusion sites notifying adverse reactions (2023)

Transfusion site	n.	%
Clinic	50	2.7
Day-Hospital	242	12.9
Emergency/ICU	141	7.5
Home	19	1.0
Hospital ward	1,402	74.5
Operating theatre	26	1.4
Total	**1,880**	**100.0**

ICU, intensive care unit.

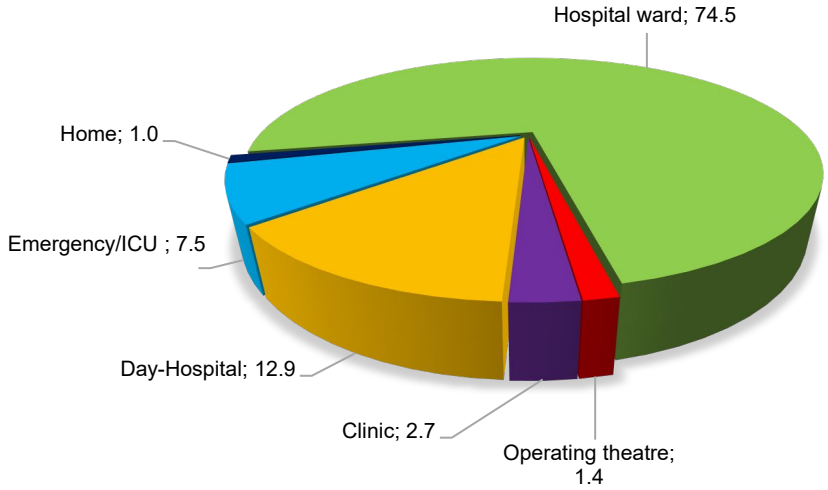

Figure 8. Adverse reactions by transfusion site (2023)

Incorrect blood component transfusion (IBCT)

The acute haemolytic reactions due to ABO incompatible transfusion were 5 (1 in 478,458 units of red blood cells transfused). The transfusions occurred in hospital ward (80.0%) and in Emergency/ICU (20.0%). The severities of reactions were "symptoms requiring therapeutic intervention" (80.0%) and 1 "death" (20.0%).

The IBCTs without symptoms were 13 (1 in 220,170 blood components transfused). Out of them, 10 were ABO compatible and 3 were incompatible transfusions. The transfusion errors occurred due to a wrong identification of the recipient (84.6%) and to a validation error (7.7 %) and an error of unit assignment (7.7%). The incorrect transfusions occurred in hospital ward (76.9%), Emergency/ICU (15.4%) and operating theatre (7.7%). In 30.8% of the IBCTs, the transfusion was interrupted.

Adverse reactions in donors

In 2023, 8,791 ARs to allogeneic donation were notified (1 every 343 donations).

The distribution of the AR notifications shows a significant regional variability with a national average of 291.1 per 100,000 collection procedures. Friuli Venezia Giulia recorded the highest value (914.8 per 100,000 collection procedures) (Figure 9).

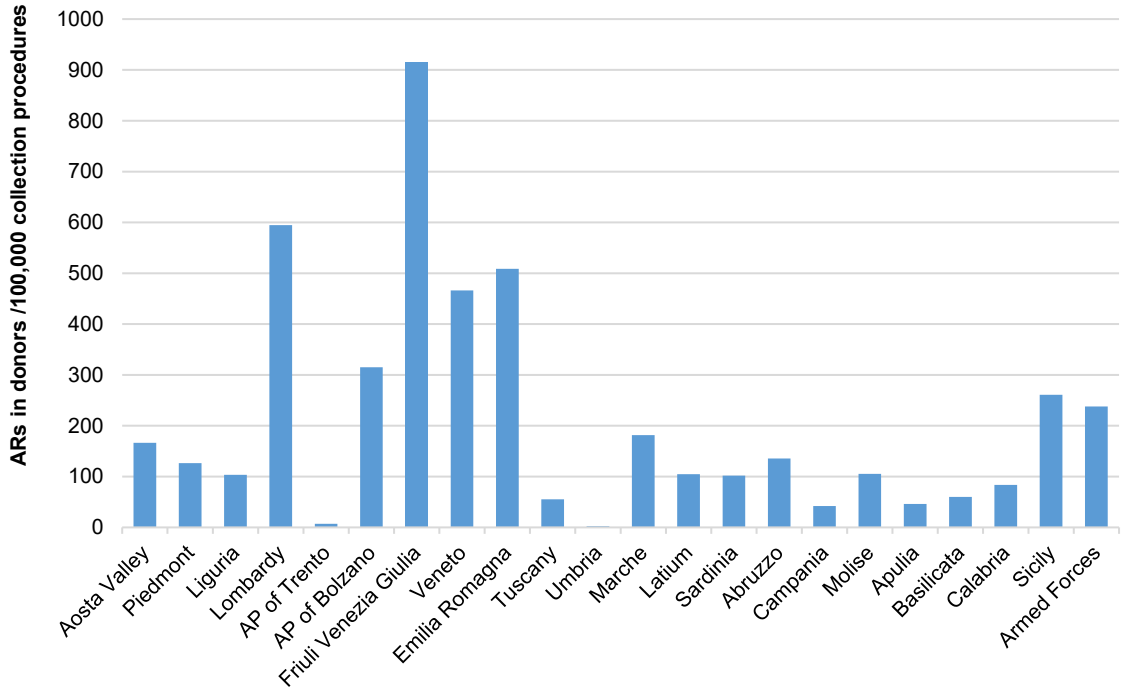

Figure 9. Adverse reactions in donors by Region, per 100,000 collection procedures (2023)

As reported in Table 21, 6,400 (72.8%) ARs were related to whole blood donations and 2,391 (27.2%) to apheresis donations. The highest ARs frequency, by type of collection procedure, was observed for apheresis donation (524.6 per 100,000 apheresis collection procedures vs. 249.6 per 100.000 whole blood collection procedures).

Table 21. Adverse reactions to donations, by collection procedure (2023)

Collection procedure			ARs			ARs/100,000 collection procedures		
Whole blood	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*
2,563,717	455,754	3,019,471	6,400	2,391	8,791	249.6	524.6	291.1

ARs, adverse reactions.

Immediate vasovagal reactions, delayed vasovagal reactions and haematomas were the most observed ARs in blood donors (227, 24.9 and 22.6 per 100,000 total collection procedures, respectively) (Table 22). Immediate vasovagal reactions were more frequent in apheresis collection (362.7 per 100,000 procedures) than in whole blood collection (202.8 per 100,000 procedures). The appearance of haematomas was also more frequent in apheresis collection (98.5 per 100,000 procedures) than in whole blood collection (9.1 per 100,000 procedures).

Table 22. Adverse reactions in donors (2023)

ARs	n.	%	ARs/100,000 collection procedures		
			Whole blood	*Apheresis*	*Total*
Angina pectoris	1	0.01	0.00	0.22	0.03
Arterial puncture	40	0.46	1.52	0.22	1.32
Citrate reaction	77	0.88	0.00	16.90	2.55
Cold/shivers	29	0.33	0.16	5.49	0.96
Delayed vasovagal reaction	752	8.55	25.51	21.50	24.91
Delayed vasovagal reaction with complications	20	0.23	0.74	0.22	0.66
Haematoma	684	7.78	9.17	98.52	22.65
Immediate vasovagal reaction	6,854	77.97	202.87	362.70	226.99
Immediate vasovagal reaction with complications	50	0.57	1.72	1.32	1.66
Incidents tied to vasovagal syndrome	5	0.06	0.08	0.66	0.17
Local allergic reaction	3	0.03	0.04	0.44	0.10
Local infection	2	0.02	0.08	0.00	0.07
Nerve injury	9	0.10	0.27	0.44	0.30
Nerve injury due to a haematoma	3	0.03	0.12	0.00	0.10
Systemic allergic reaction	3	0.03	0.04	0.44	0.10
Thrombophlebitis	6	0.07	0.20	0.22	0.20
Other	202	2.30	6.05	10.31	6.69
Other incidents	51	0.58	1.09	5.05	1.69
Total	**8,791**	**100.00**	**249.64**	**524.63**	**291.14**

ARs, Adverse Reactions.

The severity of the notified reactions was mainly mild (73.6%) (Table 23). The severe ARs to donation occurred in 10.0 per 100,000 total collection procedures. The frequency distribution for mild, moderate and severe ARs shows a higher prevalence for the immediate vasovagal reactions.

Table 23. Adverse reactions to donation, by severity level (2023)

ARs	Mild	%	Moderate	%	Severe	%
Angina pectoris	1	0.02		0.00		0.00
Arterial puncture		0.00	39	1.94	1	0.33
Citrate reaction	39	0.60	21	1.04	17	5.63
Cold/shivers	22	0.34		0.00	7	2.32
Delayed vasovagal reaction	474	7.32	240	11.91	38	12.58
Delayed vasovagal reaction with complications	4	0.06	9	0.45	7	2.32
Haematoma	549	8.48	73	3.62	62	20.53
Immediate vasovagal reaction	5,136	79.33	1,582	78.51	136	45.03
Immediate vasovagal reaction with complications	18	0.28	22	1.09	10	3.31
Incidents tied to vasovagal syndrome		0.00		0.00	5	1.66
Local allergic reaction	2	0.03	1	0.05		0.00
Local infection	2	0.03		0.00		0.00
Nerve injury	6	0.09	3	0.15		0.00
Nerve injury due to a haematoma	1	0.02	2	0.10		0.00
Systemic allergic reaction		0.00		0.00	3	0.99
Thrombophlebitis		0.00		0.00	6	1.99
Other	173	2.67	19	0.94	10	3.31
Other incidents	47	0.73	4	0.20		0.00
Total (%)	**6,474 (73.6)**	**100.00**	**2,015 (22.9)**	**100.00**	**302 (3.4)**	**100.00**
Total ARs/100,000 total collection procedures	**214.4**		**66.7**		**10.0**	

ARs, adverse reactions.

The severe ARs were more frequent in apheresis than in whole blood donation procedures (25.0 vs. 7.3 per 100,000 collection procedures, respectively) (Table 24).

Table 24. Severe adverse reactions to donation, by collection procedure (2023)

Collection procedure			ARs			ARs/100,000 collection procedures		
Whole blood	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*
2,563,717	455,754	3,019,471	188	114	302	7.3	25.0	10.0

SARs, severe adverse reactions.

Serious adverse events

In 2023, 28 SAEs were notified. The regional distribution of the notifications shows a wide variability with a national average of 0.92 per 100,000 issued units. Emilia-Romagna recorded the highest value (3.45 per 100,000 issued units) (Figure 10).

Human error (1 every 276,091 issued units) was the main cause of SAE. Other SAEs were due to organisational error and equipment failure (0.33 and 0.10 per 100,000 issued units, respectively) (Table 25 and Figure 11).

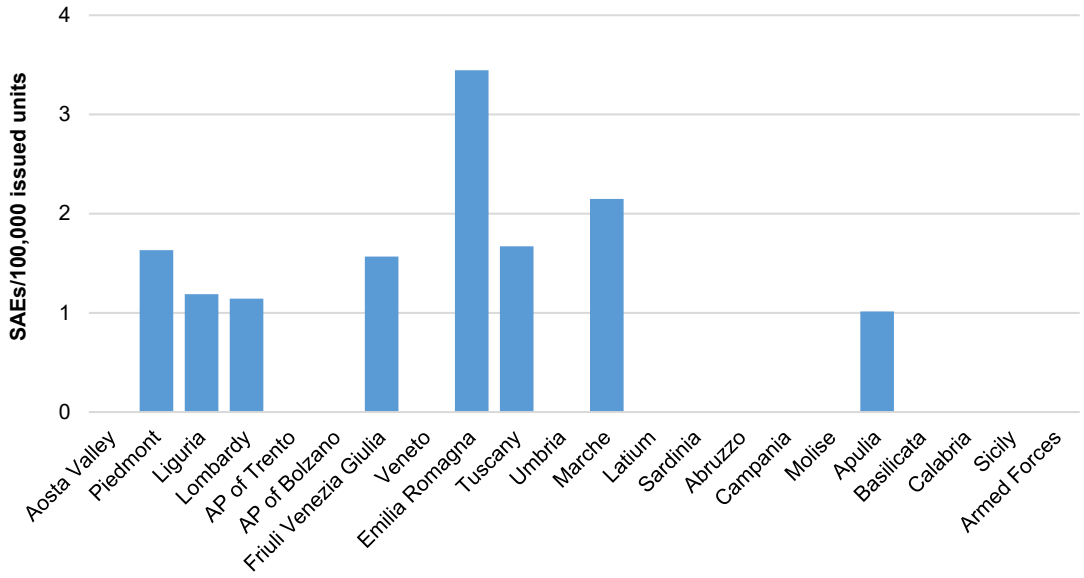

Figure 10. Serious adverse events notified by Region, per 100,000 issued units (2023)

Table 25. Cause of serious adverse events (2023)

Cause	n.	%	SAEs/100,000 issued units
Equipment failure	3	10.7	0.10
Human error	11	39.3	0.36
Organisational error	10	35.7	0.33
Other	4	14.3	0.13
Total	**28**	**100.0**	**0.92**

SAEs, Serious Adverse Events

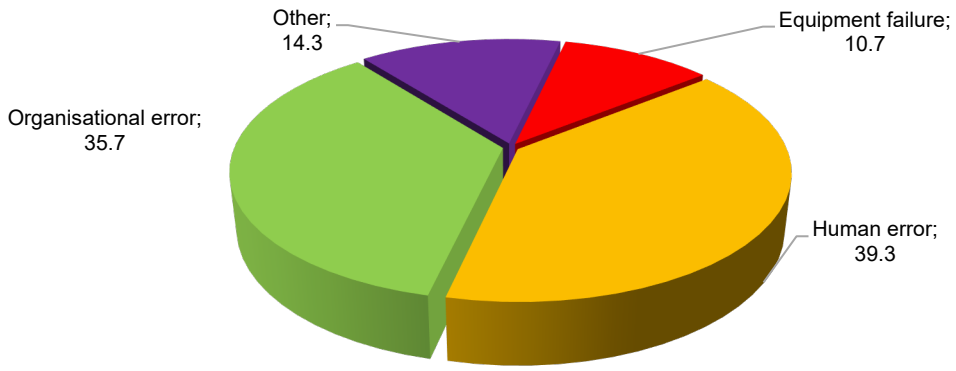

Figure 11. Cause of serious adverse events (2023)

The majority of SAEs occurred in the phase “other (issue / assignment)” (50.0%) (Table 26 and Figure 12).

Table 26. Phases in which serious adverse events occurred (2023)

Phase	n.	%	SAEs/100,000 issued units
Collection	2	7.1	0.07
Distribution	2	7.1	0.07
Storage	1	3.6	0.03
Other	8	28.6	0.26
Other (issue / assignment)	14	50.0	0.46
Other (issue / labelling)	1	3.6	0.03
Total	**28**	**100.0**	**0.92**

SAEs, serious adverse events.

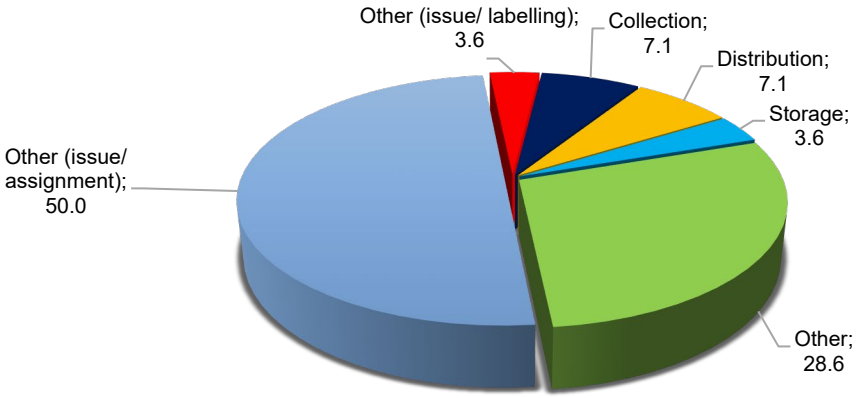

Figure 12. Phases in which serious adverse events occurred (2023)

The notified SAEs occurred in clinical wards and in BEs with a frequency of 78.6% and 21.4%, respectively (Table 27 and Figure 13).

Table 27. Serious adverse events by site of occurrence (2023)

Site	n.	%
Blood establishment	6	21.4
Clinical ward	22	78.6
Total	**28**	**100.0**

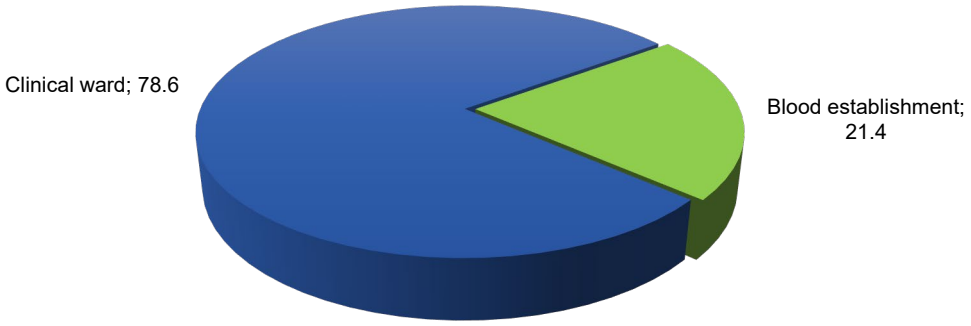

Figure 13. Site in which serious adverse events occurred (2023)

Near miss

In 2023, 233 near miss events (7.7 per 100,000 units issued), as defined by the EDQM Guide (13), were notified. Many notifications were about "wrong information on the tube label" (3.19 per 100,000 units issued) and "wrong patient" (3.03 per 100,000 units issued) (Table 28); many "avoided transfusions of blood component not intended for the patient" (0.79 per 100,000 units issued) were also reported.

Table 28. Near miss events (2023)

Type of primary error (near miss)	n.	%	Near miss/100,000 issued units
Avoided transfusion of blood component not intended for the patient	24	10.3	0.79
Avoided transfusion of expired blood component	4	1.7	0.13
Avoided transfusion of inappropriate blood component	3	1.3	0.10
Error in pre-transfusion test	2	0.9	0.07
Wrong information on the blood unit label	7	3.0	0.23
Wrong information on the tube label	97	41.6	3.19
Wrong patient	92	39.5	3.03
Wrong/inappropriate blood component type requested	4	1.7	0.13
Total	**233**	**100**	**7.67**

Comments and recommendations

As in the previous year (6), the 2023 haemovigilance data reported that the most frequent blood transfusion's ARs, considering all the imputability and severity levels, were febrile non-haemolytic reactions (28.9 per 100,000 transfused units) and allergic manifestations with only mucosal and cutaneous symptoms (17.9 per 100,000 transfused units). The ARs involving the respiratory system were 12.3% of the total notifications.

In 2023, 5 acute haemolytic reactions due to ABO incompatible transfusions (0.21 per 100,000 units of red blood cells transfused) were notified. The imputability of the above-mentioned events, reported as probable or certain, is related to errors or deviations from the standard procedures or policies. A root cause analysis of these events has been carried out to highlight and implement appropriate corrective actions. Monitoring and reporting of these events are important for the adoption of appropriate preventive measures.

Among the 1,880 reported ARs in recipient, 737 (39.2%) were with a high imputability (level 2-3), of which 8 with a high severity (level 3 - severe symptoms requiring resuscitation procedures or 4 - death) with a frequency of 0.28 per 100,000 units transfused. In detail, there were notified 1 acute haemolytic reaction due to ABO incompatible transfusion and 7 ARs involving the respiratory system (2 TAD, 4 TACO and 1 allergic reaction).

The adverse reactions to allogeneic donation were 8,791. The immediate vasovagal reactions, which represented 78.5% of the total notified ARs in blood donor, occurred in 1 every 437 collection procedures and were the most frequent ARs for both apheresis and whole blood collection (364.0 vs. 204.6 per 100,000 collection procedures, respectively). Moreover, the other ARs with a high frequency of occurrence were haematomas in apheresis collection (98.5 per 100.000 collection procedures) and delayed vasovagal reactions in whole blood collection (25.5 per 100,000 collection procedures).

In 2023, 28 SAEs and 233 near miss errors were notified. The frequency of SAEs was 1 every 108,464 issued units. Human error was the main cause of adverse events (0.36 per 100,000 issued

units) and the "other (issue / assignment)" phase (0.46 per 100,000 issued units) was the most involved in the SAEs.

Wrong information on the tube label and wrong patient collected were the most commonly near miss reported (6.22 per 100,000 issued units), due to deviations from standard procedures or policies or by poor practices. Root cause analysis of near miss events should be carried out to highlight and resolve these system failures. The improvement of near miss reporting is important to support learning from the errors and adopting preventive measures.

Transfusion transmitted infections in Italy: blood donors' epidemiological surveillance

The epidemiological surveillance of transfusion transmitted infections is the indispensable tool for assessing the safety of donated blood and blood components (11, 12).

By means of SISTRA, the CNS monitors the national epidemiological situation of blood donors and the efficiency of analytical systems used in biological qualification activities.

The collected epidemiological data are related to the donor category (*first time and repeat tested*) and to the possible infectious risk factors.

The collected information refers to donors who tested positive to the mandatory tests for the purpose of qualifying blood and blood components (8). The following serological tests are performed: hepatitis B virus surface antigen (HBsAg), anti-HIV 1-2 antibodies (HIV1-2 Ab) and the HIV antigen, antibodies against hepatitis C virus (HCV Ab) and anti-*Treponema pallidum* (TP). The Nucleic Acid Test (NAT) makes it possible to detect the presence of HCV (HCV RNA), HIV 1-2 (HIV 1-2 RNA) and HBV (HBV DNA) viral genomes.

This information is extremely useful for:

- monitoring the epidemiological progress of transfusion transmitted diseases in blood donors;
- identifying behaviours related to the condition of illness and groups at risk;
- detecting at national and regional level the frequency of transfusion-transmissible infections;
- evaluating the effectiveness over time of intervention programmes and tools to prevent the spread of transfusion-transmissible diseases.

In this section of the report, all essential data relative to 2023 are reported.

Materials and methods

SISTRA records the infections detected in blood donors. Notifications are compiled on the information system directly by the BE or the RBCC through the regional information systems.

For better comparability, some data are reported per 1,000 donors (‰) and the incidence and prevalence values are multiplied by a k-factor equal to 100,000 donors.

Definitions

The definitions and indices used for the epidemiological surveillance of blood donors and blood components are both entirely based on what is set in the Italian law in force regarding blood transfusion (8) and compliant with the document issued by the European Medicines Agency (EMA) "Guideline on epidemiological data on blood transmissible infections" (14).

The definitions of the principal terms used in the document are:

– *First-time tested donor (FT)*
Person whose blood/plasma is tested for the first time for infectious disease markers (with or without donation) without evidence of prior testing in a given blood system.

– *Repeat tested donor (RT)*
Person whose blood/plasma has been tested previously for infectious disease markers in a given blood system.

It should be noted that the number of RT and FT donors, reported in this report, and notified on SISTRA by the competent regional authorities, is obtained according to blood donor definitions provided by the national legislation (8).

– *Positive donor*
A donor (*first-time tested* or *repeat tested donor*) repeatedly reactive in serological and molecular screening tests, as set out in Annex IV to the Ministerial Decree of November 2nd, 2015 and confirmed as positive according to the procedures set out in Annex VIII to the above-mentioned Decree (8).

– *Risk factor*
Behaviour or condition that exposes the donor to the risk of contracting transfusion-transmissible infections. The risk factors considered here are predefined within SISTRA. For the positive donor, one or more factors considered likely to be the source of infection can be indicated.

– *Screening test*
Serological or molecular test used for the biological qualification of blood and blood components.

– *Confirmatory test*
Serological test confirming the repeatedly reactive test used to verify a positive result detected in the screening test.

– *Prevalence*
Measurement of the frequency of infection detected at a specified point in time or over a specified period in a defined population. In the context of donor population studies, the prevalence can be calculated in *first time-tested* donors as follows:

$$Prevalence = \frac{N.positive\ FT\ tested\ donors\ in\ a\ specified\ period}{Total\ N.FT\ tested\ donors\ in\ the\ same\ specified\ period} \cdot k$$

where, k is a constant of 10 or a multiple thereof.

– *Incidence*
Rate of new (or newly diagnosed) cases of a disease. It is generally reported as the number of new cases occurring within a period of time (e.g., per month, per year). It is more meaningful when the incidence rate is reported as a fraction of the population at risk of developing the disease (e.g., per 100,000 or per 1,000,000 population).
In the context of donor population studies, the incidence can be calculated in *repeat tested* donors as follows:

$$Incidence = \frac{N.of\ positive\ RT\ donors\ in\ a\ calendar\ year}{Total\ N.of\ RT\ donors\ in\ the\ same\ calendar\ year} \cdot k$$

where, k is a constant of 10 or a multiple thereof.

General data

The data come from the information flows starting in the Italian BEs.

The BEs notify the infections detected in blood donors to the RBCCs that in turn draft their annual regional report.

From January 1st to December 31st 2023, out of a total of 1,898,502 blood donors, 1,310 were tested and turned out to be positive for the currently mandatory infectious disease markers.

Table 29 shows the total number of positive donors per Italian Region, and the number of positive donors per 1,000 tested donors (‰). The Region with the highest number of positive donors detected was Campania (2.74‰), followed by Apulia (1.28‰) and Latium (0.88‰) regions.

Table 29. Tested donors and positive donors to infectious markers at national and regional level (2023)

Region/AP	Tested donors	Positive donors	
	n.	n.	‰
Aosta Valley	3,950	0	0.00
Piedmont	126,129	64	0.51
Liguria	50,962	33	0.65
Lombardy	298,646	127	0.43
AP of Trento	23,059	9	0.39
AP of Bolzano	17,507	4	0.23
Friuli Venezia Giulia	49,541	20	0.40
Veneto	177,919	19	0.11
Emilia-Romagna	172,480	80	0.46
Tuscany	142,020	60	0.42
Umbria	30,058	10	0.33
Marche	55,838	32	0.57
Latium	148,091	130	0.88
Sardinia	57,120	42	0.74
Abruzzo	40,516	18	0.44
Campania	138,459	380	2.74
Molise	9,787	6	0.61
Apulia	122,101	156	1.28
Basilicata	19,209	7	0.36
Calabria	48,426	22	0.45
Sicily	165,777	91	0.55
Armed Forces	907	0	0.00
Italy	**1,898,502**	**1,310**	**0.69**

AP, Autonomous Province

Figure 14 reports the same data shown in Table 29 (positive donors per 1,000 tested donors (‰)). The analysis of the distribution of positive donors by age class shows that positive blood donors are more frequent in the central age classes (36-45, 45-55) (highlighted in grey) (Table 30, column 5). The data on the incidence of infections by age classes (Table 31, column 6) show very similar values for the central age classes (36-45, 46-55 and 56-65).

Table 31 shows the distribution by age class and gender of the 1,310 positive donors; the number of male positive donors appears to be on average 2.6 times higher than the number of female positive donors (Figure 15).

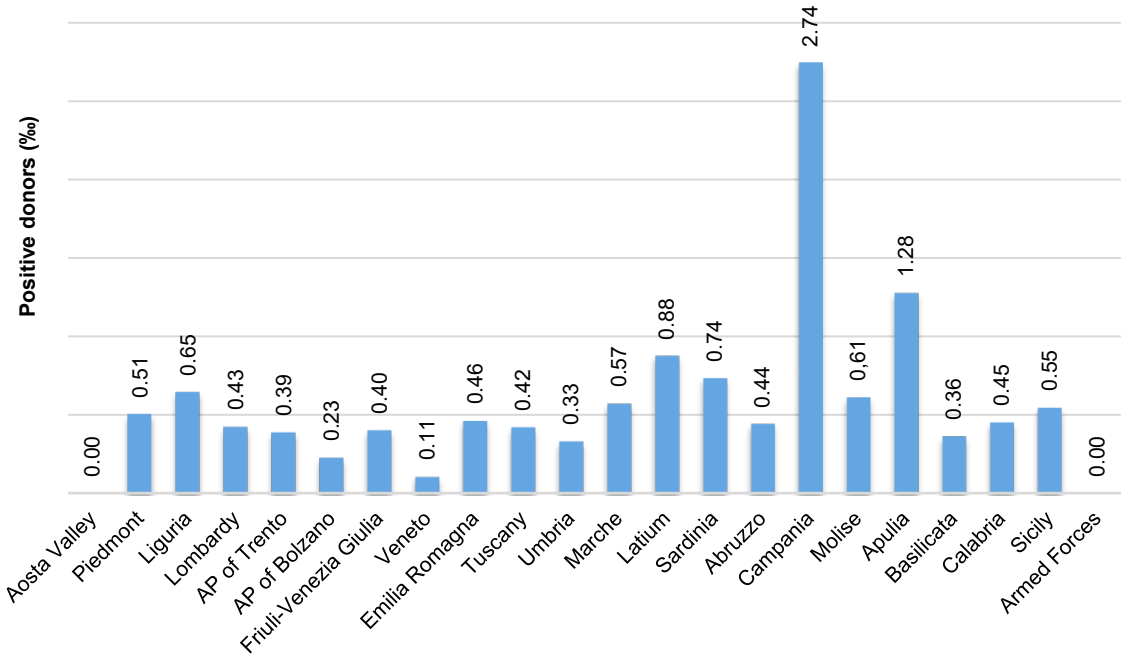

Figure 14. Positive donors per 1,000 tested donors (‰) by Italian Regions (2023)

Table 30. Positive donor by age class (2023)

Age class	Total donors		Positive donors		
	n.	%	n.	%	‰
18-25	262,475	13.8	88	6.7	0.34
26-35	346,075	18.2	218	16.6	0.63
36-45	406,290	21.4	327	25.0	0.80
46-55	529,767	27.9	394	30.1	0.74
56-65	326,919	17.2	269	20.5	0.82
over 65	26,976	1.4	14	1.1	0.52
Total	**1,898,502**	**100**	**1,310**	**100**	**0.69**

Table 31. Positive donors by age class and gender (2023)

Age class	Male				Female			
	donors		positive donors		donors		positive donors	
	n.	%	n.	%	n.	%	n.	%
18-25	135,556	11.0	67	7.1	126,919	19.0	21	5.8
26-35	213,203	17.3	169	17.8	132,872	19.9	49	13.6
36-45	273,214	22.2	241	25.4	133,076	19.9	86	23.8
46-55	359,255	29.2	270	28.5	170,512	25.5	124	34.3
56-65	228,351	18.6	191	20.1	98,568	14.7	78	21.6
over 65	20,520	1.7	11	1.2	6,456	1.0	3	0.8
Total	**1,230,099**	**100**	**949 (72%)**	**100**	**668,403**	**100**	**361 (28%)**	**100**

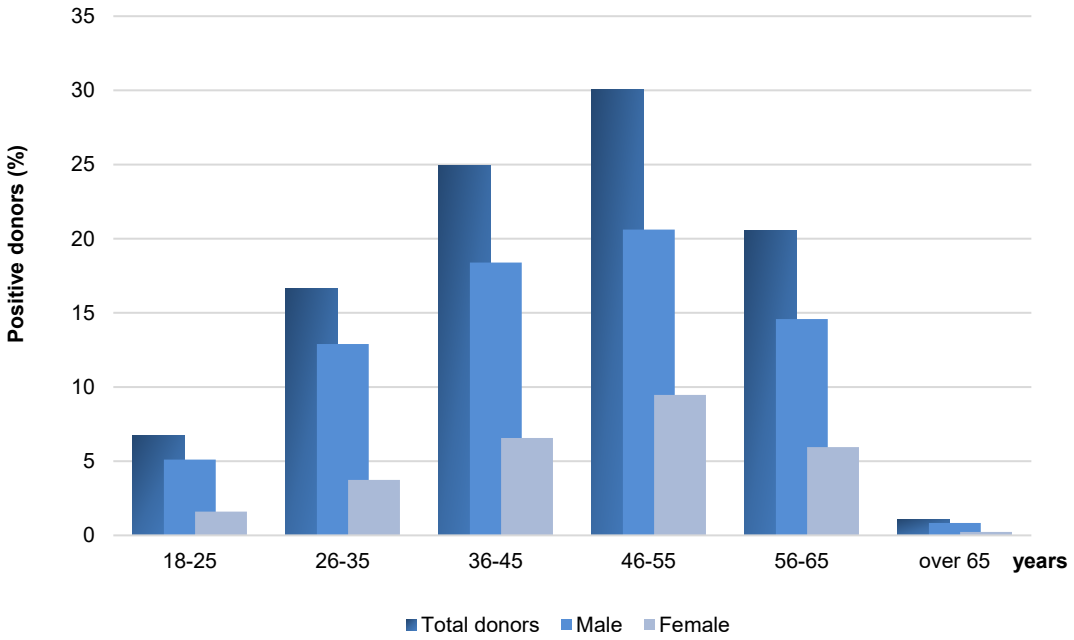

Figure 15. Positive donors (total, male and female donors) by age class (%) (2023)

Considering the number of infections detected in the total number of donors (‰ tested donors) for each age class, the biggest difference in the number of infections between males and females was found in the 18-25, 26-35 and 36-45 age classes (Figure 16).

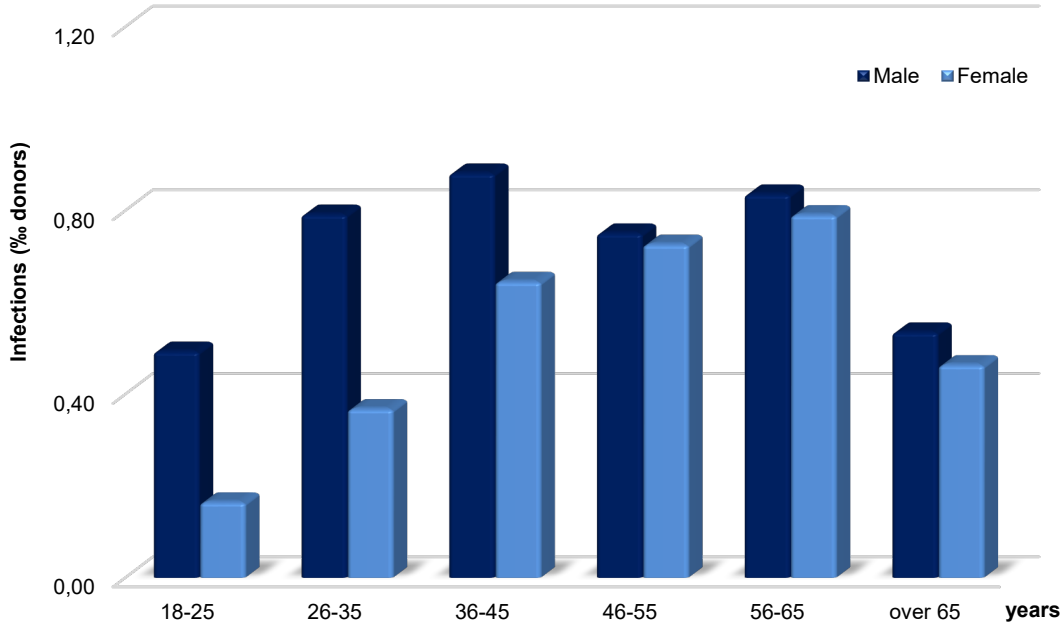

Figure 16. Positive donors by age class and gender (‰ total donors) (2023)

Figure 17 shows the percentages of infections observed for each single marker (HIV, HBV, HCV and TP) and the percentage of all tested donors, distributed by age class. The results show significant variations between the distribution trend of the tested donors and the positive donors for each marker of infections. HIV and TP infections are more frequent in the 36-45 and in the 26-35 and 36-45 age classes, respectively; on the contrary, HBV and HCV infections are both more frequent in the 46-55 and 56-65 age classes.

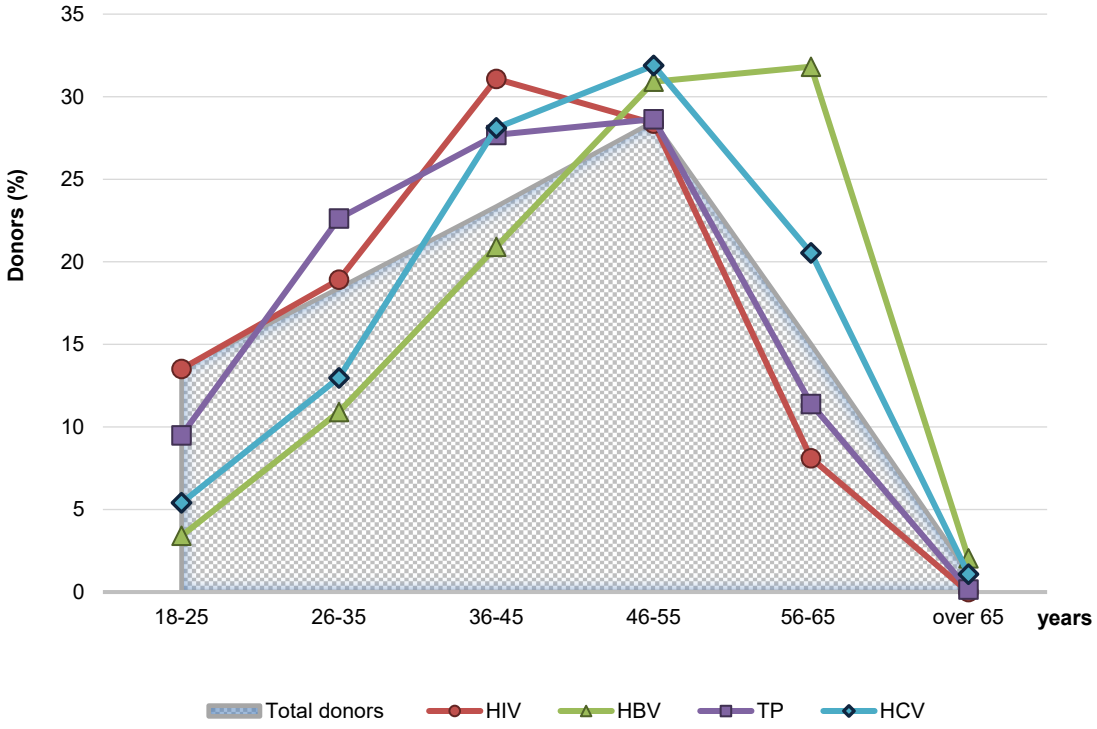

Figure 17. Total donors and HIV, HBV, HCV and TP positive donors by age class (%) (2023)

The number of positive donors significantly differs also among the categories of the donors. In fact, it emerged that 2.07‰ of FT donors were positive to one of the infectious markers compared to 0.30‰ of RT donors (Table 32). Figure 18 shows the same data reported in Table 32.

Table 32. Positive donors per 100 (%) and 1,000 (‰) tested donors: distribution by category (2023)

Donor category	Donors	Positive donors		
	n.	n.	%	(‰)
First-time tested donors	**422,623**	**874**	**66.72**	**2.07**
Prospective donors (first screening without donation)	187,051	258	19.69	1.38
First-time not pre-qualified donors	235,572	616	47.02	2.61
Repeat tested donors	**1,475,879**	**436**	**33.28**	**0.30**
First-time pre-qualified donors	124,731	15	1.15	0.12
Regular donors	1,351,148	421	32.14	0.31
Total donors	**1,898,502**	**1,310**	**100**	**0.69**

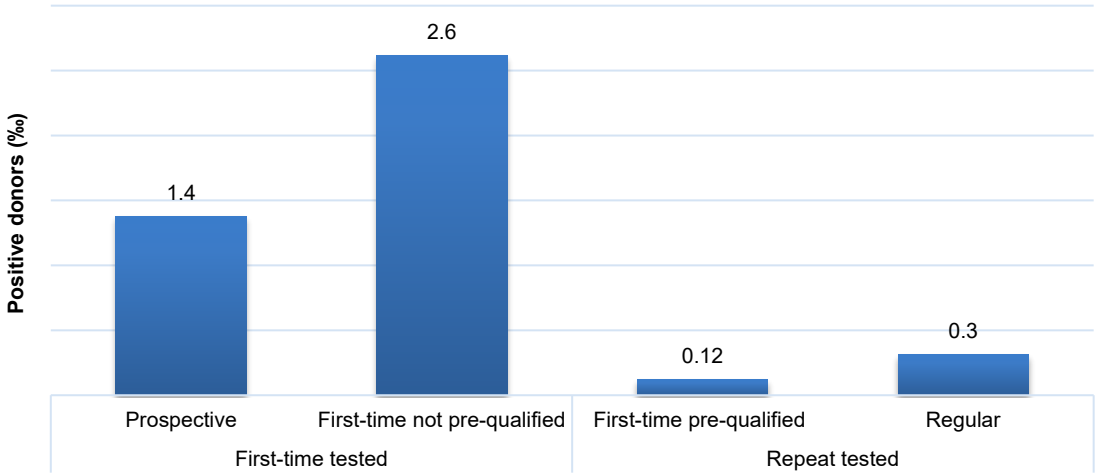

Figure 18. Categories of positive donors (2023)

Table 33 shows the number of FT and RT positive donors in Italy per Region. The regions with the highest number of positive FT and RT are Campania and Apulia: (FT: Campania 5.16‰, Apulia 3.16‰; RT: Apulia 0.78‰, Campania 0.65‰).

Table 33. FT and RT positive donors (total and per 1,000 (‰) tested donors) in Italy (2023)

Region/AP	Total of donors		Positive donors			
	FT	RT	FT	RT	FT (‰ FT)	RT (‰ RT)
Aosta Valley	646	3,304	0	0	0.00	0.00
Piedmont	20,039	106,090	34	30	1.70	0.28
Liguria	12,737	38,225	23	10	1.81	0.26
Lombardy	52,924	245,722	69	58	1.30	0.24
AP of Trento	3,575	19,484	3	6	0.84	0.31
AP of Bolzano	1,874	15,633	2	2	1.07	0.13
Friuli Venezia Giulia	11,933	37,608	12	8	1.01	0.21
Veneto	29,017	148,902	12	7	0.41	0.05
Emilia-Romagna	27,180	145,300	54	26	1.99	0.18
Tuscany	27,883	114,137	39	21	1.40	0.18
Umbria	7,075	22,983	7	3	0.99	0.13
Marche	9,014	46,824	20	12	2.22	0.26
Latium	53,158	94,933	102	28	1.92	0.29
Sardinia	17,316	39,804	25	17	1.44	0.43
Abruzzo	6,547	33,969	12	6	1.83	0.18
Campania	64,321	74,138	332	48	5.16	0.65
Molise	2,558	7,229	2	4	0.78	0.55
Apulia	25,651	96,450	81	75	3.16	0.78
Basilicata	4,400	14,809	3	4	0.68	0.27
Calabria	8,967	39,459	9	13	1.00	0.33
Sicily	35,240	130,537	33	58	0.94	0.44
Armed Forces	568	339	0	0	0.00	0.00
Italy	**422,623**	**1,475,879**	**874**	**436**	**2.07**	**0.30**

AP, Autonomous Province

Figure 19 shows the percentage of positive donors by category (FT/RT). On a distribution of 100% positivity for each Region, with 50% as the cut-off value (red line), the percentages of FT with respect to RT were evaluated. In general, with the exception of Sicily, Calabria, Basilicata, Molise, regions and AP of Trento, in all regions more than 50% of positive donors were FT.

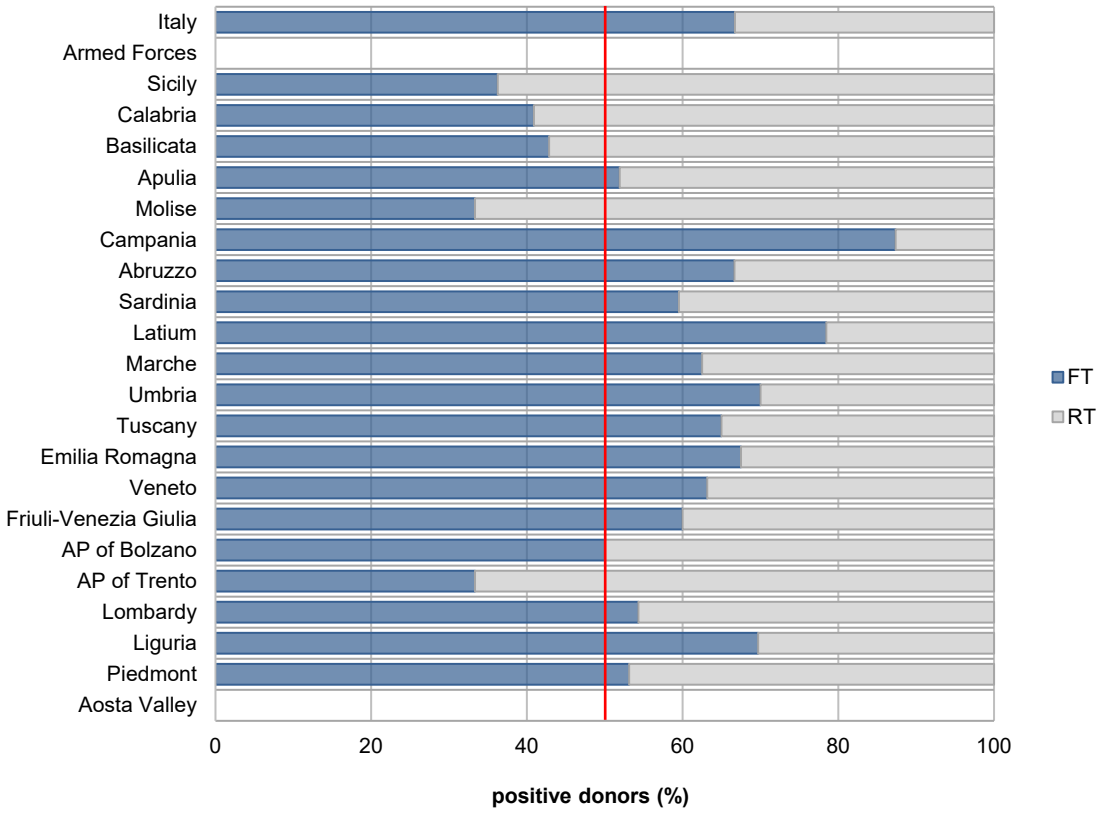

Figure 19. Positive donors by FT and RT category (%) at national and regional level (2023)

The male/female ratio for FT and RT positive donors was about 2:1 (Figure 20).

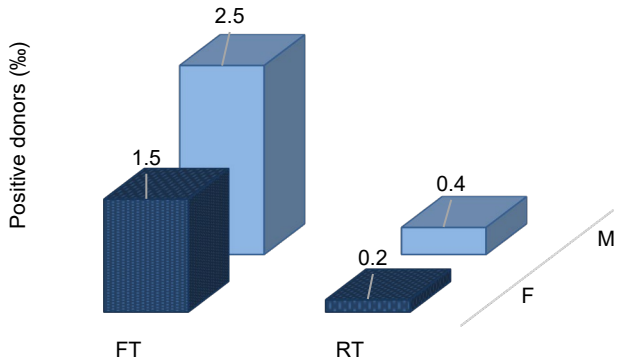

Figure 20. Positive donors by FT and RT category (‰ total male and female donors) and gender (2023)

Figure 21 shows the positive donor distribution at national and regional level for each infectious marker per 100,000 tested donors. The Region with the highest number of HCV, HBV and TP infections was Campania (HBV: 108.3/100,000, HCV: 61.4/100,000, TP: 98.2/100,000 tested donors). These values were from 4.6 (HBV) to 6.3 times (HCV) higher compared to the national data.

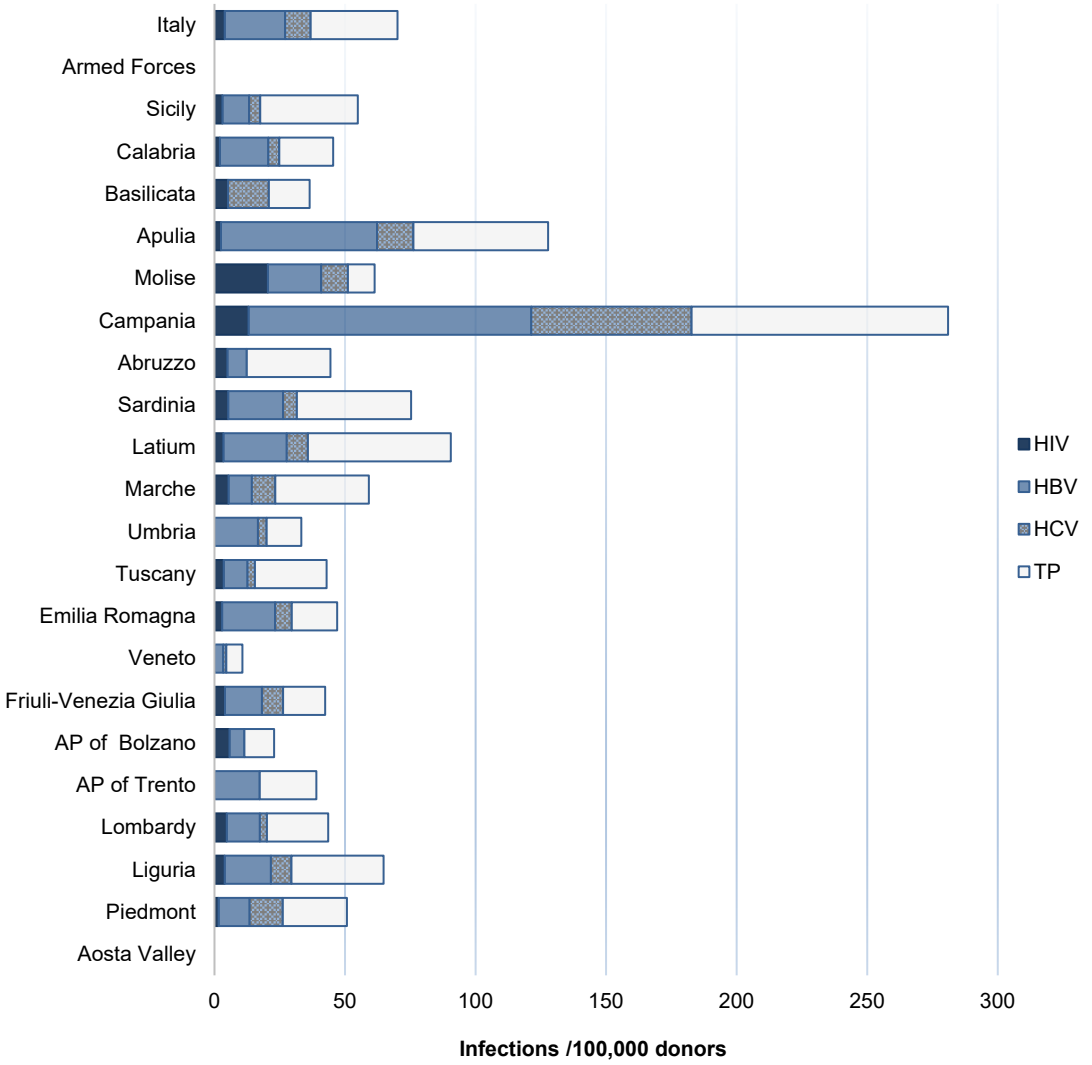

Figure 21. Positive donor distribution at national and regional level for each infectious marker per 100,000 donors (2023)

The Region with the highest number of HIV infections was Molise (HIV: 20.4/100,000 tested donors). This value was about three times higher compared to national data.

Figure 22 shows the distribution of HIV, HBV, HCV and TP positivity in FT and RT donors by gender.

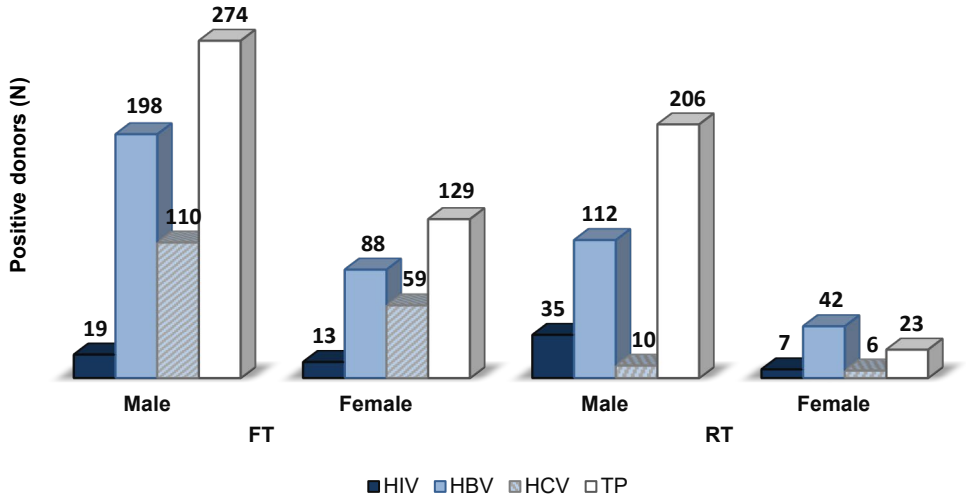

Figure 22. Infections by donor category (FT/RT), gender and infectious marker (2023)

In Tables 34 and 35 data on HIV, HBV, HCV and TP prevalence and incidence at national and regional level are reported. At national level, the highest prevalence value was for TP (95.4/100,000 FT donors), followed by HBV (67.7/100,000 FT donors).

Table 34. Prevalence by infectious marker/100,000 FT donors (2023)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	0.0	44.9	69.9	54.9
Liguria	15.7	23.6	31.4	109.9
Lombardy	5.7	39.7	15.1	69.9
AP of Trento	0.0	28.0	0.0	55.9
AP of Bolzano	0.0	53.4	0.0	53.4
Friuli Venezia Giulia	0.0	50.3	25.1	33.5
Veneto	0.0	13.8	3.5	24.1
Emilia-Romagna	3.7	80.9	33.1	84.6
Tuscany	10.8	43.0	7.2	82.5
Umbria	0.0	70.7	14.1	14.1
Marche	11.1	44.4	55.5	110.9
Latium	7.5	54.6	20.7	116.6
Sardinia	0.0	40.4	11.6	98.2
Abruzzo	15.3	45.8	0.0	122.2
Campania	21.8	192.8	130.6	183.5
Molise	0.0	78.2	0.0	0.0
Apulia	3.9	101.4	62.4	148.1
Basilicata	22.7	0.0	45.5	0.0
Calabria	0.0	22.3	22.3	55.8
Sicily	2.8	14.2	14.2	62.4
Armed Forces	0.0	0.0	0.0	0.0
Italy	**7.6**	**67.7**	**40.0**	**95.4**

AP, Autonomous Province

As reported in Table 35, the highest incidence value was for TP (15.5/100,000 RT donors) and HBV (10.4/100,000 RT donors) infections. Moreover, it is important to note that, as in 2022, in 54% of cases no information on the causes of missed deferral of positive donors was reported in SISTRA. When the cause of missed deferral was reported (46%), in most cases the donor "denied the risk factor" (Figure 23).

Table 35. Incidence by infectious marker/100,000 RT donors (2023)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	1.9	5.7	1.9	18.9
Liguria	0.0	15.7	0.0	10.5
Lombardy	4.5	6.9	0.0	13.4
AP of Trento	0.0	15.4	0.0	15.4
AP of Bolzano	6.4	0.0	0.0	6.4
Friuli Venezia Giulia	5.3	2.7	2.7	10.6
Veneto	0.0	1.3	0.7	2.7
Emilia-Romagna	2.8	9.0	1.4	4.8
Tuscany	1.8	0.9	1.8	14.0
Umbria	0.0	0.0	0.0	13.1
Marche	4.3	2.1	0.0	21.4
Latium	1.1	7.4	1.1	20.0
Sardinia	7.5	12.6	2.5	20.1
Abruzzo	2.9	0.0	0.0	14.7
Campania	5.4	35.1	1.4	24.3
Molise	27.7	0.0	13.8	13.8
Apulia	2.1	48.7	1.0	25.9
Basilicata	0.0	0.0	6.8	20.3
Calabria	2.5	17.7	0.0	12.7
Sicily	3.1	9.2	1.5	30.6
Armed Forces	0.0	0.0	0.0	0.0
Italy	**2.9**	**10.4**	**1.1**	**15.5**

AP, Autonomous Province

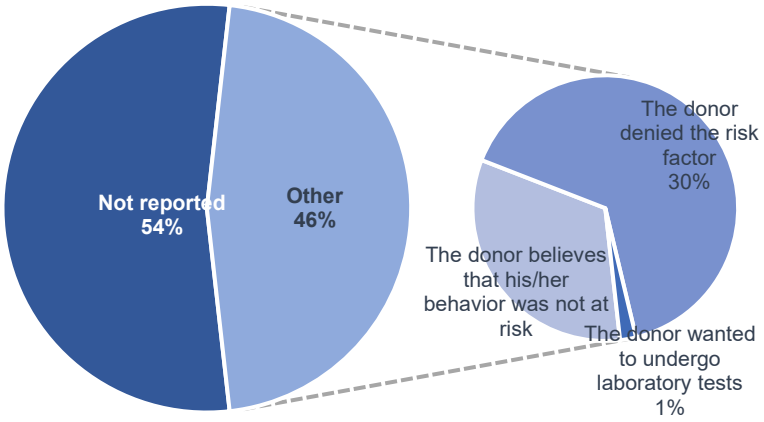

Figure 23. Causes of missed deferral of donor positive to infectious markers (2023)

Table 36 shows the number of donors positive to infectious markers by nationality and category (FT/RT).

Table 36. Positive donors to infectious markers by nationality and category (FT/RT) (2023)

Nationality	Positive donors		FT		RT	
	n.	%	n.	%	n.	%
Italians	990	75.6	586	67.0	404	92.7
Foreigners	320	24.4	288	33.0	32	7.3
Total	**1,310**	**100**	**874**	**100**	**436**	**100**

Table 37 shows the distribution of positive donors to infectious markers by geographical area of birth and category (FT/RT). The data shown in Table 37 were the same as those shown in Figure 24.

Table 37. Positive donors to infectious markers by category (FT/RT) and by geographical area of birth (2023)

Geographical area of birth	FT	RT	Total
Africa	58	7	65
America	15	3	18
Asia	33	2	35
Europe	182	20	202
Italy	586	404	990
Total	**874**	**436**	**1,310**

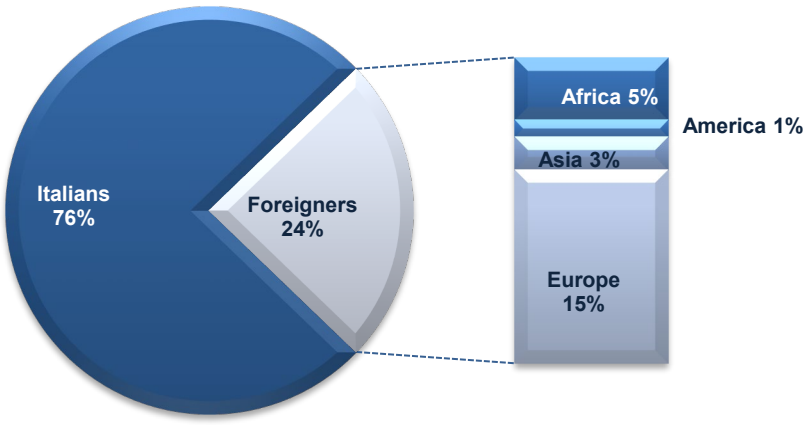

Figure 24. Positive donors to infectious markers by nationality (%) (2023)

HIV surveillance data

Table 38 the number of HIV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2023, 74 HIV infections were reported, with a prevalence of 7.6 per 100,000 FT donors and an incidence of 2.9 per 100,000 RT donors. The highest prevalence (22.7 per 100,000) of HIV infections was found in Basilicata Region; the highest incidence (27.7 per 100,000) was found in Molise Region.

Table 38. Number, prevalence and incidence of HIV infections per 100,000 donors at national and regional level (2023)

Region/AP	HIV infections		
	n.	prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	2	0.0	1.9
Liguria	2	15.7	0.0
Lombardy	14	5.7	4.5
AP of Trento	0	0.0	0.0
AP of Bolzano	1	0.0	6.4
Friuli-Venezia Giulia	2	0.0	5.3
Veneto	0	0.0	0.0
Emilia-Romagna	5	3.7	2.8
Tuscany	5	10.8	1.8
Umbria	0	0.0	0.0
Marche	3	11.1	4.3
Latium	5	7.5	1.1
Sardinia	3	0.0	7.5
Abruzzo	2	15.3	2.9
Campania	18	21.8	5.4
Molise	2	0.0	27.7
Apulia	3	3.9	2.1
Basilicata	1	22.7	0.0
Calabria	1	0.0	2.5
Sicily	5	2.8	3.1
Armed Forces	0	0.0	0.0
Italy	**74**	**7.6**	**2.9**

AP, Autonomous Province

Figure 25 shows the distribution, expressed as a percentage, of HIV positive donors by nationality; 15% of all positive donors were foreigners.

Table 39 shows the distribution of HIV positive donors by geographical area of birth.

In about 28% of the HIV positive donors (21/74), it was not possible to identify the risk factor; in the remaining 72%, who denied the risk factor or who believed that his/her behaviour was not at risk, the most frequently identified risk factor was “occasional exposure” (Figure 26).

Moreover, in most cases (65/74) the molecular (NAT), serological and confirmatory tests were positive.

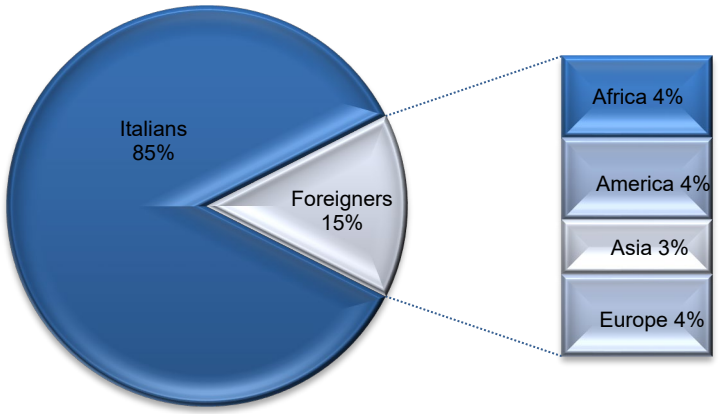

Figure 25. Distribution of HIV positive donors by nationality (%) (2023)

Table 39. HIV infections by geographical area of birth (2023)

Geographical area of birth	N. of infections
Africa	3
America	3
Asia	2
Europe	3
Italy	63
Total	**74**

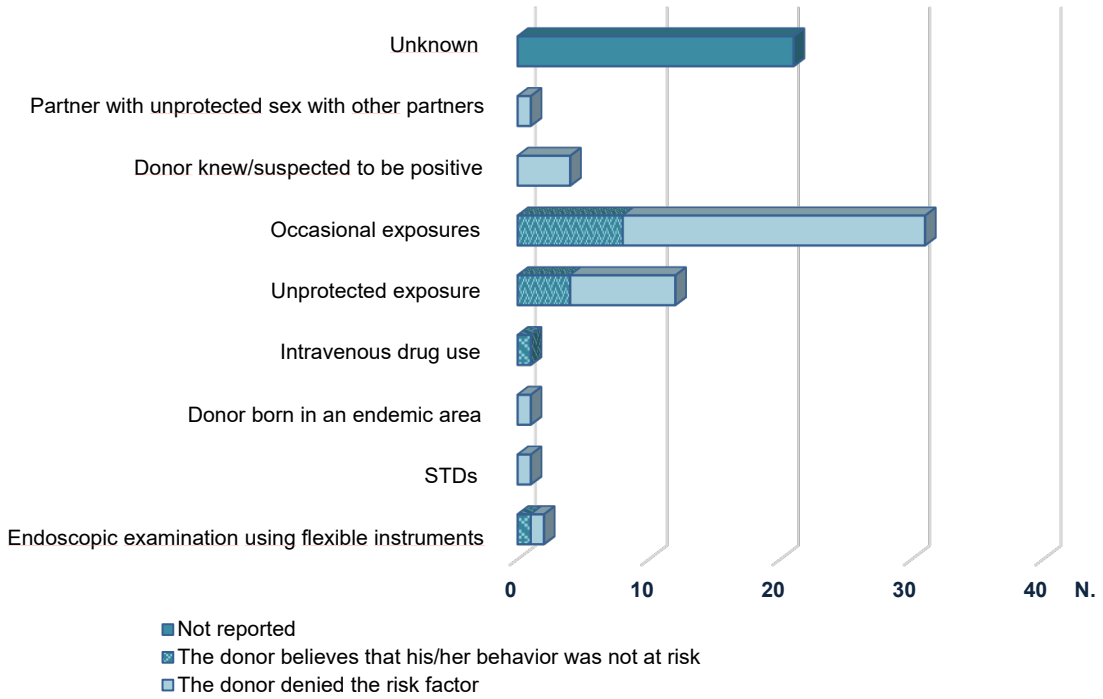

Figure 26. Causes of failed deferral and risk factors detected in HIV positive donors (2023)

HCV surveillance data

Table 40 reports the number of HCV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2023, 185 HCV infections were reported, with a prevalence of 40.0 infections per 100,000 FT donors and an incidence of 1.1 infections per 100,000 RT donors. The highest number of HCV infections was found in the Campania Region (85/185), which reported the highest value of prevalence (130.6). The highest value of incidence was found in the Molise Region (13.8).

Table 40. Number, prevalence and incidence of HCV infections per 100,000 donors at national and regional level (2023)

Region/AP	HCV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	16	69.9	1.9
Liguria	4	31.4	0.0
Lombardy	8	15.1	0.0
AP of Trento	0	0.0	0.0
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	4	25.1	2.7
Veneto	2	3.5	0.7
Emilia-Romagna	11	33.1	1.4
Tuscany	4	7.2	1.8
Umbria	1	14.1	0.0
Marche	5	55.5	0.0
Latium	12	20.7	1.1
Sardinia	3	11.6	2.5
Abruzzo	0	0.0	0.0
Campania	85	130.6	1.4
Molise	1	0.0	13.8
Apulia	17	62.4	1.0
Basilicata	3	45.5	6.8
Calabria	2	22.3	0.0
Sicily	7	14.2	1.5
Armed Forces	0	0.0	0.0
Italy	**185**	**40.0**	**1.1**

AP, Autonomous Province

Table 41 shows the distribution of HCV positive donors by geographical area of birth.

Table 41. HCV infections by geographical area of birth (2023)

Geographical area of birth	N. of infections
Africa	6
Asia	11
Europe	38
Italy	130
Total	**185**

Figure 27 shows the distribution, expressed as a percentage, of HCV positive donors by nationality; 30% of all positive donors were foreigners.

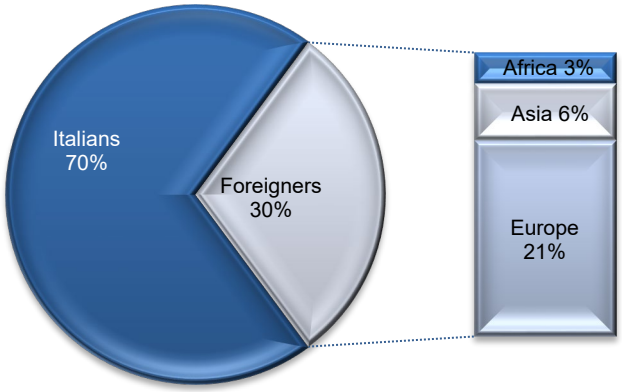

Figure 27. HCV positive donors by nationality (%) (2023)

In about 64% of HCV positive donors (119/185), it was not possible to identify the risk factor; in the remaining 36%, who denied the risk factor or who believed that his/her behaviour was not at risk or wanted to be tested, the most frequently identified risk factor was "Unprotected" and "occasional" exposure (Figure 28).

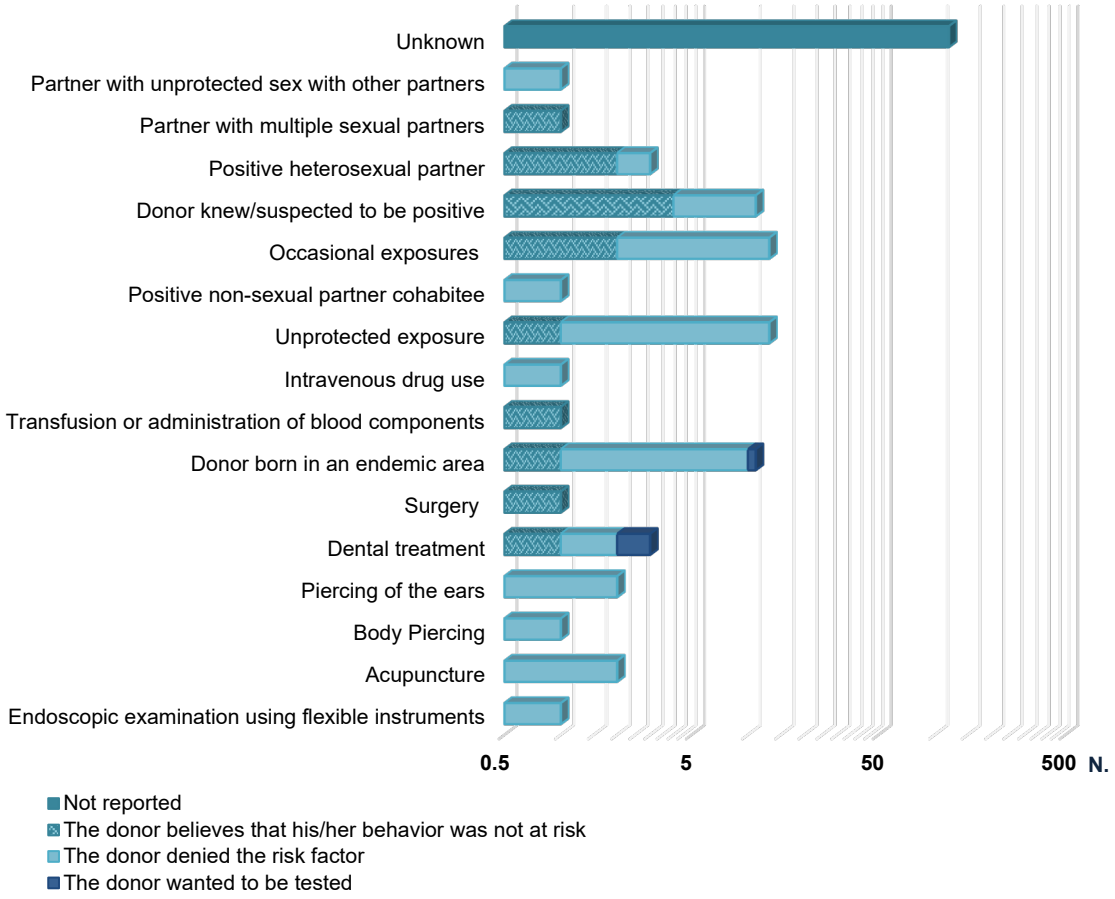

Figure 28. Causes of failed deferral and risk factors detected in HCV positive donors (values reported on a logarithmic scale) (2023)

In most cases (77/185), the molecular test (NAT) was negative with a positive serological screening and confirmatory tests.

HBV surveillance data

Table 42 reports the number of HBV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2023, 440 HBV infections were reported with a prevalence of 67.7 infections per 100.000 FT donors and an incidence of 10.4 infections per 100.000 RT donors. The highest number of HBV infections was found in the Campania Region (150/440). The Region with the highest prevalence was Campania (192.8). The Region with the highest incidence was Apulia (48.7).

Table 42. Number. prevalence and incidence of HBV infections per 100.000 donors at national and regional level (2023)

Region/AP	HBV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	15	44.9	5.7
Liguria	9	23.6	15.7
Lombardy	38	39.7	6.9
AP of Trento	4	28.0	15.4
AP of Bolzano	1	53.4	0.0
Friuli Venezia Giulia	7	50.3	2.7
Veneto	6	13.8	1.3
Emilia-Romagna	35	80.9	9.0
Tuscany	13	43.0	0.9
Umbria	5	70.7	0.0
Marche	5	44.4	2.1
Latium	36	54.6	7.4
Sardinia	12	40.4	12.6
Abruzzo	3	45.8	0.0
Campania	150	192.8	35.1
Molise	2	78.2	0.0
Apulia	73	101.4	48.7
Basilicata	0	0.0	0.0
Calabria	9	22.3	17.7
Sicily	17	14.2	9.2
Armed Forces	0	0.0	0.0
Italy	**440**	**67.7**	**10.4**

AP, Autonomous Province

Table 43 reports the distribution of HBV positive donors by geographical area of birth.

Table 43. HBV infections by geographical area of birth (2023)

Geographical area of birth	N. of infections
Africa	31
Asia	14
Europe	93
Italy	302
Total	**440**

Figure 29 shows the distribution expressed as a percentage of HBV positive donors by nationality; 31% of all positive donors were foreigners.

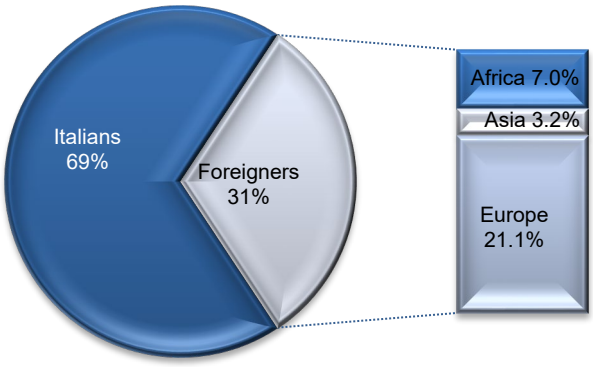

Figure 29. HBV positive donors by nationality (%) (2023)

In about 62% of the HBV positive donors (272/440), it was not possible to identify the risk factor; in the remaining 38%, who denied the risk factor or who believed that his/her behaviour was not at risk or wanted to be tested, the most frequently identified risk factors were "donor born in an endemic area" and "unprotected exposure" (Figure 30). In 167/440 cases the infection was detected exclusively by NAT test (NAT only).

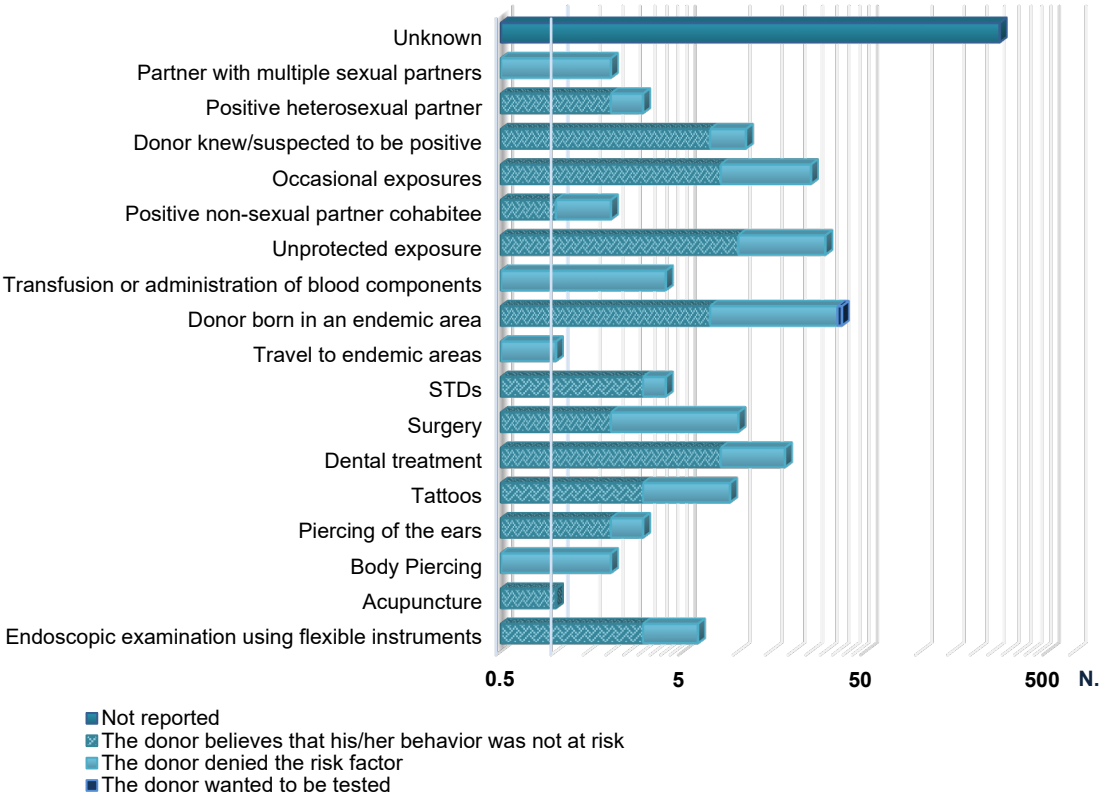

Figure 30. Causes of failed deferral and risk factors detected in HBV positive donors (values reported on a logarithmic scale) (2023)

TP surveillance data

Table 44 reports the number of TP positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2023, 632 TP infections were reported with a prevalence of 95.4 infections per 100,000 FT donors and an incidence of 15.5 infections per 100,000 RT donors. The highest number of TP infections was found in the Latium Region (136/632). The Region with the highest prevalence was Campania (183.5); the highest incidence was found in Sicily Region (30.6).

Table 44. Number. prevalence and incidence of TP infections per 100.000 donors at national and regional level (2023)

Region/AP	TP infections		
	n.	prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	31	54.9	18.9
Liguria	18	109.9	10.5
Lombardy	70	69.9	13.4
AP of Trento	5	55.9	15.4
AP of Bolzano	2	53.4	6.4
Friuli Venezia Giulia	8	33.5	10.6
Veneto	11	24.1	2.7
Emilia-Romagna	30	84.6	4.8
Tuscany	39	82.5	14.0
Umbria	4	14.1	13.1
Marche	20	110.9	21.4
Latium	81	116.6	20.0
Sardinia	25	98.2	20.1
Abruzzo	13	122.2	14.7
Campania	136	183.5	24.3
Molise	1	0.0	13.8
Apulia	63	148.1	25.9
Basilicata	3	0.0	20.3
Calabria	10	55.8	12.7
Sicily	62	62.4	30.6
Armed Forces	0	0.0	0.0
Italy	**632**	**95.4**	**15.5**

AP, Autonomous Provinces

Table 45 shows the distribution of TP positive donors by geographical area of birth.

Table 45. Number of TP infections by geographical area of birth (2023)

Geographical area of birth	N. of infections
Africa	25
America	16
Asia	10
Europe	76
Italy	505
Total	**632**

Figure 31 shows the distribution, expressed as a percentage, of the TP positive donors by nationality; 19% of all positive donors were foreigners.

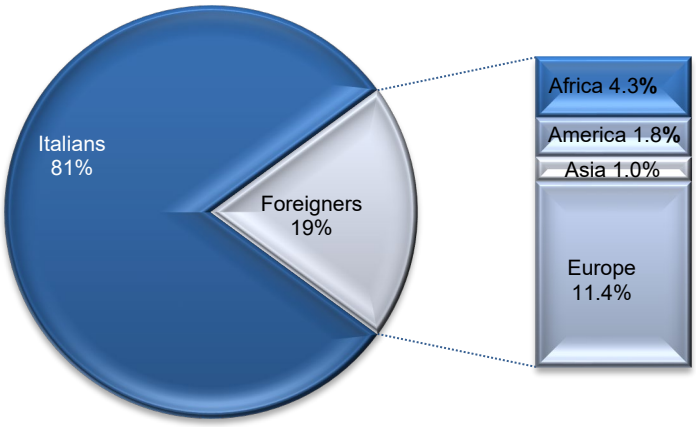

Figure 31. Distribution of TP positive donors by nationality (%) (2023)

In about 48% of the TP positive donors (301/632), it was not possible to identify the risk factor. In the remaining 53%, who denied the risk factor or who believed that his/her behaviour was not at risk or wanted to be tested, the most frequently identified risk factors were "occasional exposures" and "unprotected exposure" (Figure 32).

In all the reported cases, both serological tests (screening and confirmatory) were positive.

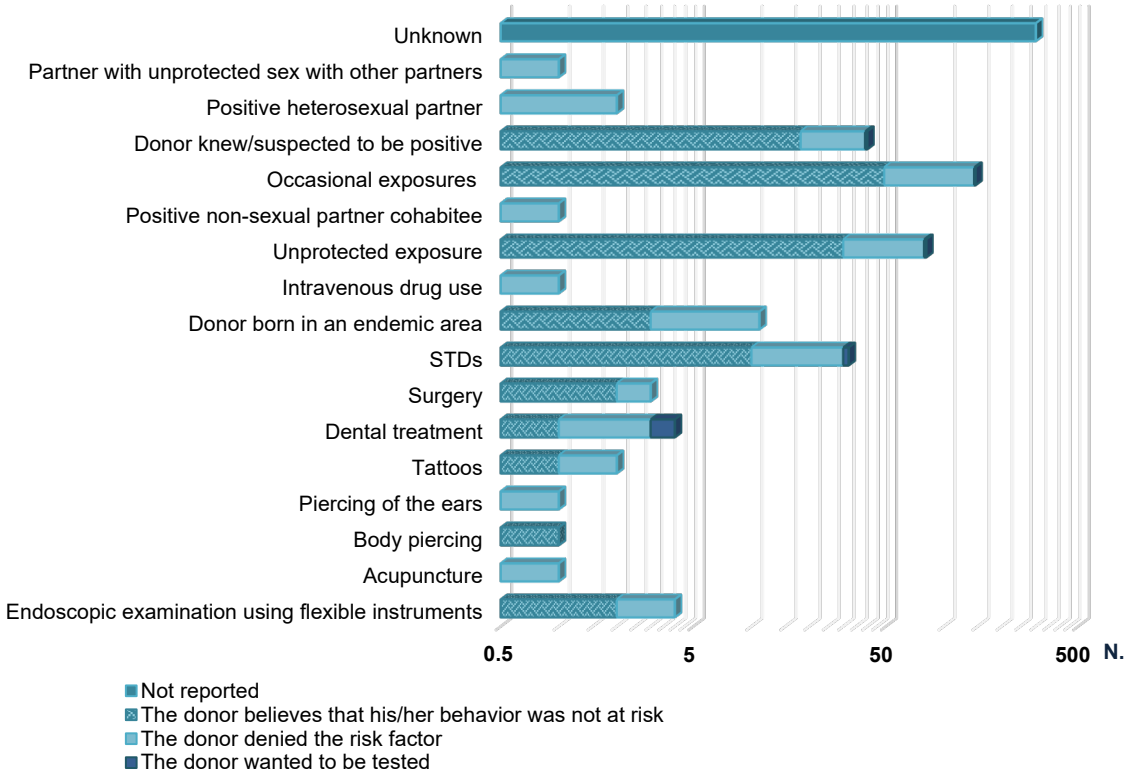

Figure 32. Causes of failed deferral and risk factors detected in TP positive donors (values reported on a logarithmic scale) (2023)

Coinfections

In this paragraph, the authors want to provide more accurate epidemiological data on notified coinfection in blood donors in year 2023.

Figure 33 shows the number of coinfected donors by gender and type of coinfection diagnosed; 17/20 coinfections included TP. The majority of the coinfected donors were males (14/20). In particular, about 50% of the coinfection cases was diagnosed in male donors in the 36-45 and 46-55 age classes (Figure 34).

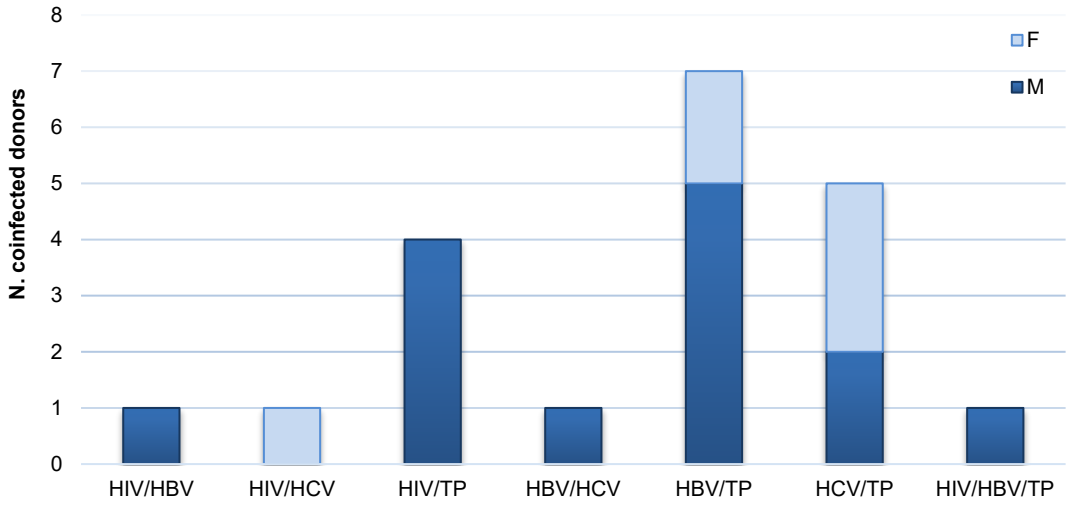

Figure 33. Number of coinfected donors by type of coinfection and by gender (2023)

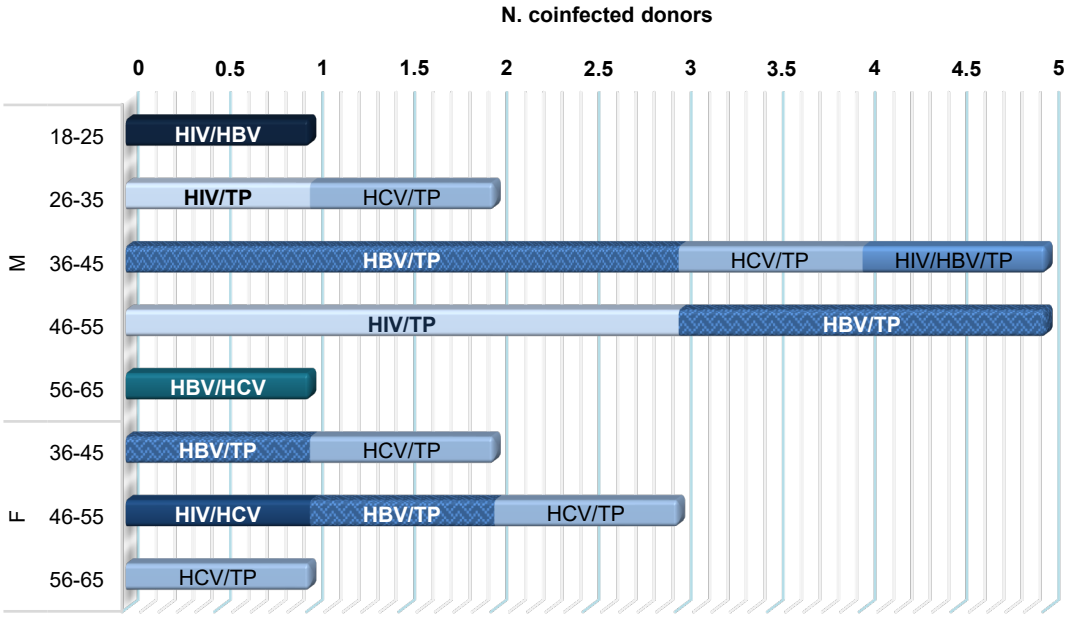

Figure 34. Number of coinfected donors by type of coinfection, age class and gender (2023)

For 12/20 of coinfected donors, it was not possible to trace the reasons for missed deferral and the risk factors are not known. For 6 cases of coinfection, the risk factors were identified and were generally due to high-risk sexual behaviours; in the remaining 2 cases, the risk factor identified was “Donor born in endemic areas” (Figure 35).

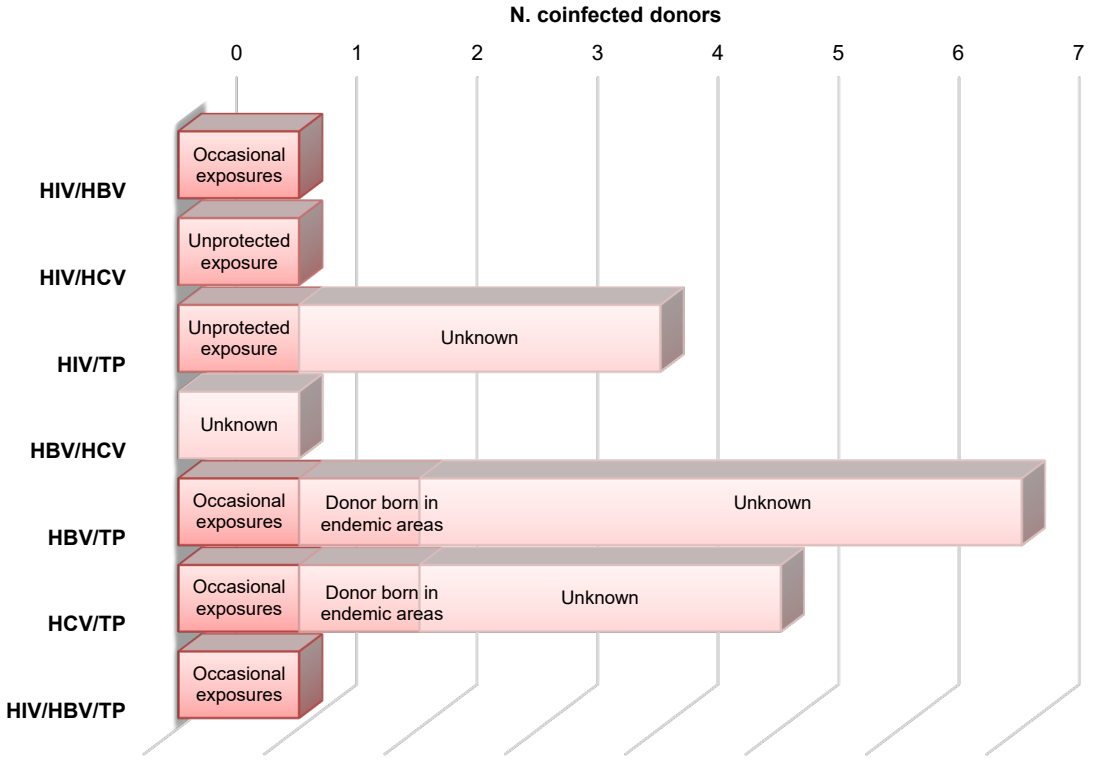

Figure 35. Number of coinfected donors by type of coinfection and risk factor (2023)

Comments and recommendations

The detection of positive blood donors through SISTRA allows to calculate the incidence and prevalence of transmissible infections on an annual basis, as well as to both monitor the trends and assess the risk with the aim to guarantee the blood donation safety.

As in the previous years, a considerable regional variability in the total number of positive donors is still present in 2023 with the highest numbers in Campania, Apulia, Latium and Lombardy Regions.

The majority of donors who turned out to be positive to infectious markers was males (72%) and FT (67%). The highest number of positives are distributed among the 36-45 and 46-55 age classes.

About 76% of the positive donors were Italian, while the remaining 24% were foreigners. Most foreign donors belonged to the FT category and came from other European countries. However, it is not possible to make further epidemiological assessments as the total number of foreign donors donating in the year is not known.

National data show the highest values of incidence (15.5) and prevalence (95.4) for TP infection in blood donor population.

Regarding hepatitis viruses (HBV and HCV), chronic infections are more frequent in blood donors compared to those detected in the general population by the national epidemiological system, which mainly reports acute symptomatic infections.

In 2023, a slight increase in HBV cases was reported in the general population in Italy compared to 2022 (incidence 0.29 per 100,000 inhabitants). Emilia-Romagna, Lombardy and Tuscany reported the highest number of cases. The most affected are the subjects aged between 35 and 54 years. While the highest number of acute HCVs was reported in the Latium, Lombardy and Emilia-Romagna Regions (incidence 0.1 per 100,000 inhabitants); 96.5% of cases are older than 34 years (15).

For HBV and HCV infections, a slight decrease in the incidence trend has been observed in recent years. This downward trend is certainly justified by the introduction, in the 90s, of the mandatory HBV vaccination to all subjects born since 1979, and by the introduction, for the treatment of HCV, of new direct-acting anti-viral therapies.

Compared to general population, blood donors' population recorded in 2023 higher rates of HBV incidence and prevalence in the Southern Italian Regions (respectively Apulia and Campania), with 38% NAT-only infections. On the other hand, HCV new infections are more frequent in Molise Region and the highest prevalence was registered in Campania Region.

According to national data, HBV and HCV infections in blood donors are more frequent in over 36-year age classes, with a peak at 46-55 age class for HCV and 56-65 age class for HBV. For both infections, more than 60% of cases did not state the risk factor.

The distribution of HIV positivity in blood donors is higher in 36-46 age classes. The peak for TP positivity is recorded in the 46-55 age class. For HIV infections, about 28% of risk factors are not stated; for TP infection, in about 48% of the positive donors it was not possible to identify the risk factor. For both infections, the most commonly reported risk factors were sexual risk behaviors. These data correspond to the findings in the general population: in 2022, the highest incidence of HIV infection was observed in 30-39 age class; diagnosis of syphilis I-II and latent syphilis were more frequent in subjects aged 45 years or older (16-17). As in the general population, in recent years, an increase in the incidence of TP infection was observed also in blood donors (17).

In 2022, the HIV geographical distribution in the general population showed the highest incidence in Latium Region followed by Tuscany, Abruzzo and Campania Regions (16). The blood donor population shows, in 2023, a higher incidence in Molise Region, followed by Sardinia.

The analysis of coinfections showed that 17/20 coinfected donors were TP positive.

As in the previous years, many coinfected and monoinfected donors did not declare any risk factor. This phenomenon indicates a probable criticality in the collection of post-donation information. In order to optimise and standardise the collection of post-donation information, homogeneous counselling techniques across the country are recommended to make communication with donors more effective.

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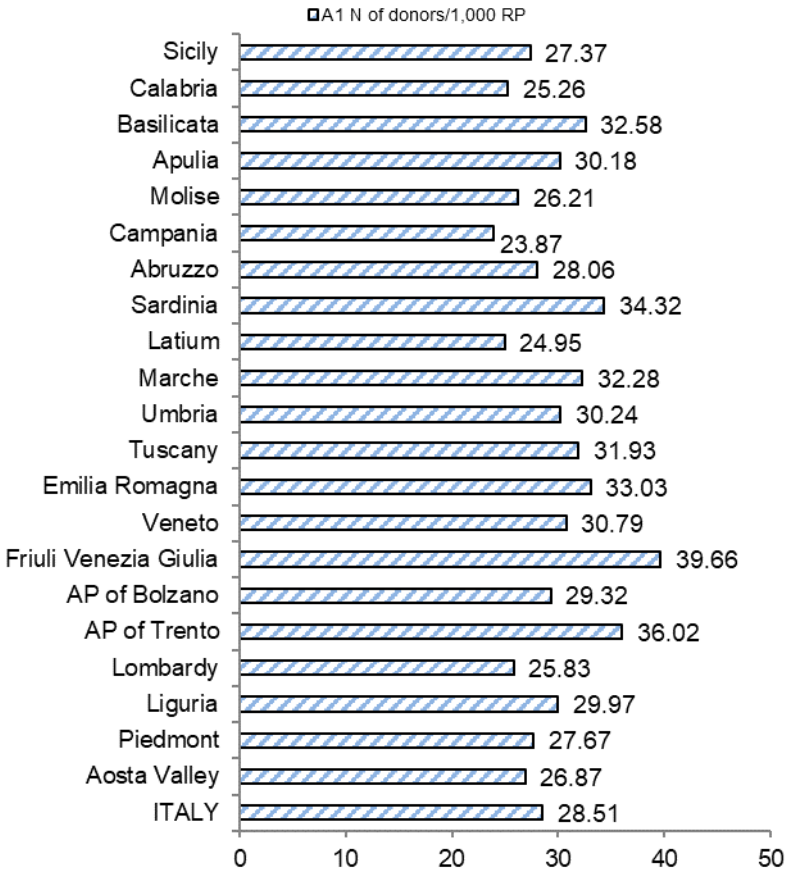
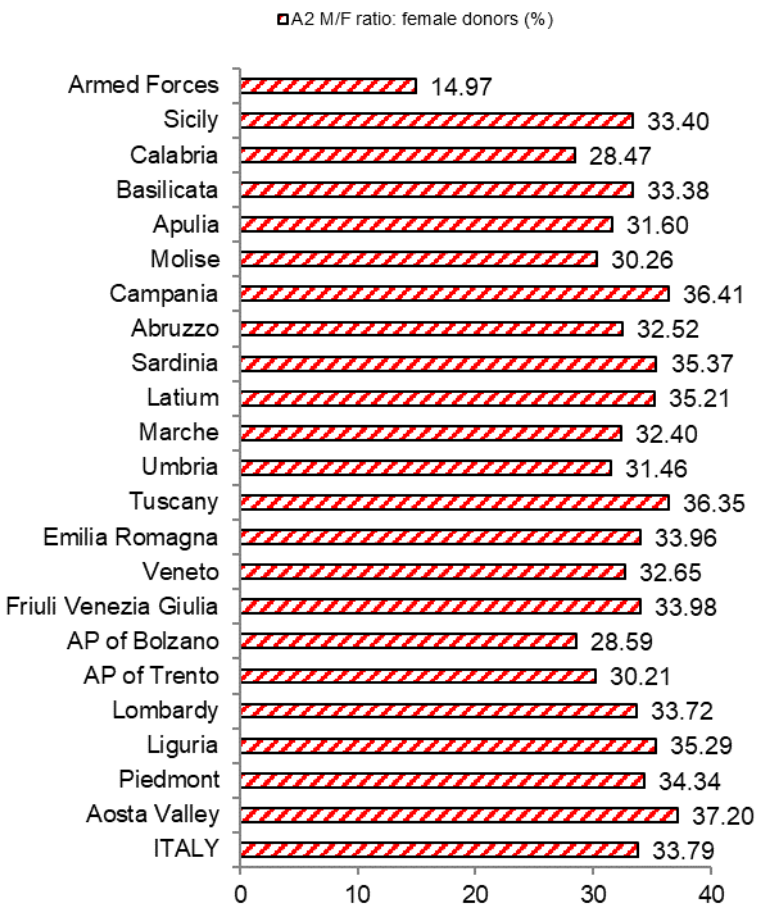
APPENDIX A
Regional and national indicators 2023



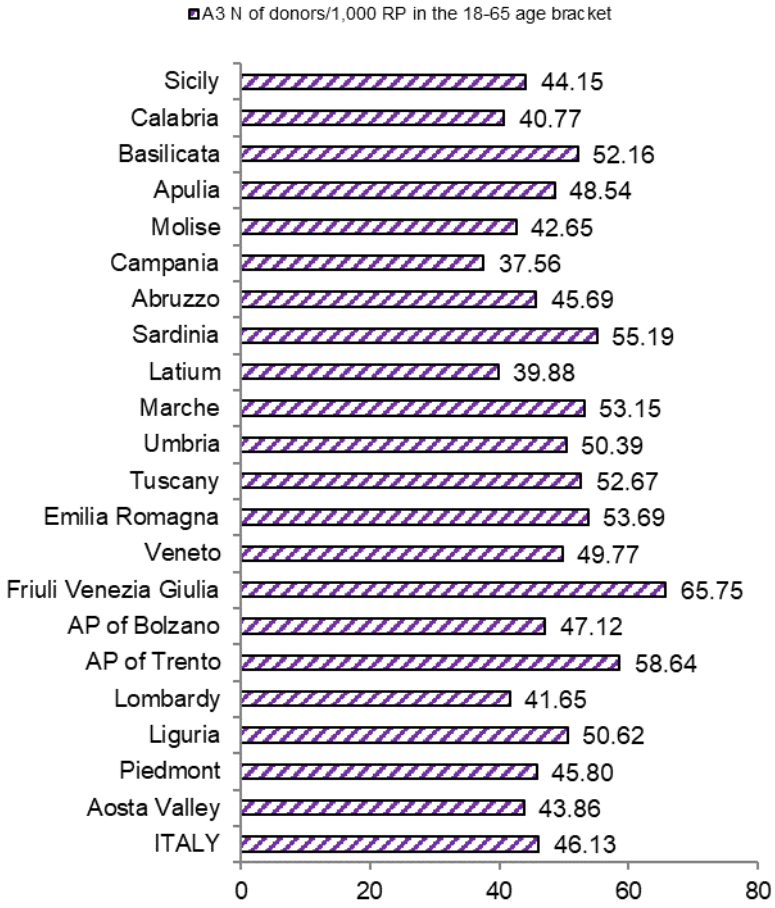
N. number; RP resident population; AP Autonomous Province

Figure A1. INDICATOR A1: Regional blood donors' distribution/1,000 resident population (2023)



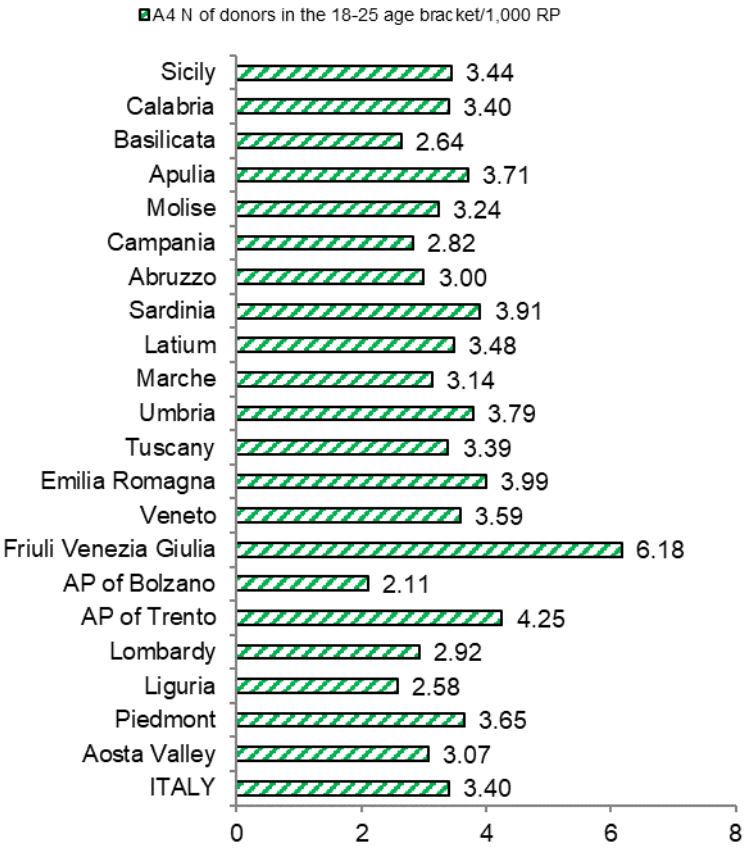
AP Autonomous Province; M male; F Female

Figure A2. INDICATOR A2: M/F ratio, female donors' percentage (2023)



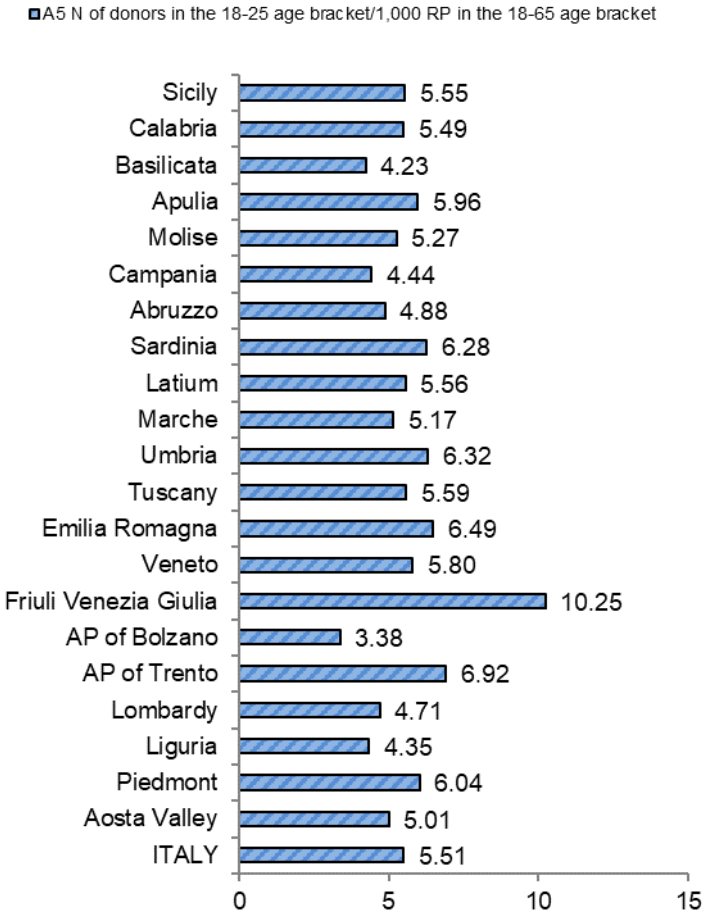
N. number; RP resident population; AP Autonomous Province

Figure A3. INDICATOR A3: N. of donors/1,000 resident population in the 18-65 age class (2023)



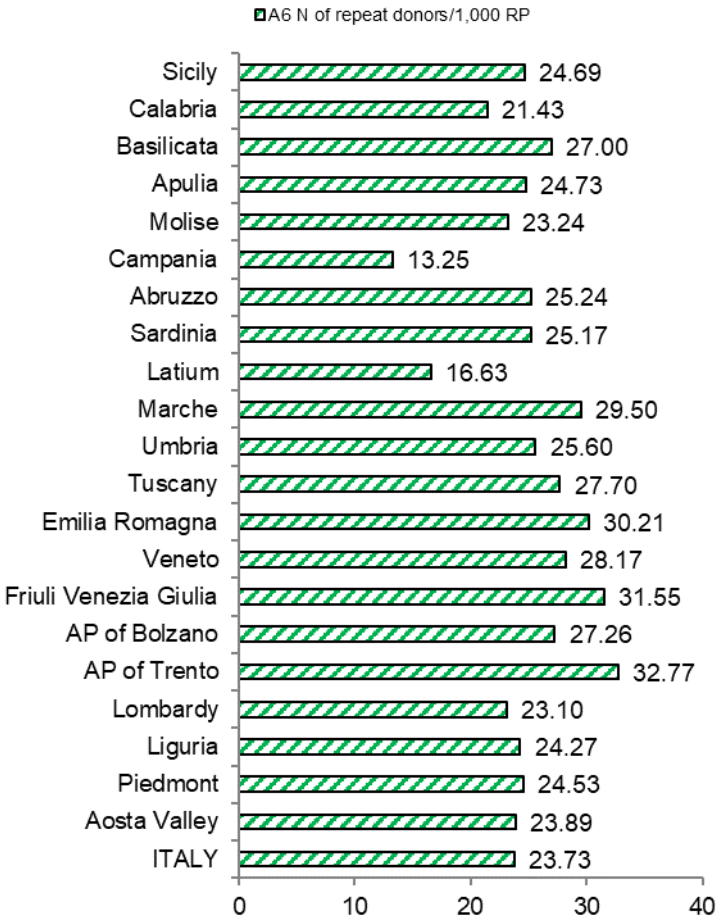
N. number; RP resident population; AP Autonomous Province

Figure A4. INDICATOR A4: N. of donors in the 18-25 age class/1,000 resident population (2023)



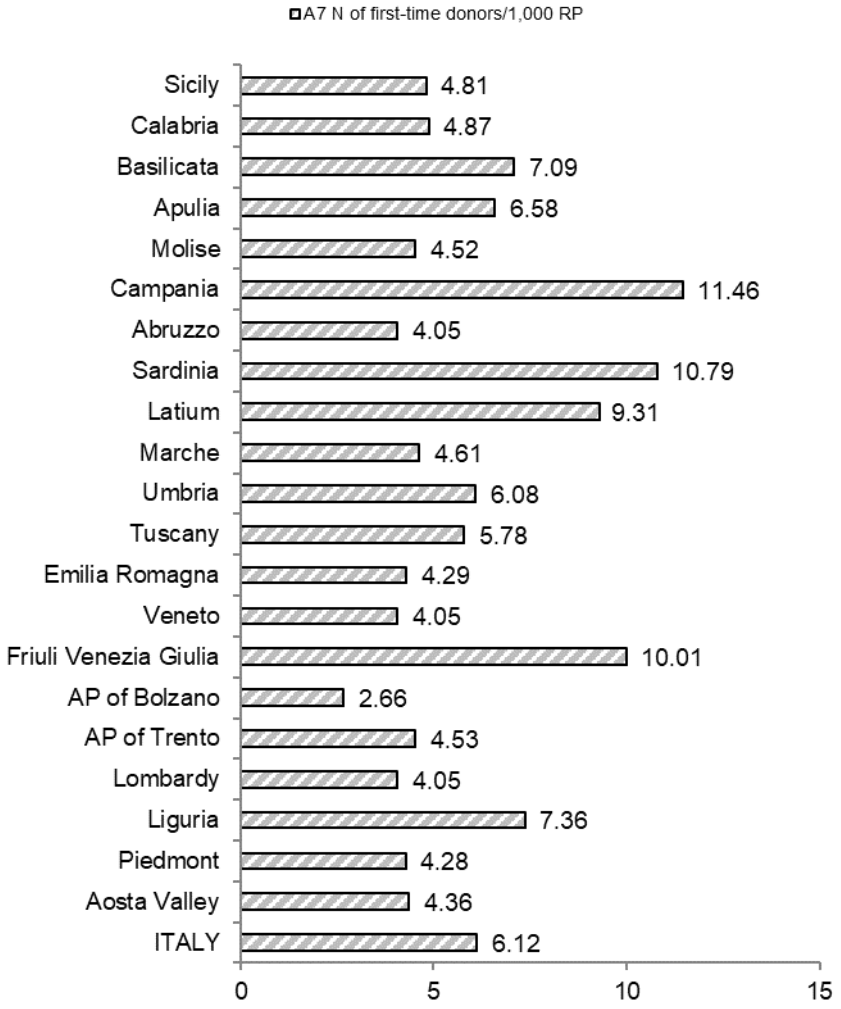
N. number; RP resident population; AP Autonomous Province

Figure A5. INDICATOR A5: N. of donors in the 18-25 age class/1,000 resident population in the 18-65 age class (2023)



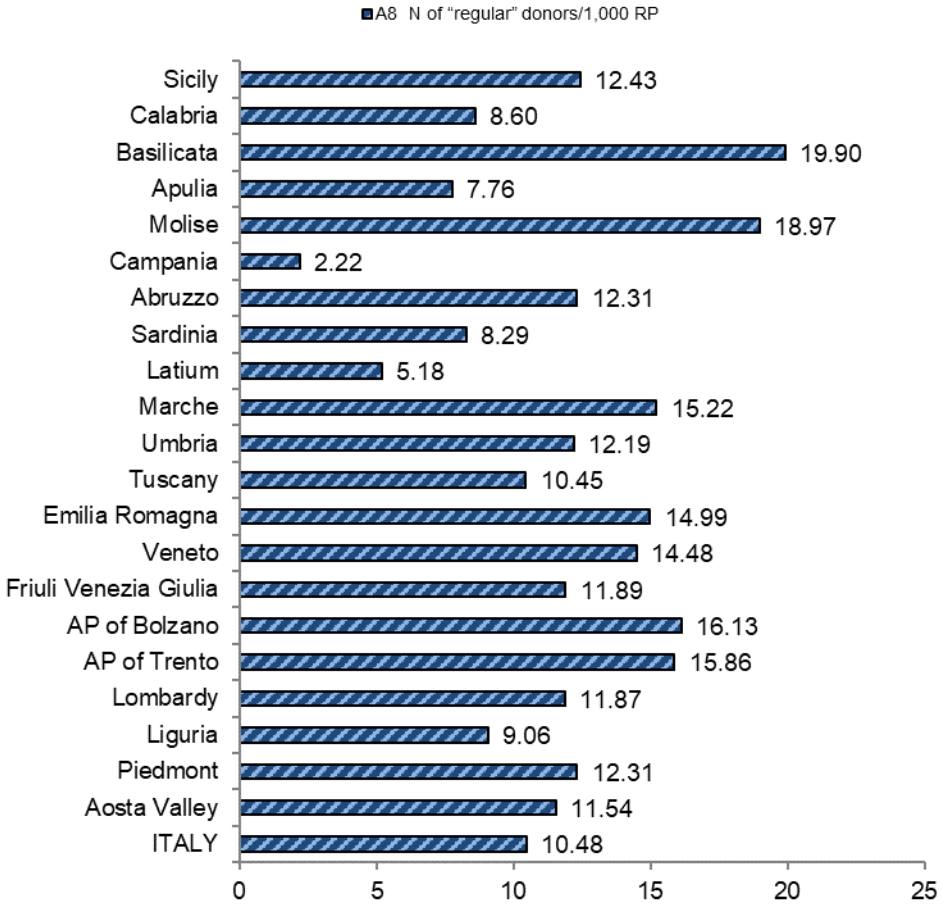
N. number; RP resident population; AP Autonomous Province

Figure A6. INDICATOR A6: N. of repeat donors/1,000 resident population (2023)



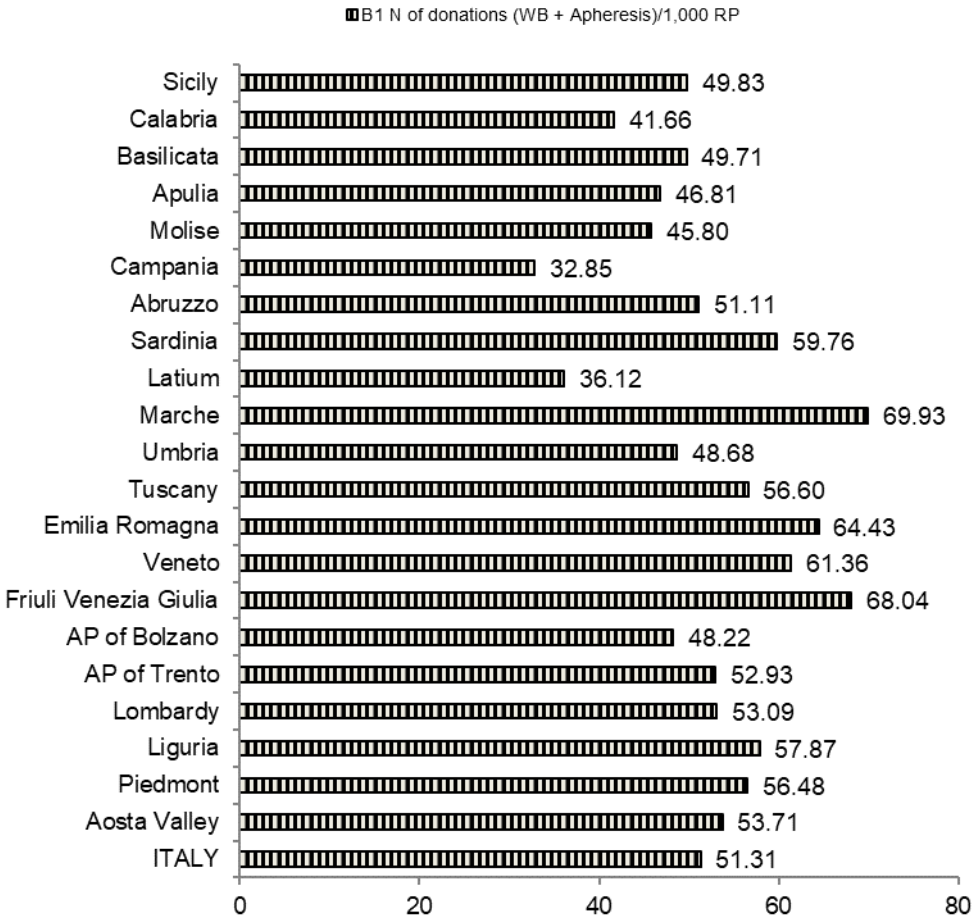
N. number; RP resident population; AP Autonomous Province

Figure A7. INDICATOR A7: N. of first-time donors/1,000 resident population (2023)



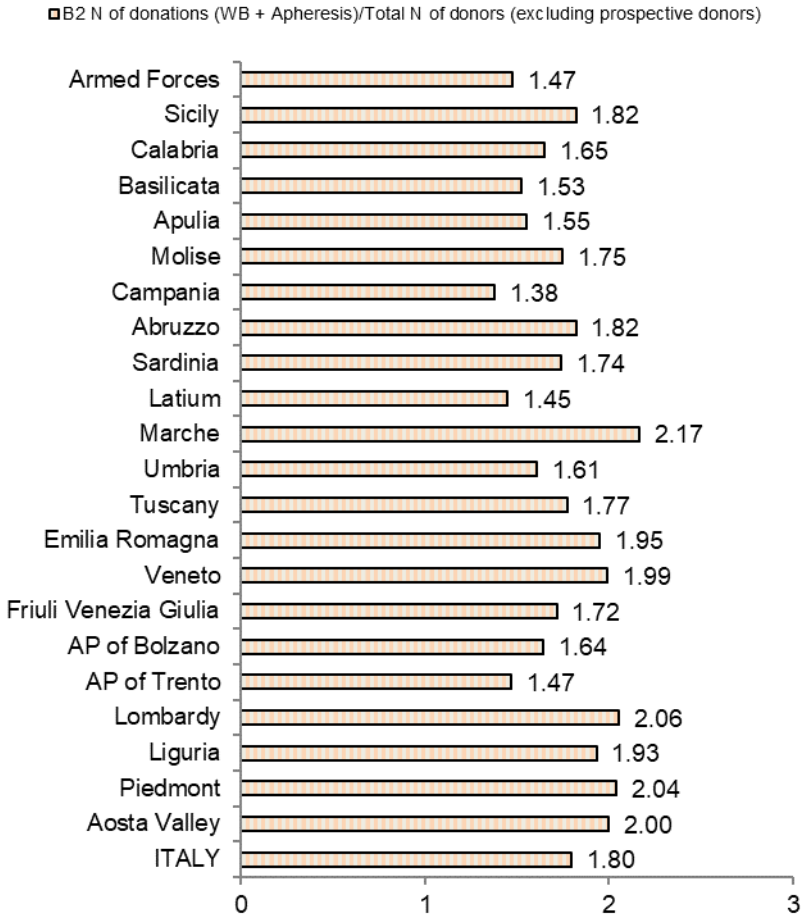
N. number; RP resident population; AP Autonomous Province

Figure A8. INDICATOR A8: N. of "regular" donors/1,000 resident population (2023



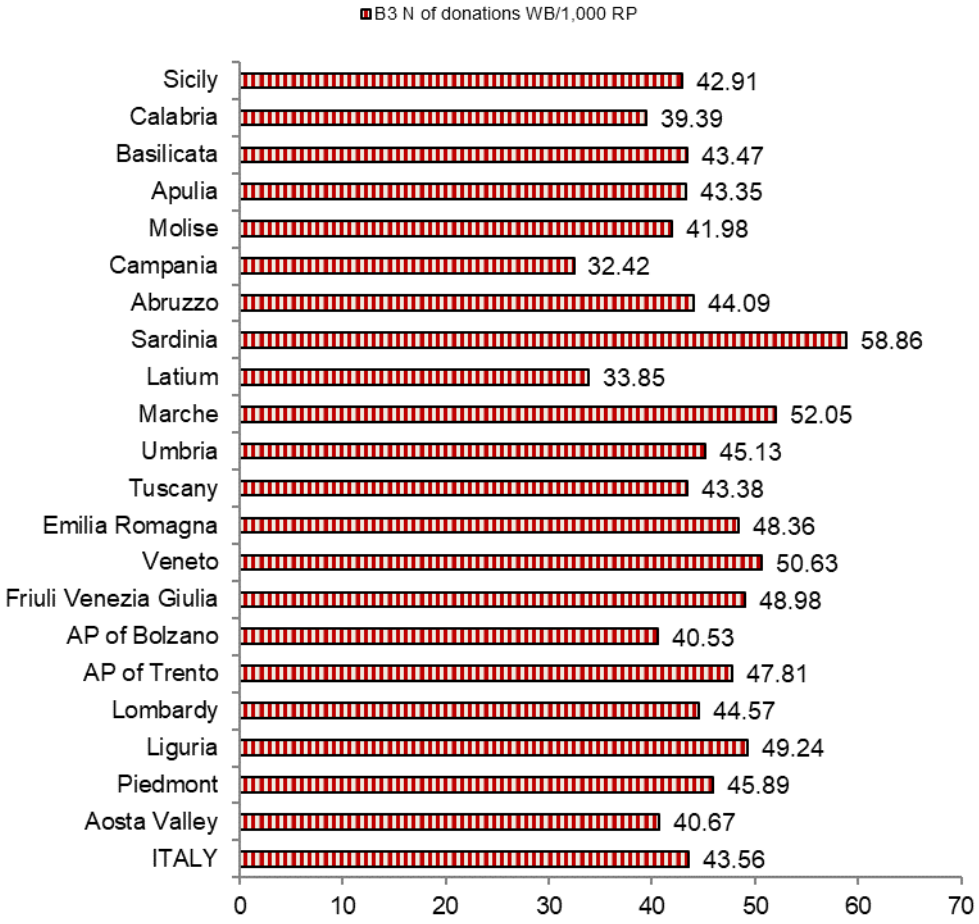
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A9. INDICATOR B1: N. of whole blood and apheresis donations/1,000 resident population (2023)



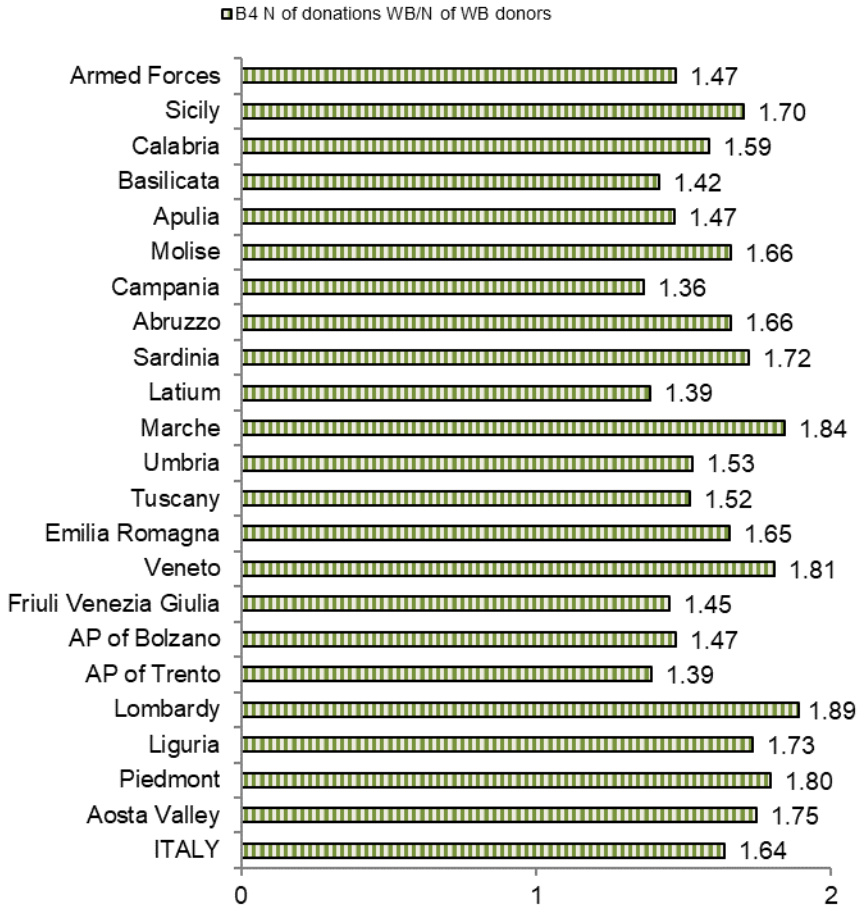
N. number; AP Autonomous Province; WB whole blood

Figure A10. INDICATOR B2: N. of whole blood and apheresis donations/Total N. of donors (excluding prospective donors) (2023)



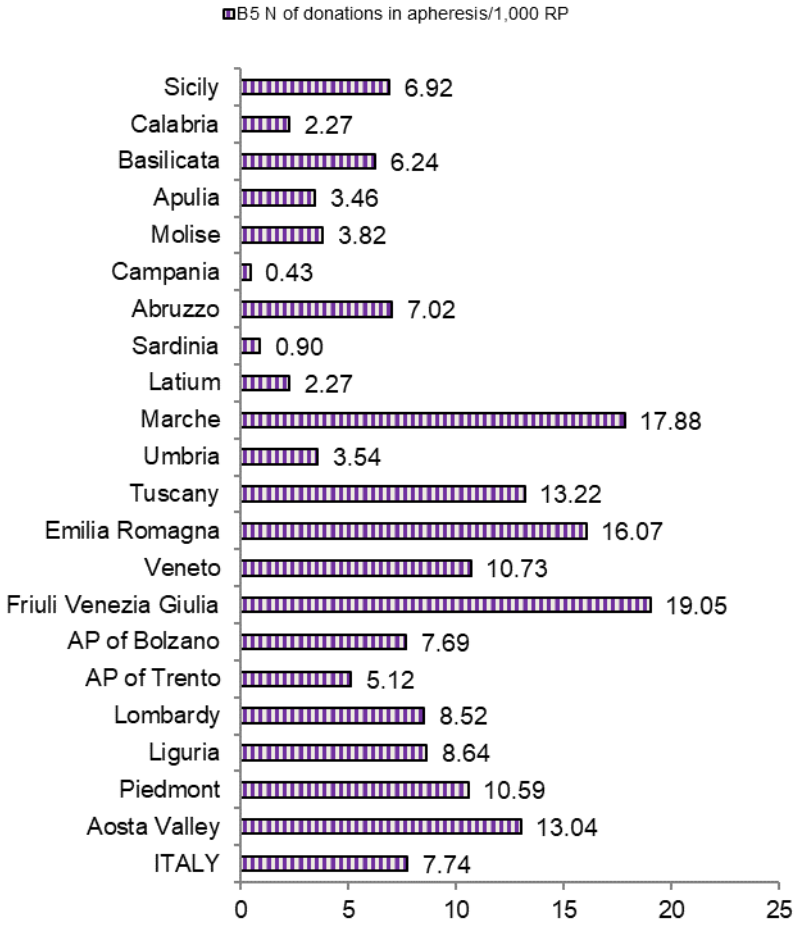
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A11. INDICATOR B3: N. of whole blood donations/1,000 resident population (2023)



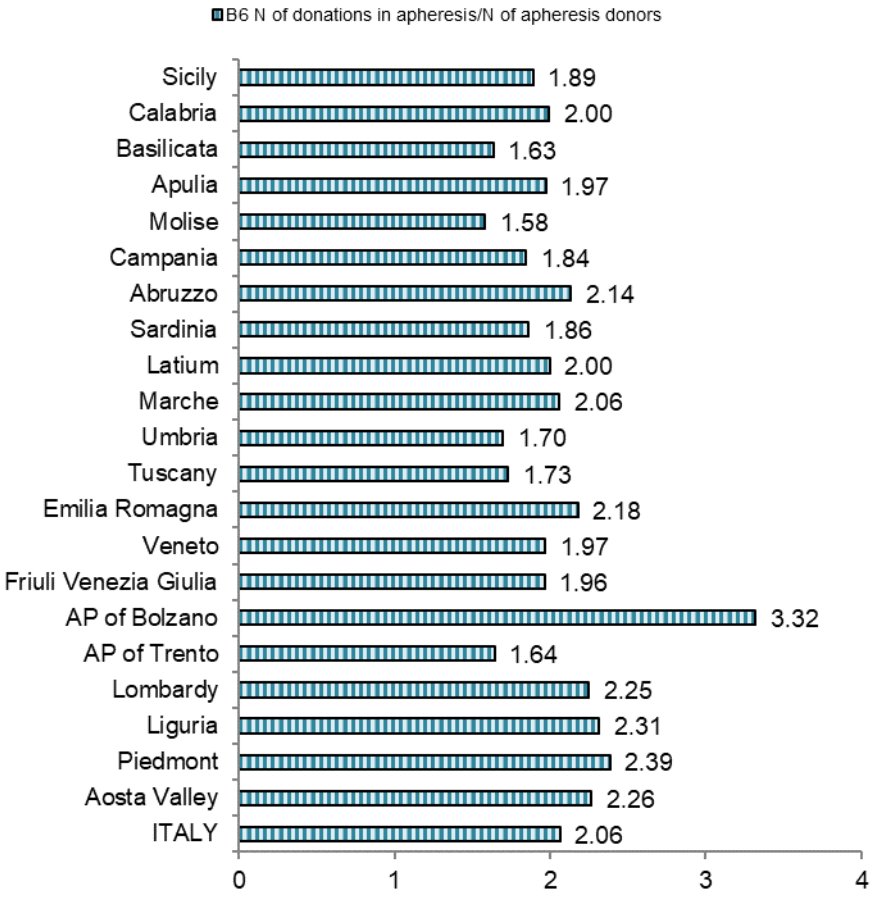
N. number; AP Autonomous Province; WB whole blood

Figure A12. INDICATOR B4: N. of whole blood donations/N. of whole blood donors (2023)



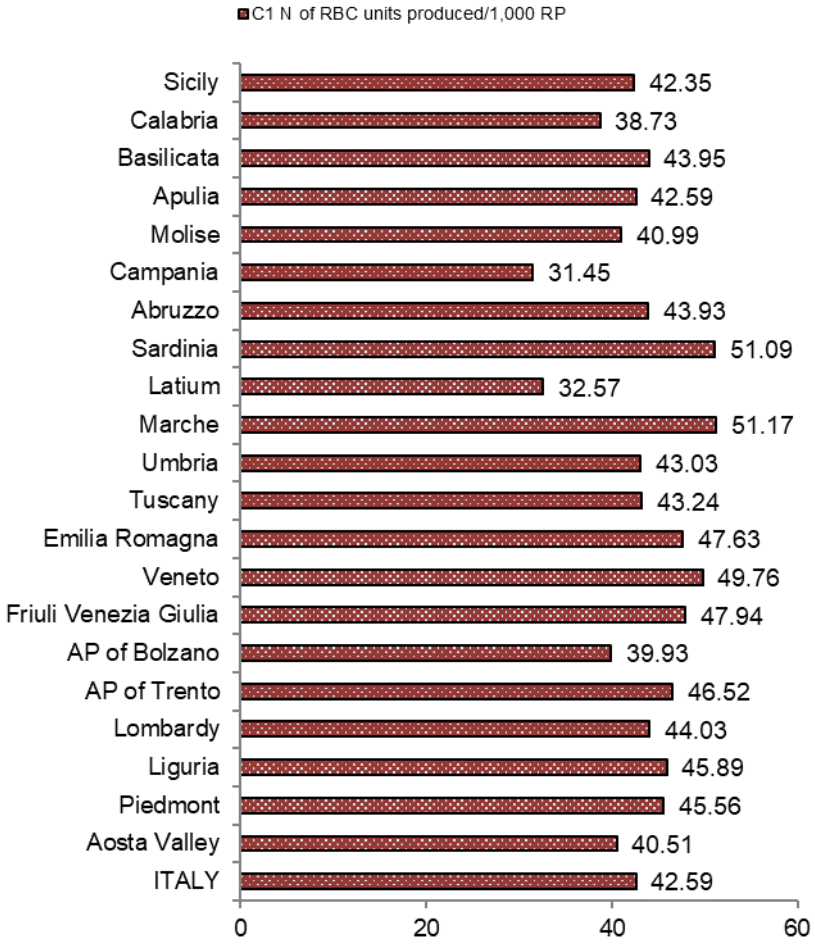
N. number; RP resident population; AP Autonomous Province

Figure A13. INDICATOR B5: N. of donations in apheresis/1,000 resident population (2023)



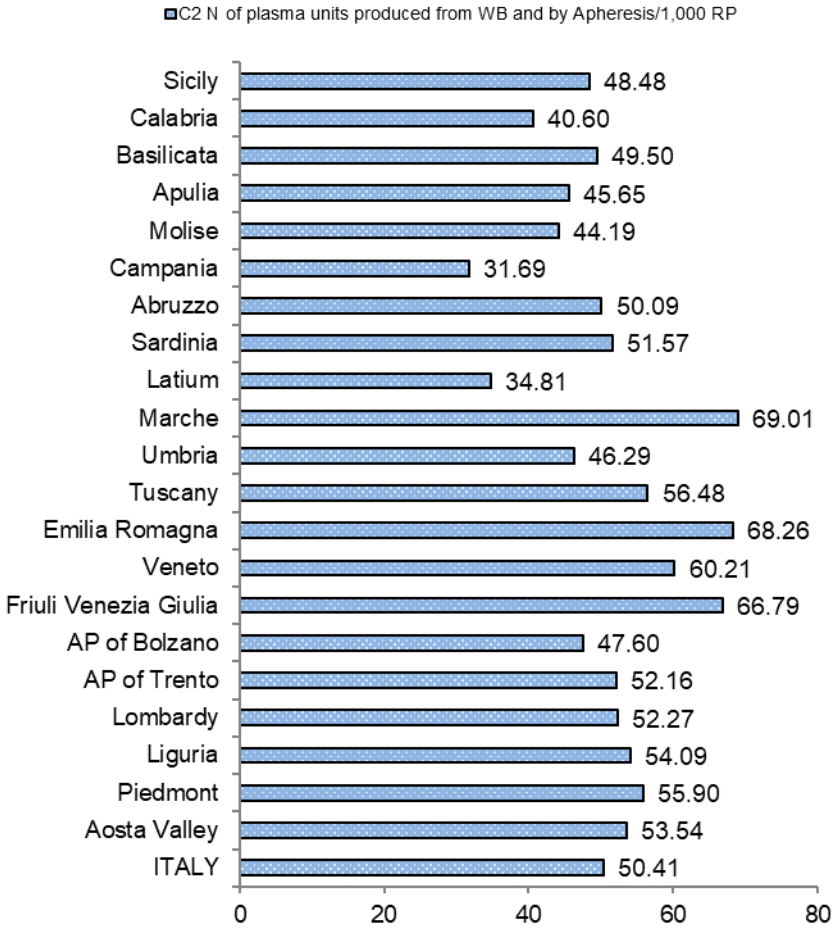
N. number; AP Autonomous Province

Figure A14. INDICATOR B6: N. of apheresis donations/N. of apheresis donors (2023)



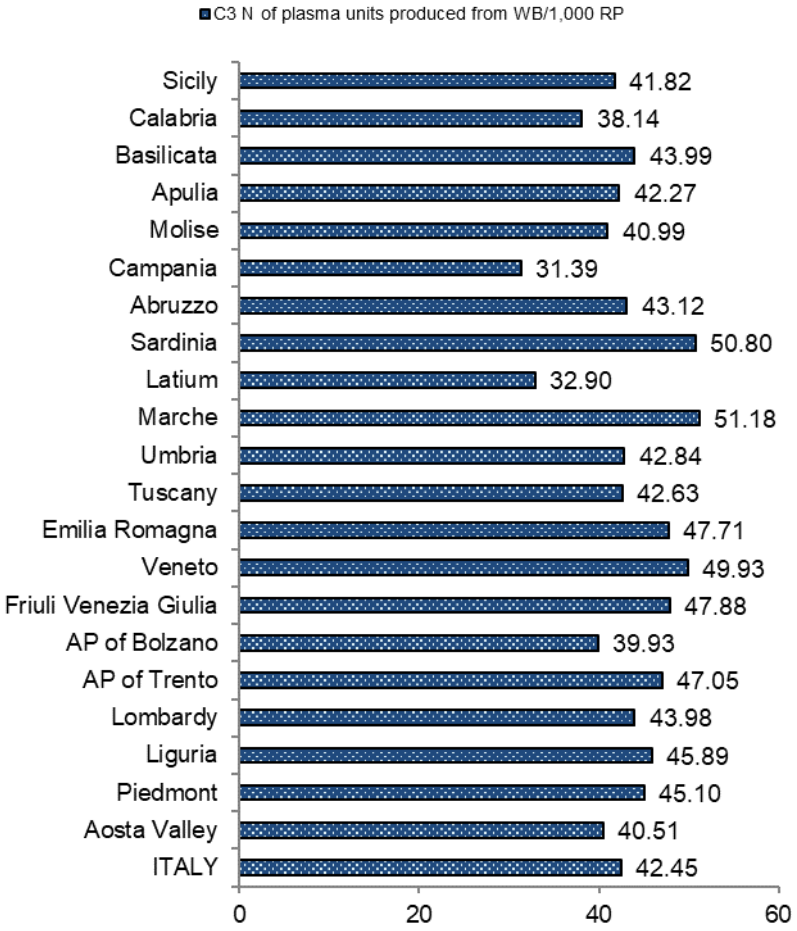
N. number; RP resident population; AP Autonomous Province

Figure A15. INDICATOR C1: RBC units produced/1,000 resident population (2023)



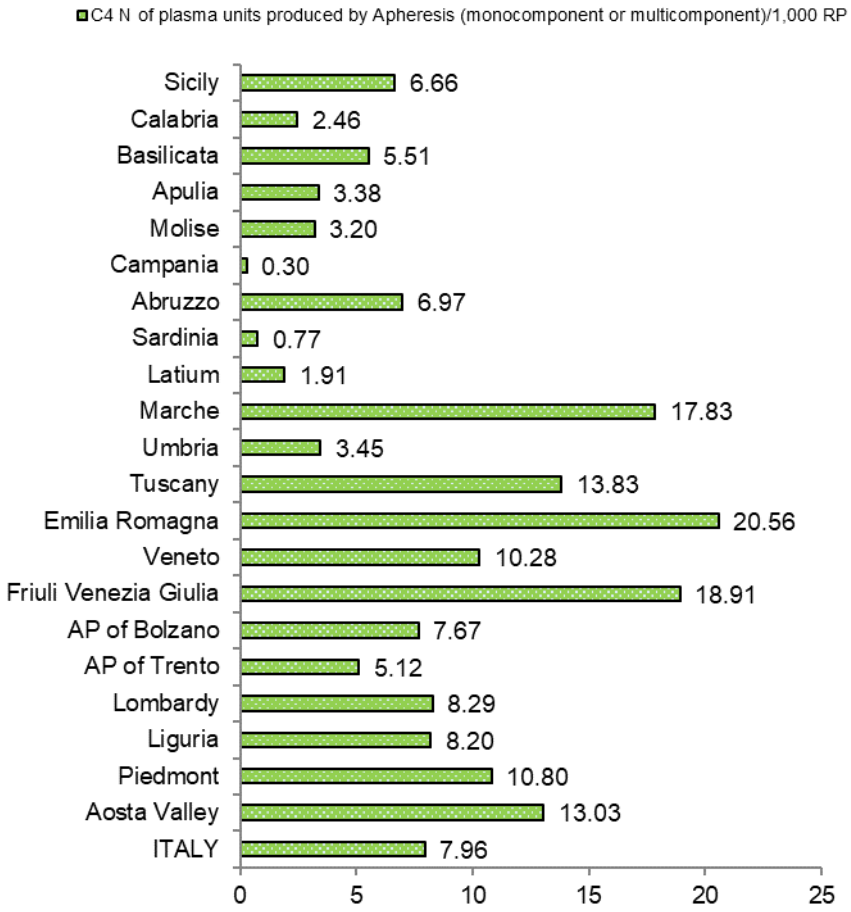
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A16. INDICATOR C2: N. of plasma units produced from whole blood and by apheresis/1,000 resident population (2023)



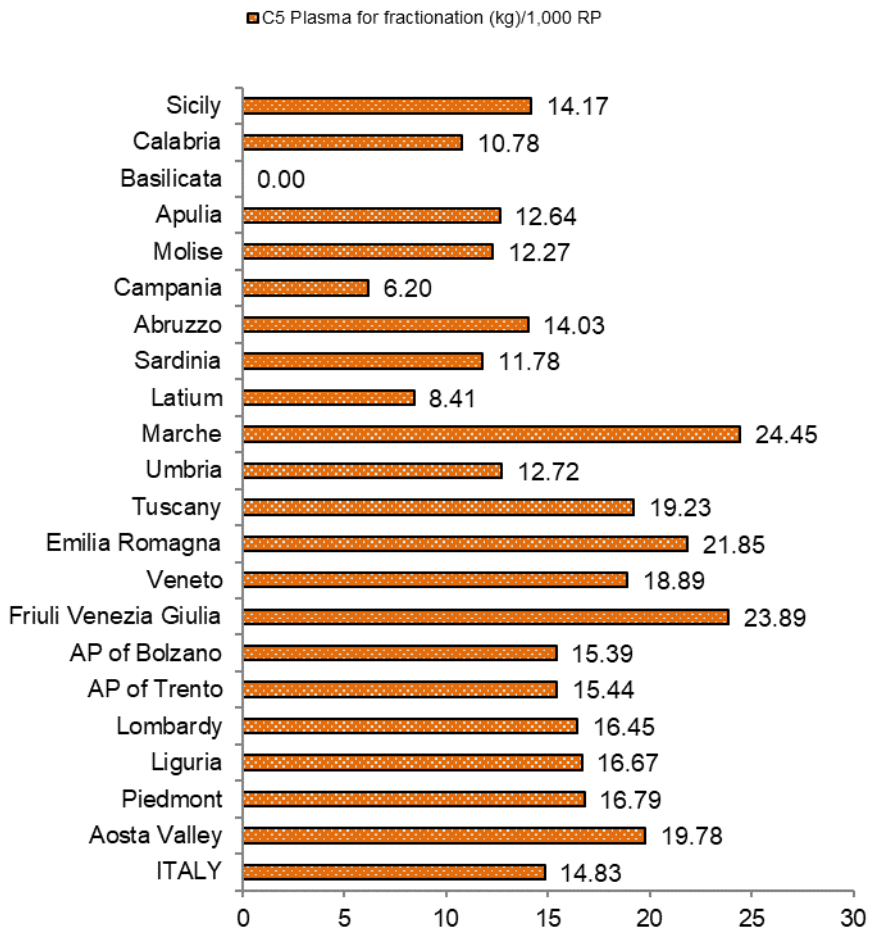
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A17. INDICATOR C3: N. of plasma units produced from whole blood/1,000 resident population (2023)



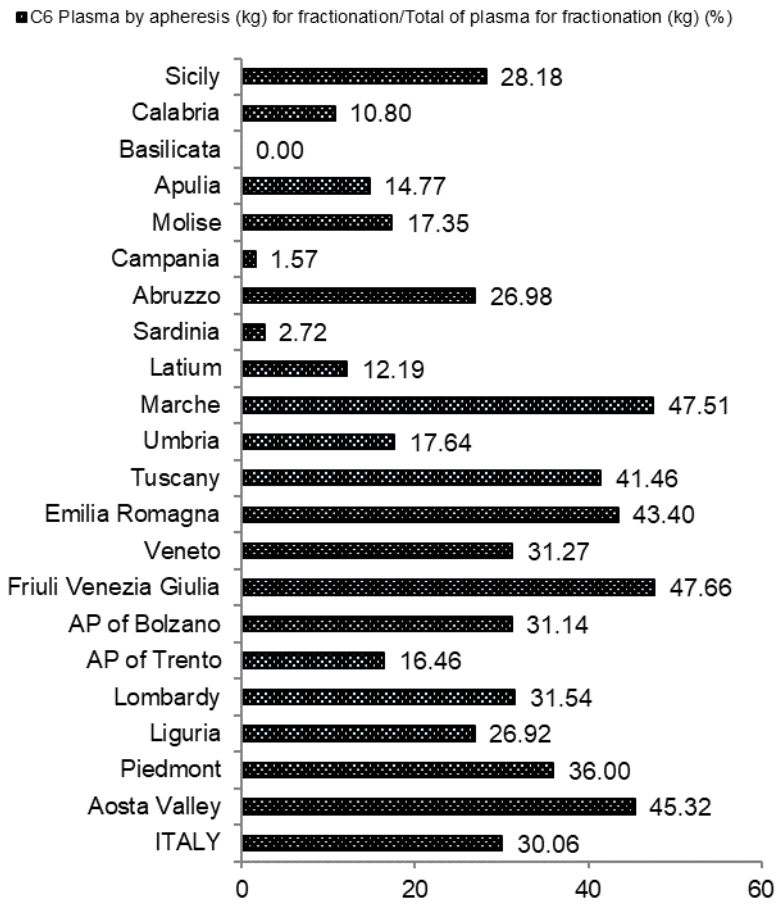
N. number; RP resident population; AP Autonomous Province

Figure A18. INDICATOR C4: N. of plasma units produced from apheresis (monocomponent + multicomponent)/1,000 resident population (2023)



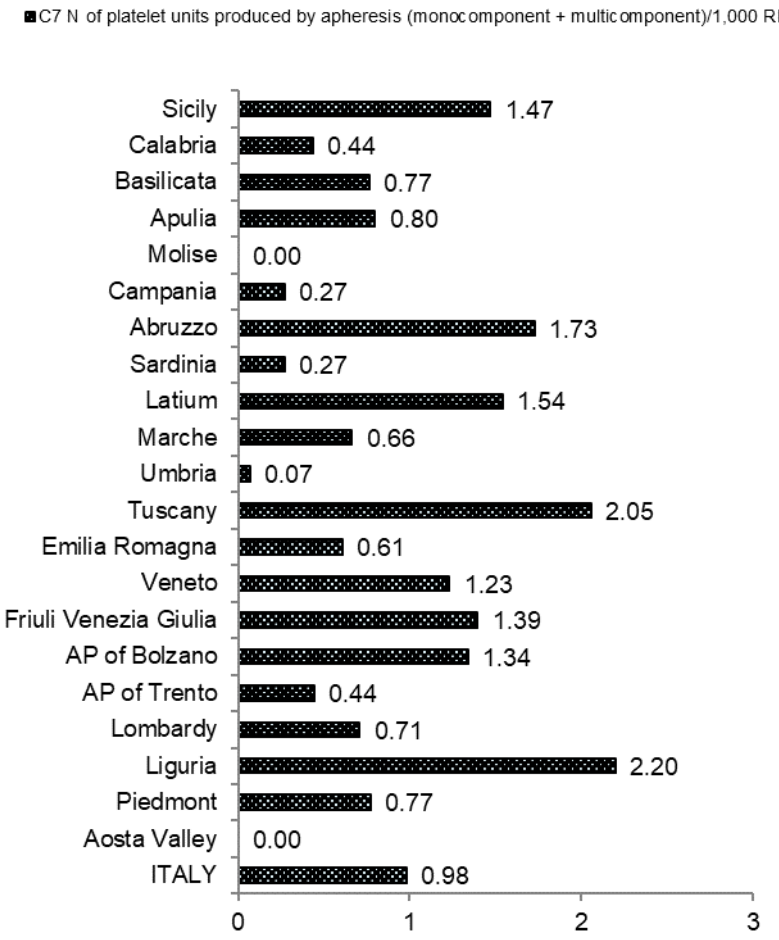
kg kilograms; RP resident population; AP Autonomous Province

Figure A19. INDICATOR C5: plasma (kg) for fractionation/1,000 resident population (from SISTRA) (2023)



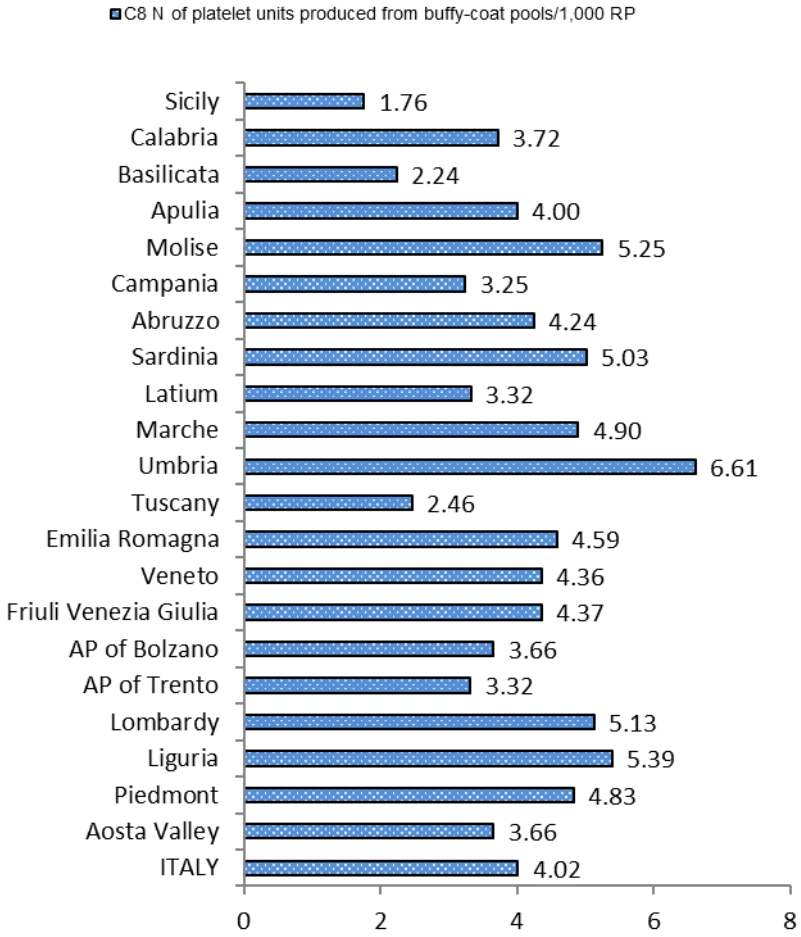
kg kilograms; AP Autonomous Province

Figure A20. INDICATOR C6: plasma by apheresis (kg) for fractionation/total of plasma for fractionation (kg) (%) (2023)



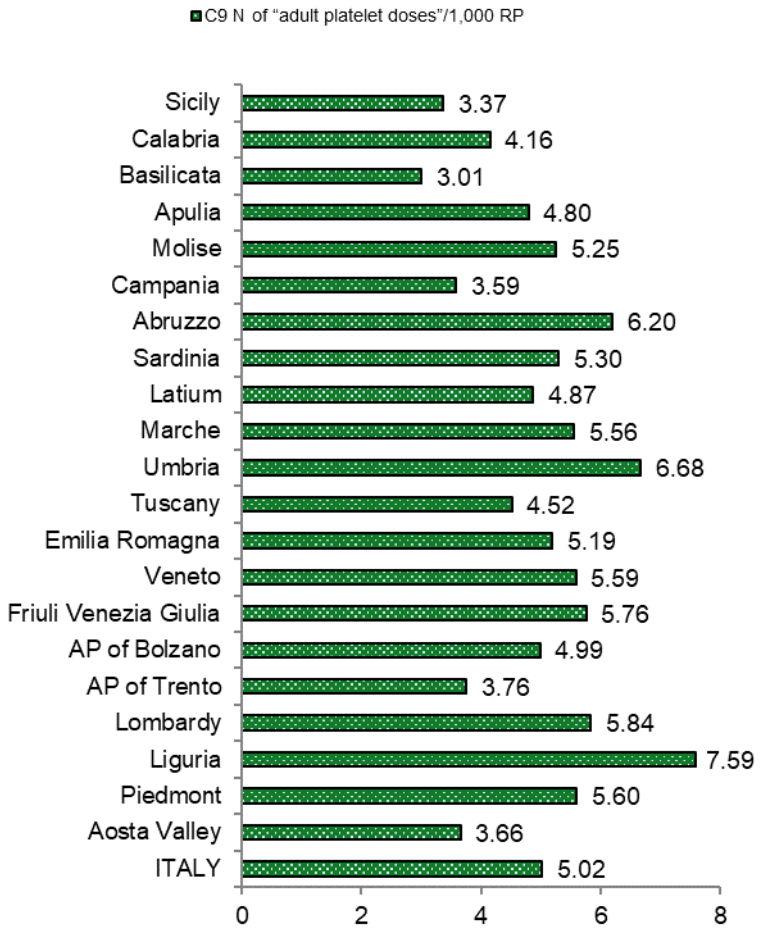
N. number; RP resident population; AP Autonomous Province

Figure A21. INDICATOR C7: N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 resident population (2023)



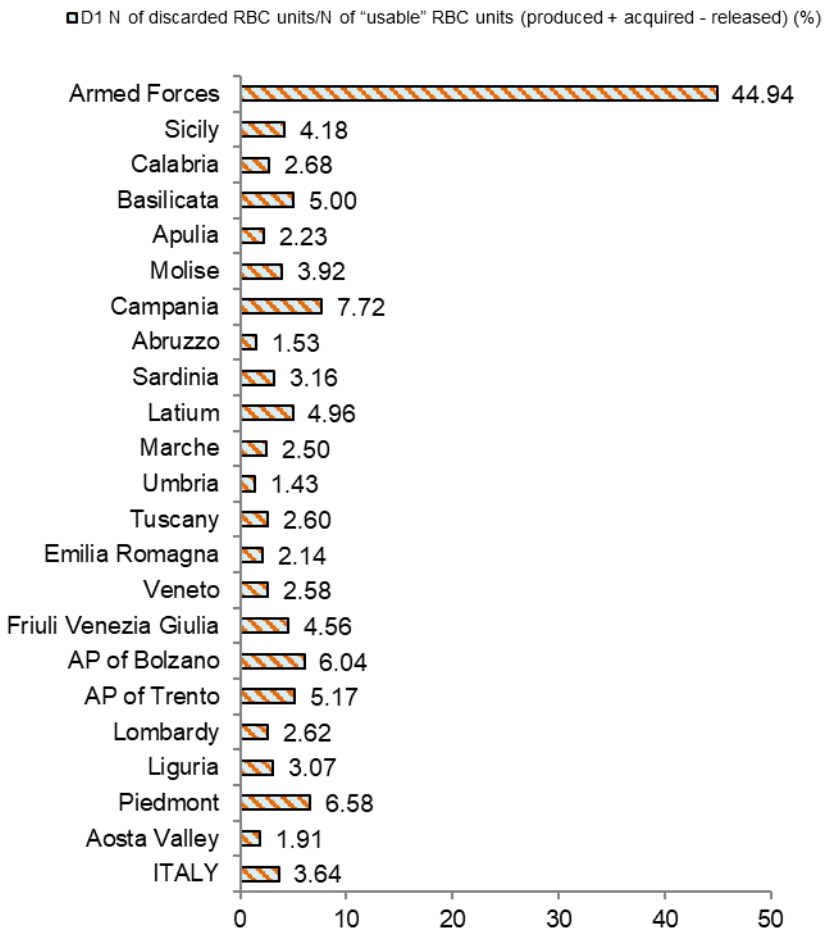
N. number; RP resident population; AP Autonomous Province

Figure A22. INDICATOR C8: N. of platelet units produced from buffy-coat pools/1,000 resident population (2023)



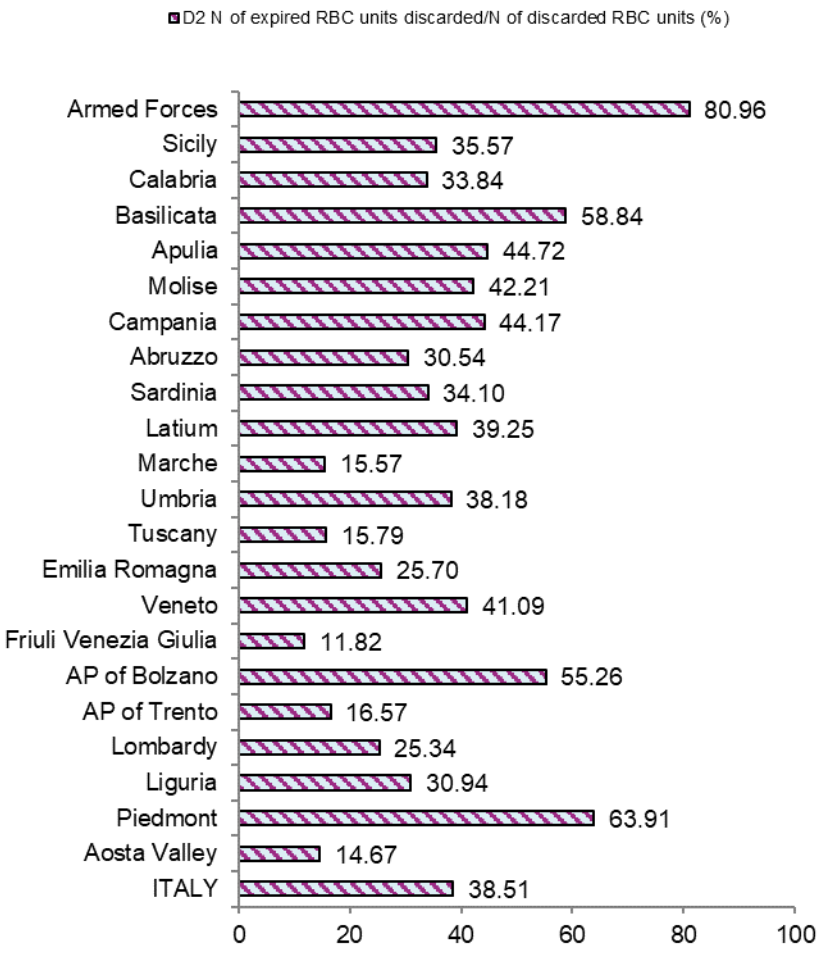
N. number; RP resident population; AP Autonomous Province

Figure A23. INDICATOR C9: N. of "adult platelet doses"/1,000 resident population (2023)



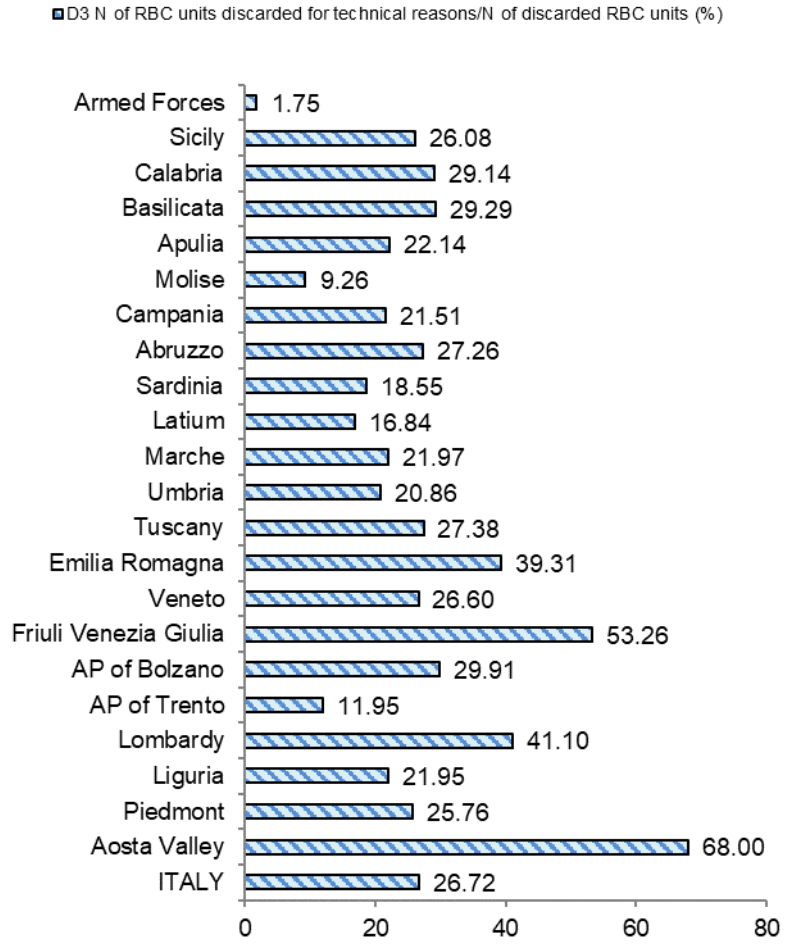
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A24. INDICATOR D1: N. of discarded RBC units/N. of "usable" RBC units (produced + acquired- released) (%) (2023)



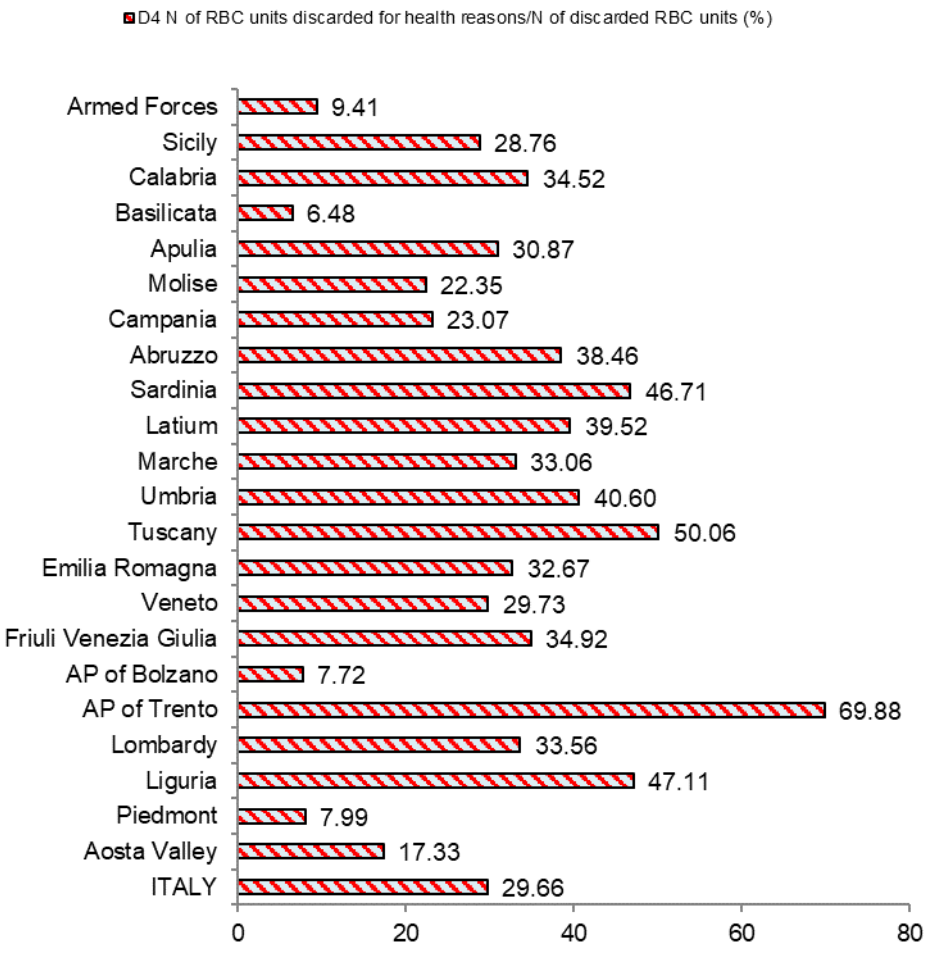
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A25. INDICATOR D2: N. of expired RBC units discarded/N. of discarded RBC units (%) (2023)



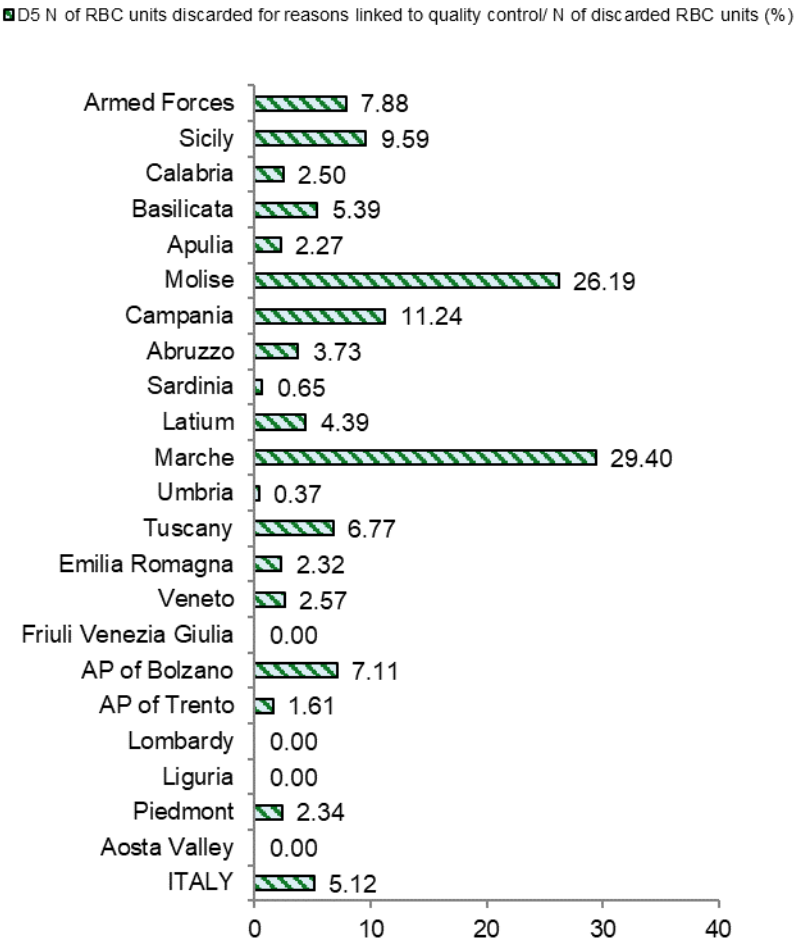
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A26. INDICATOR D3: N. of RBC units discarded for technical reasons/N. of discarded RBC units (%) (2023)



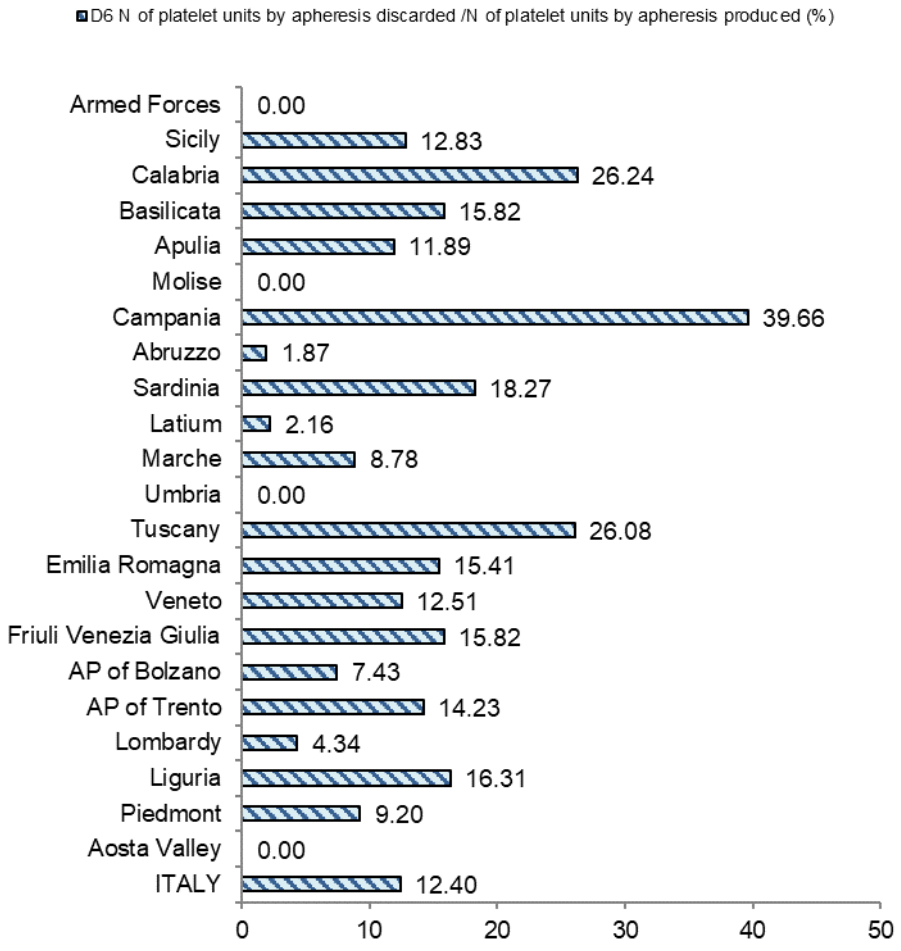
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A27. INDICATOR D4: N. of RBC units discarded for health reasons/N. of discarded RBC units (%) (2023)



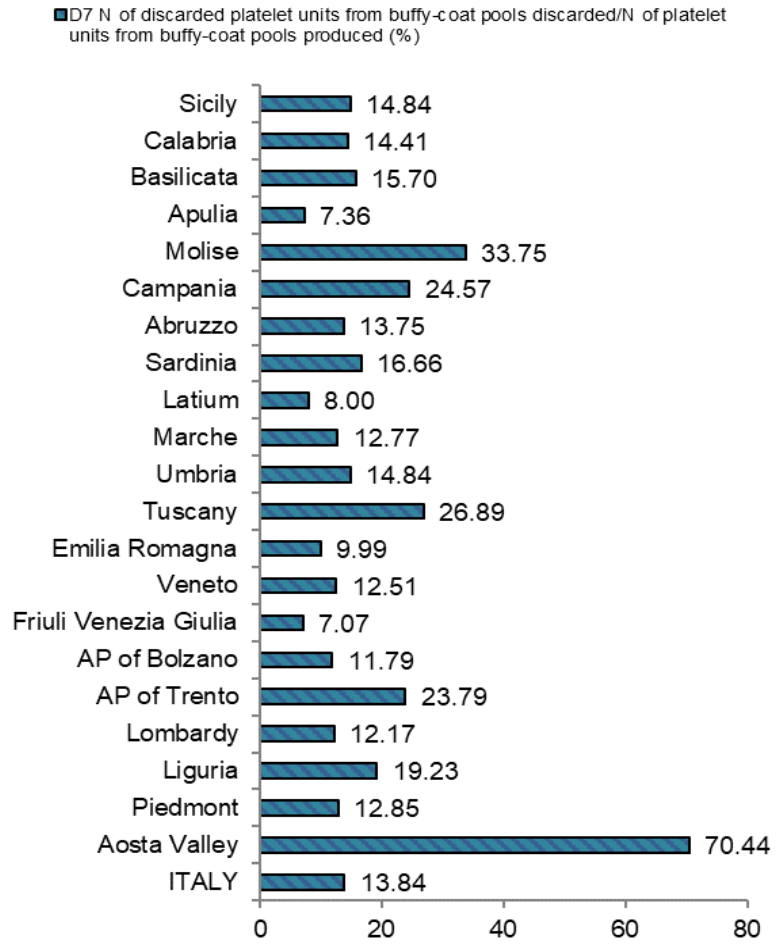
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A28. INDICATOR D5: N. of RBC units discarded for reasons linked to quality control/N. of discarded RBC units (%) (2023)



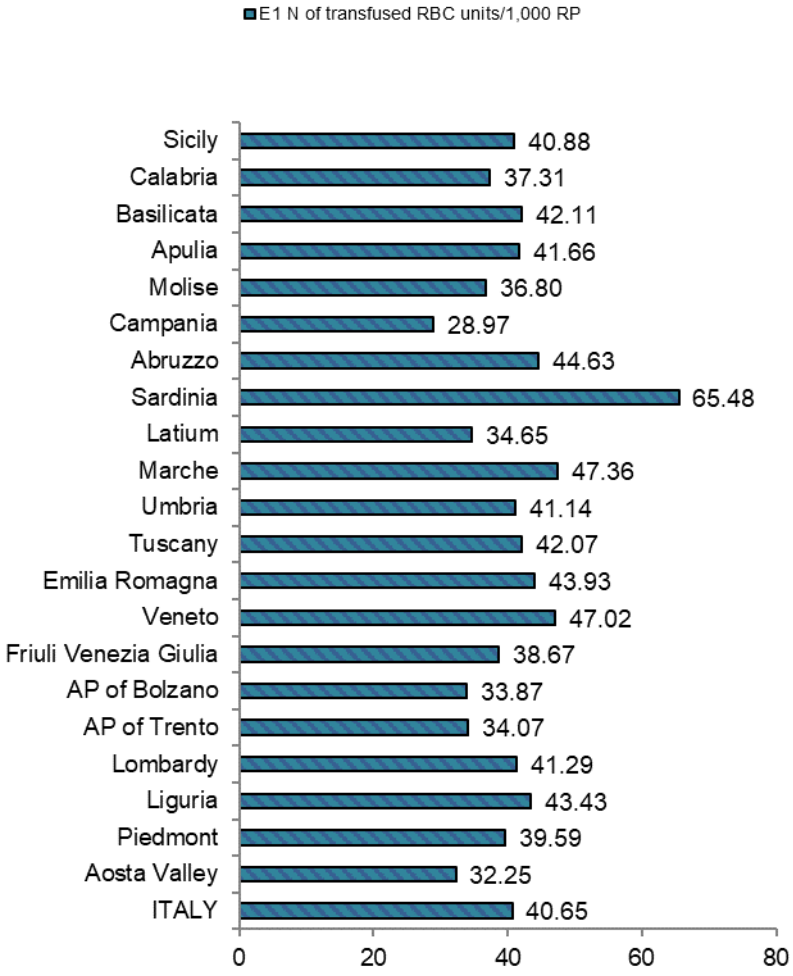
N. number; AP Autonomous Province

Figure A29. INDICATOR D6: N. of platelet units by apheresis discarded/N. of platelet units by apheresis produced (%) (2023)



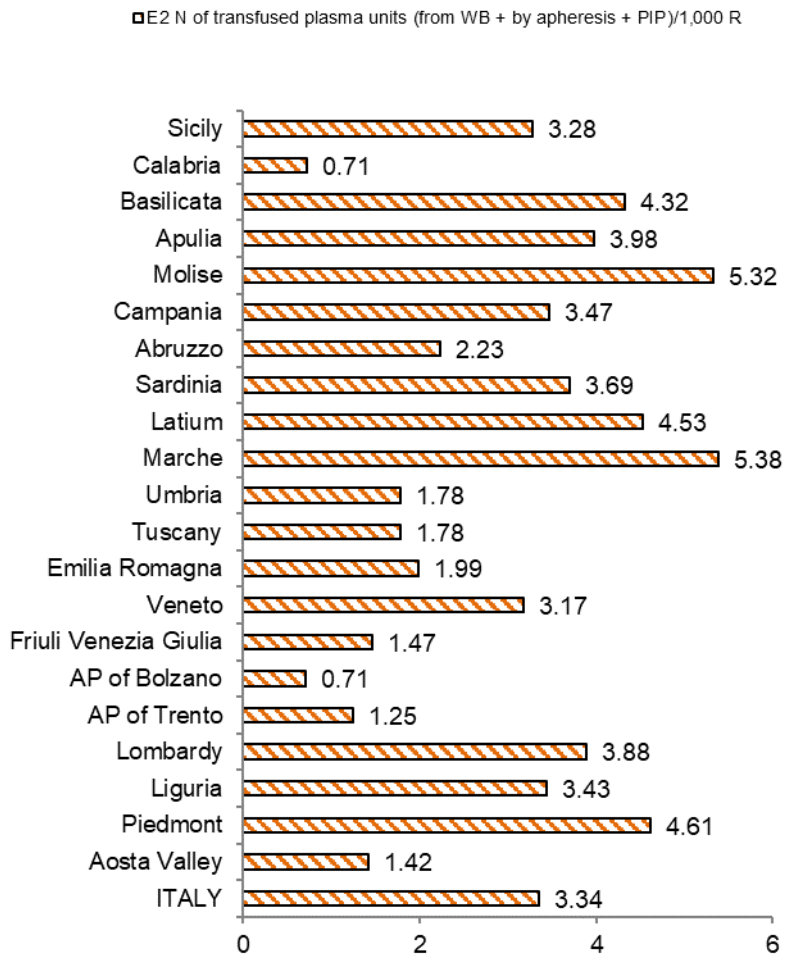
N. number; AP Autonomous Province

Figure A30. INDICATOR D7: N. of platelet units from buffy-coat pools discarded/N. of platelet units from buffy-coat pools produced (%) (2023)



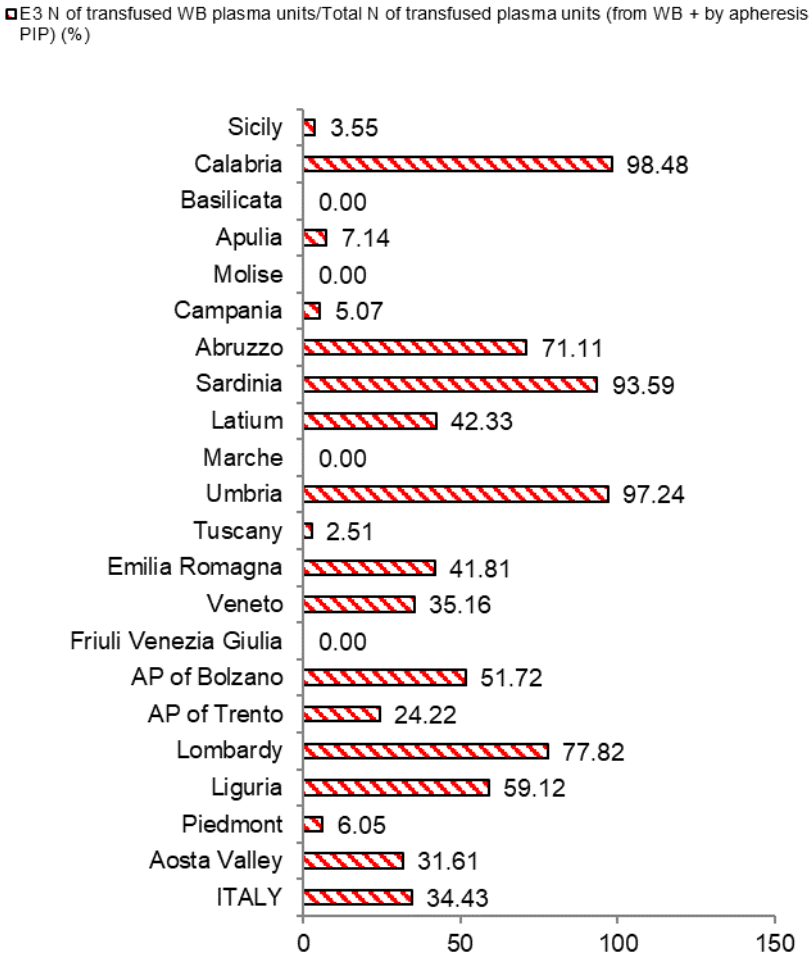
N. number; RBC Red Blood Cells; RP resident population; AP Autonomous Province

Figure A31. INDICATOR E1: N. of transfused RBC units/1,000 resident population (2023)



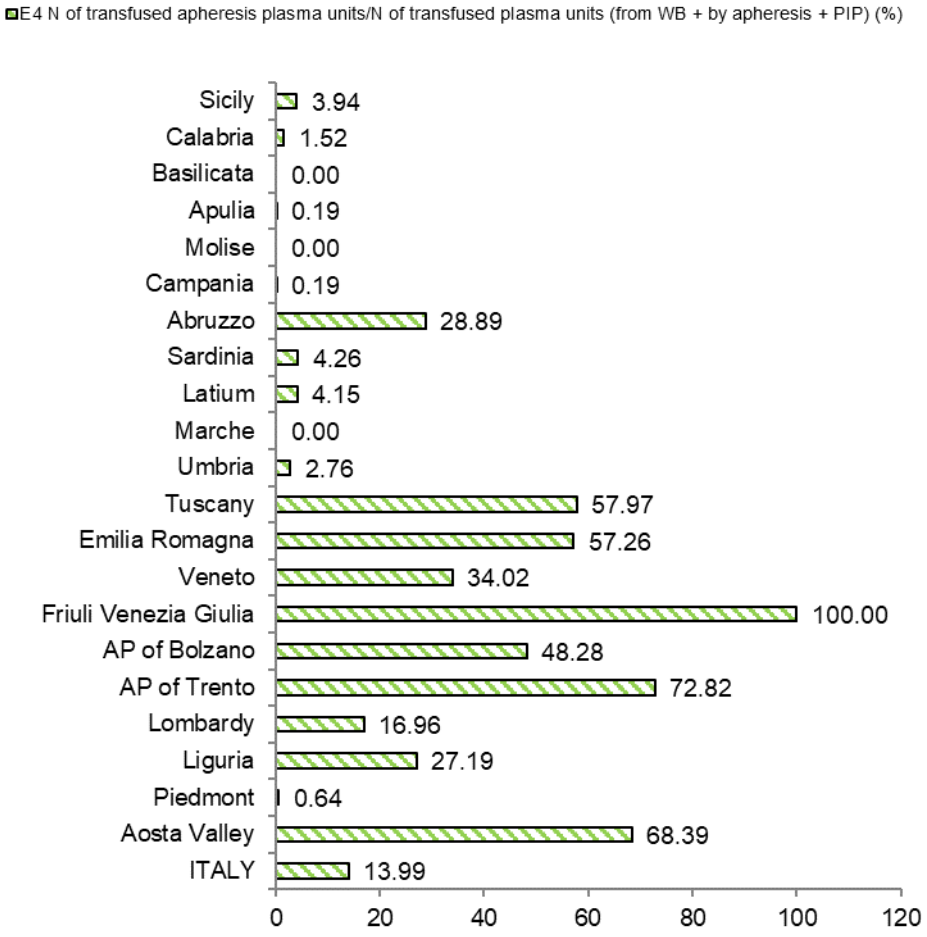
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; RP resident population; AP Autonomous Province

Figure A32. INDICATOR E2: N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma)/1,000 resident population (2023)



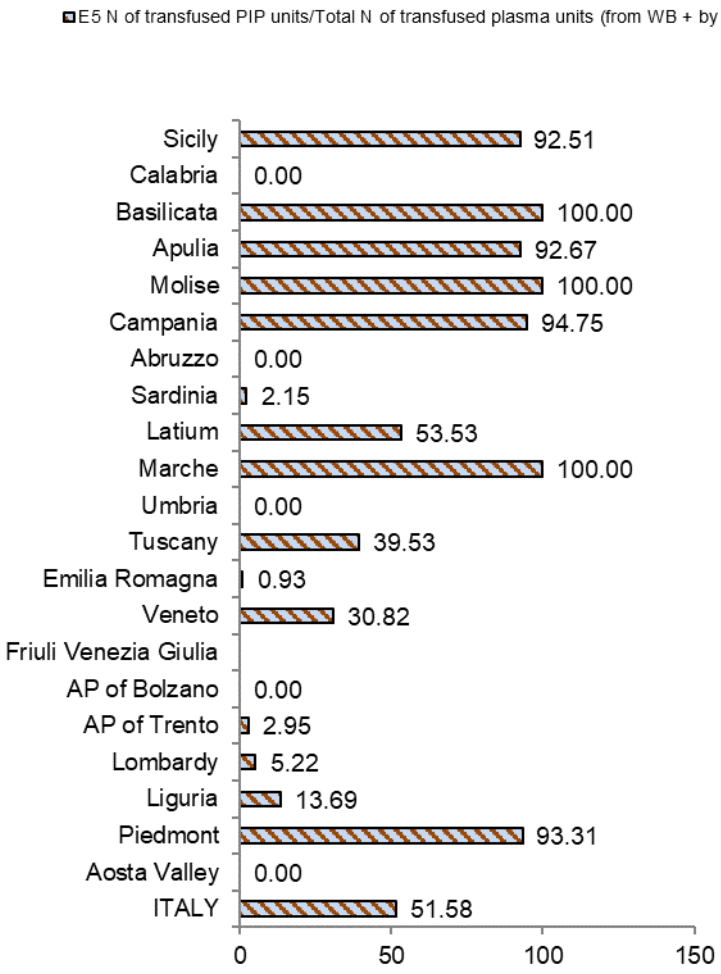
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A33. INDICATOR E3: N. of transfused whole blood plasma units/total N. of transfused plasma units (from whole blood + by apheresis + plasma pooled and treated for virus inactivation) (%) (2023)



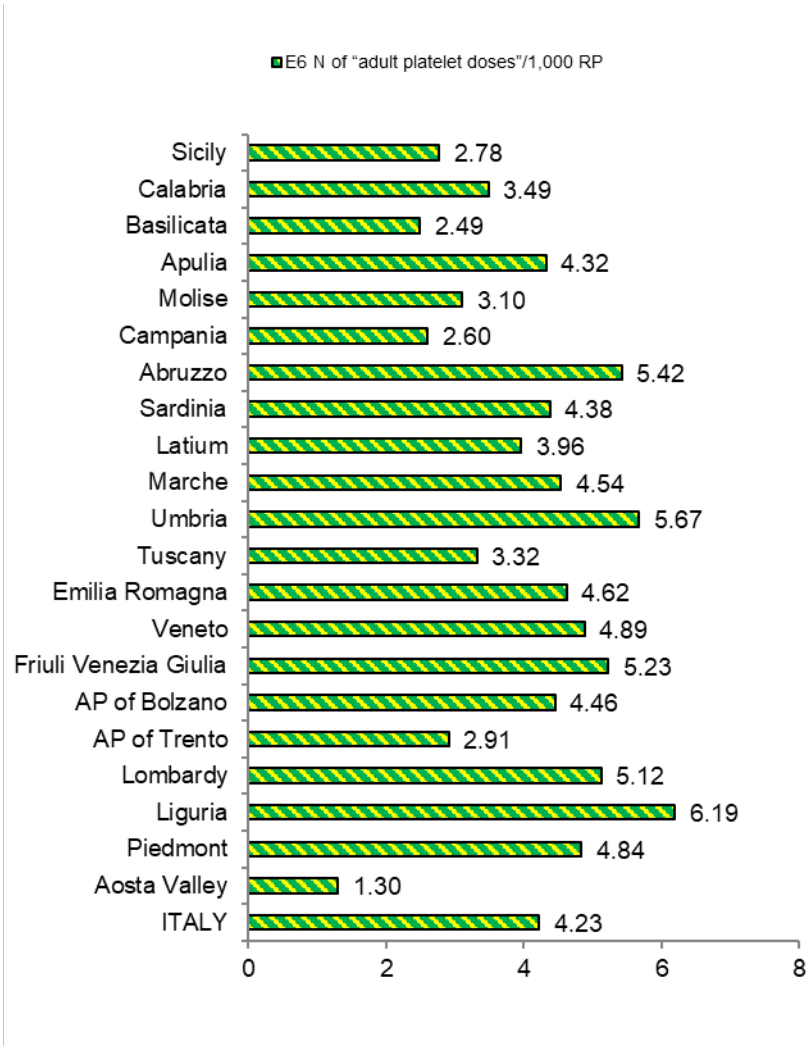
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A34. INDICATOR E4: N. of transfused apheresis plasma units/N. of transfused plasma units (from whole blood + by apheresis + plasma pooled and treated for virus inactivation) (%) (2023)



N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A35. INDICATOR E5: N. of transfused pharmaceutical virus-inactivated plasma units/total N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2023)



N. number; RP resident population; AP Autonomous Province

Figure A36. INDICATOR E6: N. of "adult platelet doses"/1,000 resident population (2023)

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