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Italian Blood System 2024: activity data, haemovigilance and epidemiological surveillance

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EPIDEMIOLOGIA
E SANITA' PUBBLICA

ISTITUTO SUPERIORE DI SANITÀ

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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 2024.

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 2024: dati di attività, emovigilanza e sorveglianza epidemiologica.
Liviana Catalano, Vanessa Piccinini, Ilaria Pati, Francesca Masiello, Ursula La Rocca, Luciana Teofili
2025, iii, 88 p. Rapporti ISTISAN 25/32 (in inglese)

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, di emovigilanza e sorveglianza epidemiologica del sistema trasfusionale italiano per l'anno 2024.

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

I nostri ringraziamenti vanno sia ai Direttori dei Centri Regionali di Coordinamento del Sangue sia ai Responsabili dell'Emovigilanza per la loro preziosa collaborazione.

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La responsabilità dei dati scientifici e tecnici è dei singoli autori, che dichiarano di non avere conflitti di interesse.

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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 Coordination 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), instituted by specific Ministerial Decree (1) and operating 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 being validated by the Regional Blood Coordination 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 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 included four modules based on the following notifications: adverse reactions in recipients, adverse reactions in donors, serious adverse events, and epidemiological surveillance of donors.

The data in this report are relevant to the year 2024.

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 a Regional/Autonomous Provincial (APs) IT system 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 2024 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 (ISTAT) as of 1st January, 2024, available at https://demo.istat.it/ (last accessed September 2024).

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:

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

National data

In 2024, 248 blood transfusion activity records, which include data from 276 BEs, were validated by the RBCCs on SISTRA. Compared to 2023, there was a decrease in the number of BEs peripheral organisational sites (-3%) and an increase in the number of BCSs (+3.2%) (Table 1).

Male donors are more prevalent in the 36-55 age group than in the resident population of the corresponding 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 (2023-2024)

Blood facilities and population	2023	2024	Δ%
BEs	276	276	0.0
BEs peripheral organisational sites	829	804	-3.0
BCSs	186	192	3.2
BCSs peripheral organisational sites	1,290	1,290	0.0
Population	58,850,717	58,989,749	0.2

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

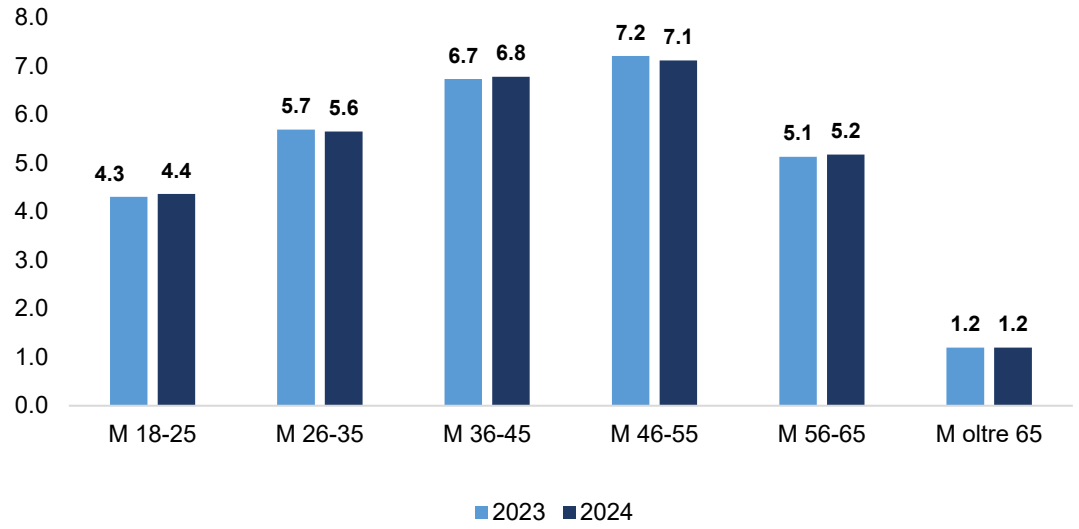

Figure 1. Male donors out of the resident population eligible for donation/100 inhabitant (2024)

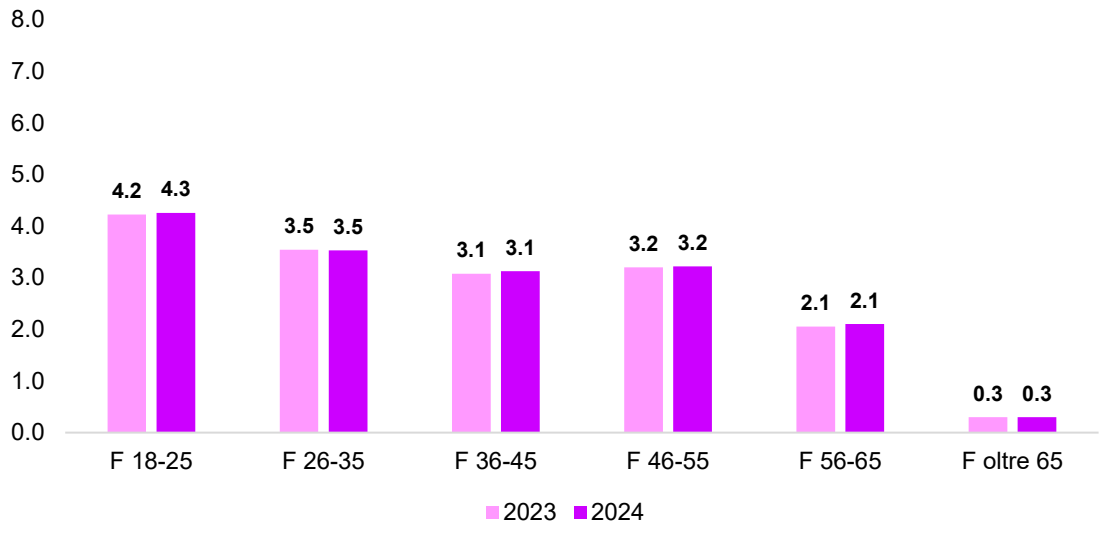

Figure 2. Female donors out of the resident population eligible for donation/100 inhabitant (2024)

Table 2 shows data concerning donors of blood and blood components per type of donation. Compared to 2023, there was an increase of 1.3% in the total number of first-time donors and of 4.9% in the total number of apheresis donors. The total number of donors did not change (0.1%).

Table 2. Donors of blood and blood components (2023-2024)

Donors	2023	2024	Δ%
First-time	**360,303**	**364,880**	1.3
Those who re-donated in the period under examination	*79,339*	81,314	2.5
Regular	**1,396,734**	**1,395,007**	-0.1
Those who re-donated at least once a year in the last 5 years	*616,995*	614,766	-0.4
Total	**1,677,698**	**1,678,573**	0.1
Apheresis	220,141	230,846	4.9
Those who donated only in apheresis	*113,211*	118,904	5.0
Permanently deferred	45,812	46,152	0.7
Members of VBDAs	**1,537,237**	**1,515,680**	-1.4

VBDAs: Voluntary Blood Donors Associations/Federations.

Table 3 shows the total number of collection procedures (carried out by both BEs and BCSs) per type. The total number of whole blood collection was the same as the previous year while the total number of apheresis procedures increased of 7.6%.

Table 3. Collection procedures (2023-2024)

Collection procedures	2023	2024	Δ%
Whole blood	**2,563,717**	**2,563,784**	0.0
Apheresis	**455,754**	**490,172**	7.6
Monocomponent apheresis	*401,798*	*437,797*	9.0
Multicomponent apheresis	*53,956*	*52,375*	-2.9
Total	**3,019,471**	**3,053,956**	1.1
Type			
Plasmapheresis	393,974	430,149	9.2
Plateletpheresis	5,349	4,710	-11.9
Stem Cells apheresis	1,894	1,969	4.0
Granulocytapheresis	115	133	15.7
Lymphocytapheresis	466	836	79.4
Red Blood Cell/Platelet apheresis	2,219	1,756	-20.9
Double Red Blood Cell unit apheresis	205	127	-38.0
Plasma/Platelet apheresis	44,606	44,645	0.1
Red Blood Cell/Plasma apheresis	5,062	4,234	-16.4
Double Platelet unit apheresis	1,308	1,167	-10.8
Red Blood Cell/Platelet/Plasma apheresis	556	446	-19.8

Table 4 shows the number of collections carried out by BCSs (total and by Association/Federation); 90.5% 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 (2023-2024)

Association/Federation	2023	2024	Δ%
AVIS	864,415	885,088	2.4
FIDAS	102,838	101,945	-0.9
FRATRES	18,831	18,143	-3.7
CRI	13,897	13,986	0.6
Other	66,060	106,061	60.6
Total	**1,066,041**	**1,125,223**	**5.6**

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 2023, there was decrease (-2.1%) in the total number of units of blood components produced.

Table 5. Blood component production (2023-2024)

Blood component	2023	2024	Δ%
Red Blood Cells	**2,506,415**	**2,505,273**	0.0
Platelets			
Platelet pools	236,348	236,498	0.1
Platelets by apheresis	57,728	54,320	-5.9
Plasma	**2,966,653**	**3,148,875**	6.1
Recovered Plasma	2,498,147	2,489,240	-0.4
Source Plasma	417,276	452,658	8.5
Source Plasma from multiple apheresis	51,230	49,682	-3.0
Total	**5,774,202**	**5,654,148**	**-2.1**

In 2024, 6,983 units of blood components were transfused per day. Compared to the previous year, there was a slight decrease (-9.9%) (Table 6).

Table 6. Transfused units of blood components (2023-2024)

Blood component	2023	2024	Δ%
Red Blood Cells	**2,392,289**	**2,384,052**	-0.3
Platelets			
Platelet pools	201,316	199,204	-1.0
Platelets by apheresis	47,292	46,256	-2.2
Plasma	**196,795**	**171,695**	-12.8
Recovered Plasma	67,762	58,190	-14.1
Source Plasma	23,615	21,241	-10.1
Source Plasma from multiple apheresis	3,900	3,425	-12.2
Plasma pooled and treated for virus inactivation	101,518	88,839	-12.5
Total	**2,837,805**	**2,555,747**	**-9.9**

Moreover, compared to 2023, there was:

a) an overall increase in the total number of red blood cell and platelet pools units discarded while there was a reduction in the number of 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 a decrease of allogeneic platelets gel not intended for transfusion (Table 9);

d) a reduction in the production of autologous fibrin glue and an increase in platelet gel produced not intended for transfusion (Table 10);

e) a slight increase in the number of transfused patients, including those transfused in BEs (day hospital) (Table 11).

Table 7. Blood components discarded for reasons linked to health, technical issues, quality control and expiry dates (2023-2024)

Blood component	2023	2024	Δ%
Red Blood Cells	**91,235**	**104,605**	**14.7**
Platelets			
Platelet pools	32,720	36,567	11.8
Platelets by apheresis	7,159	7,456	4.1
Plasma	**124,449**	**119,668**	**-3.8**
Recovered Plasma	*105,532*	*101,688*	-3.6
Source Plasma	*16,329*	*15,590*	-4.5
Source Plasma from multiple apheresis	*2,588*	*2,390*	-7.7
Total	**260,511**	**224,273**	**-13.9**

Table 8. Plasma for fractionation (2023-2024)

Blood component	2023	2024	Δ%
Plasma for fractionation (kg)	879,600	906,938	3.11

Data source: Pharmaceutical industry - year 2023 data updated to December 2024.

Table 9. Production and use of allogeneic blood components for non-transfusion use (2023-2024)

Blood component	2023	2024	Δ%
Platelet Gel			
Produced	**30,366**	**24,018**	**-20.9**
- Used	18,892	*17,964*	-4.9
- Not used	11,474	*6,054*	-47.2
Fibrin Glue			
Produced	**162**	**168**	**3.7**
- Used	154	*156*	1.3
- Not used	8	*12*	50.0

Table 10. Production and use of autologous blood components for non-transfusion use (2023-2024)

Blood component	2023	2024	Δ%
Platelet Gel			
Produced	**7,824**	**10,253**	**31,0**
- Used	7,812	*9,797*	25,4
- Not used	12	*456*	3700,0
Fibrin Glue			
Produced	**689**	**683**	**-0.9**
- Used	677	*681*	0.6
- Not used	12	*2*	-83.3

Table 11. Transfused patients (2023-2024)

Patients* transfused with:	2023	2024	Δ%
Whole Blood^	23	36	56.5
Red Blood Cells	603,125	604,838	0.3
Plasma	43,415	40,634	-6.4
Platelets	55,431	55,254	-0.3
Other	5,445	8,085	48.5
Total**	**638,046**	**640,713**	**0.4**

* 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 year 2024 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) and regional level (Appendix A).

Table 13. Quantitative indicators for transfusion activities in Italy (2024)

Indicators		Index
A. Donors		
A1	N. of donors/1,000 RP	28.46
A2	M/F ratio: female donors (%)	33.93
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	23.66
A7	N. of first-time donors/1,000 RP	6.12
A8	N. of “regular” donors/1,000 RP	10.42

Indicators		Index
B. Donations		
B1	N. of donations (WB + apheresis)/1,000 RP	51.79
B2	N. of donations (WB + apheresis)/Total N. of donors (excluding prospective donors)	1.82
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	8.31
B6	N. of donations in apheresis/N. of apheresis donors	2.12
C. Produced blood components		
C1	N. of RBC units produced/1,000 RP	42.48
C2	N. of plasma units produced from WB and by apheresis/1,000 RP	53.40
C3	N. of plasma units produced from WB/1,000 RP	42.21
C4	N. of plasma units produced by apheresis (monocomponent or multicomponent)/1,000 RP	11.19
C5	Plasma for fractionation (kg)/1,000 RP	15.27
C6	Plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%)	31.95
C7	N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 RP	0.92
C8	N. of platelet units produced from buffy-coat pools/1,000 RP	4.01
C9	N. of “adult platelet doses”/1,000 RP	4.95
D. Discarded blood components		
D1	N. of discarded RBC units/N. of “usable” RBC units (produced + acquired - released) (%)	4.18
D2	N. of expired RBC units discarded/N. of discarded RBC units (%)	39.76
D3	N. of RBC units discarded for technical reasons/N. of discarded RBC units (%)	28.21
D4	N. of RBC units discarded for health reasons/N. of discarded RBC units (%)	28.12
D5	N. of RBC units discarded for reasons linked to QC/ N. of discarded RBC units (%)	3.91
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 (%)	15.46
E. Transfused blood components		
E1	N. of transfused RBC units/1,000 RP	40.43
E2	N. of transfused plasma units (from WB + by apheresis + PIP)/1,000 RP	2.91
E3	N. of transfused plasma units from WB/Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	33.89
E4	N. of transfused apheresis plasma units/N. of transfused plasma units (from WB + by apheresis + PIP) (%)	14.37
E5	N. of transfused PIP units/Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	51.74
E6	N. of “adult platelet doses”/1,000 RP	4.16

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 2023, in 2024 the number of total donors was almost the same, but the number of the apheresis donors increased.

Data showed a slight increased (1.1%) in the overall collection of blood components: in particular, monocomponent apheresis procedures increased (9.0%), on the contrary multicomponent apheresis procedures decreased (-2.9%).

In 2024, there was a decrease in the number of units of blood components transfused (-9.9%) compared to 2023. 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 2024 (7)), have been applied quite uniformly nationwide.

In 2024, there was an overall decrease in the production of allogeneic platelet gel and an increase 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), as well as by the recent Regulation (EU) 2024/1938 (13), 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.

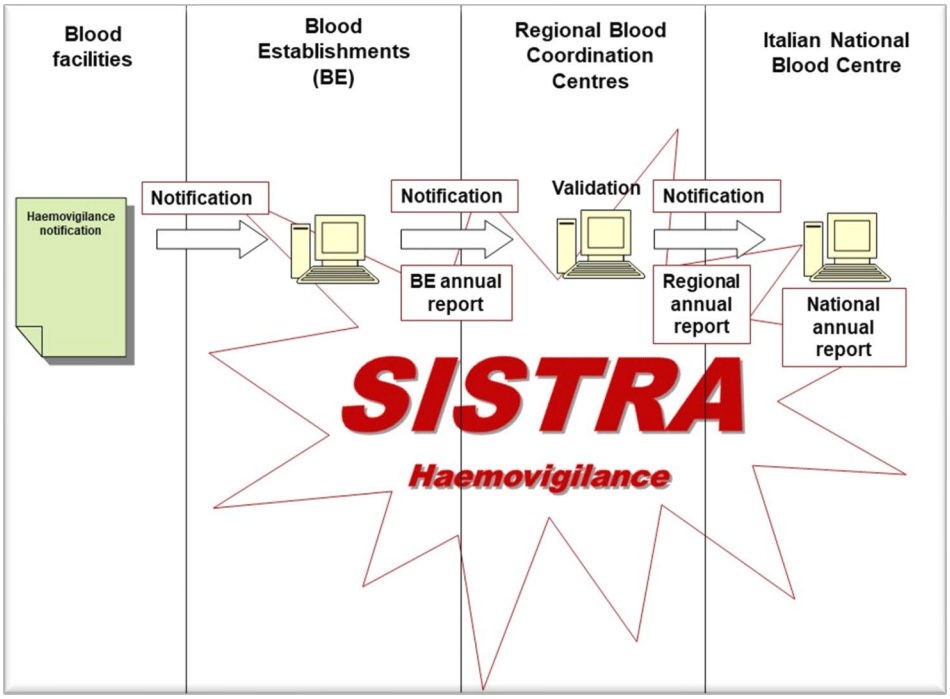

Figure 3. Haemovigilance information flow in SISTRA

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

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.

Serious adverse events and adverse reactions in recipients and in donors

General data

In 2024, the notified adverse events concerned 2,833,890 units of blood components transfused, 3,053,956 procedures of blood donation and 3,169,291 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 2024, 1,933 ARs in recipients (68.2 per 100,000 transfused units) and 9,553 ARs in blood donors (312.8 per 100,000 collection procedures) were reported. There were 20 notified SAEs (0.63 per 100,000 issued units).

As shown in Figure 4, the notification system improved over the years, recording a significant increase in ARs in donors, from 2009 to 2016, and in recipients, from 2009 to 2012. Since then, the number of notifications has been almost constant, with a last slight increase in ARs in donors in 2024. Since 2016, SAEs notification shows a slight and constant decrease over the years.

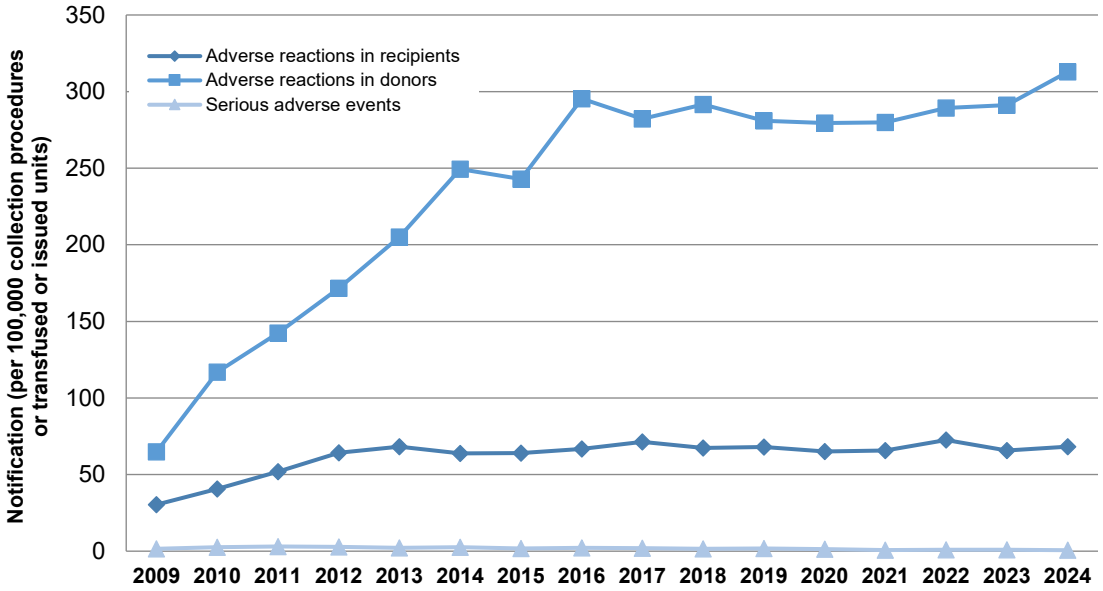

Figure 4. Number of haemovigilance notifications (per 100,000), per year (2009-2024)

Adverse reactions in recipients

From January 1st to December 31st 2024, 1,933 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 (6), the notifications show a significant regional variability with a national average of 68.2 per 100,000 transfused units. Friuli Venezia Giulia (223.2 per 100,000 transfused units), Piedmont (149.8 per 100,000 transfused units) and Emilia-Romagna (127.7 per 100,000 transfused units) recorded the highest values (Figure 5).

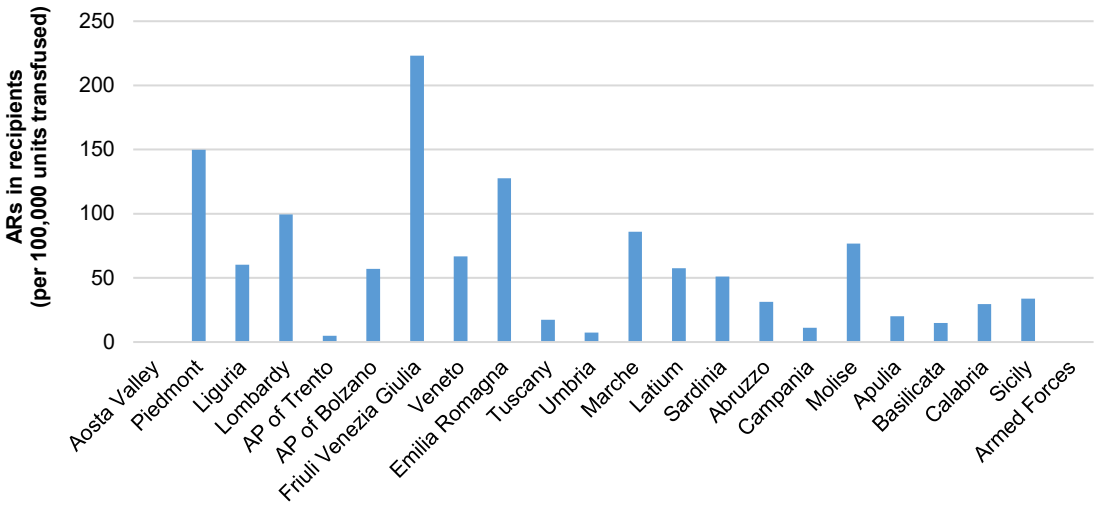

Figure 5. Adverse reactions in recipients by region, per 100,000 units transfused (2024)

Table 14 reports all ARs notified in blood transfusion recipients in 2024. The most frequently notified reactions were febrile non-haemolytic reactions (FNHTRs) (28.58 per 100,000 transfused units) and allergic reactions with only mucosal and cutaneous symptoms (18.88 per 100,000 transfused units): these reactions represent 69.6% of all ARs notified in recipients.

Table 14. Adverse reactions in recipients (2024)

ARs	n.	%	ARs/100,000 transfused units
Acute haemolytic reaction - ABO incompatible	2	0.10	0.07
Acute haemolytic reaction - other blood groups	2	0.10	0.07
Allergic manifestations - only mucosal and cutaneous symptoms	535	27.68	18.88
Allergic reactions - respiratory and/or cardiovascular system	91	4.71	3.21
Anaphylactic shock	7	0.36	0.25
Delayed haemolytic reaction - other blood groups	1	0.05	0.04
FNHTR - Febrile non-haemolytic reaction	810	41.90	28.58
Hyperkalemia	3	0.16	0.11
Hypotensive transfusion reaction	42	2.17	1.48
IBCT - Incorrect Blood Component Transfused	1	0.05	0.04
IBCT - Incorrect Blood Component Transfused (wrong patient)	10	0.52	0.35
Non-immunological haemolysis - chemical cause	4	0.21	0.14
Non-immunological haemolysis - mechanical cause	4	0.21	0.14
Non-immunological haemolysis - physical cause	1	0.05	0.04
Other	293	15.16	10.34
Post-transfusion purpura	2	0.10	0.07
TACO - Transfusion-associated circulatory overload	36	1.86	1.27
TAD - Transfusion associated dyspnoea	85	4.40	3.00
TRALI - Transfusion-related acute lung injury	1	0.05	0.04
TTI - Bacterial infection*	2	0.10	0.07
TTI - Viral infection**	1	0.05	0.04
Total	**1,933**	**100.0**	**68.21**

* The bacterial infections were at level 0 of imputability and level 2 of severity.
** The viral infection referred to Parvovirus B19 with level 1 of imputability and level 2 of severity.
ARs, adverse reactions.

The reactions with cardiac and/or respiratory symptoms were: 91 allergic reactions (3.21 per 100,000 transfused units), 85 TADs (3.0 per 100,000 transfused units), 36 TACOs (1.27 per 100,000 transfused units) and 1 TRALI (0.04 per 100,000 transfused units).

Table 15 shows the notified ARs by imputability level: 57.2% were associated with a low imputability level (46.1% possible and 11.1% excluded/improbable) and 37.5% to high imputability level (32.4% probable and 6.1% certain). For 5.3% of ARs, the level of imputability was "not assessable".

Table 15. Adverse reactions in recipients by imputability level (2024)

ARs	Imputability level*					
	0	1	2	3	NA	Total
Acute haemolytic reaction - ABO incompatible			1	1		2
Acute haemolytic reaction - other blood groups		2				2
Allergic manifestations - only mucosal and cutaneous symptoms	22	200	252	48	13	535
Allergic reactions - respiratory and/or cardiovascular system	4	36	41	6	4	91
Anaphylactic shock		4	3			7
Delayed haemolytic reaction - other blood groups				1		1
FNHTR - Febrile non-haemolytic reaction	85	407	231	45	42	810
Hyperkalemia		2	1			3
Hypotensive transfusion reaction	6	26	7	1	2	42
IBCT - Incorrect Blood Component Transfused					1	1
IBCT - Incorrect Blood Component Transfused (wrong patient)				7	3	10
Non-immunological haemolysis - chemical cause	3		1			4
Non-immunological haemolysis - mechanical cause		3	1			4
Non-immunological haemolysis - physical cause		1				1
Other	75	148	34	4	32	293
Post-transfusion purpura	1	1				2
TACO - Transfusion-associated circulatory overload	1	20	10	3	2	36
TAD - Transfusion associated dyspnoea	14	41	25	2	3	85
TRALI - Transfusion-related acute lung injury	1					1
TTI - Bacterial infection	2					2
TTI - Viral infection		1				1
Total (%)	**214** (11.1)	**892** (46.1)	**607** (31.4)	**118** (6.1)	**102** (5.3)	**1,933** (100.0)

* 0 Excluded/Improbable; 1 Possible; 2 Probable; 3 Certain;
NA: Not assessable.
ARs, Adverse Reactions

In 2024, the frequency of ARs in blood component recipients was 1 in 1,466 transfused units. As reported in Table 16, most of the 1,933 notified ARs were related to platelets transfusion (199.12 per 100,000 units transfused). For the 19 ARs related to multi-component transfusions, it was not possible to assign the AR to a specific blood component.

Table 17 shows 725 ARs with a probable and certain imputability level.

Table 16. Adverse reactions in recipients by blood component transfused (2024)

Blood component transfused	ARs	Transfused units	ARs/100,000 transfused units
Red Blood Cells	1,271	2,384,052	53.31
Plasma*	152	171,694	88.53
Platelets	489	245,576	199.12
Other	2	32,568	6.14
More than one blood component transfused**	19	NA	NA
Total	**1,933**	**2,833,890**	**68.21**

* Includes plasma pooled and treated for virus inactivation (16 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 (2024)

ARs	Total	%	ARs/100,000 transfused units
Acute haemolytic reaction - ABO incompatible	2	0.28	0.07
Allergic manifestations - only mucosal and cutaneous symptoms	300	41.38	10.59
Allergic reactions - respiratory and/or cardiovascular system	47	6.48	1.66
Anaphylactic shock	3	0.41	0.11
Delayed haemolytic reaction - other blood groups	1	0.14	0.04
FNHTR - Febrile non-haemolytic reaction	276	38.07	9.74
Hyperkalaemia	1	0.14	0.04
Hypotensive transfusion reaction	8	1.10	0.28
IBCT - Incorrect Blood Component Transfused (wrong patient)	7	0.97	0.25
Non-immunological haemolysis - chemical cause	1	0.14	0.04
Non-immunological haemolysis - mechanical cause	1	0.14	0.04
Other	38	5.24	1.34
TACO - Transfusion-associated circulatory overload	13	1.79	0.46
TAD - Transfusion associated dyspnoea	27	3.72	0.95
Total	**725**	**100.00**	**25.58**

ARs, Adverse Reactions

The frequency of the ARs with a high imputability level is 1 every 3,908 transfused units. As reported in Table 18, the frequency distribution of ARs, per 100,000 transfused units, is 15.7 for red blood cells (RBCs), 77.2 for plasma, 108.7 for platelets, 9.0 for virus-inactivated plasma and 3.0 for other type of blood component.

The most frequent ARs related to the transfusion of RBCs was the febrile non-haemolytic reaction (8.5 per 100,000 transfused units); the allergic manifestation with only mucosal and cutaneous symptoms was the most frequent AR related to plasma (62.7 per 100,000 transfused units), platelets (62.7 per 100,000 transfused units) and virus-inactivated plasma (4.5 per 100,000 transfused units).

Table18. Adverse reactions in recipients with imputability level 2-3 regardless of severity levels, by blood component transfused (2024)

Blood component transfused	ARs	n.	ARs/100,000 transfused units
RBCs	Acute haemolytic reaction - ABO incompatible	2	0.08
	Allergic manifestations - only mucosal and cutaneous symptoms	85	3.57
	Allergic reactions - respiratory and/or cardiovascular system	15	0.63
	Anaphylactic shock	1	0.04
	Delayed haemolytic reaction - other blood groups	1	0.04
	FNHTR - Febrile non-haemolytic reaction	204	8.56
	Hyperkalaemia	1	0.04
	Hypotensive transfusion reaction	4	0.17
	IBCT - Incorrect Blood Component Transfused (wrong patient)	7	0.29
	Non-immunological haemolysis - chemical cause	1	0.04
	Non-immunological haemolysis - mechanical cause	1	0.04
	Other	25	1.05
	TACO - Transfusion-associated circulatory overload	12	0.50
	TAD - Transfusion associated dyspnoea	17	0.71
Total		*376*	*15.77*
Plasma	Allergic manifestations - only mucosal and cutaneous symptoms	52	62.76
	Allergic reactions - respiratory and/or cardiovascular system	6	7.24
	FNHTR - Febrile non-haemolytic reaction	1	1.21
	Hypotensive transfusion reaction	1	1.21
	Other	3	3.62
	TAD - Transfusion associated dyspnoea	1	1.21
Total		*64*	*77.24*
Platelets	Allergic manifestations - only mucosal and cutaneous symptoms	154	62.71
	Allergic reactions - respiratory and/or cardiovascular system	25	10.18
	Anaphylactic shock	1	0.41
	FNHTR - Febrile non-haemolytic reaction	65	26.47
	Hypotensive transfusion reaction	3	1.22
	Other	10	4.07
	TACO - Transfusion-associated circulatory overload	1	0.41
	TAD - Transfusion associated dyspnoea	8	3.26
Total		*267*	*108.72*
Virus-inactivated plasma	Allergic manifestations - only mucosal and cutaneous symptoms	4	4.50
	Anaphylactic shock	1	1.13
	FNHTR - Febrile non-haemolytic reaction	3	3.38
Total		*8*	*9.01*
Other type of blood components	Allergic manifestations - only mucosal and cutaneous symptoms	1	3.07
Total		*1*	*3.07*
More than one blood component transfused**	Allergic manifestations - only mucosal and cutaneous symptoms	4	NA
	Allergic reactions - respiratory and/or cardiovascular system	1	NA
	FNHTR - Febrile non-haemolytic reaction	3	NA
	TAD - Transfusion associated dyspnoea	1	NA
Total		*9*	*NA*
Total ARs		**725**	

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

Table 19 shows 11 ARs with imputability level 2-3 and severity level 3-4 (severe symptoms requiring resuscitation procedures or death) by blood component transfused. In 2024, the frequency of these ARs was 1 every 257,626 transfused units.

Table 19. Adverse reactions to transfusion with imputability level 2-3 and severity level 3-4, by blood component transfused (2024)

Blood component transfused	ARs	n.	ARs/100.000 transfused units
RBCs	Allergic reactions - respiratory and/or cardiovascular system	2	0.08
	Anaphylactic shock	1	0.04
	TACO - Transfusion-associated circulatory overload	2	0.08
	TAD - Transfusion associated dyspnoea	1	0.04
Total		*6*	*0.24*
Plasma	Allergic reactions - respiratory and/or cardiovascular system	2	2.41
	Other	1	1.21
Total		*3*	*3.62*
Platelets	Allergic reactions - respiratory and/or cardiovascular system	2	0.81
Total		*2*	*0.81*
Total ARs		**11**	**0.41**

ARs, Adverse Reactions; RBCs, red blood cells.

Considering the severity of the total notified ARs to blood transfusion, 71.5% required therapeutic intervention, 1.4% required resuscitation procedures and 0.1% led to death (Figure 6). The death had a not assessable imputability of the transfusion.

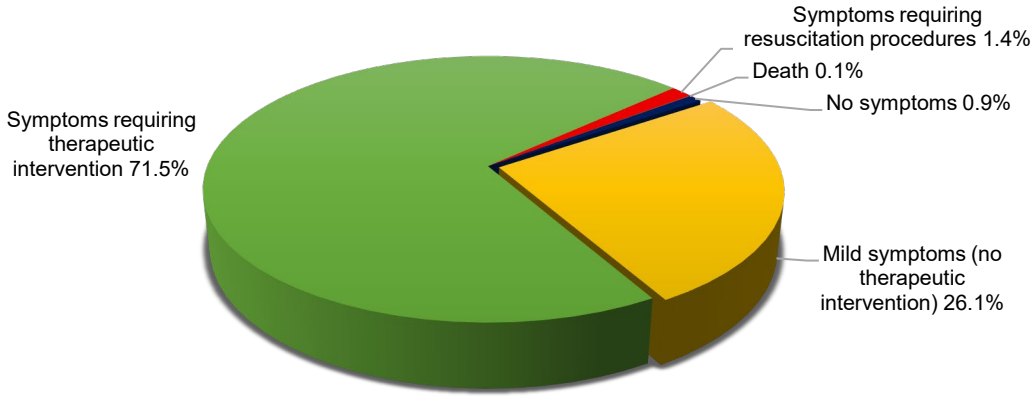

Figure 6. Severity level of adverse reactions in recipients (%) (2024)

In 92.2% of ARs, the clinical resolution was observed within a few hours and in 1.6% within a few days (Figure 7).

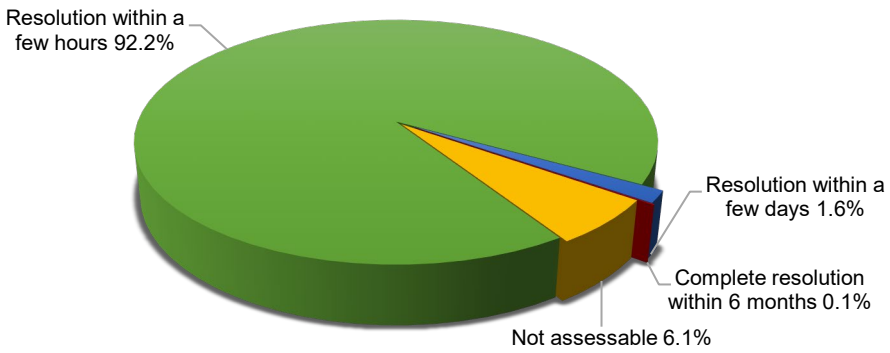

Figure 7. Adverse reactions in recipients by outcome (2024)

The majority of the ARs occurred in hospital ward (74.9%) and in day-hospital (12.2%) (outpatient clinics (8.9%) and BEs (3.3%)) (Table 20 and Figure 8).

Table 20. Transfusion sites notifying adverse reactions (2024)

Transfusion site	n.	%
Clinic	87	4.5
Day-Hospital	235	12.2
Emergency/ICU	110	5.7
Home	28	1.4
Hospital ward	1,448	74.9
Operating theatre	25	1.3
Total	**1,933**	**100.0**

ICU, intensive care unit.

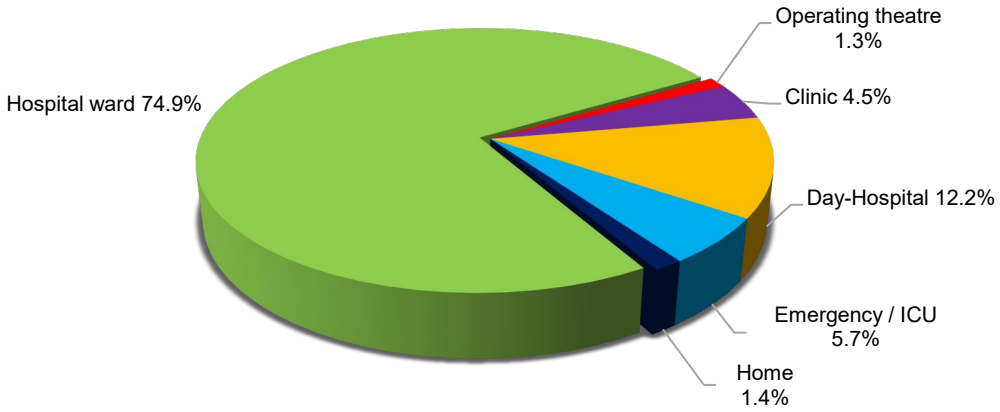

Figure 8. Adverse reactions by transfusion site (2024)

Incorrect blood component transfusion (IBCT)

The acute haemolytic reactions due to ABO incompatible transfusion were 2 (1 in 1,192,026 units of red blood cells transfused). The transfusions occurred in a hospital ward and in an operating theatre and were both interrupted. The severity of the reactions was "symptoms requiring therapeutic intervention" with a probable and certain imputability.

The IBCTs were 11 transfusions not intended for the recipient (1 in 257,626 blood components transfused). Out of them, 7 were ABO compatible and 4 ABO incompatible transfusions. Excluding 4 IBCTs with a NA imputability, that included 1 death with a pre-existing very serious clinical picture, 1 not required transfusion due to a not valid pre-transfusion test and 2 AB0 compatible transfusions, the residual IBCTs were with certain imputability. Out of these 7 certain IBCTs, 6 were without symptoms and 1 reported a dyspnoea required therapeutic intervention.

The transfusion errors occurred due to a failure (44.4%) or a wrong (33.3%) identification of the recipient, the use of a unit not intended for the patient (11.1%) and a wrong patient withdrawal (11.1%); the transfusion sites were hospital wards (55.6%), operating theatres (22.2%), Emergency/ICUs (11.1%) and home (11.1%).

Adverse reactions in blood donors

In 2024, 9,553 ARs to allogeneic donation were notified (1 every 319 donations).

The distribution of the AR notifications shows a significant regional variability with a national average of 312.8 per 100,000 collection procedures. Friuli Venezia Giulia recorded the highest value (1,084.3 per 100,000 collection procedures) (Figure 9).

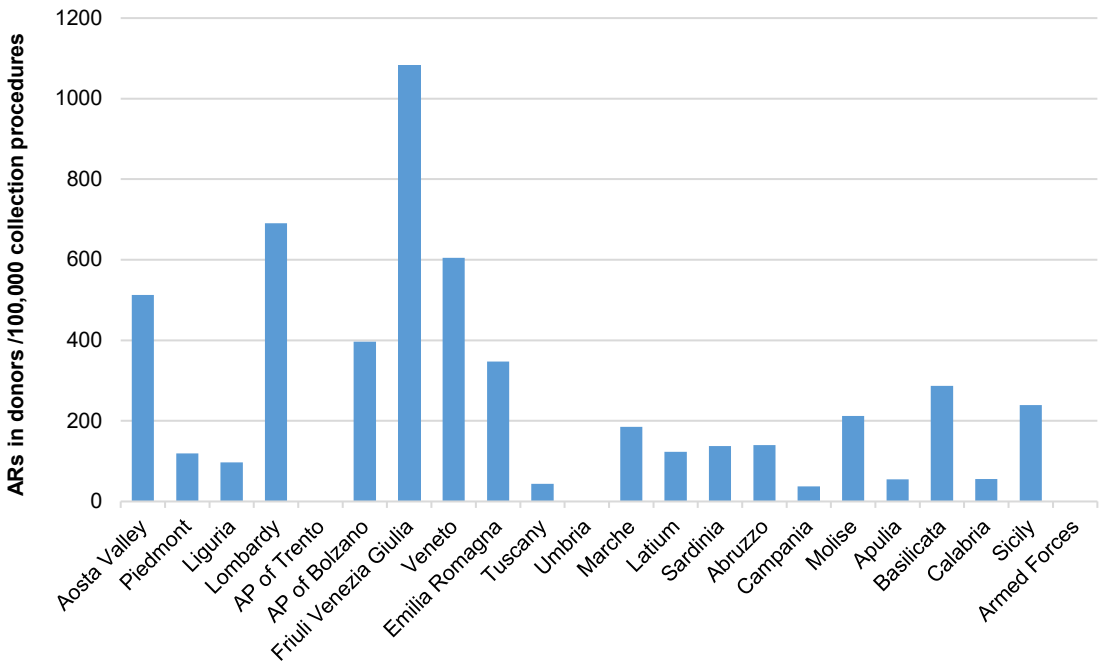

Figure 9. Adverse reactions in donors by region, per 100,000 collection procedures (2024)

As reported in Table 21, 6,985 (73.1%) ARs were related to whole blood donations and 2,568 (26.9%) to apheresis donations. The highest ARs frequency, by type of collection procedure, was

observed for apheresis donation (523.9 per 100,000 apheresis collection procedures vs. 272.4 per 100,000 whole blood collection procedures).

Table 21. Adverse reactions to donations, by collection procedure (2024)

Collection procedure			ARs			ARs/100,000 collection procedures		
Whole blood	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*
2,563,784	490,172	3,053,956	6,985	2,568	9,553	272.4	523.9	312.8

ARs, Adverse Reactions.

Immediate vasovagal reactions, delayed vasovagal reactions and haematomas were the most observed ARs in blood donors (245.9, 27.8 and 23.1 per 100,000 total collection procedures, respectively) (Table 22). Immediate vasovagal reactions were more frequent in apheresis collection (356.4 per 100,000 procedures) than in whole blood collection (224.8 per 100,000 procedures). The appearance of haematomas was also more frequent in apheresis collection (99.5 per 100,000 procedures) than in whole blood collection (8.4 per 100,000 procedures).

Table 22. Adverse reactions in donors (2024)

ARs	n.	%	ARs/100,000 collection procedures		
			Whole blood	*Apheresis*	*Total*
Angina pectoris	1	0.01	0.00	0.20	0.03
Arterial puncture	34	0.36	1.25	0.41	1.11
Arteriovenous fistula	1	0.01	0.04	0.00	0.03
Citrate reaction	72	0.75	0.00	14.69	2.36
Cold/shivers	9	0.09	0.00	1.84	0.29
Delayed vasovagal reaction	849	8.89	28.55	23.87	27.80
Delayed vasovagal reaction with complications	27	0.28	0.74	1.63	0.88
Haematoma	705	7.38	8.46	99.56	23.08
Immediate vasovagal reaction	7,511	78.62	224.82	356.41	245.94
Immediate vasovagal reaction with complications	64	0.67	1.79	3.67	2.10
Incidents tied to vasovagal syndrome	6	0.06	0.23	0.00	0.20
Local allergic reaction	15	0.16	0.08	2.65	0.49
Local infection	2	0.02	0.08	0.00	0.07
Nerve injury	11	0.12	0.31	0.61	0.36
Nerve injury due to a haematoma	3	0.03	0.12	0.00	0.10
Other	206	2.16	5.07	15.50	6.75
Other incidents	28	0.29	0.74	1.84	0.92
Systemic allergic reaction	3	0.03	0.00	0.61	0.10
Thrombophlebitis	6	0.06	0.16	0.41	0.20
Total	**9,553**	**100.00**	**272.45**	**523.90**	**312.81**

ARs, Adverse Reactions.

The severity of the notified reactions was mainly mild (72.9%) (Table 23). The severe ARs to donation occurred in 11.8 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 (2024)

ARs	Mild	%	Moderate	%	Severe	%
Angina pectoris	1	0.01		0.00		0.00
Arterial puncture		0.00	34	1.53		0.00
Arteriovenous fistula		0.00		0.00	1	0.28
Citrate reaction	40	0.57	18	0.81	14	3.87
Cold/shivers	7	0.10		0.00	2	0.55
Delayed vasovagal reaction	563	8.08	245	11.02	41	11.33
Delayed vasovagal reaction with complications	3	0.04	17	0.76	7	1.93
Haematoma	597	8.57	61	2.74	47	12.98
Immediate vasovagal reaction	5,515	79.15	1,776	79.89	220	60.77
Immediate vasovagal reaction with complications	13	0.19	44	1.98	7	1.93
Incidents tied to vasovagal syndrome		0.00		0.00	6	1.66
Local allergic reaction	14	0.20	1	0.04		0.00
Local infection	1	0.01	1	0.04		0.00
Nerve injury	8	0.11	3	0.13		0.00
Nerve injury due to a haematoma	2	0.03	1	0.04		0.00
Other	185	2.65	14	0.63	7	1.93
Other incidents	19	0.27	8	0.36	1	0.28
Systemic allergic reaction		0.00		0.00	3	0.83
Thrombophlebitis		0.00		0.00	6	1.66
Total (%)	**6,968 (72.9)**	**100.00**	**2,223 (23.3)**	**100.00**	**362 (3.8)**	**100.00**
Total ARs/100,000 total collection procedures	**228.2**		**72.8**		**11.8**	

ARs, Adverse Reactions.

The severe ARs were more frequent in apheresis than in whole blood donation procedures (25.0 vs. 9.3 per 100,000 collection procedures, respectively) (Table 24).

Table 24. Severe adverse reactions to donation, by collection procedure (2024)

Collection procedure			ARs			ARs/100,000 collection procedures		
Whole blood	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*
2,563,784	490,172	3,053,956	239	123	362	9.32	25.09	11.85

SARs, severe adverse reactions.

Serious adverse events

In 2024, 20 SAEs were notified. The regional distribution of the notifications shows a wide variability with a national average of 0.63 per 100,000 issued units. Marche and Latium recorded the highest values (2.37 and 2.09 per 100,000 issued units, respectively) (Figure 10).

Human error (1 every 198,080 issued units) was the main cause of SAE (0.50 per 100,000 issued units). Other SAEs were due to organisational error and equipment or material failure, for a total of 0.12 per 100,000 issued units (Table 25 and Figure 11).

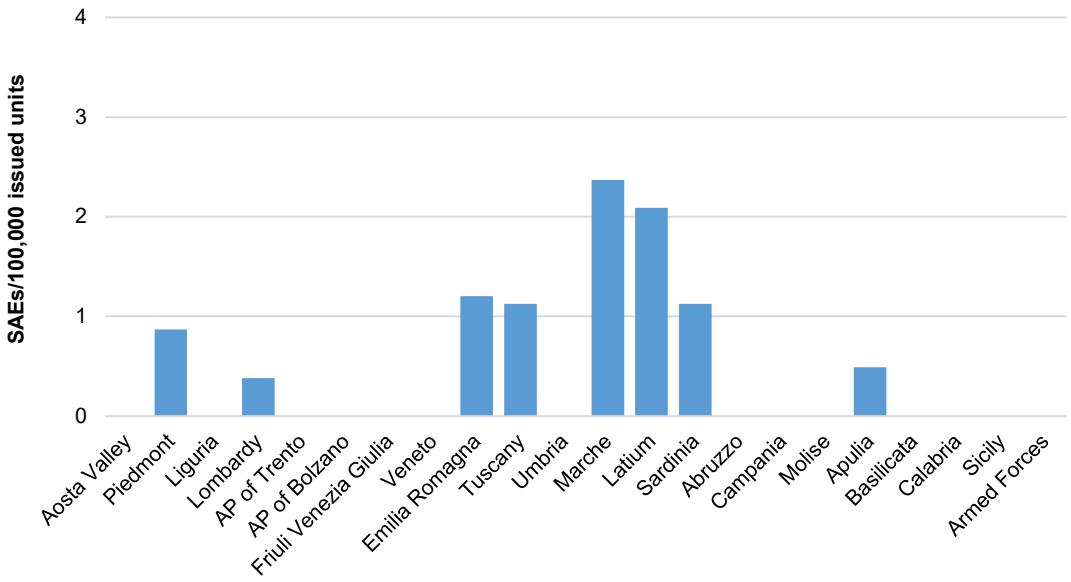

Figure 10. Serious adverse events notified by region, per 100,000 issued units (2024)

Table 25. Cause of serious adverse events (2024)

Cause	n.	%	SAEs/100,000 issued units
Equipment failure	1	5.0	0.03
Human error	16	80.0	0.50
Material failure	1	5.0	0.03
Organisational error	2	10.0	0.06
Total	**20**	**100.0**	**0.63**

SAEs, Serious Adverse Events

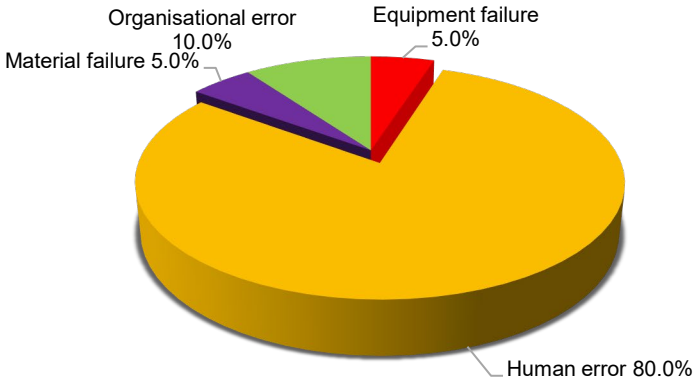

Figure 11. Cause of serious adverse events (2024)

The majority of SAEs occurred in the phase “other (issue / assignment)” (45.0%) (Table 26 and Figure 12). The notified SAEs occurred in clinical wards and in BEs with a frequency of 55.0% and 40.0%, respectively (Table 27 and Figure 13).

Table 26. Phases in which serious adverse events occurred (2024)

Phase	n.	%	SAEs/100,000 issued units
Collection	4	20.0	0.13
Distribution	3	15.0	0.09
Storage	1	5.0	0.03
Other	3	15.0	0.09
Other (issue / assignment)	9	45.0	0.28
Total	**20**	**100.0**	**0.63**

SAEs, Serious Adverse Events.

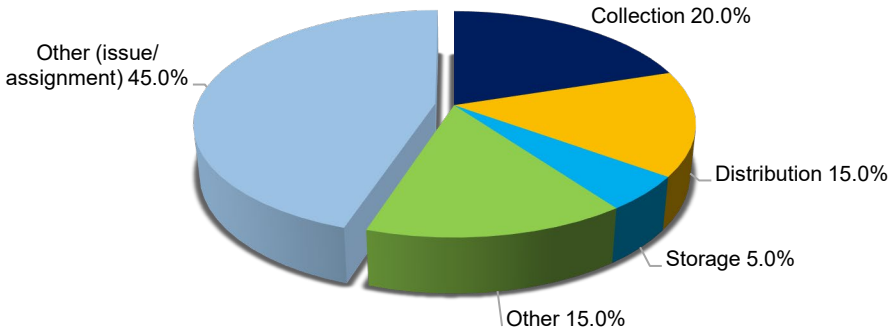

Figure 12. Phases in which serious adverse events occurred (2024)

Table 27. Serious adverse events by site of occurrence (2024)

Site	n.	%
BCS	1	5.0
BE	8	40.0
Clinical ward	11	55.0
Total	**20**	**100.0**

BE Blood Establishment, BCS Blood Collection Site

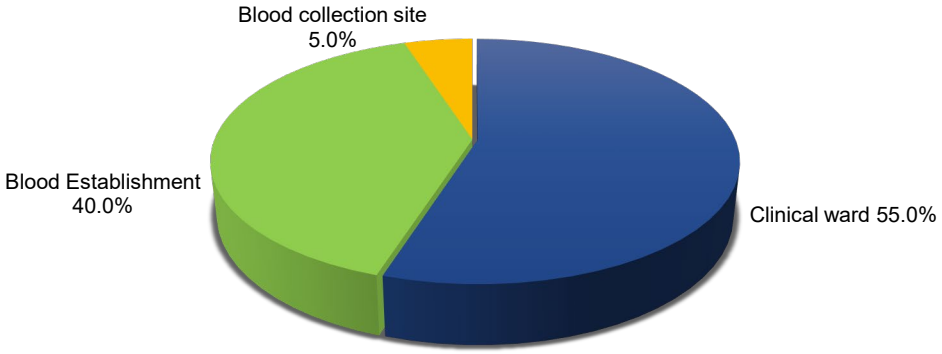

Figure 13. Site in which serious adverse events occurred (2024)

Near miss

In 2024, 281 near miss events (8.87 per 100,000 units issued), as defined by the EDQM Guide (14), were notified. Many notifications were about "wrong information on the tube label" (4.26 per 100,000 units issued) and "wrong patient" (3.34 per 100,000 units issued) (Table 28); many "avoided transfusions of blood component not intended for the patient" (0.54 per 100,000 units issued) were also reported.

Table 28. Near miss events (2024)

Type of primary error (near miss)	n.	%	Near miss/100,000 issued units
Avoided transfusion of blood component not intended for the patient	17	6.0	0.54
Avoided transfusion of expired blood component	1	0.4	0.03
Avoided transfusion of inappropriate blood component	3	1.1	0.09
Error in pre-transfusion test	3	1.1	0.09
Wrong group of blood component	2	0.7	0.06
Wrong information on the blood unit label	3	1.1	0.09
Wrong information on the tube label	135	48.0	4.26
Wrong patient collected	106	37.7	3.34
Wrong/inappropriate blood component type requested	11	3.9	0.35
Total	**281**	**100.0**	**8.87**

Comments and recommendations

As in the previous year (6), the 2024 haemovigilance data reported that the most frequent blood transfusion's ARs, considering all the imputability and severity levels, were febrile non-haemolytic reactions (28.6 per 100,000 transfused units) and allergic manifestations with only mucosal and cutaneous symptoms (18.9 per 100,000 transfused units). The ARs involving the respiratory system were 11.0% of the total notifications.

In 2024, 2 acute haemolytic reactions due to ABO incompatible transfusions (0.08 per 100,000 units of red blood cells transfused) were notified. The imputability of the above-mentioned events, reported as probable or certain, was 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 1,933 reported ARs in recipient, 725 (37.5%) were with a high imputability (level 2-3), of which 11 with a high severity (level 3 - severe symptoms requiring resuscitation procedures or 4 - death) with a frequency of 0.39 per 100,000 units transfused. In detail, there were notified 1 anaphylactic shock, 9 ARs involving the respiratory system (1 TAD, 2 TACOs and 6 allergic reactions) and 1 other likely non-specific reaction to plasma transfusion.

The adverse reactions to allogeneic donation were 9,553. The immediate vasovagal reactions, which represented 78.6% of the total notified ARs in blood donors, occurred in 1 every 406 collection procedures and were the most frequent ARs for both whole blood and apheresis collection (224.8 and 356.4 per 100,000 collection procedures, respectively). Moreover, the other ARs with a high frequency of occurrence were haematomas in apheresis collection (99.5 per 100,000 collection procedures) and delayed vasovagal reactions (28.5 in whole blood and 23.8 in apheresis, per 100,000 collection procedures).

In 2024, 20 SAEs and 281 near miss errors were notified. The frequency of SAEs was 1 every 158,464 issued units. Human error was the main cause of adverse events (0.50 per 100,000 issued

units) and the "other (issue / assignment)" phase (0.28 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 (7.6 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 related to 2024 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 forth 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" (15).

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 2024, out of a total of 1,895,811 blood donors, 1,239 were tested and turned out to be positive for the currently mandatory infectious disease markers.

Table 29 shows the total number of positive donors by 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 (2.43‰), followed by Molise (2.06‰) and Apulia (1.37‰) regions.

Table 29. Tested donors and positive donors to infectious markers at national and regional level (2024)

Region/AP	Tested donors	Positive donors	
	n.	n.	‰
Aosta Valley	4,098	4	0.98
Piedmont	126,861	80	0.63
Liguria	50,172	37	0.74
Lombardy	299,340	105	0.35
AP of Trento	22,590	6	0.27
AP of Bolzano	17,643	2	0.11
Friuli Venezia Giulia	49,674	19	0.38
Veneto	178,457	7	0.04
Emilia-Romagna	173,698	78	0.45
Tuscany	139,403	53	0.38
Umbria	28,947	15	0.52
Marche	56,194	24	0.43
Latium	151,757	132	0.87
Sardinia	55,657	43	0.77
Abruzzo	41,976	8	0.19
Campania	134,355	327	2.43
Molise	10,700	22	2.06
Apulia	118,599	162	1.37
Basilicata	19,530	1	0.05
Calabria	48,405	22	0.45
Sicily	167,050	92	0.55
Armed Forces	705	0	0.00
Italy	**1,895,811**	**1,239**	**0.65**

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, 46-55) (highlighted in grey) (Table

30, column 5). The data on the incidence of infections by age classes (Table 30, column 6) show very similar values for the central age classes (36-45 and 46-55).

Table 31 and Figure 15 show the percentage distribution by age class and gender of the 1,239 positive donors.

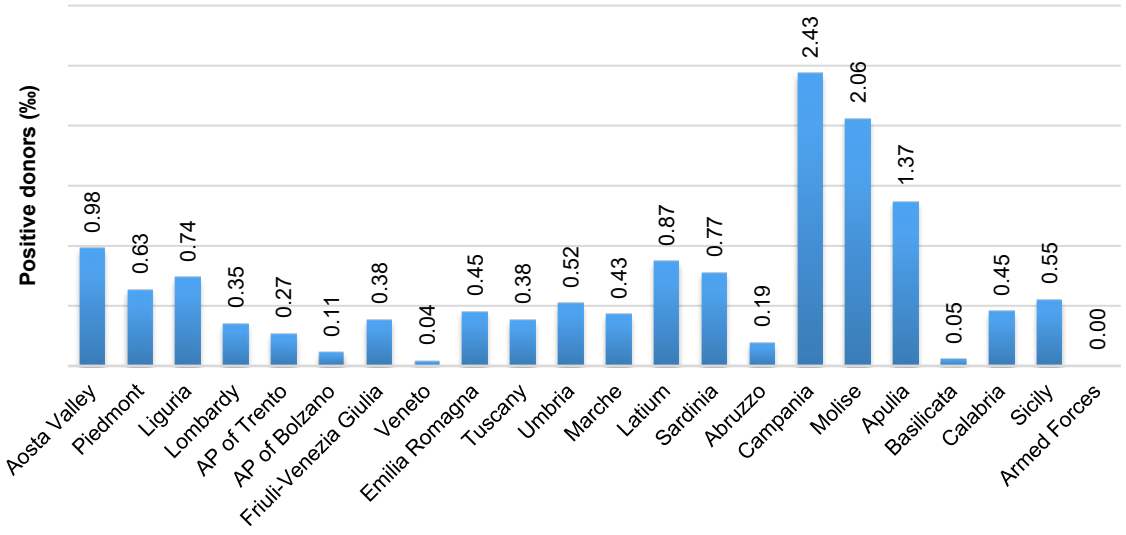

Figure 14. Positive donors per 1,000 tested donors (‰) by Italian Regions (2024)

Table 30. Positive donor by age class (2024)

Age class	Total donors		Positive donors		
	n.	%	n.	%	‰
18-25	266,761	14.1	101	8.2	0.38
26-35	345,170	18.2	201	16.2	0.58
36-45	401,355	21.2	295	23.8	0.74
46-55	518,114	27.3	390	31.5	0.75
56-65	336,751	17.8	240	19.4	0.71
over 65	27,660	1.5	12	1.0	0.43
Total	**1,895,811**	**100**	**1,239**	**100**	**0.65**

Table 31. Positive donors by age class and gender (2024)

Age class	Male				Female			
	donors		positive donors		donors		positive donors	
	n.	%	n.	%	n.	%	n.	%
18-25	138,477	11.3	77	8.3	128,284	19.2	24	7.6
26-35	213,047	17.4	164	17.7	132,123	19.7	37	11.8
36-45	269,699	22.0	225	24.3	131,656	19.7	70	22.3
46-55	349,716	28.5	267	28.9	168,398	25.2	123	39.2
56-65	234,416	19.1	180	19.5	102,335	15.3	60	19.1
over 65	21,044	1.7	12	1.3	6,616	1.0	0	0.0
Total	**1,226,399**	**100**	**925**	**100**	**669,412**	**100**	**314**	**100**

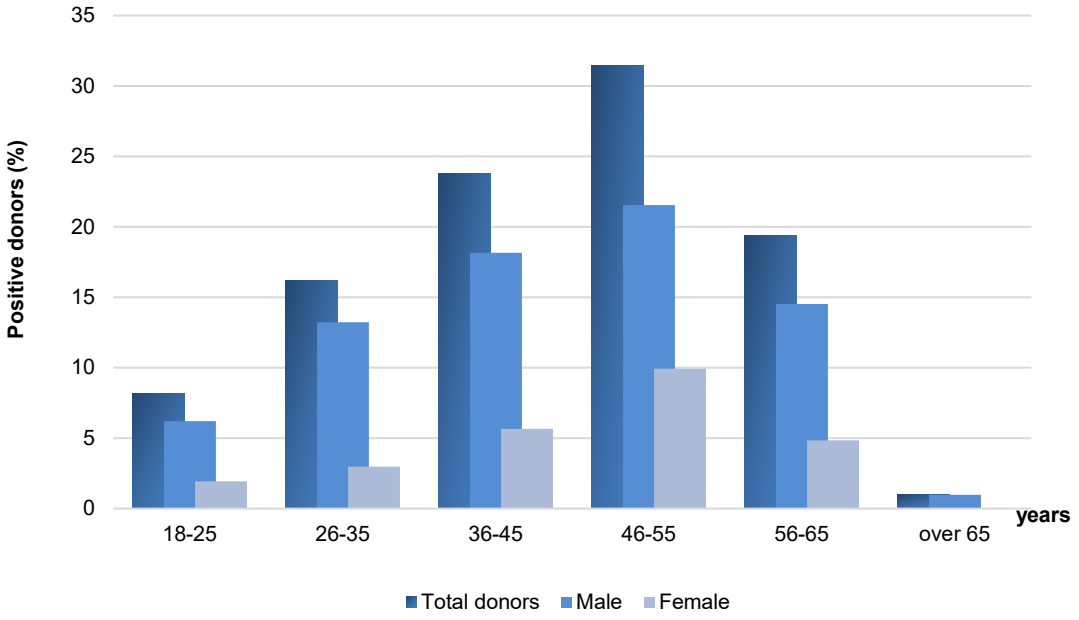

Figure 15. Distribution of positive donors (total, male and female donors) by age class (%) (2024)

Considering the number of infections detected in the total number of donors (‰ tested donors) for each age class, in almost all age classes, the highest number of positivity is found in male donors (Figure 16).

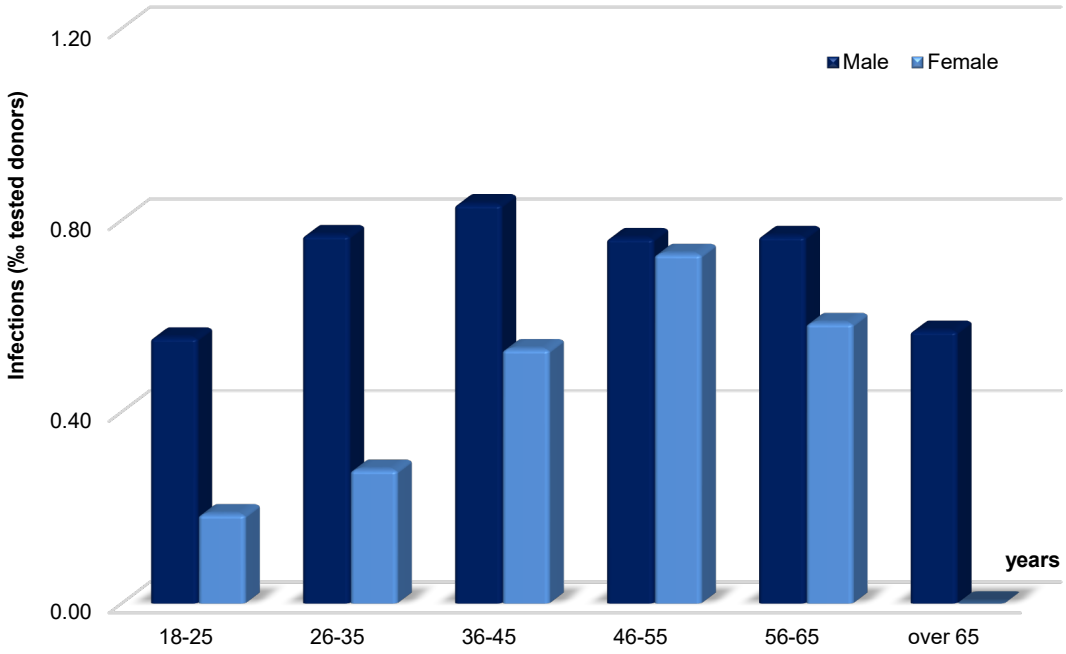

Figure 16. Positive donors by age class and gender (‰ total donors) (2024)

Figure 17 shows the percentages of positive donors for each single marker (HIV, HBV, HCV and TP), distributed by age class. The results show a different distribution of positive donors with respect to age classes. TP infection is prevalent in younger age groups (26-45 years). The trend in HIV positivity is almost constant in the age groups up to 55 years. HBV and HCV are prevalent in the older age classes (46-65 years).

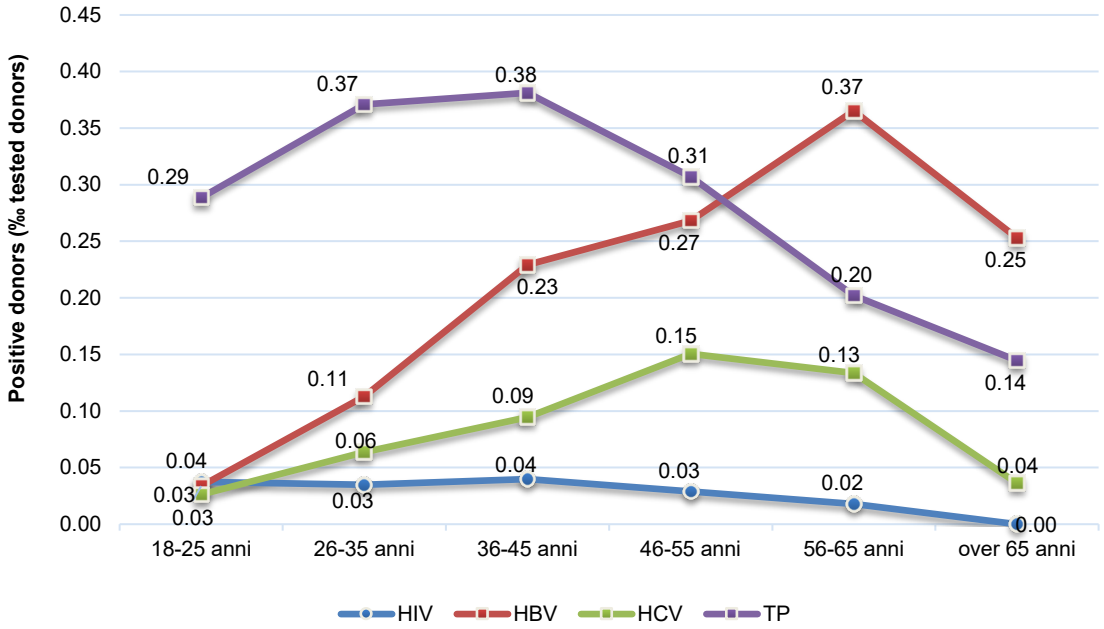

Figure 17. HIV, HBV, HCV and TP positive donors by age class (‰) (2024)

The number of positive donors significantly differs also between the categories of the donors. In fact, 2.02‰ of FT donors were positive to one of the infectious markers compared to 0.26‰ 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 (2024)

Donor category	Donors	Positive donors		
	n.	n.	%	(‰)
First-time tested donors	**421,491**	**853**	**68.85**	**2.02**
Prospective donors (first screening without donation)	183,201	269	21.71	1.47
First-time not pre-qualified donors	238,290	584	47.13	2.45
Repeat tested donors	**1,474,320**	**386**	**31.15**	**0.26**
First-time pre-qualified donors	126,590	7	0.56	0.06
Regular donors	1,347,730	379	30.59	0.28
Total donors	**1,895,811**	**1,239**	**100**	**0.65**

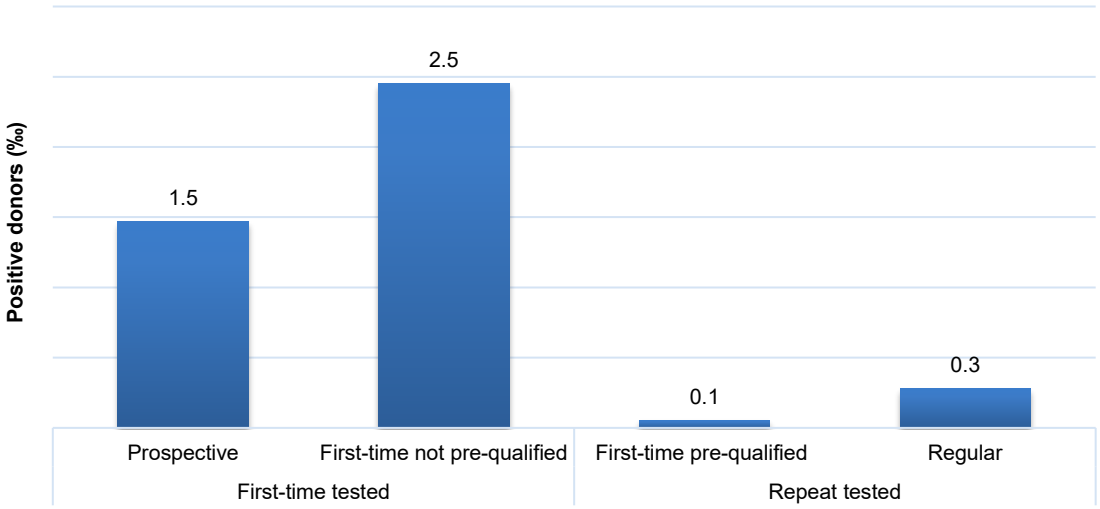

Figure 18. Categories of positive donors (2024)

Table 33 shows the number of FT and RT positive donors in Italy per region. The regions with the highest number of positive FT are Molise (6.96‰) and Campania (4.89‰); conversely the regions with the highest number of positive RT are Apulia (0.89‰) and Campania (0.71‰).

Table 33. FT and RT positive donors (total and per 1,000 (‰) tested donors) in Italy (2024)

Region/AP	Total of donors		Positive donors			
	FT	RT	FT	RT	FT (‰ FT)	RT (‰ RT)
Aosta Valley	652	3,446	2	2	3.07	0.58
Piedmont	20,842	106,019	47	33	2.26	0.31
Liguria	11,519	38,653	28	9	2.43	0.23
Lombardy	53,460	245,880	53	52	0.99	0.21
AP of Trento	3,499	19,091	4	2	1.14	0.10
AP of Bolzano	1,822	15,821	1	1	0.55	0.06
Friuli Venezia Giulia	11,095	38,579	16	3	1.44	0.08
Veneto	30,549	147,908	7	0	0.23	0.00
Emilia-Romagna	28,727	144,971	55	23	1.91	0.16
Tuscany	25,278	114,125	33	20	1.31	0.18
Umbria	5,081	23,866	10	5	1.97	0.21
Marche	8,897	47,297	16	8	1.80	0.17
Latium	56,753	95,004	113	19	1.99	0.20
Sardinia	16,411	39,246	28	15	1.71	0.38
Abruzzo	8,991	32,985	4	4	0.44	0.12
Campania	55,459	78,896	271	56	4.89	0.71
Molise	3,017	7,683	21	1	6.96	0.13
Apulia	31,357	87,242	84	78	2.68	0.89
Basilicata	4,527	15,003	1	0	0.22	0.00
Calabria	8,825	39,580	8	14	0.91	0.35
Sicily	34,359	132,691	51	41	1.48	0.31
Armed Forces	371	334	0	0	0.00	0.00
Italy	**421,491**	**1,474,320**	**853**	**386**	**2.02**	**0.26**

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Figure 19 reports the same data shown in Table 33 (positive donors per 1,000 tested donors (‰)). The data reported in Figure 20 show a prevalence of positivity in male FT donors.

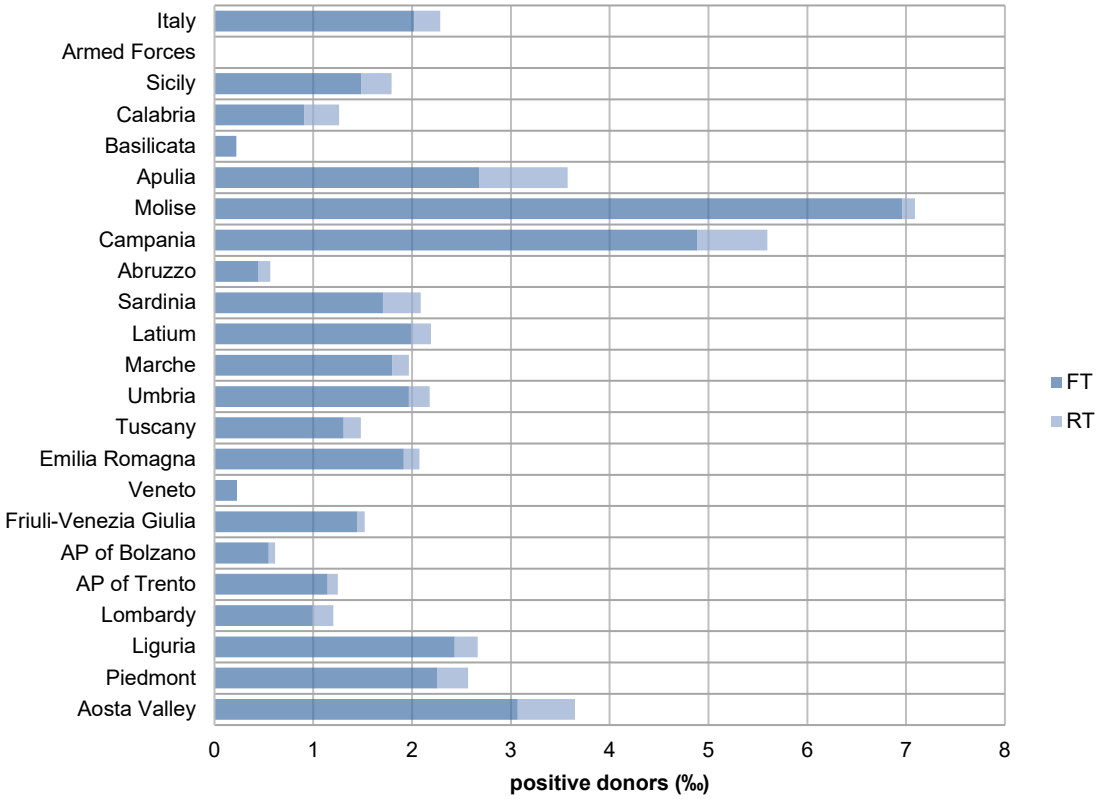

Figure 19. Positive donors by FT and RT category (‰) at national and regional level (2024)

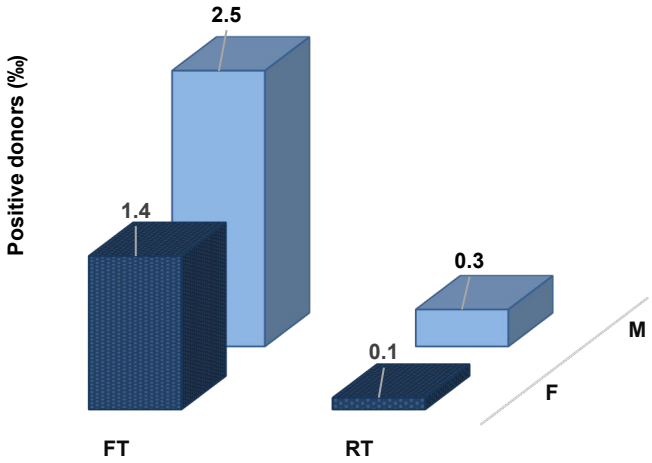

Figure 20. Positive donors by FT and RT category (‰ total male and female donors) and gender (2024)

Figure 21 shows the positive donor distribution at national and regional level for each infectious marker per 100,000 tested donors. Molise is the region with the highest ratio of HIV and HBV infections per 100,000 donors (HIV: 9.3/100,000, HBV: 158.9/100,000). The regions with the highest ratio of HCV and TP infections per 100,000 donors are Campania (HCV: 52.1/100,000) and Aosta Valley (TP: 97.6/100,000), respectively.
These values were from 3 (HIV) to 7.4 times (HBV) higher compared to the national data (HIV 3.1/100,000; HBV (21.6/100,000).

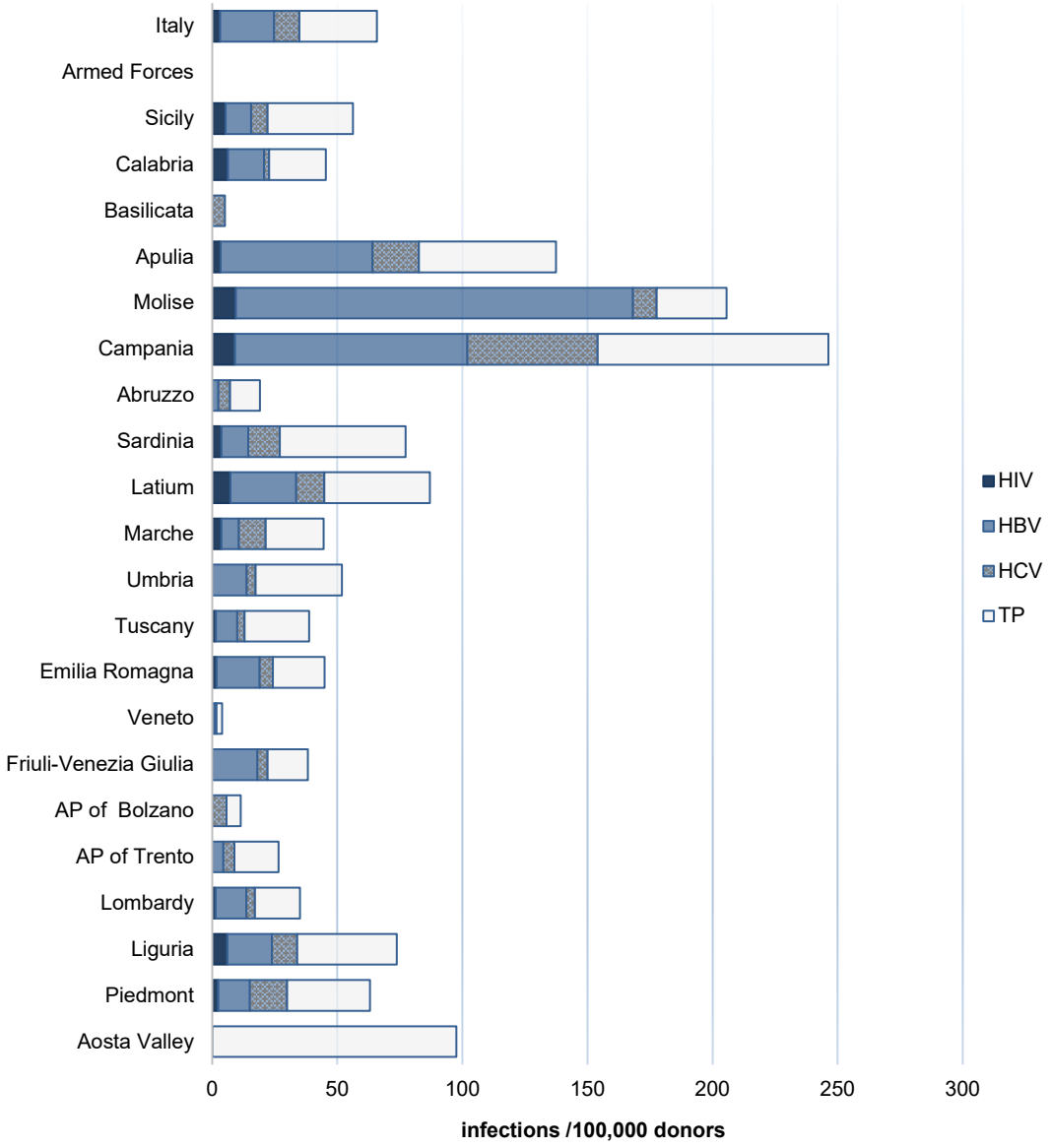

Figure 21. Positive donor distribution at national and regional level for each infectious marker per 100,000 donors (2024)

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

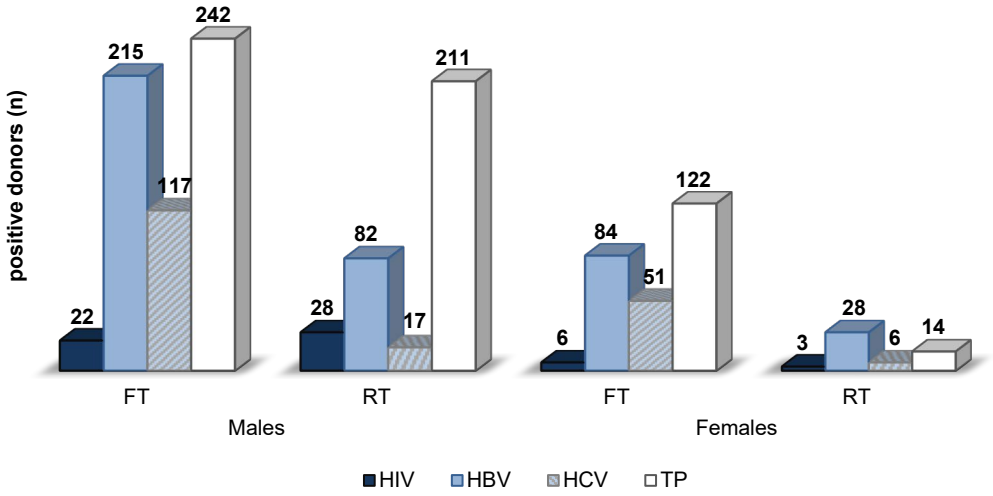

Figure 22. Infections by donor category (FT/RT), gender and infectious marker (2024)

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 (86.4/100,000 FT donors), followed by HBV (70.9/100,000 FT donors).

Table 34. Prevalence by infectious marker/100,000 FT donors (2024)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	306.8
Piedmont	4.8	43.2	86.4	91.2
Liguria	17.4	78.1	17.4	130.2
Lombardy	1.9	37.4	15.0	44.9
AP of Trento	0.0	28.6	28.6	57.2
AP of Bolzano	0.0	0.0	54.9	0.0
Friuli Venezia Giulia	0.0	81.1	9.0	54.1
Veneto	0.0	6.6	3.3	13.1
Emilia-Romagna	3.5	80.1	24.4	83.6
Tuscany	7.9	43.5	7.9	75.2
Umbria	0.0	78.7	19.7	98.4
Marche	0.0	33.7	67.4	78.7
Latium	7.1	63.4	30.0	98.7
Sardinia	6.1	36.6	30.5	97.5
Abruzzo	0.0	0.0	22.2	22.2
Campania	14.4	189.3	113.6	176.7
Molise	33.2	563.5	33.2	66.3
Apulia	6.4	89.3	67.0	108.4
Basilicata	0.0	0.0	22.1	0.0
Calabria	11.3	11.3	11.3	56.7
Sicily	11.6	43.7	26.2	69.9
Armed Forces	0.0	0.0	0.0	0.0
Italy	**6.6**	**70.9**	**39.9**	**86.4**

AP, Autonomous Province

As reported in Table 35, the highest incidence value was for TP (15.3/100,000 RT donors) and HBV (7.5/100,000 RT donors) infections. Moreover, it is important to note that, as in previous

years, in 51% 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 (49%), in most cases the donor "denied the risk factor" (31%) (Figure 23).

Table 35. Incidence by infectious marker/100,000 RT donors (2024)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	58.0
Piedmont	1.9	6.6	0.9	21.7
Liguria	2.6	0.0	7.8	12.9
Lombardy	1.2	6.9	0.8	12.2
AP of Trento	0.0	0.0	0.0	10.5
AP of Bolzano	0.0	0.0	0.0	6.3
Friuli Venezia Giulia	0.0	0.0	2.6	5.2
Veneto	0.0	0.0	0.0	0.0
Emilia-Romagna	1.4	4.8	1.4	8.3
Tuscany	0.0	0.9	1.8	14.9
Umbria	0.0	0.0	0.0	21.0
Marche	4.2	2.1	0.0	12.7
Latium	7.4	4.2	0.0	8.4
Sardinia	2.6	0.0	5.1	30.6
Abruzzo	0.0	3.0	0.0	9.1
Campania	5.1	25.4	8.9	33.0
Molise	0.0	0.0	0.0	13.0
Apulia	2.3	50.4	1.2	35.5
Basilicata	0.0	0.0	0.0	0.0
Calabria	5.1	15.2	0.0	15.2
Sicily	3.8	1.5	1.5	24.9
Armed Forces	0.0	0.0	0.0	0.0
Italy	**2.1**	**7.5**	**1.6**	**15.3**

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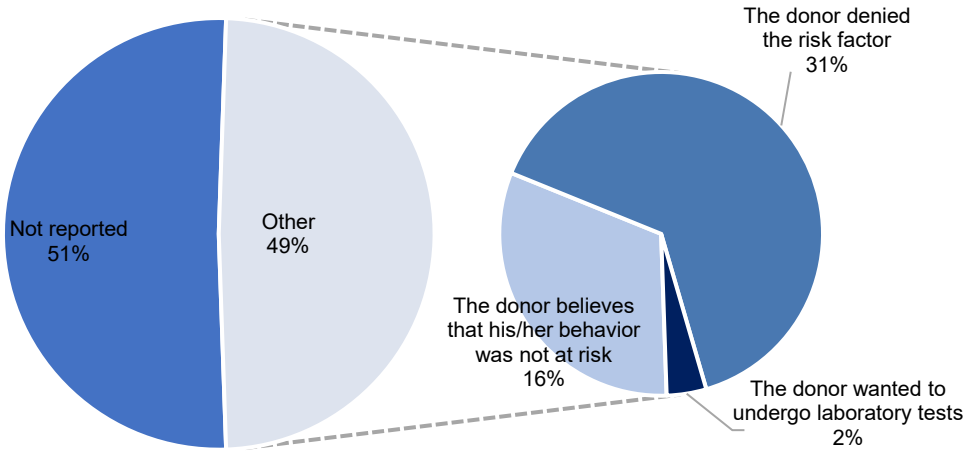

Figure 23. Causes of missed deferral of donor positive to infectious markers (2024)

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) (2024)

Nationality	Positive donors		FT		RT	
	n.	%	n.	%	n.	%
Italians	944	76.2	575	67.4	369	95.6
Foreigners	295	23.8	278	32.6	17	4.4
Total	**1,239**	**100**	**853**	**100**	**386**	**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 (2024)

Geographical area of birth	FT	RT	Total
Africa	45	3	48
America	28	4	32
Asia	27	1	28
Europe	178	9	187
Italy	575	369	944
Total	**853**	**386**	**1,239**

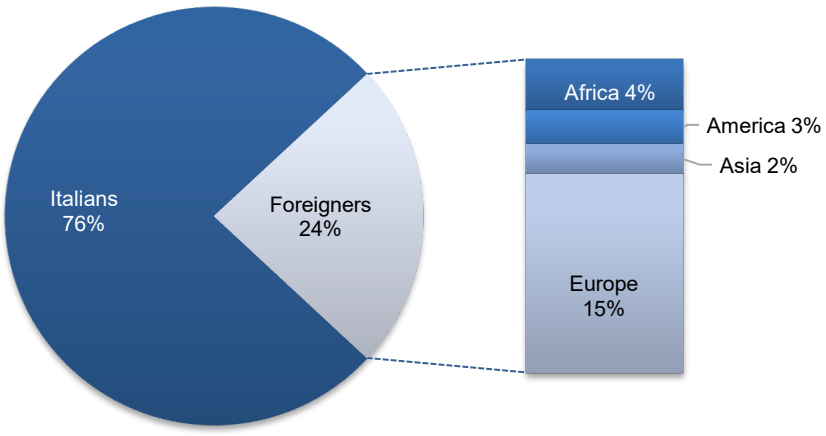

Figure 24. Positive donors to infectious markers by nationality (%) (2024)

HIV surveillance data

Table 38 shows the number of HIV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2024, 59 HIV infections were reported, with a prevalence of 6.6 per 100,000 FT donors and an incidence of 2.1 per 100,000 RT donors. The highest prevalence (33.2 per 100,000) of HIV infections was found in Molise Region; the highest incidence (7.4 per 100,000) was found in Latium Region.

Table 38. Number, prevalence and incidence of HIV infections per 100,000 donors at national and regional level (2024)

Region/AP	HIV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	3	4.8	1.9
Liguria	3	17.4	2.6
Lombardy	4	1.9	1.2
AP of Trento	0	0.0	0.0
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	0	0.0	0.0
Veneto	0	0.0	0.0
Emilia-Romagna	3	3.5	1.4
Tuscany	2	7.9	0.0
Umbria	0	0.0	0.0
Marche	2	0.0	4.2
Latium	11	7.1	7.4
Sardinia	2	6.1	2.6
Abruzzo	0	0.0	0.0
Campania	12	14.4	5.1
Molise	1	33.2	0.0
Apulia	4	6.4	2.3
Basilicata	0	0.0	0.0
Calabria	3	11.3	5.1
Sicily	9	11.6	3.8
Armed Forces	0	0.0	0.0
Italy	**59**	**6.6**	**2.1**

AP, Autonomous Province

Figure 25 shows the distribution, expressed as a percentage, of HIV positive donors by nationality; 12% of all positive donors were foreigners.

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

In about 36% of the HIV positive donors (21/59) it was not possible to identify the risk factor; in the remaining 64%, 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 (49/59) the molecular (NAT), serological and confirmatory tests were positive.

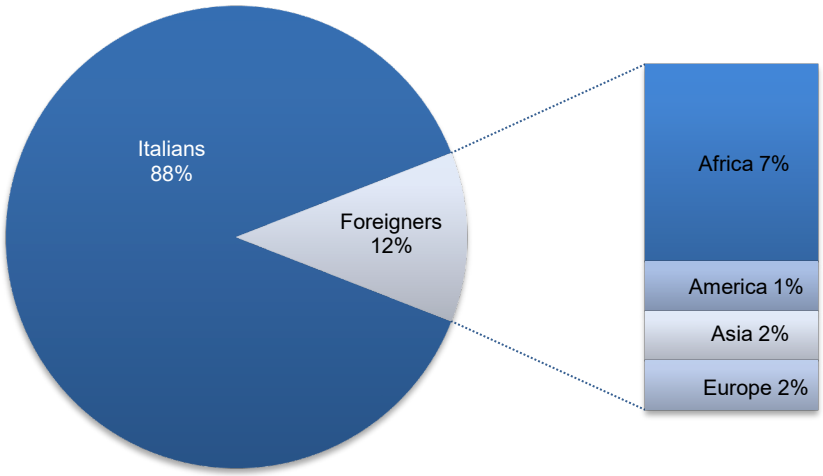

Figure 25. Distribution of HIV positive donors by nationality (%) (2024)

Table 39. HIV infections by geographical area of birth (2024)

Geographical area of birth	N. of infections
Africa	4
America	1
Asia	1
Europe	1
Italy	52
Total	**59**

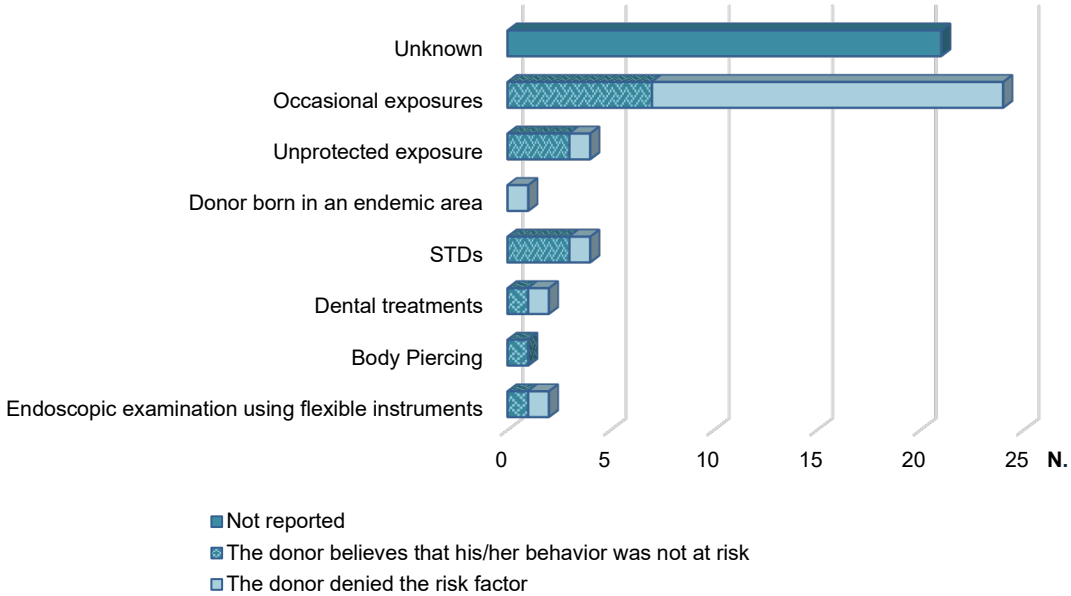

Figure 26. Causes of failed deferral and risk factors detected in HIV positive donors (2024)

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 2024, 191 HCV infections were reported, with a prevalence of 39.9 infections per 100,000 FT donors and an incidence of 1.6 infections per 100,000 RT donors. The highest prevalence (113.6 per 100,000 FT) and incidence (8.9 per 100,000 RT) values were found in the Campania Region.

Table 40. Number, prevalence and incidence of HCV infections per 100,000 donors at national and regional level (2024)

Region/AP	HCV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	19	86.4	0.9
Liguria	5	17.4	7.8
Lombardy	10	15.0	0.8
AP of Trento	1	28.6	0.0
AP of Bolzano	1	54.9	0.0
Friuli Venezia Giulia	2	9.0	2.6
Veneto	1	3.3	0.0
Emilia-Romagna	9	24.4	1.4
Tuscany	4	7.9	1.8
Umbria	1	19.7	0.0
Marche	6	67.4	0.0
Latium	17	30.0	0.0
Sardinia	7	30.5	5.1
Abruzzo	2	22.2	0.0
Campania	70	113.6	8.9
Molise	1	33.2	0.0
Apulia	22	67.0	1.2
Basilicata	1	22.1	0.0
Calabria	1	11.3	0.0
Sicily	11	26.2	1.5
Armed Forces	0	0.0	0.0
Italy	**191**	**39.9**	**1.6**

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 (2024)

Geographical area of birth	N. of infections
Africa	2
America	2
Asia	4
Europe	23
Italy	160
Total	**191**

Figure 27 shows the distribution, expressed as a percentage, of HCV positive donors by nationality; 16% of all positive donors were foreigners.

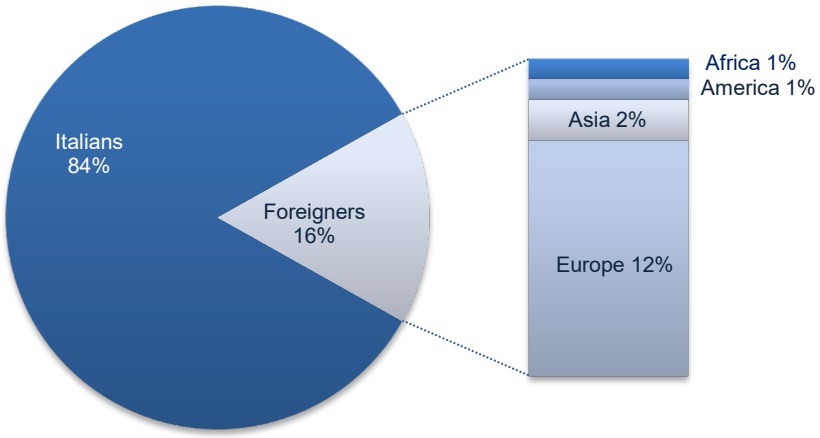

Figure 27. HCV positive donors by nationality (%) (2024)

In about 63% of HCV positive donors (120/191) it was not possible to identify the risk factor; in the remaining 37%, 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 "Donor knew/suspected to be positive" (Figure 28). In most cases (93/191), the molecular test (NAT) was negative with a positive serological screening and confirmatory tests.

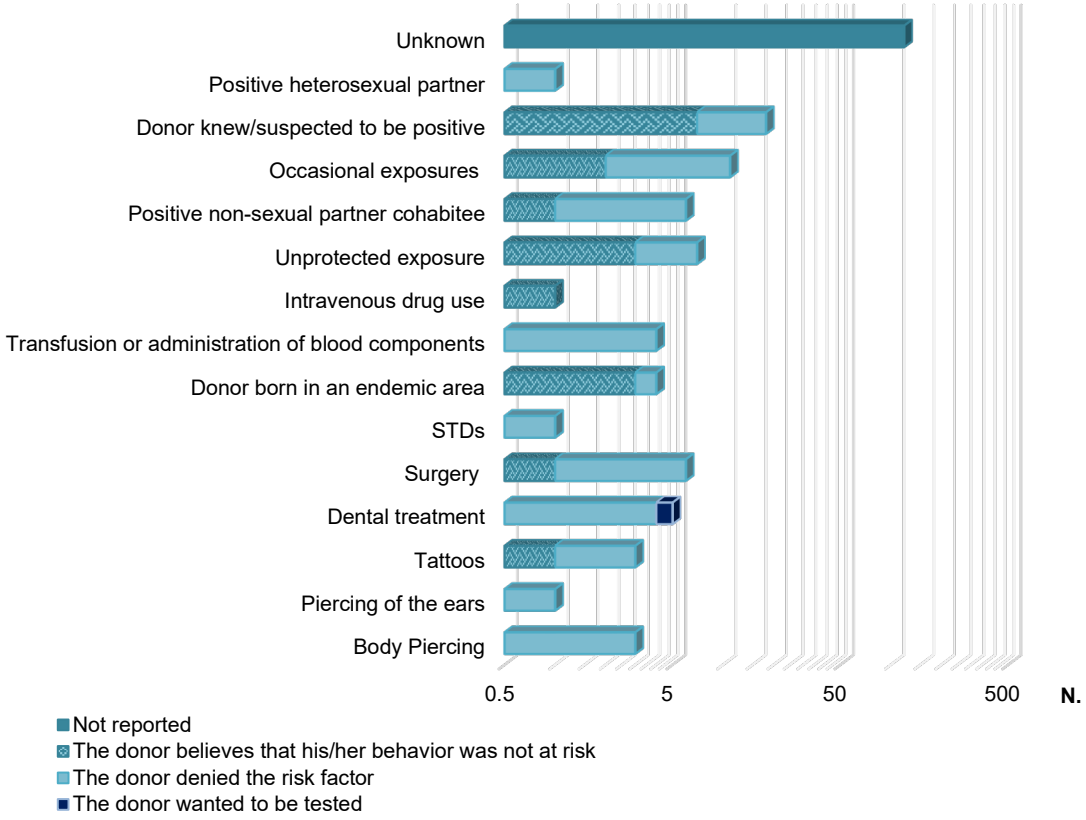

Figure 28. Causes of failed deferral and risk factors detected in HCV positive donors (values reported on a logarithmic scale) (2024)

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 2024, 409 HBV infections were reported with a prevalence of 70.9 infections per 100,000 FT donors and an incidence of 7.5 infections per 100,000 RT donors. The Region with the highest prevalence was Molise (563.5 per 100,000 FT); the highest incidence was found in Apulia Region (50.4 per 100,000 RT).

Table 42. Number, prevalence and incidence of HBV infections per 100,000 donors at national and regional level (2024)

Region/AP	HBV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	16	43.2	6.6
Liguria	9	78.1	0.0
Lombardy	37	37.4	6.9
AP of Trento	1	28.6	0.0
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	9	81.1	0.0
Veneto	2	6.6	0.0
Emilia-Romagna	30	80.1	4.8
Tuscany	12	43.5	0.9
Umbria	4	78.7	0.0
Marche	4	33.7	2.1
Latium	40	63.4	4.2
Sardinia	6	36.6	0.0
Abruzzo	1	0.0	3.0
Campania	125	189.3	25.4
Molise	17	563.5	0.0
Apulia	72	89.3	50.4
Basilicata	0	0.0	0.0
Calabria	7	11.3	15.2
Sicily	17	43.7	1.5
Armed Forces	0	0.0	0.0
Italy	**409**	**70.9**	**7.5**

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 (2024)

Geographical area of birth	N. of infections
Africa	34
America	2
Asia	16
Europe	105
Italy	252
Total	**409**

Figure 29 shows the distribution expressed as a percentage of HBV positive donors by nationality; 38% of all positive donors were foreigners.

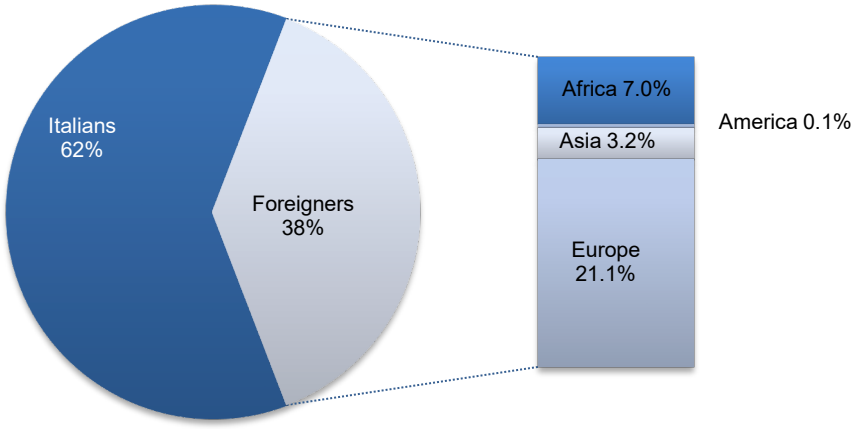

Figure 29. HBV positive donors by nationality (%) (2024)

In about 65% of the HBV positive donors (265/409), it was not possible to identify the risk factor; in the remaining 35%, 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" (Figure 30). In 210/409 cases the molecular (NAT), serological and confirmatory tests were positive.

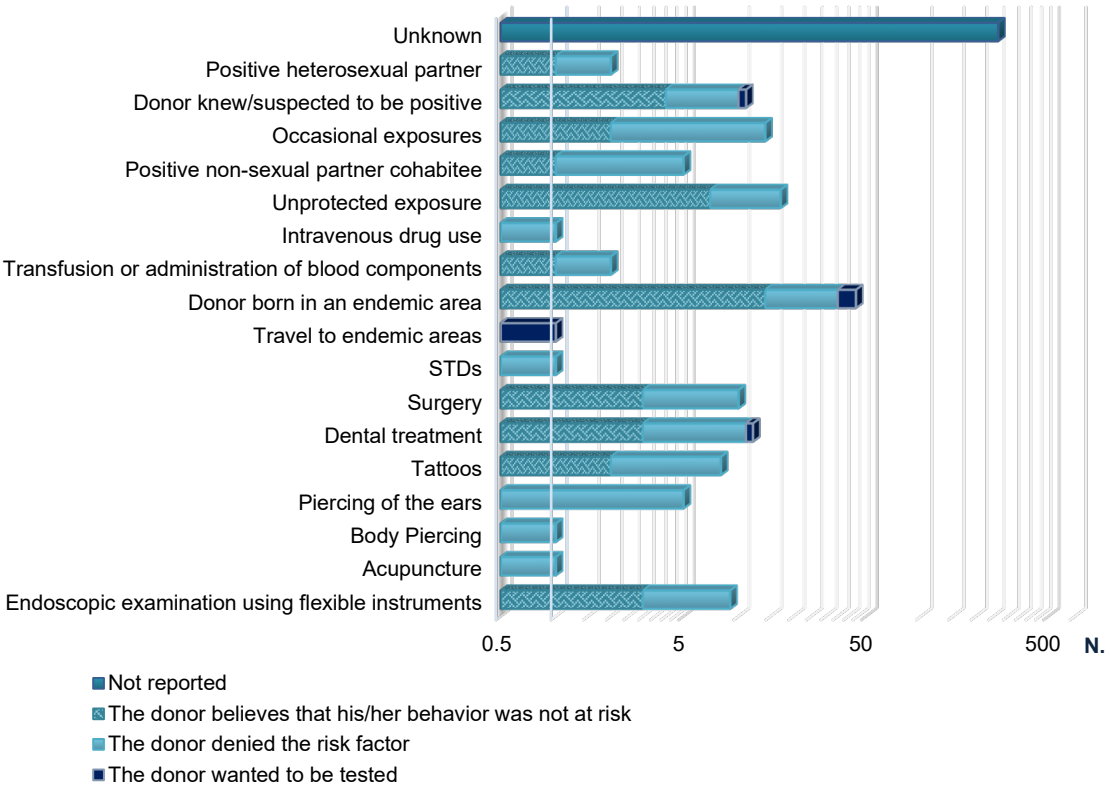

Figure 30. Causes of failed deferral and risk factors detected in HBV positive donors (values reported on a logarithmic scale) (2024)

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 2024, 589 TP infections were reported with a prevalence of 86.4 infections per 100,000 FT donors and an incidence of 15.3 infections per 100,000 RT donors. The Region with the highest prevalence (306.8 per 100,000 FT) and incidence (58.0 per 100,000 RT donors) was Aosta Valley.

Table 44. Number, prevalence and incidence of TP infections per 100,000 donors at national and regional level (2024)

Region/AP	TP infections		
	n.	prevalence	Incidence
Aosta Valley	4	306.8	58.0
Piedmont	42	91.2	21.7
Liguria	20	130.2	12.9
Lombardy	54	44.9	12.2
AP of Trento	4	57.2	10.5
AP of Bolzano	1	0.0	6.3
Friuli Venezia Giulia	8	54.1	5.2
Veneto	4	13.1	0.0
Emilia-Romagna	36	83.6	8.3
Tuscany	36	75.2	14.9
Umbria	10	98.4	21.0
Marche	13	78.7	12.7
Latium	64	98.7	8.4
Sardinia	28	97.5	30.6
Abruzzo	5	22.2	9.1
Campania	124	176.7	33.0
Molise	3	66.3	13.0
Apulia	65	108.4	35.5
Basilicata	0	0.0	0.0
Calabria	11	56.7	15.2
Sicily	57	69.9	24.9
Armed Forces	0	0.0	0.0
Italy	**589**	**86.4**	**15.3**

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 (2024)

Geographical area of birth	N. of infections
Africa	8
America	27
Asia	7
Europe	58
Italy	489
Total	**589**

Figure 31 shows the distribution, expressed as a percentage, of the TP positive donors by nationality; 17% of all positive donors were foreigners.

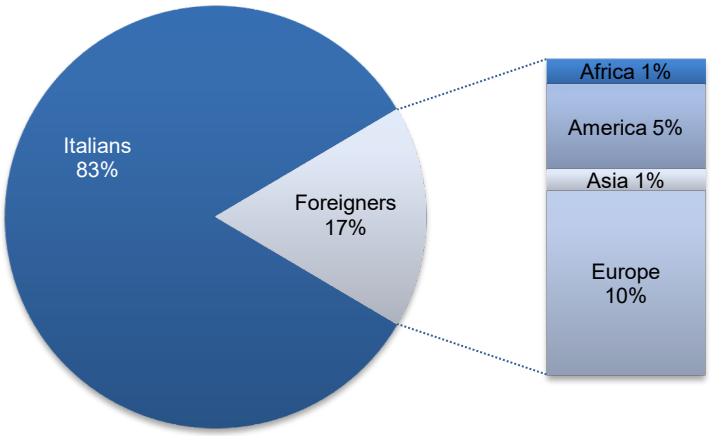

Figure 31. Distribution of TP positive donors by nationality (%) (2024)

In about 51% of the TP positive donors (298/589) it was not possible to identify the risk factor. In the remaining 49%, 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" (Figure 32).

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

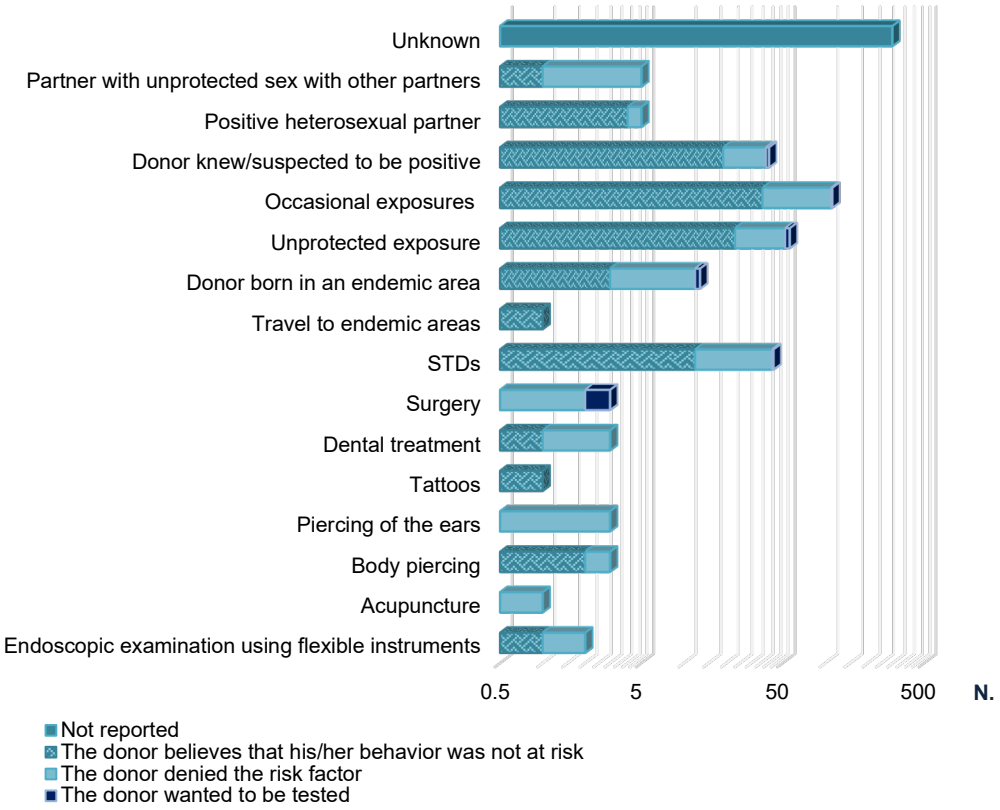

Figure 32. Causes of failed deferral and risk factors detected in TP positive donors (values reported on a logarithmic scale) (2024)

Coinfections

In this paragraph the authors want to provide more accurate epidemiological data on coinfection notified in blood donors for the year 2024.

Figure 33 shows the number of coinfected donors by gender and type of coinfection diagnosed; 7/9 coinfections included TP. Coinfections are found only in male subjects. More than 50% of coinfections are distributed across age classes 18-25 and 36-45 (Figure 34).

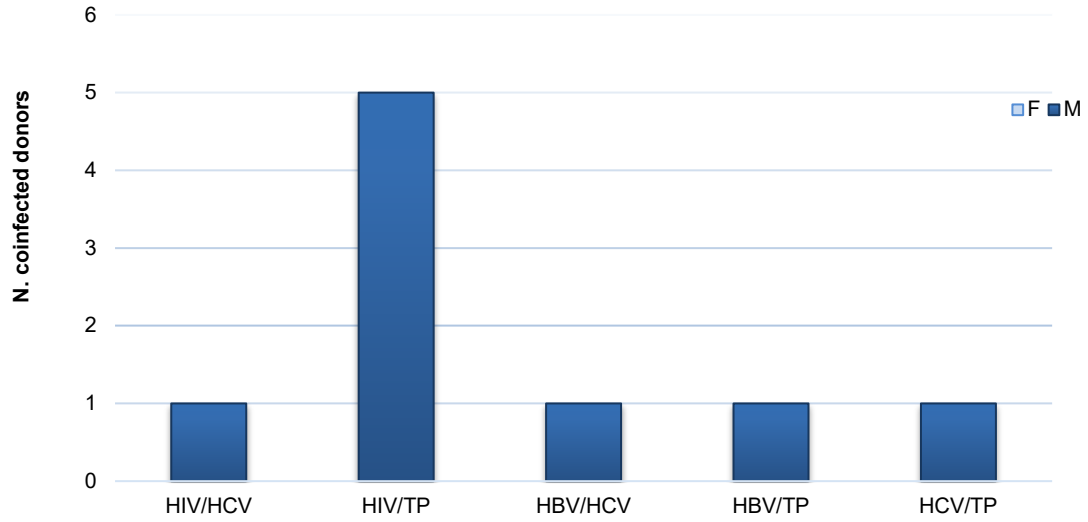

Figure 33. Number of coinfected donors by type of coinfection and by gender (2024)

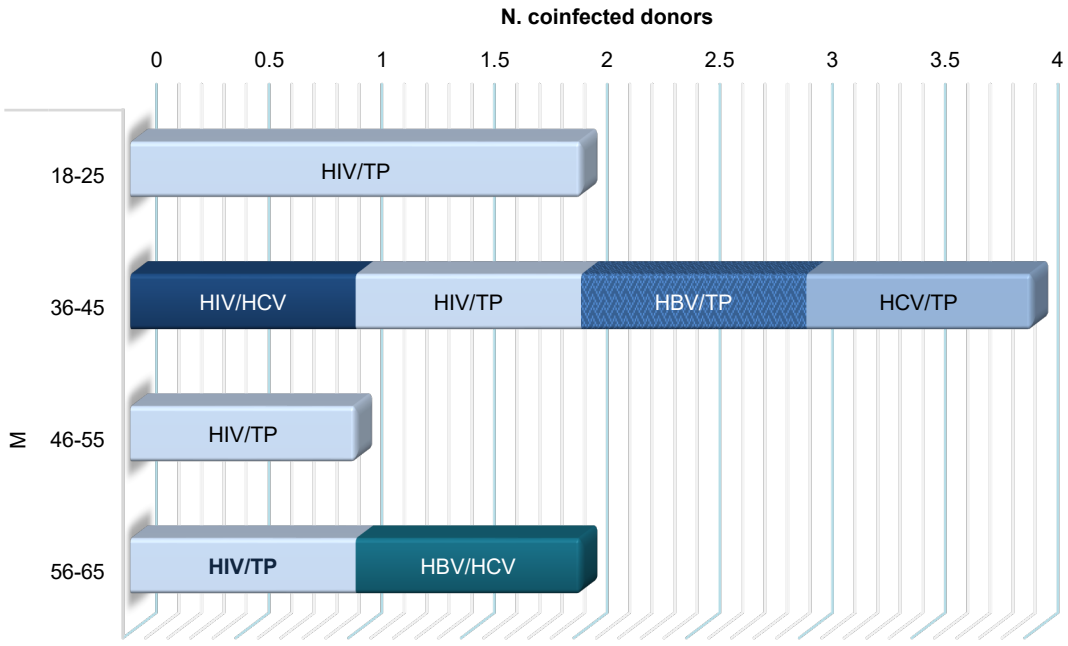

Figure 34. Number of coinfected donors by type of coinfection, age class and gender (2024)

For 3 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 due to high-risk sexual behaviours (Figure 35).

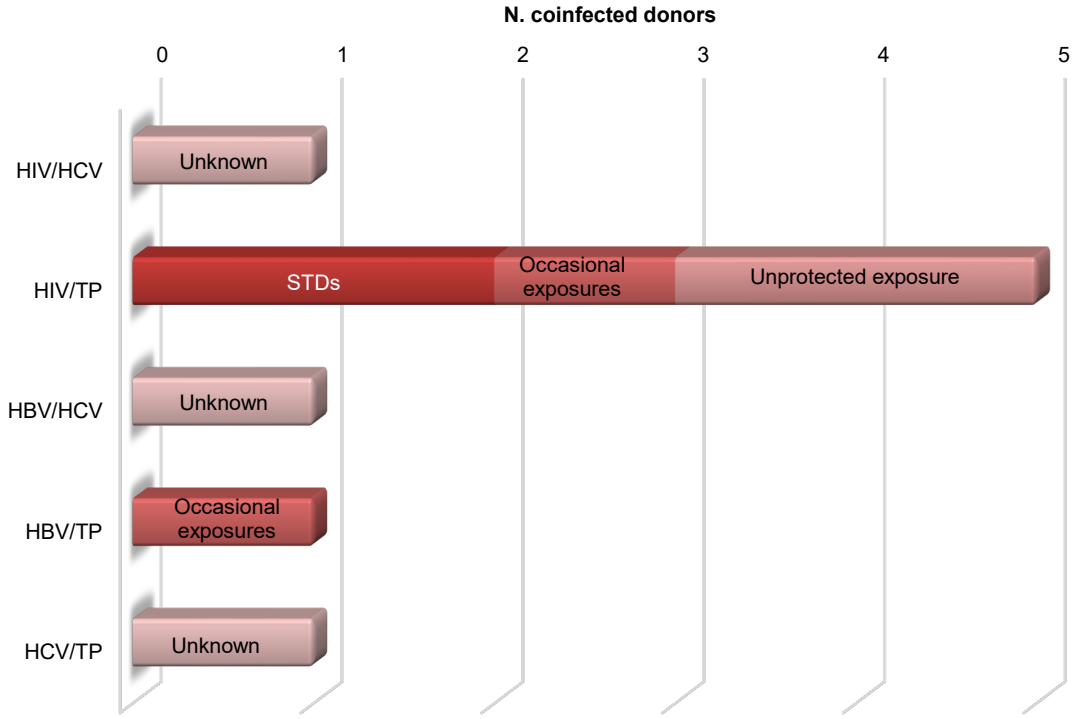

Figure 35. Number of coinfected donors by type of coinfection and risk factor (2024)

Discussion

The detection, through SISTRA, of positive blood donors allows to calculate the incidence and prevalence of transmissible infections on an annual basis as well as to monitor the trends and to 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 2024 with the highest numbers recorded in Campania, Molise and Apulia Regions.

The majority of donors who turned out to be positive to infectious markers were males (75%) and FT (69%). 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 (15.3) and prevalence (86.4) 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 2024, a slight increase in HBV cases was reported in the general population in Italy compared to 2023 (incidence 0.36 per 100,000 inhabitants). Lombardy, Emilia-Romagna and Tuscany reported the highest number of cases. The most affected are the subjects aged between 35 and 54 years (16).

In blood donors a slight decrease in the HBV incidence trend has been observed in recent years. This downward trend is certainly justified, in addition to the strict selection procedures, by the introduction, in the 90s, of the mandatory HBV vaccination to all subjects born since 1979. Compared to general population, blood donors' population recorded in 2024 higher rates of HBV incidence and prevalence in the Central-Southern Italian Regions (respectively Apulia and Molise), with about 32% of NAT-only infections.

HCV infections recorded, in general population, an incidence of 0.12 per 100,000 inhabitants, remaining almost constant in recent years. The highest number of acute HCVs was reported in the Lombardy and Veneto Regions. About 65% of cases are older than 34 years (16).

In keeping with data from the general population, HCV infection incidence in blood donors does not show significant increases in recent years. The highest HCV incidence and prevalence values are recorded in the Campania Region.

According to national data, HBV and HCV infections in blood donors are more frequent in 36-65 (HCV) and 36-over 65 age classes (HBV), 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 and TP positivity in blood donors is higher in 36-45 age class. For HIV infections about 36% of risk factors are not stated; for TP infection in about 51% 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 behaviours. These data correspond to the findings in the general population: in 2023, the highest incidence of HIV infection has been observed in 30-39 age class (9.9 cases per 100,000 residents); diagnosis of syphilis I-II and latent syphilis were more frequent in subjects aged 45 years or older (17-18). As in the general population, in recent years, an increase in the incidence of TP infection has also been observed in blood donors (18).

In 2023, the HIV geographical distribution in the general population showed the highest incidence in Aosta Valley, followed by Liguria, Emilia-Romagna, Tuscany, Lazio, Umbria, Campania, Molise, and Sicily Regions (17). The blood donor population shows, in 2024, a higher HIV incidence in Latium Region, followed by Campania and Calabria.

The analysis of coinfections showed that 7/9 coinfected donors were TP positive.

As in the previous years, many infected 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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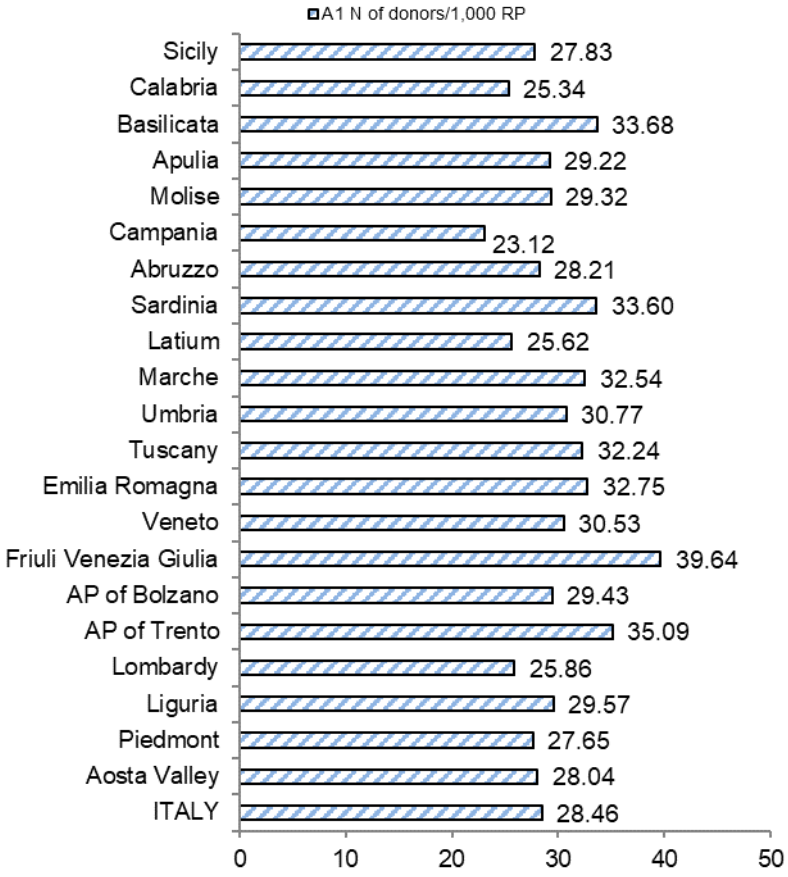
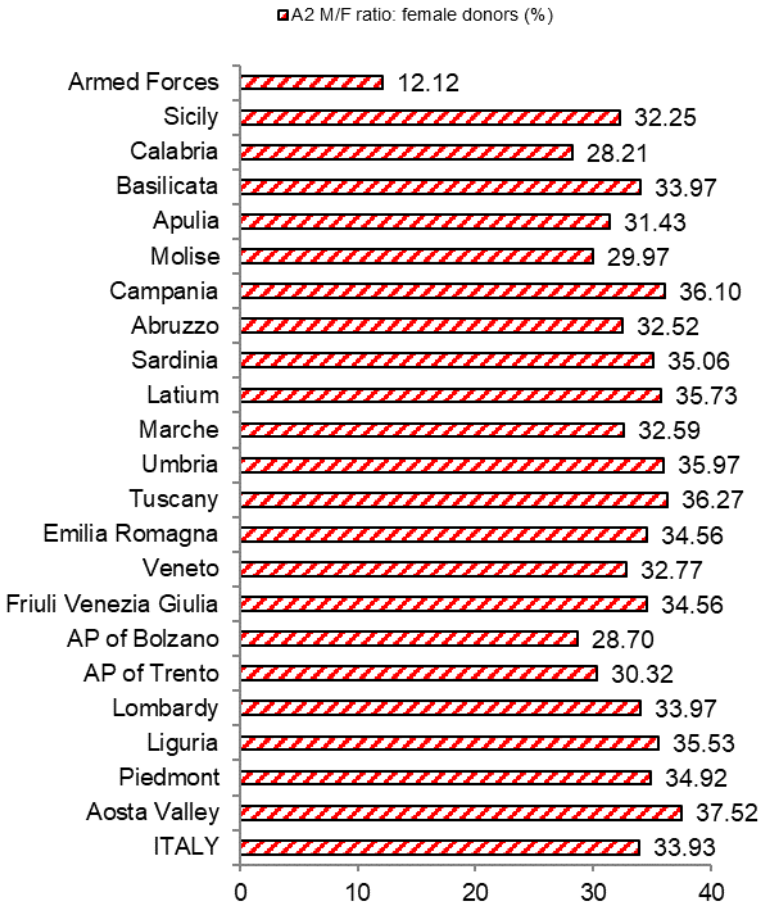
APPENDIX A
Regional and national indicators 2024



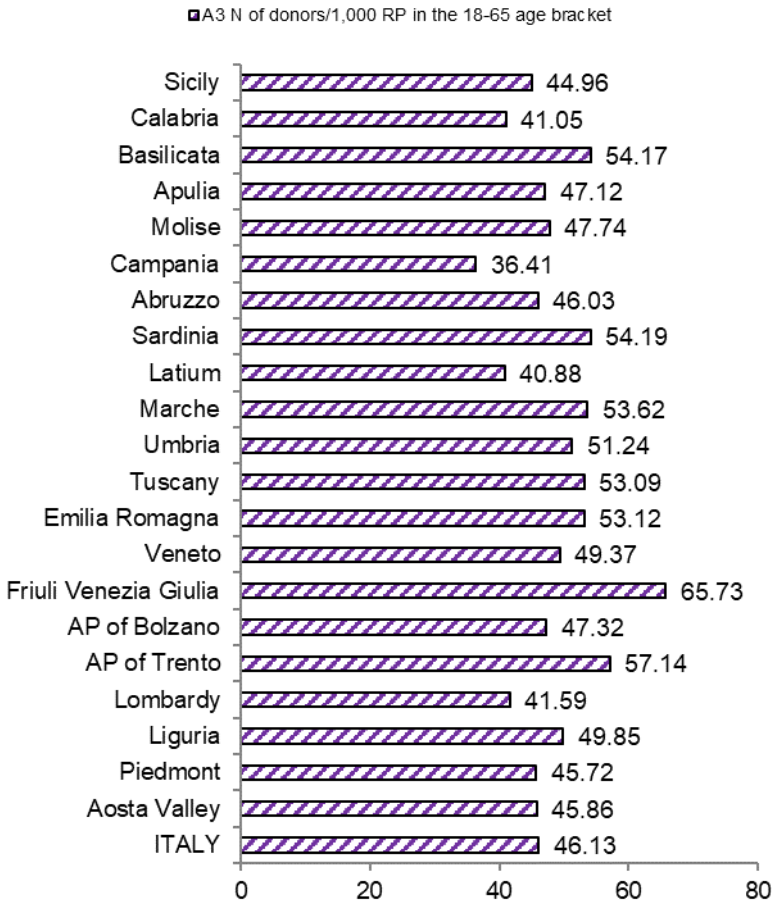
N. number; RP resident population; AP Autonomous Province

Figure A1. INDICATOR A1: Regional blood donors' distribution/1,000 resident population (2024)



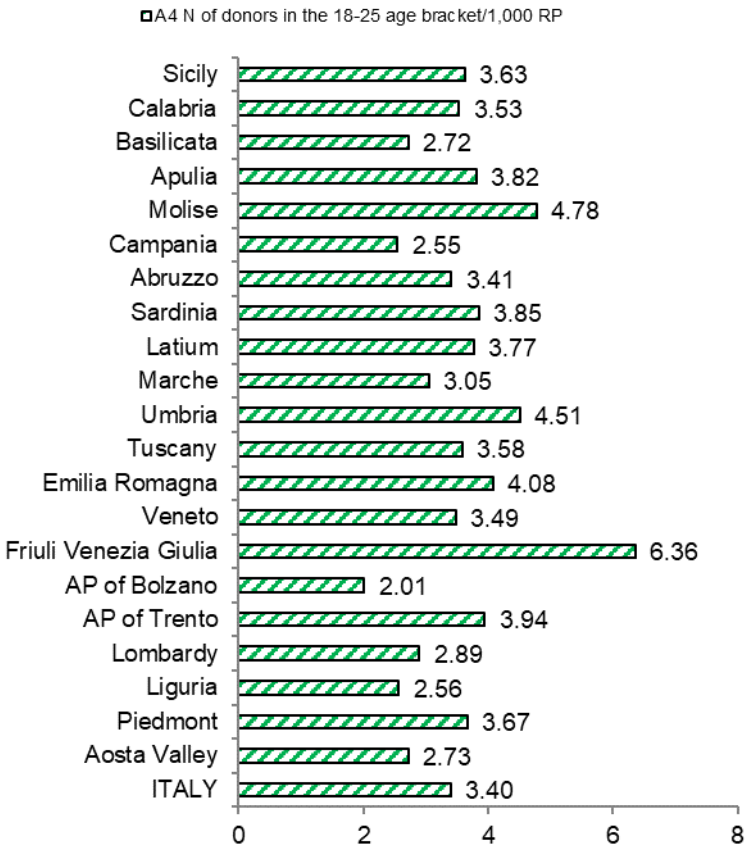
AP Autonomous Province; M male; F Female

Figure A2. INDICATOR A2: M/F ratio, female donors' percentage (2024)



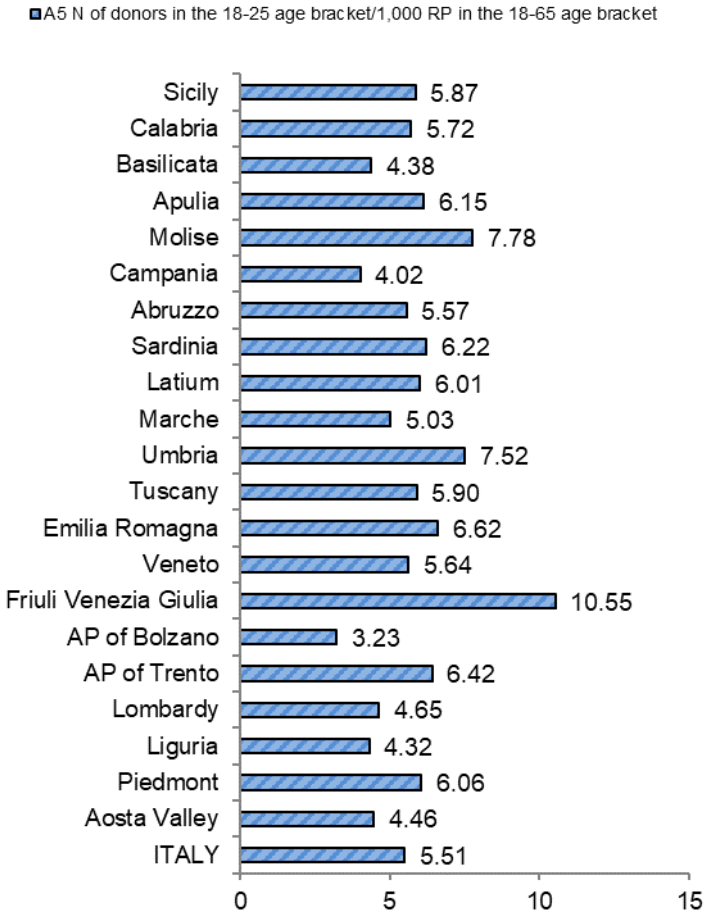
N. number; RP resident population; AP Autonomous Province

Figure A3. INDICATOR A3: N. of donors/1,000 resident population in the 18-65 age class (2024)



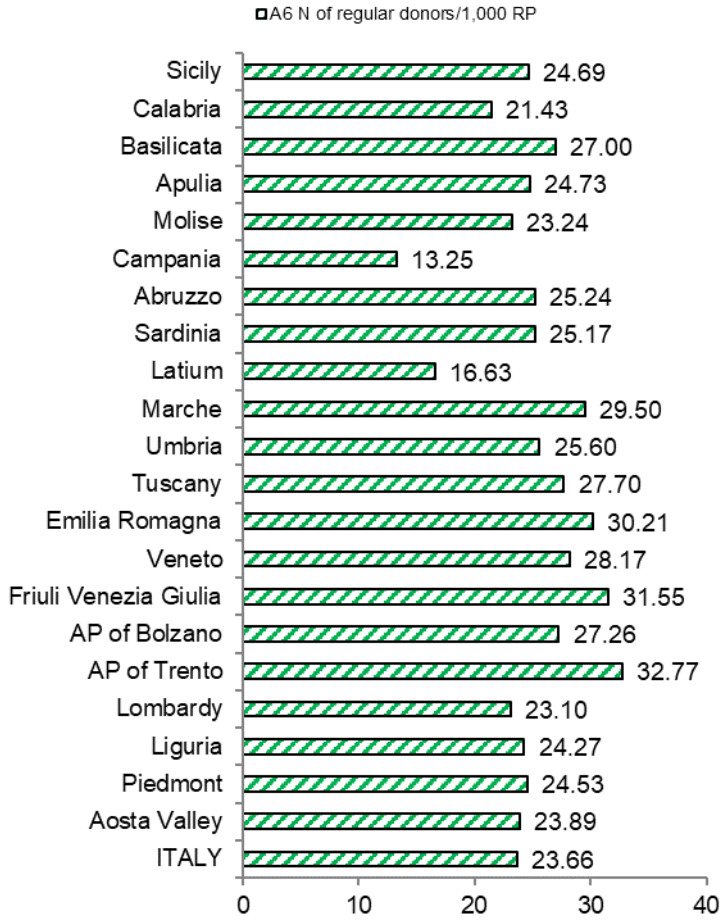
N. number; RP resident population; AP Autonomous Province

Figure A4. INDICATOR A4: N. of donors in the 18-25 age class/1,000 resident population (2024)



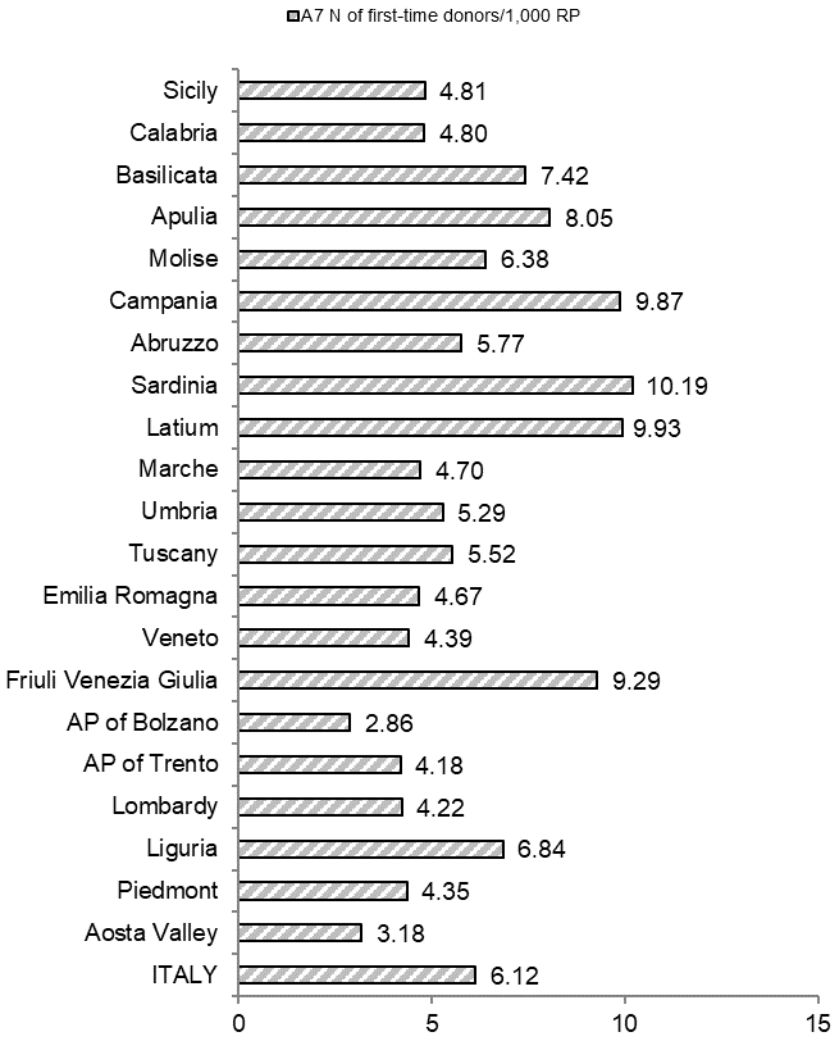
N. number; RP resident population; AP Autonomous Province

Figure A5. INDICATOR A5: N. of donors in the 18-25 age class/1,000 resident population in the 18-65 age class (2024)



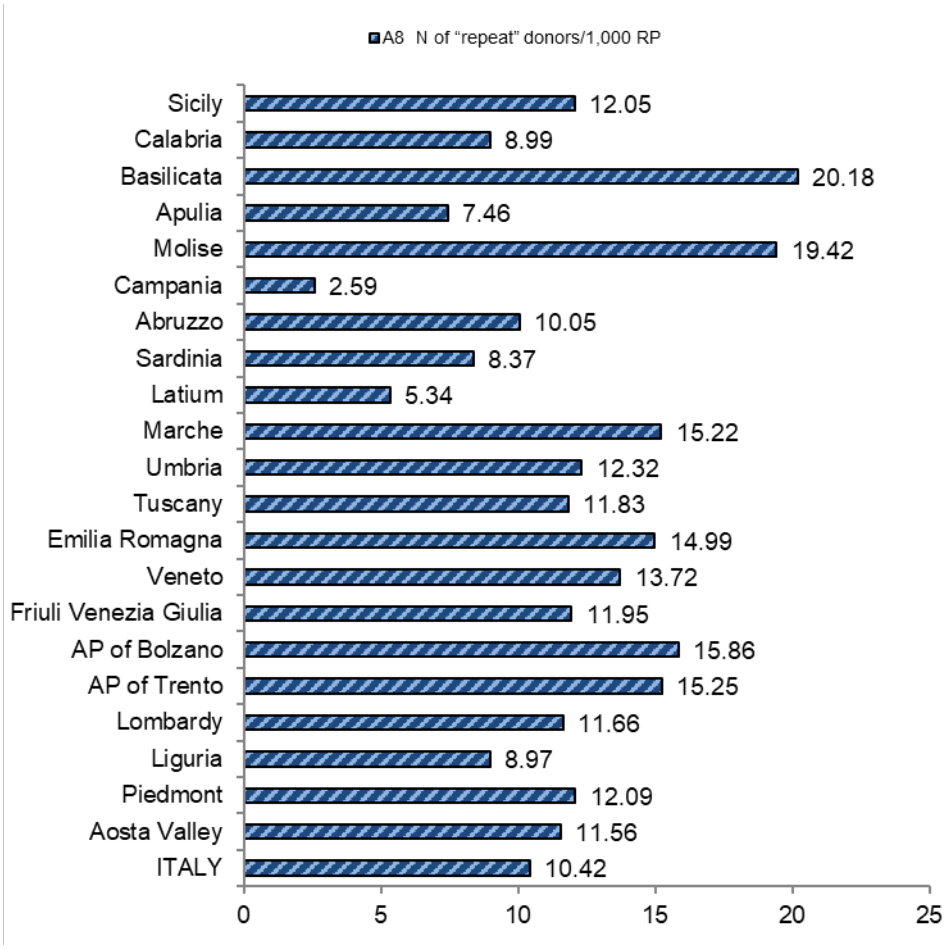
N. number; RP resident population; AP Autonomous Province

Figure A6. INDICATOR A6: N. of regular donors/1,000 resident population (2024)



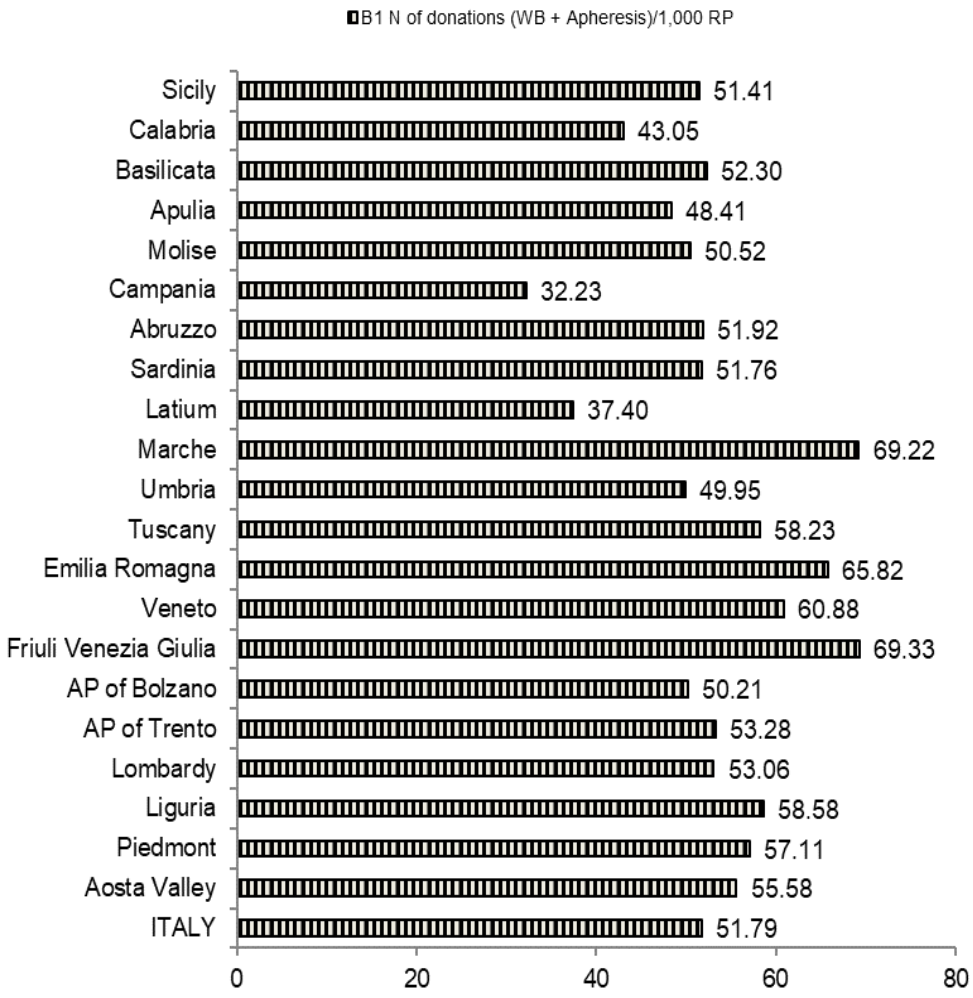
N. number; RP resident population; AP Autonomous Province

Figure A7. INDICATOR A7: N. of first-time donors/1,000 resident population (2024)



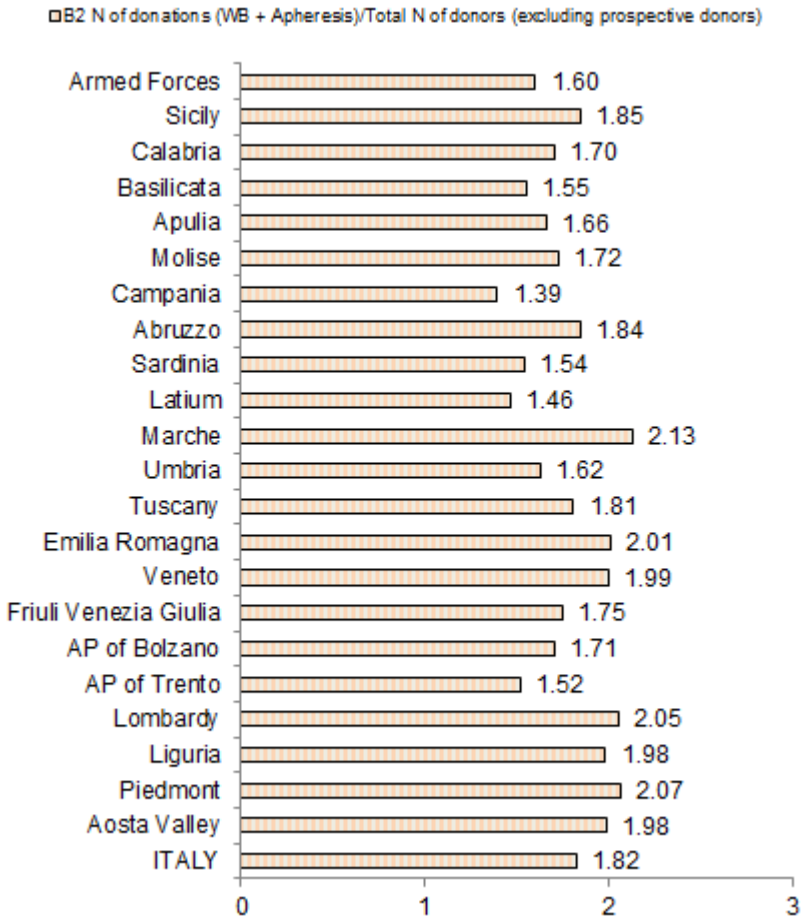
N. number; RP resident population; AP Autonomous Province

Figure A8. INDICATOR A8: N. of "repeat" donors/1,000 resident population (2024)



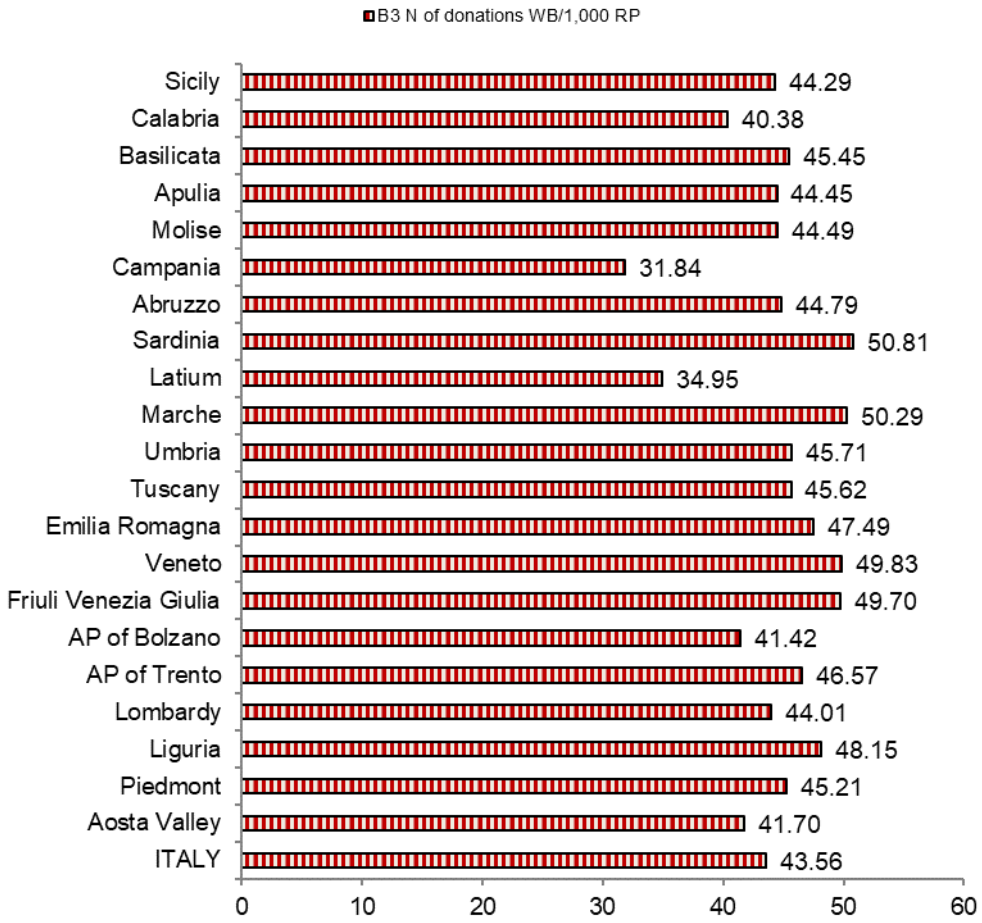
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A9. INDICATOR B1: N. of whole blood and apheresis donations/1,000 resident population (2024)



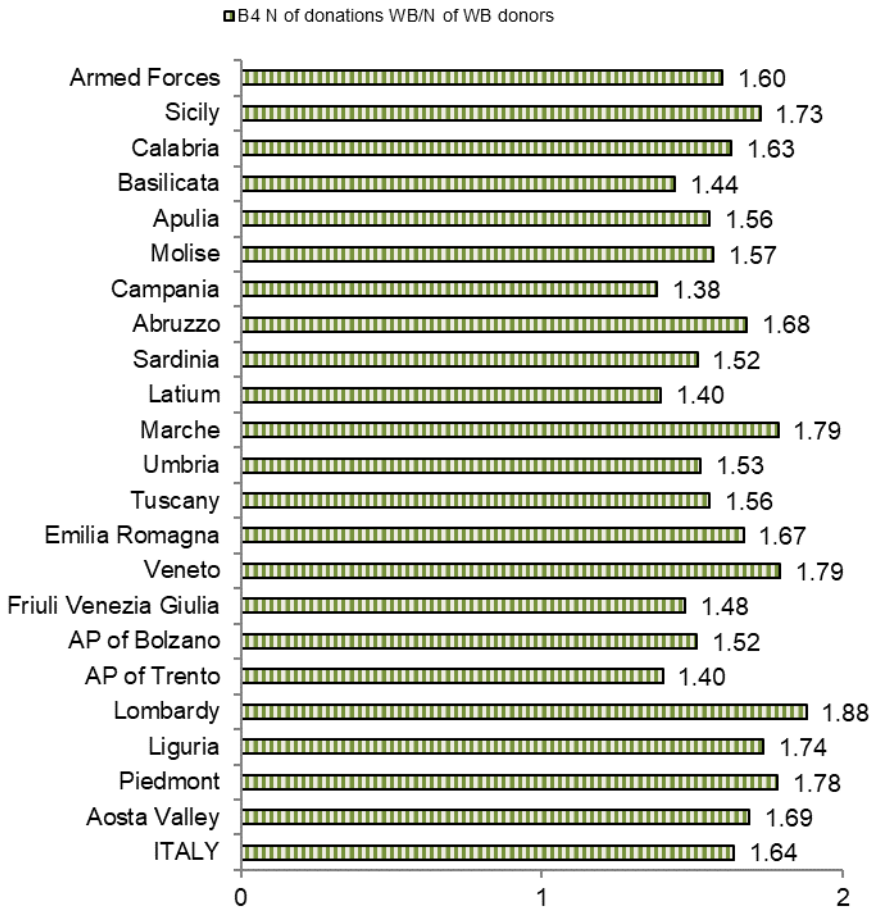
N. number; AP Autonomous Province; WB whole blood

Figure A10. INDICATOR B2: N. of whole blood and apheresis donations/Total N. of donors (excluding prospective donors) (2024)



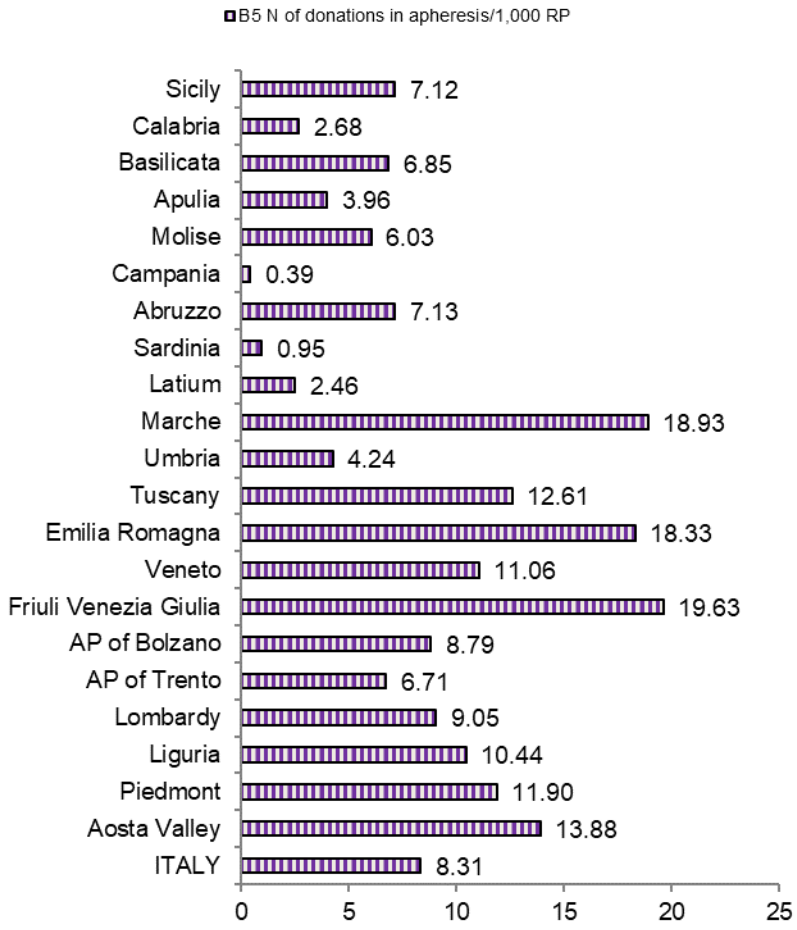
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A11. INDICATOR B3: N. of whole blood donations/1,000 resident population (2024)



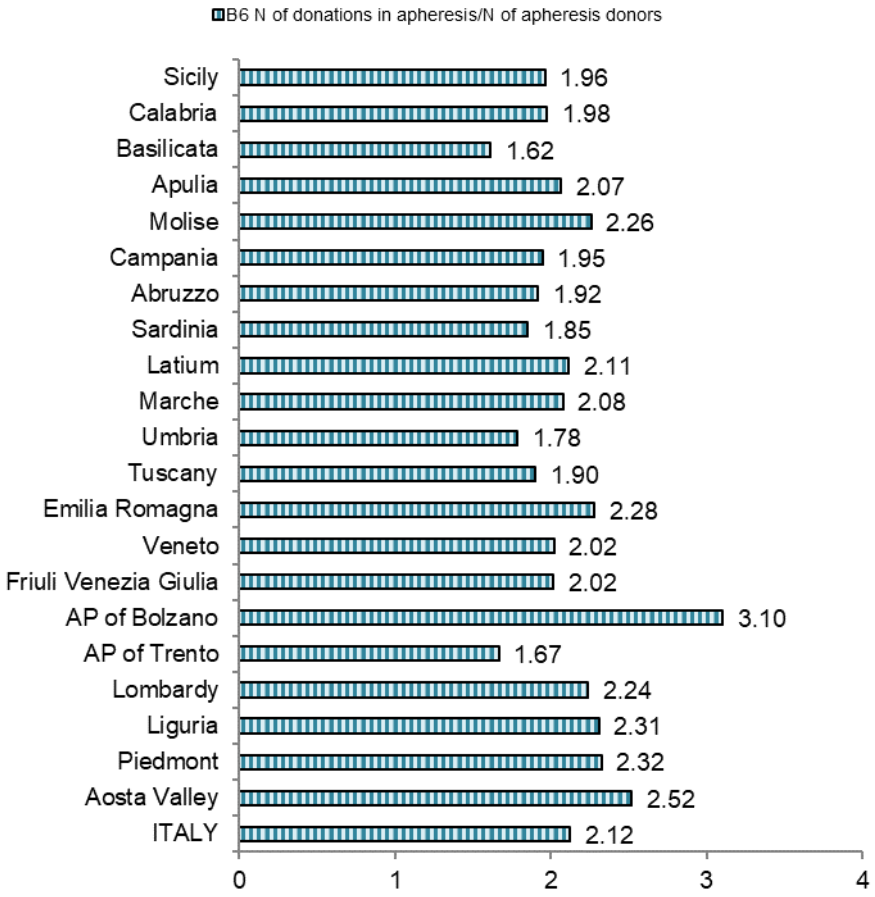
N. number; AP Autonomous Province; WB whole blood

Figure A12. INDICATOR B4: N. of whole blood donations/N. of whole blood donors (2024)



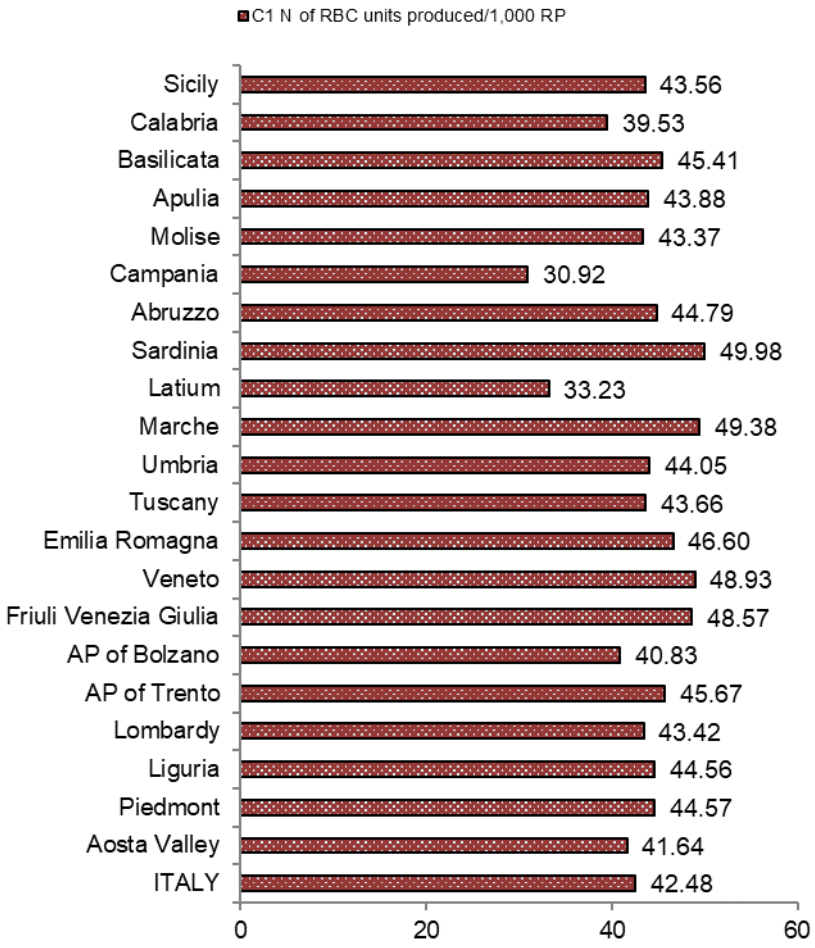
N. number; RP resident population; AP Autonomous Province

Figure A13. INDICATOR B5: N. of donations in apheresis/1,000 resident population (2024)



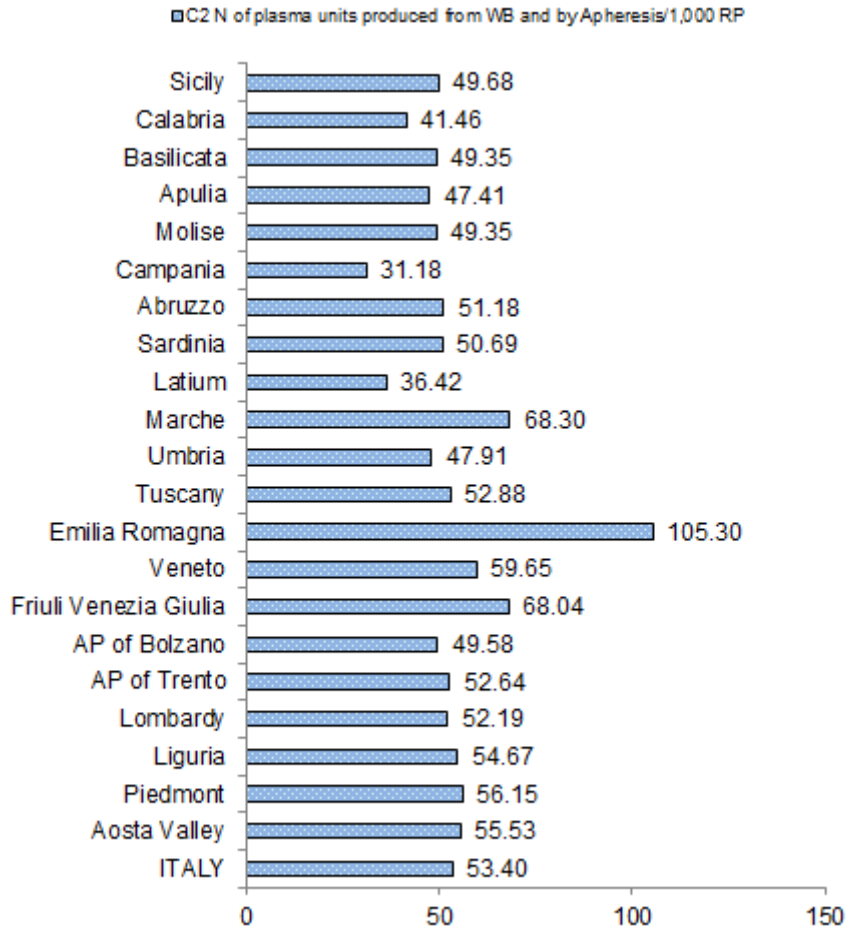
N. number; AP Autonomous Province

Figure A14. INDICATOR B6: N. of apheresis donations/N. of apheresis donors (2024)



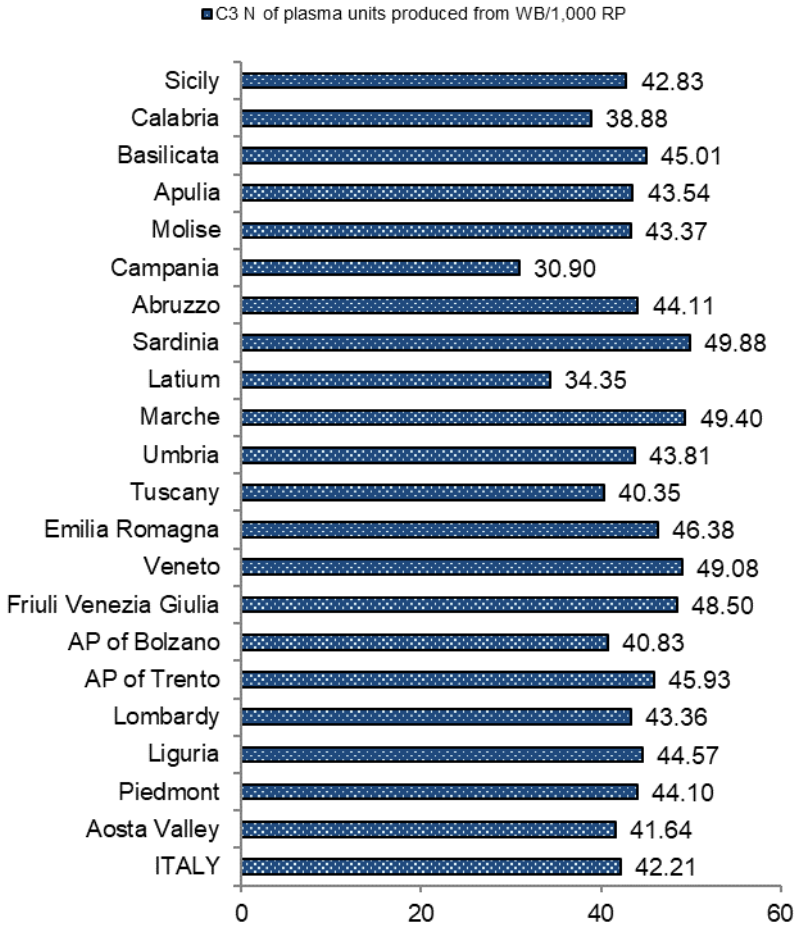
N. number; RP resident population; AP Autonomous Province

Figure A15. INDICATOR C1: RBC units produced/1,000 resident population (2024)



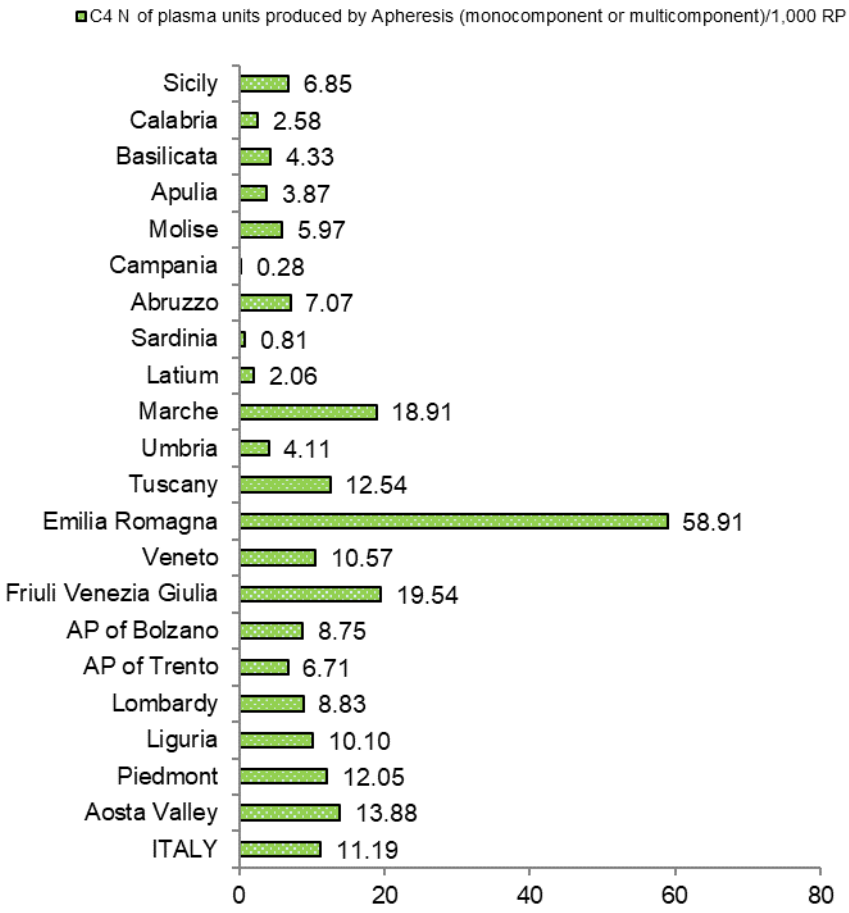
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A16. INDICATOR C2: N. of plasma units produced from whole blood and by apheresis/1,000 resident population (2024)



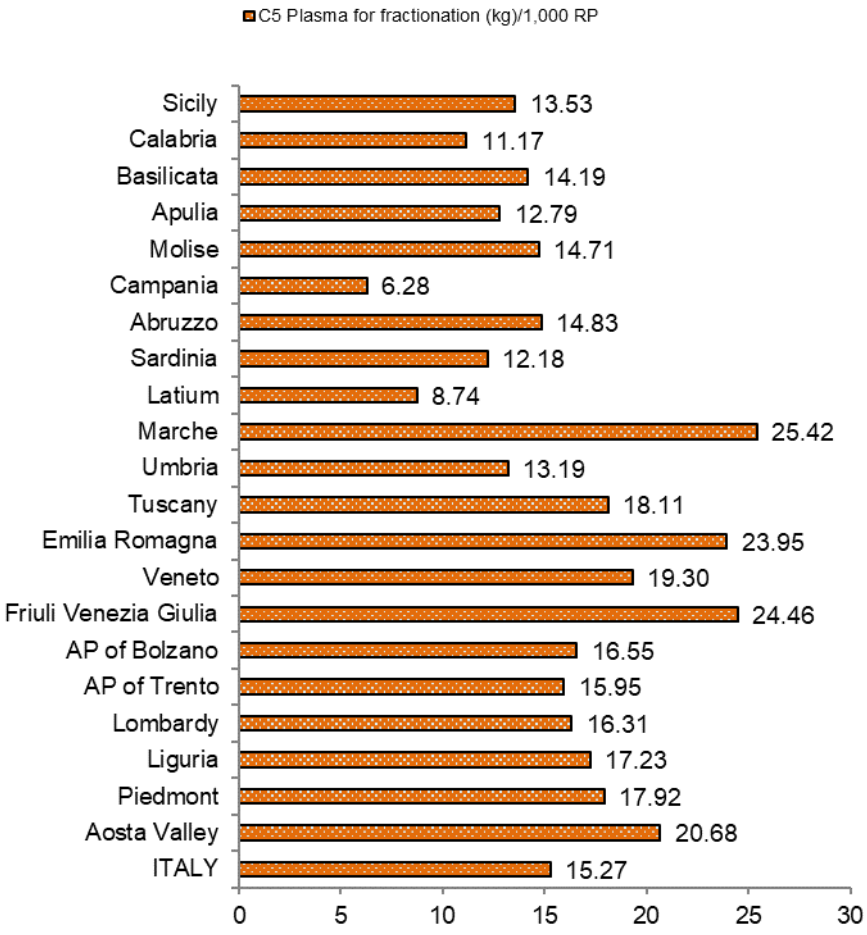
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A17. INDICATOR C3: N. of plasma units produced from whole blood/1,000 resident population (2024)



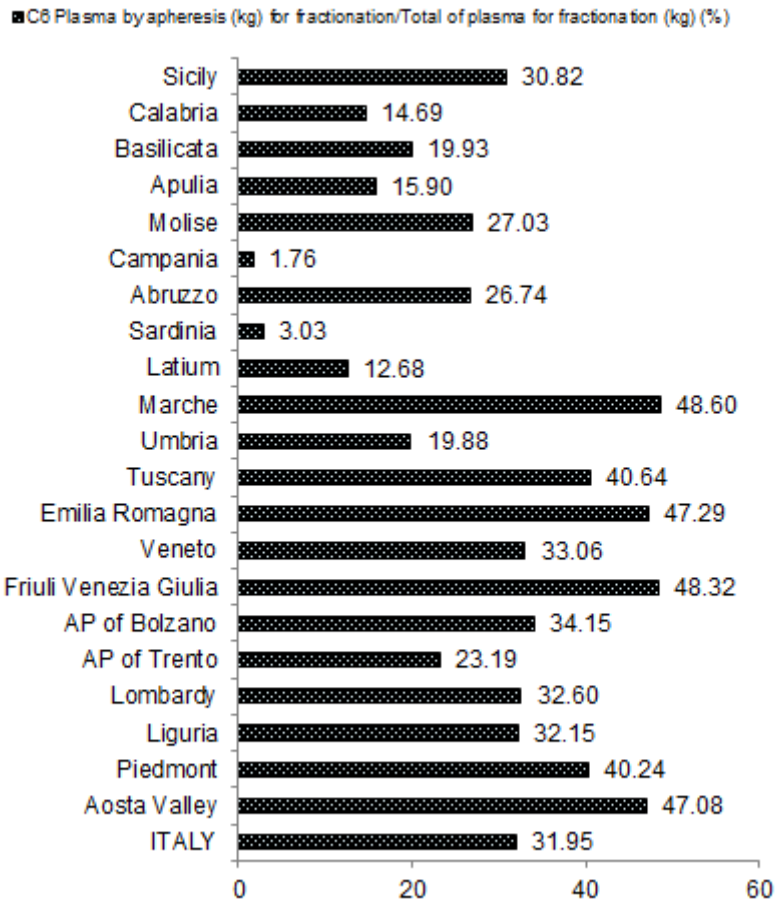
N. number; RP resident population; AP Autonomous Province

Figure A18. INDICATOR C4: N. of plasma units produced from apheresis (monocomponent + multicomponent)/1,000 resident population (2024)



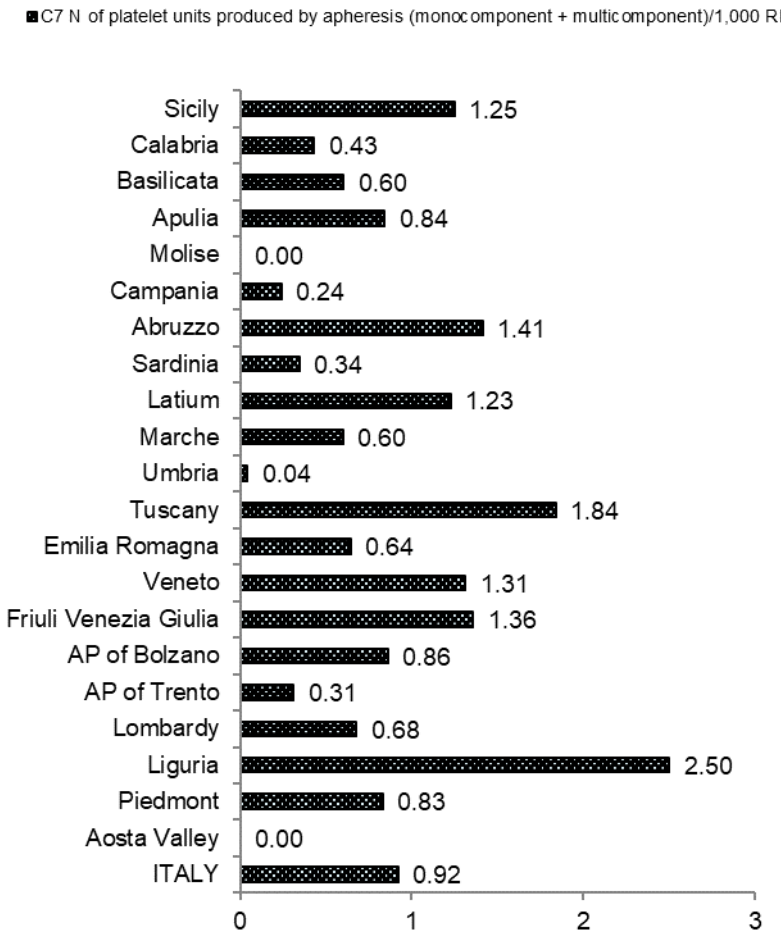
kg kilograms; RP resident population; AP Autonomous Province

Figure A19. INDICATOR C5: plasma (kg) for fractionation/1,000 resident population (from SISTRA) (2024)



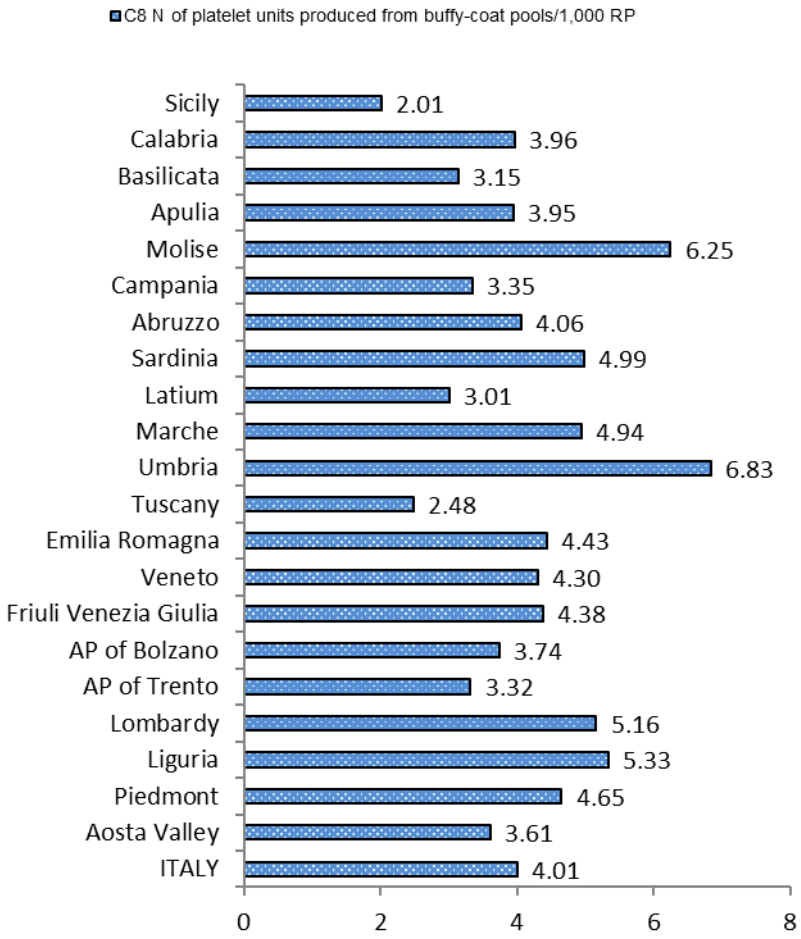
kg kilograms; AP Autonomous Province

Figure A20. INDICATOR C6: plasma by apheresis (kg) for fractionation/total of plasma for fractionation (kg) (%) (2024)



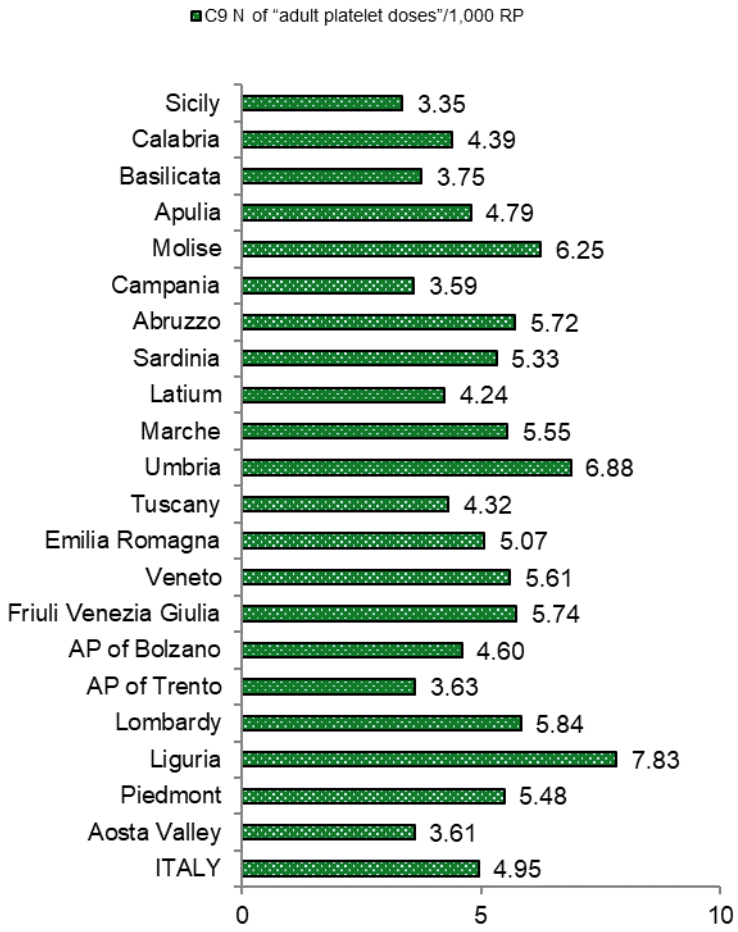
N. number; RP resident population; AP Autonomous Province

Figure A21. INDICATOR C7: N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 resident population (2024)



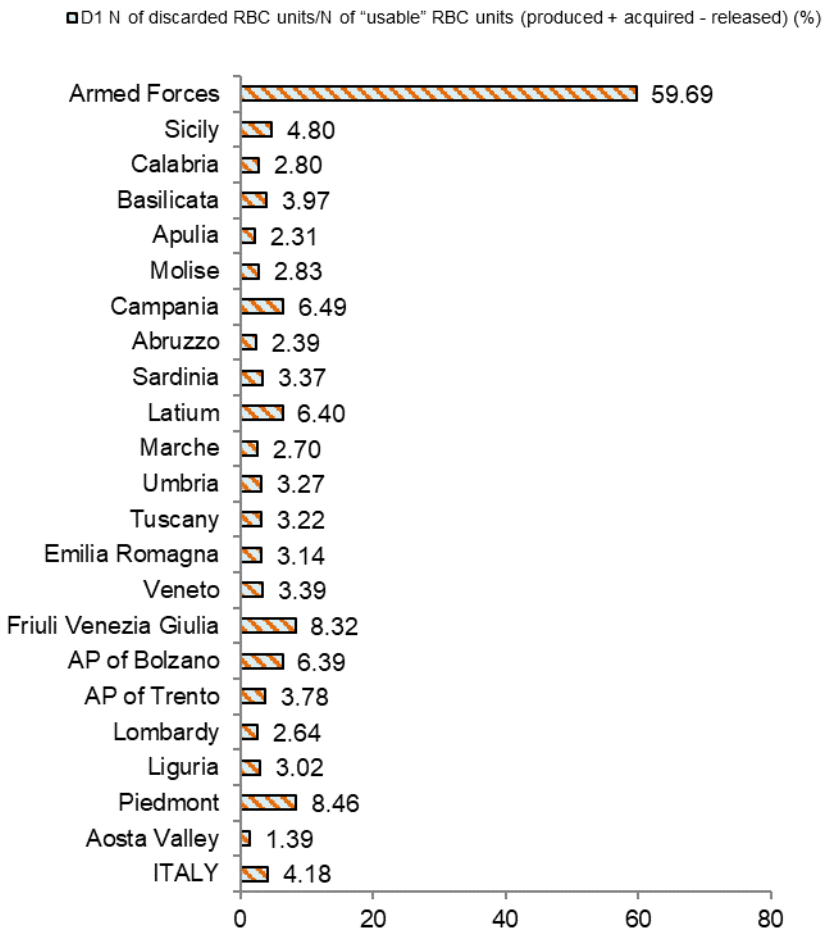
N. number; RP resident population; AP Autonomous Province

Figure A22. INDICATOR C8: N. of platelet units produced from buffy-coat pools/1,000 resident population (2024)



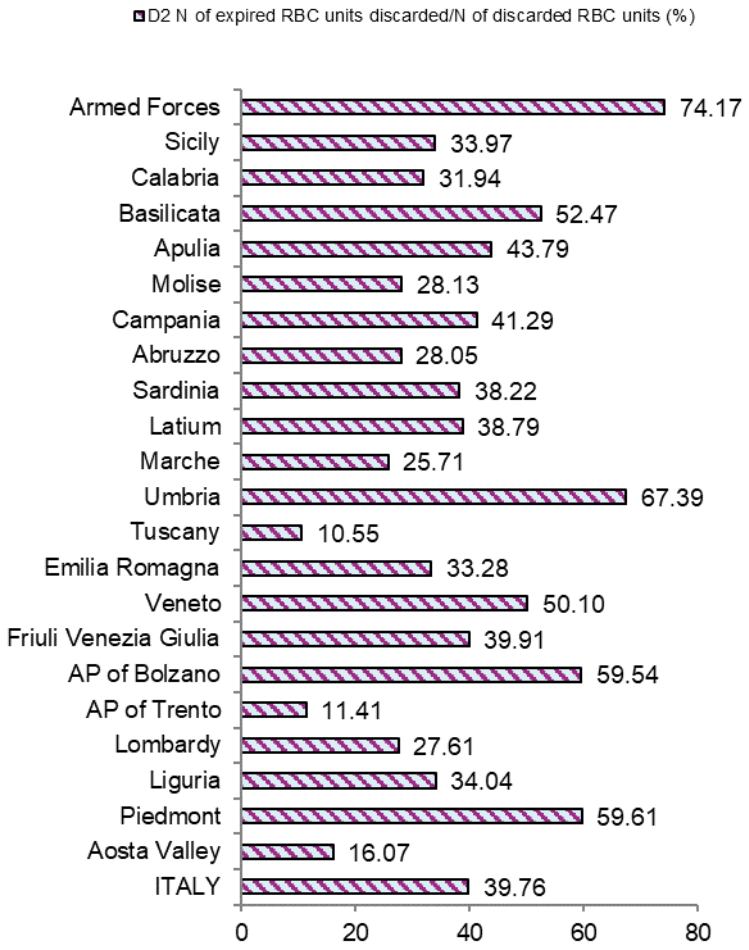
N. number; RP resident population; AP Autonomous Province

Figure A23. INDICATOR C9: N. of "adult platelet doses"/1,000 resident population (2024)



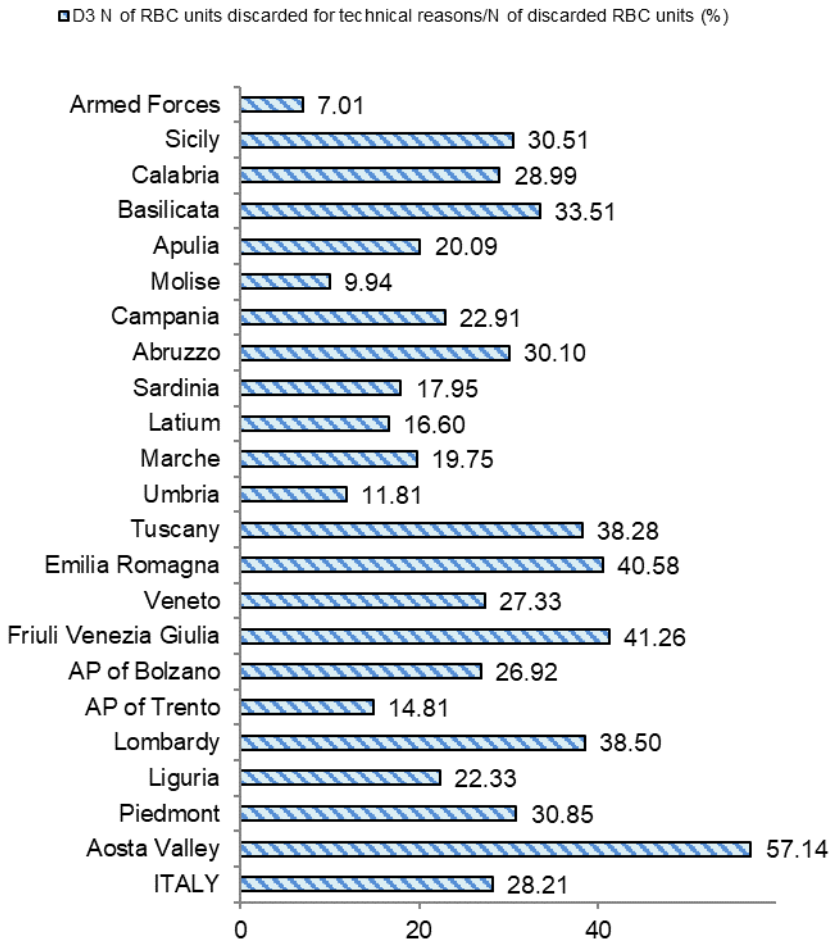
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A24. INDICATOR D1: N. of discarded RBC units/N. of "usable" RBC units (produced + acquired- released) (%) (2024)



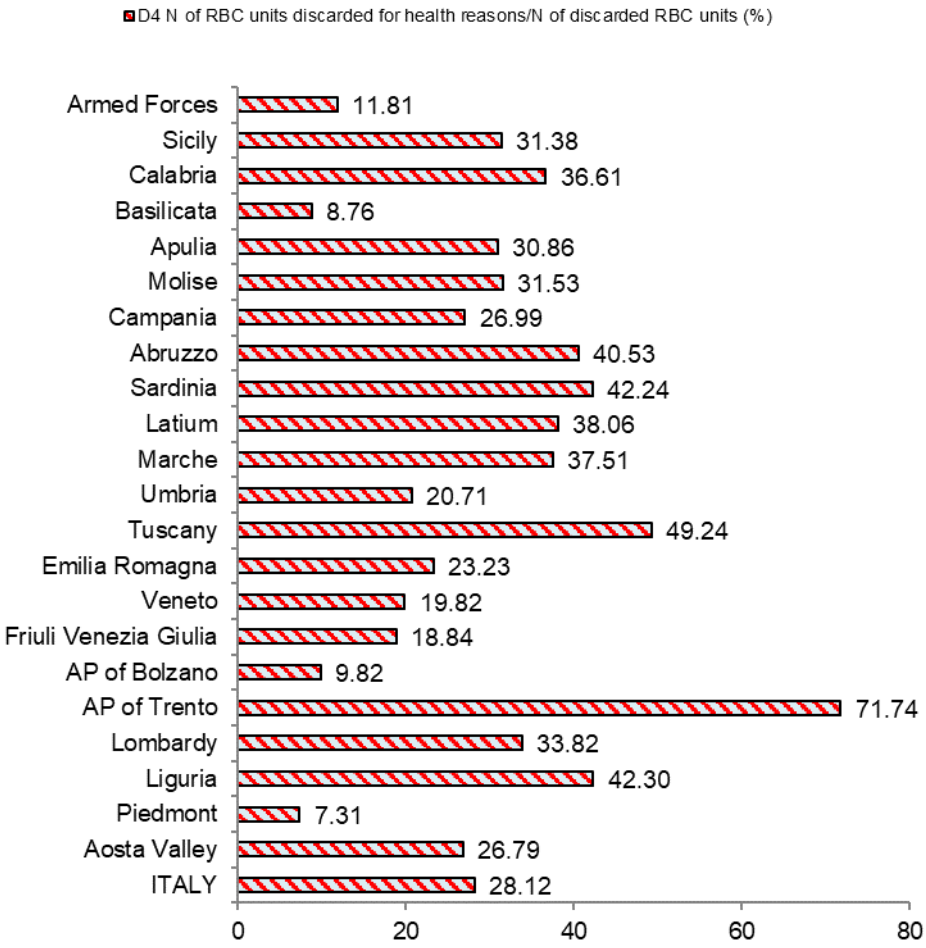
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A25. INDICATOR D2: N. of expired RBC units discarded/N. of discarded RBC units (%) (2024)



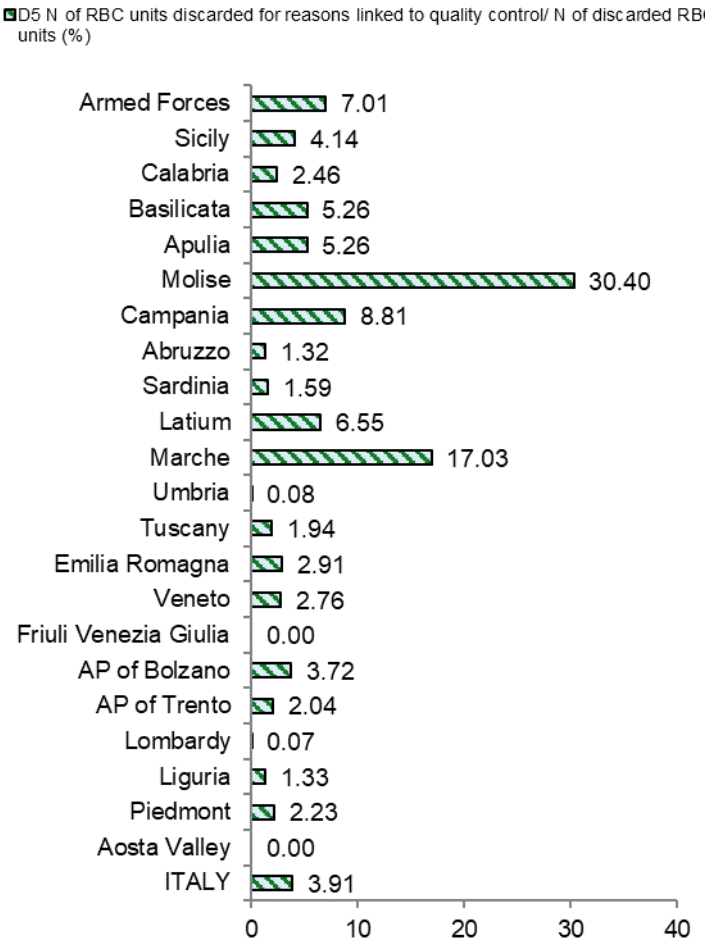
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A26. INDICATOR D3: N. of RBC units discarded for technical reasons/N. of discarded RBC units (%) (2024)



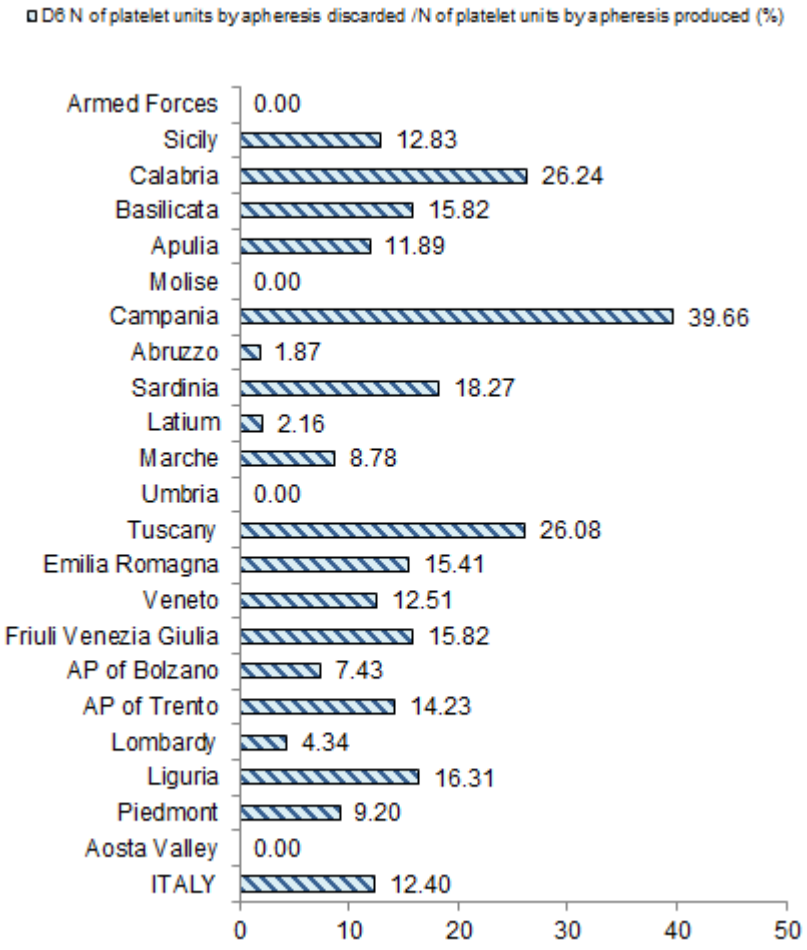
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A27. INDICATOR D4: N. of RBC units discarded for health reasons/N. of discarded RBC units (%) (2024)



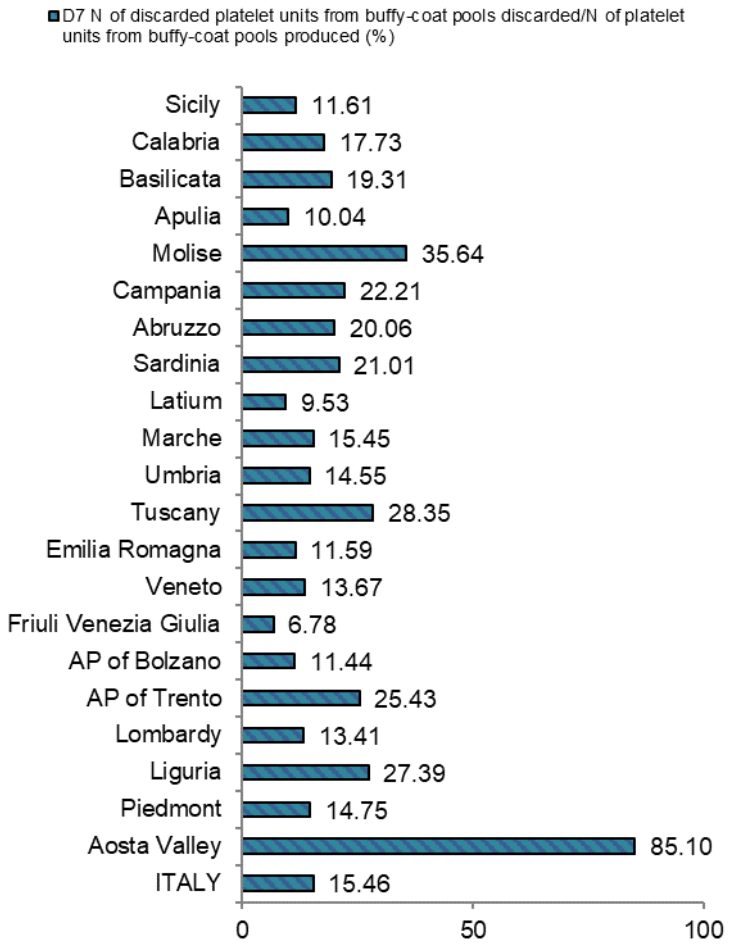
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A28. INDICATOR D5: N. of RBC units discarded for reasons linked to quality control/N. of discarded RBC units (%) (2024)



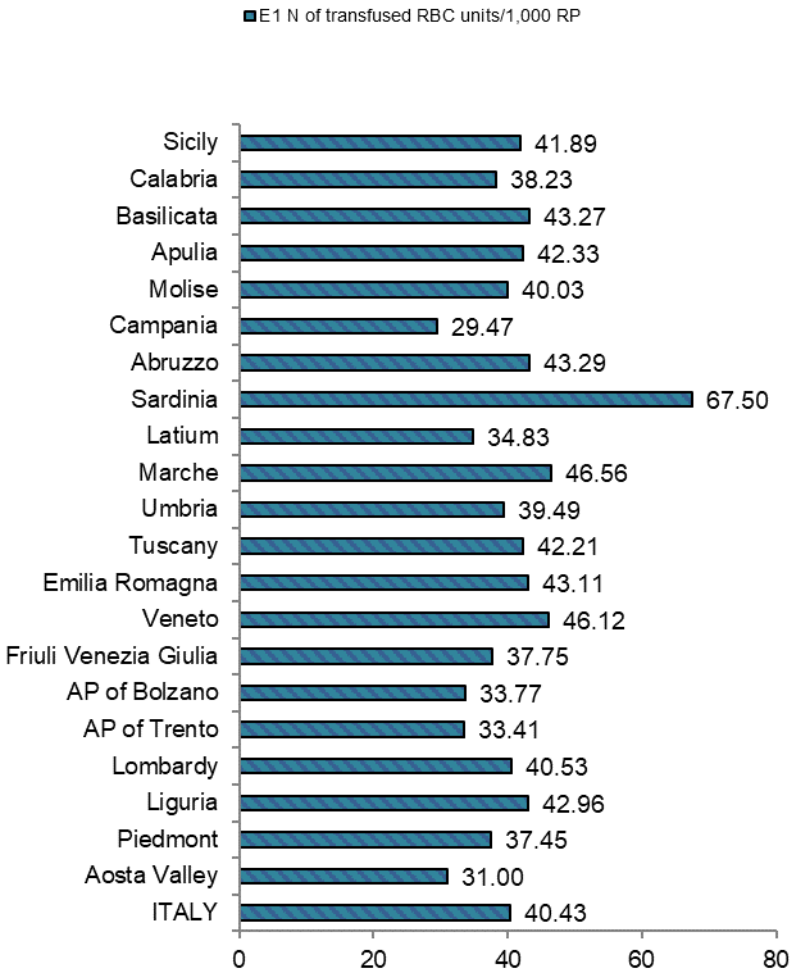
N. number; AP Autonomous Province

Figure A29. INDICATOR D6: N. of platelet units by apheresis discarded/N. of platelet units by apheresis produced (%) (2024)



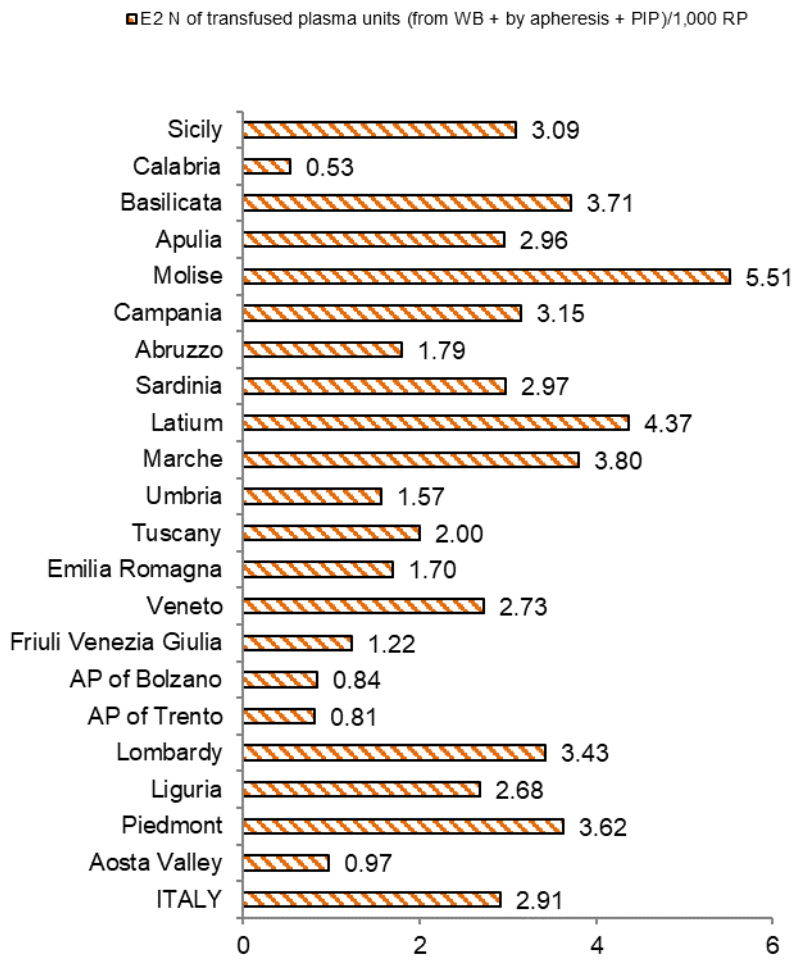
N. number; AP Autonomous Province

Figure A30. INDICATOR D7: N. of platelet units from buffy-coat pools discarded/N. of platelet units from buffy-coat pools produced (%) (2024)



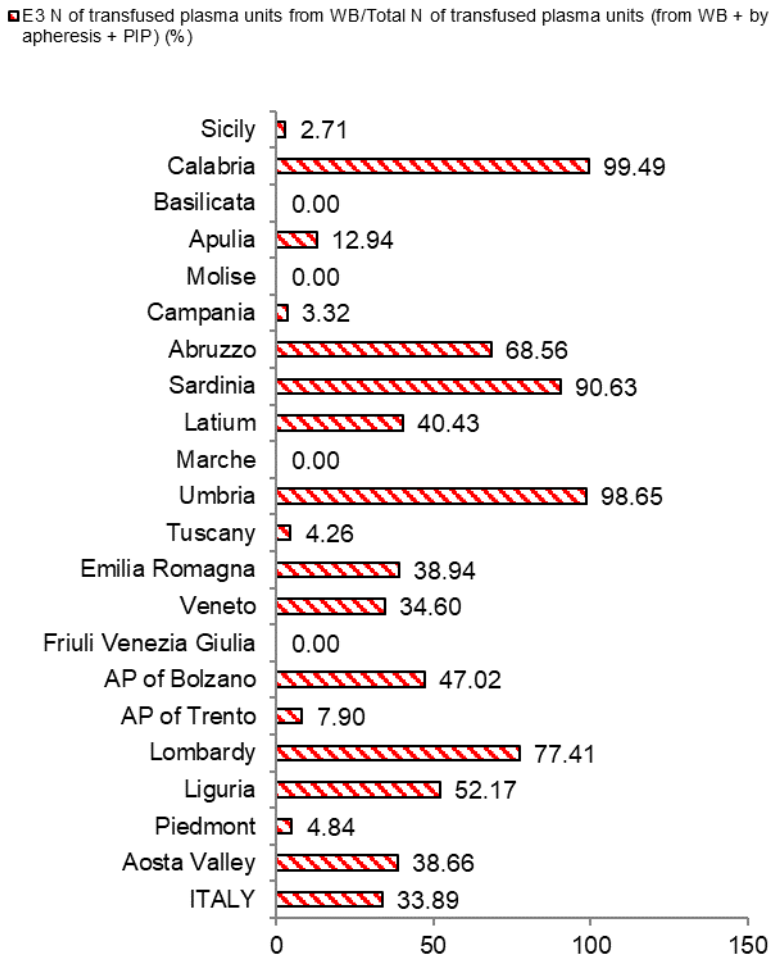
N. number; RBC Red Blood Cells; RP resident population; AP Autonomous Province

Figure A31. INDICATOR E1: N. of transfused RBC units/1,000 resident population (2024)



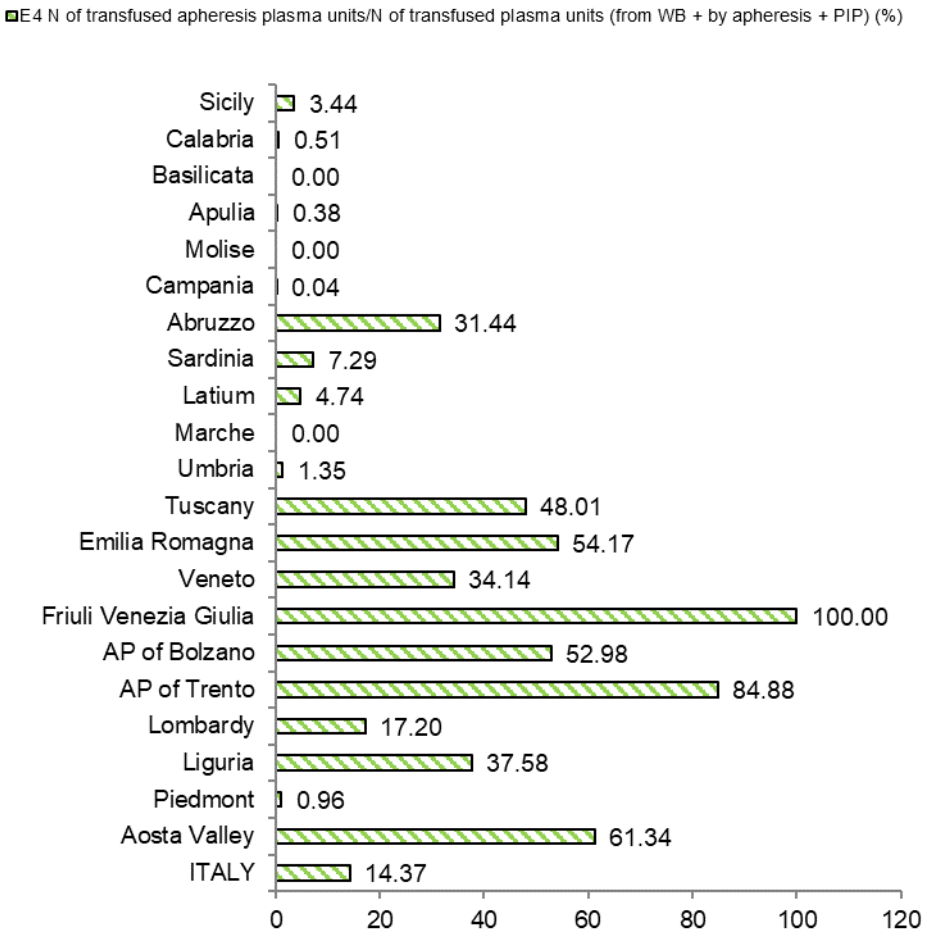
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; RP resident population; AP Autonomous Province

Figure A32. INDICATOR E2: N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma)/1,000 resident population (2024)



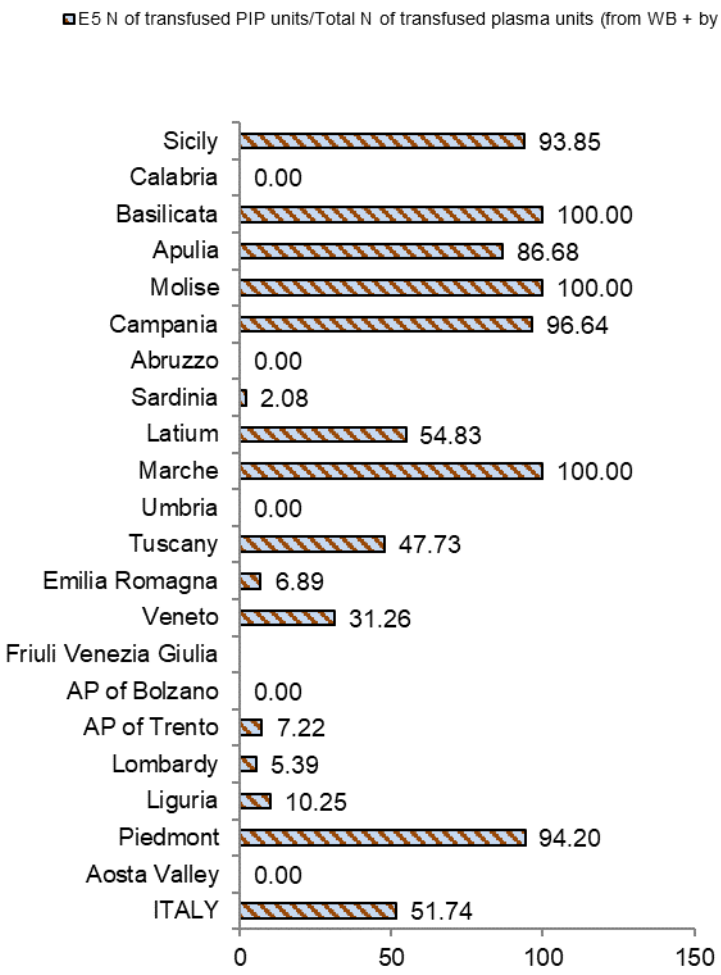
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A33. INDICATOR E3: N. of transfused plasma units from whole blood / total N. of transfused plasma units (from whole blood + by apheresis + plasma pooled and treated for virus inactivation) (%) (2024)



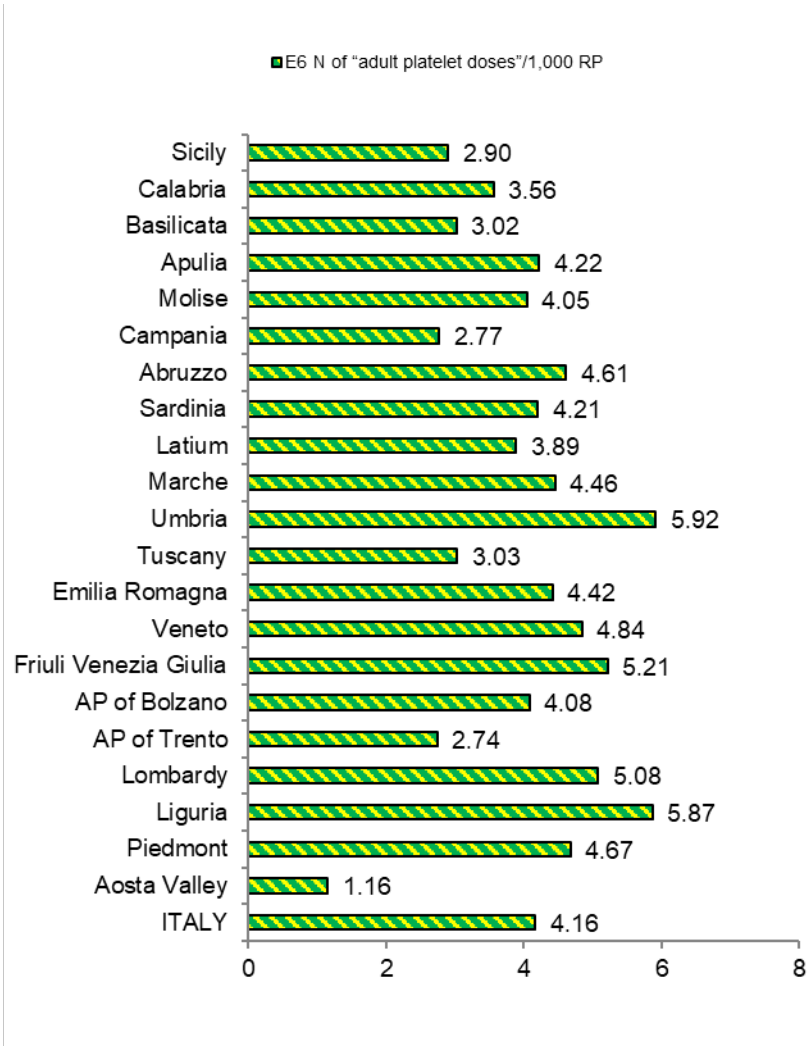
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

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) (%) (2024)



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) (%) (2024)



N. number; RP resident population; AP Autonomous Province

Figure A36. INDICATOR E6: N. of "adult platelet doses"/1,000 resident population (2024)

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