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Italian Blood System 2022: activity data, haemovigilance and epidemiological surveillance

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ISTITUTO SUPERIORE DI SANITÀ

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2024, iii, 86 p. Rapporti ISTISAN 24/5

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 2022.

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 2022: dati di attività, emovigilanza e sorveglianza epidemiologica.
Liviana Catalano, Vanessa Piccinini, Ilaria Pati, Francesca Masiello, Simonetta Pupella, Vincenzo De Angelis
2024, iii, 86 p. Rapporti ISTISAN 24/5 (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 del sistema trasfusionale italiano per l'anno 2022.

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

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

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viale Regina Elena, 299 – 00161 Roma

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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 Events
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 (*Nuovo Sistema Informativo Sanitario*, NSIS). SISTRA collects the 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 instrument for the strategic planning and coordination of the blood system.

For the purpose of this report, data relative to two of SISTRA's macro areas were taken into account: the section regarding activity data and the section regarding haemovigilance. 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 is divided in four modules based on the following notifications: serious adverse reactions in recipients, serious adverse reactions in donors, serious adverse events, and epidemiological surveillance of donors.

The data in this report are relevant to the year 2022.

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

ACTIVITIES OF THE ITALIAN BLOOD SYSTEM

Introduction

From 31 March 2022, the end of the health emergency caused by the COVID-19 pandemic has allowed a general resumption of health activities (6).

The blood transfusion system has kept up with the pandemic by guaranteeing the necessary supply of blood and blood derivatives to meet the needs of patients.

Through the detailed data of BEs and Blood Collection Sites (BCSs) and their respective peripheral organisational 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 2022 national data relative to blood and blood component donors, and the collection, production, and use of blood components, including plasma destined for the production of PDMPs, against the data of the previous year (7).

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

Methods

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

The above-mentioned indicators are presented in graphs and according to the geographic classification specified by the UNI 10529 standard (5). The data processing was carried out with the utilisation of "SAP Business Objects", which is the business intelligence system made available by the Ministry of Health on the NSIS. The reference population for the calculation of the relative indicators is that provided by the Italian National Institute of Statistics (*Istituto Nazionale di Statistica*, ISTAT) as of 1st January, 2022, available at https://demo.istat.it/ (last accessed November 2022).

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 2022, 248 blood transfusion activity records, which include data from 276 BEs, were validated by the RBCCs on SISTRA. Compared to 2021, the number of BEs and BCSs has slightly reduced (Table 1).

Table 2 shows data concerning donors of blood and blood components subdivided by type of donation. Compared to 2021, there was an increase of 2.61% in the total number of first-time donors and of 3.09% in the total number of regular donors who re-donated at least once a year in the last 5 years. The regular (-0.66%) and apheresis donors (-6.37%) decreased; permanently deferred donors increased (7.22%). Table 3 shows the total number of collection procedures (carried out by both BEs and BCSs) subdivided by type.

Table 1. BEs and BCSs and their respective peripheral organisational sites (2021-2022)

Blood facilities and population	2021	2022	Δ%
BEs	277	276	-0.36
BEs peripheral organisational sites	838	827	-1.31
BCSs	189	186	-1.59
BCSs peripheral organisational sites	1,289	1,290	0.08
Population	59,236,213	58,983,122	-0.43

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

Table 2. Donors of blood and blood components (2021-2022)

Donors	2021	2022	Δ%
First-time	**345,715**	**354,750**	2.61
Those who re-donated in the period under examination	77,766	73,929	-4.93
Regular	**1,385,319**	**1,376,212**	-0.66
Those who re-donated at least once a year in the last 5 years	587,709	605,861	3.09
Total	**1,653,268**	**1,657,033**	0.23
Apheresis	215,325	201,601	-6.37
Those who donated only in apheresis	112,865	106,781	-5.39
Permanently deferred	42,131	45,172	7.22
Members of VBDAs	**1,519,500**	**1,510,602**	-0.59

VBDAs: Voluntary Blood Donors Associations/Federations.

Table 3. Collection procedures (2021-2022)

Collection procedures	2021	2022	Δ%
Whole blood	**2,566,235**	**2,555,886**	-0.40
Apheresis	**454,908**	**426,738**	-6.19
Monocomponent apheresis	*396,826*	*372,209*	-6.20
Multicomponent apheresis	*58,082*	*54,529*	-6.12
Total	**3,021,143**	**2,982,624**	-1.27
Type			
Plasmapheresis*	386,673	362,694	-6.20
Plateletpheresis	8,232	7,632	-7.29
Stem Cells apheresis	1,563	1,487	-4.86
Granulocytapheresis	63	54	-14.29
Lymphocytapheresis	295	342	15.93
Red Blood Cell/Platelet apheresis	3,185	3,239	1.70
Double Red Blood Cell unit apheresis	206	174	-15.53
Plasma/Platelet apheresis	44,372	42,137	-5.04
Red Blood Cell/Plasma apheresis	8,313	7,207	-13.30
Double Platelet unit apheresis	1,192	1,159	-2.77
Red Blood Cell/Platelet/Plasma apheresis	814	613	-24.69

*In 2022, plasmapheresis includes 3,715 COVID-19 convalescent plasma collections (in 2021 includes 9,301 COVID-19 convalescent plasma collections).

Table 4 shows the number of collections carried out by BCSs (total and by Association/Federation); 94% were carried out by the four Associations/Federations that form the Inter-associative Committee of Voluntary Italian Blood Donors Associations/Federations (CIVIS). Table 5 shows data concerning the production of blood components. Compared to 2021, there was a decrease (-0.94%) in the total number of units of blood components produced.

Table 4. Number of collections carried out by blood collection sites (2021-2022)

Association/Federation	2021	2022	Δ%
AVIS	895,796	886,358	-1.05
FIDAS	99,340	101,020	1.69
FRATRES	24,232	20,188	-16.69
CRI	12,709	12,618	-0.72
Other	59,875	62,103	3.72
Total	**1,091,952**	**1,082,287**	-0.89

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. Blood component production (2021-2022)

Blood component	2021	2022	Δ%
Red Blood Cells	**2,505,318**	**2,485,068**	-0.81
Red Blood Cells from whole blood	*2,488,880*	*2,473,806*	-0.61
Red Blood Cells by apheresis	*16,438*	*11,262*	-31.49
Platelets from single donors	8,670	13,673	57.70
Platelet pools	224,174	228,881	2.10
Platelets by apheresis	62,032	55,912	-9.87
Plasma	**2,942,474**	**2,905,083**	-1.27
Recovered Plasma	*2,485,242*	*2,471,627*	-0.55
*Source Plasma**	*399,915*	*382,363*	-4.39
Source Plasma from multiple apheresis	*57,317*	*51,093*	-10.86
Total	**5,742,668**	**5,688,617**	-0.94

*The number of aliquots of COVID-19 donor-convalescent patient plasma for the 2022 (145) and 2021 (14,558) is not included.

In 2022, 7,783 units of blood components were transfused per day. Compared to the previous year, there was a decrease (-1.10%) in the total number of units of blood components transfused (Table 6). Moreover, compared to 2021, there was:

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

Table 6. Transfused units of blood components (2021-2022)

Blood component	2021	2022	Δ%
Red Blood Cells	**2,413,673**	**2,393,798**	-0.82
Red Blood Cells from whole blood	*2,401,838*	*2,383,058*	-0.78
Red Blood Cells by apheresis	*11,835*	*10,740*	-9.25
Platelets from single donors	1,088	934	-14.15
Platelets Pools	185,433	193,041	4.10
Platelets by apheresis	50,393	47,305	-6.13
Plasma	**221,638**	**205,552**	-7.26
Recovered Plasma	*75,376*	*68,893*	-8.60
*Source Plasma**	*28,586*	*24,141*	-15.55
Source Plasma from multiple apheresis	*5,624*	*4,873*	-13.35
Plasma pooled and treated for virus inactivation	*112,052*	*107,645*	-3.93
Total	**2,872,225**	**2,840,630**	-1.10

*The number of aliquots of Covid-19 donor-convalescent patient plasma for the 2022 (605) and 2021 (13,526) is not included.

Table 7. Blood components discarded for reasons linked to health, technical issues, quality control and expiry dates (2021-2022)

Blood component	2021	2022	Δ%
Red Blood Cells	73,196	68,189	-6.84
Platelets from single donors	5,870	10,934	86.27
Platelet Pools	33,167	32,684	-1.46
Platelets by apheresis	6,752	5,932	-12.14
Plasma	**114,624**	**124,453**	8.57
Recovered Plasma	*94,677*	*105,591*	11.53
*Source Plasma**	*16,973*	*15,981*	-5.84
Source Plasma from multiple apheresis	*2,974*	*2,881*	-3.13
Total	**233,609**	**242,192**	3.67

The number of aliquots of Covid-19 donor-convalescent patient plasma for 2022 (2,080) and 2021 (1,192) is not included.

Table 8. Plasma for fractionation (2020-2021)

Blood component	2021	2022	Δ%
Plasma for fractionation (kg)	861,707	842,949	-2.18

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

Table 9. Production and use of allogeneic blood components for non-transfusion use (2021-2022)

Blood component	2021	2022	Δ%
Platelet Gel			
Produced	24,647	28,238	14.57
- Used	18,839	21,148	12.26
- Not used	5,808	7,090	22.07
Fibrin Glue			
Produced	130	91	-30.00
- Used	121	85	-29.75
- Not used	9	6	-33.33

Table 10. Production and use of autologous blood components for non-transfusion use (2021-2022)

Blood component	2021	2022	Δ%
Platelet Gel			
Produced	10,912	14,036	28.63
- Used	10,215	13,090	28.14
- Not used	697	946	35.72
Fibrin Glue			
Produced	*254*	476	87.40
- Used	253	471	86.17
- Not used	1	5	400.00

Table 11. Autologous donation and transfusion (2021-2022)

Patients and autologous donation activities	2021	2022	Δ%
Patients who pre-deposited blood components for autologous transfusion	12,247	13,622	11.23
Patients who underwent an autologous transfusion	10,512	11,178	6.34

Table 12. Transfused patients (2021-2022)

Patients* transfused with:	2021	2022	Δ%
Whole Blood^	34	32	-5.88
Red Blood Cells	610,452	604,761	-0.93
Plasma	55,486	46,426	-16.33
Platelets	57,868	54,512	-5.80
Other	5,879	5,472	-6.92
Total**	**656,998**	**639,003**	-2.74

* 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 2022 year are:

A. Donors,
B. Donations,
C. Produced blood components,
D. Discarded blood components,
E. Transfused blood components.

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

Table 13. Quantitative indicators for transfusion activities in Italy (2022)

Indicators		Index
A. Donors		
A1	N. of donors/1,000 RP	28.09
A2	M/F ratio: female donors (%)	33.36
A3	N. of donors/1,000 RP in the 18-65 age class	45.42
A4	N. of donors in the 18-65 age class/1,000 RP	3.33
A5	N. of donors in the 18-25 age class /1,000 RP in the 18-65 age class	5.38
A6	N. of donors/1,000 RP	23.33
A7	N. of first-time donors/1,000 RP	6.01
A8	N. of "regular" donors/1,000 RP	10.27
B. Donations		
B1	N. of donations (WB + apheresis)/1,000 RP	50.57
B2	N. of donations (WB + apheresis)/Total N. of donors (excluding prospective donors)	1.80
B3	N. of donations WB/1,000 RP	43.33
B4	N. of donations WB/N. of WB donors	1.65
B5	N. of donations in apheresis/1,000 RP	7.23
B6	N. of donations in apheresis/N. of apheresis donors	2.12
C. Production of blood components		
C1	N. of RBC units produced/1,000 RP	42.13
C2	N. of plasma units produced from WB and by apheresis/1,000 RP	49.26
C3	N. of plasma units produced from WB/1,000 RP	41.90
C4	N. of plasma units produced by apheresis (monocomponent or multicomponent)/1,000 RP	7.29
C5	Plasma for fractionation (kg)/1,000 RP	13.77
C6	Plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%)	27.49
C7	N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 RP	0.95
C8	N. of platelet units produced from buffy-coat pools/1,000 RP	3.88
C9	N. of "adult platelet doses"/1,000 RP	4.87
D. Discarded blood components		
D1	N. of discarded RBC units/N. of "usable" RBC units (produced + acquired - released) (%)	2.74
D2	N. of expired RBC units discarded/N. of discarded RBC units (%)	27.49
D3	N. of RBC units discarded for technical reasons/N. of discarded RBC units (%)	30.23
D4	N. of RBC units discarded for health reasons/N. of discarded RBC units (%)	35.90
D5	N. of RBC units discarded for reasons linked to QC/ N. of discarded RBC units (%)	6.37
D6	N. of platelet units by apheresis discarded /N. of platelet units by apheresis produced (%)	10.61
D7	N. of platelet units from buffy-coat pools discarded /N. of platelet units from buffy-coat pools produced (%)	14.28
E. Transfused blood components		
E1	N. of transfused RBC units/1,000 RP	40.58
E2	N. of transfused plasma units (from WB + by apheresis + PIP)/1,000 RP	3.50
E3	N. of transfused WB plasma units/Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	33.42
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) (%)	52.22
E6	N. of "adult platelet doses"/1,000 RP	4.08

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

In 2022 the total number of donors increased slightly compared to 2021 due to the increase in new donors (2.61%).

The data showed a slight decrease (-1.3%) in the overall production of blood components: in particular, both multicomponent and monocomponent apheresis procedures decreased.

In 2022 there was a decrease in the number of units of blood components transfused (-1.10%) compared to 2021. 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 2021) (8), have been applied uniformly nationwide.

Overall, in 2022, an increase in the production of allogeneic platelet gel (approx. 15%) and a decrease in the production of allogeneic fibrin glue (-30%) confirm the trend of the previous years. Although the emergency phase related to COVID-19 appears to be over, it is now clear that given new variants of SARS-CoV-2, the health care system, including the blood transfusion system, will have to cope with their impact also in the future.

In particular, specific measures introduced in 2020 (e.g. donation booking), may be confirmed to avoid long waits for the donors and allow donor calls consistently with the supply needs.

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 (SAEs), including the surveillance of events caused by a medical device failure in the transfusion process, as well as the epidemiological surveillance of donors (9). Haemovigilance systems are regulated by specific national laws and by European Directives (10, 11), transposed into national laws (12, 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 1).

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

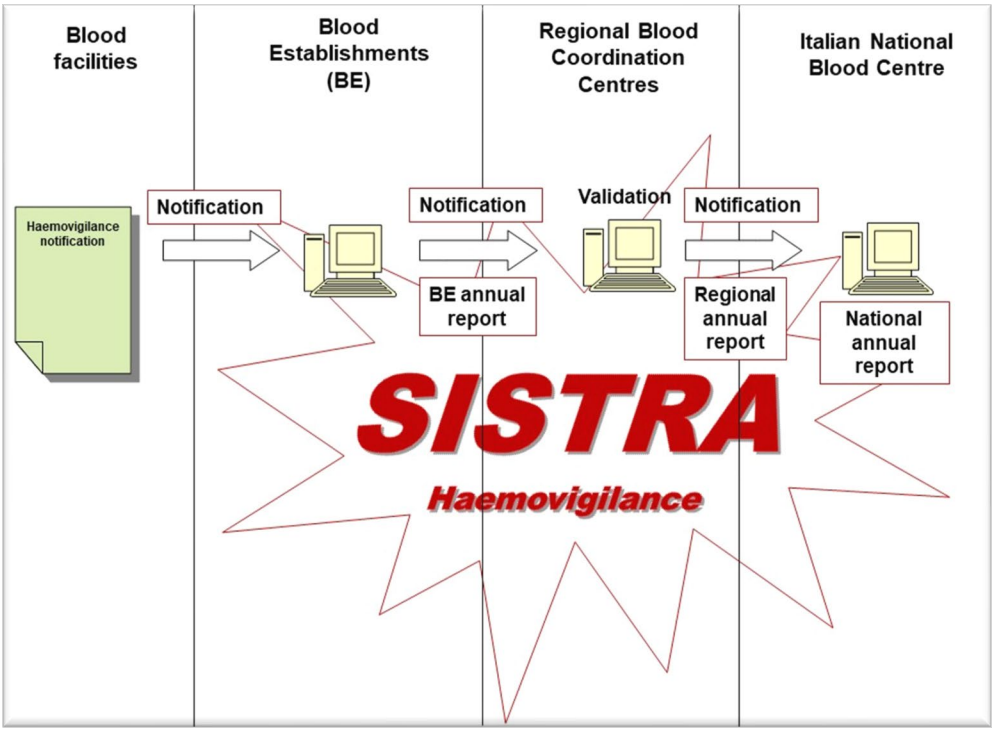

Figure 1. Haemovigilance information flow in SISTRA

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

Adverse reactions in recipients and donors and serious adverse events

General data

The notified adverse events, occurred in 2022, concerns 2,866,709 units of blood components transfused, 2,982,624 procedures of blood donation and 3,139,883 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 2022, 2,080 ARs in recipients (72.5 per 100,000 transfused units) and 8,626 ARs in blood donors (289,2 per 100,000 collection procedures) were reported. The notified SAEs were 30 (0.96 per 100,000 issued units). As shown in Figure 2, the notification system improved over the years, recording a significant increase in both ARs in donors and recipients, from 2009 to 2016. Since 2016, the number of notifications has been almost constant. SAE notifications do not show significant variations over the years.

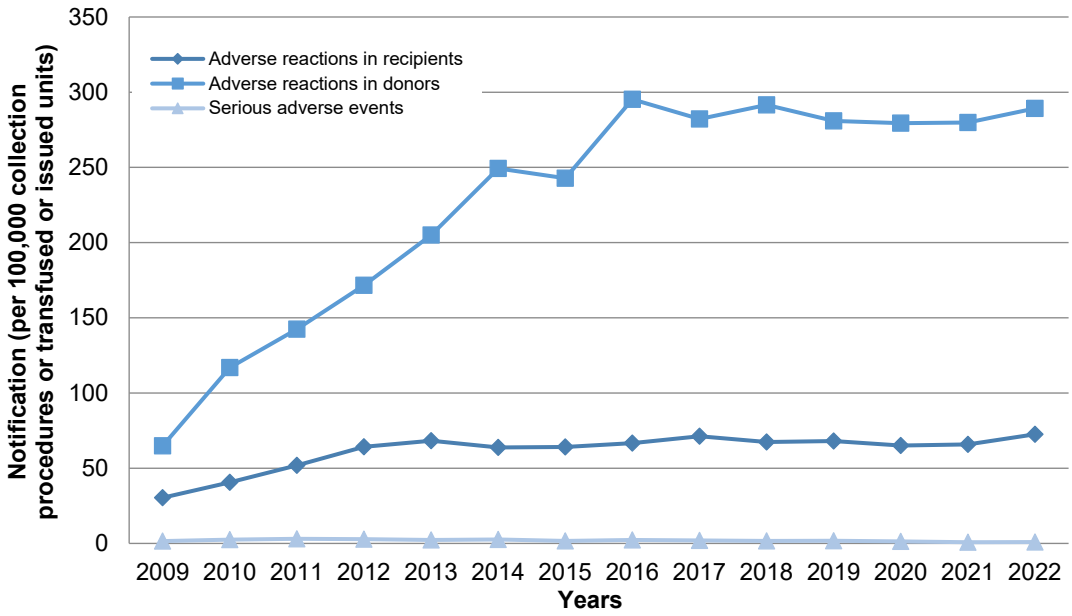

Figure 2. Number of haemovigilance notifications (per 100,000), per year (2009-2022)

Adverse reactions in recipients

Definitions

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.

Reporting on 2022

From January 1st to December 31st 2022, 2,080 ARs were notified in blood components recipients. The ARs related to the transfusion of autologous blood units were excluded from the analysis. As in the previous year (7), the notifications show a significant regional variability with a national average of 72.5 per 100,000 transfused units. Friuli Venezia Giulia recorded the highest value (358.9 per 100,000 transfused units) (Figure 3).

Table 14 reports all ARs notified in blood transfusion recipients in 2022. The most frequently notified reactions were Febrile Non-Haemolytic Reactions (FNHTR) (32.30 per 100,000 transfused units) and allergic manifestations with only mucosal and cutaneous symptoms (18.56 per 100,000 transfused units): these reactions represent 70.1% of all ARs notified in recipients.

The remaining reported reactions concern cardiac and/or respiratory symptoms: 99 allergic reactions (3.45 per 100,000 transfused units), 84 TAD (2.93 per 100,000 transfused units), 49 TACO (1.71 per 100,000 transfused units) and 3 TRALI (0.10 per 100,000 transfused units).

The frequency of ARs in blood component recipients was 1 in 1.38 transfused units. As reported in Table 15, most of the 2,080 notified ARs were related to platelets transfusion (196.9 per 100,000 units transfused). For the 17 ARs related to multi-component transfusions, it was not possible to assign the AR to a specific blood component.

Table 16 reports the imputability levels for the notified ARs: 56.5% were associated with a low imputability level (45.8% possible and 10.8% excluded/improbable) and 38.2% to high imputability level (32.6% probable and 5.5% certain). For 5.3% of ARs, the level of imputability was “not assessable”.

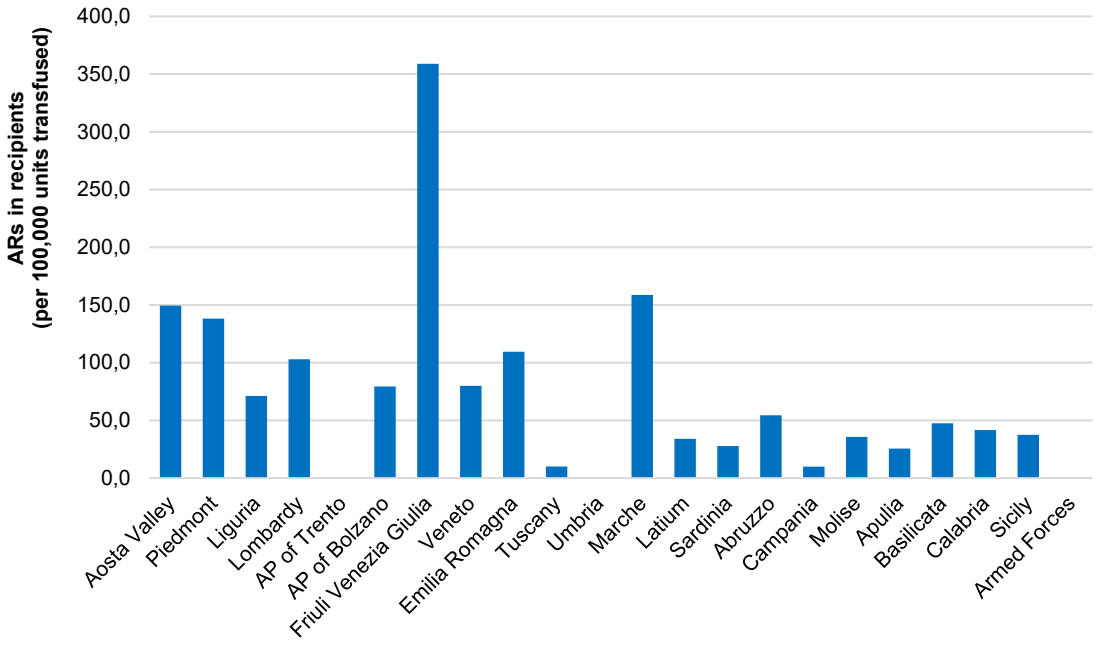

Figure 3. Adverse reactions in recipients by region, per 100,000 units transfused (2022)

Table 14. Adverse reactions in recipients (2022)

ARs	n.	%	ARs/100,000 transfused units
Acute haemolytic reaction - ABO incompatible	6	0.3	0.21
Allergic reactions - mucosal and cutaneous symptoms	532	25.6	18.56
Allergic reactions - respiratory and/or cardiovascular system	99	4.8	3.45
Alloimmunisation	2	0.1	0.07
Anaphylactic shock	4	0.2	0.14
Delayed haemolytic transfusion reactions - other blood groups	1	0.0	0.03
Delayed haemolytic transfusion reactions – Rh	2	0.1	0.07
FNHTR	926	44.5	32.30
Haemolytic transfusion reactions – autoantibodies	3	0.1	0.10
Hyperkalemia	1	0.0	0.03
Hypotensive transfusion reaction	38	1.8	1.33
IBCT	8	0.4	0.28
Non-immunological haemolysis - physic cause	3	0.1	0.10
Post-transfusion purpura	4	0.2	0.14
TACO	49	2.4	1.71
TAD	84	4.0	2.93
TRALI	3	0.1	0.10
TTI*	1	0.0	0.03
Other	314	15.1	10.95
Total	**2,080**	**100**	**72.56**

* Bacterial infection referred to *Listeria monocytogenes*.

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

Table 15. Adverse reactions in recipients by blood component transfused (2022)

Blood component transfused	ARs	Transfused units	ARs/100,000 transfused units
Red blood cells	1,414	2,393,798	59.1
Platelets	475	241,280	196.9
Plasma*	169	205,486	82.2
Other	5	26,145	19.1
More than one blood component transfused**	17	NA	NA
Total	**2,080**	**2,866,709**	**72.5**

ARs, Adverse Reactions; NA, Not Assessable.
* Includes plasma pooled and treated for virus inactivation (24 ARs).
** ARs not ascribable to specific blood component.

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

Level	Imputability	n.	%
0	Excluded/Improbable	224	10.8
1	Possible	952	45.8
2	Probable	679	32.6
3	Certain	114	5.5
NA	Not assessable	111	5.3
	Total	**2,080**	**100.0**

Tables 17 show 793 ARs with a probable and certain imputability level.

Table 17. Adverse reactions in recipients with imputability level 2-3 regardless of severity levels (2022)

ARs	Total	%	ARs/100,000 transfused units
Acute haemolytic reaction - ABO incompatible transfusion	6	0.76	0.21
Allergic manifestations with only mucosal and cutaneous symptoms	306	38.59	10.67
Allergic reactions involving the respiratory and/or cardiovascular system	52	6.56	1.81
Alloimmunisation	1	0.13	0.03
Anaphylactic shock	3	0.38	0.10
Delayed haemolytic transfusion reactions - other blood groups	1	0.13	0.03
Delayed haemolytic transfusion reactions – Rh	1	0.13	0.03
FNHTR	302	38.08	10.53
Haemolytic transfusion reactions – autoantibodies	1	0.13	0.03
Hypotensive transfusion reaction	6	0.76	0.21
IBCT	5	0.63	0.17
Non-immunological haemolysis - physic cause	1	0.13	0.03
Post-transfusion purpura	1	0.13	0.03
TACO	21	2.65	0.73
TAD	26	3.28	0.91
TRALI	1	0.13	0.03
TTI – Bacterial	1	0.13	0.03
Other	58	7.31	2.02
Total	**793**	**100.00**	**27.66**

ARs, Adverse Reactions; NA, Not Assessable; RBCs, Red Blood Cells; FNHTR, Febrile Non-Haemolytic Reaction; IBCT, Incorrect Blood Component Transfused; TACO, Transfusion-Associated Circulatory Overload; TAD, Transfusion Associated Dyspnoea; TRALI, Transfusion-Related Acute Lung Injury; TTI, Transfusion Transmitted Infections.

The frequency of the ARs with a high imputability level is 1 every 3,615 transfused units. As reported in Table 18, the frequency distribution of ARs, per 100,000 transfused units, is 18.5 for red blood cells (RBCs), 88.9 for plasma, 98.2 for platelets, 9.3 for virus-inactivated plasma and 19.1 for other type of blood component. The most frequent ARs related to the transfusion of RBCs was the febrile non-haemolytic reaction (10.2 per 100,000 transfused units); the allergic manifestation with only mucosal and cutaneous symptoms was the most frequent AR related to plasma (72.6 per 100,000 transfused units), platelets (57.6 per 100,000 transfused units), virus-inactivated plasma (7.4 per 100,000 transfused units) and other type of blood component (7.6 per 100,000 transfused units).

Table 18. Adverse reactions in recipients with imputability level 2-3 regardless of severity levels, by Blood Component Transfused (BCT) (2022)

BCT	ARs	n.	ARs/100,000 transfused units
RBCs	Acute haemolytic reaction - ABO incompatible transfusion	6	0.25
	Allergic reactions - mucosal and cutaneous symptoms	81	3.38
	Allergic reactions - respiratory and/or cardiovascular system	26	1.09
	Alloimmunisation	1	0.04
	Delayed haemolytic transfusion reactions - other blood groups	1	0.04
	Delayed haemolytic transfusion reactions - Rh	1	0.04
	FNHTR	244	10.19
	Haemolytic transfusion reactions - autoantibodies	1	0.04
	Hypotensive transfusion reaction	2	0.08
	IBCT	5	0.21
	Non-immunological haemolysis - physic cause	1	0.04
	TACO	18	0.75
	TAD	21	0.88
	TRALI	1	0.04
	Other	35	1.46
Total		**444**	**18.55**
Plasma	Allergic reactions - mucosal and cutaneous symptoms	71	72.57
	Allergic reactions - respiratory and/or cardiovascular system	4	4.09
	Anaphylactic shock	1	1.02
	FNHTR	1	1.02
	Hypotensive transfusion reaction	1	1.02
	Post-transfusion purpura	1	1.02
	TACO	1	1.02
	TAD	1	1.02
	Other	6	6.13
Total		**87**	**88.92**
Platelets	Allergic reactions - mucosal and cutaneous symptoms	139	57.61
	Allergic reactions - respiratory and/or cardiovascular system	19	7.87
	Anaphylactic shock	2	0.83
	FNHTR	54	22.38
	Hypotensive transfusion reaction	3	1.24
	TACO	1	0.41
	TAD	4	1.66
	TTI – Bacterial	1	0.41
	Other	14	5.80
Total		**237**	**98.23**
Virus-inactivated plasma	Allergic reactions - mucosal and cutaneous symptoms	8	7.43
	Allergic reactions - respiratory and/or cardiovascular system	1	0.93
	TACO	1	0.93
Total		**10**	**9.29**

BCT	ARs	n.	ARs/100,000 transfused units
Other type of blood components	Allergic reactions - mucosal and cutaneous symptoms	2	7.65
	FNHTR	1	3.82
	Other	2	7.65
Total		**5**	**19.12**
More than one blood component transfused*	Allergic reactions - mucosal and cutaneous symptoms	5	NA
	Allergic reactions - respiratory and/or cardiovascular system	2	NA
	FNHTR	2	NA
	Other	1	NA
Total		**10**	NA
Total ARs		**793**	

ARs, Adverse Reactions; NA, Not Assessable; RBCs, Red Blood Cells; FNHTR, Febrile Non-Haemolytic Reaction; IBCT, Incorrect Blood Component Transfused; TACO, Transfusion-Associated Circulatory Overload; TAD, Transfusion Associated Dyspnoea; TRALI, Transfusion-Related Acute Lung Injury; TTI, Transfusion Transmitted Infections.
*ARs not ascribable to specific blood component.

Table 19 shows 9 ARs with imputability level 2-3 and severity level 3-4 (severe symptoms requiring resuscitation procedures or death) by blood component transfused. In 2022, the frequency of these ARs was 1 every 318,523 transfused units.

Table 19. Adverse reactions to transfusion with imputability level 2-3 and severity level 3-4, by Blood Component Transfused (BCT) (2022)

BCT	ARs	n.	ARs/100,000 transfused units
RBCs	Acute haemolytic reaction - ABO incompatible transfusion	1	0.04
	FNHTR	2	0.08
	TAD	2	0.08
	TRALI	1	0.04
Total		6	0.25
Platelets	Anaphylactic shock	2	0.83
	TACO	1	0.41
Total		3	1.24
Total ARs		**9**	

ARs, Adverse Reactions; RBCs, Red Blood Cells; FNHTR, Febrile Non-Haemolytic Reaction; TACO, Transfusion-Associated Circulatory Overload; TAD, Transfusion Associated Dyspnoea; TRALI, Transfusion-Related Acute Lung Injury.

Considering the severity of the total notified ARs to blood transfusion, 72.8% required therapeutic intervention, 1.1% required resuscitation procedures and 0.1% led to death (Figure 4).

For the 2 deaths, the imputability of the transfusion was excluded/unlikely. In 91.1% of ARs, the clinical resolution was observed within a few hours and, in 2%, within a few days (Figure 5).

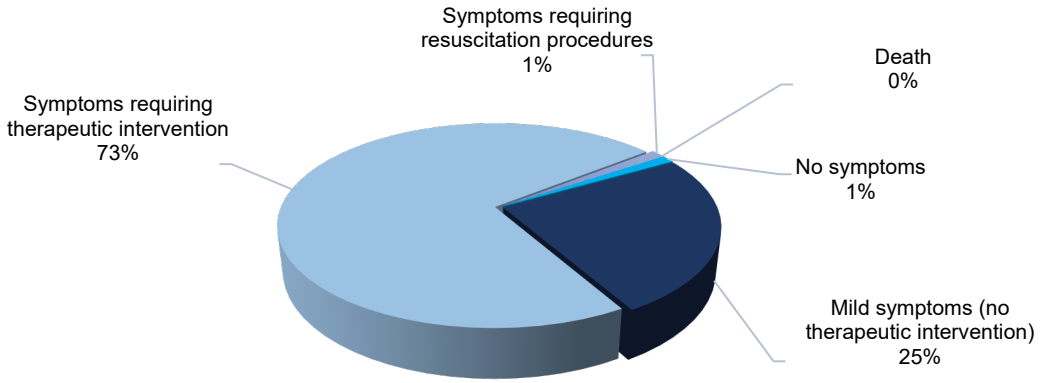

Figure 4. Severity level of adverse reactions in recipients (2022)

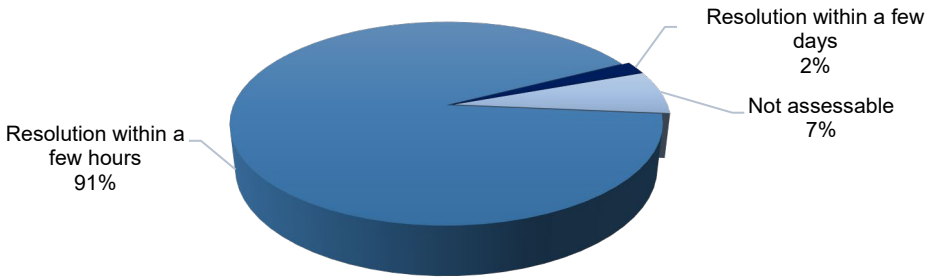

Figure 5. Adverse reactions in recipients by outcome (2022)

The majority of the ARs occurred in hospital ward (78.9%) and in day-hospital (12.0%) (outpatient clinics (8.0%) and BEs (4%)) (Table 20 and Figure 6).

Table 20. Transfusion sites notifying adverse reactions (2022)

Transfusion site	n.	%
Clinic	53	2.5
Day-hospital	249	12.0
Emergency/ICU	93	4.5
Home	21	1.0
Hospital ward	1,641	78.9
Operating theatre	23	1.1
Total	**2,080**	**100**

ICU, Intensive Care Unit.

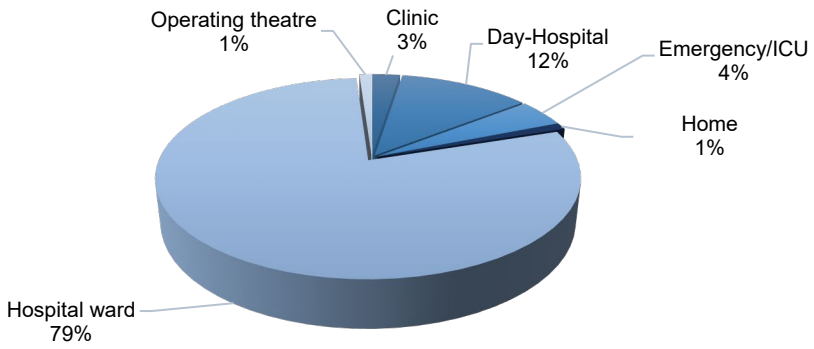

Figure 6. Adverse reactions by transfusion site (2022)

Incorrect blood component transfusions (IBCT)

The acute haemolytic reaction due to ABO incompatible transfusion were 6 (1 in 398,966 units of red blood cells transfused). The transfusions occurred in hospital ward (83.3%) and in day-hospital (16.7%). The symptoms in recipients were "symptoms requiring therapeutic intervention" (83.3%) and "symptoms requiring resuscitation procedures" (16.7%). No death occurred.

The IBCTs without symptoms (ABO compatible or incompatible) were 8 transfusions not intended for the recipient (1 in 299,224 blood components transfused). The transfusion errors occurred due to a wrong identification of the recipient. The transfused units were red blood cells units ABO compatible (75%) and incompatible (25%). The incorrect transfusions occurred in hospital ward (50%), operating theatre (25%), day-hospital (12.5%) and emergency/ICU (12.5%). In 50% of the IBCTs, the transfusion was interrupted.

Adverse reactions in blood donors

In 2022, 8,626 ARs to allogeneic donation were notified (1 every 346 donations). The distribution of the AR notifications shows a significant regional variability with a national average of 289.2 per 100,000 collection procedures. Friuli Venezia Giulia and Lombardy recorded the highest values (870.2 and 679.0 per 100,000 collection procedures, respectively) (Figure 7).

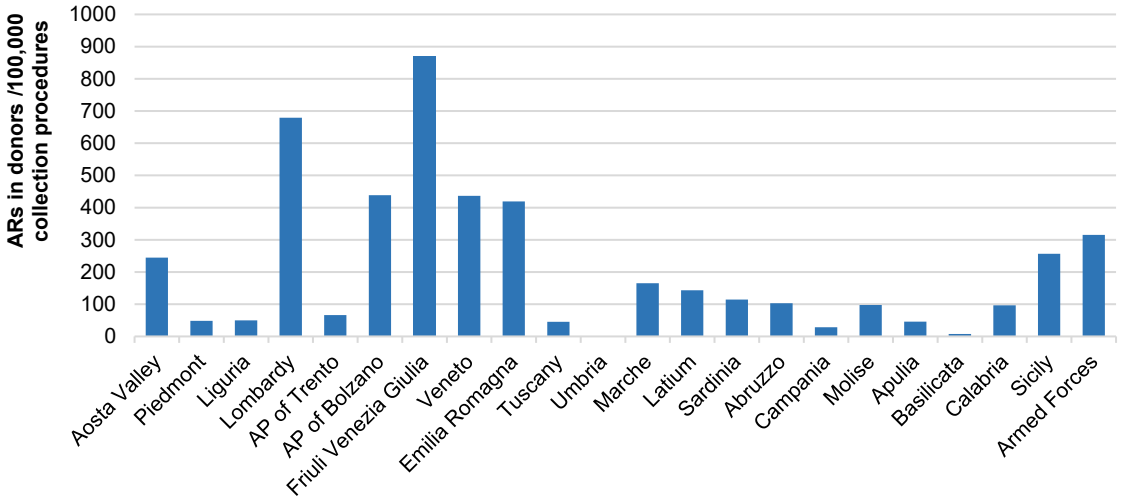

Figure 7. Adverse reactions in donors by region, per 100,000 collection procedures (2022)

As reported in Table 21, 6,424 (74.5%) ARs were related to whole blood donations and 2,202 (25.5%) to apheresis donations. The highest ARs frequency, by type of collection procedure, was observed for apheresis donation (516.0 per 100,000 apheresis collection procedures *vs.* 251.3 per 100,000 whole blood collection procedures).

Table 21. Adverse reactions to donations, by collection procedure (2022)

Collection procedure			ARs			ARs/100,000 collection procedures		
Whole blood	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*
2,555,886	426,738	2,982,624	6,424	2,202	8,626	251.3	516.0	289.2

ARs, Adverse Reactions.

Immediate vasovagal reactions, delayed vasovagal reactions and haematomas were the most observed ARs in blood donors (221.2, 27.5 and 24.7 per 100,000 collection procedures, respectively) (Table 22). Immediate vasovagal reactions were more frequent in apheresis collection (324.8 per 100.000 procedures) than in whole blood collection (204.0 per 100.000 procedures). The appearance of haematomas was also more frequent in apheresis collection (105 per 100,000 procedures) than in whole blood collection (11.3 per 100,000 procedures).

Table 22. Adverse reactions in donors (2022)

ARs	n.	%	ARs/100,000 collection procedures		
			Total	*Apheresis*	*Whole blood*
Angina pectoris	2	0.02	0.07	0.23	0.04
Arterial puncture	43	0.50	1.44	0.47	1.60
Citrate reaction	93	1.08	3.12	21.79	0.00
Cold/shivers	27	0.31	0.91	5.62	0.12
Deep venous thrombosis	1	0.01	0.03	0.00	0.04
Delayed vasovagal reaction	819	9.49	27.46	28.59	27.27
Delayed vasovagal reaction with complications	30	0.35	1.01	1.17	0.98
Haematoma	736	8.53	24.68	104.98	11.27
Immediate vasovagal reaction	6,599	76.50	221.25	324.79	203.96
Immediate vasovagal reaction with complications	51	0.59	1.71	2.81	1.53
Incidents tied to vasovagal syndrome	13	0.15	0.44	1.17	0.31
Local allergic reaction	5	0.06	0.17	1.17	0.00
Local infection	2	0.02	0.07	0.00	0.08
Nerve injury	6	0.07	0.20	0.23	0.20
Nerve injury due to a haematoma	3	0.03	0.10	0.23	0.08
Systemic allergic reaction	2	0.02	0.07	0.47	0.00
Tendon lesion	1	0.01	0.03	0.23	0.00
Thrombocytopenia	2	0.02	0.07	0.47	0.00
Thrombophlebitis	7	0.08	0.23	0.47	0.20
Other incidents	42	0.49	1.41	2.34	1.25
Other	142	1.65	4.76	18.75	2.43
Total	**8,626**	**100**	**289.2**	**516.0**	**251.3**

ARs, Adverse Reactions.

The severity of the notified reactions was mainly mild (214.7 per 100,000 collection procedures) (Table 23). The severe ARs to donation occurred in 10.3 per 100,000 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 (2022)

ARs	Mild	%	Moderate	%	Severe	%
Angina pectoris	2	0.03		0.00		0.00
Arterial puncture		0.00	41	2.14	2	0.65
Citrate reaction	45	0.70	39	2.04	9	2.92
Cold/shivers	24	0.37		0.00	3	0.97
Deep venous thrombosis		0.00		0.00	1	0.32
Delayed vasovagal reaction	564	8.81	216	11.28	39	12.66
Delayed vasovagal reaction with complications	3	0.05	13	0.68	14	4.55
Haematoma	545	8.51	128	6.68	63	20.45
Immediate vasovagal reaction	5,028	78.53	1,433	74.83	138	44.81
Immediate vasovagal reaction with complications	19	0.30	25	1.31	7	2.27
Incidents tied to vasovagal syndrome		0.00		0.00	13	4.22
Local allergic reaction	4	0.06		0.00	1	0.32
Local infection	1	0.02	1	0.05		0.00
Nerve injury	5	0.08		0.00	1	0.32
Nerve injury due to a haematoma	2	0.03	1	0.05		0.00
Systemic allergic reaction		0.00		0.00	2	0.65
Tendon lesion		0.00		0.00	1	0.32
Thrombocytopenia	2	0.03		0.00		0.00
Thrombophlebitis		0.00		0.00	7	2.27
Other	119	1.86	16	0.84	7	2.27
Other incidents	40	0.62	2	0.10		0.00
Total (%)	**6,403 (74.2)**	**100**	**1,915 (22.2)**	**100**	**308 (3.6)**	**100**
Total ARs/100,000 collection procedures	**214.7**		**64.2**		**10.3**	

ARs, Adverse Reactions.

The severe ARs were more frequent in apheresis than in whole blood donation procedures (24.61 *vs.* 7.94 per 100,000 collection procedures, respectively) (Table 24).

Table 24. Severe adverse reactions to donation, by collection procedure (2022)

Collection procedure			Severe ARs			Severe ARs/100,000 collection procedures		
Whole blood	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*	*Whole blood*	*Apheresis*	*Total*
2,555,886	426,738	2,982,624	203	105	308	7.94	24.61	10.33

ARs, Adverse Reactions

Serious adverse events

In 2022, 30 SAEs were notified. The regional distribution of the notifications shows a wide variability with a national average of 0.96 per 100,000 issued units. Emilia-Romagna and Friuli Venezia Giulia recorded the highest values (3.64 and 3.17 per 100,000 issued units, respectively) (Figure 8).

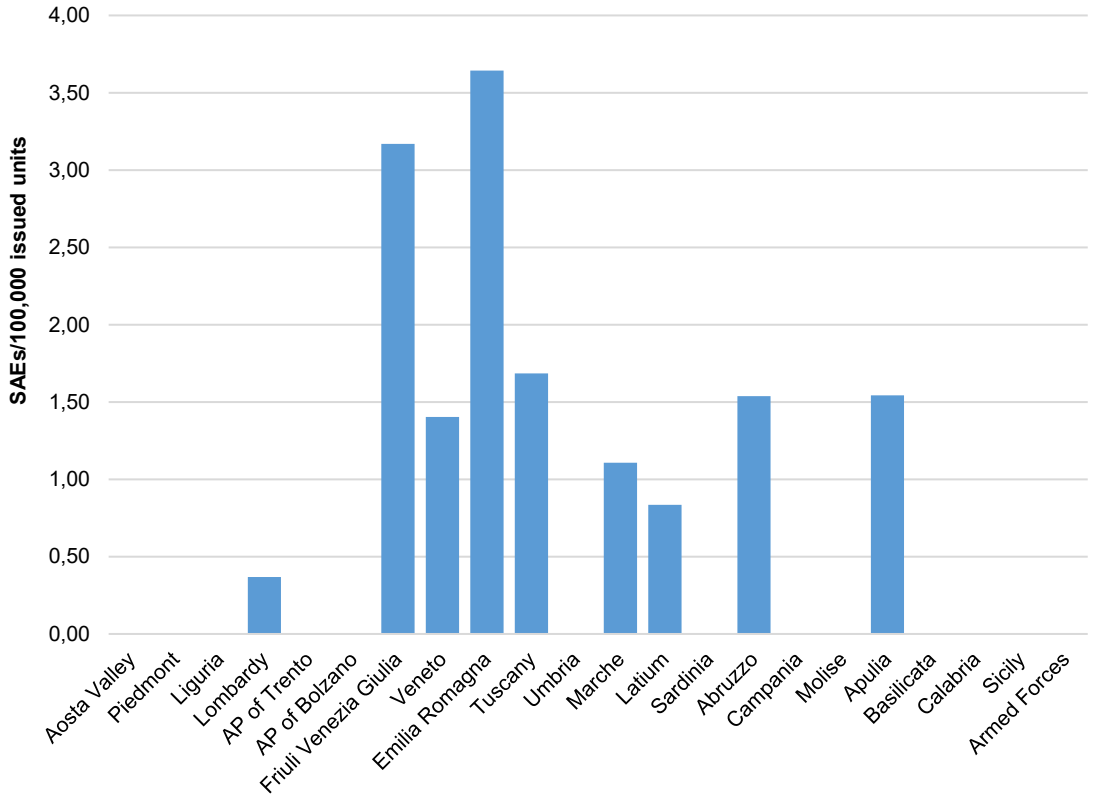

Figure 8. Serious adverse events notified by region, per 100,000 issued units (2022)

Human error (1 every 149,518 issued units) was the main cause of SAE. Other SAEs were due to organisational error and equipment failure (0.16 and 0.10 per 100,000 issued units, respectively) (Table 25 and Figure 9).

Table 25. Cause of serious adverse events (2022)

Cause	n.	%	SAEs/100,000 issued units
Equipment failure	3	10.0	0.10
Human error	21	70.0	0.67
Organisational error	5	16.7	0.16
Other	1	3.3	0.03
Total	**30**	**100.0**	**0.96**

SAEs, Serious Adverse Events

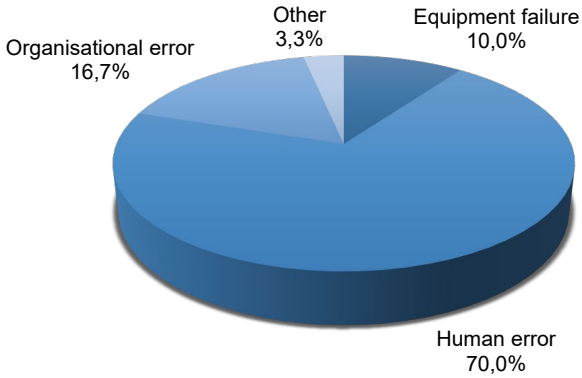

Figure 9. Cause of serious adverse events (2022)

The majority of SAEs occurred in the phases of issue/assignment and issue/labelling (0.38 and 0.13 per 100,000 issued units, respectively) and in the collection phase (0.13 per 100,000 issued units) (Table 26 and Figure 10).

Table 26. Phases in which serious adverse events occurred (2022)

Phase	n.	%	SAEs/100,000 issued units
Collection	4	13.3	0.13
Distribution	1	3.3	0.03
Issue/assignment	12	40.0	0.38
Issue/labelling	4	13.3	0.13
Processing	1	3.3	0.03
Storage	2	6.7	0.06
Other	6	20.0	0.19
Total	**30**	**100.0**	**0.96**

SAEs, serious adverse events.

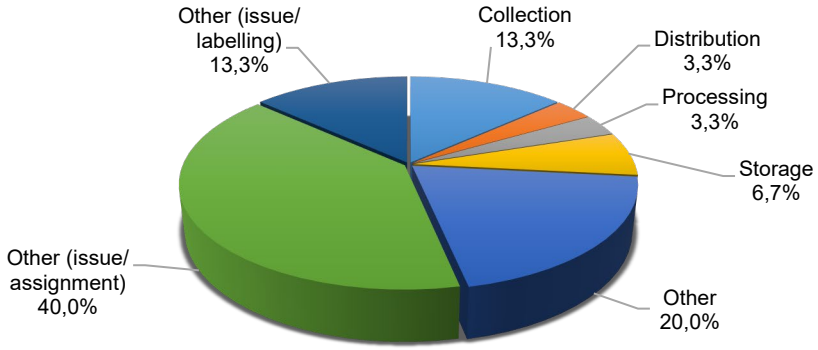

Figure 10. Phases in which serious adverse events occurred (2022)

The notified SAEs occurred in clinical wards and in BEs with a frequency distribution of 76.7% and 23.3%, respectively (Table 27 and Figure 11).

Table 27. Serious adverse events by site of occurrence (2022)

Site	n.	%
Blood establishment	7	23.3
Clinical ward	23	76.7
Total	**30**	**100**

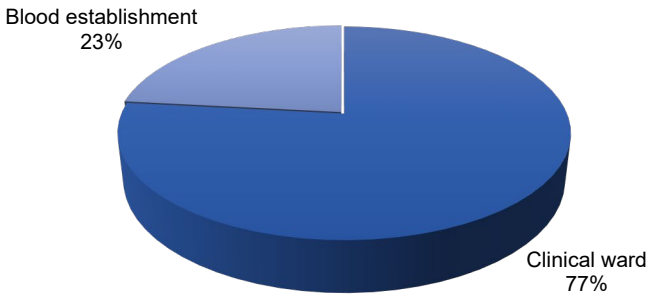

Figure 11. Site in which serious adverse events occurred (2022)

Near miss

In 2022, 241 near miss events (7.7 per 100,000 units issued), as defined by the EDQM Guide (14), were notified. Many notifications were about "wrong information on the tube label" (3.5 per 100,000 units issued) and "wrong patient" (2.6 per 100,000 units issued) (Table 28); avoided transfusions of blood component not intended for the patient (0.92 per 100,000 units issued) and wrong/inappropriate blood component type requested (0.25 per 100,000 units issued), were also reported.

Table 28. Near miss events (2022)

Type of primary error (near miss)	n.	%	Near miss/100,000 issued units
Avoided transfusion of blood component not intended for the patient	29	12.0	0.92
Avoided transfusion of expired blood component	4	1.7	0.13
Avoided transfusion of inappropriate blood component	4	1.7	0.13
Error in pre-transfusion test	3	1.2	0.10
Wrong information on the blood unit label	3	1.2	0.10
Wrong information on the tube label	109	45.2	3.47
Wrong patient	81	33.6	2.58
Wrong/inappropriate blood component type requested	8	3.3	0.25
Total	**241**	**100**	**7.68**

Comments and recommendations

As in the previous year (7), the 2022 haemovigilance data reported that the most frequent blood transfusion ARs, considering all the imputability and severity levels, were febrile non-haemolytic reactions (32.3 per 100,000 transfused units) and allergic reactions with only mucosal

and cutaneous symptoms (18.6 per 100,000 transfused units). The ARs involving the respiratory system were 11.3% of the total notifications.

In 2022, 6 acute haemolytic reactions due to ABO incompatible transfusions (0.25 per 100,000 units of red blood cells transfused) were notified. The imputability of the above-mentioned events, reported as probable or certain, is related to errors or deviations from the standard procedures or policies. Root cause analysis of these events has been carried out to highlight and implement appropriate corrective action. Monitoring and reporting of these events are important for the adoption of appropriate preventive measures.

Among the 2,080 reported ARs in recipient, 793 (38%) were with a high imputability (level 2-3), of which 9 with a high severity (level 3 - severe symptoms requiring resuscitation procedures or 4 - death) with a frequency of 0.31 per 100,000 units transfused. In detail, there were notified 1 acute haemolytic reaction due to ABO incompatible transfusion, 4 ARs involving the respiratory system (2 TAD, 1 TRALI and 1 TACO), 2 FNHTR and 2 anaphylactic shocks.

The adverse reactions to allogeneic donation were 8,626. The immediate vasovagal reactions, that represented 76.5% of the total notified ARs in blood donor, occurred in 1 every 452 collection procedures and were the most frequent ARs for both apheresis and whole blood collection (324.8 *vs.* 204.0 per 100,000 collection procedures, respectively). Moreover, the other ARs having had high frequency of occurrence were haematomas in apheresis collection (105.0 per 100,000 collection procedures) and delayed vasovagal reactions in whole blood collection (27.3 per 100,000 collection procedures).

In 2022, 30 SAEs and 241 near miss errors were notified. The frequency of SAEs was 1 every 104,662 issued units; the human error was the main cause of adverse events (0.67 per 100,000 issued units) and the "other" phase of issue/assignment (0.38 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, 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 (12-13).

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 (9). The following serological tests are performed: Hepatitis B virus surface antigen (HBsAg), anti-Human Immunodeficiency Virus 1-2 antibodies (HIV1-2 Ab) and the HIV-1 antigen, antibodies against Hepatitis C Virus (HCV Ab) and anti-*Treponema pallidum* (TP). The Nucleic Acid Test (NAT) make it possible to detect the presence of HCV (HCV RNA), HIV 1-2 (HIV 1-2 RNA) and Hepatitis B Virus (HBV DNA) viral genomes.

This information is extremely useful for:

- monitoring the epidemiological progress of transfusion transmitted diseases in 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 part of the report, all essential data relative to 2022 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 (9) 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 (9).

- *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 (9).

- *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 2022, out of a total of 1,860,654 blood donors, 1,154 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, and the number of positive donors per 1,000 tested donors (‰). The with the highest number of positive donors detected was Campania (2.15‰), followed by Apulia (1.22‰) and Latium (1.08‰) Regions. Figure 12 reports the same data shown in Table 29 (positive donors per 1,000 tested donors (‰)).

The analysis of the distribution of positive donors by age class shows that positive blood donors are more frequent in the central age classes (36-45, 45-55) (highlighted in grey) (Table 30, column 5). The data on the incidence of infections by age classes (Table 30, column 6) show very similar values for the central age classes (36-45, 46-55 and 56-65).

Table 29. Tested donors and positive donors to infectious markers at national and regional level (2022)

Region/AP	Tested donors	Positive donors	
	n.	n.	‰
Aosta Valley	3,739	0	0.00
Piedmont	125,228	55	0.44
Liguria	50,088	24	0.48
Lombardy	293,627	107	0.36
AP of Trento	22,517	6	0.27
AP of Bolzano	17,311	2	0.12
Friuli Venezia Giulia	48,283	9	0.19
Veneto	173,845	34	0.20
Emilia-Romagna	162,913	70	0.43
Tuscany	139,311	66	0.47
Umbria	27,368	17	0.62
Marche	53,968	24	0.44
Latium	142,794	154	1.08
Sardinia	58,426	28	0.48
Abruzzo	40,579	0	0.00
Campania	134,699	290	2.15
Molise	9,518	0	0.00
Apulia	125,318	153	1.22
Basilicata	18,789	12	0.64
Calabria	46,417	19	0.41
Sicily	165,015	84	0.51
Armed Forces	901	0	0.00
Italy	**1,860,654**	**1,154**	**0.62**

AP, Autonomous Province

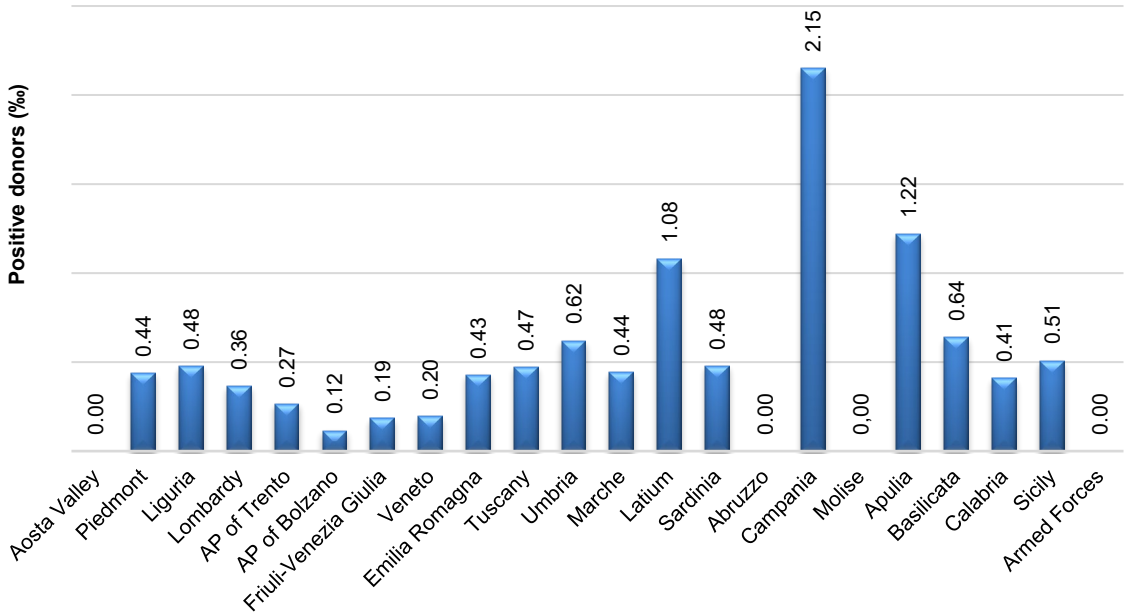

Figure 12. Positive donors per 1,000 tested donors (‰) by Region (2022)

Table 30. Positive donor by age class (2022)

Age class	Total donors		Positive donors		
	n.	%	n.	%	‰
18-25	253,884	13.6	75	6.5	0.30
26-35	336,010	18.1	201	17.4	0.60
36-45	405,124	21.8	284	24.6	0.70
46-55	526,272	28.3	356	30.8	0.68
56-65	313,796	16.9	228	19.8	0.73
over 65	25,568	1.4	10	0.9	0.39
Total	**1,860,654**	**100**	**1,154**	**100**	**0.62**

Table 31 shows the distribution by age class and gender of the 1,154 positive donors; the number of male positive donors appears to be on average 2.8 times higher than the number of female positive donors (Figure 13).

Table 31. Positive donors by age class and gender (2022)

Age class	Male				Female			
	donors		positive donors		donors		positive donors	
	n.	%	n.	%	n.	%	n.	%
18-25	131,773	10.8	57	6.7	122,111	18.9	18	6.0
26-35	208,964	17.2	155	18.2	127,046	19.7	46	15.2
36-45	274,719	22.6	203	23.8	130,405	20.2	81	26.8
46-55	359,562	29.6	266	31.2	166,710	25.8	90	29.8
56-65	220,435	18.1	162	19.0	93,361	14.5	66	21.9
over 65	19,543	1.6	9	1.1	6,025	0.9	1	0.3
Total	**1,214,996**	**100**	**852 (74%)**	**100**	**645,658**	**100**	**302 (26%)**	**100**

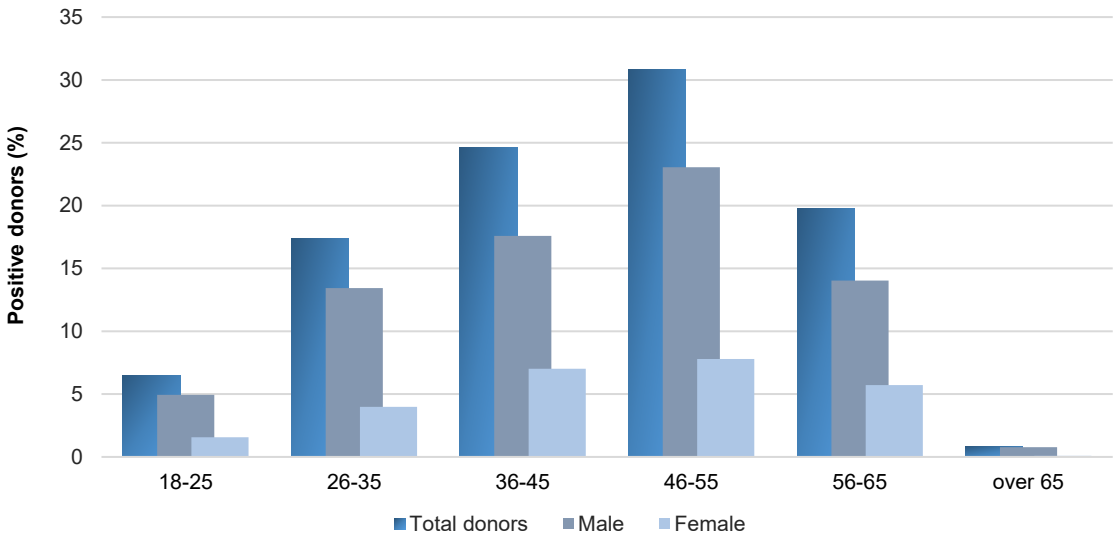

Figure 13. Positive donors (total, male and female donors) by age class (%) (2022)

Considering the number of infections detected in the total number of donors (‰ tested donors) for each age class, the biggest difference in the number of infections between males and females was found in the 18-25, 26-35 and over 65 age classes (Figure 14).

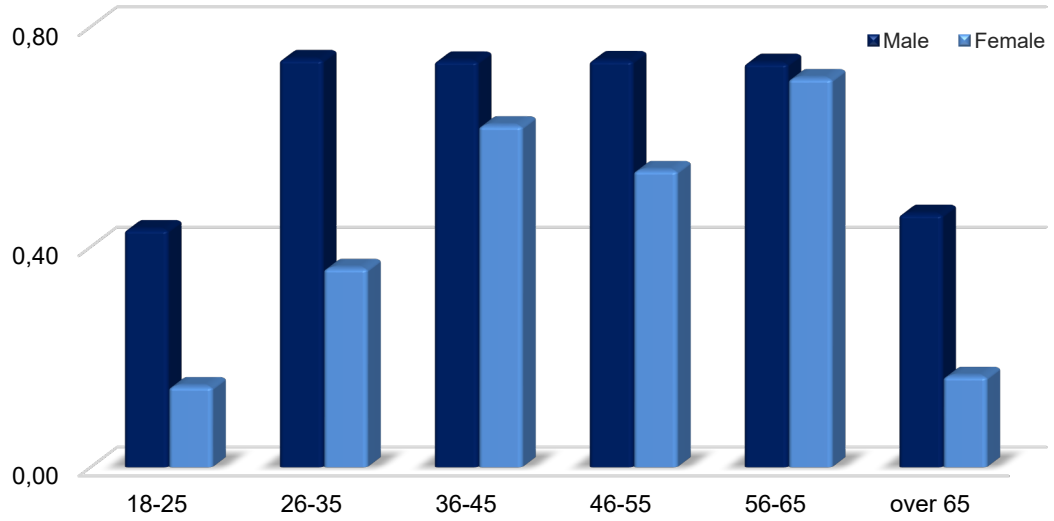

Figure 14. Positive donors by age class and gender (‰ total donors) (2022)

Figure 15 shows the percentages of infections observed for each single marker (HIV, HBV, HCV and TP) and the percentage distribution of all tested donors, distributed by age class. The results show significant variations between the distribution trend of the tested donors and the positive donors for each marker of infections. HIV and TP infections are more frequent in the 26-35 and in the 26-35 and 36-45 age classes, respectively; on the contrary, HBV and HCV infections are both more frequent in the 46-55 and 56-65 age classes.

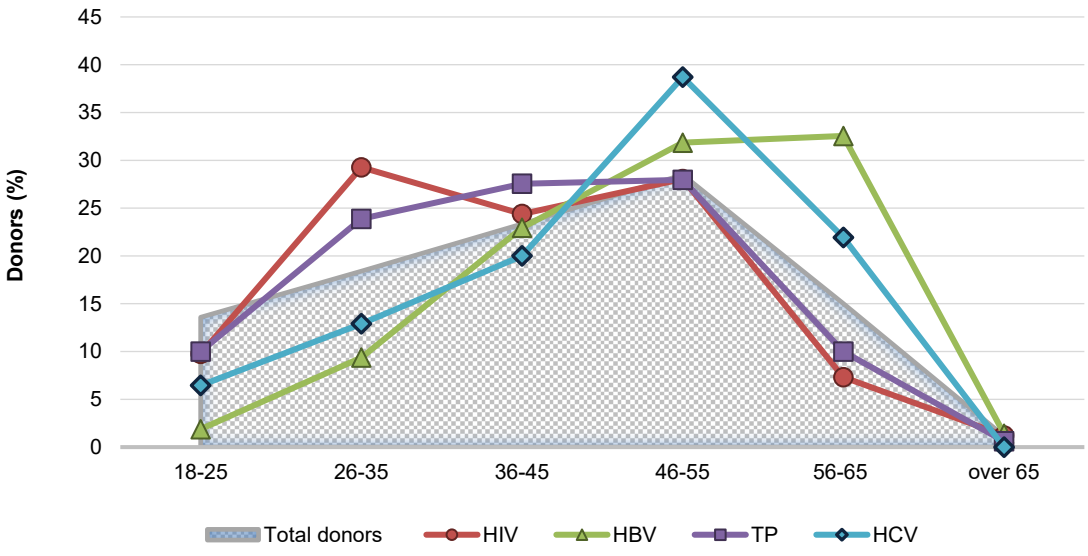

Figure 15. Total donors and HIV, HBV, HCV and TP positive donors by age class (%) (2022)

The number of positive donors significantly differs also between the categories of the donors. In fact, it emerged that 1.93‰ of FT donors were positive to one of the infectious markers compared to 0.25‰ of RT donors (Table 32). Figure 16 shows the same data reported in Table 32.

Table 32. Positive donors per 100 (%) and 1,000 (‰) tested donors: distribution by category (2022)

Donor category	Donors	Positive donors		
	n.	n.	%	(‰)
First-time tested donors	**408,452**	**789**	**68.37**	**1.93**
Prospective donors (first screening without donation)	172,095	254	22.01	1.48
First-time not pre-qualified donors	236,357	535	46.36	2.26
Repeat tested donors	**1,452,202**	**365**	**31.63**	**0.25**
First-time pre-qualified donors	118,393	6	0.52	0.05
Regular donors	1,333,809	359	31.11	0.27
Total donors	**1,860,654**	**1,154**	**100**	**0.62**

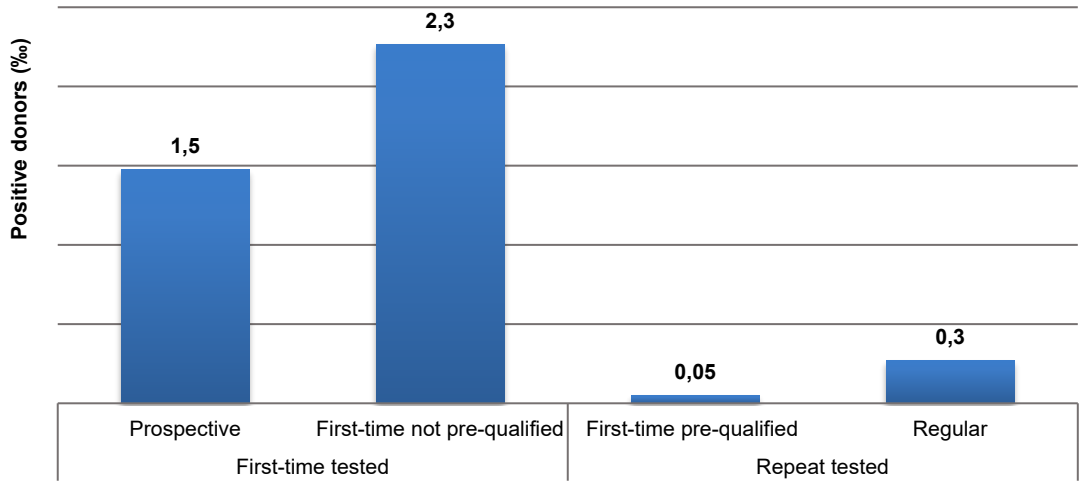

Figure 16. Categories of positive donors (2022)

Table 33 shows the number of FT and RT positive donors in Italy per region. The Regions with the highest number of FT and RT positive donors are Campania (3.67‰ FT) and Apulia (0.81‰ RT), respectively.

Figure 17 shows the percentage of positive donors by category (FT/RT). On a distribution of 100% positivity for each region, with 50% as the cut-off value (red line), the percentages of FT with respect to RT were evaluated. In general, with the exception of Sicily, Basilicata, Lombardy, Piedmont Regions and AP of Bolzano, in all Regions more than 50% of positive donors were FT.

The male/female ratio for FT and RT positive donors was about 2:1 and 3:1, respectively (Figure 18).

Figure 19 shows the positive donor distribution at national and regional level for each infectious marker per 100,000 tested donors. The Region with the highest number of HIV, HCV and HBV infections was Campania (HIV: 21.5/100,000, HBV: 103.9/100,000, HCV: 39.3/100,000 tested donors). These values were from 4.5 (HBV) to 4.9 times (HIV) higher compared to the national data.

Table 33. FT and RT positive donors (total and per 1,000 (‰) tested donors) in Italy (2022)

Region/AP	Total of donors		Positive donors			
	FT	RT	FT	RT	FT (‰ FT)	RT (‰ RT)
Aosta Valley	543	3,196	0	0	0.00	0.00
Piedmont	18,334	106,894	27	28	1.47	0.26
Liguria	12,471	37,617	15	9	1.20	0.24
Lombardy	48,435	245,192	52	55	1.07	0.22
AP of Trento	3,477	19,040	5	1	1.44	0.05
AP of Bolzano	1,478	15,833	0	2	0.00	0.13
Friuli Venezia Giulia	11,052	37,231	6	3	0.54	0.08
Veneto	26,199	147,646	26	8	0.99	0.05
Emilia-Romagna	22,912	140,001	48	22	2.09	0.16
Tuscany	25,952	113,359	51	15	1.97	0.13
Umbria	5,544	21,824	9	8	1.62	0.37
Marche	8,121	45,847	17	7	2.09	0.15
Latium	51,962	90,832	129	25	2.48	0.28
Sardinia	19,464	38,962	24	4	1.23	0.10
Abruzzo	6,542	34,037	0	0	0.00	0.00
Campania	65,394	69,305	240	50	3.67	0.72
Molise	2,223	7,295	0	0	0.00	0.00
Apulia	34,054	91,264	79	74	2.32	0.81
Basilicata	4,503	14,286	6	6	1.33	0.42
Calabria	7,366	39,051	13	6	1.76	0.15
Sicily	31,856	133,159	42	42	1.32	0.32
Armed Forces	570	331	0	0	0.00	0.00
Italy	**408,452**	**1,452,202**	**789**	**365**	**1.93**	**0.25**

AP, Autonomous Province

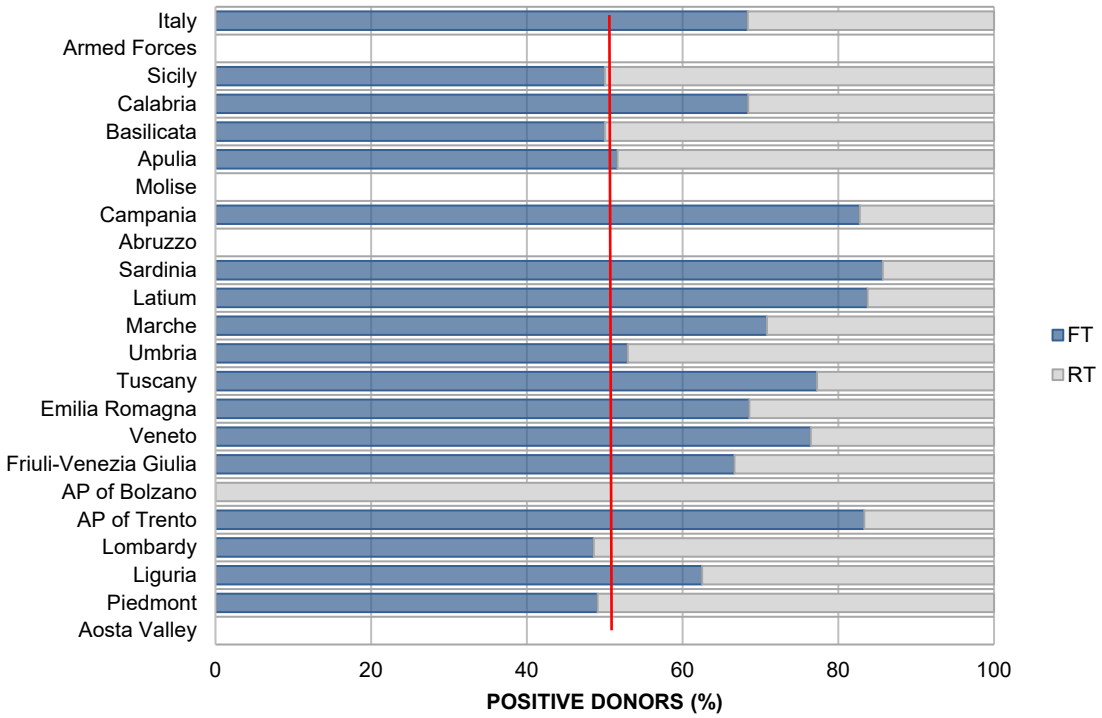

Figure 17. Positive donors by FT and RT category (%) at national and regional level (2022)

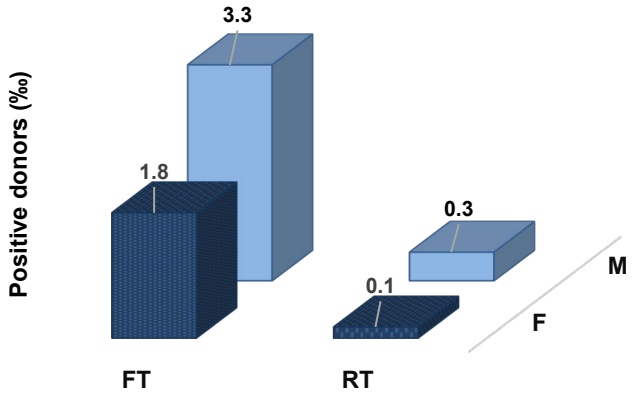

Figure 18. Positive donors by FT and RT category (‰ total male and female donors) and gender (2022)

The Region with the highest number of TP infections was Latium (TP: 56.7/100,000 tested donors). This value was about 2 times higher compared to the national data.

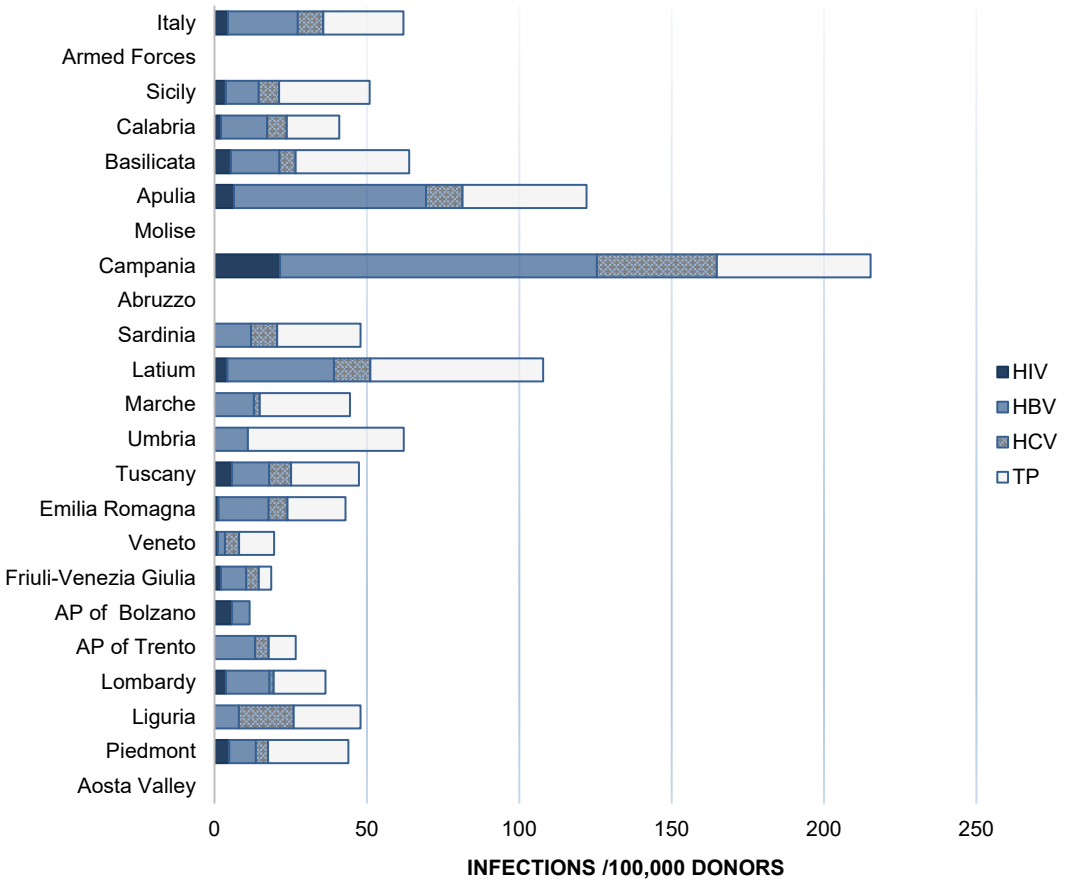

Figure 19. Positive donor distribution at national and regional level for each infectious marker per 100,000 donors (2022)

Figure 20 shows the distribution of HIV, HBV, HCV and TP positivity in FT and RT donors by gender.

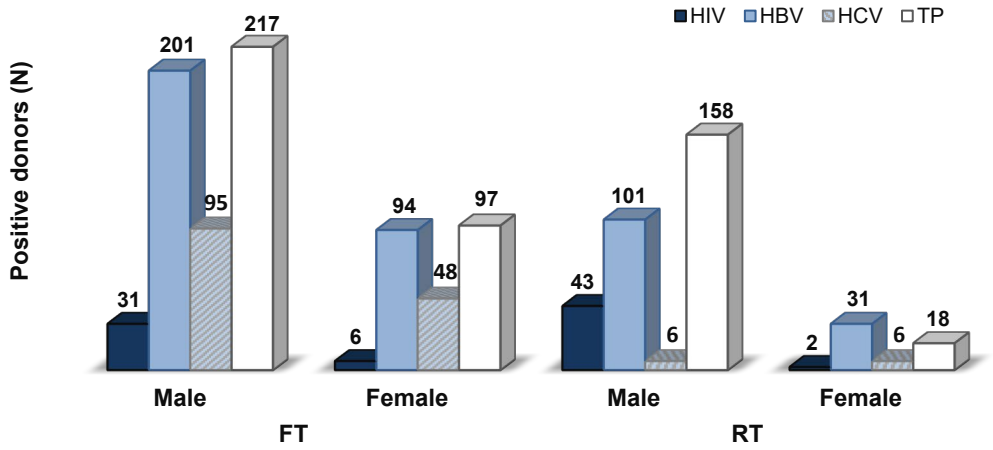

Figure 20. Infections by donor category (FT/RT), gender and infectious marker (2022)

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 (76.9/100,000 FT donors), followed by HBV (72.2/100,000 FT donors).

Table 34. Prevalence by infectious marker/100,000 FT donors (2022)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.00	0.00	0.00	0.00
Piedmont	5.45	38.18	27.27	76.36
Liguria	0.00	16.04	64.15	40.09
Lombardy	8.26	33.03	4.13	61.94
AP of Trento	0.00	57.52	28.76	57.52
AP of Bolzano	0.00	0.00	0.00	0.00
Friuli Venezia Giulia	0.00	27.14	9.05	18.10
Veneto	3.82	11.45	30.54	53.44
Emilia-Romagna	0.00	82.93	43.65	82.93
Tuscany	11.56	61.65	38.53	84.77
Umbria	0.00	54.11	0.00	108.23
Marche	0.00	86.20	12.31	110.82
Latium	7.70	84.68	30.79	125.09
Sardinia	0.00	30.83	25.69	66.79
Abruzzo	0.00	0.00	0.00	0.00
Campania	26.00	180.44	76.46	84.11
Molise	0.00	0.00	0.00	0.00
Apulia	8.81	93.97	38.17	91.03
Basilicata	0.00	44.41	22.21	66.62
Calabria	0.00	54.30	40.73	81.46
Sicily	12.56	34.53	28.25	56.50
Armed Forces	0.00	0.00	0.00	0.00
Italy	**9.06**	**72.22**	**35.01**	**76.88**

AP, Autonomous Province

As reported in Table 35, the highest incidence value was for TP (12.1/100,000 RT donors) and HBV (9.9/100,000 RT donors) infections.

Table 35. Incidence by infectious marker/100,000 RT donors (2022)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.00	0.00	0.00	0.00
Piedmont	4.68	3.74	0.00	17.77
Liguria	0.00	5.32	2.66	15.95
Lombardy	2.85	10.60	0.82	8.16
AP of Trento	0.00	5.25	0.00	0.00
AP of Bolzano	6.32	6.32	0.00	0.00
Friuli Venezia Giulia	2.69	2.69	2.69	0.00
Veneto	0.68	0.68	0.00	4.06
Emilia-Romagna	1.43	5.71	0.00	8.57
Tuscany	4.41	0.88	0.00	7.94
Umbria	0.00	0.00	0.00	36.66
Marche	0.00	0.00	0.00	15.27
Latium	2.20	6.61	1.10	17.61
Sardinia	0.00	2.57	0.00	7.70
Abruzzo	0.00	0.00	0.00	0.00
Campania	17.31	31.74	4.33	18.76
Molise	0.00	0.00	0.00	0.00
Apulia	5.48	51.50	2.19	21.91
Basilicata	7.00	7.00	0.00	28.00
Calabria	2.56	7.68	0.00	5.12
Sicily	1.50	5.26	1.50	23.28
Armed Forces	0.00	0.00	0.00	0.00
Italy	**3.10**	**9.9**	**0.83**	**12.12**

AP, Autonomous Province

Moreover, it is important to note that in 54% of cases no information on the causes of missed deferral of positive donors was reported in SISTRA. When the cause of missed deferral was reported (46%), in most cases the donor "denied the risk factor" (Figure 21).

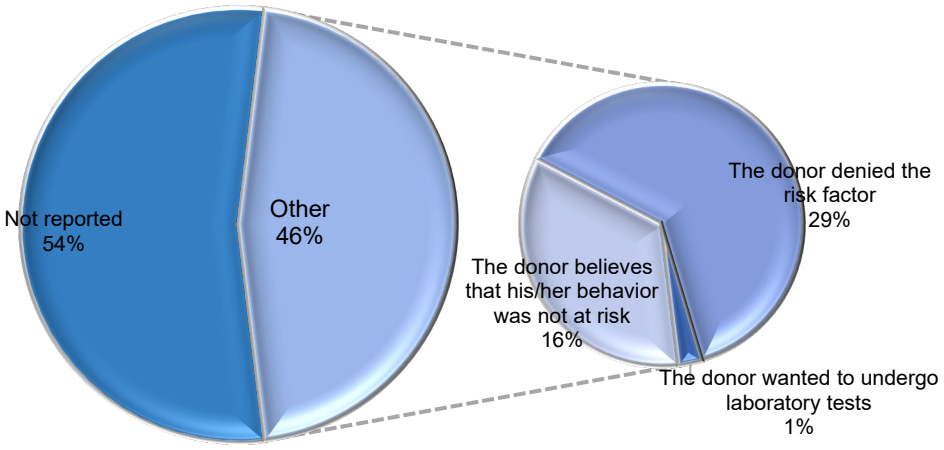

Figure 21. Causes of missed deferral of donor positive to infectious markers (2022)

Table 36 shows the number of donors positive to infectious markers by nationality and category (FT/RT). 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 22.

Table 36. Positive donors to infectious markers by nationality and category (FT/RT) (2022)

Nationality	Positive donors		FT		RT	
	n.	%	n.	%	n.	%
Italians	904	79.4	562	72.4	342	94.2
Foreigners	235	20.6	214	27.6	21	5.8
Total	**1,139**	**100**	**776**	**100**	**363**	**100**

Table 37. Positive donors to infectious markers by category (FT/RT) and by geographical area of birth (2022)

Geographical area of birth	FT	RT	Total
Africa	52	2	54
America	7	3	10
Asia	22	2	24
Europe	133	14	147
Italy	562	342	904
Total	**776**	**363**	**1,139**

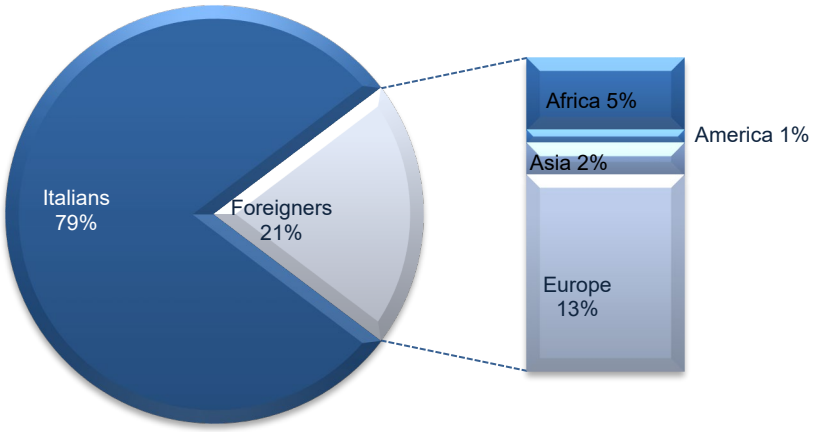

Figure 22. Positive donors to infectious markers by nationality (%) (2022)

HIV surveillance data

Table 38 the number of HIV positive donors and the incidence and prevalence by Italian Regions and in Italy. In Italy, in 2022, 82 HIV infections were reported, with a prevalence of 9.1 per 100,000 FT donors and an incidence of 3.1 per 100,000 RT donors. The highest prevalence (26.0 per 100,000) and incidence (17.3 per 100,000) of HIV infections was found in Campania Region.

Table 38. Number, prevalence and incidence of HIV infections per 100,000 donors at national and regional level (2022)

Region/AP	HIV infections		
	n.	prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	6	5.5	4.7
Liguria	0	0.0	0.0
Lombardy	11	8.3	2.9
AP of Trento	0	0.0	0.0
AP of Bolzano	1	0.0	6.3
Friuli-Venezia Giulia	1	0.0	2.7
Veneto	2	3.8	0.7
Emilia-Romagna	2	0.0	1.4
Tuscany	8	11.6	4.4
Umbria	0	0.0	0.0
Marche	0	0.0	0.0
Latium	6	7.7	2.2
Sardinia	0	0.0	0.0
Abruzzo	0	0.0	0.0
Campania	29	26.0	17.3
Molise	0	0.0	0.0
Apulia	8	8.8	5.5
Basilicata	1	0.0	7.0
Calabria	1	0.0	2.6
Sicily	6	12.6	1.5
Armed Forces	0	0.0	0.0
Italy	**82**	**9.1**	**3.1**

AP, Autonomous Province

Figure 23 shows the distribution, expressed as a percentage, of HIV positive donors by nationality; 5% of all positive donors were foreigners.

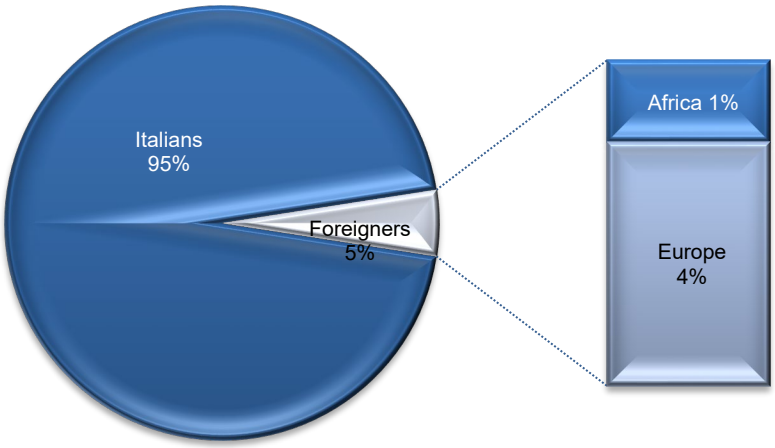

Figure 23. Distribution of HIV positive donors by nationality (%) (2022)

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

Table 39. HIV infections by geographical area of birth (2022)

Geographical area of birth	N. of infections
Africa	1
Europe	3
Italy	78
Total	**82**

In about 40% of the HIV positive donors (38/82) it was not possible to identify the risk factor; in the remaining 60%, 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 "occasional exposure" (Figure 24). Moreover, in most cases (70/82) the molecular (NAT), serological and confirmatory tests were positive.

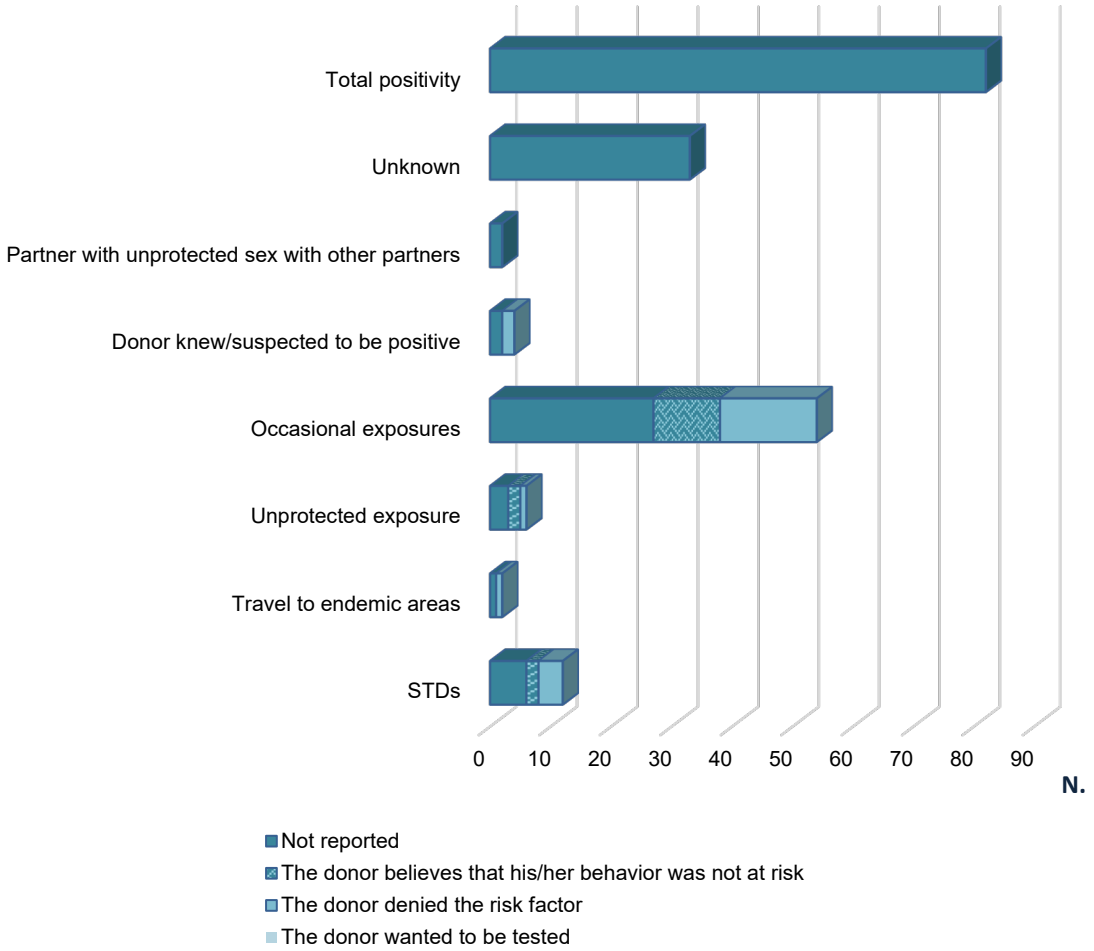

Figure 24. Causes of failed deferral and risk factors detected in HIV positive donors (2022)

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 2022, 155 HCV infections were reported, with a prevalence of 35.0 infections per 100,000 FT donors and an incidence of 0.8 infections per 100,000 RT donors. The highest number of HCV infections was found in the Campania Region (53), that reported the highest value of prevalence (76.5) and incidence (4.3).

Table 40. Number, prevalence and incidence of HCV infections per 100,000 donors at national and regional level (2022)

Region/AP	HCV infections		
	n.	Prevalence	incidence
Aosta Valley	0	0,0	0.0
Piedmont	5	27,3	0.0
Liguria	9	64,2	2.7
Lombardy	4	4,1	0.8
AP of Trento	1	28,8	0.0
AP of Bolzano	0	0,0	0.0
Friuli Venezia Giulia	2	9,1	2.7
Veneto	8	30,5	0.0
Emilia-Romagna	10	43,7	0.0
Tuscany	10	38,5	0.0
Umbria	0	0,0	0.0
Marche	1	12,3	0.0
Latium	17	30,8	1.1
Sardinia	5	25,7	0.0
Abruzzo	0	0,0	0.0
Campania	53	76,5	4.3
Molise	0	0,0	0.0
Apulia	15	38,2	2.2
Basilicata	1	22,2	0.0
Calabria	3	40,7	0.0
Sicily	11	28,3	1.5
Armed Forces	0	0,0	0.0
Italy	**155**	**35.0**	**0.8**

AP, Autonomous Province

Table 41 shows the distribution of HCV positive donors by geographical area of birth. Figure 25 shows the distribution, expressed as a percentage, of HCV positive donors by nationality; 14% of all positive donors were foreigners.

Table 41. HCV infections by geographical area of birth (2022)

Geographical area of birth	N. of infections
Africa	6
America	1
Asia	2
Europe	12
Italy	134
Total	**155**

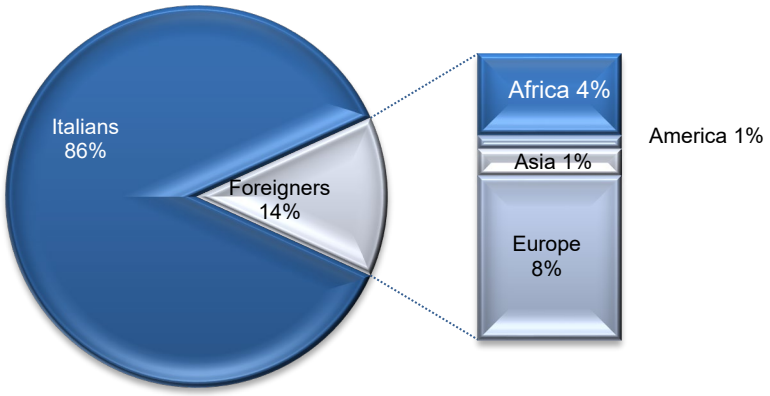

Figure 25. HCV positive donors by nationality (%) (2022)

In about 66% of HCV positive donors (103/155) it was not possible to identify the risk factor; in the remaining 34%, 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 "the donor knew/suspected to be positive" (Figure 26). In most cases (71/155), the molecular test (NAT) was negative with a positive serological screening and confirmatory tests.

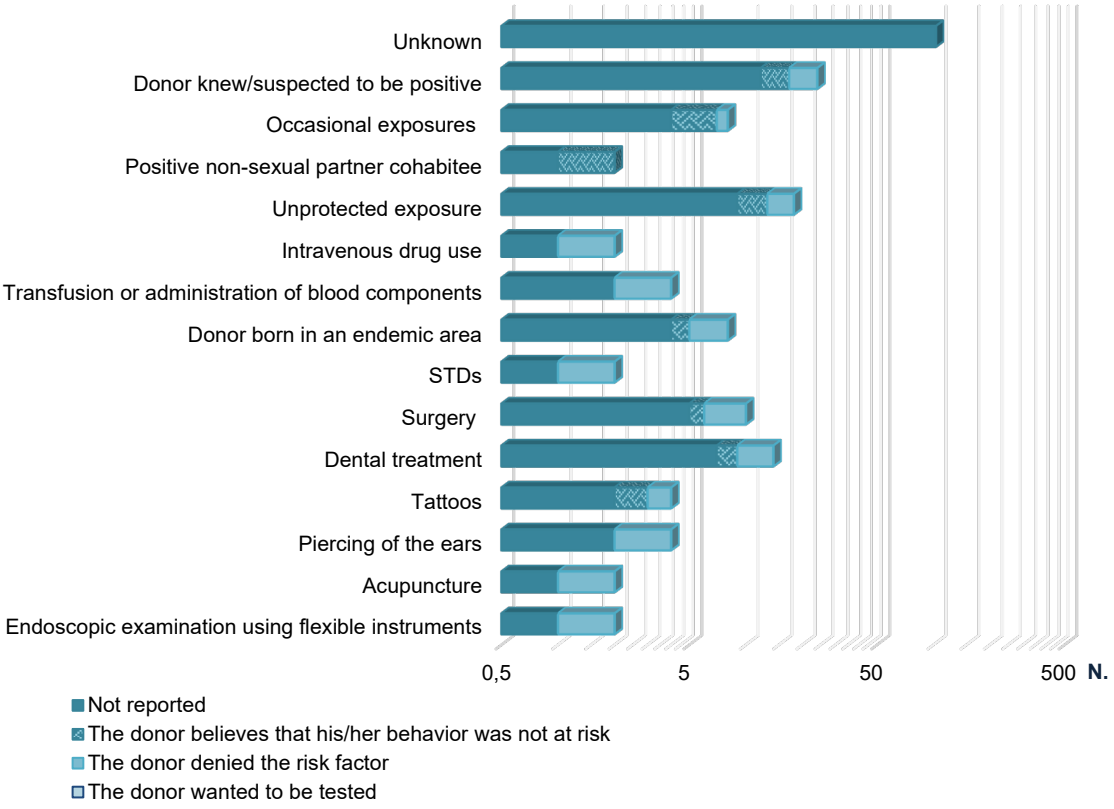

Figure 26. Causes of failed deferral and risk factors detected in HCV positive donors (values reported on a logarithmic scale) (2022)

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 2022, 427 HBV infections were reported with a prevalence of 72.2 infections per 100.000 FT donors and an incidence of 9.1 infections per 100.000 RT donors.

The highest number of HBV infections was found in the Campania Region (140). The Region with the highest prevalence (180.4) was Campania.

The Region with the highest incidence (51.5) was Apulia.

Table 42. Number. prevalence and incidence of HBV infections per 100.000 donors at national and regional level (2022)

Region/AP	HBV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	11	38.2	3.7
Liguria	4	16.0	5.3
Lombardy	42	33.0	10.6
AP of Trento	3	57.5	5.3
AP of Bolzano	1	0.0	6.3
Friuli Venezia Giulia	4	27.1	2.7
Veneto	4	11.5	0.7
Emilia-Romagna	27	82.9	5.7
Tuscany	17	61.7	0.9
Umbria	3	54.1	0.0
Marche	7	86.2	0.0
Latium	50	84.7	6.6
Sardinia	7	30.8	2.6
Abruzzo	0	0.0	0.0
Campania	140	180.4	31.7
Molise	0	0.0	0.0
Apulia	79	94.0	51.5
Basilicata	3	44.4	7.0
Calabria	7	54.3	7.7
Sicily	18	34.5	5.3
Armed Forces	0	0.0	0.0
Italy	**427**	**72.2**	**9.1**

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 (2022)

Geographical area of birth	N. of infections
Africa	27
Asia	17
Europe	78
Italy	305
Total	**427**

Figure 27 shows the distribution expressed as a percentage of HBV positive donors by nationality; 28% of all positive donors were foreigners.

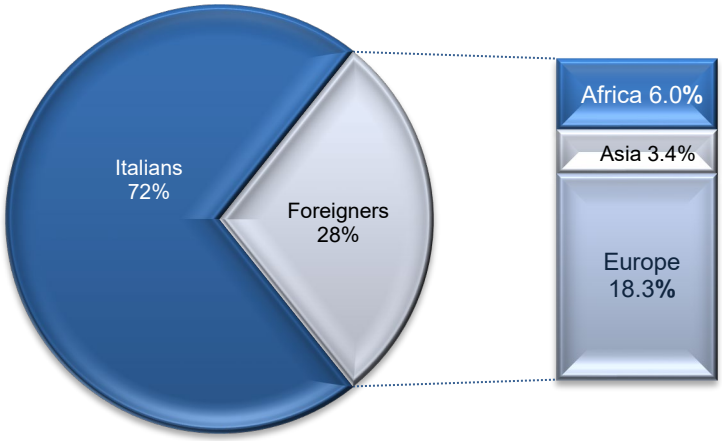

Figure 27. HBV positive donors by nationality (%) (2022)

In about 62% of the HBV positive donors (266/427), it was not possible to identify the risk factor; in the remaining 38%, who denied the risk factor or who believed that his/her behaviour was not at risk or wanted to be tested, the most frequently identified risk factors were "donor born in an endemic area" and "unprotected exposure" (Figure 28).

In 144/427 cases the infection was detected exclusively by NAT test (NAT only).

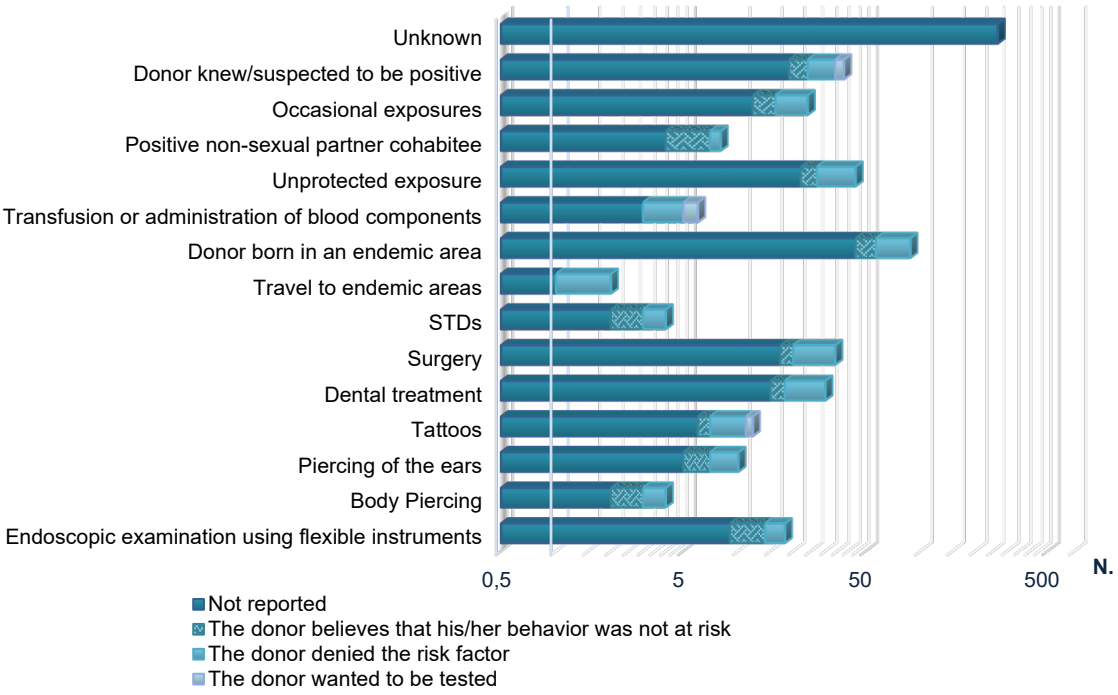

Figure 28. Causes of failed deferral and risk factors detected in HBV positive donors (values reported on a logarithmic scale) (2022)

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 2022, 490 TP infections were reported with a prevalence of 76.9 infections per 100,000 FT donors and an incidence of 12.1 infections per 100,000 RT donors. The highest number of TP infections was found in the Latium Region (81). The Region with the highest prevalence (125.1) was Latium; the highest incidence (36.7) was found in Umbria Region.

Table 44. Number. prevalence and incidence of TP infections per 100.000 donors at national and regional level (2022)

Region/AP	TP infections		
	n.	prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	33	76.4	17.8
Liguria	11	40.1	16.0
Lombardy	50	61.9	8.2
AP of Trento	2	57.5	0.0
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	2	18.1	0.0
Veneto	20	53.4	4.1
Emilia-Romagna	31	82.9	8.6
Tuscany	31	84.8	7.9
Umbria	14	108.2	36.7
Marche	16	110.8	15.3
Latium	81	125.1	17.6
Sardinia	16	66.8	7.7
Abruzzo	0	0.0	0.0
Campania	68	84.1	18.8
Molise	0	0.0	0.0
Apulia	51	91.0	21.9
Basilicata	7	66.6	28.0
Calabria	8	81.5	5.1
Sicily	49	56.5	23.3
Armed Forces	0	0.0	0.0
Italy	**490**	**76.9**	**12.1**

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 (2022)

Geographical area of birth	N. of infections
Africa	21
America	9
Asia	5
Europe	56
Italy	399
Total	**490**

Figure 29 shows the distribution, expressed as a percentage, of the TP positive donors by nationality; 19% of all positive donors were foreigners.

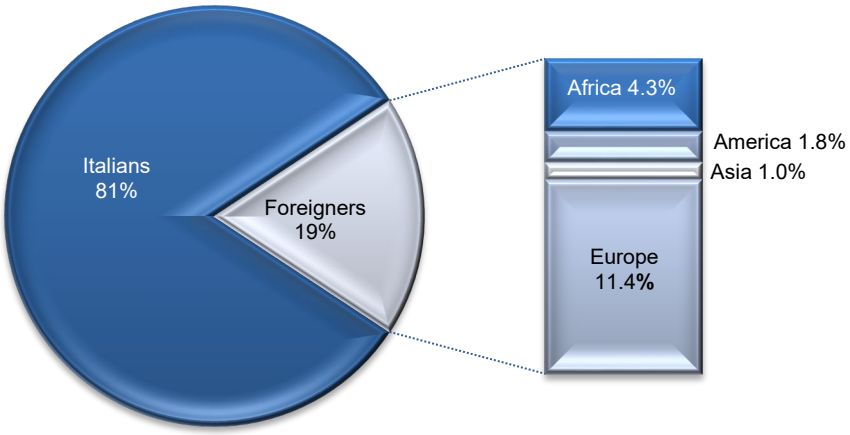

Figure 29. Distribution of TP positive donors by nationality (%) (2022)

In about 45% of the TP positive donors (219/490) it was not possible to identify the risk factor. In the remaining 55%, who denied the risk factor or who believed that his/her behaviour was not at risk or wanted to be tested, the most frequently identified risk factors were "occasional exposures" and "unprotected exposure" (Figure 30).

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

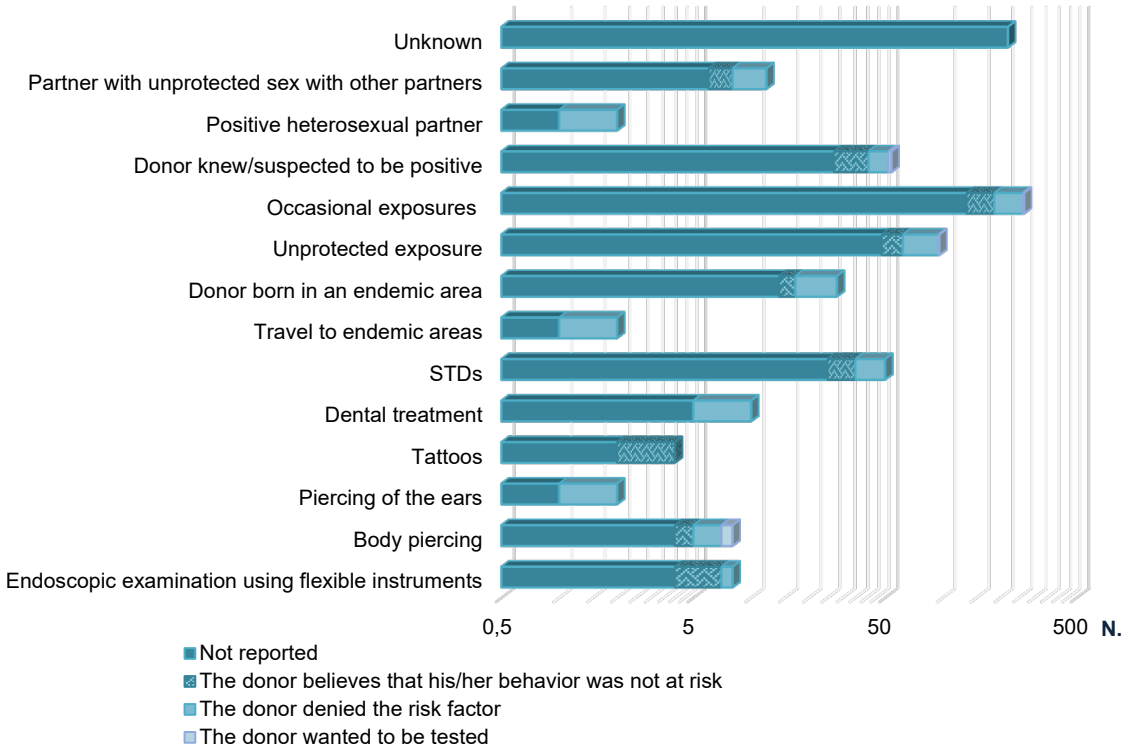

Figure 30. Causes of failed deferral and risk factors detected in TP positive donors (values reported on a logarithmic scale) (2022)

Coinfections

In this paragraph the authors want to provide more accurate epidemiological data on coinfection notified in blood donors for the year 2022.

Figure 31 shows the number of coinfected donors by gender and type of coinfection diagnosed; all 15 reported infections included TP.

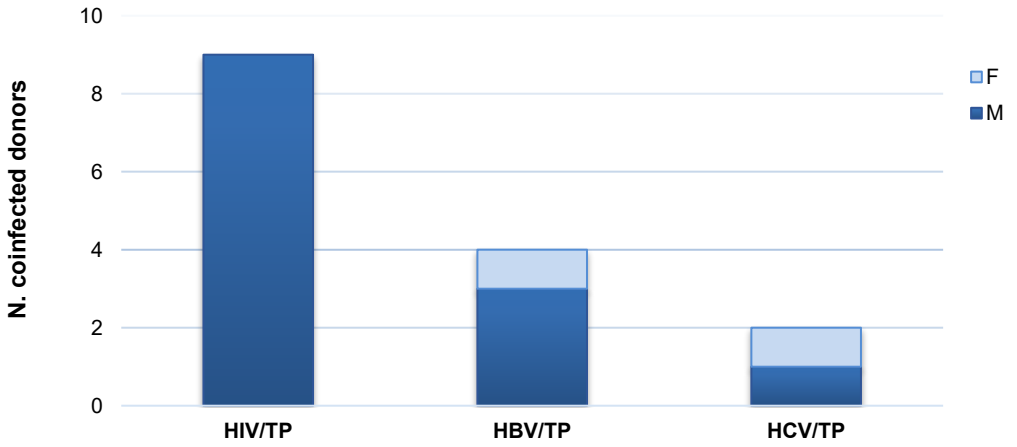

Figure 31. Number of coinfected donors by type of coinfection and by gender (2022)

The majority of the coinfected donors were males (13/15). In particular, about 60% of the coinfection cases was diagnosed in male donors in the 26-35 and 36-45 age classes (Figure 32).

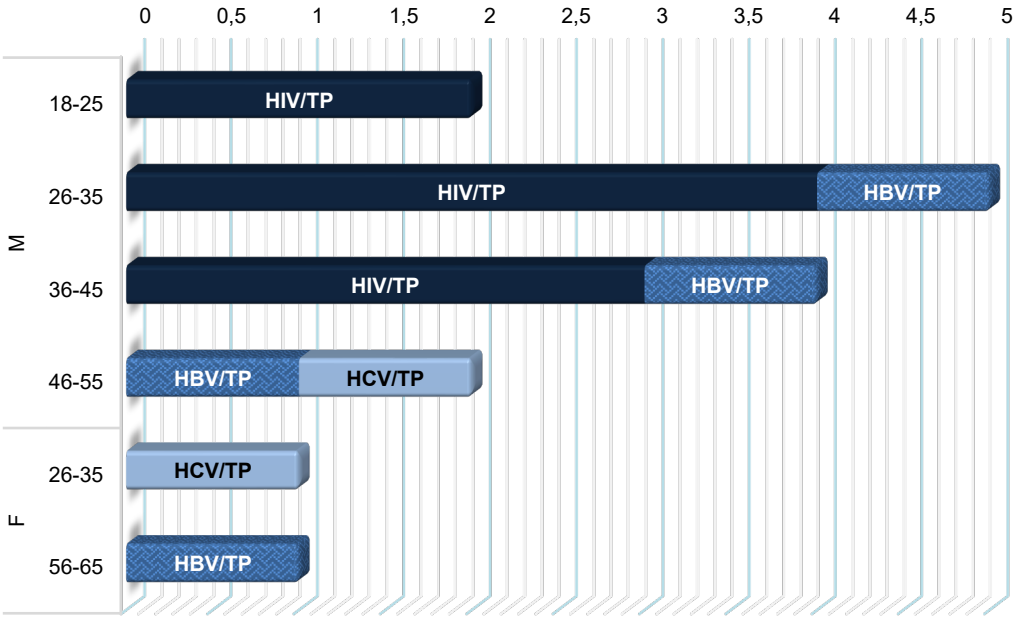

Figure 32. Number of coinfected donors by type of coinfection, age class and gender (2022)

For 8/15 of coinfected donors it was not possible to trace the reasons for missed deferral and the risk factors are not known. For 5 cases of coinfection the risk factors were identified and were generally due to high-risk sexual behaviours; in the remaining 2 cases the risk factors were identified ("the donor knew to be positive" and "STDs") (Figure 33).

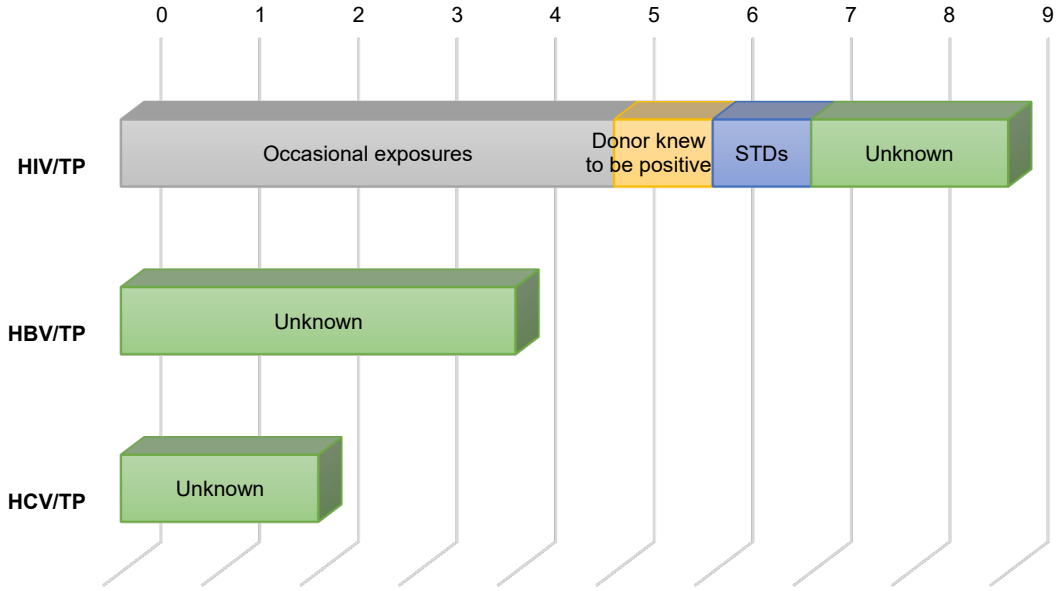

Figure 33. Number of coinfected donors by type of coinfection and risk factor (2022)

Comments and recommendations

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 2022 with the highest numbers in Campania, Latium and Apulia Regions.

The majority of donors who turned out to be positive to infectious markers were males (74%) and FT (68%). The highest number of positives are distributed among the 36-45 and 46-55 age classes.

About 79% of the positive donors were Italian, while the remaining 21% 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 and prevalence 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 mainly acute symptomatic infections.

In 2022, acute HBV infections in general population occurred mainly in the Central-Northern Italy Regions (Lombardy, Tuscany and Latium) (incidence 0.22 per 100,000 inhabitants). The most affected are the subjects aged between 35 and 54 years. While the highest number of acute

HCVs was reported in the Lombardy and Veneto Regions (incidence 0.11 per 100,000 inhabitants); 92.7% of cases are older than 34 years (16).

For HBV and HCV infections a slight decrease in the incidence trend has been observed in recent years (7). This downward trend is certainly justified by the introduction, in the 90s, of the mandatory HBV vaccination to all subjects born since 1979, and by the introduction, for the treatment of HCV, of new direct-acting anti-viral therapies.

Compared to general population, blood donors' population recorded in 2022 higher rates of HBV incidence and prevalence in the Southern Italian Regions (respectively Puglia and Campania) with 34% NAT-only infections. On the other hand, HCV new infections are more frequent in Campania Region and the highest prevalence has been registered in Campania and Liguria Regions.

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

In contrast to HBV and HCV, the distribution of HIV and TP positivity in blood donors is higher in younger age classes (26-45). For both infections, about 40% of risk factors are not stated; the most commonly reported risk factors were sexual risk behaviours.

These data correspond to the findings in the general population: the highest incidence of HIV infection has been observed in 25-29 and 30-39 age classes; subjects affected by syphilis I-II report a median age of 36 years (IQR, 29-45 years) while subjects with latent syphilis report a median age of 39 years (IQR, 30-50 years). In both cases the stated risk factors reported sexual risk behaviours (17-18).

In 2021, the HIV geographical distribution in the general population showed the highest incidence in Central-Northern Italy (the most affected area is Latium Region, followed by Liguria, Friuli Venezia Giulia, Tuscany and Emilia-Romagna Regions) compared to the South and Islands (17). The blood donor population shows, in 2022, a higher incidence in the Regions of Southern Italy (Campania Region, followed by Basilicata).

The analysis of coinfections showed that all coinfected donors were TP positive.

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

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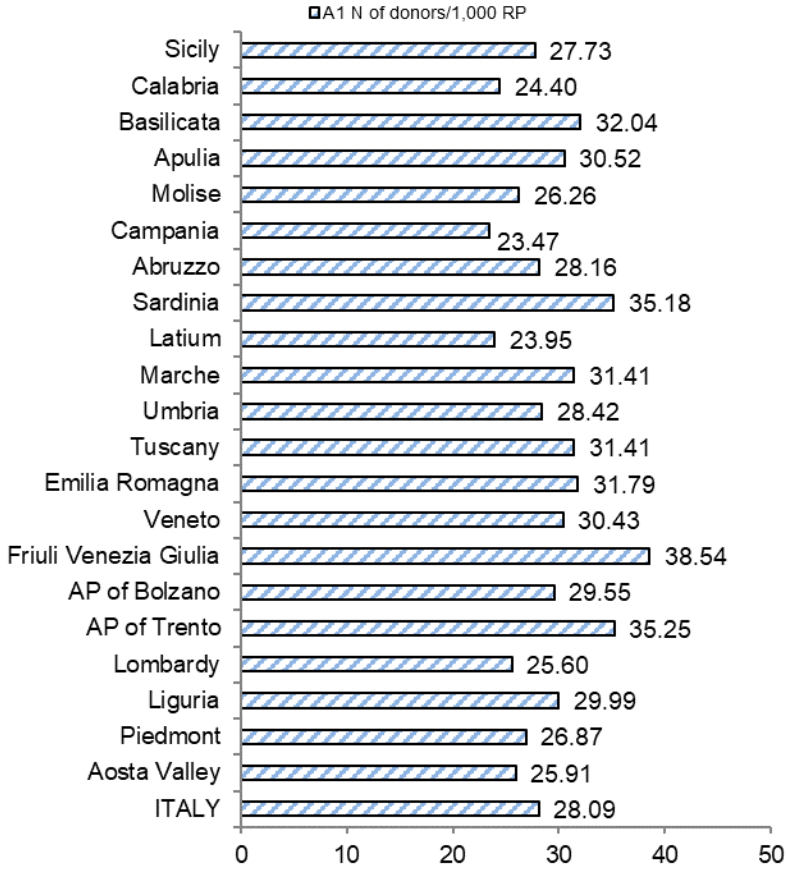
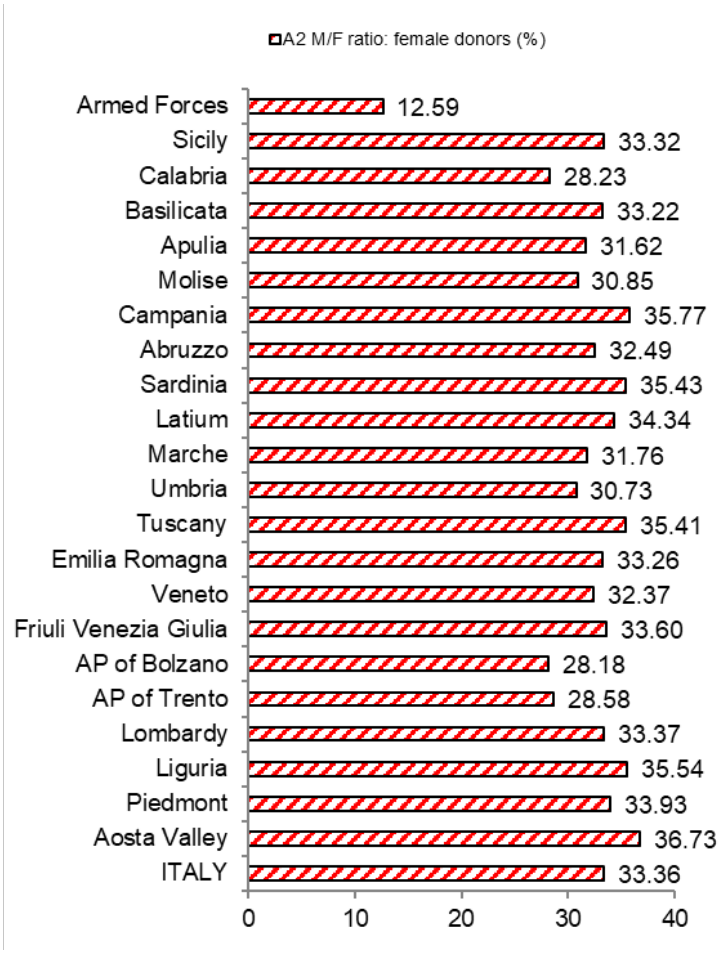
APPENDIX A
Regional and national indicators 2022



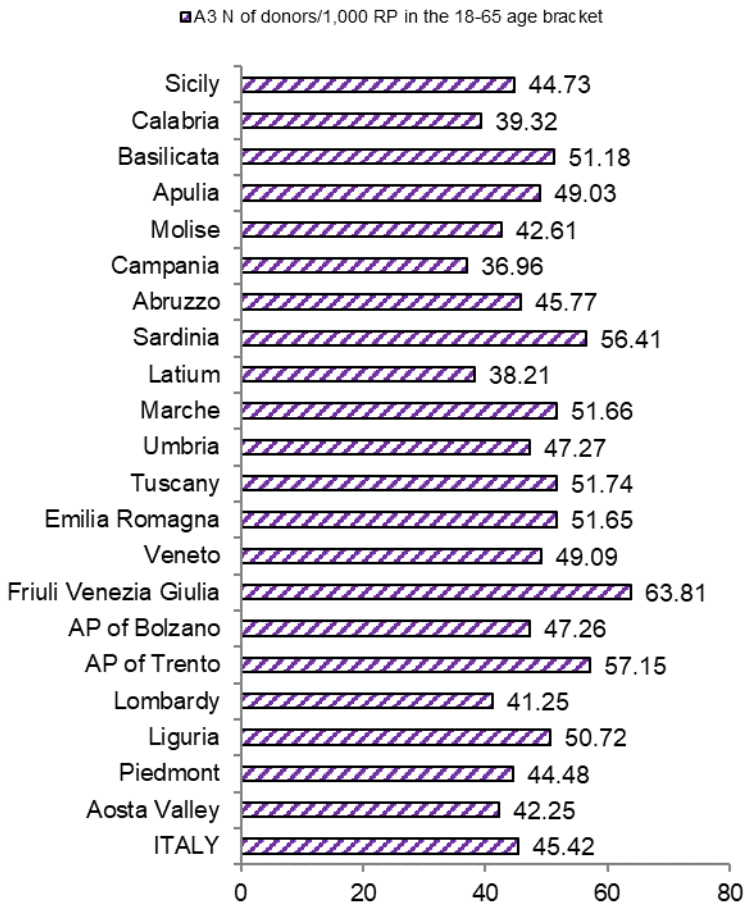
N. number; RP resident population; AP Autonomous Province

Figure A1. INDICATOR A1: Regional blood donors' distribution/1,000 resident population (2022)



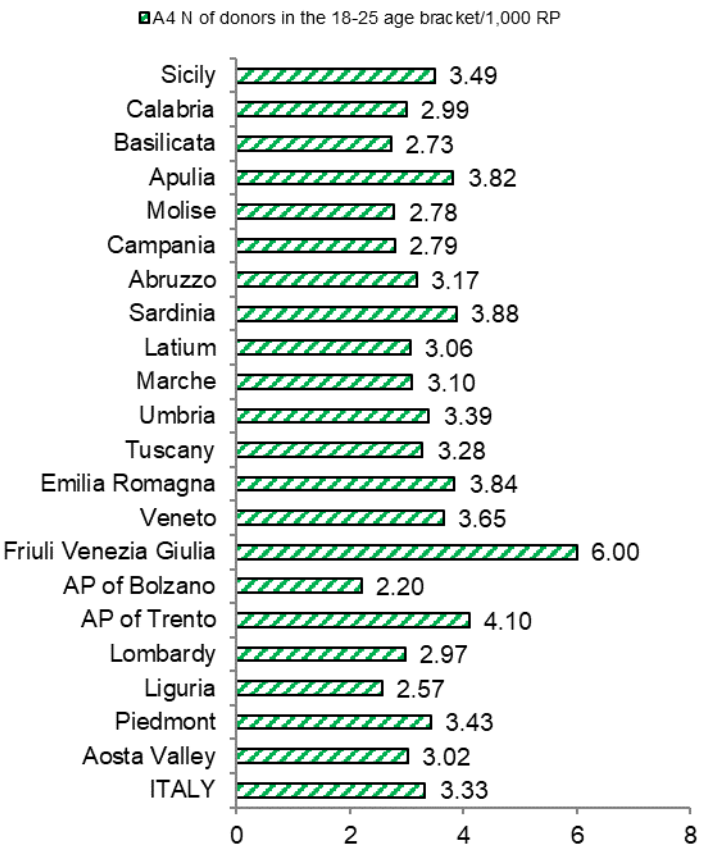
AP Autonomous Province; M male; F Female

Figure A2. INDICATOR A2: M/F ratio, female donors' percentage (2022)



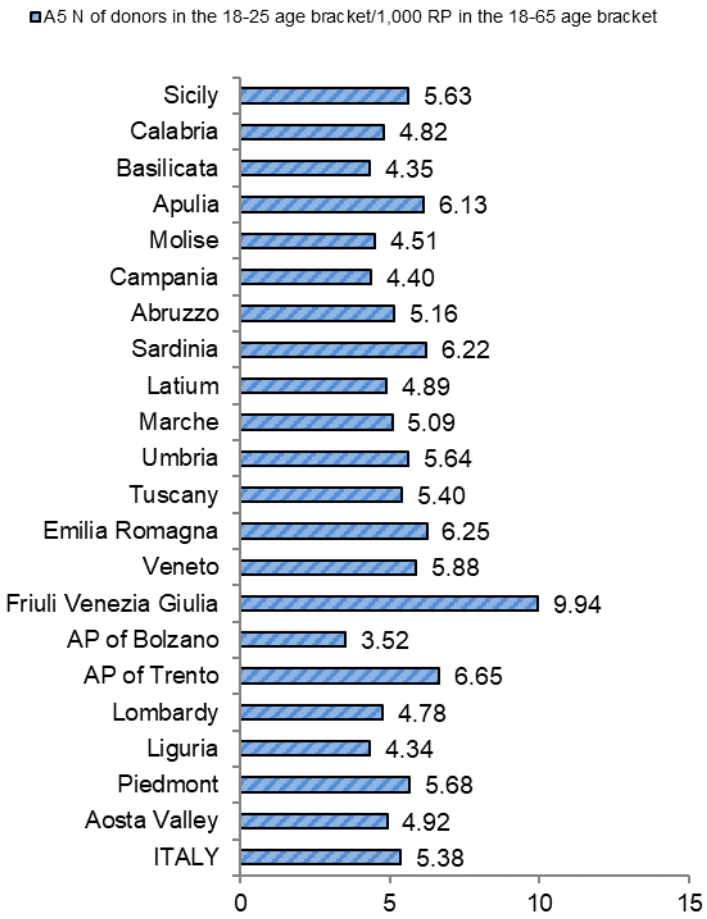
N. number; RP resident population; AP Autonomous Province

Figure A3. INDICATOR A3: N. of donors/1,000 resident population in the 18-65 age class (2022)



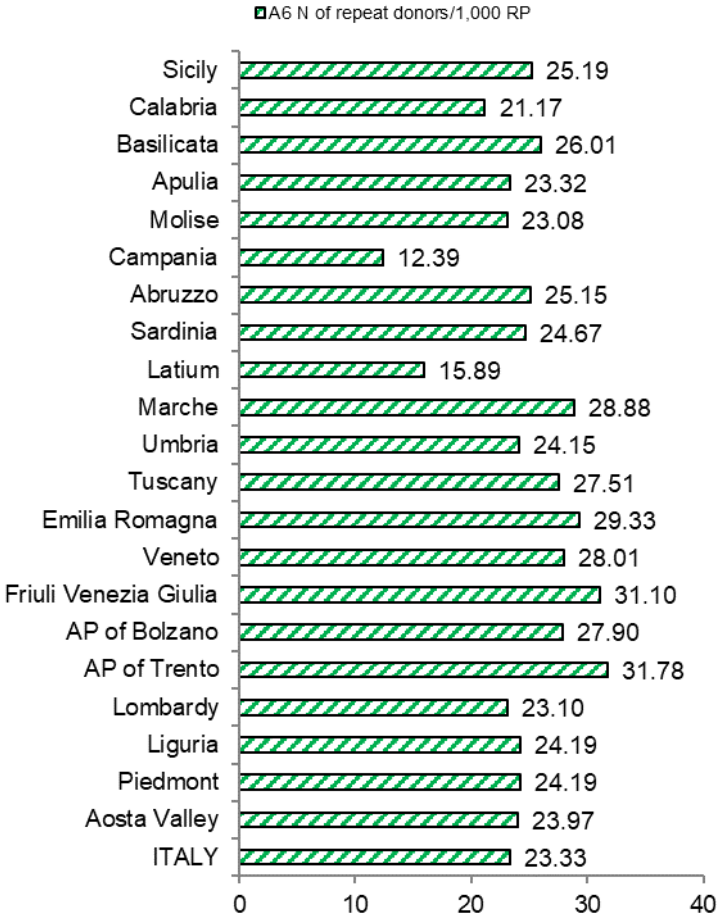
N. number; RP resident population; AP Autonomous Province

Figure A4. INDICATOR A4: N. of donors in the 18-25 age class/1,000 resident population (2022)



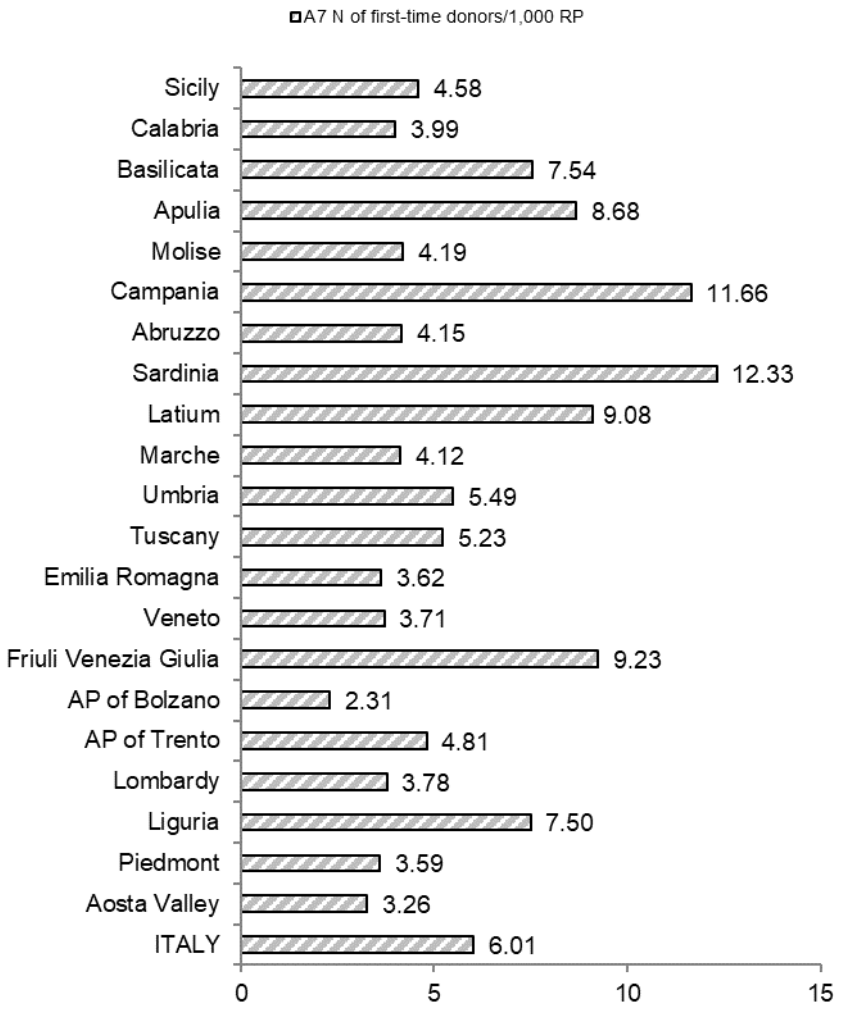
N. number; RP resident population; AP Autonomous Province

Figure A5. INDICATOR A5: N. of donors in the 18-25 age class/1,000 resident population in the 18-65 age class (2022)



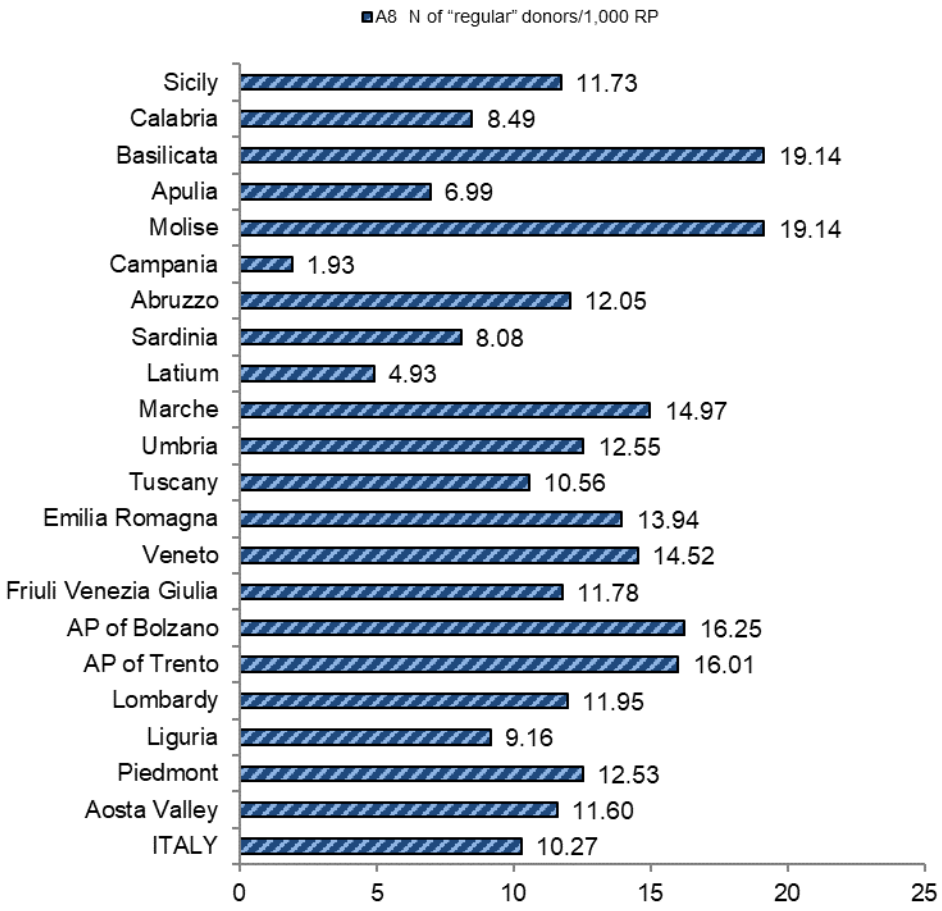
N. number; RP resident population; AP Autonomous Province

Figure A6. INDICATOR A6: N. of repeat donors/1,000 resident population (2022)



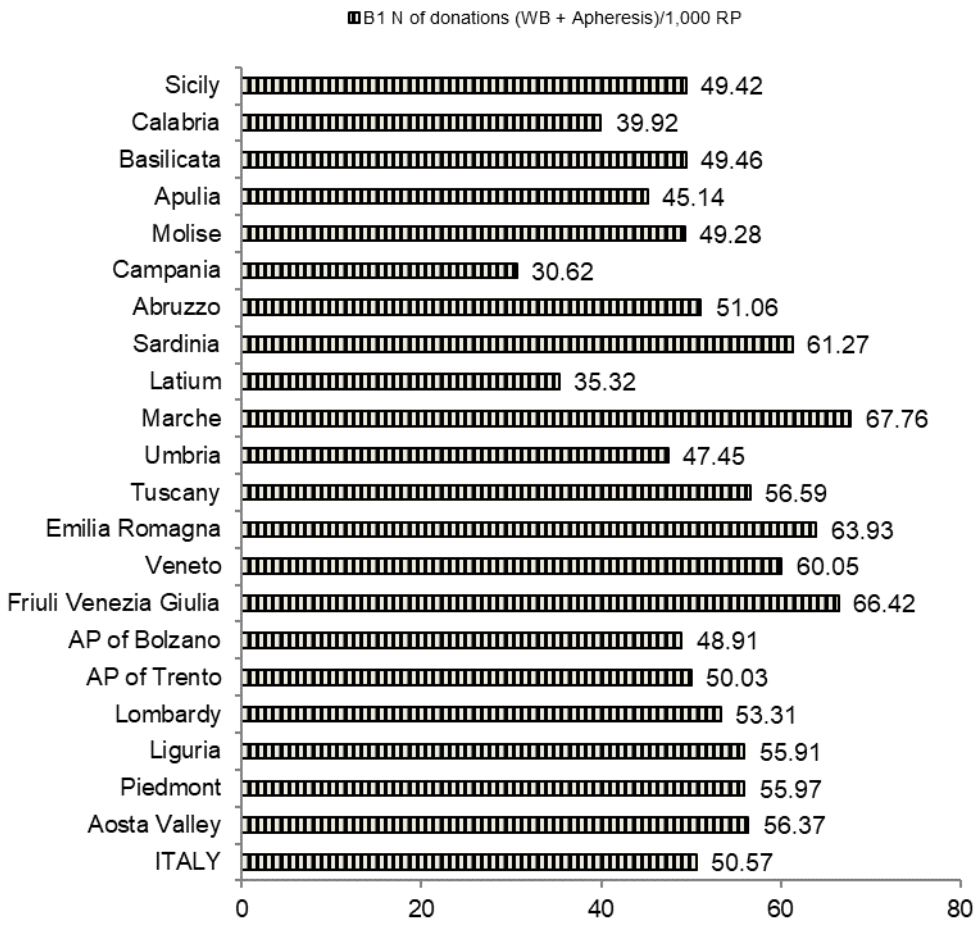
N. number; RP resident population; AP Autonomous Province

Figure A7. INDICATOR A7: N. of first-time donors/1,000 resident population (2022)



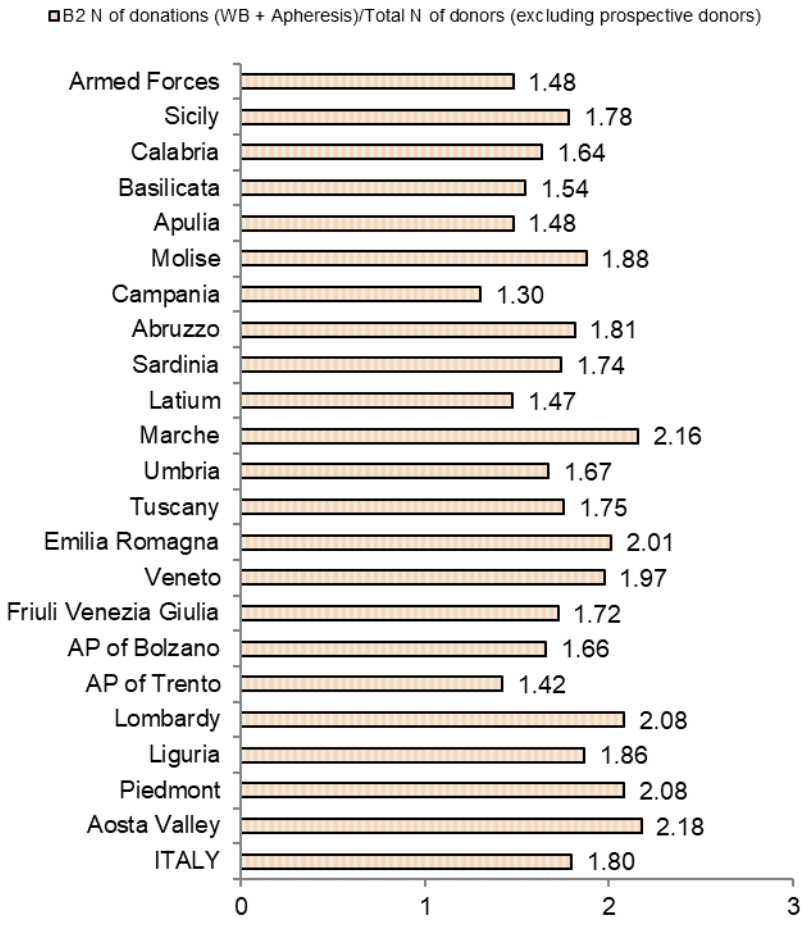
N. number; RP resident population; AP Autonomous Province

Figure A8. INDICATOR A8: N. of "regular" donors/1,000 resident population (2022)



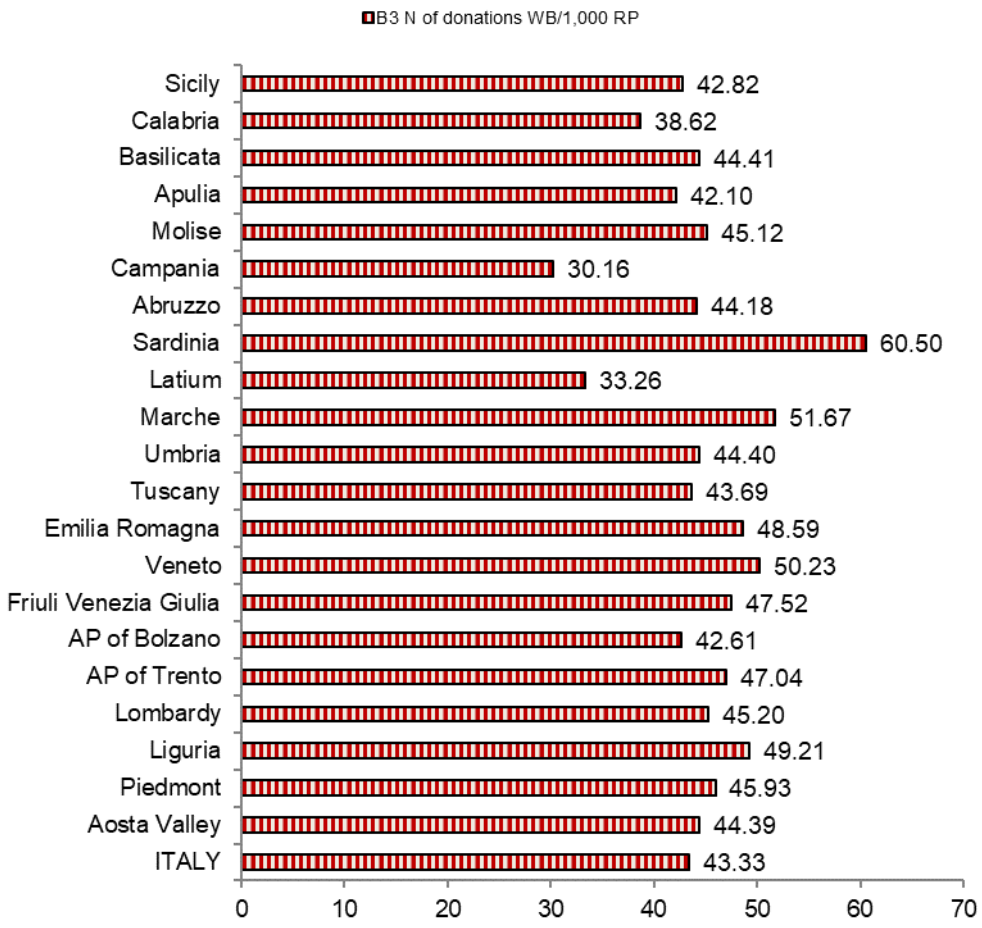
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A9. INDICATOR B1: N. of whole blood and apheresis donations/1,000 resident population (2022)



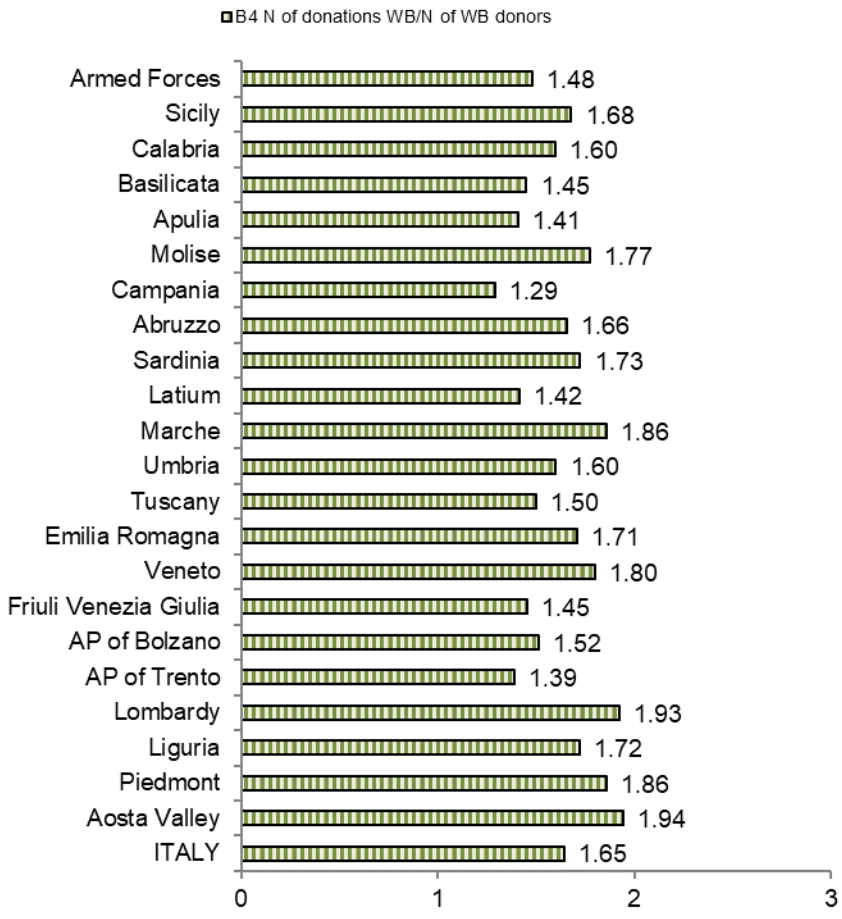
N. number; AP Autonomous Province; WB whole blood

Figure A10. INDICATOR B2: N. of whole blood and apheresis donations/Total N. of donors (excluding prospective donors) (2022)



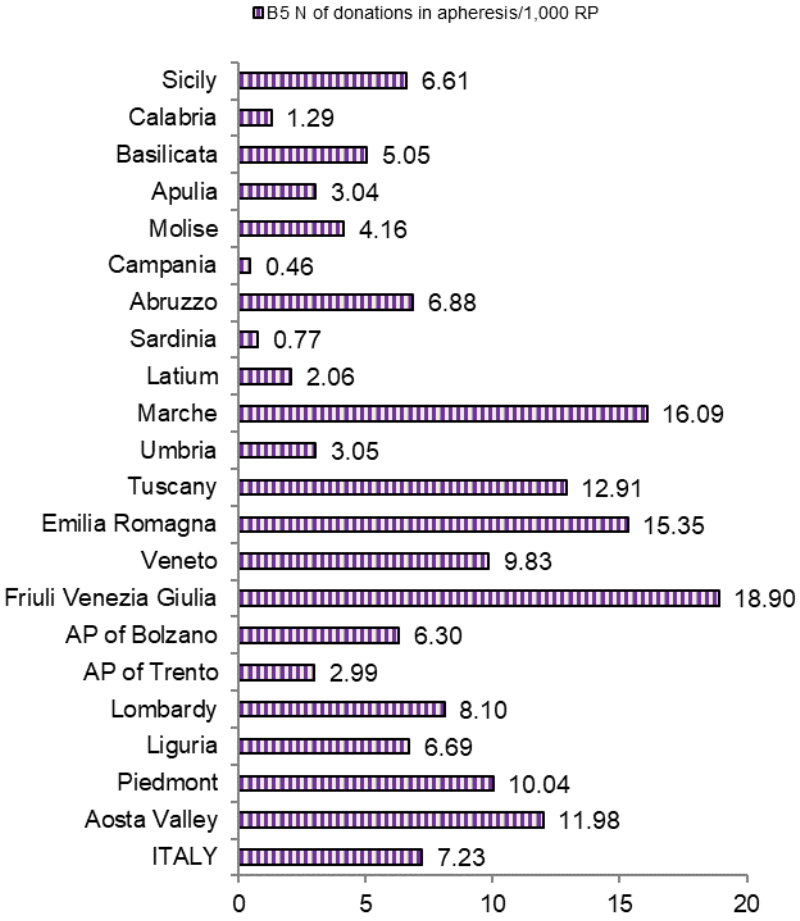
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A11. INDICATOR B3: N. of whole blood donations/1,000 resident population (2022)



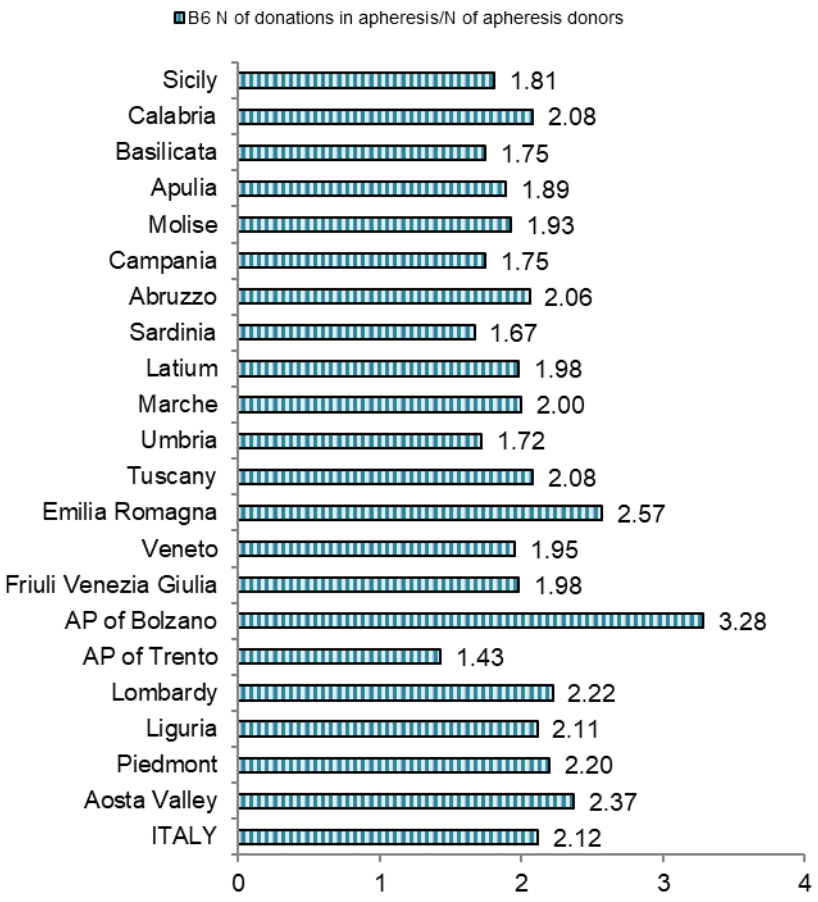
N. number; AP Autonomous Province; WB whole blood

Figure A12. INDICATOR B4: N. of whole blood donations/N. of whole blood donors (2022)



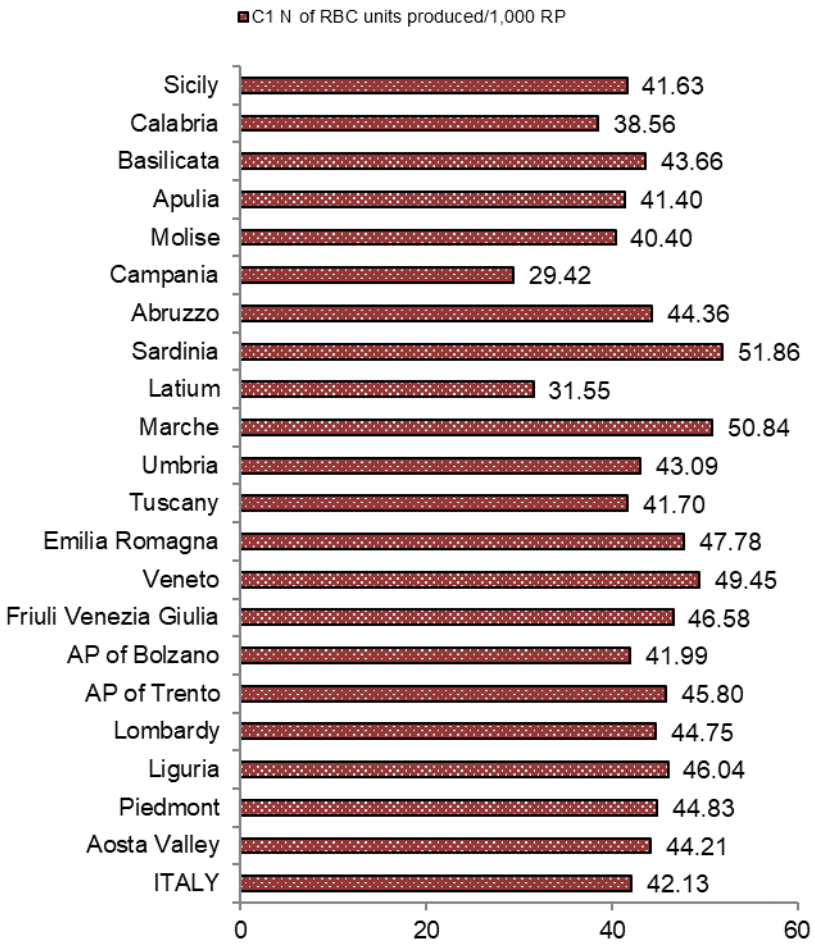
N. number; RP resident population; AP Autonomous Province

Figure A13. INDICATOR B5: N. of donations in apheresis/1,000 resident population (2022)



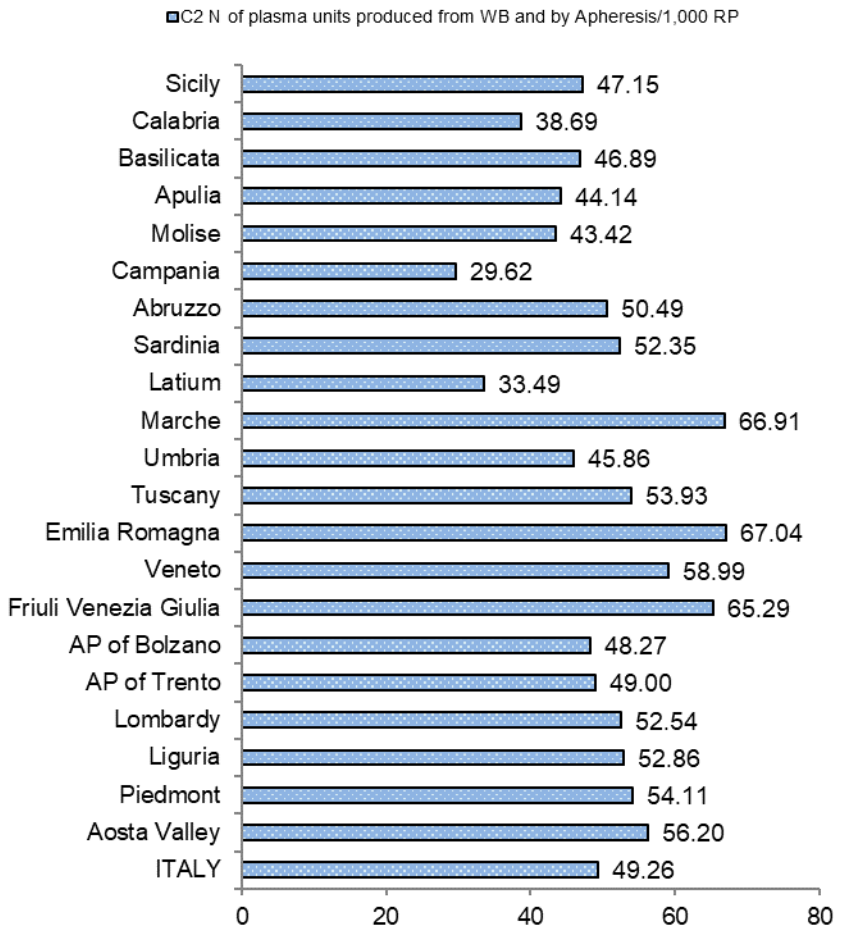
N. number; AP Autonomous Province

Figure A14. INDICATOR B6: N. of apheresis donations/N. of apheresis donors (2022)



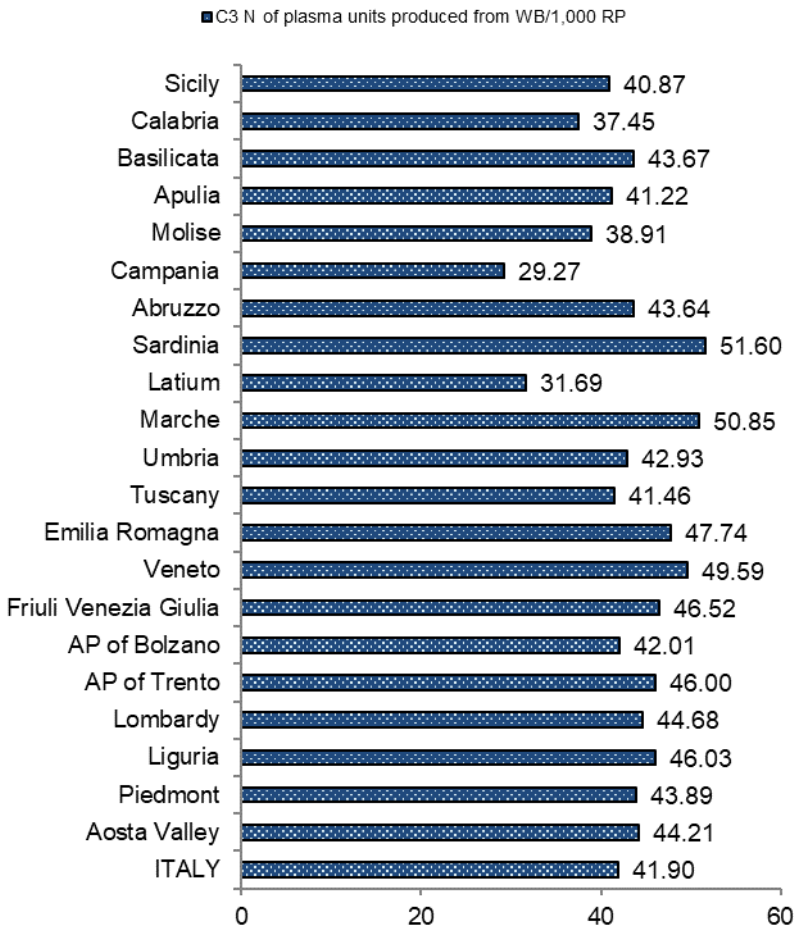
N. number; RP resident population; AP Autonomous Province

Figure A15. INDICATOR C1: RBC units produced/1,000 resident population (2022)



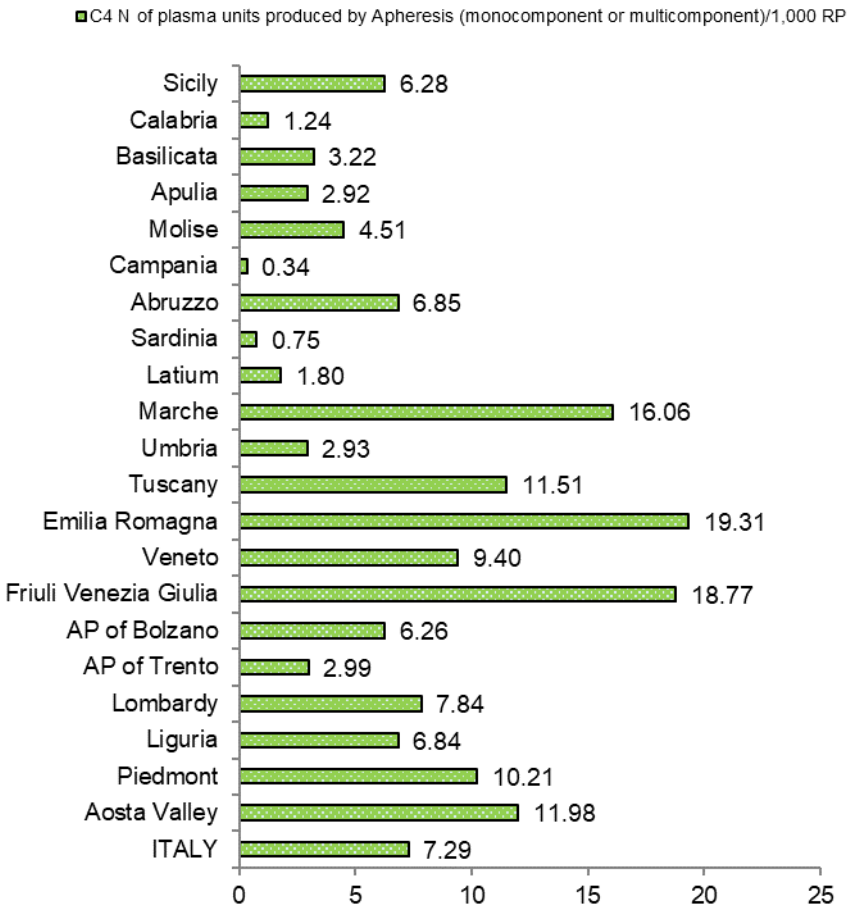
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A16. INDICATOR C2: N. of plasma units produced from whole blood and by apheresis/1,000 resident population (2022)



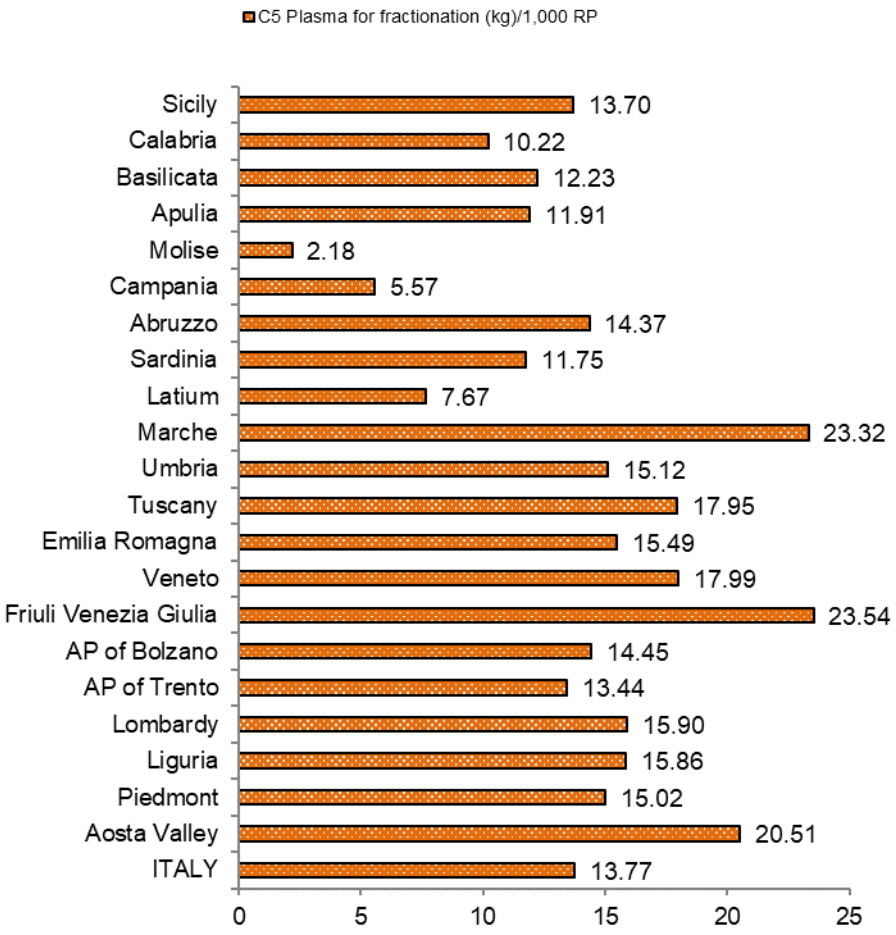
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A17. INDICATOR C3: N. of plasma units produced from whole blood/1,000 resident population (2022)



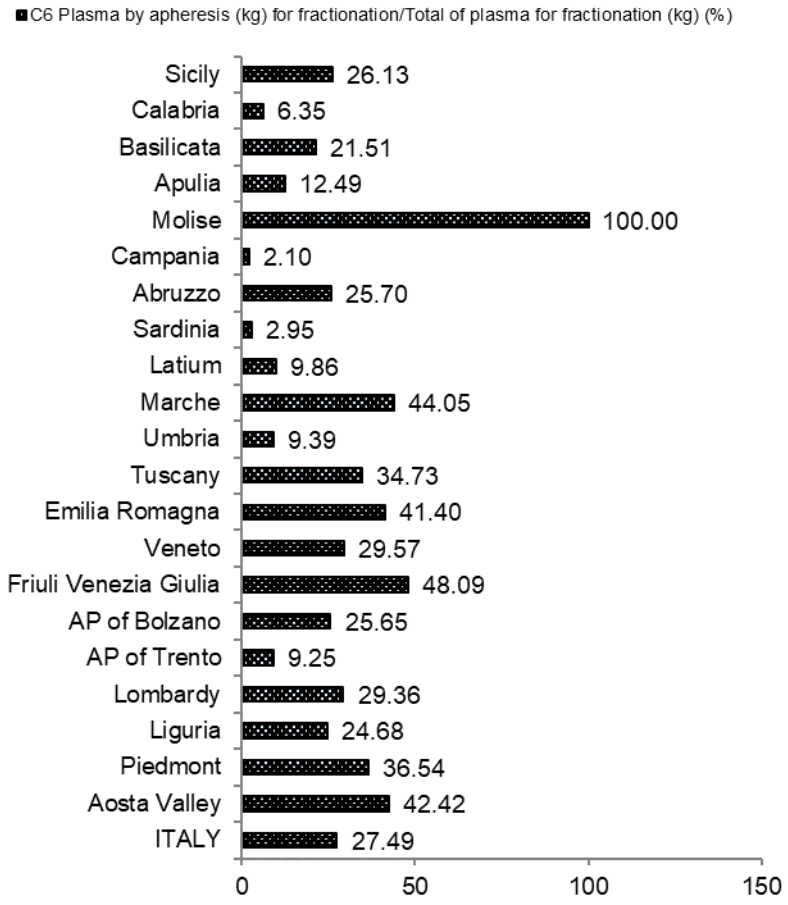
N. number; RP resident population; AP Autonomous Province

Figure A18. INDICATOR C4: N. of plasma units produced from apheresis (monocomponent + multicomponent)/1,000 resident population (2022)



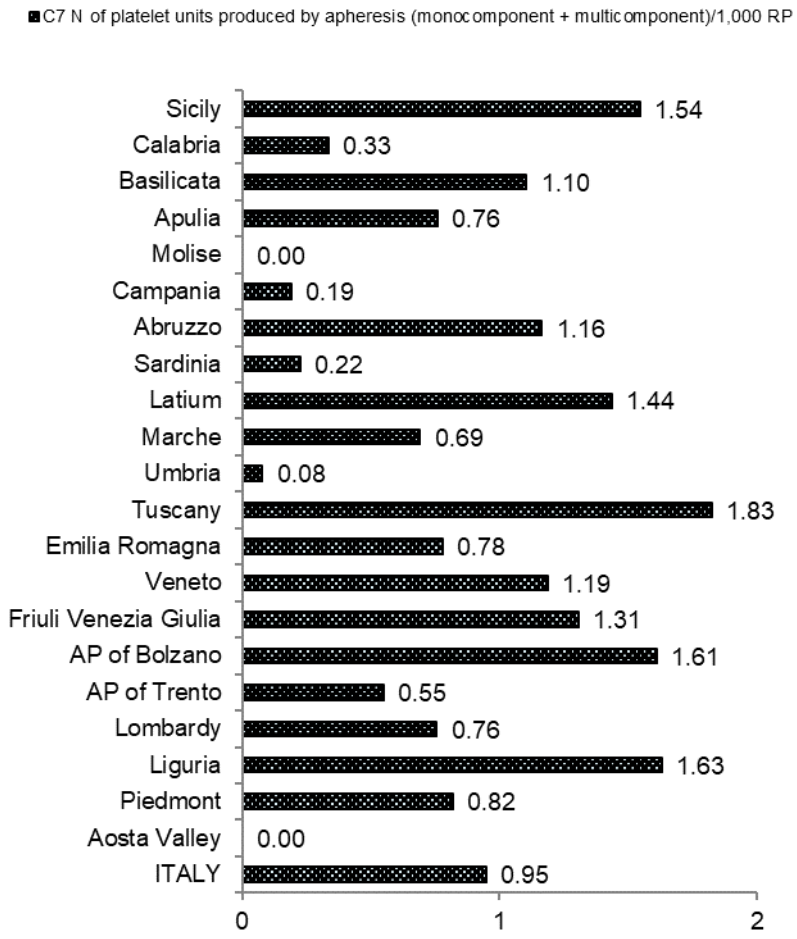
kg kilograms; RP resident population; AP Autonomous Province

Figure A19. INDICATOR C5: plasma (kg) for fractionation/1,000 resident population (from SISTRA) (2022)



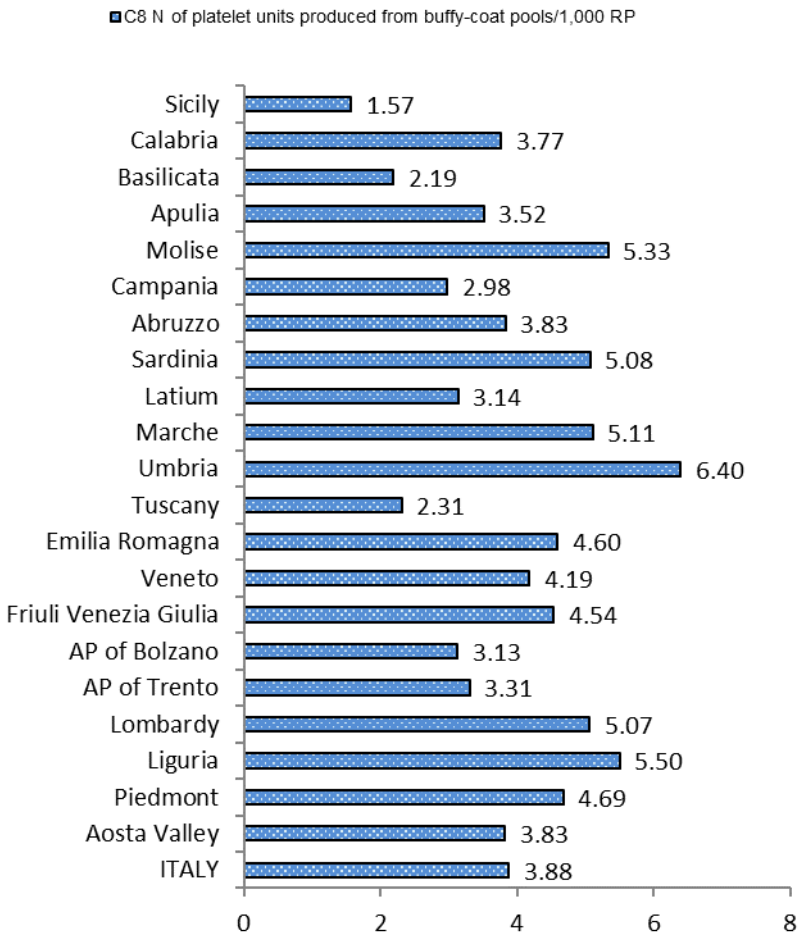
kg kilograms; AP Autonomous Province

Figure A20. INDICATOR C6: plasma by apheresis (kg) for fractionation/total of plasma for fractionation (kg) (%) (2022)



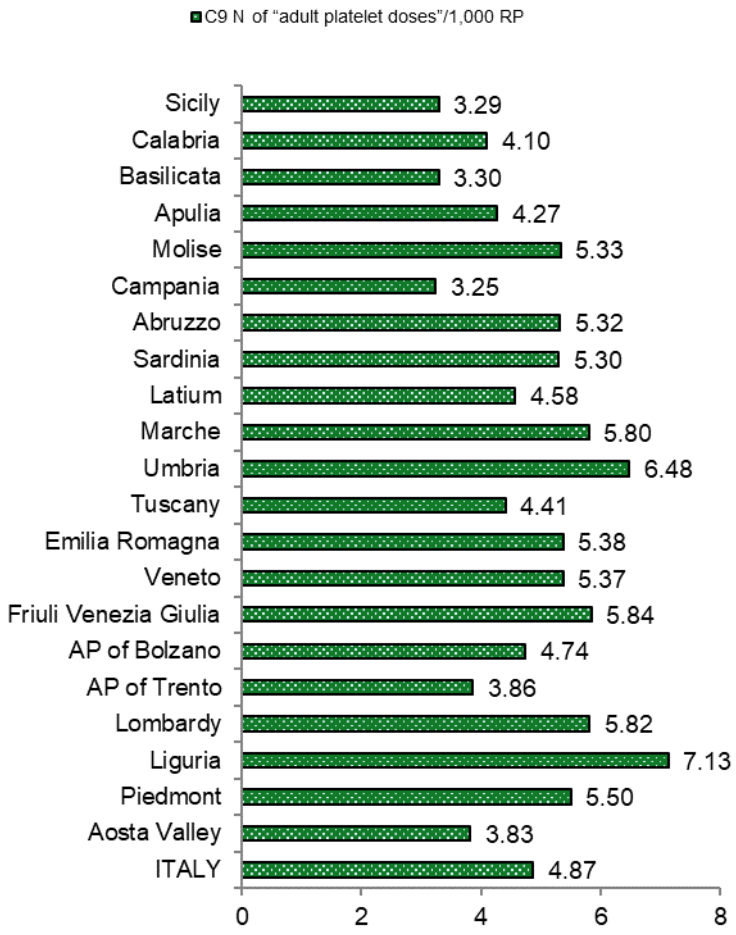
N. number; RP resident population; AP Autonomous Province

Figure A21. INDICATOR C7: N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 resident population (2022)



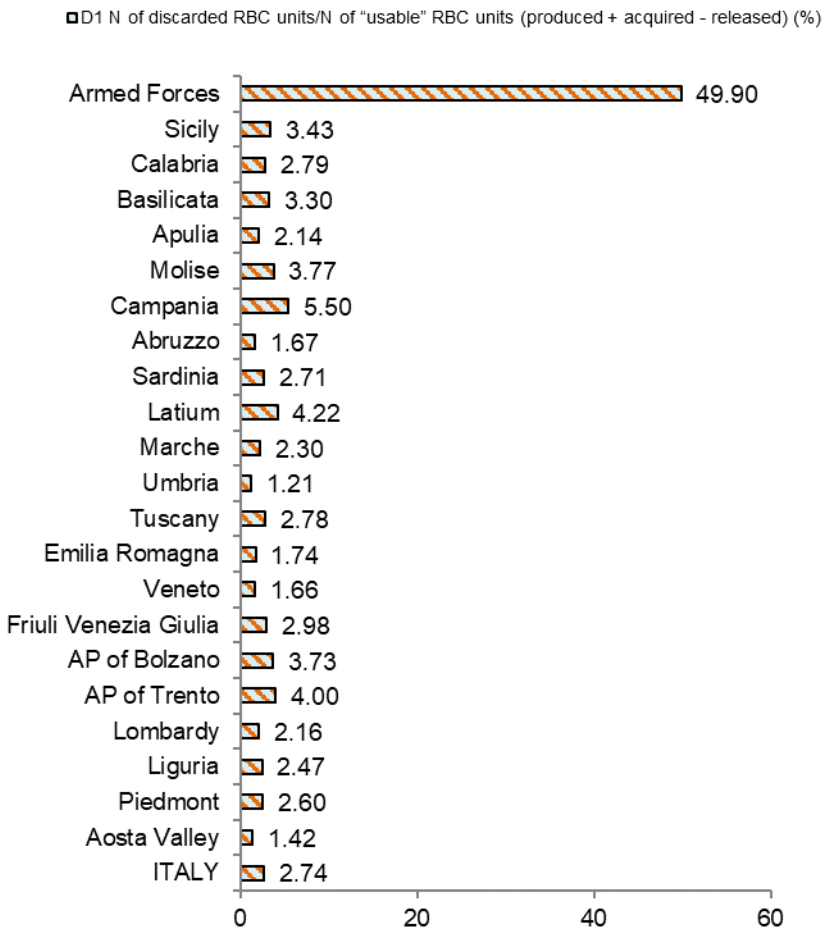
N. number; RP resident population; AP Autonomous Province

Figure A22. INDICATOR C8: N. of platelet units produced from buffy-coat pools/1,000 resident population (2022)



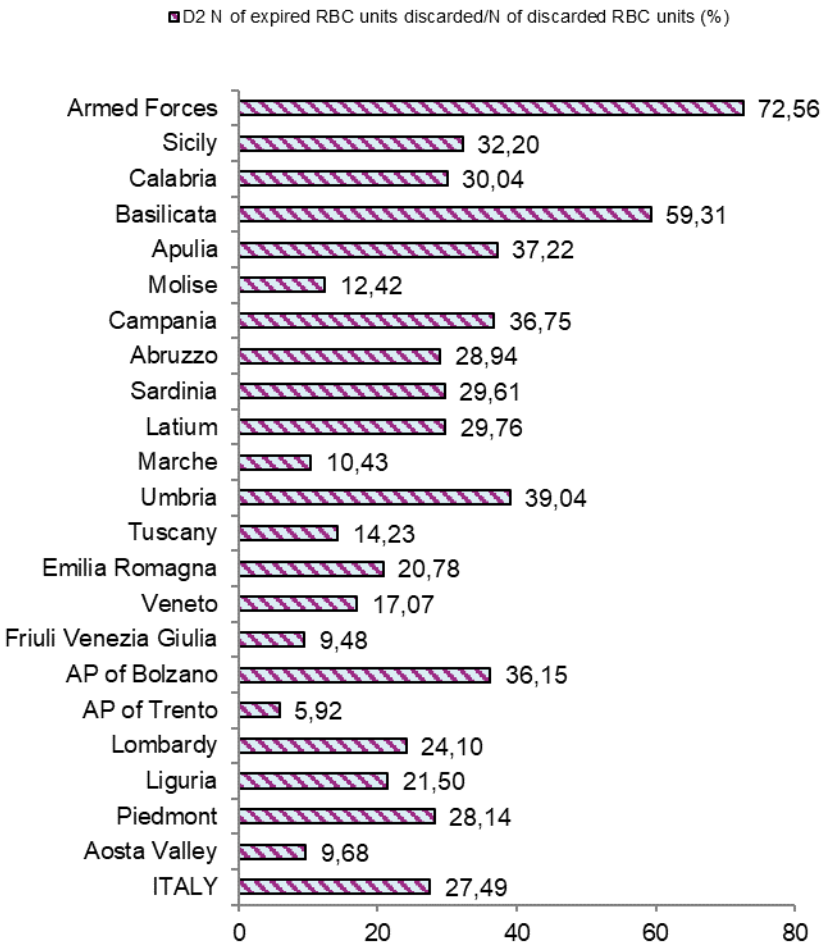
N. number; RP resident population; AP Autonomous Province

Figure A23. INDICATOR C9: N. of "adult platelet doses"/1,000 resident population (2022)



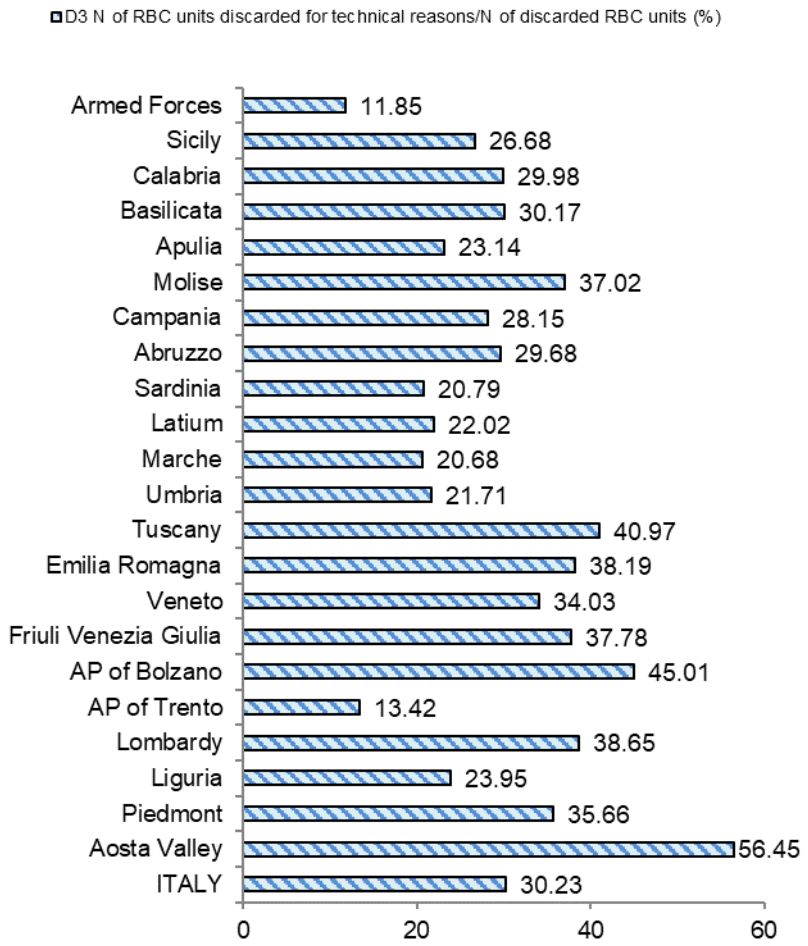
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A24. INDICATOR D1: N. of discarded RBC units/N. of "usable" RBC units (produced + acquired- released) (%) (2022)



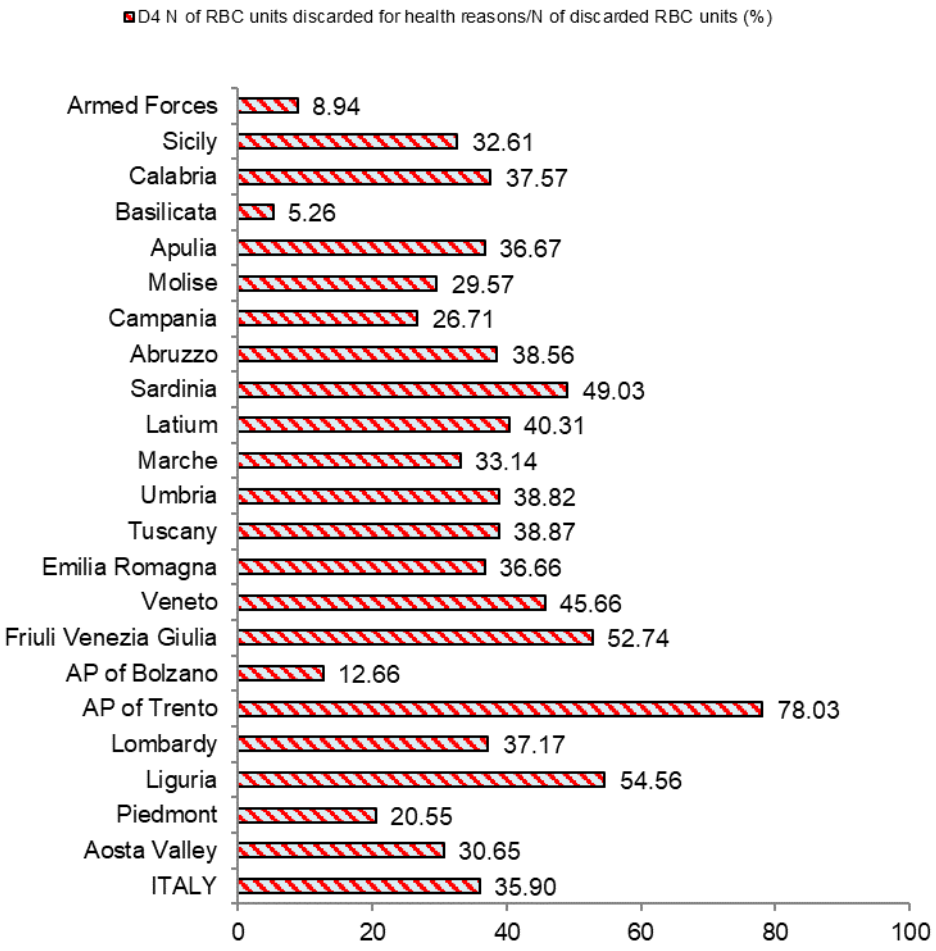
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A25. INDICATOR D2: N. of expired RBC units discarded/N. of discarded RBC units (%) (2022)



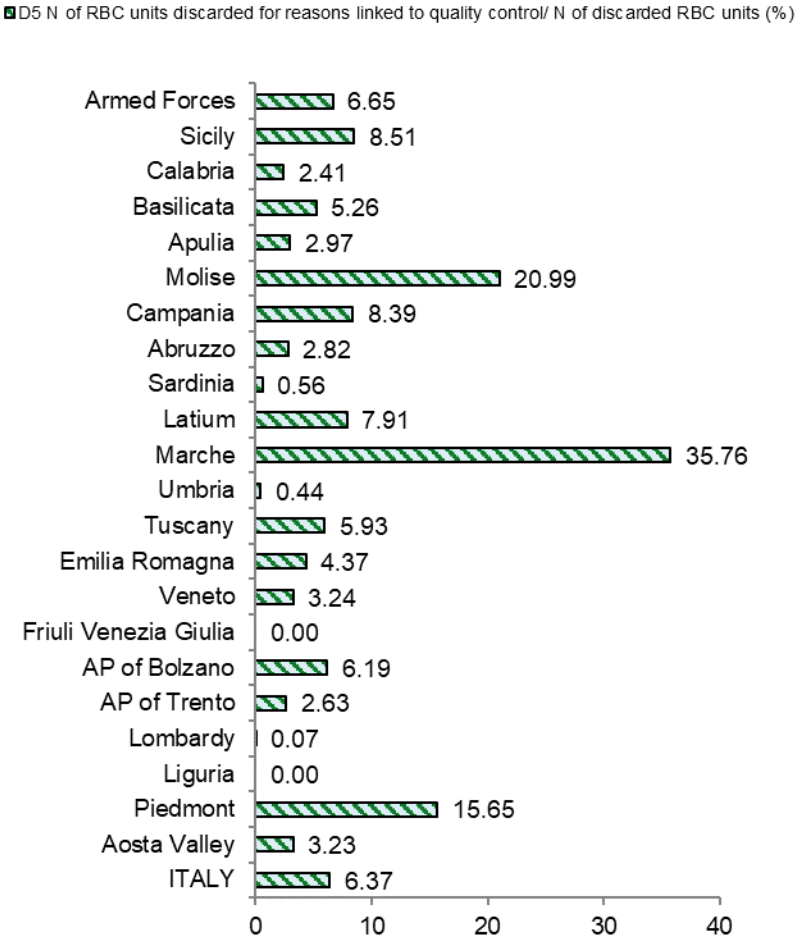
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A26. INDICATOR D3: N. of RBC units discarded for technical reasons/N. of discarded RBC units (%) (2022)



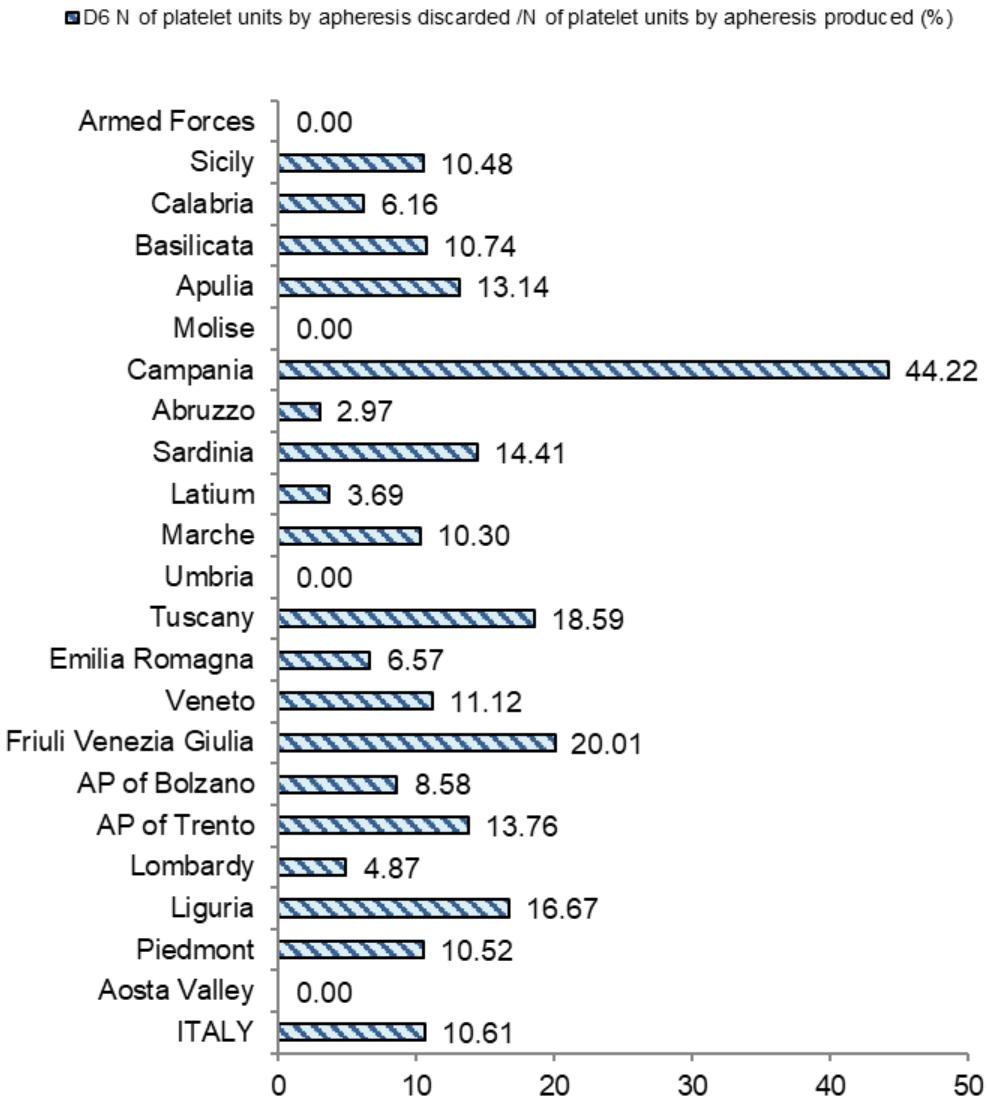
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A27. INDICATOR D4: N. of RBC units discarded for health reasons/N. of discarded RBC units (%) (2022)



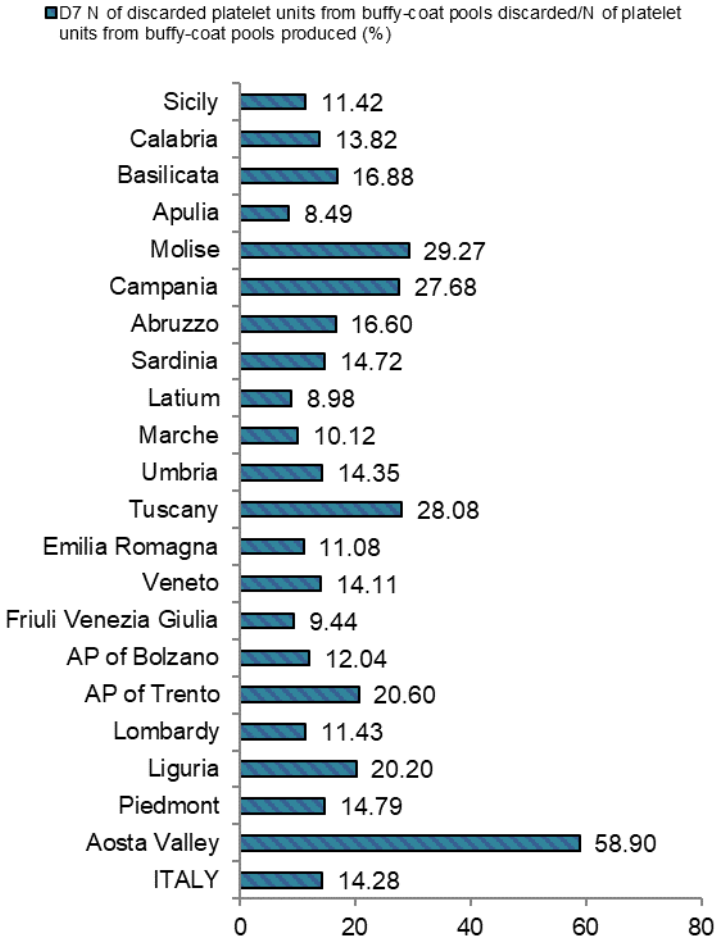
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A28. INDICATOR D5: N. of RBC units discarded for reasons linked to quality control/N. of discarded RBC units (%) (2022)



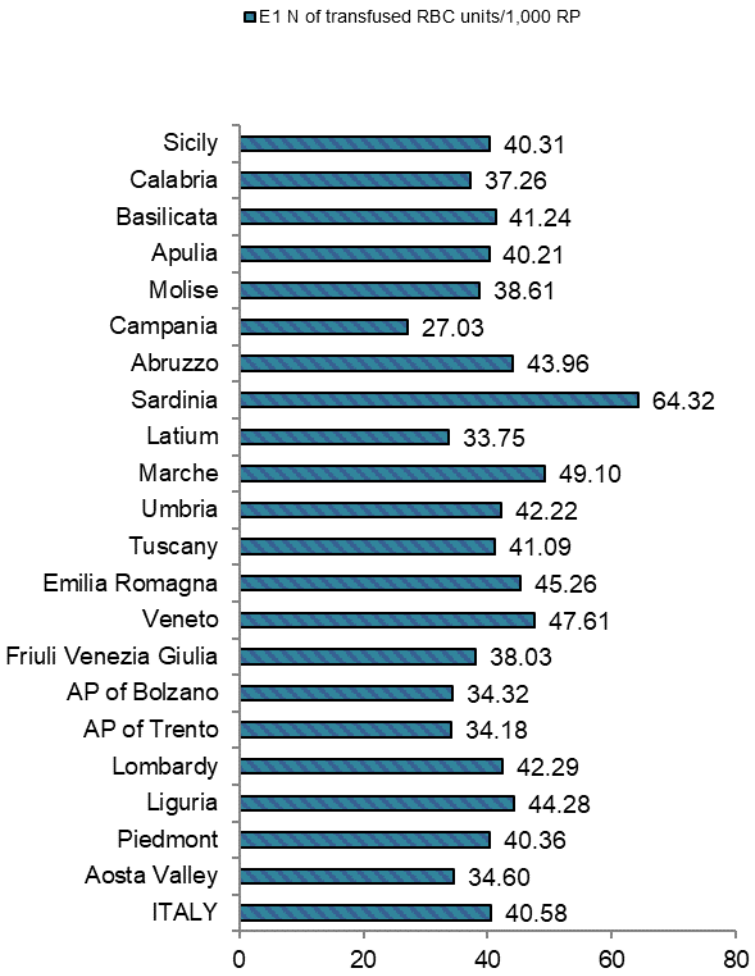
N. number; AP Autonomous Province

Figure A29. INDICATOR D6: N. of platelet units by apheresis discarded/N. of platelet units by apheresis produced (%) (2022)



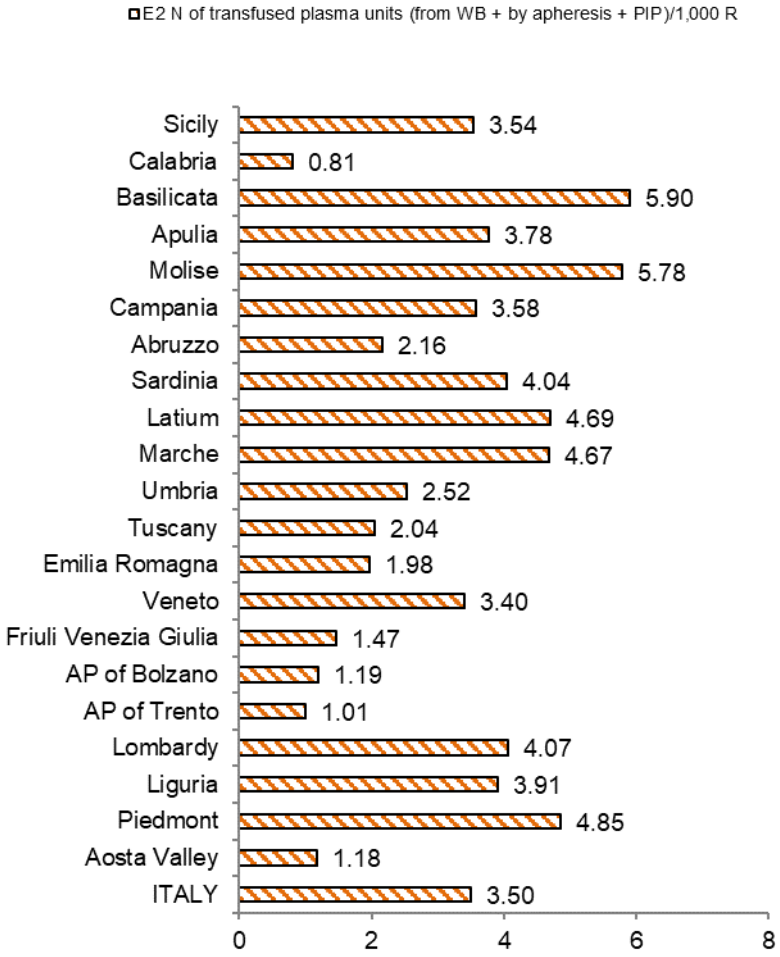
N. number; AP Autonomous Province

Figure A30. INDICATOR D7: N. of platelet units from buffy-coat pools discarded/N. of platelet units from buffy-coat pools produced (%) (2022)



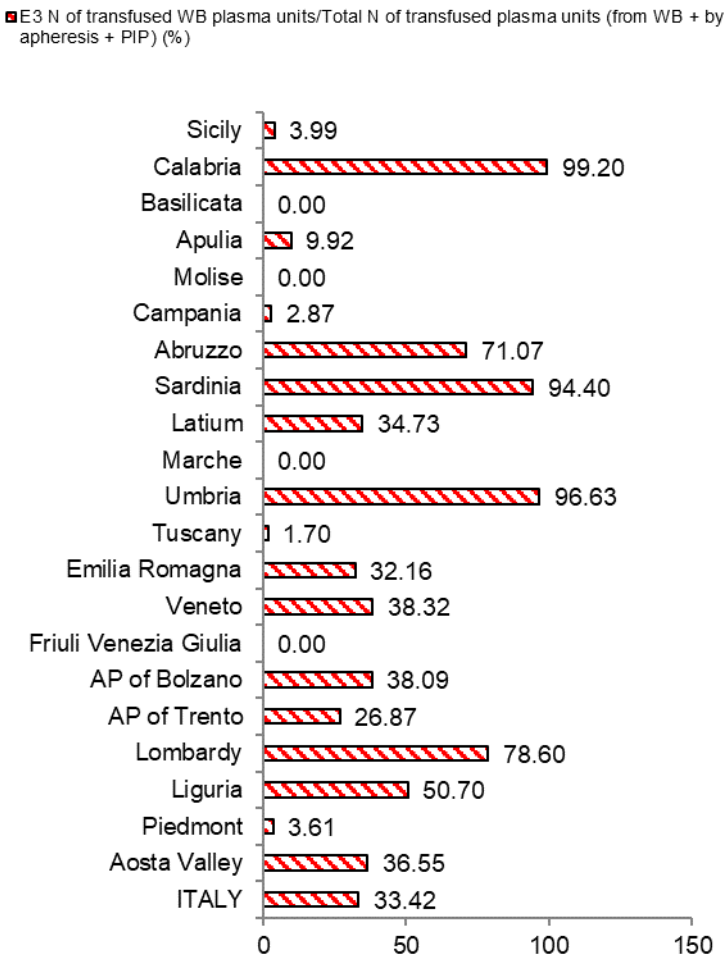
N. number; RBC Red Blood Cells; RP resident population; AP Autonomous Province

Figure A31. INDICATOR E1: N. of transfused RBC units/1,000 resident population (2022)



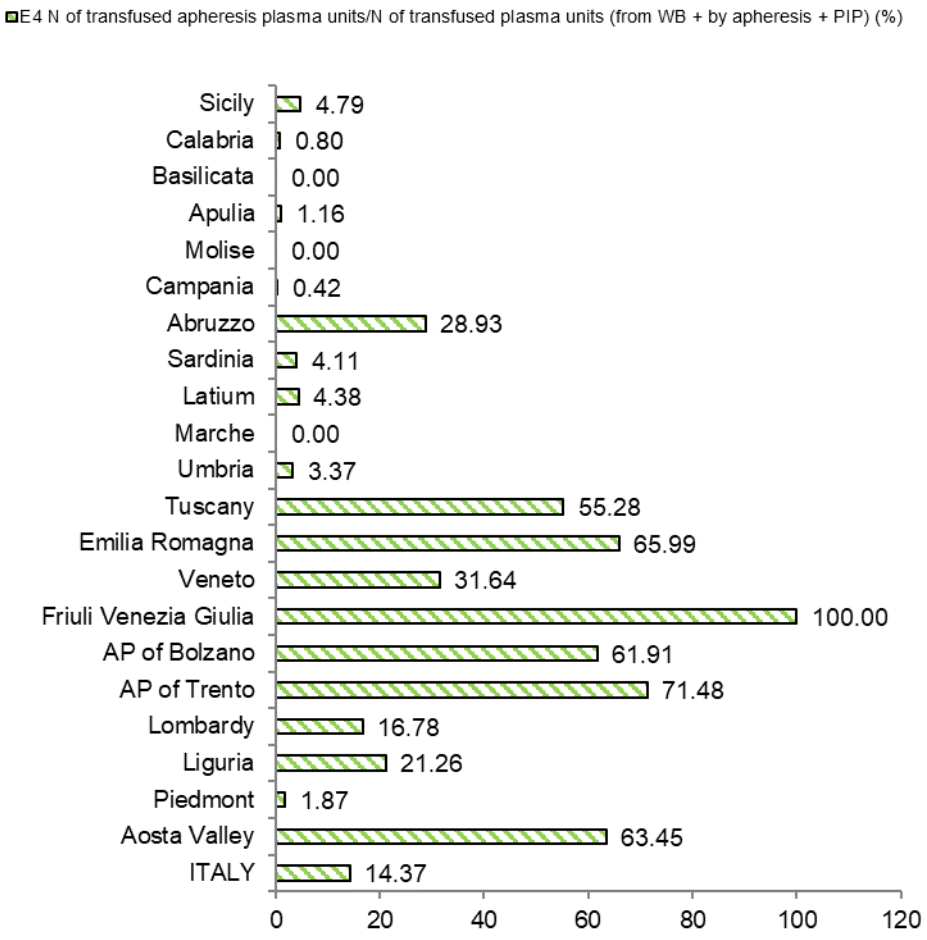
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; RP resident population; AP Autonomous Province

Figure A32. INDICATOR E2: N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma)/1,000 resident population (2022)



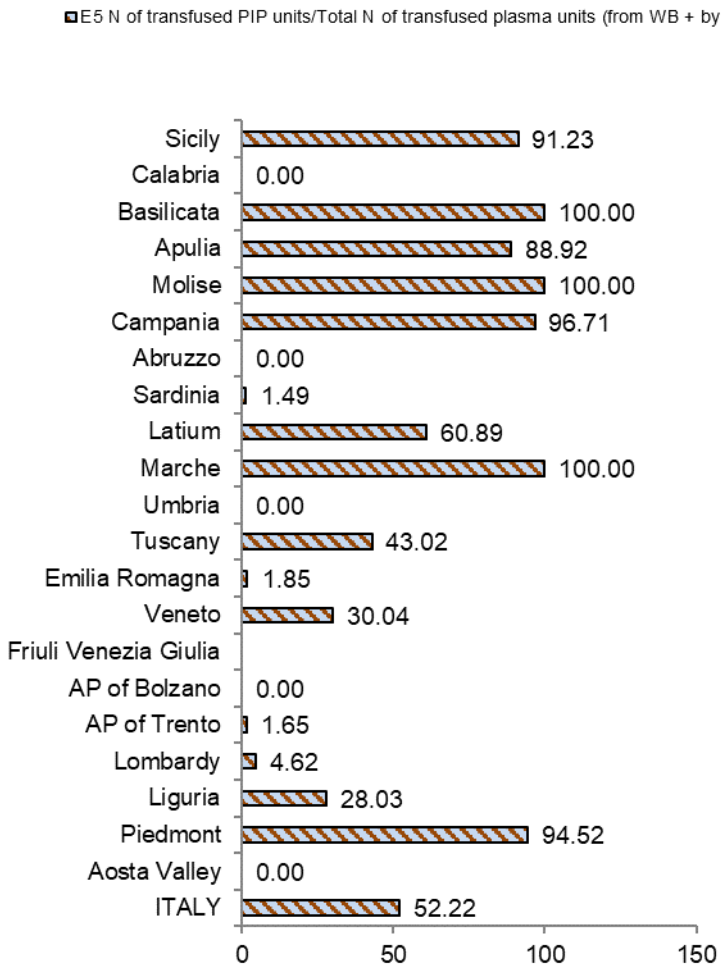
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A33. INDICATOR E3: N. of transfused whole blood plasma units/total N. of transfused plasma units (from whole blood + by apheresis + plasma pooled and treated for virus inactivation) (%) (2022)



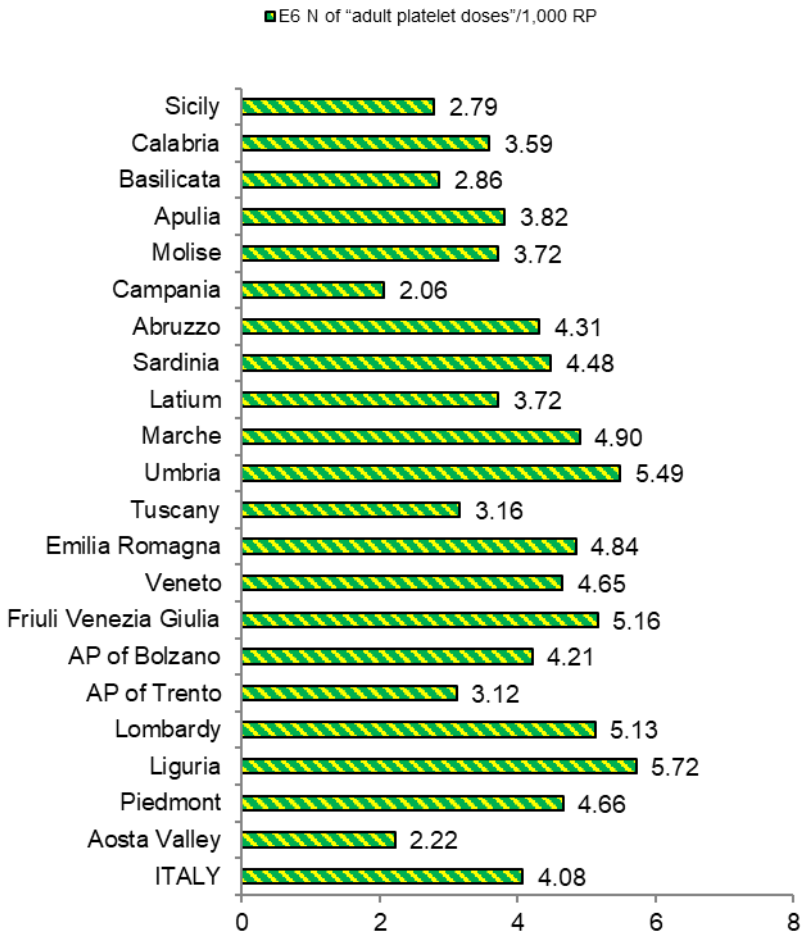
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

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) (%) (2022)



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) (%) (2022)



N. number; RP resident population; AP Autonomous Province

Figure A36. INDICATOR E6: N. of "adult platelet doses"/1,000 resident population (2022)

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