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Italian Blood System 2020: activity data, haemovigilance and epidemiological surveillance

L. Catalano, V. Piccinini, I. Pati, F. Masiello,
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EPIDEMIOLOGIA
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ISTITUTO SUPERIORE DI SANITÀ

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2021, iii, 103 p. Rapporti ISTISAN 21/14

The collection of data regarding the activities of the Italian Blood System since 2009 has been carried out through the Italian national blood information system (*Sistema Informativo dei Servizi TRAsfusionali, SISTRA*). The data collected at national level are those that are communicated to international health authorities. The data in this report are relevant to the year 2020.

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

Istituto Superiore di Sanità
Sistema trasfusionale italiano 2020: dati di attività, emovigilanza e sorveglianza epidemiologica.
Liviana Catalano, Vanessa Piccinini, Ilaria Pati, Francesca Masiello, Giuseppe Marano, Simonetta Pupella, Vincenzo De Angelis
2021, iii, 103 p. Rapporti ISTISAN 21/14 (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 2020.

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 del Sangue e i Responsabili dell'Emovigilanza per la loro preziosa collaborazione.

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viale Regina Elena, 299 – 00161 Roma

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ACRONYMS

AP	Autonomous Province
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)
CNS	*Centro Nazionale Sangue* (Italian National Blood Centre)
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
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
IRC	Italian Red Cross
ISTAT	National Institute of Statistics
NAT	Nucleic Acid Amplification Technology
NSIS	*Nuovo Sistema Informativo Sanitario* (New Health Information System)
RBCC	Regional Blood Coordination Centre
RT	Repeat tested (donor)
SISTRA	*Sistema Informativo dei Servizi TRAsfusionali* (National Blood Information System)
TACO	Transfusion Associated Circulatory Overload
TAD	Transfusion Associated Dyspnoea
TP	*Treponema pallidum*
TRALI	Transfusion-Related Acute Lung Injury
WHO	World Health Organization
XML	Extensible Markup Language

INTRODUCTION

The Italian National Blood Centre (*Centro Nazionale Sangue*, CNS) coordinates the National Blood Information System (*Sistema Informativo dei Servizi TRAsfusionali,* SISTRA), instituted by specific Ministerial Decree (1) and operating in the Ministry of Health's New Health Information System (NSIS). SISTRA collects 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 former, supports planning at regional and national level to achieve self-sufficiency in blood components and Plasma-Derived Medicinal Products (PDMPs); the latter, is divided in four sub-sections 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 2020.

SISTRA is compliant with 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 in two ways: through the regional blood transfusion information systems – by exchanging XML files (eXtensible Markup Language) – or directly through the Blood System Services (BSSs), if a Regional/Autonomous Provincial (APs) IT system does not exist or if the Regions/APs have authorised the BEs to send data directly to SISTRA.

ACTIVITIES OF THE ITALIAN BLOOD SYSTEM

Introduction

The year 2020 was marked by the pandemic COVID-19, and all the health activities were mainly aimed to manage this threat.

The blood transfusion system has kept up with the pandemic in order to guarantee the supply of blood and blood components to satisfy the needs of patients.

Through the personal data of BEs and Blood Collection Sites (BCSs) and their respective peripheral organisational sites, SISTRA makes it possible to define the national transfusion network that is in constant evolution due to the ongoing redistribution of the production activities and rationalisation of resources.

This section of the report shows national 2020 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 (6).

In the Appendix A, in order to facilitate the network's benchmarking, the quantitative activity indicators shown in the tables and graphs are reported 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 Human Resources (HR) analysis is limited to permanent staff working for BEs. 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", the business intelligence system made available by the Ministry of Health on the NSIS. The reference population, for the calculation of the relative indicators is that provided by the Italian National Institute of Statistics (ISTAT) as of 1st January, 2020, available at http://demo.istat.it/ (last access December 2020).

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 25 figures from 33 operating BEs.

We received 250 blood transfusion activity records which include data from 277 BEs.

National data

In 2020, 277 BEs were validated by the RBCCs in SISTRA.

Compared to 2019, there was a decrease in the number of peripheral organisational sites (-17.81%) that perform mainly collection of blood or blood components and, in a few cases, also transfusion activities (storage, processing, biological qualification, distribution, and issuing of

blood components as well as health care activities related to transfusion medicine); the number of BCSs decreased by 1,05% and a slight increase by 0,71% of peripheral organisational sites was registered (Table 1).

Table 1. BEs and BCSs with their respective peripheral organisational sites (2019-2020)

Blood facilities and population	2019	2020	Δ%
BEs	279	277	-0.72
BEs peripheral organisational sites	1,033	849	-17.81
BCSs	191	189	-1.05
BCSs peripheral organisational sites	1,271	1,280	0.71
Population	60,359,546	60,224,639	-0.22

BEs Blood Enstablishments, BCSs Blood Collection Sites (in Italy all BCSs are run by Voluntary Blood Donor Associations and Federations). Updated data 2020

To standardise the calculation of the number of employees in each single organisation, the professionals operating in BEs (Table 2) are reported as Full-Time Equivalent (FTE), which corresponds to 8 hours per day per 218 days/year.

Table 2. Professionals operating in BEs as of 31st December 2020* (2019-2020)

Staff	2019	2020	Δ%
Physicians	1,697.80	1,646.00	-3.05
Graduates (biologist and other professionals with a PhD)	481.2	486.00	1.00
Technicians	3,021.30	3,006.50	-0.49
Nurses	1,662.40	1,664.20	0.11
Health Operators	416.5	431.00	3.48
Administrative Staff	275.9	259.20	-6.05
Total	**7,555.10**	**7,492.90**	**-0.82**

* Data is reported as full-time equivalents and does not include professionals operating in BCSs

Table 3 shows data concerning donors of blood and blood components subdivided by type. Compared to 2019, there was a decrease by 3.38% in the total number of donors and in regular donors by 3.24%, while there was an increase in first-time donors – first-time pre-qualified donors (newly-registered donors who are screened during their first (pre-donation) visit and who donate during their second visit) – and a decrease in first-time not pre-qualified donors (newly-registered donors who are screened and donate during their first visit).

In 2020, more first-time pre-qualified donors re-donated than first-time not pre-qualified donors.

Table 4 shows the total number of collection procedures (carried out by both BEs and BCSs) subdivided by type.

Table 5 shows the percentage of blood and blood components collection procedures carried out by BCSs compared to the total number of collection procedures, subdivided by Region/APs.

Table 6 shows the number of collections carried out by BCSs (total and by Association/Federation); 95% were carried out by the four Associations/Federations that go to form the Inter-associative Committee of Voluntary Italian Blood Donors Associations / Federations (*Comitato Interassociativo del Volontariato Italiano del Sangue,* CIVIS).

Table 7 shows data concerning the production of blood components. Compared to 2019, there was a slight drop in the total number of units of blood components produced.

Table 3. Donors of blood and blood components (2019-2020)

Donors	2019	2020	Δ%
Prospective*	**183,953**	**184,371**	**0.23**
Those who did not donate in the period under examination	92,462	87,597	-5.26
First-time pre-qualified (A)	**121,536**	**125,980**	3.66
Those who re-donated at least once in the period under examination (A1)	43,815	46,565	6.28
First-time not pre-qualified (B)	**241,065**	**229,194**	-4.92
Those who re-donated at least once in the period under examination year of detection (B1)	32,788	34,265	4.5
Total First-time (A+B)	**362,601**	**355,174**	-2.05
Those who re-donated in the period under examination	76,603	80,830	5.52
Regular (R)	**1,397,472**	**1,352,162**	-3.24
Those who re-donated at least once a year in the last 5 years	626,521	588,107	-6.13
Total ((A-A1)+(B-B1)+R)	**1,683,470**	**1,626,506**	-3.38
Apheresis	202,476	217,638	7.49
Those who donated only in apheresis	109,016	114,730	5.24
Permanently deferred	50,406	39,093	-22.44
Members of VBDAs	**1,516,155**	**1,490,473**	-1.69

VBDAs: Voluntary Blood Donors Associations/Federations; * Prospective donors, persons who state their wish to give blood or plasma and undergo a preliminary anamnestic, clinical and diagnostic evaluation to determine their donor eligibility without donation

Table 4. Collection procedures carried out by BEs and BCSs (2019-2020)

Collection procedures	2019	2020	Δ%
Whole blood	**2,566,446**	**2,438,349**	-4.99
Apheresis	**429,818**	**455,439**	5.96
Monocomponent apheresis	*368,294*	*393,254*	6.78
Multicomponent apheresis	*61,524*	*62,185*	1.07
Total	**2,996,264**	**2,893,788**	-3.42
Type			
Plasmapheresis*	357,610	382,927	7.08
Plateletpheresis	8,786	8,194	-6.74
Stem Cells apheresis	1,412	1,620	14.73
Granulocytapheresis	117	177	51.28
Lymphocytapheresis	369	336	-8.94
Red Blood Cell/Platelet apheresis	3,182	3,450	8.42
Double Red Blood Cell unit apheresis	673	224	-66.72
Plasma/Platelet apheresis	45,625	47,826	4.82
Red Blood Cell/Plasma apheresis	10,076	8,600	-14.65
Double Platelet unit apheresis	963	1,125	16.82
Red Blood Cell/Platelet/Plasma apheresis	1,005	960	-4.48

*In 2020, plasmapheresis includes 6,952 COVID-19 convalescent plasma collections

Table 5. Percentage of collection procedures carried out by BCSs (2019-2020)

Region/AP	% 2019	% 2020	Δ%
Aosta Valley	0.00	0.00	-
Piedmont	53.61	55.07	2.73
Liguria	43.93	48.66	10.77
Lombardy	36.20	37.49	3.58
AP of Trento	0.00	0.00	-
AP of Bolzano	0.00	0.00	-
Friuli Venezia Giulia	0.00	0.00	-
Veneto	11.08	12.76	15.22
Emilia Romagna	55.35	64.68	16.85
Tuscany	4.25	3.91	-7.83
Umbria	0.00	0.00	-
Marche	4.51	3.87	-14.27
Latium	33.22	33.85	1.88
Sardinia	28.53	29.18	2.28
Abruzzo	10.47	10.25	-2.11
Campania	52.41	59.21	12.99
Molise	0.00	41.86	-
Apulia	0.00	0.00	-
Basilicata	72.71	78.39	7.82
Calabria	76.02	80.35	5.69
Sicily	82.31	78.22	-4.96
Armed Forces	0.00	0.00	-
Italy	**33.89**	**36.44**	**7.52**

Table 6. Number of collections carried out by BCSs (2019-2020)

Association/Federation	2019	2020	Δ%
AVIS	831,728	867,355	4.28
FIDAS	94,659	96,463	1.91
FRATRES	18,033	23,255	28.96
CRI	10,850	11,609	7.00
Other	60,106	55,683	-7.36
Total	**1,015,376**	**1,054,365**	**3.84**

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 7. Blood component production (2019-2020)

Blood component	2019	2020	Δ%
Red Blood Cells	**2,546,914**	**2,406,222**	-5.52
Red Blood Cells from whole blood	*2,527,426*	*2,388,888*	-5.48
Red Blood Cells by apheresis	*19,488*	*17,334*	-11.05
Platelets from single donors	13,904	16,006	15.12
Platelet Pools	213,522	206,334	-3.37
Platelets by apheresis	66,059	66,300	0.36
Plasma	**2,957,515**	**2,855,827**	-3.44
*Recovered Plasma**	*2,525,372*	*2,403,200*	-4.84
Source Plasma	*368,653*	*392,033*	6.34
Source Plasma from multiple apheresis	*63,490*	*60,594*	-4.56
Total	**5,797,918**	**5,550,689**	-4.26

*In 2020, recovered plasma includes 13,731 aliquots of COVID-19 convalescent plasma

In 2020, 7,732 units of blood components were transfused per day. Compared to the previous year, there was a slight drop in the total number of units of blood components transfused (Table 8). Moreover, compared to 2019, there was:

a) an overall increase in the total number of units of blood components discarded but a decrease of the units of plasma discarded (Table 9);
b) a decrease in the quantity of plasma for fractionation (Table 10);
c) a decrease in the production of allogeneic fibrin glue and an increase of allogeneic platelets gel for non-transfusional use (Table 11);
d) a decrease in the production of autologous blood components for non-transfusional use (Table 12);
e) a decrease in the number of patients who predeposited blood components for autologous transfusion (Table 13);
f) a decrease of the number of transfused patients, including those transfused in BEs (day hospital) (Table 14).

Table 8. Transfused units of blood components (2019-2020)

Blood component	2019	2020	Δ%
Red Blood Cells	**2,449,139**	**2,364,088**	-3.47
Red Blood Cells from whole blood	2,435,651	2,351,435	-3.46
Red Blood Cells by apheresis	13,488	12,653	-6.19
Platelets from single donors	5,360	4,118	-23.17
Platelets Pools	175,854	173,359	-1.42
Platelets by apheresis	52,784	54,057	2.41
Plasma	**253,367**	**226,882**	-10.45
*Recovered Plasma**	*93,091*	*83,209*	-10.62
Source Plasma	*30,555*	*26,861*	-12.09
Source Plasma from multiple apheresis	*6,731*	*6,321*	-6.09
Pharmaceutical Inactivated Plasma	*123,367*	*110,491*	-10.44
Total	**2,936,881**	**2,822,504**	**-3.89**

*In 2020, recovered plasma includes 6,912 aliquots of COVID-19 convalescent plasma

Table 9. Blood components discarded for reasons linked to health, technical issues, quality control and expiry dates (2019-2020)

Blood component	2019	2020	Δ%
Red Blood Cells	75,061	86,477	15.21
Platelets from single donors	8,505	7,268	-14.54
Platelet Pools	33,640	33,987	1.03
Platelets by apheresis	6,449	7,645	18.55
Plasma	**116,424**	**111,020**	-4.64
*Recovered Plasma**	*96,167*	*92,415*	-3.90
Source Plasma	*16,619*	*15,125*	-8.99
Source Plasma from multiple apheresis	*3,638*	*3,480*	-4.34
Total	**240,079**	**246,397**	2.63

*In 2020, recovered plasma includes 581 aliquots of COVID-19 convalescent plasma

Table 10. Plasma for fractionation (2019-2020)

Blood component	2019	2020	Δ%
Plasma for fractionation (kg)	858,170	843,149	-1.75

Data source: Pharmaceutical industry - year 2020 data updated to February 2021

Table 11. Production and use of allogeneic blood components for non-transfusion use (2019-2020)

Blood component	2019	2020	Δ%
Platelet Gel			
Produced	9,288	17,921	92.95
*of which those that could be further evaluated **	8,634	13,048	51.12
Used	7,644	9,574	25.25
Not Used	990	3,474	250.91
Fibrin Glue			
Produced	188	161	-14.36
*of which those that could be further evaluated **	*199*	*157*	-21.11
Used	174	149	-14.37
Not Used	25	8	-68.00

* In some cases only the number of produced units or only the number of used units was reported

Table 12. Production and use of autologous blood components for non-transfusion use (2019-2020)

Blood component	2019	2020	Δ%
Platelet Gel			
Produced	25,727	14,067	-45.32
*of which those that could be further evaluated **	**18,705**	***9,901***	-47.07
Used	17,086	9,237	-45.94
Not Used	1,619	664	-58.99
Fibrin Glue			
Produced	244	218	-10.66
*of which those that could be further evaluated **	*203*	*188*	-7.39
Used	202	188	-6.93
Not Used	1	0	-100.00

***** In some cases only the number of produced units was reported

Table 13. Autologous donation and transfusion (2019-2020)

Patients and autologous donation activities	2019	2020	Δ%
Patients who predeposited blood components for autologous transfusion	14,613	11,189	-23.43
Patients who underwent an autologous transfusion	12,684	9,197	-27.49

Table 14. Transfused patients (2019-2020)

Patients* transfused with:	2019	2020	Δ%
Whole Blood^	53	54	1.89
Red Blood Cells	599,782	566,199	-5.60
Plasma	53,783	48,907	-9.07
Platelets	53,679	51,519	-4.02
Other	3,934	5,875	49.34
Total**	**638,131**	**603,352**	**-5,45**

* 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 six classes of quantitative indicators identified:

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

for a total of 49 indicators, are presented at national level (Table 15) and regional level (Appendix 1- Supplemental figures).

Table 15. Quantitative indicators for transfusion activities in Italy (2020)

Indicators		Index
A. General		
A1	N. BE / 1,000,000 RP	4.60
A2	N. of professionals operating in BE 100,000 RP	12.44
A3	N. of professionals operating in BE / N. of BE	27.05
A4	N. of physicians operating in BE / Total of professionals operating in BE (%)	21.97
B. Donors		
B1	N. of donors / 1,000 RP	27
B2	M / F ratio: female donors (%)	32.8
B3	N. of donors / 1,000 RP in the 18-65 age bracket	43.39
B4	N. of donors in the 18-65 age bracket / 1,000 RP	3.21
B5	N. of donors in the 18-25 age bracket / 1,000 RP in the 18-65 age bracket	5.16
B6	N. of donors / 1,000 RP	22.44
B7	N. of prospective donors / 1,000 RP	3.06
B8	N. of first-time donors / 1,000 RP	5.9
B9	N. of first-time not pre-qualified donors / 1,000 RP	3.81
B10	N. of first-time pre-qualified donors / 1,000 RP	2.09
B11	N. of prospective donors who did not donate / Total N. of prospective donors (%)	47.51
B12	N. of “regular” donors / 1,000 RP	9.76
C. Donations		
C1	N. of donations (WB + apheresis) / 1,000 RP	48.03
C2	N. of donations (WB + apheresis) / Total N. of donors (excluding prospective donors)	1.78
C3	N. of donations WB / 1,000 RP	40.47
C4	N. of donations WB / N. of WB donors	1.61
C5	N. of donations in apheresis / 1,000 RP	7.56
C6	N. of donations in apheresis / N. of apheresis donors	2.09
D. Production of blood components		
D1	N. of RBC units produced / 1,000 RP	39.94
D2	N. of plasma units produced from WB and by apheresis / 1,000 RP	47.4
D3	N. of plasma units produced from WB / 1,000 RP	39.56
D4	N. of plasma units produced by apheresis (monocomponent or multicomponent) / 1,000 RP	7.51
D5	Plasma for fractionation (kg) / 1,000 RP	13.72
D6	Plasma by apheresis (kg) for fractionation / Total of plasma for fractionation (kg) (%)	29.5
D7	N. of platelet units produced by apheresis (monocomponent + multicomponent) / 1,000 RP	1.1
D8	N. of platelet units produced from buffy-coat pools / 1,000 RP	3.42
D9	N. of platelet units produced from PRP and single buffy-coats / 1,000 RP	0.27
D10	N. of pre-storage leukodepleted RBC units / N. of RBC units produced (%)	100
D11	N. of pre-storage leukodepleted platelet units produced by apheresis / N. of platelet units produced by apheresis (%)	71.32
D12	N. of “adult platelet doses” / 1,000 RP	4.58

Indicators		Index
E. Discarded blood components		
E1	N. of discarded RBC units / N. of "usable" RBC units (produced + acquired - released) (%)	3.59
E2	N. of expired RBC units discarded / N. of discarded RBC units (%)	38.34
E3	N. of RBC units discarded for technical reasons / N. of discarded RBC units (%)	24.57
E4	N. of RBC units discarded for health reasons / N. of discarded RBC units (%)	31.88
E5	N. of RBC units discarded for reasons linked to QC / N. of discarded RBC units (%)	5.21
E6	N. of discarded plasma units / N. of produced plasma units (%)	3.89
E7	N. of platelet units from PRP and from single buffy-coats discarded / N. of platelet units from PRP and from single buffy-coats produced (%)	45.41
E8	N. of platelet units by apheresis discarded / N. of platelet units by apheresis produced (%)	11.53
E9	N. of platelet units from buffy-coat pools discarded / N. of platelet units from buffy-coat pools produced (%)	16.47
F. Transfused blood components		
F1	N. of transfused RBC units / 1,000 RP	39.24
F2	N. of transfused plasma units (from WB + by apheresis + PIP) / 1,000 RP	3.77
F3	N. of transfused WB plasma units / Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	33.34
F4	N. of transfused apheresis plasma units / N. of transfused plasma units (from WB + by apheresis + PIP) (%)	14.63
F5	N. of transfused PIP units / Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	48.7
F6	N. of "adult platelet doses" / 1,000 RP	3.79

WB: whole blood; **RP**: resident population; **PRP**: patelet rich plasma; **PIP**: pharmaceutical inactivated plasma (total obtained from the sum of PIP produced in tool fractionation plus acquired PIP): **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 2020, the mapping of the BEs, BCSs, and their respective peripheral organisational sites showed little change in the regional transfusion networks due to the redistribution of the production and testing activities and rationalisation of resources. Compared to 2019, a slight decrease in the number of employees operating in BEs was noted.

Although there was a decrease in the total number of donors of blood and blood components (-3.38%), especially regular donors (-3.24%), the national self-sufficiency was ensured. In 2020 an overall drop in the number of transfused units of blood components (-3.89%) was noted, and was more marked particularly for plasma for clinical use compared to the previous year (-10.45%).

Data showed a reduction in the overall production of blood components. Red blood cells from apheresis and plasma were slightly decreased in the quantity compared to the previous year. A high percentage of donors who redonated during 2020 were first-time pre-qualified donors (37%).

Compared to 2019 the slight reduction of the use of RBCs shows that the Patient Blood Management strategies and techniques (6), first specified in the Italian national blood and blood products self-sufficiency plans dating back to 2012 (see the latest Italian self-sufficiency plan 2018 (7), have not been applied uniformly nationwide.

Finally, in SISTRA some discrepancies in the notification of data concerning the blood components for non-transfusional use were noted. In some cases, the BEs provided only the

number of units produced or only the number of units used. Overall, in 2020, an increase in the production of allogeneic platelet gel (approx. +93%) and a decrease in the production of allogeneic fibrin glue (-14%) was noted.

The blood transfusion system was able to guarantee, during the COVID-19 pandemic in 2020, the blood supply and to meet the needs of patients requiring transfusion therapies. Concerning the blood and blood component donations, measures have been introduced to guarantee donor and staff safety in compliance with the public health recommendations provided by the Ministry of Health and the Government. The most part of them, introduced for the pandemic, could be applied routinely by the transfusion system.

HAEMOVIGILANCE IN ITALY

Haemovigilance is a set of surveillance procedures covering the monitoring, reporting, investigation and analysis of adverse reactions in recipients, adverse events, adverse reactions in donors as well as the epidemiological surveillance of donors and the surveillance of medical devices used in transfusion activities (Ministry of Health Decree of 2nd November, 2015) (8). Haemovigilance systems are regulated by specific national laws and by European Directives (9, 10), transposed into national laws (11, 12), which state the procedures that must be adopted for the reporting of adverse reactions in recipients during or after transfusion, related to the quality and safety of transfused blood components, including the reporting of every case of transfusion transmitted infection. Haemovigilance also includes adverse reactions 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 adverse reactions 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.

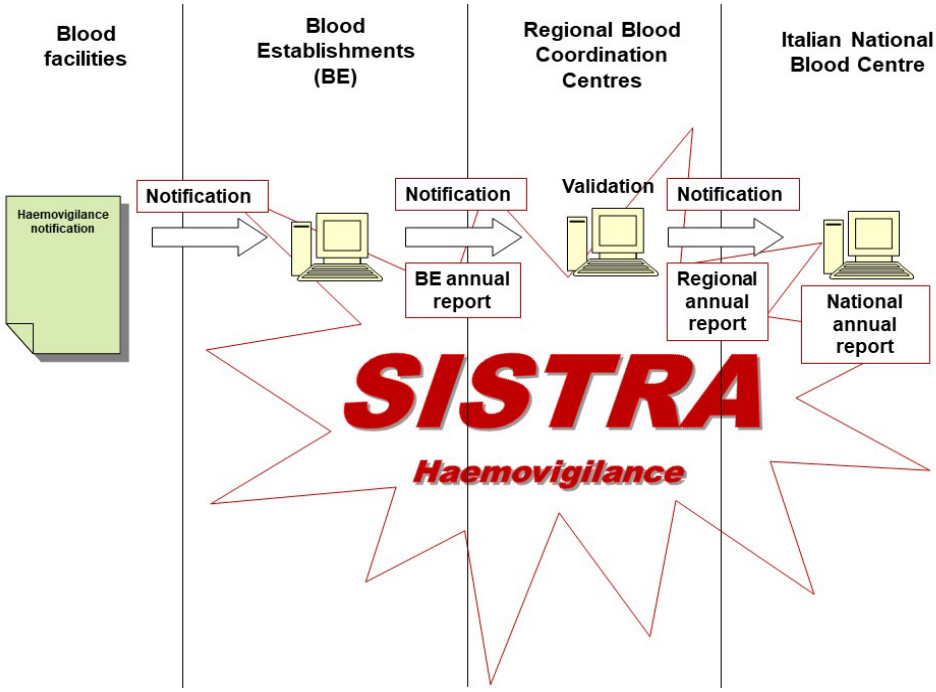


Figure 1. Haemovigilance information flow in SISTRA

The specific section of SISTRA dedicated to the haemovigilance includes:
– adverse reactions in recipients;
– adverse reactions in donors;
– adverse events;
– epidemiological surveillance of donors.

Adverse events and reactions in recipients and in donors

Definitions

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

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

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 (11), 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*
  - *N.A. - 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 2020

For 2020, the haemovigilance data validated from each RBCC was sent until March 30th, 2021; an extension for data consolidation and validation was allowed.

The notified information concerns 2,822,504 transfused blood components and 2,893,788 donations of blood and blood components. The reporting of haemovigilance system, expressed as number of notifications per year, increased constantly up to 2016 and appears to be stable in the period 2017-2020, especially in the number of blood donors' adverse reactions (Figure 2). As in the previous years (6, 13), the number of notifications shows a significant regional variability (Figures 3-5).

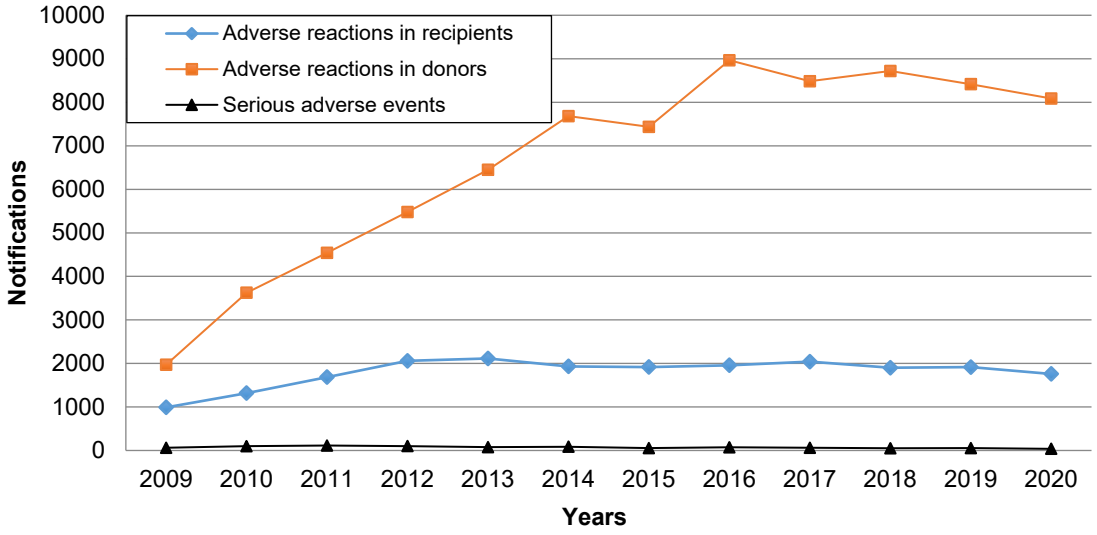


Figure 2. Number of haemovigilance notifications per year (2009-2020)

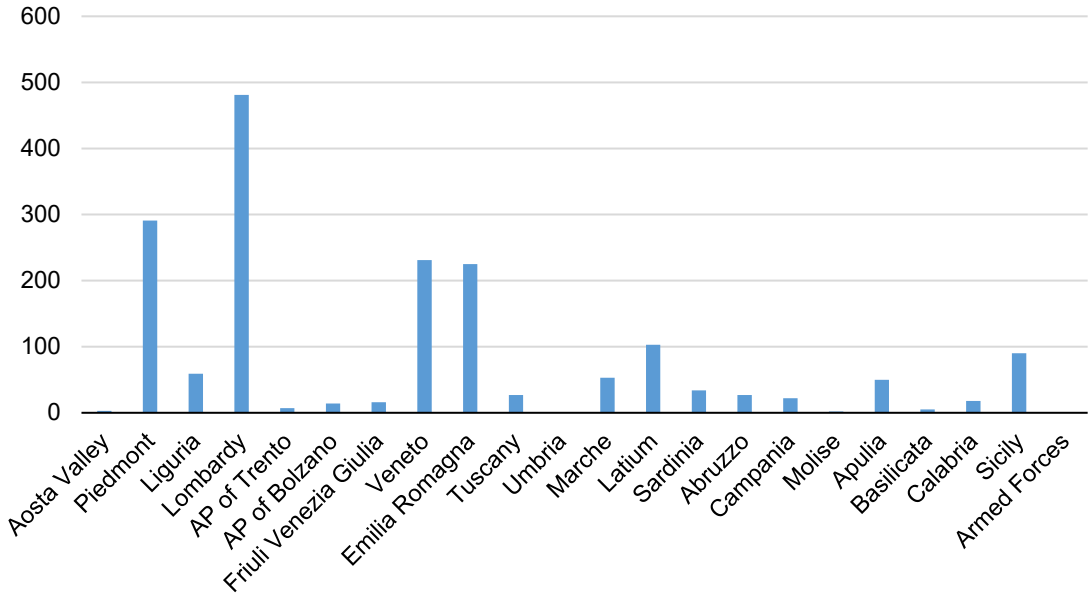


Figure 3. Adverse reactions in recipients notified by region (2020)

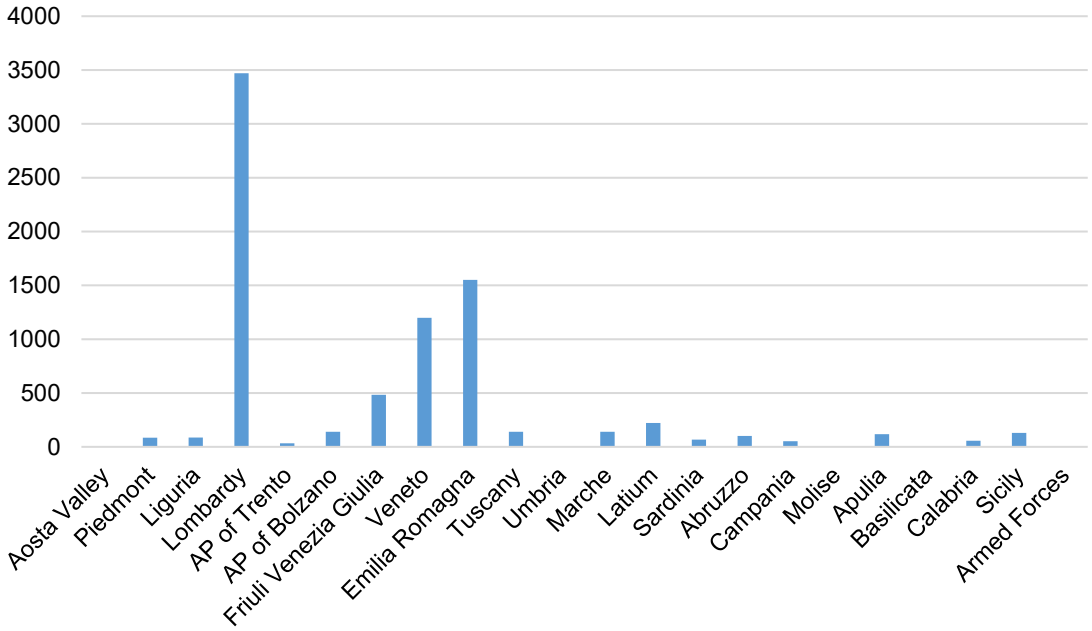
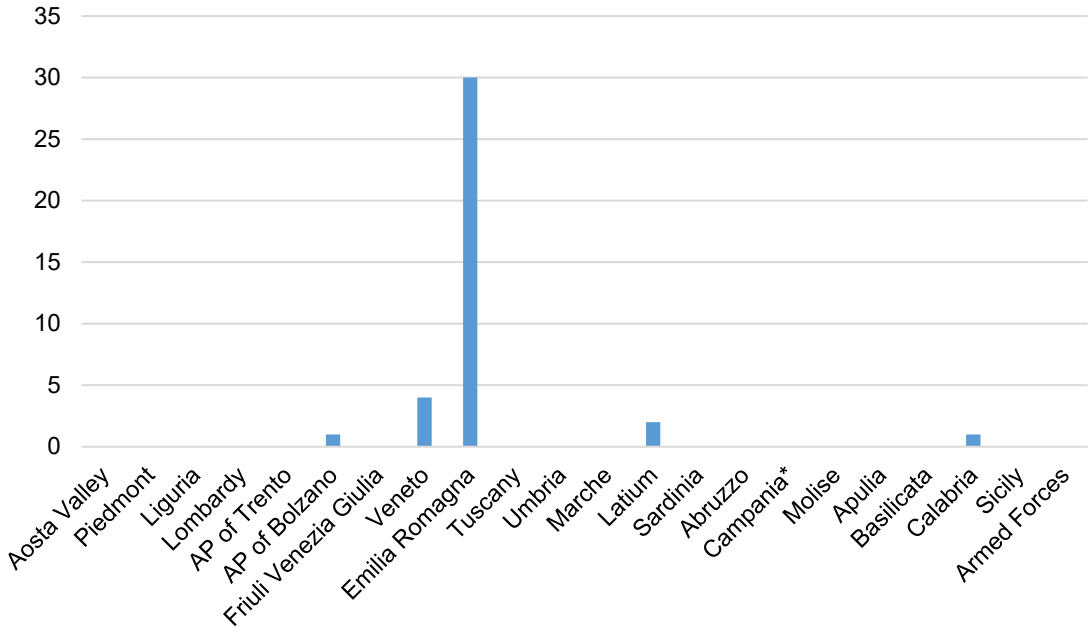


Figure 4. Adverse reactions in donors notified by region (2020)



* Campania Region: data not validated by the Regional Blood Coordination Centre

Figure 5. Adverse events notified by region (2020)

Adverse reactions in recipients

From January 1st to December 31st 2020, 1,759 adverse reactions were notified in recipients of blood components (one every 1,604 transfused units) (Table 16).

Table 16 shows adverse reactions in recipients by absolute number and percentage.

Table 16. Adverse reactions in recipients regardless of severity and imputability levels (2020)

Adverse reaction	n.	%
Alloimmunisation	2	0.11
Transfusion Associated Dyspnoea (TAD)	78	4.43
Transfusion-Related Acute Lung Injury (TRALI)	5	0.28
Transfusion-Associated Circulatory Overload (TACO)	35	1.99
Non-immunological haemolysis - chemical cause	3	0.17
Hypotensive transfusion reaction	24	1.36
Allergic reactions involving the respiratory and/or cardiovascular system	88	5.00
Allergic manifestations with only mucosal and cutaneous symptoms	546	31.04
Post-transfusion purpura	3	0.17
Acute haemolytic reaction due to ABO incompatible transfusion	6	0.34
Acute haemolytic transfusion reactions due to others blood group	1	0.06
Haemolytic transfusion reactions due to autoantibodies	3	0.17
Febrile Non-Haemolytic Reaction (FNHTR)	639	36.33
Anaphylactic shock	4	0.23
Probable Transfusion Transmitted HEV *	1	0.06
Incorrect Blood Component Transfused without reaction	3	0.17
Other	318	18.08
Total	**1,759**	**100.00**

* Transfusion Transmitted Hepatitis E infection (Severity level 1 - Mild symptoms, no therapeutic intervention; Imputability level 2 - Probable; Complete resolution within 6 months)

In 2020, the most frequently notified reactions were Febrile Non-Haemolytic Reactions (FNHTR) (36.3%) and allergic manifestations with only mucosal and cutaneous symptoms (31%), representing 67.3% of all notified adverse reactions in recipients.

Adverse reactions to transfusion with an imputability level 2-3 regardless of severity levels

In 2020, among the 1,759 adverse reactions to transfusion 732 were with a high imputability level (imputability level 2-3) (Table 17).

Taking into account only these adverse reactions, the frequency is one every 3,856 transfused units.

Table 17. Adverse reactions in recipients with an imputability level 2-3 regardless of severity levels (2020)

Adverse reaction	n.	%
Transfusion Associated Dyspnoea (TAD)	24	3.28
Transfusion-Related Acute Lung Injury (TRALI)	2	0.27
Transfusion-Associated Circulatory Overload (TACO)	13	1.78
Non-immunological haemolysis - chemical cause	1	0.14
Hypotensive transfusion reaction	6	0.82
Allergic reactions involving the respiratory and/or cardiovascular system	52	7.10
Allergic manifestations with only mucosal and cutaneous symptoms	329	44.95
Post-transfusion purpura	2	0.27
Acute haemolytic reaction due to ABO incompatible transfusion	6	0.82
Acute haemolytic transfusion reactions due to others blood group	1	0.14
Haemolytic transfusion reactions due to autoantibodies	2	0.27
Febrile Non-Haemolytic Reaction (FNHTR)	228	31.15
Anaphylactic shock	4	0.55
Probable Transfusion Transmitted HEV *	1	0.14
Incorrect Blood Component Transfused without reaction	1	0.14
Other	60	8.20
Total	**732**	**100.00**

* Transfusion Transmitted Hepatitis E infection (Severity level 1 - Mild symptoms, no therapeutic intervention; Imputability level 2 - Probable; Complete resolution within 6 months)

Adverse reactions to transfusion classified by transfused blood component with an imputability level 2-3 and a severity level 3-4

Table 18 shows the 11 adverse reactions with an imputability level 2-3 and a severity level 3-4 by transfused blood component. Taking into account only these adverse reactions, the frequency is one every 256,594 transfused units.

Table 18. Adverse reactions to transfusion classified by transfused blood component with an imputability level 2-3 and a severity level 3-4 (2020)

Adverse reactions	RBCs	Platelets	Plasma	Total
Transfusion Associated Dyspnoea (TAD)	1	0	0	1
Transfusion-Related Acute Lung Injury (TRALI)	1	0	1	2
Transfusion-Associated Circulatory Overload (TACO)	1	0	0	1
Allergic manifestations with only mucosal and cutaneous symptoms	1	0	0	1
Acute haemolytic reaction due to ABO incompatible transfusion	4	0	0	4
Anaphylactic shock	0	1	1	2
Total	**8**	**1**	**2**	**11**

Severity and imputability levels of adverse reactions

The severity of adverse reactions to transfusion required therapeutic intervention in 71.7% of the cases; no therapeutic intervention was required in 25.8% (Table 19 and Figure 6).

Table 19. Adverse reactions in recipients classified by severity level (2020)

Level	Severity	n.	%
0	No symptoms	17	1.0
1	Mild symptoms (no therapeutic intervention)	454	25.8
2	Symptoms requiring therapeutic intervention	1,262	71.7
3	Symptoms requiring resuscitation procedures	24	1.4
4	Death	2	0.1
	Total	**1,759**	**100.0**

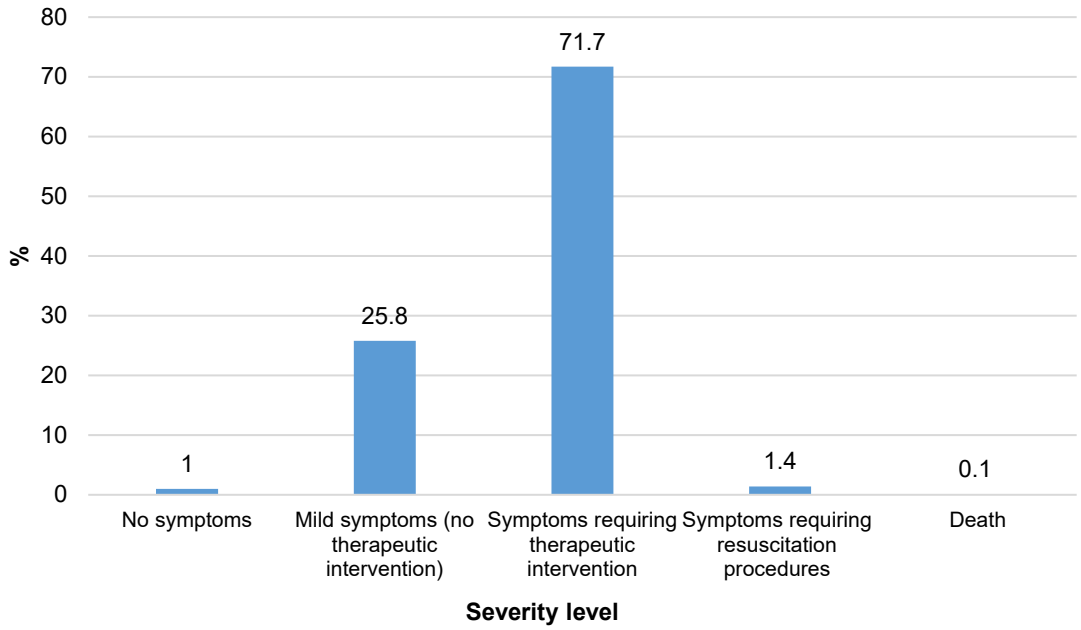


Figure 6. Severity level of adverse reactions in recipients (2020)

In 89.2% of adverse reactions the clinical resolution occurred in a few hours and only in 2 cases a disease persistence within 6 months was observed (Table 20).

Table 20. Adverse reactions in recipients by outcome (2020)

Outcome	n.	%
Resolution within a few hours	1,569	89.2
Resolution within a few days	24	1.4
Complete resolution within 6 months	2	0.1
Not assessable	164	9.3
Total	**1,759**	**100.0**

Concerning the imputability level, data show that 58.4% of adverse reactions in recipients were associated with low levels of imputability (Table 21 and Figure 7); more than 38.6% were possibly imputable, 11.9% were excluded/improbably related to the transfusion, and in 138 cases (7.8%) the imputability was not assessable.

Table 21. Adverse reactions in recipients by imputability level (2020)

Level	Imputability	n.	%
0	Excluded/Improbable	210	11.9
1	Possible	679	38.6
2	Probable	634	36.0
3	Certain	98	5.6
N.A.	Not assessable	138	7.8
	Total	**1,759**	**100.0**

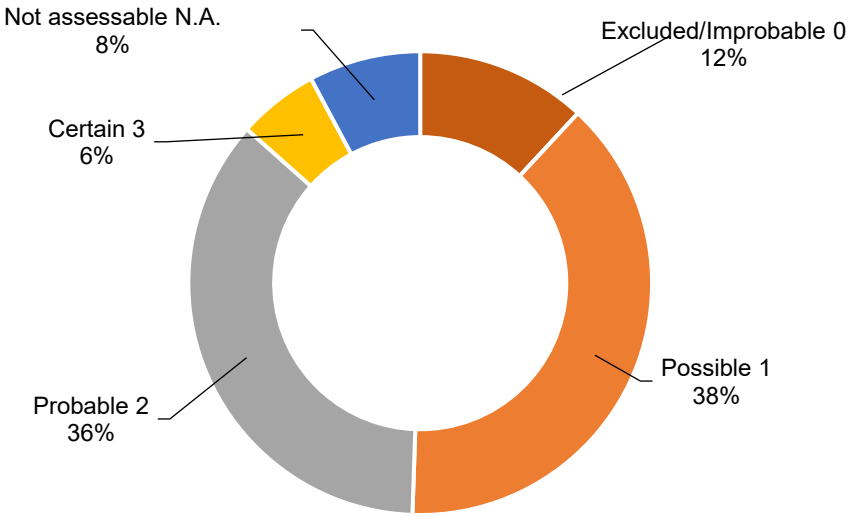


Figure 7. Adverse reactions in recipients linked to the imputability level expressed as a percentage (2020)

Transfusion sites

The majority of adverse reactions occurred in hospital ward (75%) or in day-hospital (9.3%) (Table 22 and Figure 8).

Table 22. Transfusion sites notifying adverse reactions (2020)

Transfusion site	n.	%
Hospital ward	1,320	75.0
Day-hospital	163	9.3
Emergency/ICU	98	5.6
Blood establishment	71	4.0
Clinic	57	3.2
Operating theatre	25	1.4
Home	25	1.4
Total	**1,759**	**100.0**

ICU: Intensive Care Unit

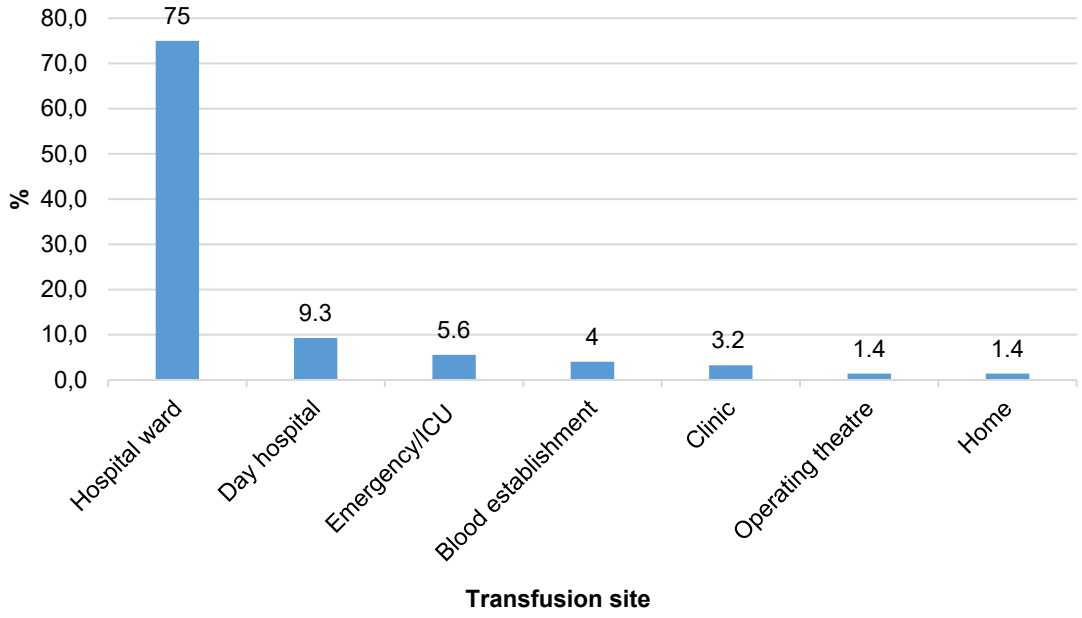


Figure 8. Adverse reactions by transfusion site as a percentage (2020)

Adverse reactions classified by transfused blood component

Among the notified 1,759 adverse reactions in recipients, most were related to RBC transfusion (61.5%). In 14 cases it was not possible to relate the adverse reaction to a specific blood component because more than one blood component had been transfused (Table 23).

Table 23. Adverse reactions in recipients classified by transfused blood component (2020)

Blood component	n.	%
Red Blood Cells	1,083	61.5
Platelets	456	25.9
Plasma*	195	11.1
More than one blood component transfused**	14	0.8
Haemopoietic Stem Cells	9	0.6
Whole Blood (Autologous)	2	0.1
Total	**1,759**	**100.0**

* Includes Pharmaceutical Virus-Inactivated Plasma (12 adverse reactions) and COVID-19 Convalescent Plasma (5 adverse reactions)
** Adverse reactions not ascribable to a specific blood component

Although the absolute number of adverse reactions linked to the transfusion of RBCs was slightly higher than that linked to the transfusion of platelet concentrates and plasma, if expressed in the number of adverse reactions per 1,000 units of transfused blood components, the highest incidence is found in platelets concentrate transfusions (Table 24).

In addition, 12 adverse reactions resulting from infused pharmaceutical virus-inactivated plasma equal to 0.1 adverse reactions per 1,000 transfused units and 5 adverse reactions resulting from COVID-19 Convalescent Plasma equal to 0.7 adverse reactions per 1,000 transfused units were notified (Table 24).

Table 24. Adverse reactions/1,000 transfused units grouped by blood component regardless of the imputability and severity levels (2020)

Blood component	Transfused units	Adverse reactions	Adverse reactions/ 1,000 transfused units
Red Blood Cells	2,364,088	1,083	0.5
Plasma*	226,882	195	0.9
Platelets	231,534	456	2.0

* Plasma includes Pharmaceutical Virus-Inactivated Plasma (12 adverse reactions to 110,491 transfused units) and COVID-19 Convalescent Plasma (5 adverse reactions to 7.488 transfused units)

ABO incompatible transfusions

In 2020, 7 cases of ABO-incompatible transfusions were notified as follows:

– 6 cases as "Acute haemolytic reaction" of which 2 notified also as "Adverse Event".
– 1 case as "ABO-incompatible Blood Component Transfused without reaction".

Moreover, 2 cases of ABO-compatible transfusions (wrong recipient transfused due to a wrong identification) were notified.

Near misses

As reported in the EDQM "Guide to the preparation, use and quality assurance of blood components" (14), a near-miss event is defined as: "any error which, if undetected, could result in determination of a wrong blood group or failure to detect a red cell antibody or the issuance, collection or administration of an incorrect, inappropriate or unsuitable component, but where the mistake was recognised before transfusion took place".

In 2020, 162 near misses (the blood component was not transfused) were notified. The most cases (72 cases equal to 44.4%) were "wrong patient collected" and "Wrong information on the tube label" (65 cases equal to 40.1%) (Table 25).

Table 25. Near misses (2020)

Type of primary error	Near miss (not transfused)	%
Wrong blood component label	1	0.6
Wrong recipient identification on unit	12	7.4
Wrong group of blood component	1	0.6
Error in pre-transfusion test	2	1.2
Wrong information on the tube label	65	40.1
Wrong patient collected	72	44.4
Wrong/inappropriate blood component type requested	5	3.1
Expired blood component	4	2.5
Total	**162**	**100.0**

Adverse reactions involving the respiratory and/or cardiovascular system

In 2020, 11.7% of all the notifications (206/1,759) were related to the respiratory system; 88 were allergic reactions involving the respiratory and/or cardiovascular system, 78 TAD, 35 TACO and 5 TRALI. The frequency of the aforementioned reactions per transfused blood components

was 1 allergic reaction every 32,074, 1 TAD every 36,186, 1 TACO every 80,643, and 1 TRALI every 564,506. However, only 3.9% of TAD, 2.9% of TACO, 2.9% and none of TRALI were certainly imputable.

Viral infections

In 2020, 1 case of "Other viral infection" was notified as follows:

– Hepatitis E virus: (Severity: 1 - Mild symptoms (no therapeutic intervention); Imputability: Level 2 - Probable; Complete resolution within 6 months).

After the notification by the plasma fractionation industry of a plasma pool positive to HEV RNA, a look back on the donor and the recipients of RBCs and platelets was done. The donor was suspended from donation and tested for HEV; the exams repeated three months after the blood donation were Ab anti-HEV IgG/IgM positive and HEV RNA negative. A female patient who had undergone haematopoietic stem cell transplantation for haematological disease was transfused with one unit of leukodepleted and treated with psoralens inactivated pre-storage platelets. The patient did not develop any specific symptom related to HEV infection. In the month following the transfusion, an increase in transaminase was reported. In the same period, she presented hyperferritinaemia. The patient's pre-transfusion serological status was unknown. The exams repeated three months after the transfusion were Ab anti-HEV IgG/IgM negative, HEV RNA positive. No information about HEV genotyping, in order to verify the homology between the donor's and the recipient's virus sequences, was provided.

Deaths

In 2020, 2 cases of death were notified:

– *Case 1*: the case was excluded/unlikely imputable to the RBCs transfused unit. Cardiovascular arrest occurred in an 80-year-old male cardiopathic patient receiving one unit of pre-storage leukodepleted RBCs for severe anaemia.

– *Case 2*: the imputability to the transfusion was notified as "not assessable". Death occurred in an 87-year-old male patient receiving one unit of pre-storage leukodepleted RBCs for chronic severe anaemia as palliative care. Death was probably related to the progression of the underlying pathology (myelofibrosis) that rapidly worsening during the days before the transfusion.

Adverse reactions in donors

In 2020, 8,086 adverse reactions to allogeneic donation were notified (1 every 358 donations) (Table 26); 432 of these reactions were severe (1 every 6,907 donations). Autologous donations were excluded from the analysis. Another reason for exclusion was miscoded reaction category (1 citrate reaction recorded after whole blood donation).

Table 26 shows the number of adverse reactions in donors and their related percentage, while Table 27 shows them by severity level.

In 2020, of all notified reactions, 6,022 (74.5%) were mild, 1,632 (20.2%) moderate, and only 432 (5.3%) severe. The most frequent type of notified reaction was the immediate vasovagal reaction (76.7%), of which 5.3% (264/6,200) was severe.

The more frequent type of severe reaction notified was immediate vasovagal reaction (61.1%), delayed vasovagal reaction (17.3%), and haematoma (12.9%) (Table 27).

Table 26. Adverse reactions in donors (2020)

Adverse reaction	n.	%
Immediate vasovagal reaction	6,200	76.68
Immediate vasovagal reaction with complications	49	0.61
Delayed vasovagal reaction	790	9.77
Delayed vasovagal reaction with complications	7	0.09
Haematoma	664	8.21
Arterial puncture	38	0.47
Cold/shivers	24	0.30
Thrombophlebitis	8	0.10
Incidents tied to vasovagal syndrome	2	0.02
Nerve injury	10	0.12
Tendon injury	2	0.02
Citrate reactions	43	0.53
Nerve injury due to a haematoma	1	0.01
Tightness in the chest	3	0.04
Systemic allergic reaction	1	0.01
Local allergic reaction	4	0.05
Local infection (venipunture site)	1	0.01
Other incidents	32	0.40
Other	207	2.56
Total	**8,086**	**100.0**

Table 27. Adverse reactions to donations classified per severity level (2020)

Adverse reaction	Mild	%	Moderate	%	Severe	%
Immediate vasovagal reaction	4,672	77.58	1,264	77.45	264	61.11
Immediate vasovagal reaction with complications	21	0.35	20	1.23	8	1.85
Delayed vasovagal reaction	500	8.30	215	13.17	75	17.36
Delayed vasovagal reaction with complications	0	0.00	6	0.37	1	0.23
Haematoma	553	9.18	55	3.37	56	12.96
Arterial puncture	0	0.00	38	2.33	0	0.00
Cold/shivers	20	0.33	0	0.00	4	0.93
Thrombophlebitis	0	0.00	0	0.00	8	1.85
Incidents tied to vasovagal syndrome	0	0.00	0	0.00	2	0.46
Nerve injury	10	0.17	0	0.00	0	0.00
Tendon injury	0	0.00	1	0.06	1	0.23
Citrate reactions	31	0.51	6	0.37	6	1.39
Nerve injury due to a haematoma	0	0.00	1	0.06	0	0.00
Tightness in the chest	3	0.05	0	0.00	-	0.00
Systemic allergic reaction	0	0.00	0	0.00	1	0.23
Local allergic reaction	3	0.05	0	0.00	1	0.23
Local infection (venipunture site)	1	0.02	0	0.00	-	0.00
Other incidents	26	0.43	5	0.31	1	0.23
Other	182	3.02	21	1.29	4	0.93
Total	**6,022**	**74.5**	**1,632**	**20.20**	**432**	**5.30**

In 2020, of all notified reactions, 5,865 (72.5%) were related to whole blood donations and 2,221 (27.5%) were related to apheresis donations. The most frequent type of notified reaction related to whole blood donations and to apheresis donations was the immediate vasovagal reaction (79.9% and 68.2% respectively).

If the absolute number of adverse reactions are compared to the total number of donation procedures, there are more adverse reactions related to whole blood donations than to apheresis donations (5,865 against 2,221).

Nevertheless, if expressed in the number of adverse reactions per every 1,000 donation procedures, the highest incidence is linked to apheresis donation (4.9 against 2.4/1,000 donations) (Table 28). These figures are in line with those of previous years.

Table 28. Adverse reactions to donations classified per donation procedure (2020)

Donation procedure			Adverse reactions			Adverse reactions/ 1,000 donation procedures		
whole blood	***apheresis***	***total***	***whole blood***	***apheresis***	***total***	***whole blood***	***apheresis***	***total***
2,438,349	455,439	2,893,788	5,865	2,221	8,086	2.4	4.9	2.8

Considering only the 432 severe adverse reactions, there were more adverse reactions related to whole blood donations than to apheresis donations (290 against 142).

Nevertheless, if expressed in the number of adverse reactions per every 1,000 donation procedures, the highest incidence was linked to the apheresis donation (0.12 against 0.31/1,000 donations) (Table 29).

Table 29. Severe adverse reactions to donations classified per donation procedure (2020)

Donation procedure			Severe adverse reactions			Severe adverse reactions/ 1,000 donation procedures		
whole blood	***apheresis***	***total***	***whole blood***	***apheresis***	***total***	***whole blood***	***apheresis***	***total***
2,438,349	455,439	2,893,788	290	142	432	0.12	0.31	0.15

In 2020, the majority of adverse reactions to donation (51.4%) occurred in BEs and 31.8% in BCSs (Table 30).

Table 30. Adverse reaction classified by donation site (2020)

Donation site	**n.**	**%**
BEs	4,160	51.4
BE peripheral organisational site	1,241	15.3
BCSs	2,570	31.8
In itinere	115	1.4
Total	**8,086**	**100.0**

BEs Blood establishments; BCSs Blood collection Sites

Adverse events

In 2020, 38 adverse events were notified; the majority (68.4%) was due to human error, whereas 13.2% to organisational error and 10.5% to material defect (Table 31 and Figure 9).

Table 31. Cause of adverse events (2020)

Cause	n.	%
Material defect	4	10.5
Equipment malfunction	1	2.6
Human error	26	68.4
Organisational error	5	13.2
Other	2	5.3
Total	**38**	**100.0**

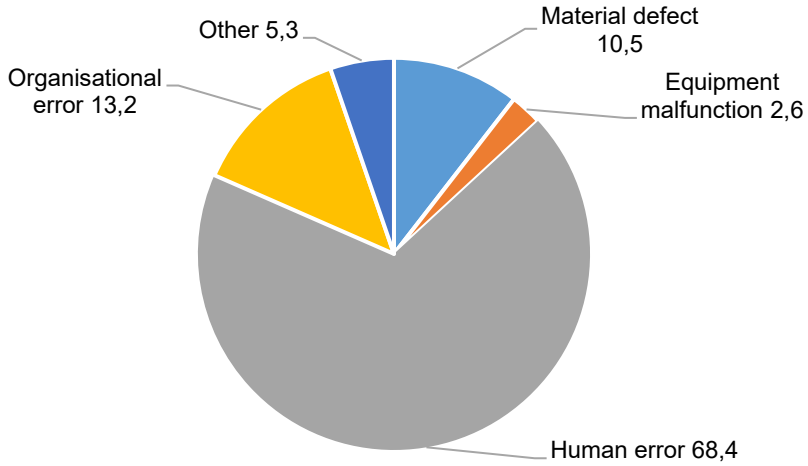


Figure 9. Cause of adverse events (2020)

For the majority of the adverse events (about 76%) the phase was not reported and they were notified as "Other" (Table 32 and Figure 10).

Table 32. Phases in which adverse events occurred (2020)

Phase	n.	%
Collection	6	15.8
Distribution	2	5.3
Storage	1	2.6
Other	29	76.3
Total	**38**	**100.0**

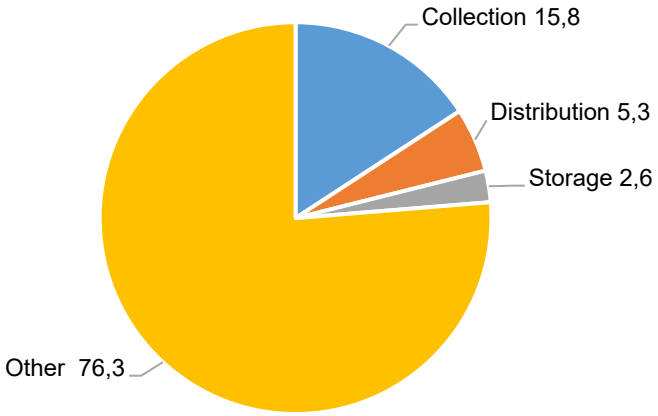


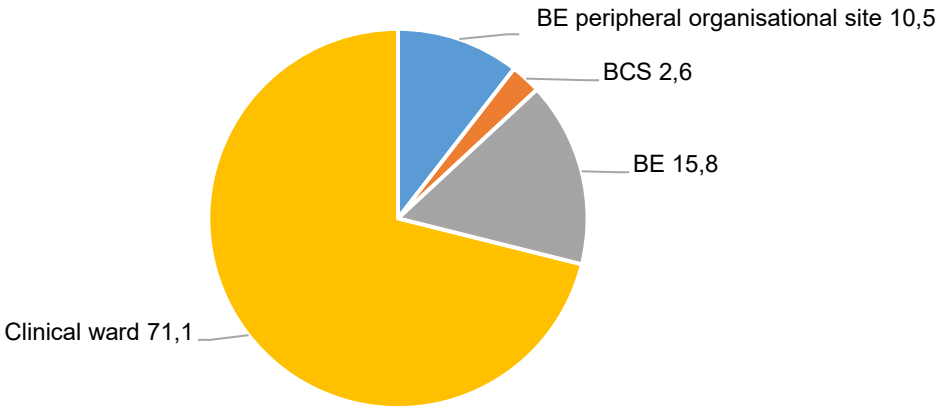
Figure 10. Phases in which adverse events occurred (2020)

In 2020, the majority of the adverse events (71.1%) occurred in clinical wards and 15.8% in BEs (Table 33 and Figure 11).

Table 33. Adverse events classified by site of the occurrence (2020)

Donation site	n.	%
BE peripheral organisational site	4	10.5
BCS	1	2.6
BE	6	15.8
Clinical ward	27	71.1
Total	**38**	**100.0**

BE: Blood establishment; BCS: Blood Collection Site



BE: Blood establishment; BCS: Blood Collection Site

Figure 11. Site in which adverse events occurred (2020)

Comments and recommendations

The analysis of the 2020-haemovigilance data confirms that, as in the previous years (6, 13), the most frequent adverse reactions to transfusion, considering all the imputability and severity levels, are FNHTR (36.3%) and allergic reactions with only mucosal and cutaneous symptoms (31%).

Among the 1,759 adverse reactions to transfusion 732 were with a high imputability level (imputability level 2-3) and there were only 11 reactions with probable or certain imputability requiring resuscitation procedures.

There were 7 cases of ABO-incompatible transfusion, 6 of which were notified as "Acute haemolytic reaction", 2 of those were also notified as "Adverse Events", one case was descripted as "ABO - incompatible Blood Component Transfused without reaction". Moreover 2 cases of ABO-compatible transfusions (Wrong recipient transfused due to a wrong identification) were notified. The above-mentioned events were caused by an error or deviation from standard procedures or policies. Root cause analysis of these events has been carried out to highlight and resolve these system failures. Monitoring and reporting this type of event is important so that suitable preventive measures can be adopted.

In 2020, reactions involving the respiratory system accounted for 11.7% of all the notifications of which 88 were allergic reactions involving the respiratory and/or cardiovascular system, 78 TAD, 35 TACO and 5 TRALI. Although data from scientific literature show variable frequency regarding these adverse reactions associated to several factors (definitions, diagnostic criteria, study population and type of haemovigilance system adopted (active or passive), the unsatisfied quality of TACO and TRALI notifications on SISTRA and of several cases of TAD notified with a low imputability level suggests that, as far as the haemovigilance is concerned, obtaining useful data for a differential diagnosis is often problematical. Further efforts are necessary to minimise the number of incomplete and low grade imputability notifications.

In 2020, 162 near misses were notified. Errors in patient identification (wrong group wrong name on tube, and wrong patient sample) were commonly reported. The above-mentioned near misses are errors or deviations from standard procedures or policies and often resulted from underlying poor practices. Root cause analysis of near miss events should be carried out to highlight and resolve these system failures. Improving near miss reporting is important to support learning from the errors and adopting preventive measures.

In 2020, 8,086 adverse reactions to allogeneic donation were notified (1 every 358 donations). Of all notified reactions, 74.5% were mild, 20.2% moderate, and only 5.3% severe. The most frequent type of notified reaction was immediate vasovagal reaction (76.6%), of which 5.3% (264/6,200) severe.

There were more adverse reactions related to apheresis donation than to whole blood donation. Suggested recommendations are therefore providing:

- the most accurate monitoring of apheresis donation, starting from donor selection criteria and the assessment of their physical and personal characteristics (such as venous access, haematological parameters and degree of individual compliance with the procedure);
- an adequate training and continuing education of the operators responsible for apheresis donations in order to:
  - detect the donors at "high risk" of adverse reactions in order to adopt suitable preventive measures;
  - promptly recognise, diagnose, classify and treat reactions;
  - minimise the number of individual errors and prevent as far as possible all adverse events potentially tied to equipment, sampling kits and possible usage of fluid balance, by constantly checking both materials and instruments.

A final comment concerns the low number of the adverse events notified on SISTRA (overall 38) that, in most cases, were notified without the detail of the specific phase in which the event occurred and notified as "Other". As in the previous years (6,14), a limited capacity of reporting and classify the adverse events was noted.

Transfusion transmitted infections in Italy: blood donors' epidemiological surveillance

The epidemiological surveillance of blood transfusion transmitted infections is the indispensable tool for assessing the safety of donated blood and blood components (14, 15).

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

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

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

This information is extremely useful for:

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

In this section of the report dedicated to the epidemiological surveillance of transfusion-transmissible infections detected in donors of blood and blood components, all essential data relative to 2020 are reported.

Materials and methods

SISTRA promptly and systematically 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 that corresponds to 100,000 donors.

Definitions

The definitions and indices used for the epidemiological surveillance of blood donors and blood components are entirely based on what is set forth in the Italian law in force regarding blood transfusion (8) and are 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)*
A person tested for the first-time for the currently mandatory infectious disease markers. This category includes prospective donors (persons who state their wish to give blood or plasma and undergo a preliminary anamnestic, clinical and diagnostic evaluation to determine their donor eligibility without donation) and first-time not pre-qualified donors (newly-registered donors who are screened and donate during their first visit).

– *Repeat tested donor (RT)*
A person tested previously for the currently mandatory infectious disease markers. This category includes first-time pre-qualified donors (newly-registered donors who are screened during their first pre-donation visit and who donate during their second visit) and regular donors (donors who donate and have already donated at least once in the previous 24 months).

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

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

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

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

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

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

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

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

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

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

General data

The data, reported in this section, derive from the information flows concerning blood donations performed in all Italian collection sites.

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 2020, out of a total of 1,845,142 blood donors, 1,420 tested positive for the currently mandatory infectious disease markers.

Table 34 shows the total number of positive donors by Italian Region, and the number of positive donors per 1,000 tested donors (‰). The Region with the highest number of positive donors detected was Campania (2.69‰), followed by Apulia (1.47‰) and Latium (1.16‰).

Table 34. Tested donors and positive donors to infectious markers at national and regional level (2020)

Region/AP (Autonomous Province)	Tested donors	Positive donors	
	n.	n.	‰
Aosta Valley	3,479	0	0.00
Piedmont	123,383	57	0.46
Liguria	48,879	34	0.70
Lombardy	290,322	134	0.46
AP of Trento	19,906	7	0.35
AP of Bolzano	16,746	4	0.24
Friuli Venezia Giulia	47,796	20	0.42
Veneto	175,793	45	0.26
Emilia Romagna	166,690	112	0.67
Tuscany	141,036	90	0.64
Umbria	26,632	21	0.79
Marche	55,099	23	0.42
Latium	141,073	164	1.16
Sardinia	53,811	44	0.82
Abruzzo	38,257	8	0.21
Campania	136,538	367	2.69
Molise	10,385	1	0.10
Apulia	117,087	172	1.47
Basilicata	19,107	4	0.21
Calabria	47,359	35	0.74
Sicily	164,631	78	0.47
Armed Forces	1,133	0	0.00
Italy	**1,845,142**	**1,420**	**0.77**

The data shown in Table 34 (positive donors per 1,000 tested donors, ‰) were the same as those shown in Figure 12. The analysis of the distribution of positive donors by age bracket shows that, considering the numbers of positive donors per 100,000 tested donors, the highest values

(highlighted in grey), reported as the number of positive donors per 1,000 tested donors (‰), were distributed uniformly (average value equal to 0.9‰) in the 36-65 age bracket (Table 35).

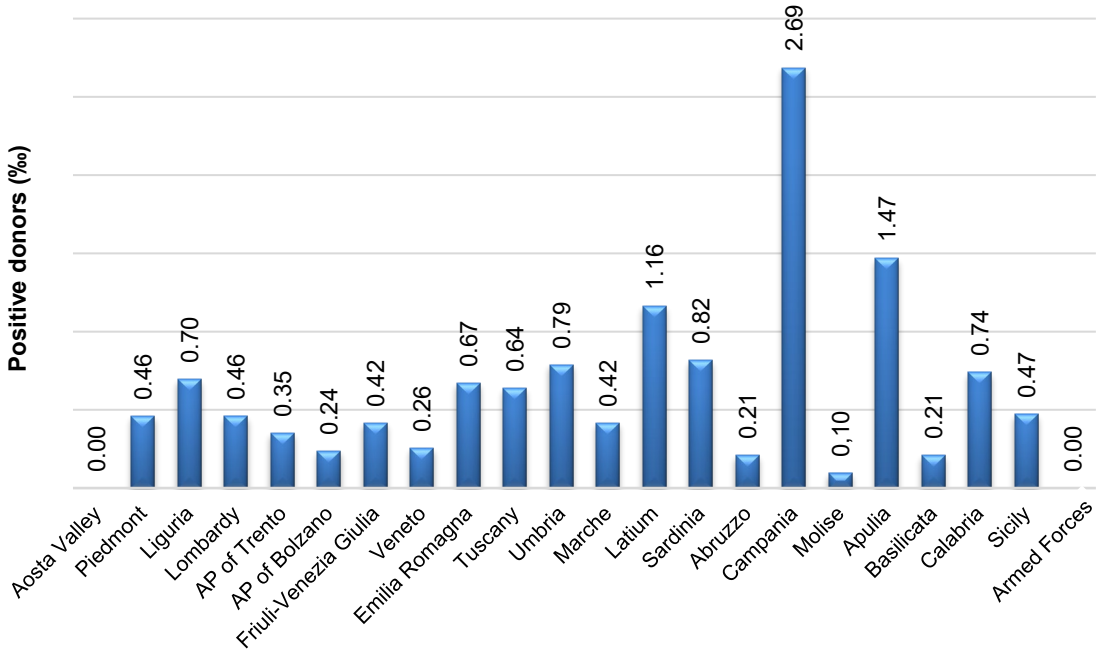


Figure 12. Positive donors per 1,000 tested donors (‰) by Italian Regions (2020)

Table 35. Positive donor by age bracket (2020)

Age bracket	Total donors		Positive donors		
	n.	%	n.	%	‰
18-25	250,491	13.6	82	5.8	0.33
26-35	339,662	18.4	217	15.3	0.64
36-45	430,819	23.3	349	24.6	0.81
46-55	525,747	28.5	486	34.2	0.92
56-65	277,055	15.0	270	19.0	0.97
over 65	21,368	1.2	16	1.1	0.75
Total	**1,845,142**	**100.0**	**1,420**	**100.0**	**0.77**

Table 36. Positive donors by age bracket and gender (2020)

Age bracket	Male				Female			
	donors		positive donors		donors		positive donors	
	n.	%	n.	%	n.	%	n.	%
18-25	131,419	10.8	64	6.2	119,072	18.8	18	4.7
26-35	211,820	17.5	165	15.9	127,842	20.2	52	13.6
36-45	294,771	24.3	262	25.2	136,048	21.5	87	22.8
46-55	362,329	29.9	343	33.0	163,418	25.8	143	37.5
56-65	196,492	16.2	192	18.5	80,563	12.7	78	20.5
over 65	16,103	1.3	13	1.3	5,265	0.8	3	0.8
Total	**1,212,934**	**100.0**	**1,039 (73%)**	**100.0**	**632,208**	**100.0**	**381 (27%)**	**100.0**

Table 36 shows the distribution by age bracket and gender of the 1,420 positive donors; for all age brackets, the number of male positive donors appears to be on overage 3 times higher than the number of female positive donors (Figure 13).

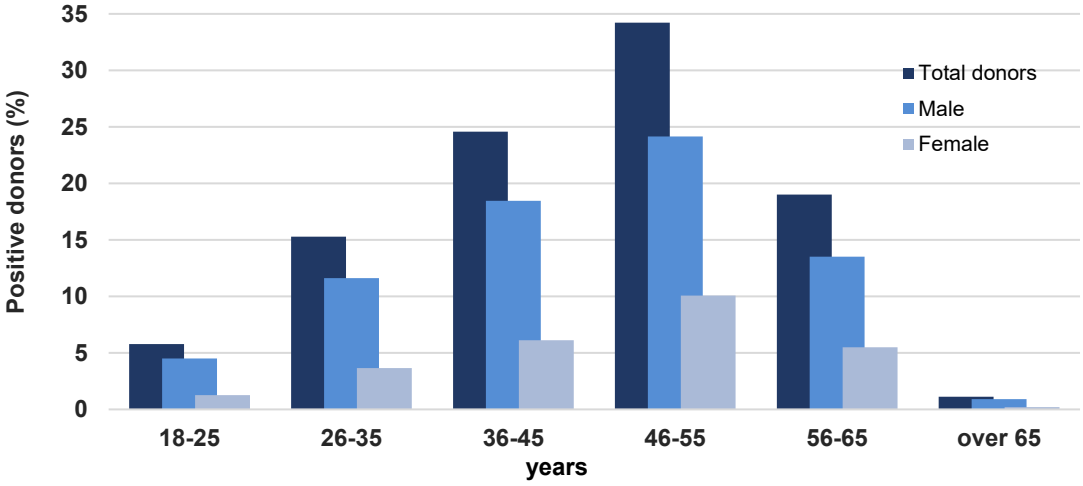


Figure 13. Positive donors (total, male and female donors) by age bracket (%) (2020)

Considering the number of infections detected in the total number of donors (‰ tested donors) for each age bracket, the biggest difference in the number of infections between males and females was found in the 18-25, 26-35 age brackets, while it was reduced in the, 36-45 and over 65 age brackets and was almost comparable in the 46-55 and 56-65 age brackets (Figure 14).

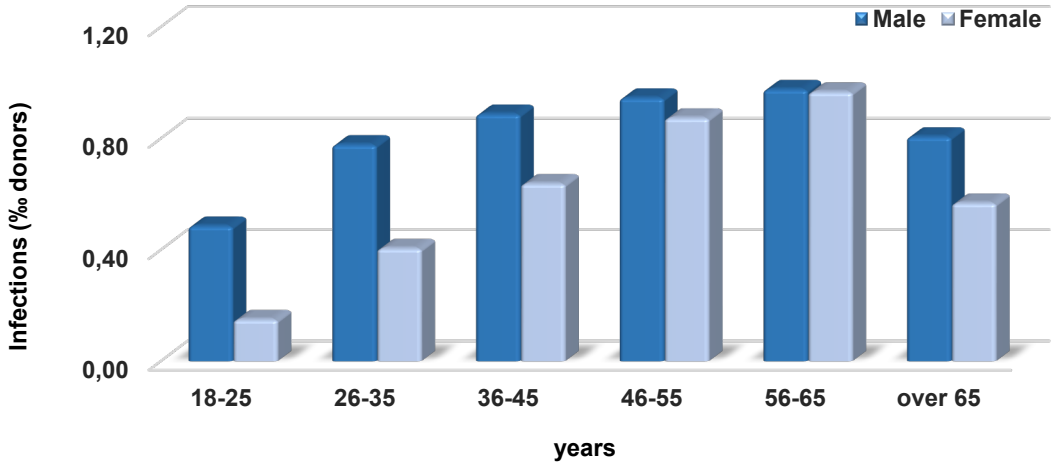


Figure 14. Positive donors by age bracket and gender (‰ total donors) (2020)

Figure 15 shows the percentages of infections observed for each single marker (HIV, HBV, HCV and TP) with the percentage distribution of all donors tested, distributed by age bracket.

The results show significant variations in the values between the trend of distribution of tested donors and that of the positive donors for each marker of infections. HIV and TP infections are

more frequent in the 26-35 and 36-45 age brackets; on the contrary, HCV infections are more frequent in the 46-55 age bracket and HBV infections in the 46-55 and 56-65 age brackets.

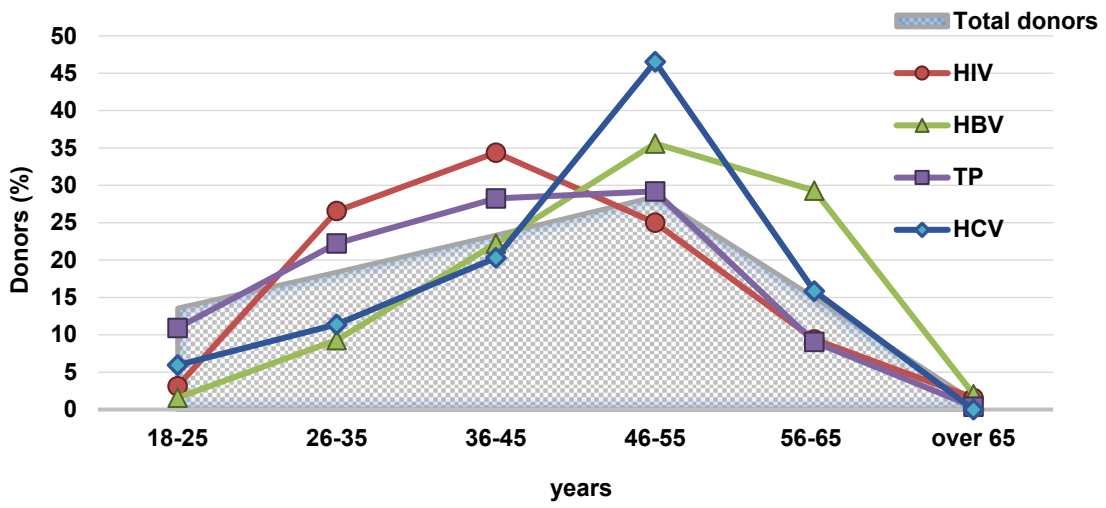


Figure 15. Total donors and HIV, HBV, HCV and TP positive donors by age bracket (2020)

The number of positive donors changed significantly also in relationship with the category (Table 37). In fact, it emerged that about 3‰ of FT donors were positive to one of the infectious markers compared to 0.25‰ of RT donors (Table 38). Figure 16 shows the same data reported in Table 38.

Table 37. Positive donors by category (2020)

Donor category	Donors	Positive donors	
	n.	n.	%
First-time tested donors	**413,565**	**1,067**	**75.14**
Prospective donors (first screening without donation)	184,371	386	27.18
First-time not pre-qualified donors	229,194	681	47.96
Repeat tested donors	**1,431,577**	**353**	**24.86**
First-time pre-qualified donors	125,980	12	0.85
Regular donors	1,305,597	341	24.01
Total donors	**1,845,142**	**1,420**	**100.00**

Table 38. Positive donors per 1,000 (‰) tested donors: distribution by category (2020)

Donor category	Donors	Positive donors	
	n.	n.	(‰)
First-time tested donors	**413,565**	**1,067**	**2.58**
Prospective donors (first screening without donation)	184,371	386	2.09
First-time not pre-qualified donors	229,194	681	2.97
Repeat tested donors	**1,431,577**	**353**	**0.25**
First-time pre-qualified donors	125,980	12	0.10
Regular donors	1,305,597	341	0.26
Total donors	**1,845,142**	**1,420**	**0.77**

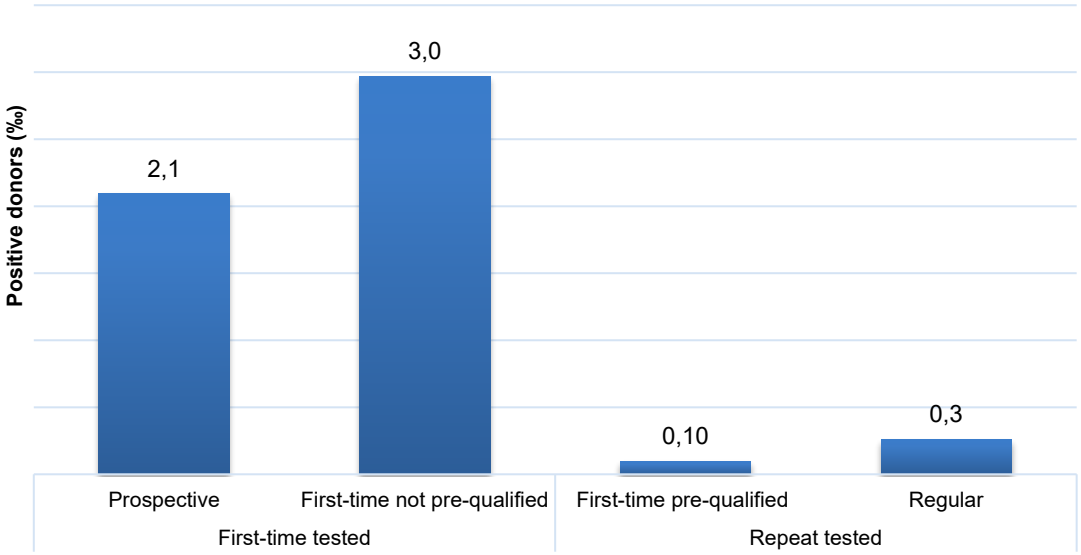


Figure 16. Categories of positive donors (2020)

Table 39 shows the number of FT and RT positive donors in Italy divided by Region.

The Region with the highest number of FT (4.86‰) was Campania and the Region with the highest number of RT (0.90‰) positive donors was Apulia.

Table 39. FT and RT positive donors (total and per 1,000 (‰) tested donors) in Italy (2020)

Region/AP	Total of donors		Positive donors			
	FT	RT	FT	RT	FT (‰ FT)	RT (‰ RT)
Aosta Valley	501	2,978	0	0	0.00	0.00
Piedmont	17,699	105,684	41	16	2.32	0.15
Liguria	12,453	36,426	25	9	2.01	0.25
Lombardy	49,563	240,759	79	55	1.59	0.23
AP of Trento	2,337	17,569	1	6	0.43	0.34
AP of Bolzano	1,440	15,306	2	2	1.39	0.13
Friuli Venezia Giulia	10,562	37,234	12	8	1.14	0.21
Veneto	27,485	148,308	31	14	1.13	0.09
Emilia Romagna	27,922	138,768	87	25	3.12	0.18
Tuscany	30,068	110,968	71	19	2.36	0.17
Umbria	5,966	20,666	15	6	2.51	0.29
Marche	9,998	45,101	21	2	2.10	0.04
Latium	55,488	85,585	143	21	2.58	0.25
Sardinia	16,045	37,766	27	17	1.68	0.45
Abruzzo	5,952	32,305	6	2	1.01	0.06
Campania	69,987	66,551	340	27	4.86	0.41
Molise	1,439	8,946	0	1	0.00	0.11
Apulia	24,403	92,684	89	83	3.65	0.90
Basilicata	2,156	16,951	3	1	1.39	0.06
Calabria	8,859	38,500	29	6	3.27	0.16
Sicily	32,554	132,077	45	33	1.38	0.25
Armed Forces	688	445	0	0	0.00	0.00
Italy	**413,565**	**1,431,577**	**1,067**	**353**	**2.58**	**0.25**

AP Autonomous Province

Figure 17 shows the percentage of positive donors by category (FT/RT). In general, with the exception of the AP of Trento and Bolzano, more than 50% were FT. The male/female ratio for FT positive donors was about 1.8:1. However, the male/female ratio for RT positive donors was about 2.4:1 (Figure 18).

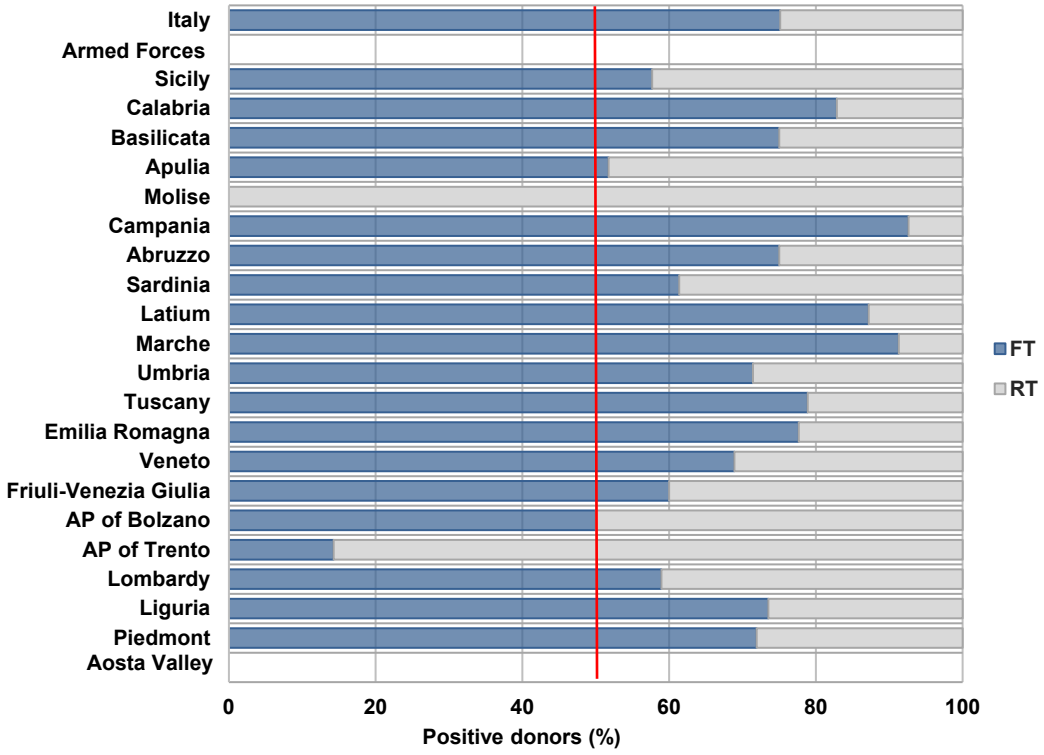


Figure 17. Positive donors by FT and RT category (%) at national and regional level (2020)

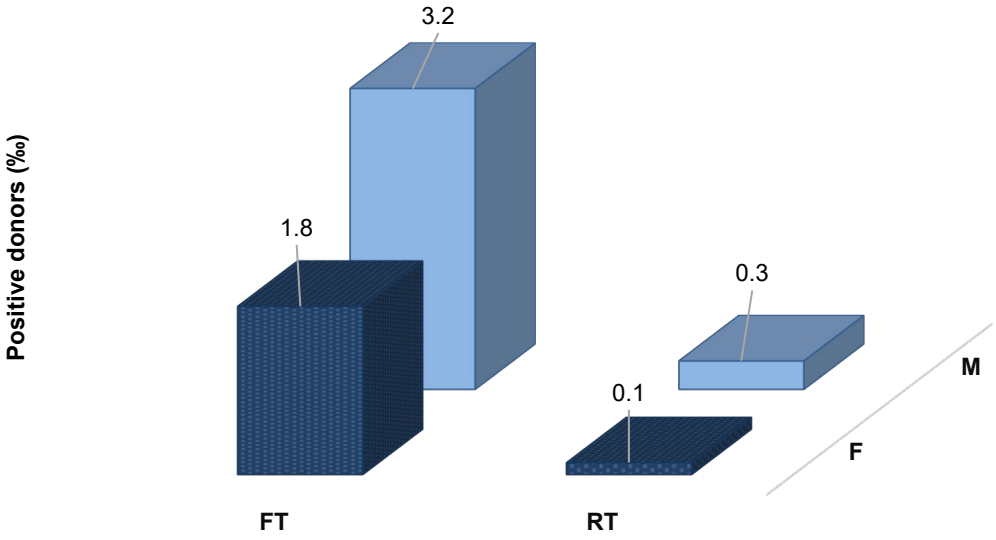


Figure 18. Positive donors by FT and RT category (‰ total male and female donors) and gender (2020)

Figure 19 shows the positive donor distribution at national and regional level for each infectious marker per 100,000 tested donors.

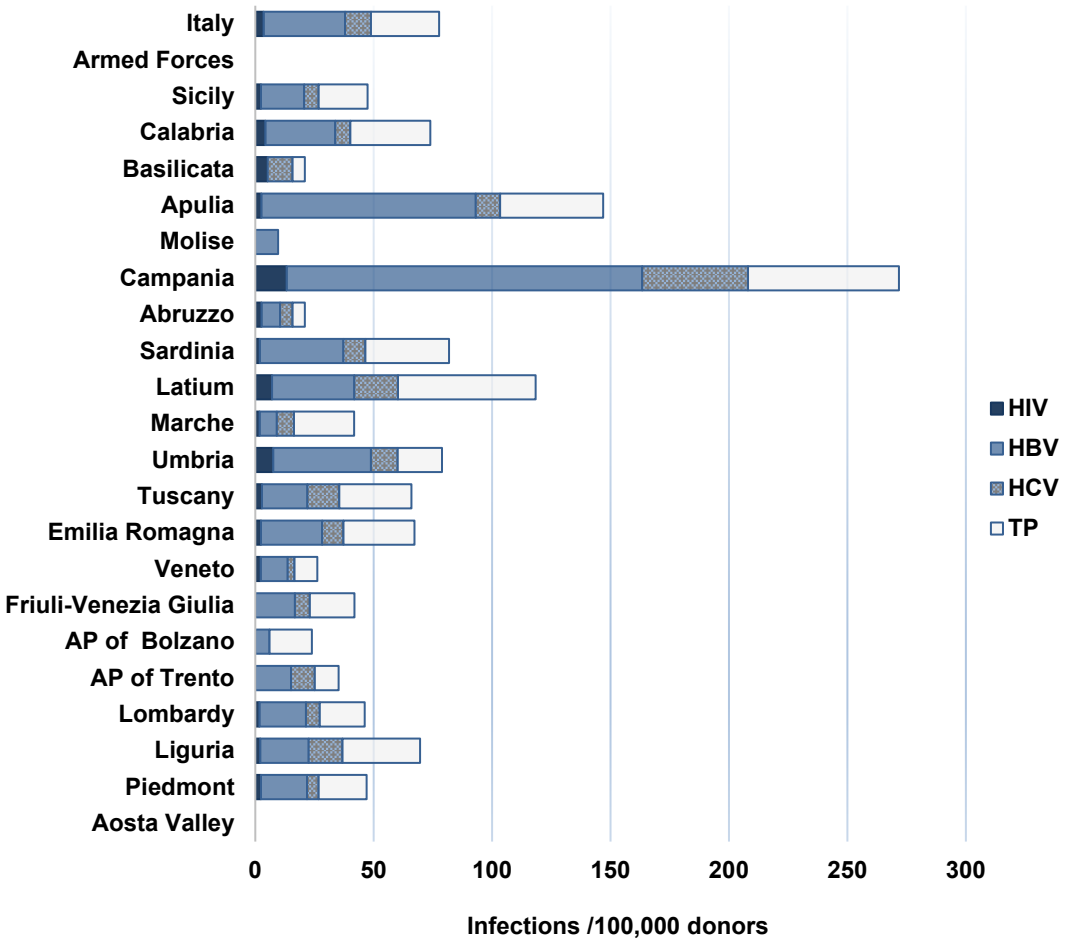


Figure 19. Number of positive donor distribution at national and regional level for each infectious marker per 100,000 donors (2020)

The Region with the highest number of all infections was Campania (HIV: 13.2/100,000, HBV: 150.1/100,000, HCV: 44.7/100,000, and TP: 63.7/100,000 tested donors). These values were from 2.2 (TP) to 4.4 times (HBV) higher compared to the national data.

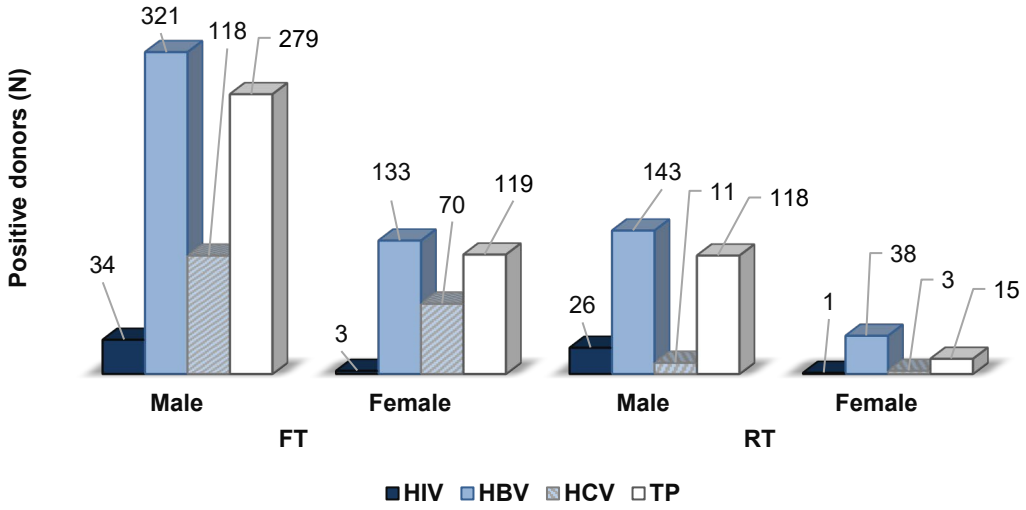
Figure 20 shows the distribution of infections by category (FT/RT), gender and infectious marker. HIV, HBV, HCV and TP in FT donors were higher compared to RT both for male and female donors. The ratio of infections between FT and RT ranges from about 1.4:1 (HIV) to about 13:1 (HBV).

In Tables 40 and 41 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 HBV (109.8/100,000 FT donors), followed by TP (96.2/100,000 FT donors) (Table 40).

Similarly, the highest incidence value was for HBV (12.6/100,000 RT donors) and TP (9.3/100,000 RT donors) infections (Table 41).

Moreover, it is important to note that in 60% of cases no information on causes of missed deferral of donors positive to infectious markers was reported in SISTRA.



FT First-time tested donors; RT Repeat tested donors

Figure 20. Infections by donor category (FT/RT), gender and infectious marker (2020)

Table 40. Prevalence by infectious marker/100,000 FT donors (2020)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	0.0	118.7	28.3	90.4
Liguria	8.0	48.2	32.1	112.4
Lombardy	0.0	54.5	30.3	74.7
AP of Trento	0.0	0.0	42.8	0.0
AP of Bolzano	0.0	69.4	0.0	69.4
Friuli Venezia Giulia	0.0	56.8	28.4	28.4
Veneto	10.9	54.6	14.6	36.4
Emilia Romagna	7.2	107.4	53.7	143.3
Tuscany	0.0	83.1	59.9	96.5
Umbria	0.0	134.1	50.3	67.1
Marche	10.0	40.0	40.0	120.0
Latium	12.6	72.1	46.9	131.6
Sardinia	0.0	56.1	24.9	87.3
Abruzzo	0.0	50.4	33.6	16.8
Campania	24.3	271.5	84.3	111.5
Molise	0.0	0.0	0.0	0.0
Apulia	8.2	184.4	45.1	127.0
Basilicata	0.0	0.0	92.8	46.4
Calabria	22.6	135.5	33.9	135.5
Sicily	6.1	36.9	27.7	67.6
Armed Forces	0.0	0.0	0.0	0.0
Italy	**9.0**	**109.8**	**45.5**	**96.2**

AP Autonomous Province

Table 41. Incidence by infectious marker/100,000 RT donors (2020)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	2.8	2.8	1.0	8.5
Liguria	0.0	11.0	8.2	5.5
Lombardy	2.1	12.5	0.8	7.5
AP of Trento	0.0	17.1	5.7	11.4
AP of Bolzano	0.0	0.0	0.0	13.1
Friuli Venezia Giulia	0.0	5.4	0.0	16.1
Veneto	0.7	3.4	0.7	4.7
Emilia Romagna	1.4	9.4	0.0	7.2
Tuscany	3.6	1.8	0.9	12.6
Umbria	9.7	14.5	0.0	4.8
Marche	0.0	0.0	0.0	4.4
Latium	3.5	10.5	0.0	10.5
Sardinia	2.7	26.5	2.7	13.2
Abruzzo	3.1	0.0	0.0	3.1
Campania	1.5	22.5	3.0	13.5
Molise	0.0	11.2	0.0	0.0
Apulia	1.1	65.8	1.1	21.6
Basilicata	5.9	0.0	0.0	0.0
Calabria	0.0	5.2	0.0	10.4
Sicily	1.5	13.6	0.8	9.1
Armed Forces	0.0	0.0	0.0	0.0
Italy	**1.9**	**12.6**	**1.0**	**9.3**

AP Autonomous Province

When the cause of missed deferral was reported (40%), in most cases the donor "denied the risk factor" (Figure 21).

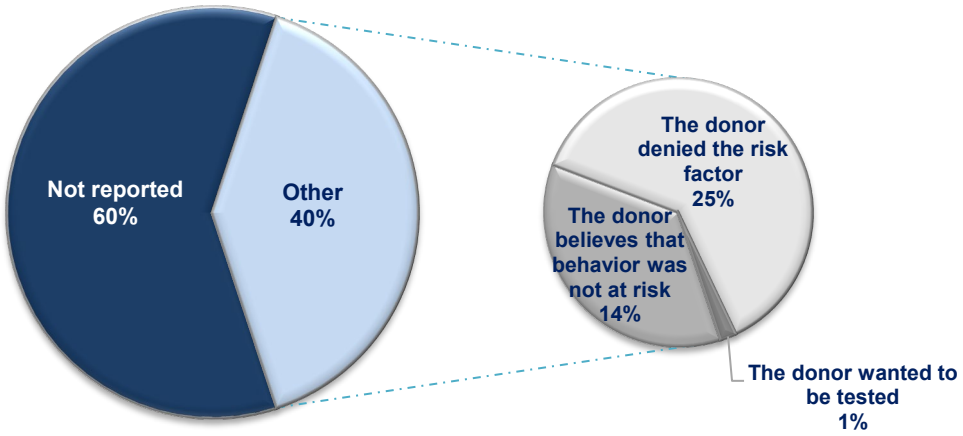


Figure 21. Causes of missed deferral of donor positive to infectious markers (2020)

Table 42 shows the number of donors positive to infectious markers by nationality and category. Table 43 shows the distribution of positive donors to infectious markers by geographical area of birth and category (FT/RT). The data shown in Table 42 and Table 43 were the same as those shown in Figure 22.

Table 42. Positive donors to infectious markers by nationality and category (FT/RT) (2020)

Nationality	Positive donors		FT		RT	
	n.	%	n.	%	n.	%
Italians	1,094	77.0	763	71.5	331	93.8
Foreigners	326	23.0	304	28.5	22	6.2
Total	**1,420**	**100.0**	**1,067**	**100.0**	**353**	**100.0**

Table 43. Positive donors to infectious markers by category (FT/RT) and by geographical area of birth (2020)

Geographical area of birth	FT	RT	Total
Africa	78	7	85
America	15	1	16
Asia	18	0	18
Europe	193	14	207
Italy	763	22	1,094
Total	**1,067**	**353**	**1,420**

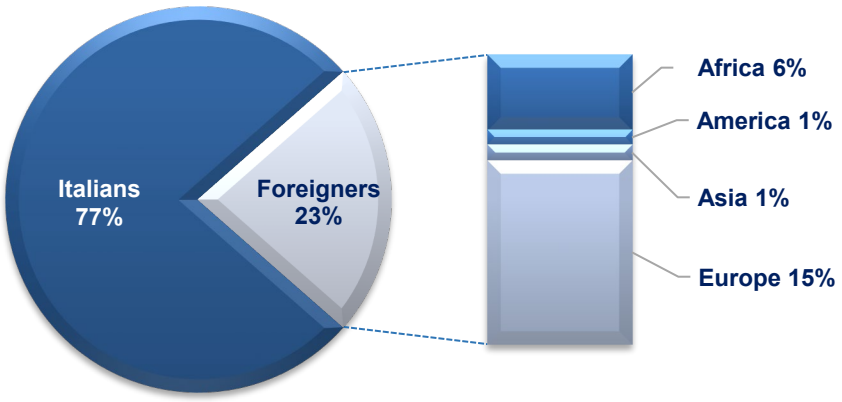


Figure 22. Positive donors to infectious markers by nationality (%) (2020)

HIV surveillance data

Table 44 reports the number of HIV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2020, 64 HIV infections were reported, with a prevalence of 9.0 per 100,000 FT donors and an incidence of 1.9 per 100,000 RT donors. The highest number of HIV infections was found in the Campania Region (18 cases). The Region with the highest prevalence was Campania (24.3) while the Region with the highest incidence was Umbria (9.7).

Table 44. Number, prevalence and incidence of HIV infections per 100,000 donors at national and regional level (2020)

Region/AP	HIV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	3	0.0	2.8
Liguria	1	8.0	0.0
Lombardy	5	0.0	2.1
AP of Trento	0	0.0	0.0
AP of Bolzano	0	0.0	0.0
Friuli-Venezia Giulia	0	0.0	0.0
Veneto	4	10.9	0.7
Emilia Romagna	4	7.2	1.4
Tuscany	4	0.0	3.6
Umbria	2	0.0	9.7
Marche	1	10.0	0.0
Latium	10	12.6	3.5
Sardinia	1	0.0	2.7
Abruzzo	1	0.0	3.1
Campania	18	24.3	1.5
Molise	0	0.0	0.0
Apulia	3	8.2	1.1
Basilicata	1	0.0	5.9
Calabria	2	22.6	0.0
Sicily	4	6.1	1.5
Armed Forces	0	0.0	0.0
Italy	**64**	**9.0**	**1.9**

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.

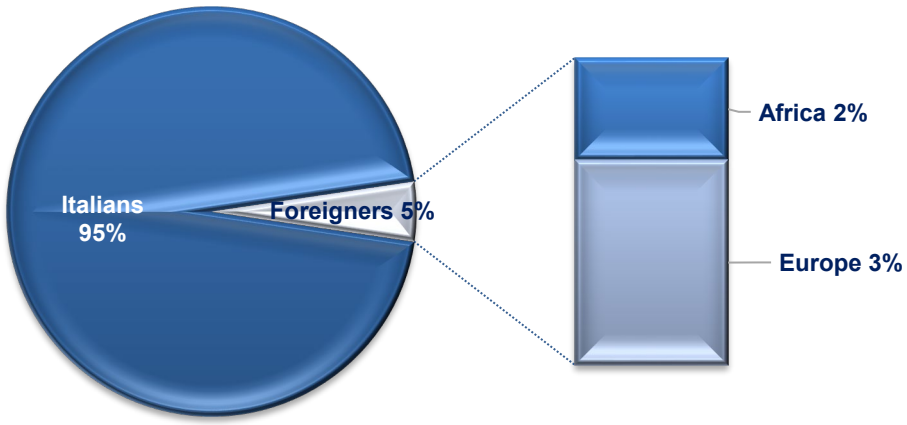


Figure 23. Distribution of HIV positive donors by nationality (%) (2020)

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

Table 45. HIV infections by geographical area of birth (2020)

Geographical area of birth	N. of infections
Africa	1
Europe	2
Italy	61
Total	**64**

In about 45% of the HIV positive donors (29/64) it was not possible to identify the risk factor; in the remaining 55%, who did not report/denied the risk factor or who believed that their behaviour was not at risk, the most frequently identified risk factors were occasional and unprotected exposures (Figure 24).

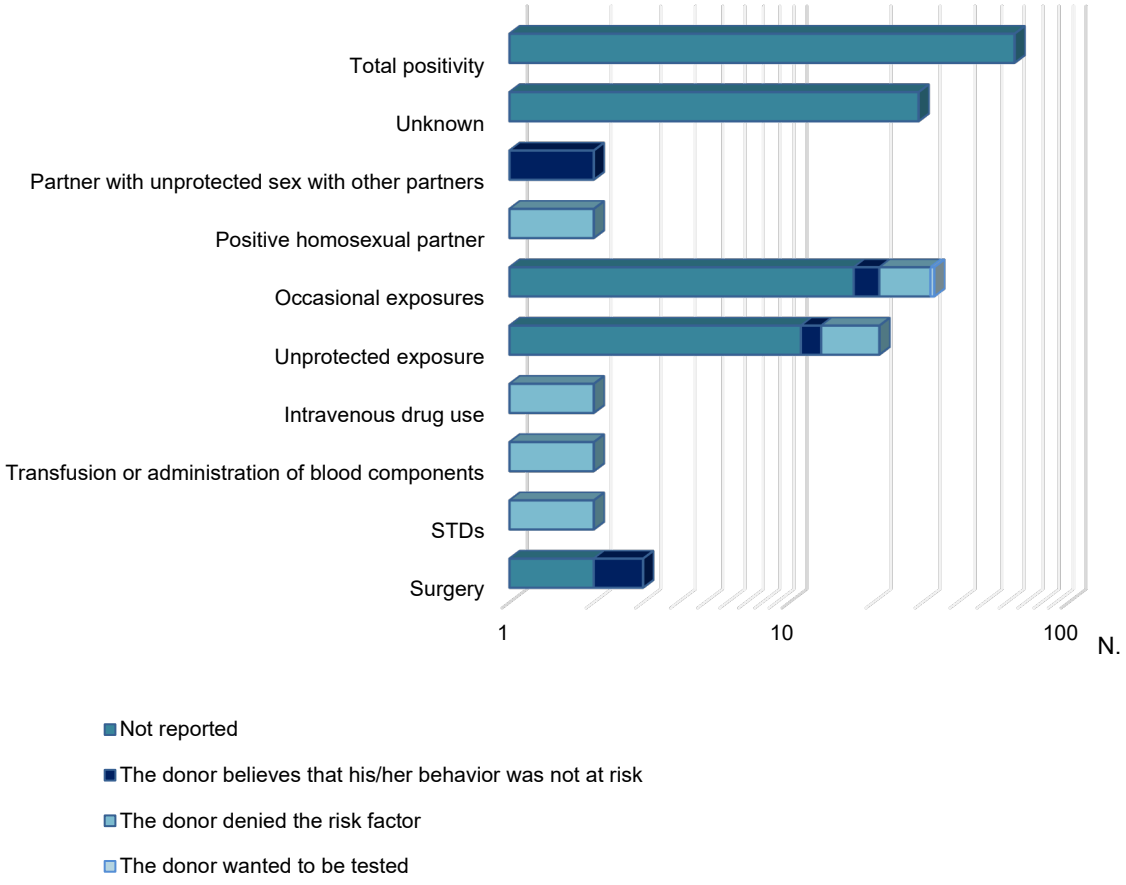


Figure 24. Causes of failed deferral and risk factors detected in HIV positive donors (2020)

Moreover, in most cases (58/64) the molecular (NAT) serological and confirmatory tests were positive; only in 2 cases the molecular test was negative with positive serological and confirmatory tests (Table 46).

Table 46. HIV infections obtained from the different combinations of the results of the individual molecular and serological tests (2020)

Combinations of results			N. of infections
NAT	SER	CONF	
+	+	+	58
+	+	+/-	1
+	-	-	1
+	-		3
-	+	+	2
ND*	+	+	2
Total			**64**

*NAT unavailable because prospective donors only underwent serological screening tests

HCV surveillance data

Table 47 reports the number of HCV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2020, 202 HCV infections were reported, with a prevalence of 45.5 infections per 100,000 FT donors and an incidence of 1.0 infections per 100,000 RT donors. The highest number of HCV infections was found in the Campania Region (61). The Region with the highest prevalence was Basilicata (92.8), while the Region with the highest incidence was Liguria (8.2). Figure 25 shows the distribution, expressed as a percentage, of HCV positive donors by nationality; 20% of all positive donors were foreigners. Table 48 shows the distribution of HCV positive donors by geographical area of birth.

Table 47. Number, prevalence and incidence of HCV infections per 100,000 donors at national and regional level (2020)

Region/AP	HCV nfections		
	N.	Prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	6	28.3	1.0
Liguria	7	32.1	8.2
Lombardy	17	30.3	0.8
AP of Trento	2	42.8	5.7
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	3	28.4	0.0
Veneto	5	14.6	0.7
Emilia Romagna	15	53.7	0.0
Tuscany	19	59.9	0.9
Umbria	3	50.3	0.0
Marche	4	40.0	0.0
Latium	26	46.9	0.0
Sardinia	5	24.9	2.7
Abruzzo	2	33.6	0.0
Campania	61	84.3	3.0
Molise	0	0.0	0.0
Apulia	12	45.1	1.1
Basilicata	2	92.8	0.0
Calabria	3	33.9	0.0
Sicily	10	27.7	0.8
Armed Forces	0	0.0	0.0
Italy	**202**	**45.5**	**1.0**

AP Autonomous Province

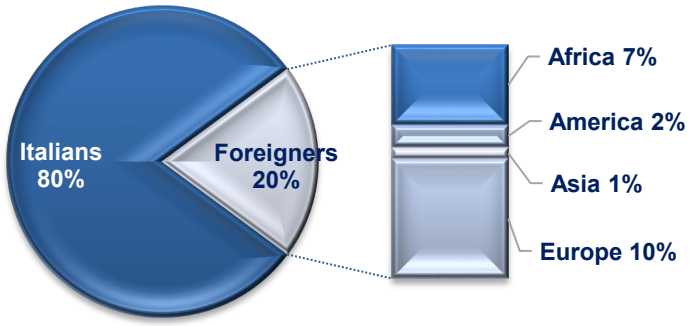


Figure 25. HCV positive donors by nationality (%) (2020)

Table 48. HCV infections by geographical area of birth (2020)

Geographical area of birth	N. of infections
Africa	14
America	4
Asia	2
Europe	21
Italy	161
Total	**202**

In about 70% of HCV positive donors (136/202) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern donor that knew or suspected to be positive, occasional exposures and donor born in an endemic area (Figure 26).

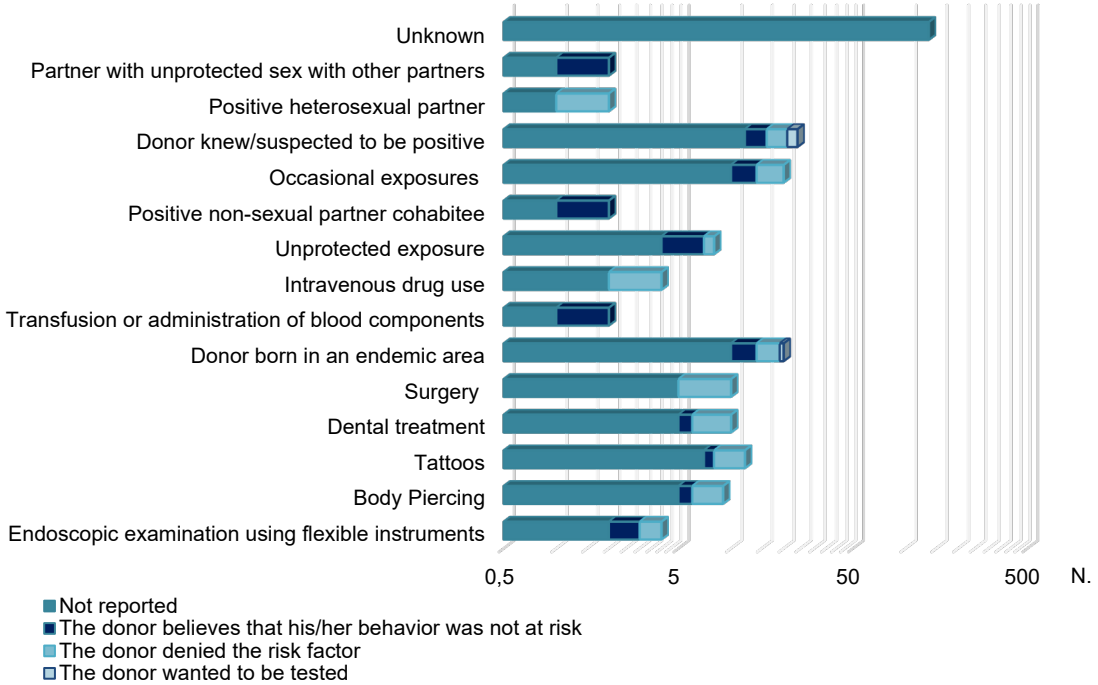


Figure 26. Causes of failed deferral and risk factors detected in HCV positive donors (values reported on a logarithmic scale) (2020)

In most cases (74/202), the molecular (NAT), serological and confirmatory tests were positive; in 84 cases the molecular test was negative with a positive serological screening and confirmatory tests. In 2 cases the infection was detected exclusively by means of the NAT test (NAT only) (Table 49).

Table 49. HCV infections obtained from the different combinations of the results of the individual molecular and serological tests (2020)

Combinations of results			N. of infections
NAT	SER	CONF	
+	+	+	74
-	+	+	84
+	+	+/-	1
+	-	-	2
-	-	+	1
ND*	+	+	40
Total			**202**

* NAT unavailable because prospective donors only underwent serological screening tests

HBV surveillance data

Table 50 reports the number of HBV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2020, 635 HBV infections were reported, with a prevalence of 109.8 infections per 100,000 FT donors and an incidence of 12.6 infections per 100,000 RT donors.

Table 50. Number, prevalence and incidence of HBV infections per 100,000 donors at national and regional level (2020)

Region/AP	HBV infections		
	n.	Prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	24	118.7	2.8
Liguria	10	48.2	11.0
Lombardy	57	54.5	12.5
AP of Trento	3	0.0	17.1
AP of Bolzano	1	69.4	0.0
Friuli Venezia Giulia	8	56.8	5.4
Veneto	20	54.6	3.4
Emilia Romagna	43	107.4	9.4
Tuscany	27	83.1	1.8
Umbria	11	134.1	14.5
Marche	4	40.0	0.0
Latium	49	72.1	10.5
Sardinia	19	56.1	26.5
Abruzzo	3	50.4	0.0
Campania	205	271.5	22.5
Molise	1	0.0	11.2
Apulia	106	184.4	65.8
Basilicata	0	0.0	0.0
Calabria	14	135.5	5.2
Sicily	30	36.9	13.6
Armed Forces	0	0.0	0.0
Italy	**635**	**109.8**	**12.6**

AP Autonomous Province

The highest number of HBV infections was found in the Campania Region (205). The Region with the highest prevalence was Campania (271.5), while the Region with the highest incidence was Apulia (65.8).

Figure 27 shows the distribution, expressed as a percentage, of HBV positive donors by nationality; 27% of all positive donors were foreigners. In about 64% of the HBV positive donors (405/635) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern donor born in an endemic area (Figure 28).

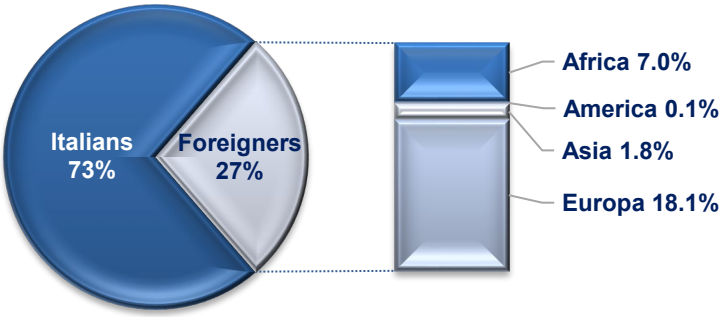


Figure 27. HBV positive donors by nationality (%) (2020)

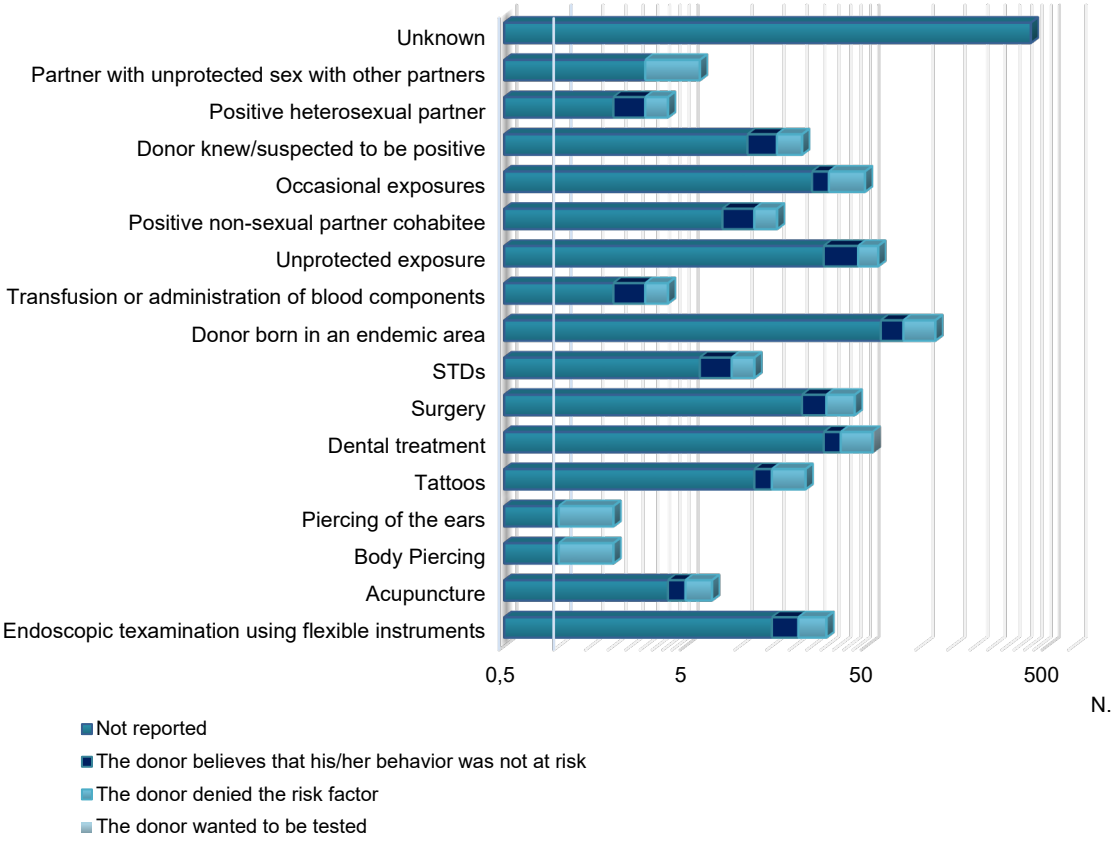


Figure 28. Causes of failed deferral and risk factors detected in HBV positive donors (values reported on a logarithmic scale) (2020)

Table 51 shows the distribution of HBV positive donors by geographical area of birth.

Table 51. HBV infections by geographical area of birth (2020)

Geographical area of birth	N. of infections
Africa	45
America	1
Asia	12
Europe	115
Italy	462
Total	**635**

Moreover, in most cases (323/635), the molecular (NAT), serological and confirmatory tests were positive; in 249 cases the infection was detected exclusively by means of the NAT test (NAT only); in 61 cases the infection was detected exclusively by means of the serological and confirmatory tests (Table 52).

Table 52. Number of HBV infections obtained from different combinations of the results of individual molecular and serological tests (2020)

Combinations of results			N. of infections
NAT	SER	CONF	
+	+	+	323
+	-	-	249
+	-	+	2
-	+	+	12
ND*	+	+	49
Total			**635**

*NAT unavailable because prospective donors only underwent serological screening tests

TP surveillance data

Table 53 reports the number of TP positive donors and the incidence and prevalence by Italian Region and in Italy.

In Italy, in 2020, 531 TP infections were reported, with a prevalence of 96.2 infections per 100,000 FT donors and an incidence of 9.3 infections per 100,000 RT donors.

The highest number of TP infections was found in the Campania Region (87).

The Region with the highest prevalence was Emilia Romagna (143.3), while the Region with the highest incidence was Apulia (21.6).

Figure 29 shows the distribution, expressed as a percentage, of the TP positive donors by nationality; 21% of all positive donors were foreigners.

Table 54 shows the distribution of TP positive donors by geographical area of birth.

In about 50% of the TP positive donors (267/531) it was not possible to identify the risk factor. The highest percentages relative to the “not reported” data mainly concern occasional exposures. In 158 cases the donor denied the risk factor, especially occasional exposures (Figure 30).

Except for one case (negative screening test and positive confirmatory test), both screening and confirmatory tests were positive (Table 55).

Table 53. Number, prevalence and incidence of TP infections per 100,000 donors at national and regional level (2020)

Region/AP	TP infections		
	N.	Prevalence	Incidence
Aosta Valley	0	0.0	0.0
Piedmont	25	90.4	8.5
Liguria	16	112.4	5.5
Lombardy	55	74.7	7.5
AP of Trento	2	0.0	11.4
AP of Bolzano	3	69.4	13.1
Friuli Venezia Giulia	9	28.4	16.1
Veneto	17	36.4	4.7
Emilia Romagna	50	143.3	7.2
Tuscany	43	96.5	12.6
Umbria	5	67.1	4.8
Marche	14	120.0	4.4
Latium	82	131.6	10.5
Sardinia	19	87.3	13.2
Abruzzo	2	16.8	3.1
Campania	87	111.5	13.5
Molise	0	0.0	0.0
Apulia	51	127.0	21.6
Basilicata	1	46.4	0.0
Calabria	16	135.5	10.4
Sicily	34	67.6	9.1
Armed Forces	0	0.0	0.0
Italy	**531**	**96.2**	**9.3**

AP Autonomous Provinces

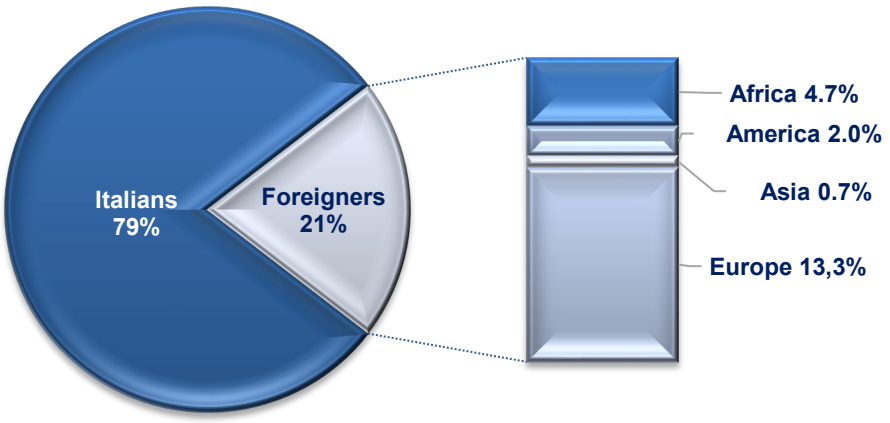


Figure 29. Distribution of TP positive donors by nationality (%) (2020)

Table 54. Number of TP infections by geographical area of birth (2020)

Geographical area of birth	N. of infections
Africa	25
America	11
Asia	4
Europe	71
Italy	420
Total	**531**

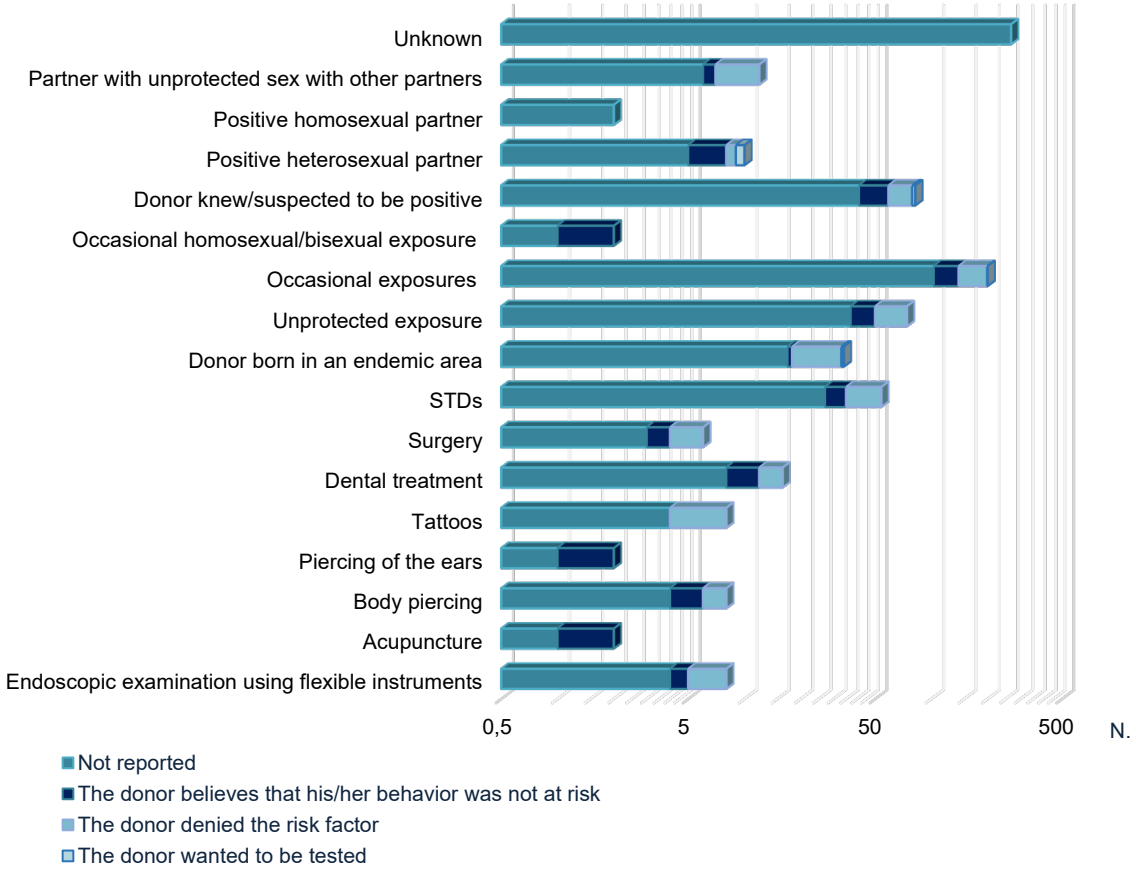


Figure 30. Causes of failed deferral and risk factors detected in TP positive donors (values reported on a logarithmic scale) (2020)

Table 55. Number of TP infections obtained from individual serological test (2020)

Results		N. of infections
SER	CONF	
+	+	530
-	+	1
Total		**531**

Coinfections

In this chapter, the authors want to provide more accurate epidemiological data on coinfection notifications regarding blood donors for the year 2020.

Figure 31 shows the number of coinfected donors by gender and type of coinfection diagnosed; of the 11 coinfections notified, 7 included TP.

The majority of coinfected donors were males. In particular, the highest number of coinfections was diagnosed in male donors in the 36-45 and 46-55 age brackets (Figure 32).

In 5/11 coinfected donors (HIV/TP, HIV/HCV, HBV/HCV and HCV/TP) it was not possible to trace the reasons for missed deferral and the risk factors are not known.

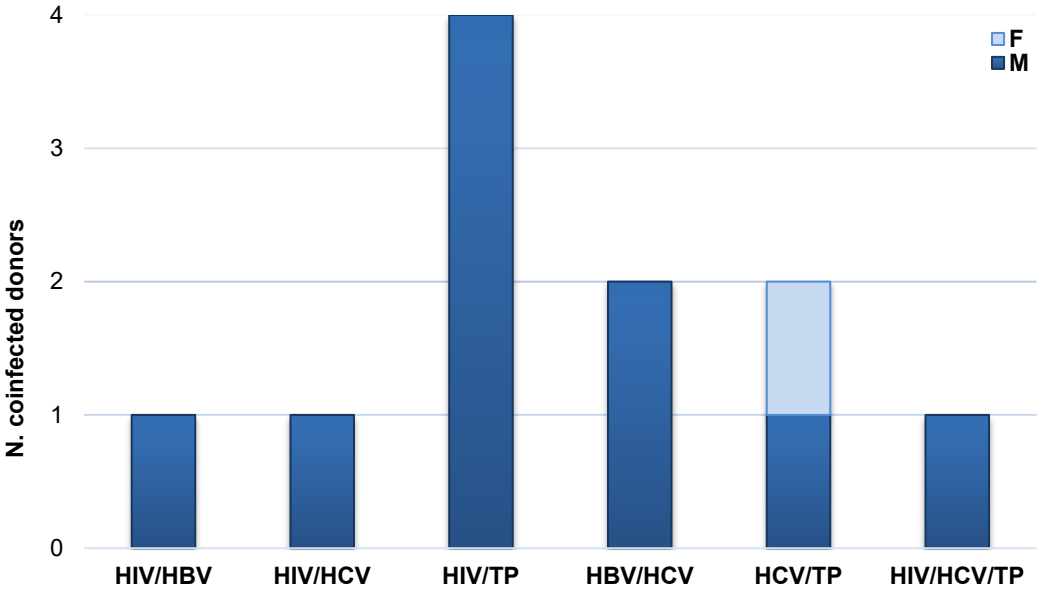


Figure 31. Number of coinfected donors by type of coinfection and by gender (2020)

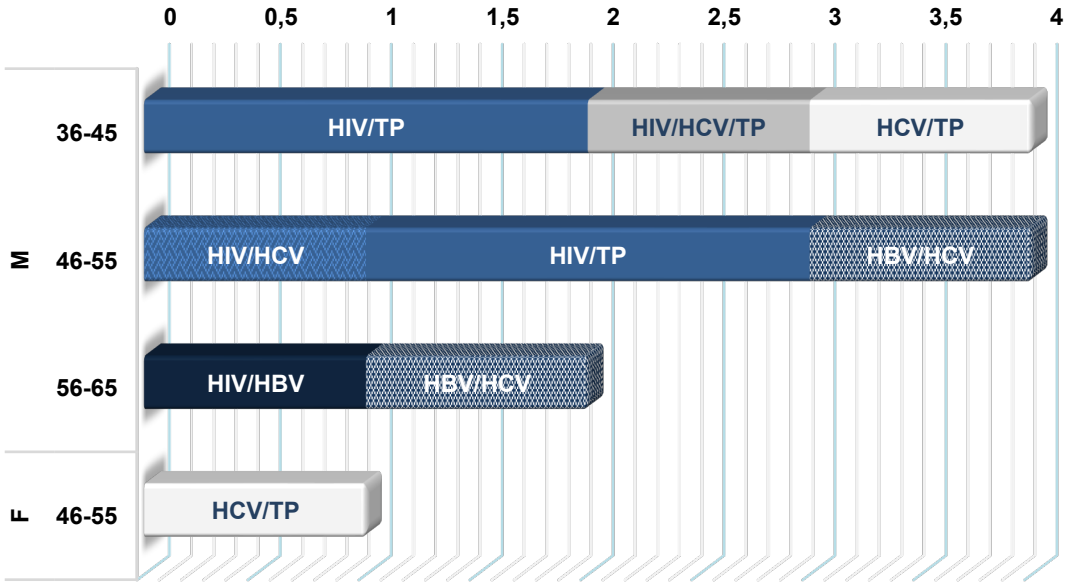


Figure 32. Number of coinfected donors by type of coinfection, age bracket and sex (2020)

For 4 cases of coinfection the risk factors were identified and were generally due to occasional exposures; in the remaining 2 cases the risk factors were identified and were attributed to STDs and dental treatment (Figure 33).

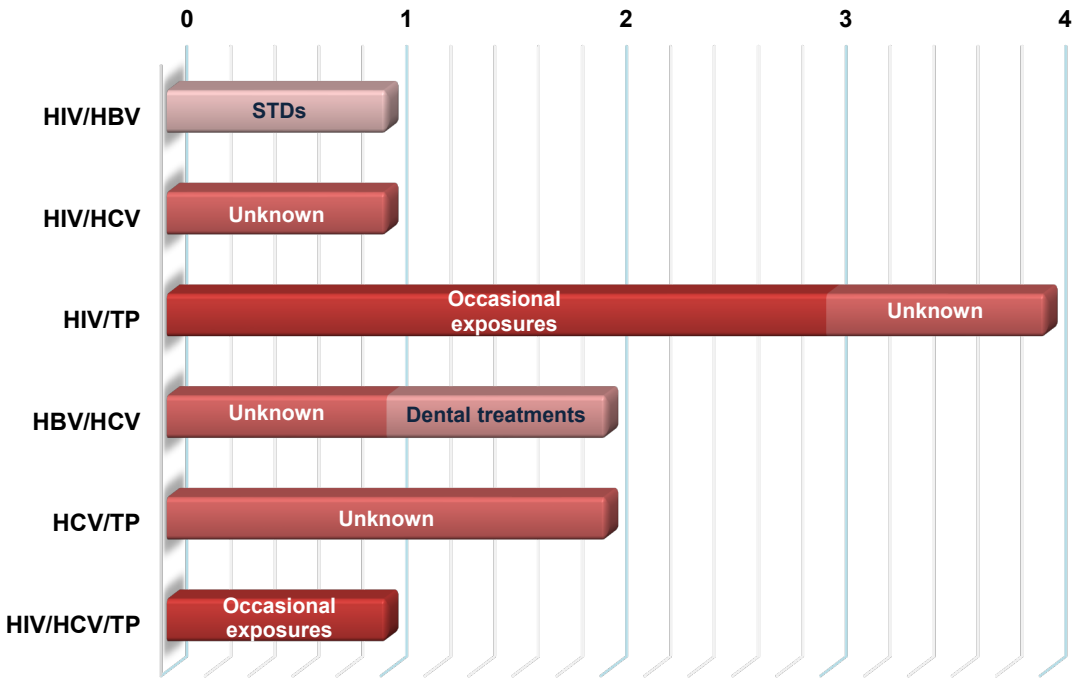


Figure 33. Number of coinfected donors by type of coinfection and risk factor (2020)

Comments and recommendations

As in previous year (6), from the analysis of the notifications received in 2020 it emerged that the number of donors positive to transfusion-transmissible infectious markers varied greatly from one region to another.

About 77% of the positive donors were Italian, while the remaining 23% were foreigners. Most foreign donors who tested positive to infectious markers belonged to the FT category and came from other European countries. It is not possible to do further statistical evaluations on foreign donor epidemiology.

The majority of donors who tested positive to the infectious markers were males (73%) and FT (75.1%).

In general, the highest number of positive donors were in the 46-55 age bracket. From the analysis of the percentage of donors who tested positive to a single infectious marker, it emerged that the distribution of HIV and TP infections were higher in the 26-35- and 36-45-year age brackets, while HBV and HCV infections were higher in the 46-65 and in the 46–55-year age brackets, respectively.

With reference to the prevalence and incidence data, the highest values were reported for HBV, followed by TP.

The analysis on coinfections showed that the majority of coinfected donors were TP positive. About half of the 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 optimize and standardize 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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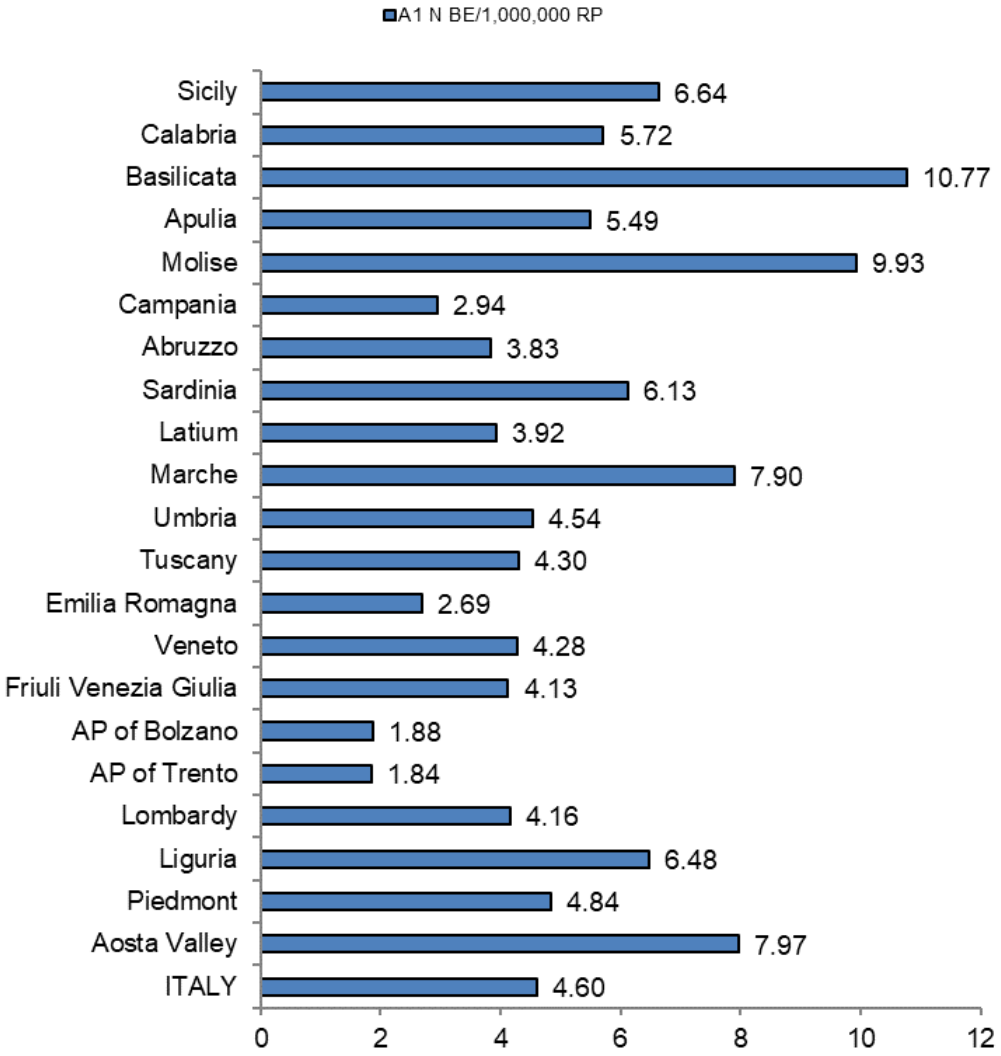
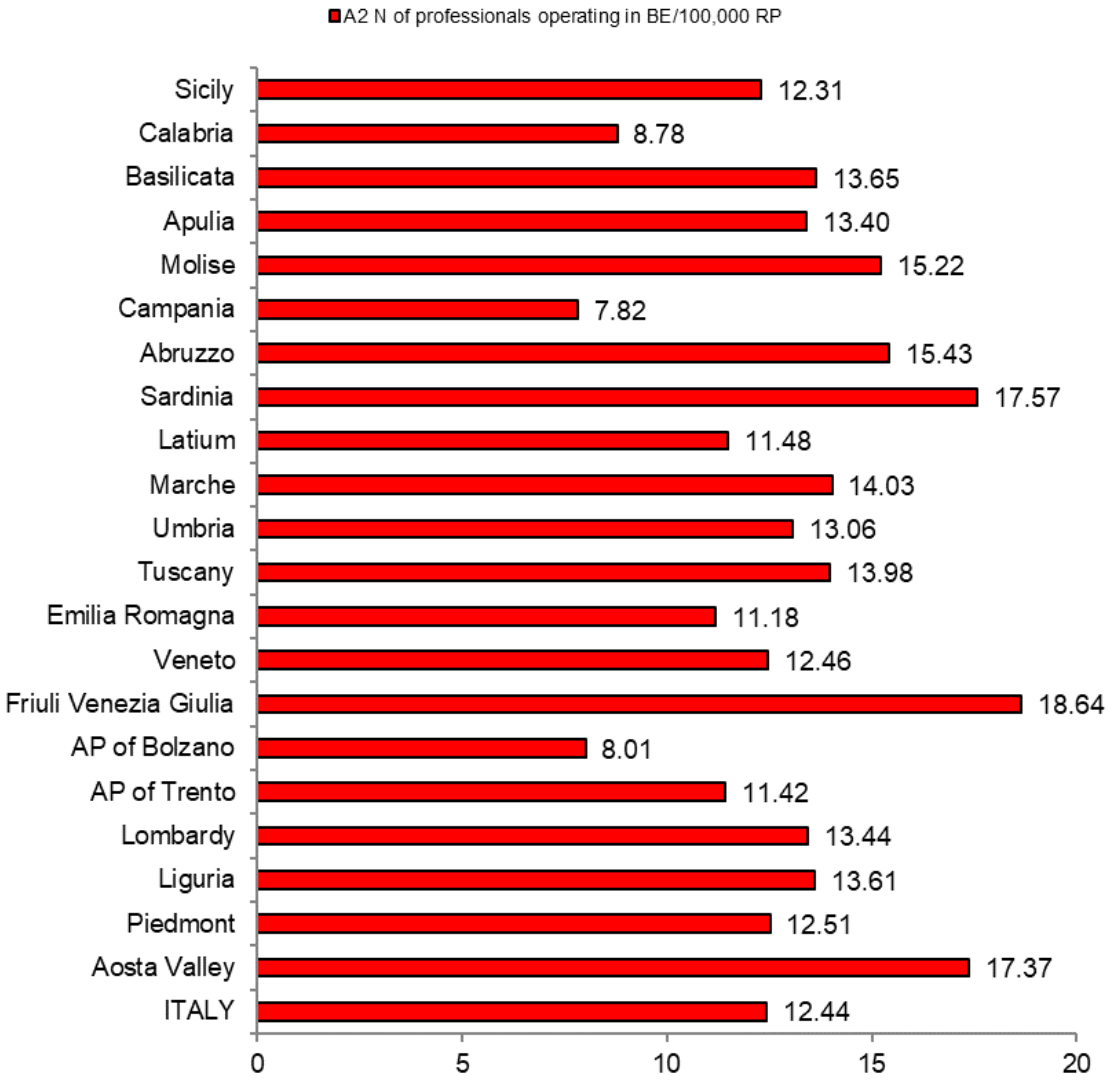
APPENDIX A
Activities of the Italian Blood System
Regional and national indicators (2020): supplemental figures



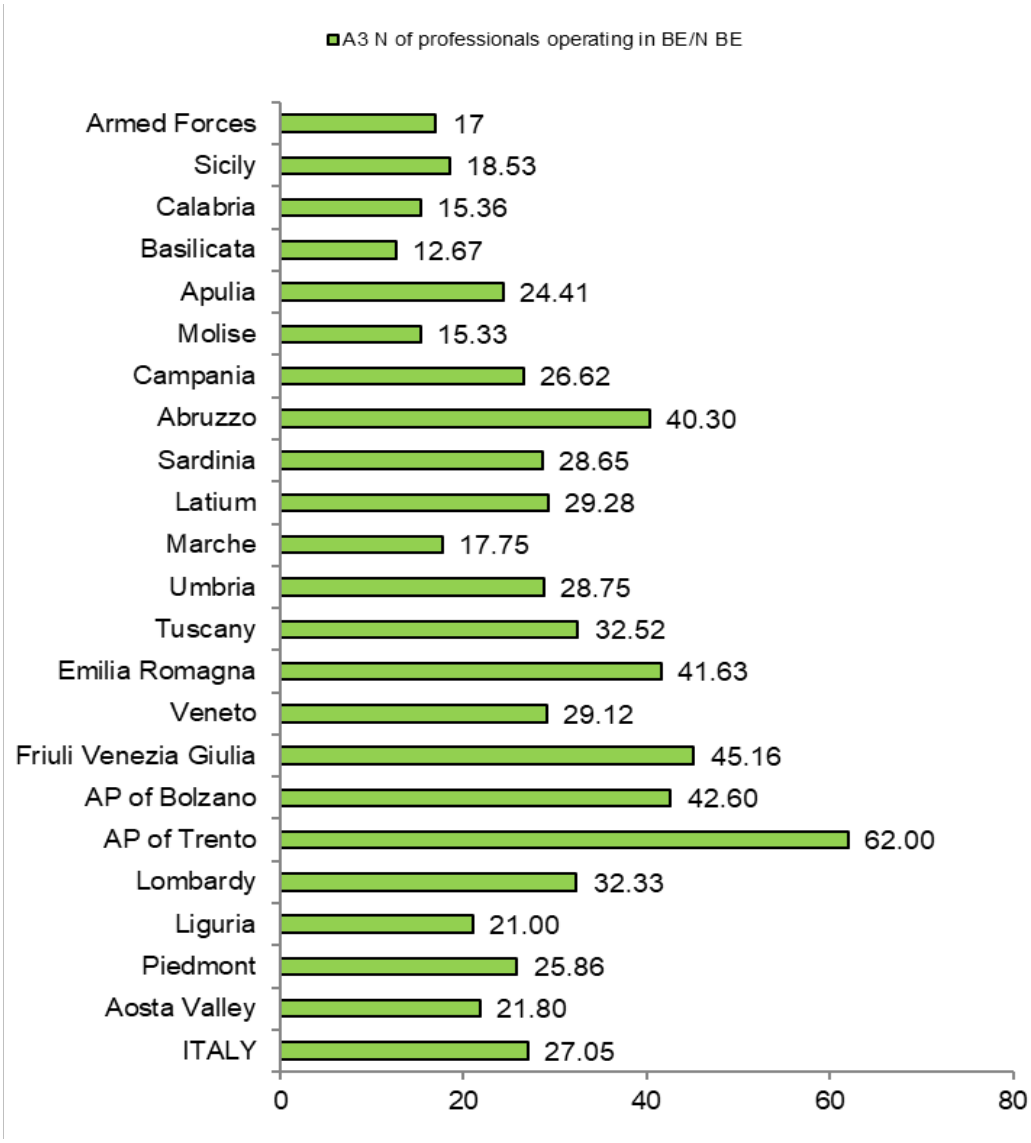
N. number; BE blood establishment/s; RP resident population; AP Autonomous Province

Figure A1. INDICATOR A1: N. of BEs (as stated by ex Art. 2, paragraph 1, letter e of Legislative decree 261/2007) /1,000,000 resident population (2020)



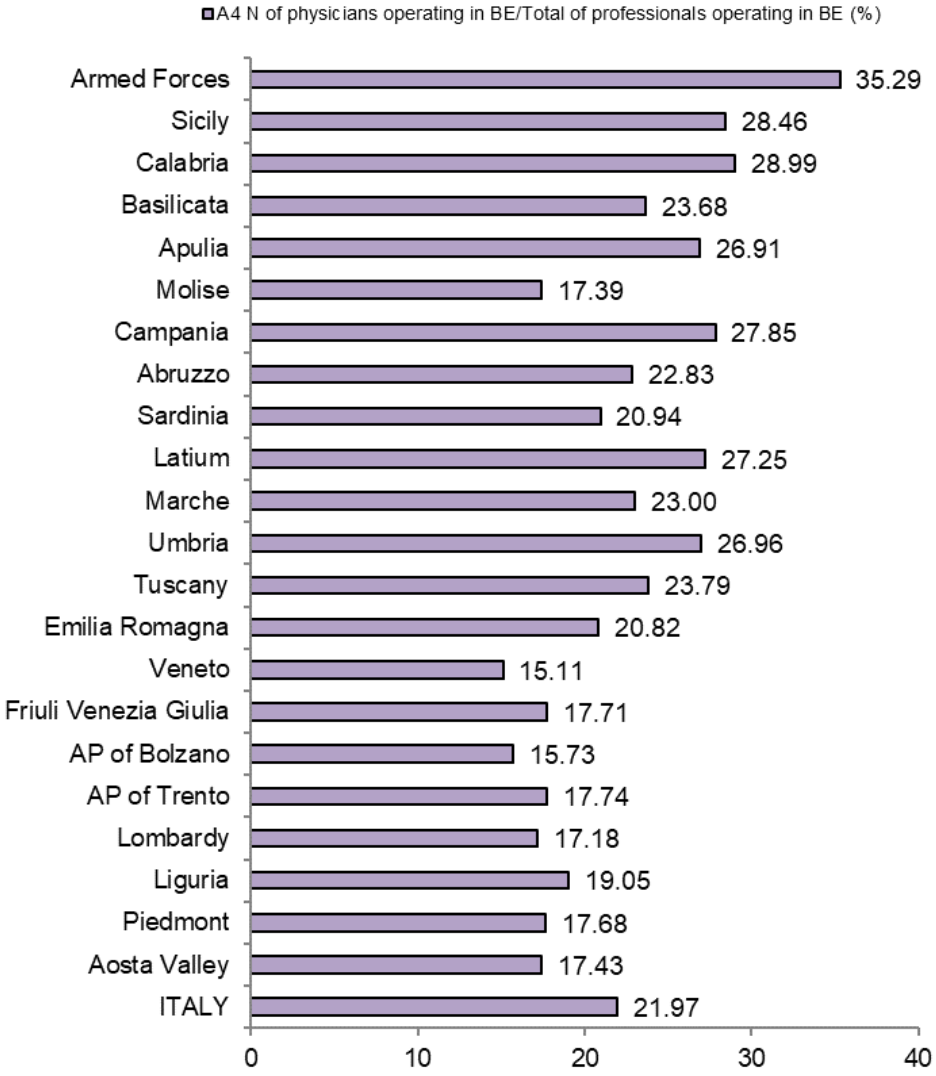
N. number; BE blood establishment/s; RP resident population; AP Autonomous Province

Figure A2. INDICATOR A2: N. of professionals operating in BEs (as stated by ex Art. 2, paragraph 1, letter e of Legislative decree 261/2007) /100,000 resident population (2020)



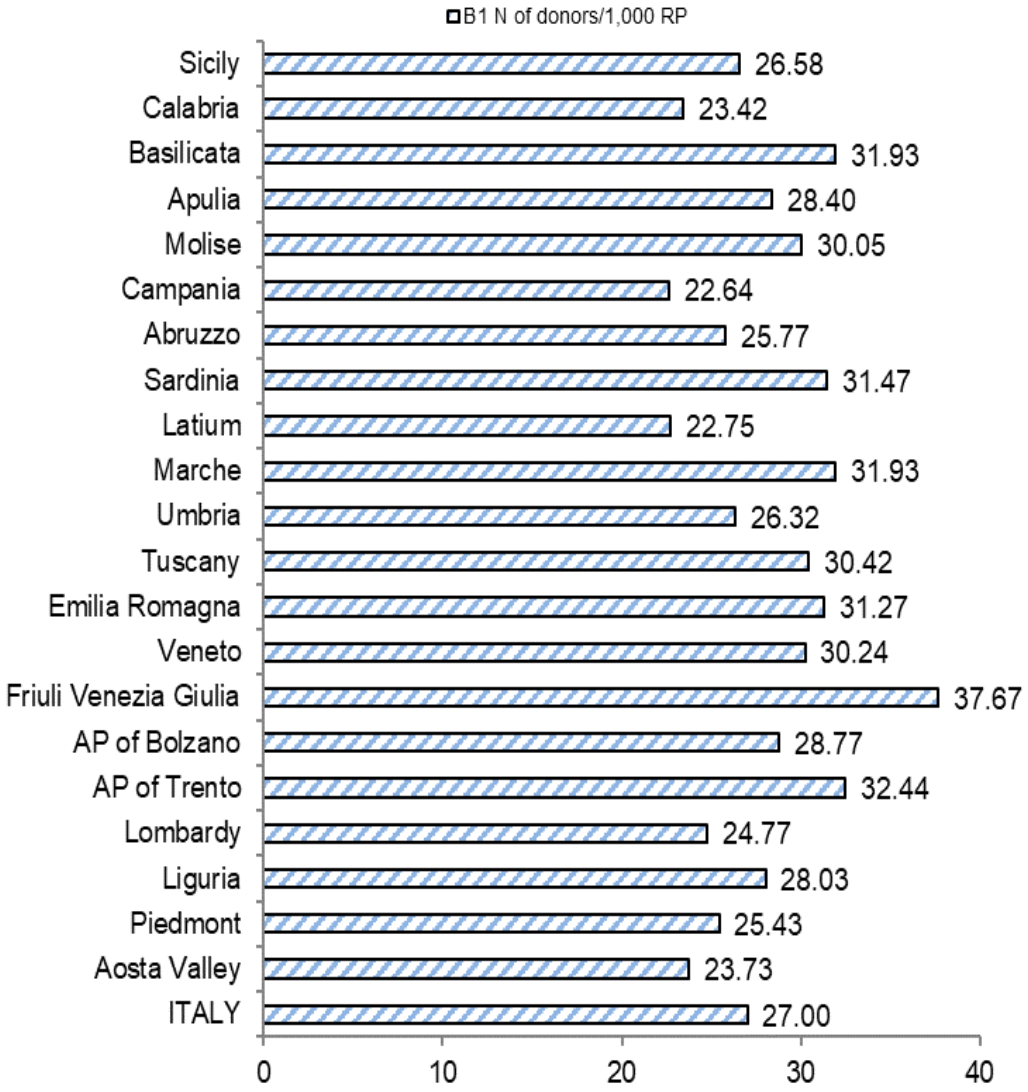
N. number; BE blood establishment/s; AP Autonomous Province

Figure A3. INDICATOR A3: N. of professionals operating in BEs (as stated by ex Art. 2, paragraph 1, letter e of Legislative decree 261/2007)/N. of BE reported in SISTRA (2020)



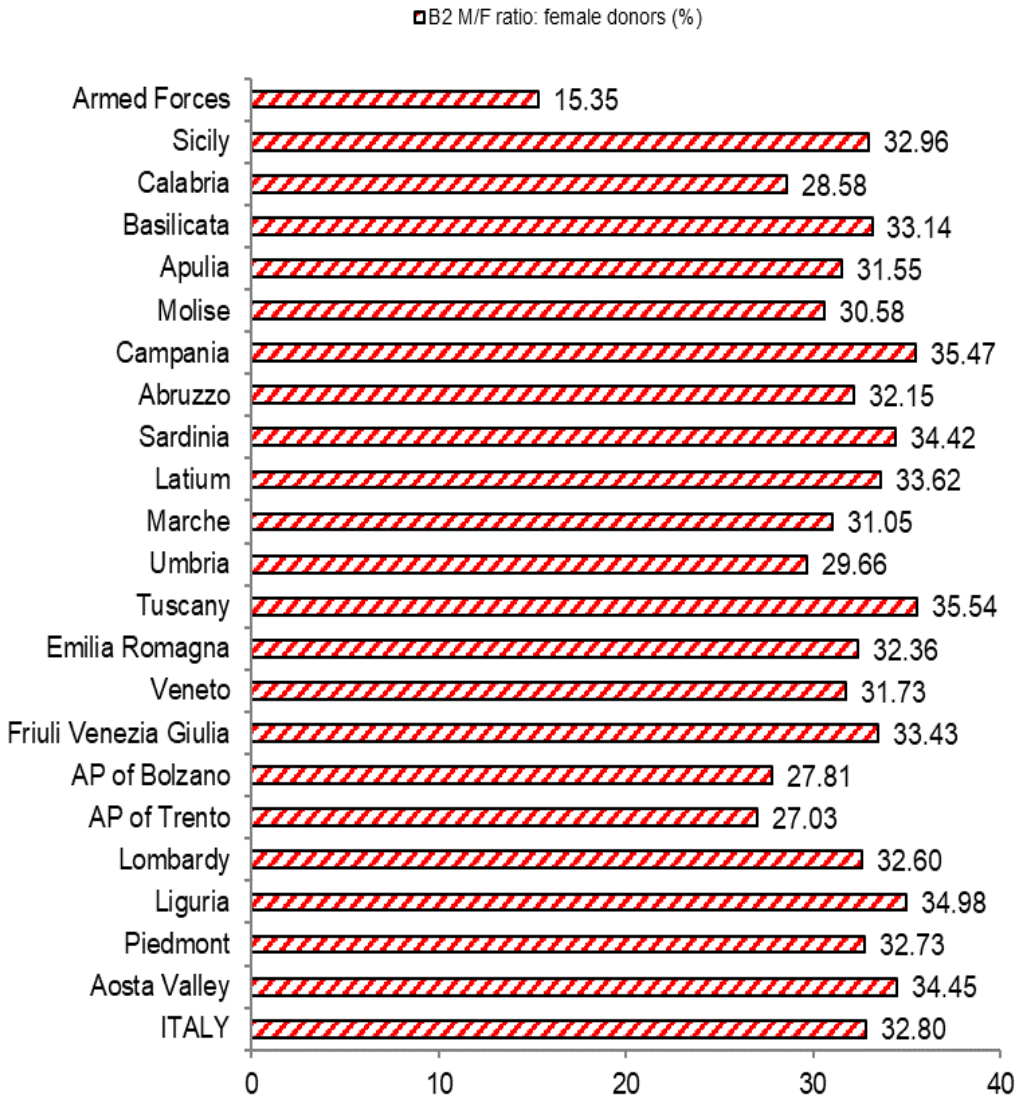
N. number; BE blood establishment/s; AP Autonomous Province

Figure A4. INDICATOR A4: N. of physicians operating in BEs/Total of professionals operating in BEs (%) (excluding physicians operating in BCSs) (2020)



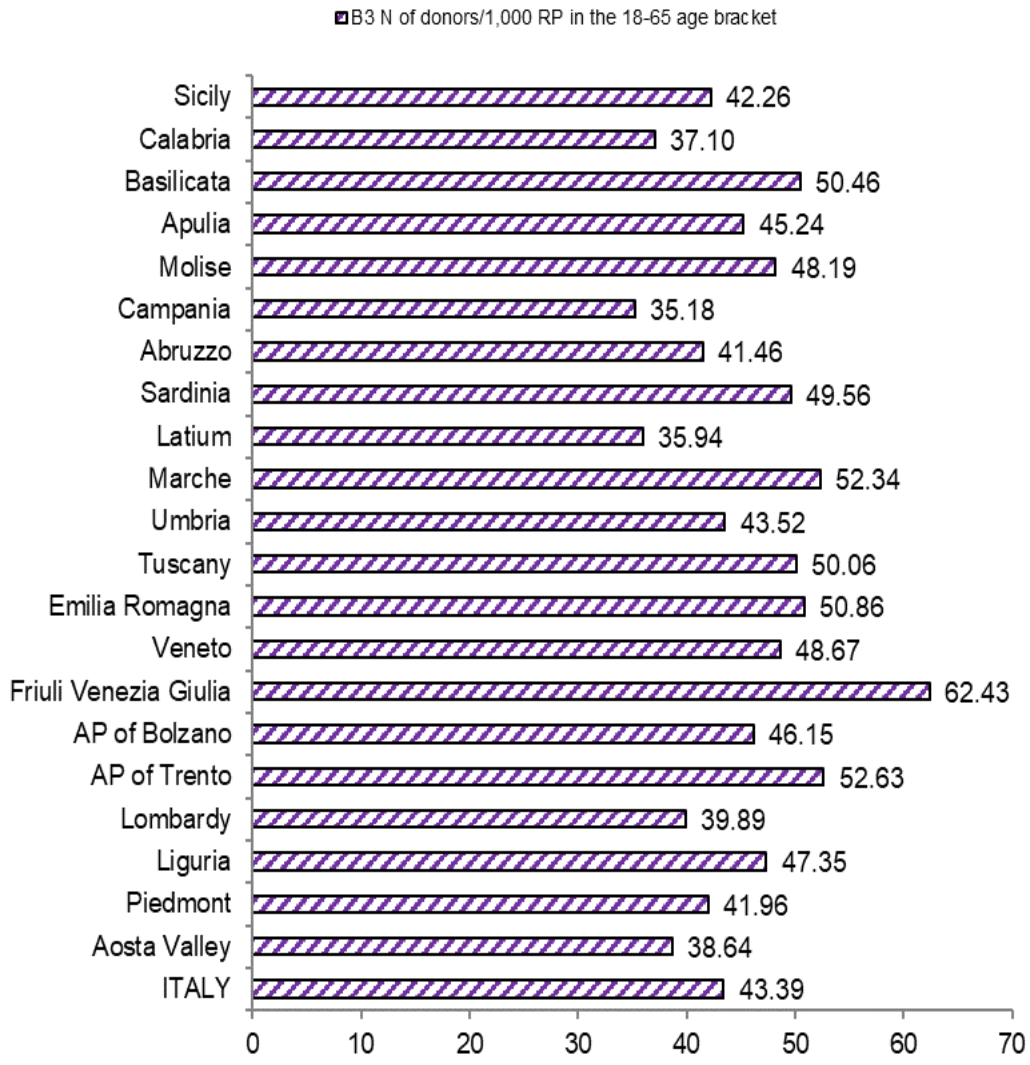
N. number; RP resident population; AP Autonomous Province

Figure A5. INDICATOR B1: Regional blood donors distribution/1,000 resident population (2020)



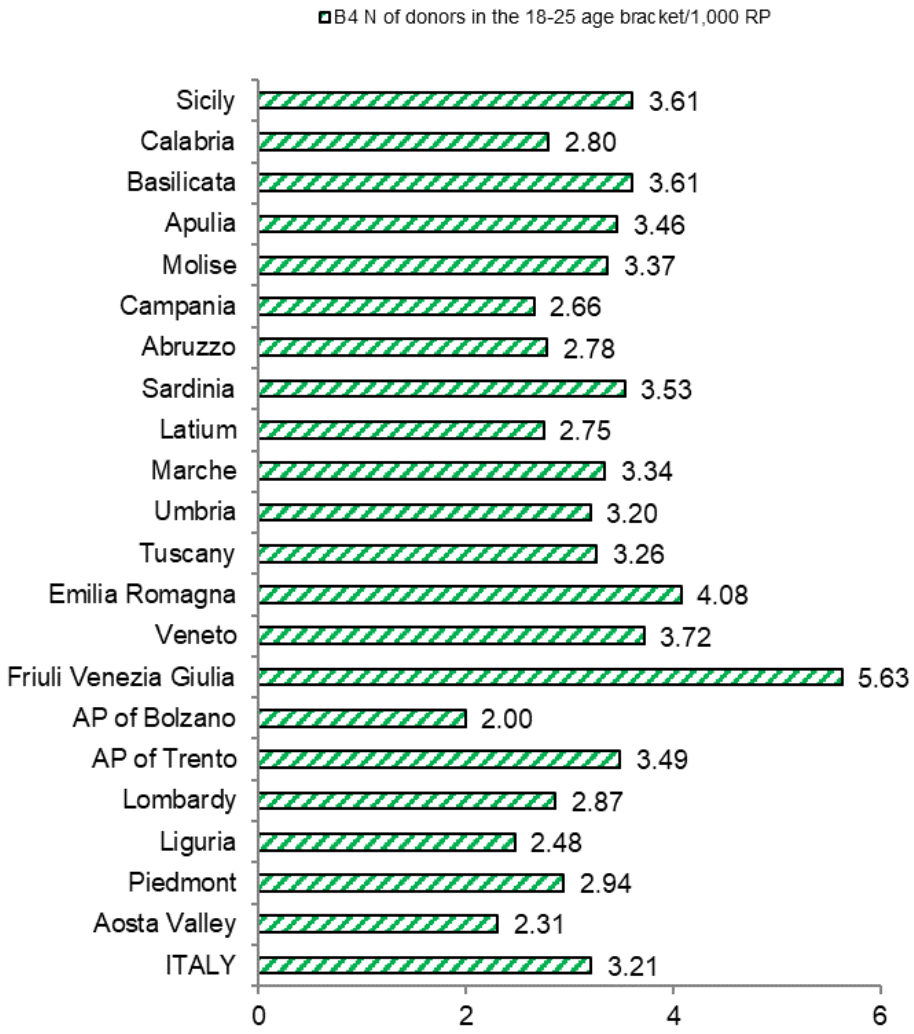
AP Autonomous Province; M male; F Female

Figure A6. INDICATOR B2: M/F ratio, female donors percentage (2020)



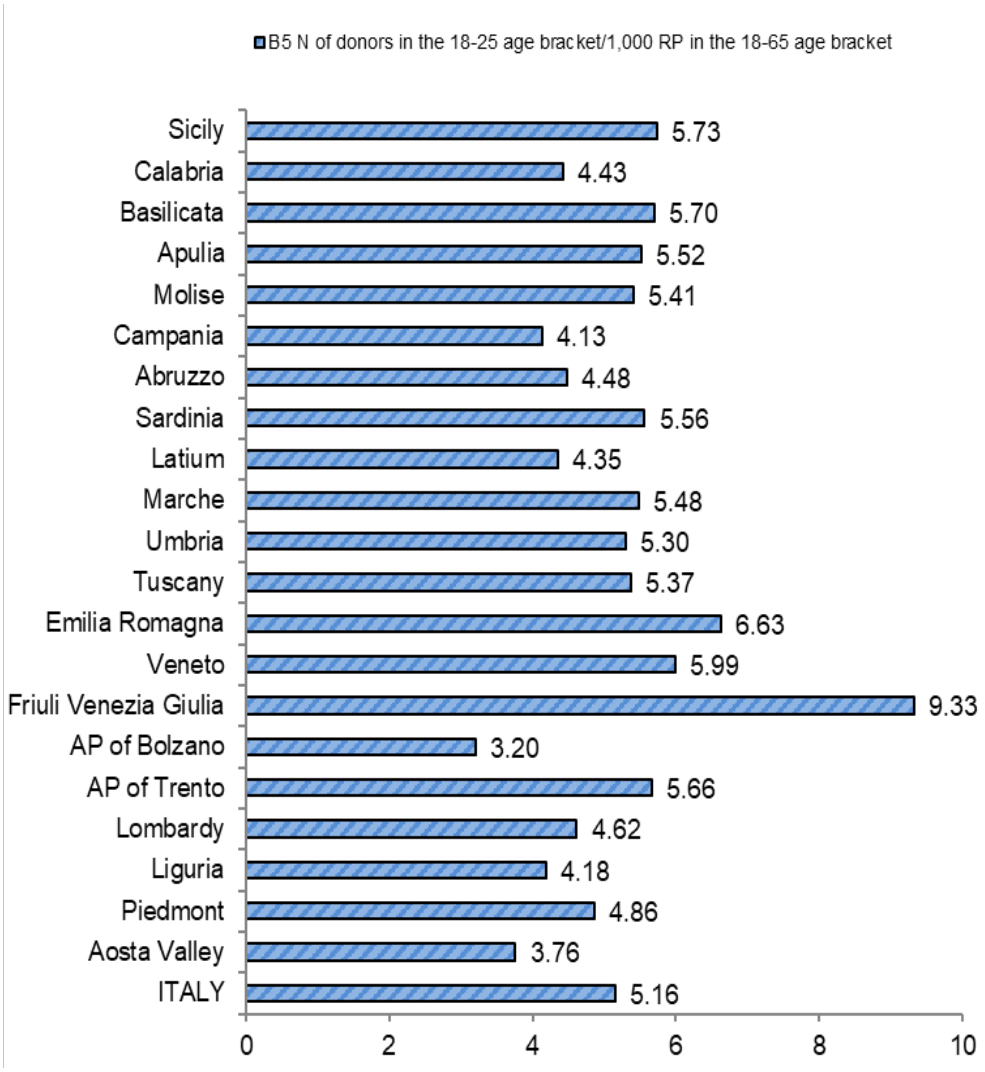
N. number; RP resident population; AP Autonomous Province

Figure A7. INDICATOR B3: N. of donors/1,000 resident population in the 18-65 age bracket (2020)



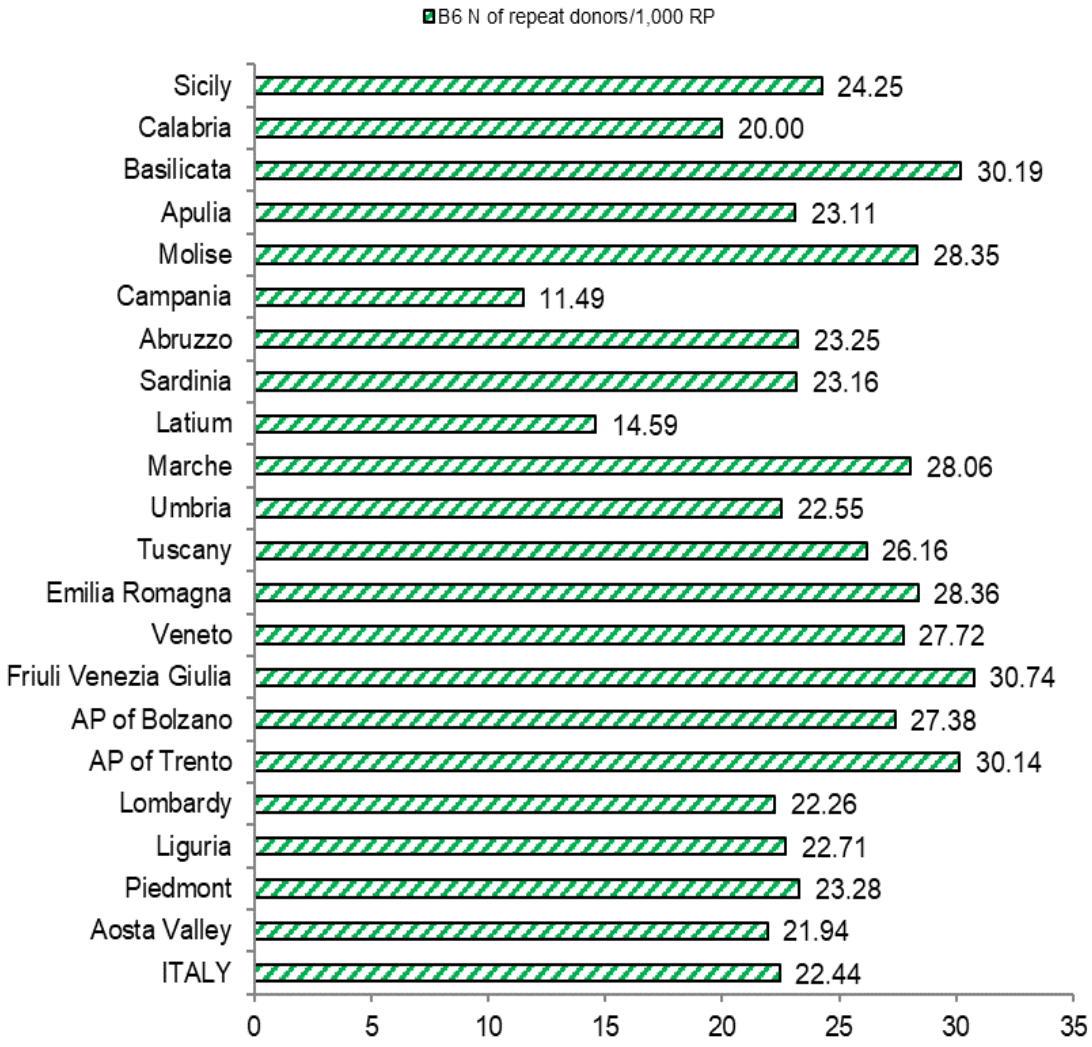
N. number; RP resident population; AP Autonomous Province

Figure A8. INDICATOR B4: N. of donors in the 18-25 age bracket/1,000 resident population (2020)



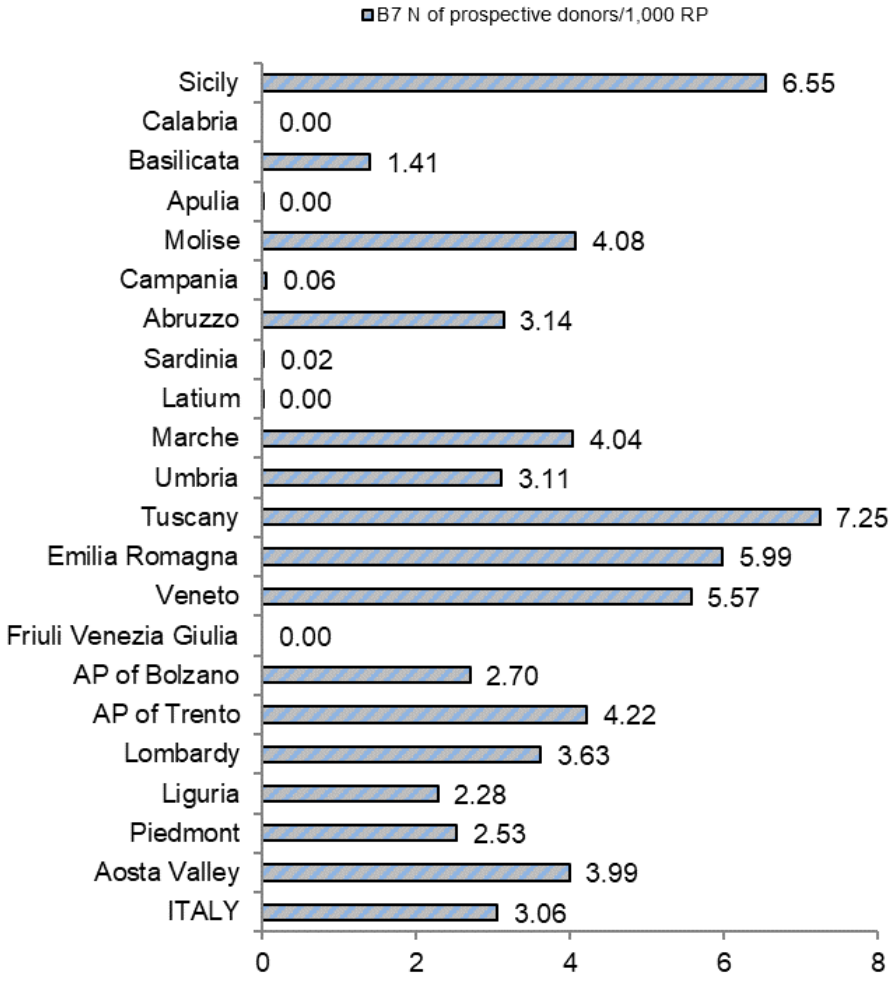
N. number; RP resident population; AP Autonomous Province

Figure A9. INDICATOR B5: N. of donors in the 18-25 age bracket/1,000 resident population in the 18-65 age bracket (2020)



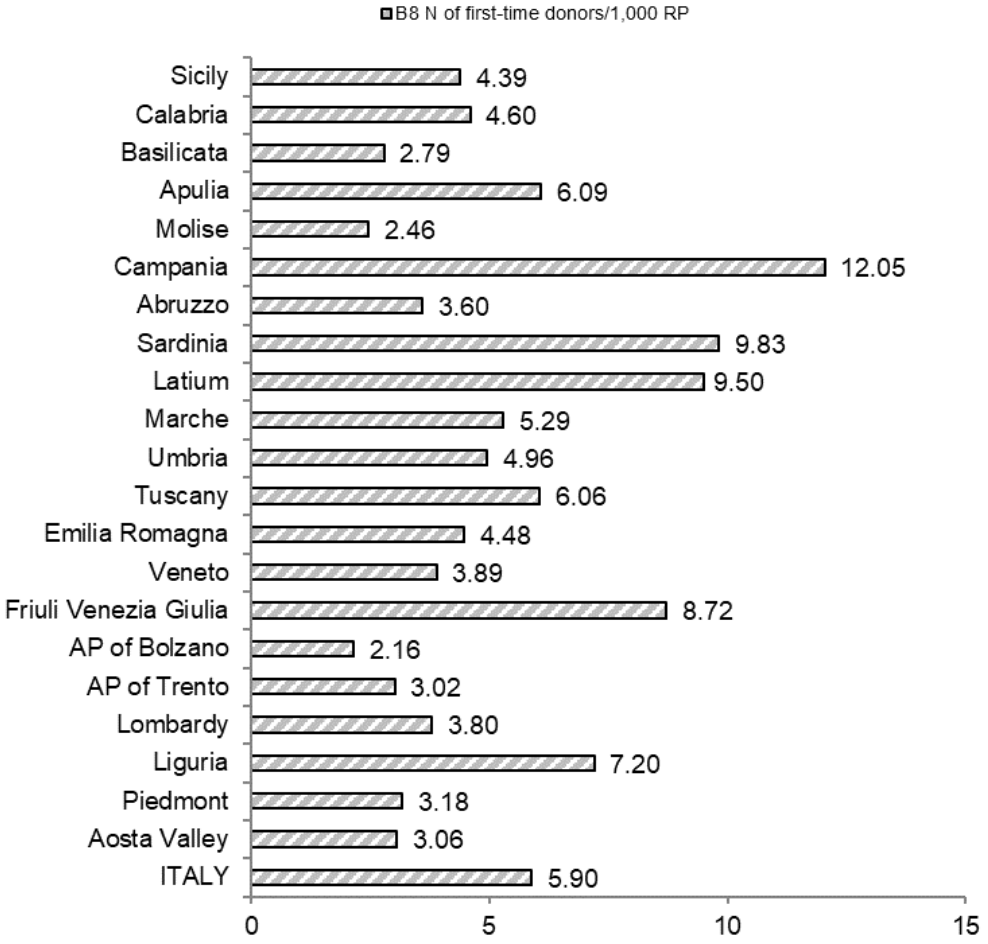
N. number; RP resident population; AP Autonomous Province

Figure A10. INDICATOR B6: N. of repeat donors/1,000 resident population (2020)



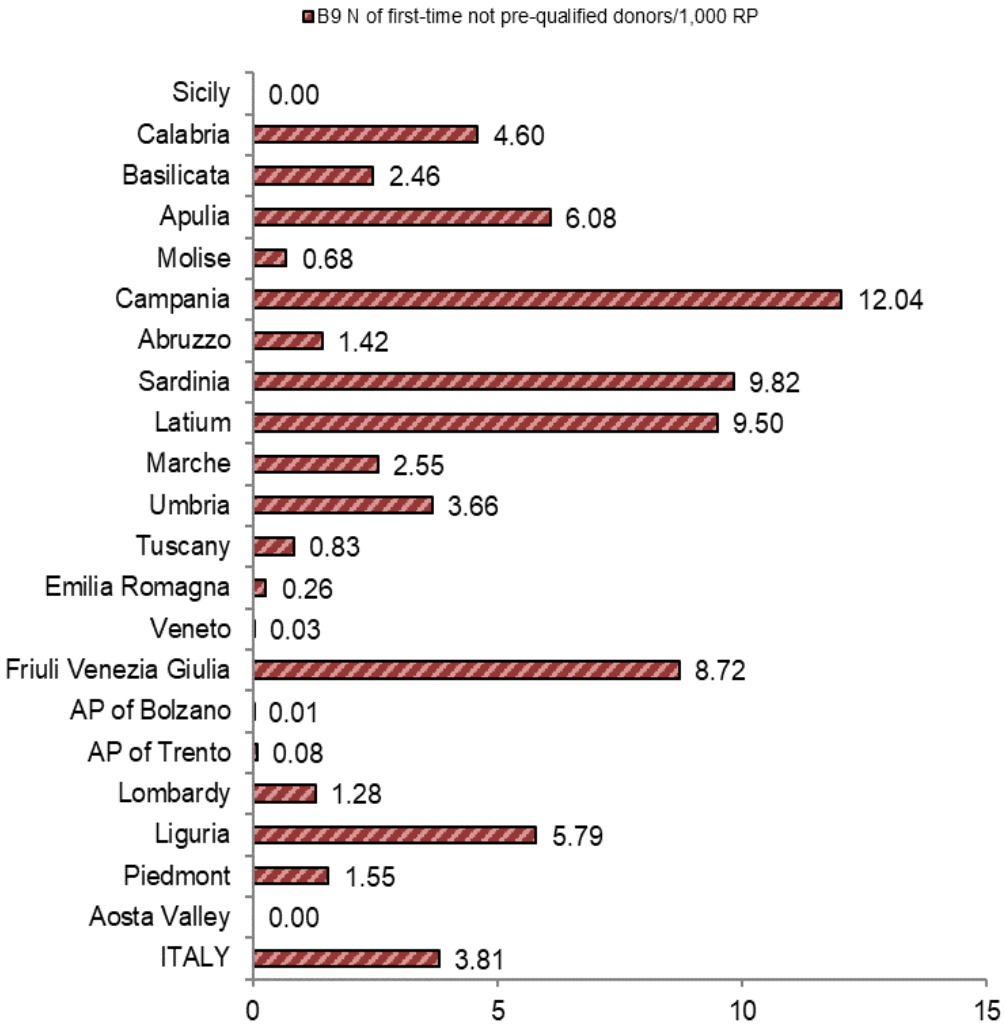
N. number; RP resident population; AP Autonomous Province

Figure A11. INDICATOR B7: N. of prospective donors/1,000 resident population (2020)



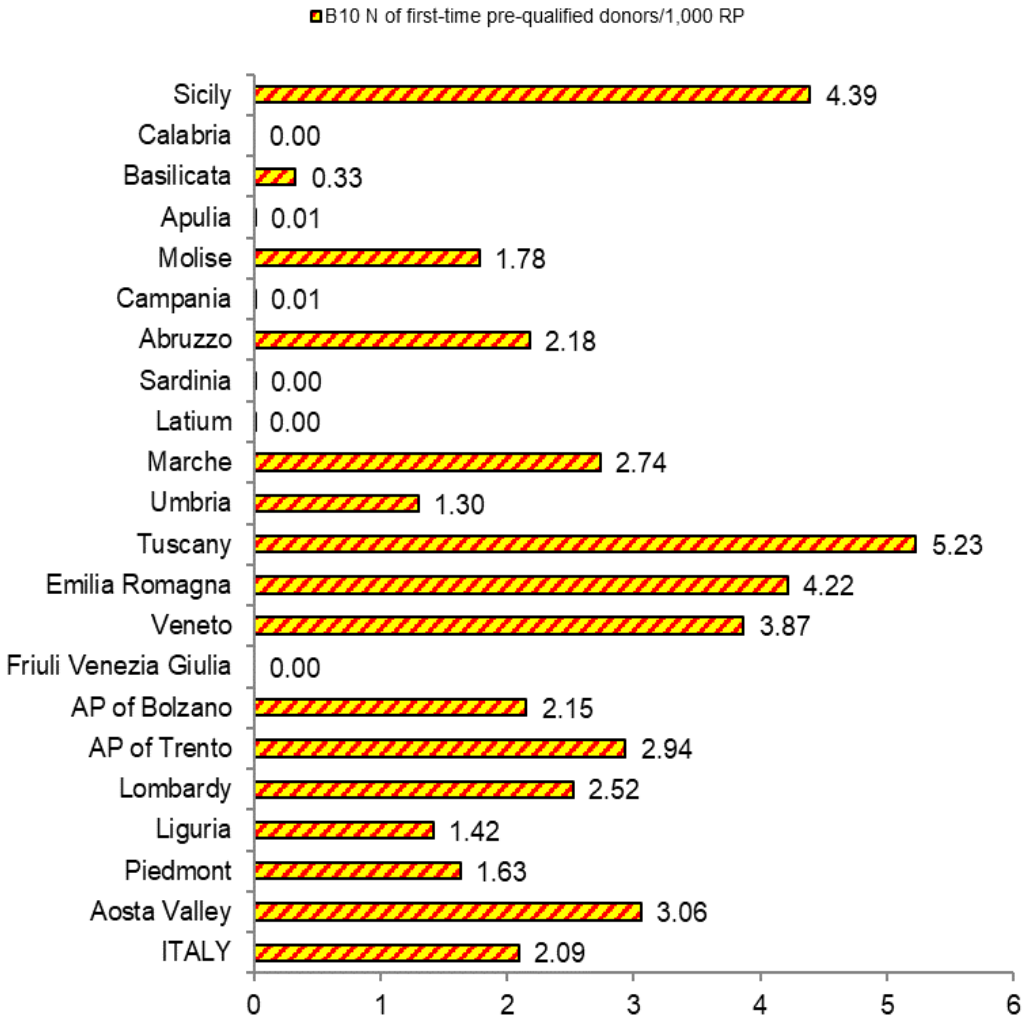
N. number; RP resident population; AP Autonomous Province

Figure A12. INDICATOR B8: N. of first-time donors/1,000 resident population (2020)



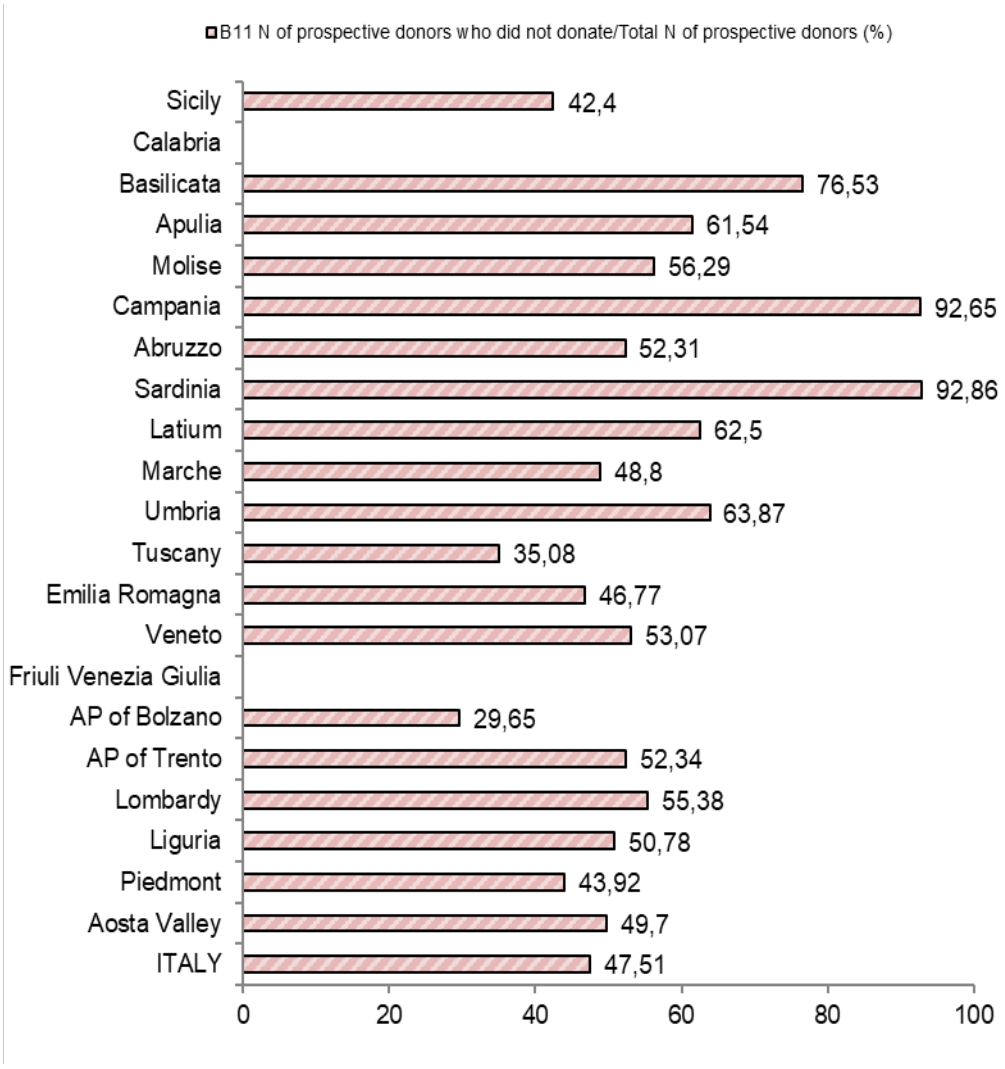
N. number; RP resident population; AP Autonomous Province

Figure A13. INDICATOR B9: N. of first-time not pre-qualified donors/1,000 resident population (2020)



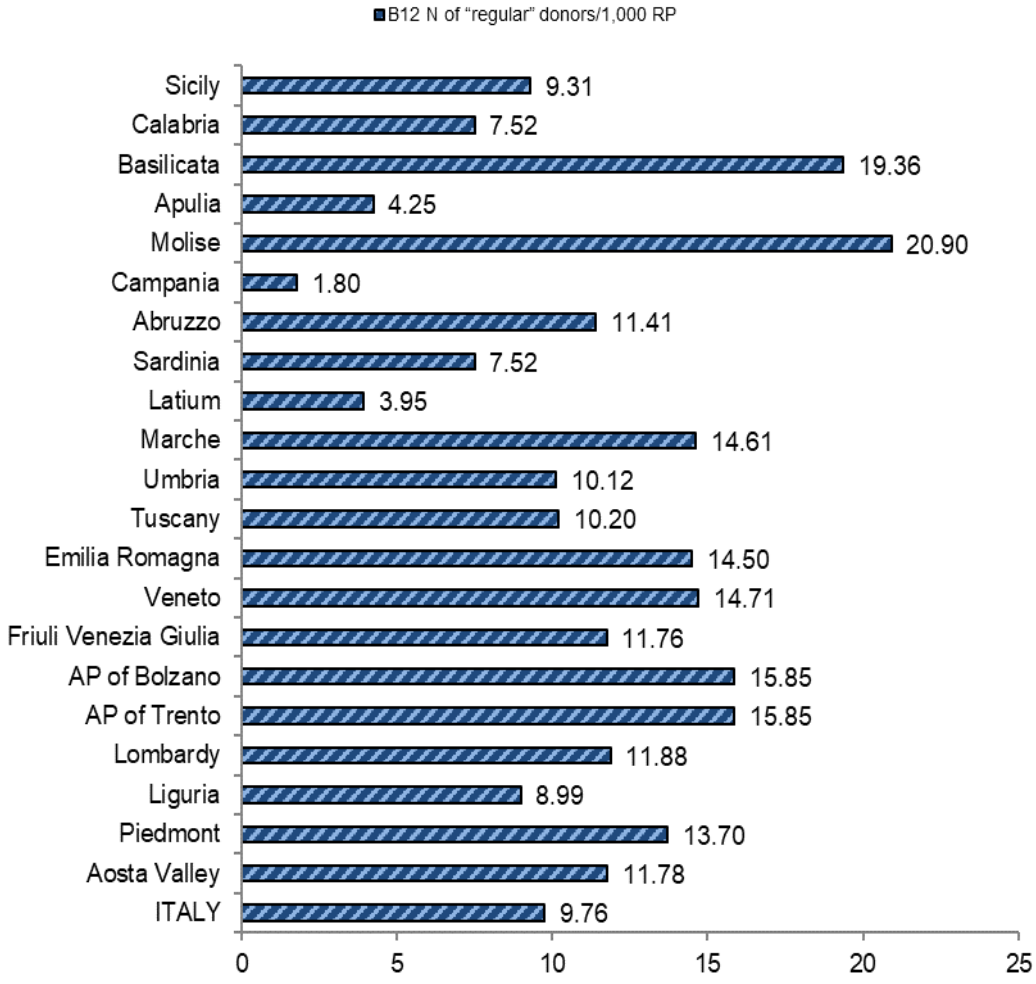
N. number; RP resident population; AP Autonomous Province

Figure A14. INDICATOR B10: N. of first-time pre-qualified donors/1,000 resident population (2020)



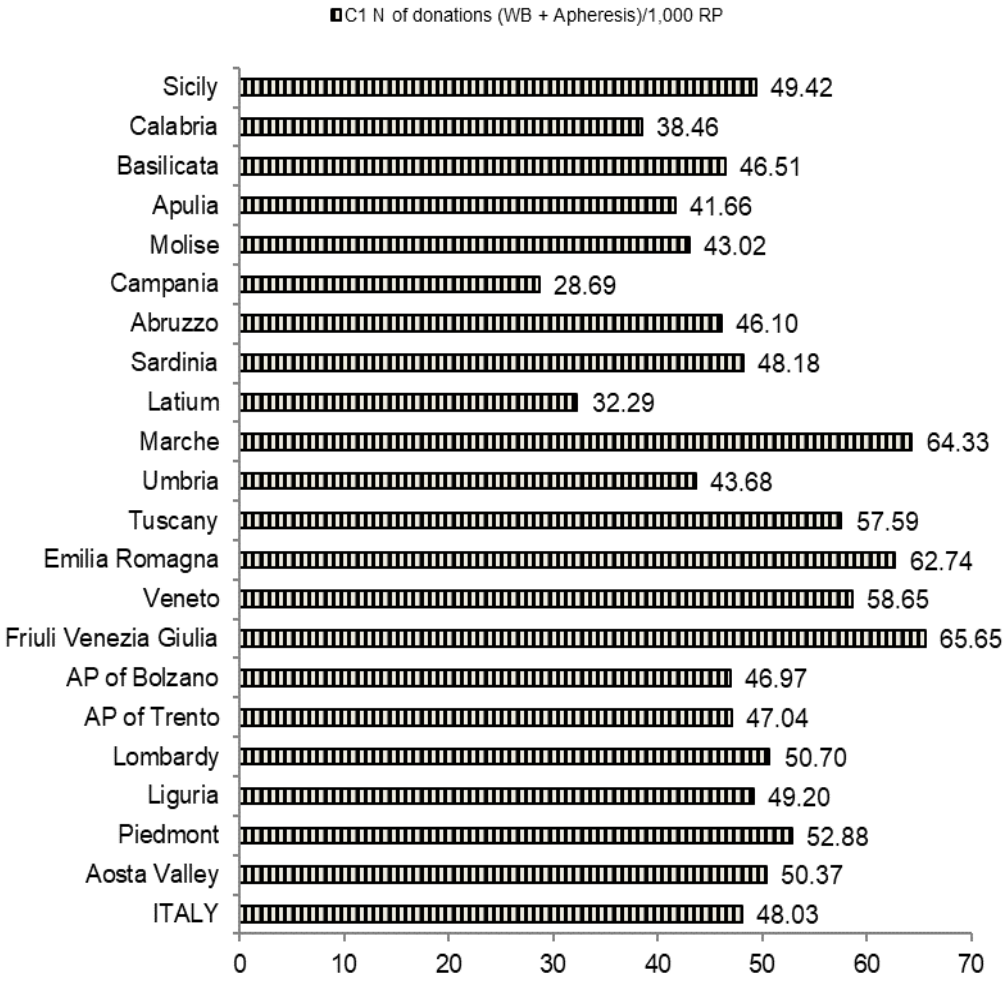
N. number; AP Autonomous Province

Figure A15. INDICATOR B11: N. of prospective donors who did not donate/Total N. of prospective donors (%) (2020)



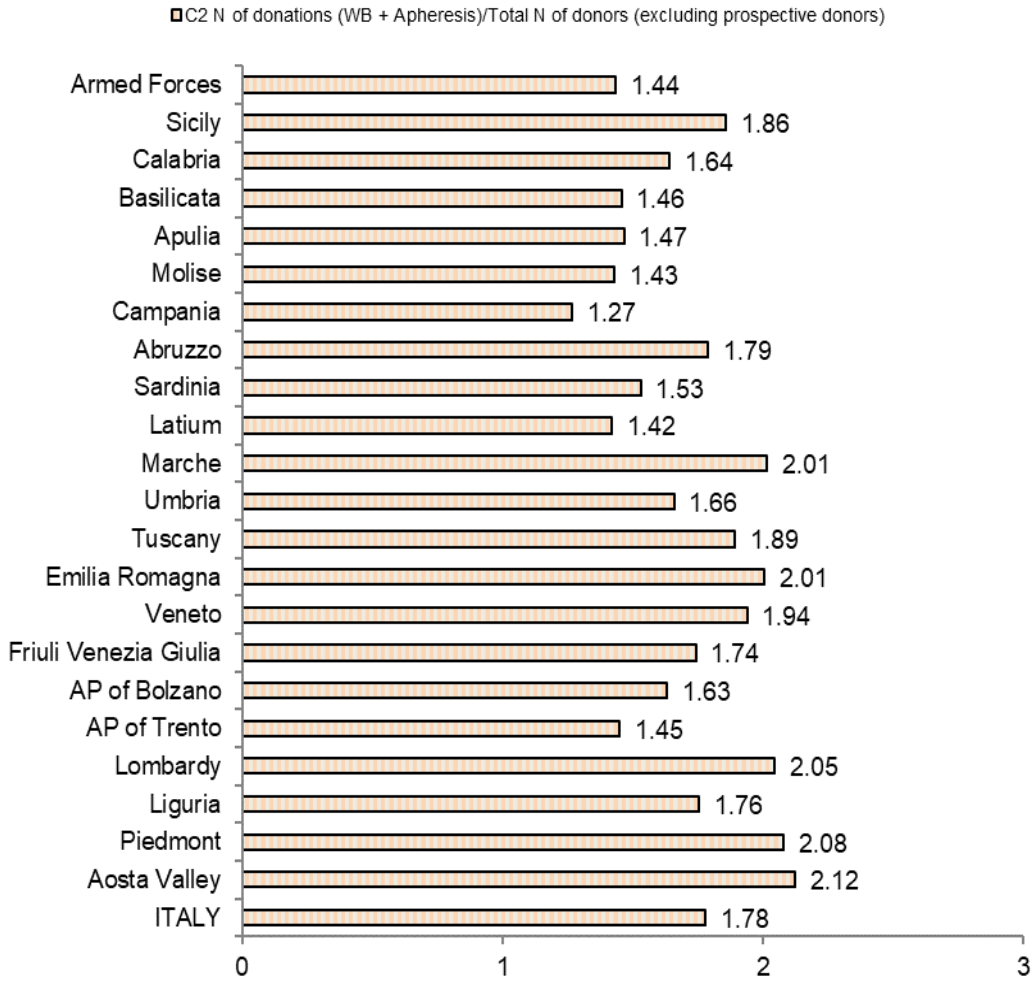
N. number; RP resident population; AP Autonomous Province

Figure A16. INDICATOR B12: N. of "regular" donors/1,000 resident population (2020)



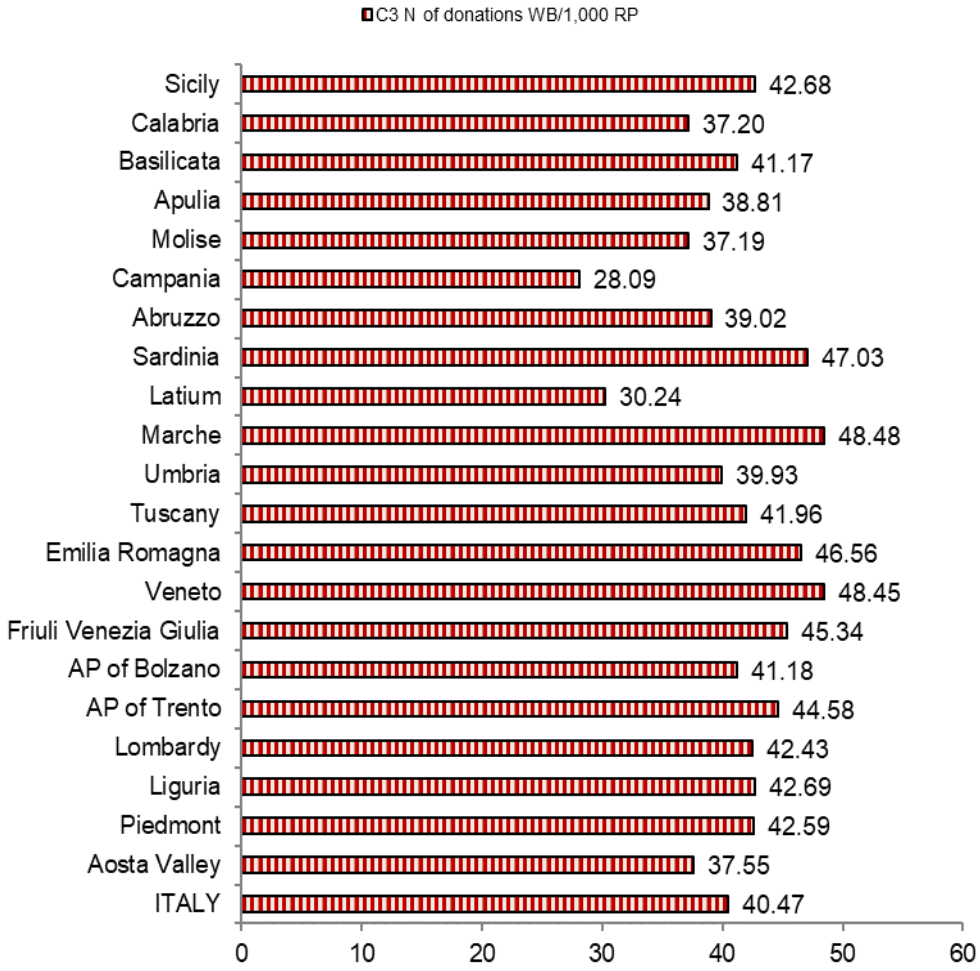
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A17. INDICATOR C1: N. of whole blood and apheresis donations/1,000 resident population (2020)



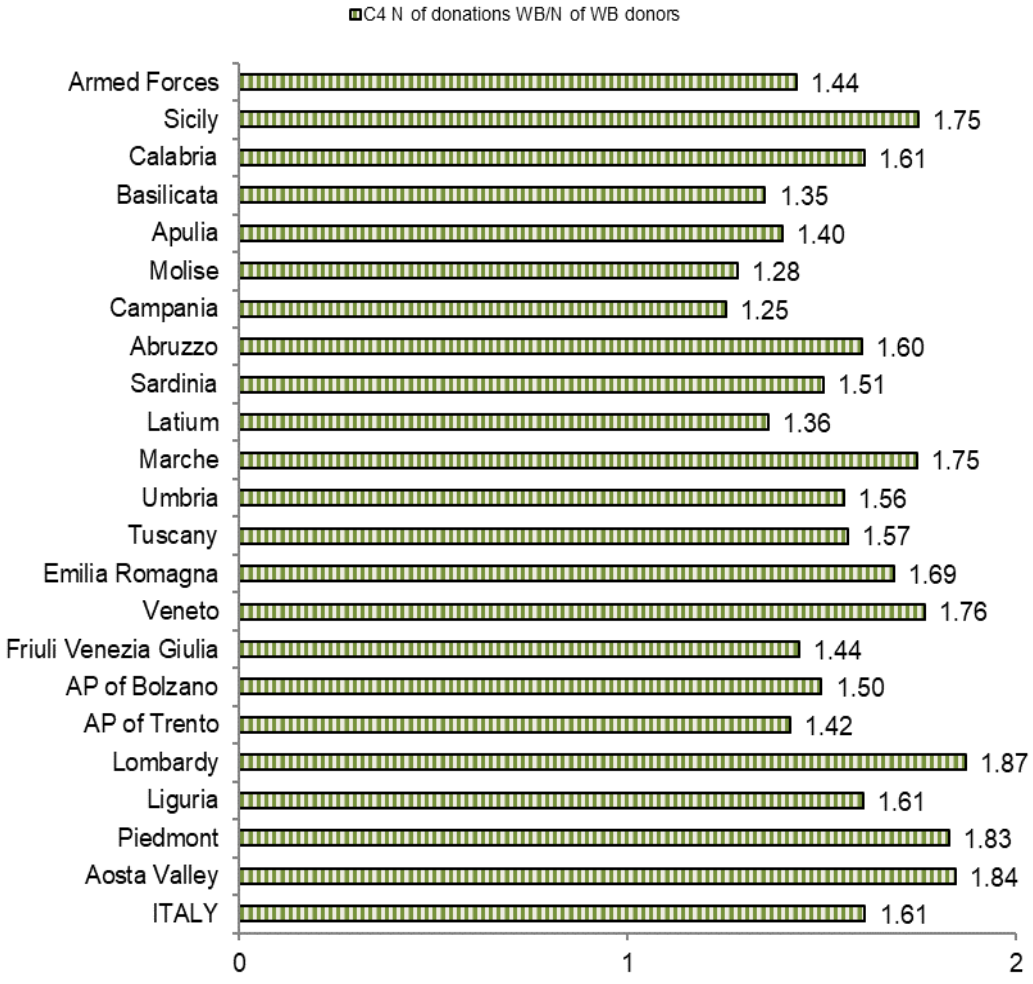
N. number; AP Autonomous Province; WB whole blood

Figure A18. INDICATOR C2: N. of whole blood and apheresis donations/Total N. of donors (excluding prospective donors) (2020)



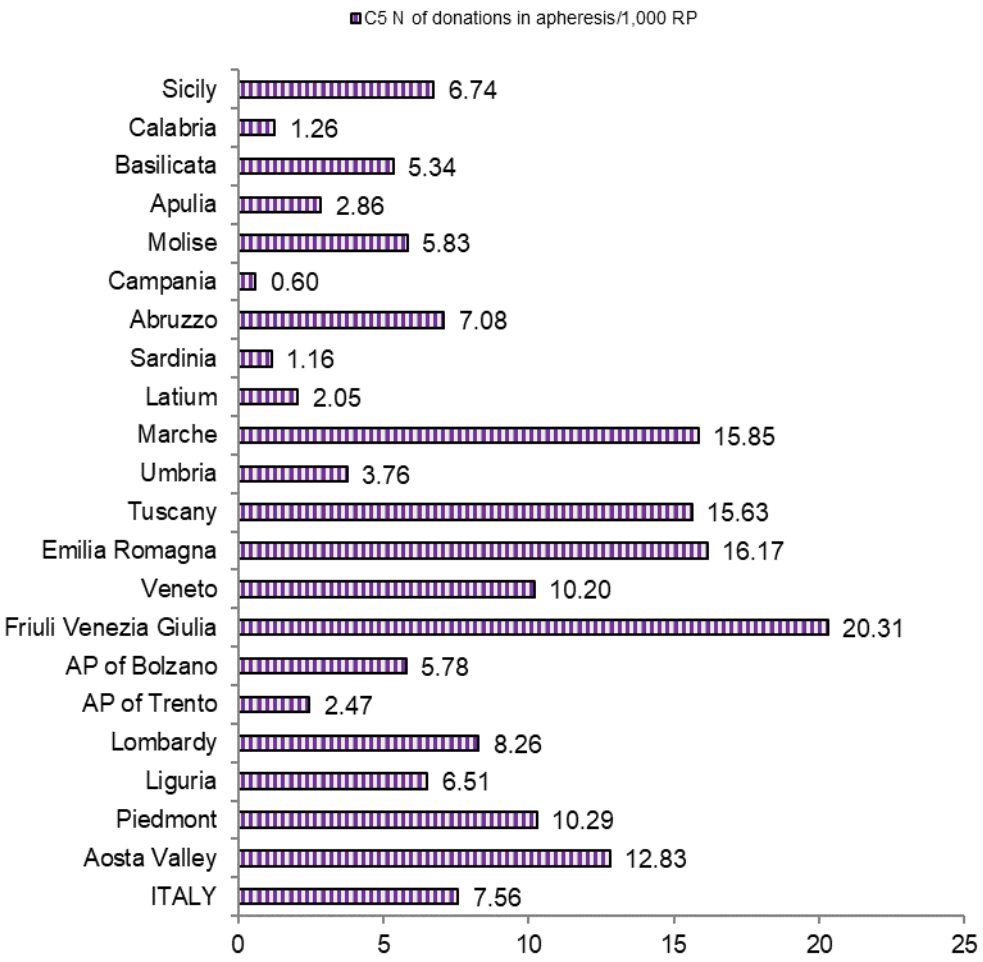
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A19. INDICATOR C3: N. of whole blood donations/1,000 resident population (2020)



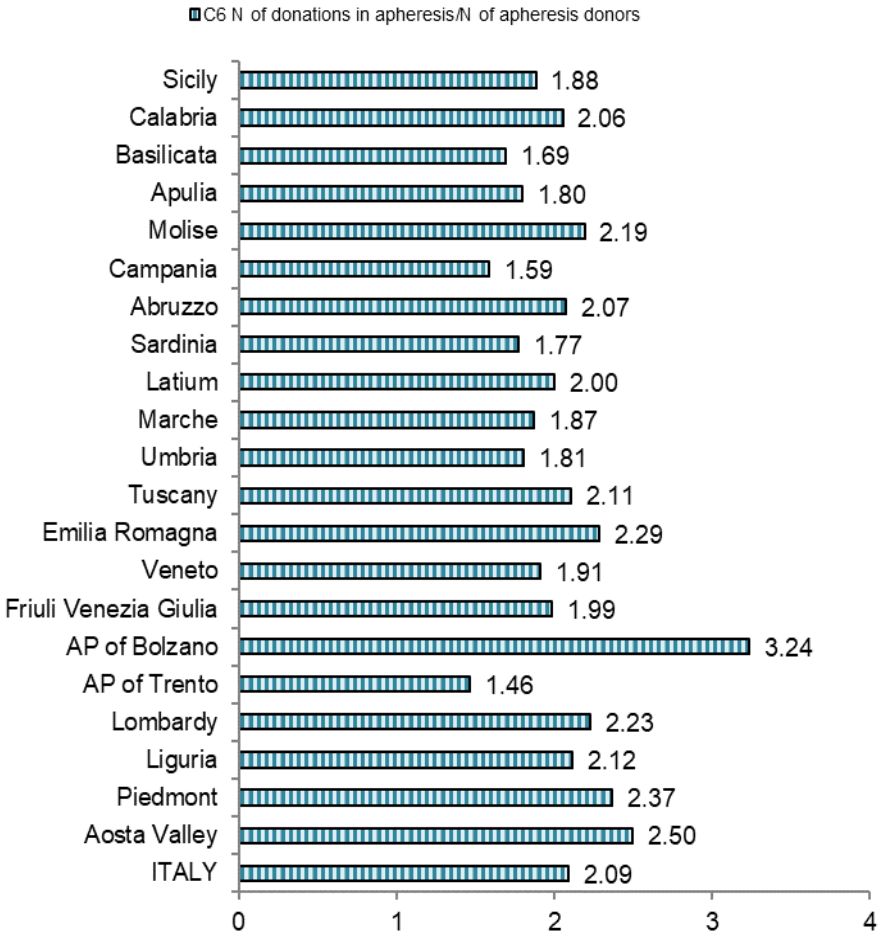
N. number; AP Autonomous Province; WB whole blood

Figure A20. INDICATOR C4: N. of whole blood donations/N. of whole blood donors (2020)



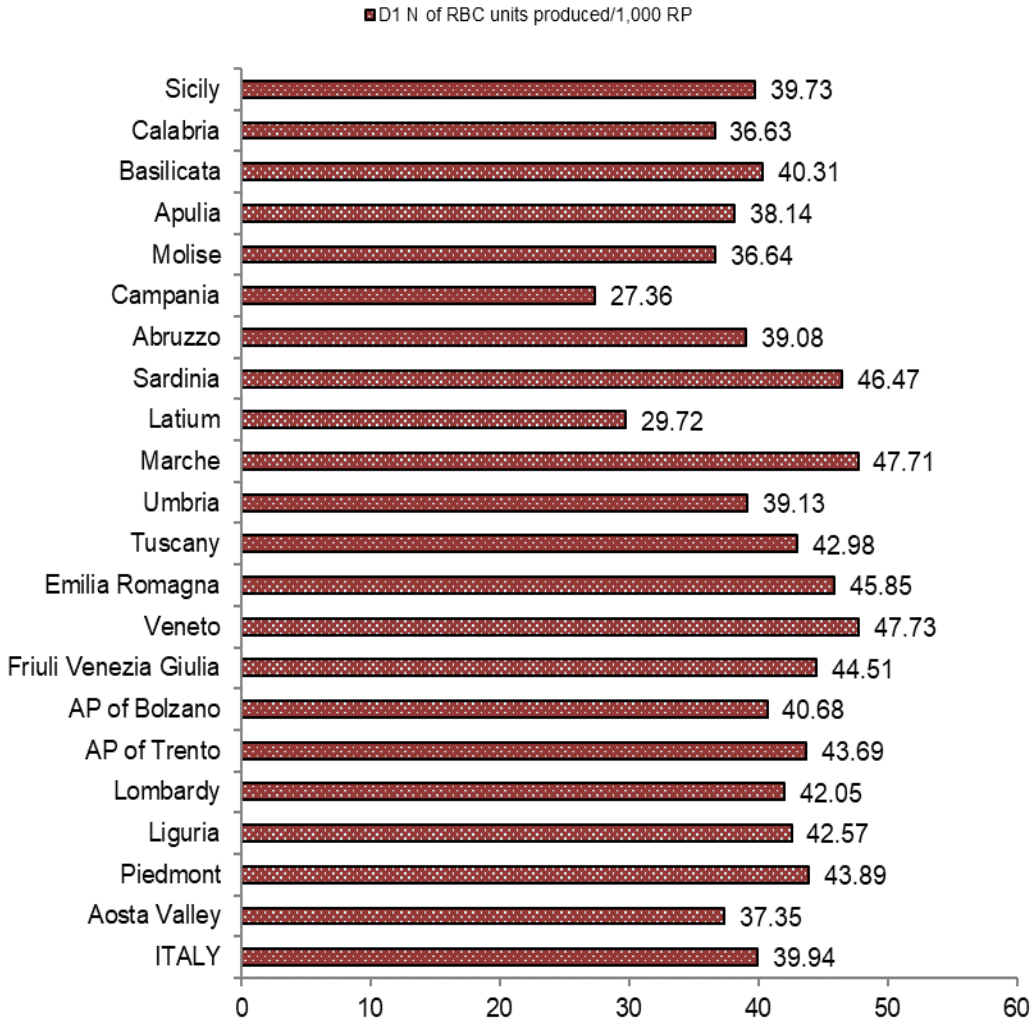
N. number; RP resident population; AP Autonomous Province

Figure A21. INDICATOR C5: N. of donations in apheresis/1,000 resident population (2020)



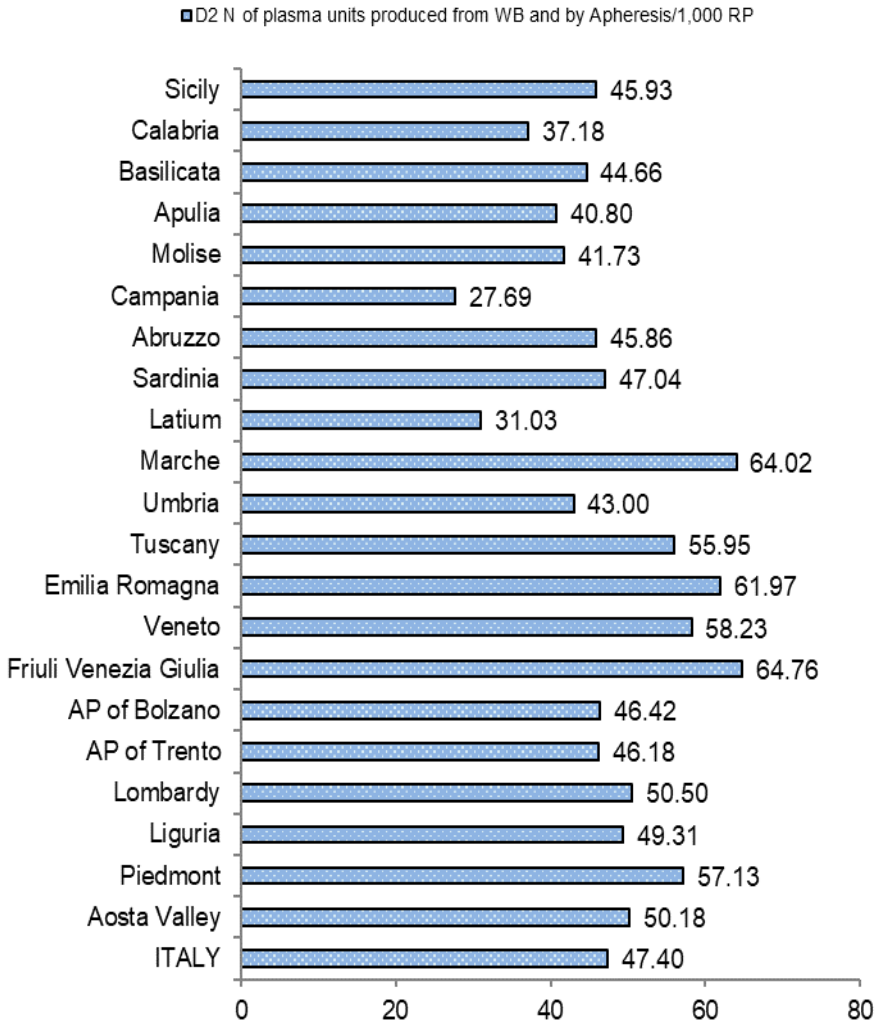
N. number; AP Autonomous Province

Figure A22. INDICATOR C6: N. of donations in apheresis/N. of apheresis donors (2020)



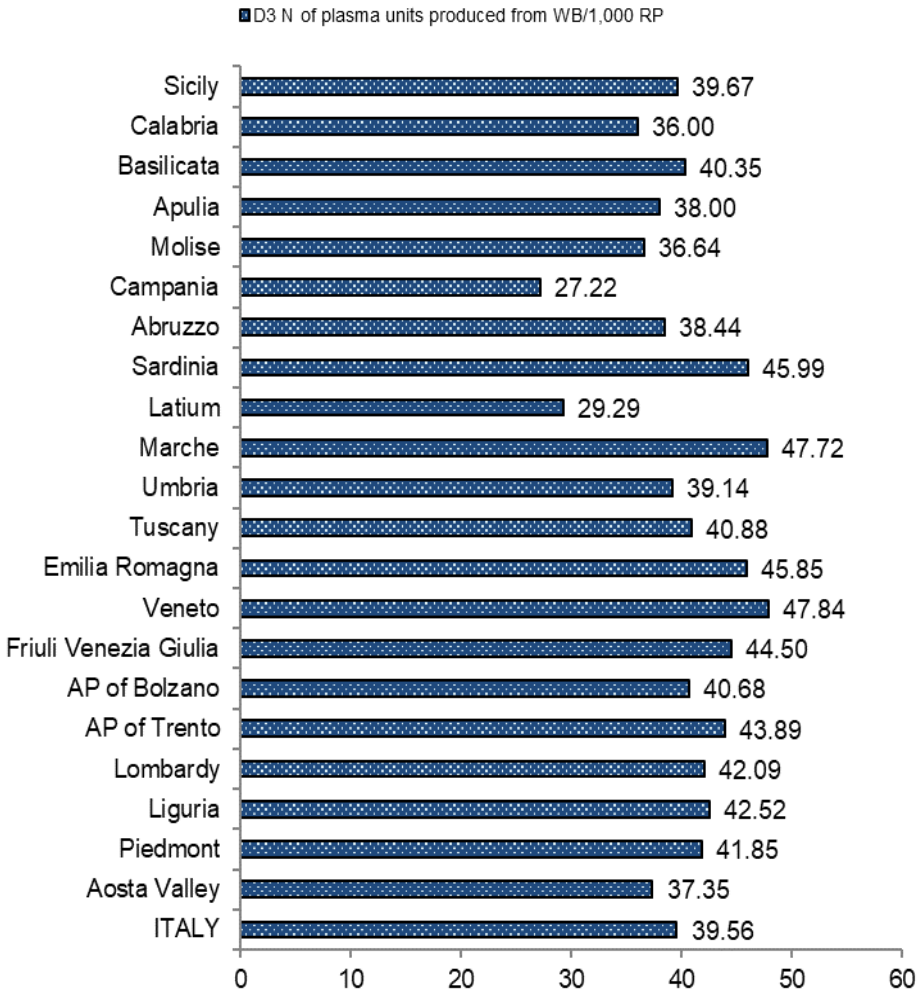
N. number; RP resident population; AP Autonomous Province

Figure A23. INDICATOR D1: RBC units produced/1,000 resident population (2020)



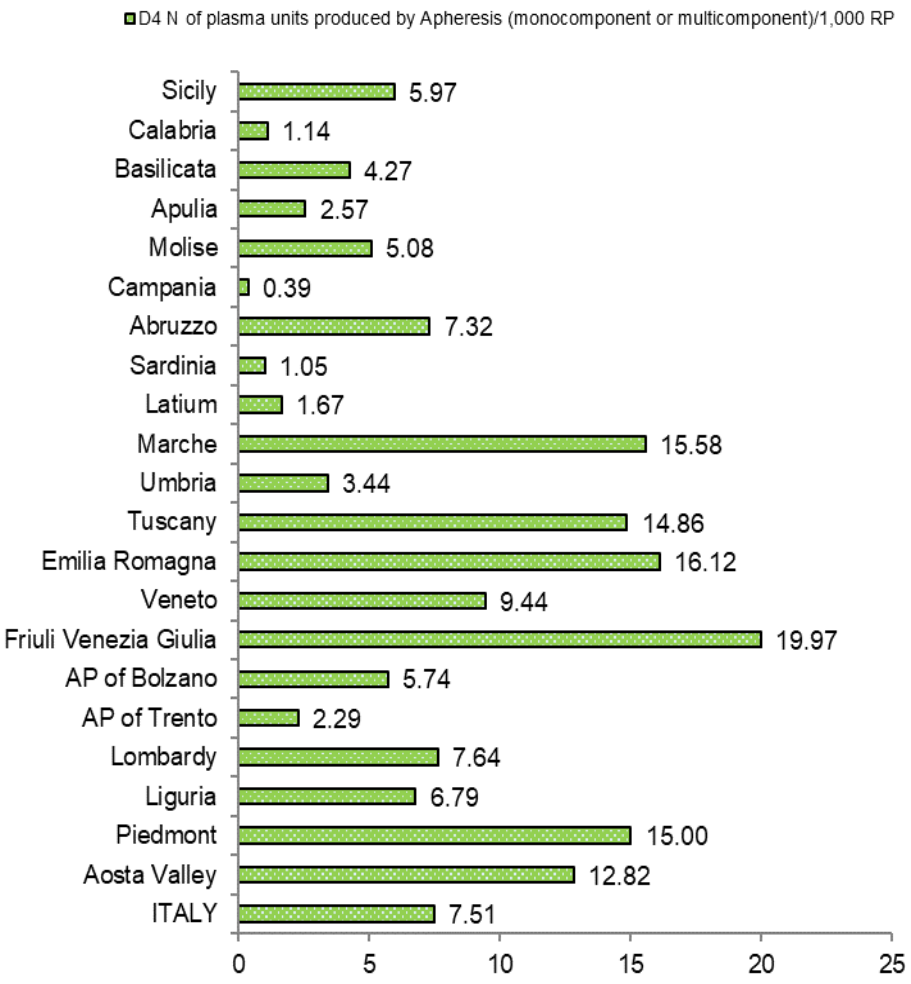
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A24. INDICATOR D2: N. of plasma units produced from whole blood and by apheresis/1,000 resident population (2020)



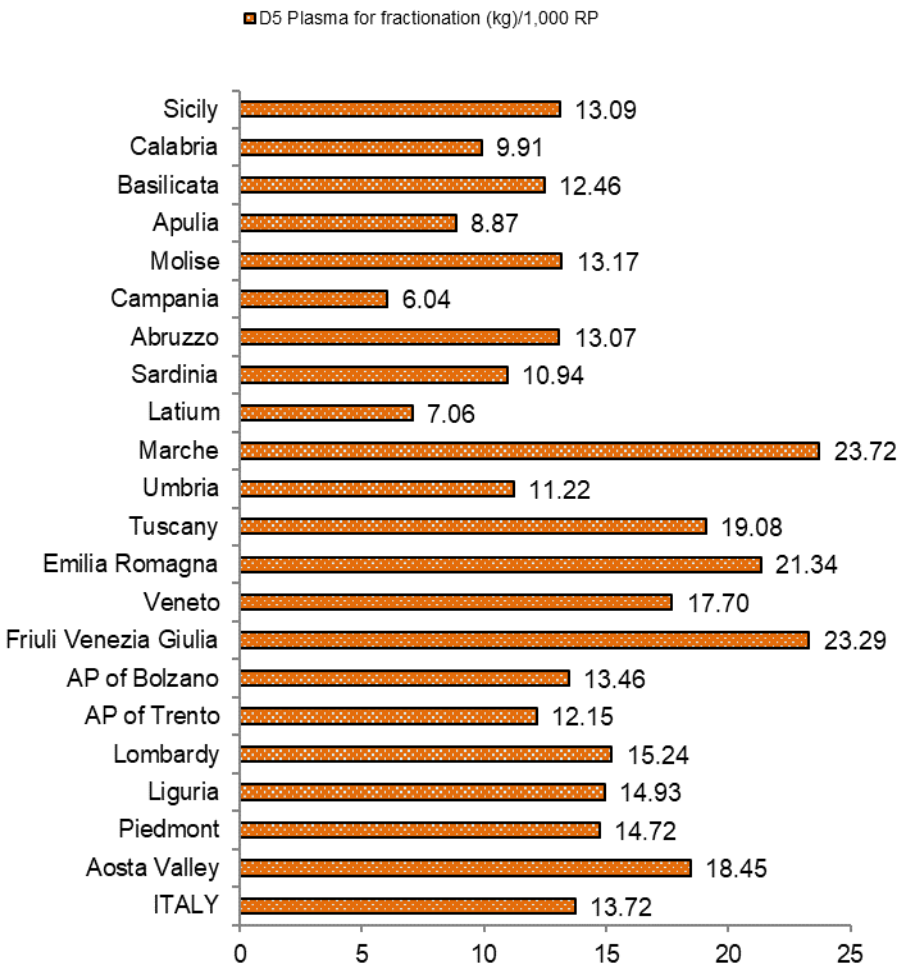
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A25. INDICATOR D3: N. of plasma units produced from whole blood/1,000 resident population (2020)



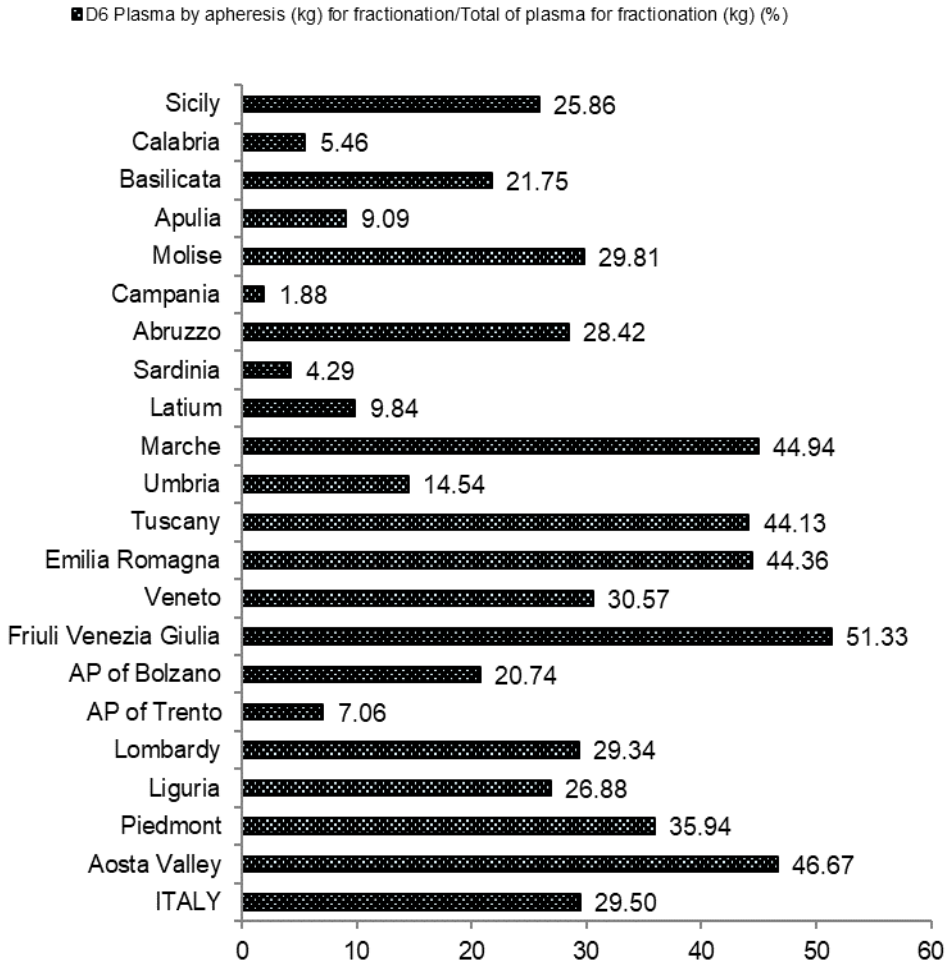
N. number; RP resident population; AP Autonomous Province

Figure A26. INDICATOR D4: N. of plasma units produced from apheresis (monocomponent + multicomponent)/1,000 resident population (2020)



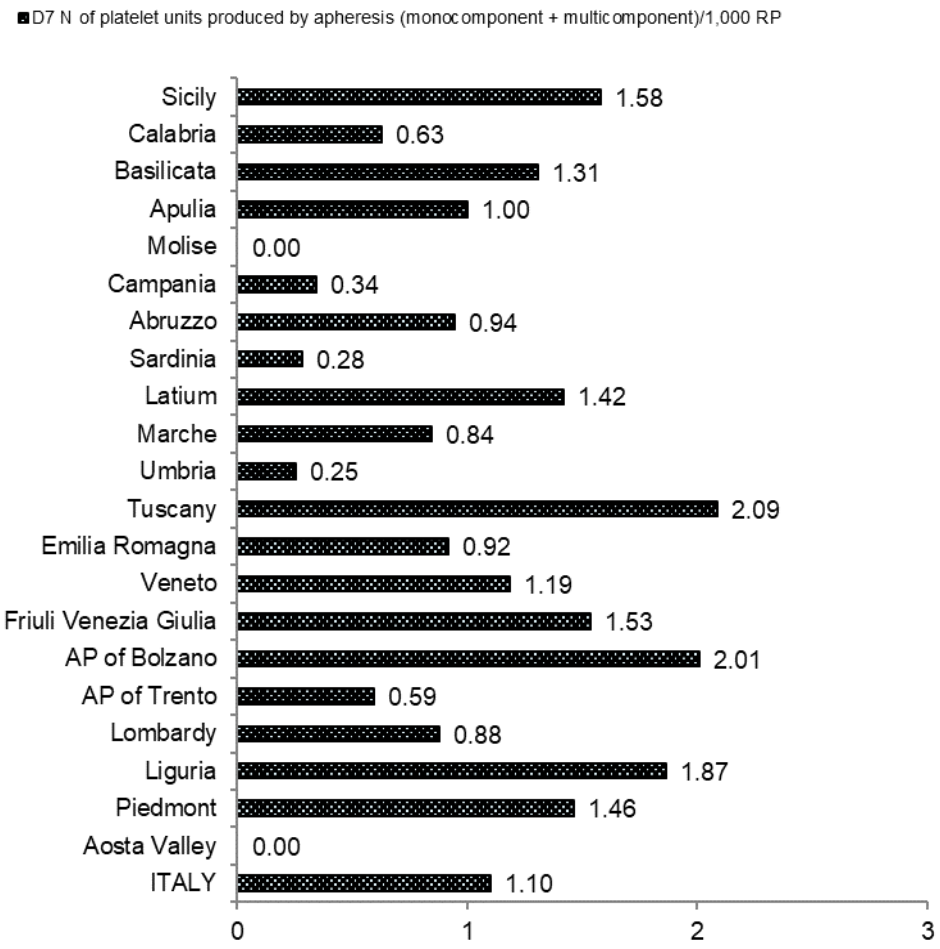
kg kilograms; RP resident population; AP Autonomous Province

Figure A27. INDICATOR D5: plasma (kg) for fractionation/1,000 resident population (from SISTRA) (2020)



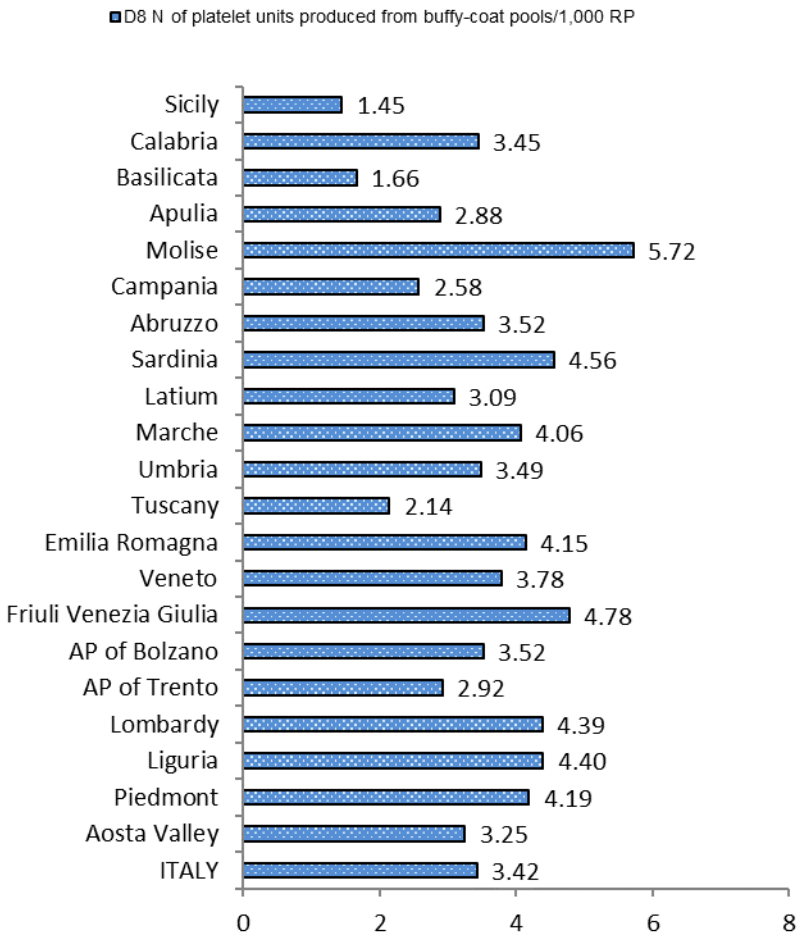
kg kilograms; AP Autonomous Province

Figure A28. INDICATOR D6: plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%) (2020)



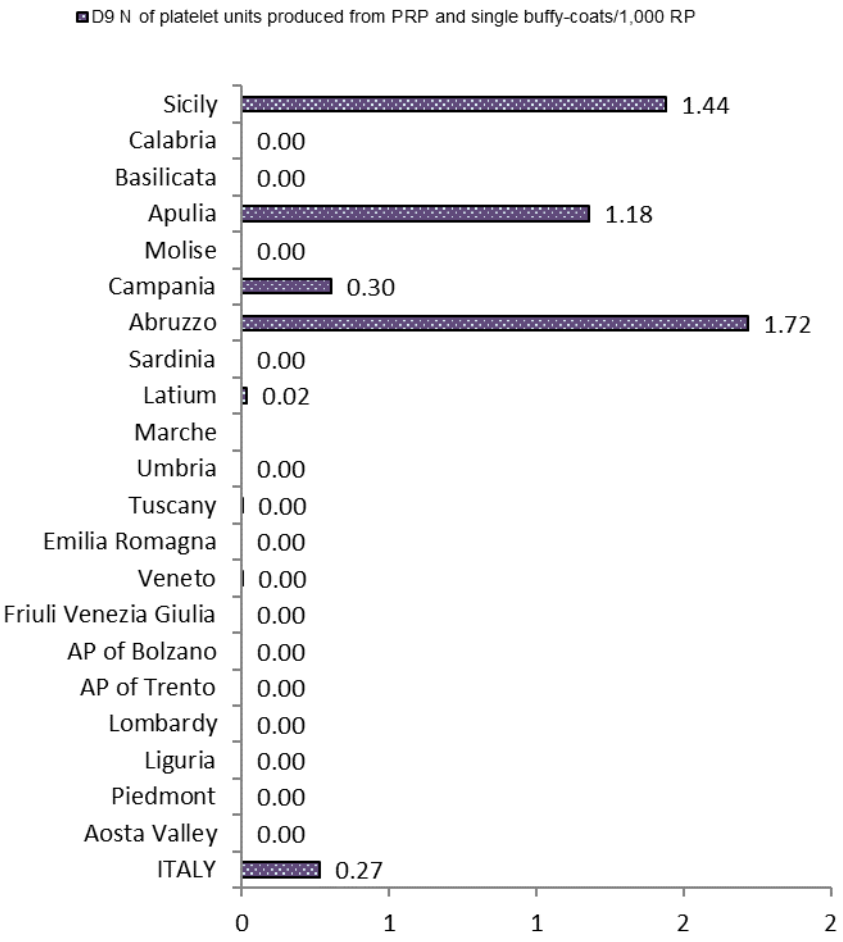
N. number; RP resident population; AP Autonomous Province

Figure A29. INDICATOR D7: N. of platelet units produced by apheresis (monocomponent + multicomponents)/1,000 resident population (2020)



N. number; RP resident population; AP Autonomous Province

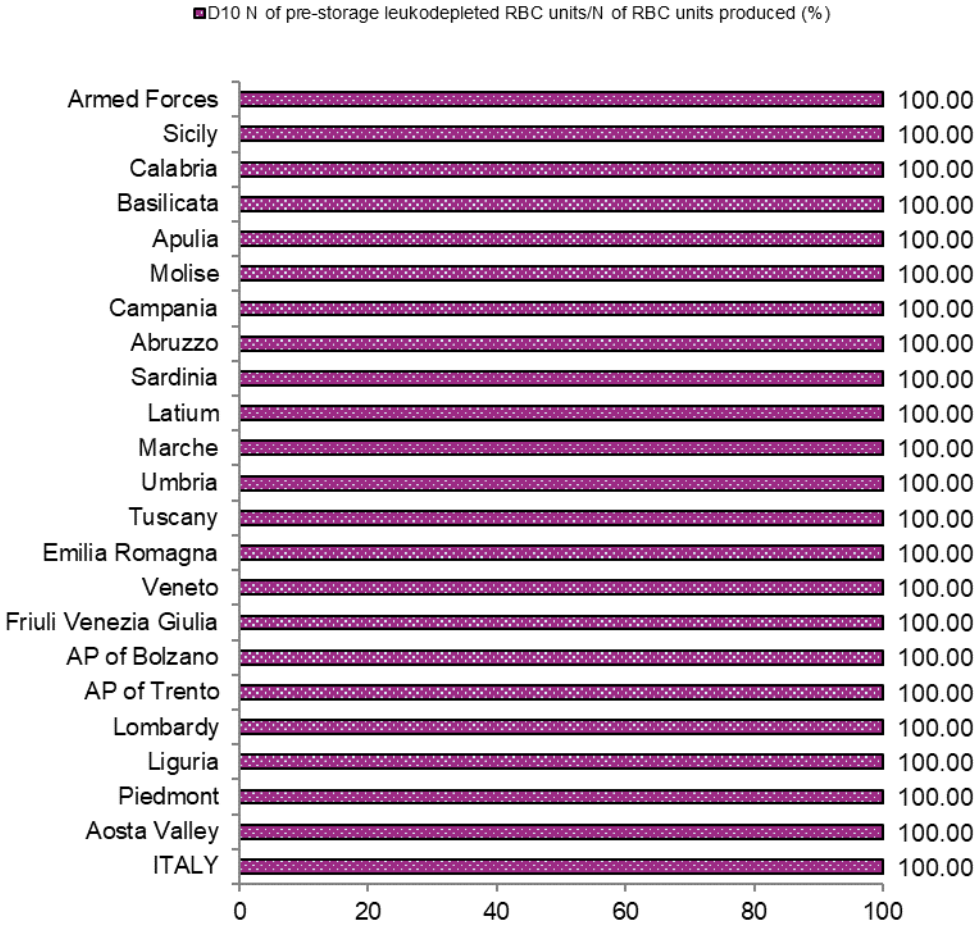
Figure A30. INDICATOR D8: N. of platelet units produced from buffy-coat pools/1,000 resident population (2020)



N. number; RP resident population; PRP patelet rich plasma; AP Autonomous Province

Figure A31. INDICATOR D9: N. of platelet units produced from PRP* and single buffy-coats/1,000 resident population (2020)

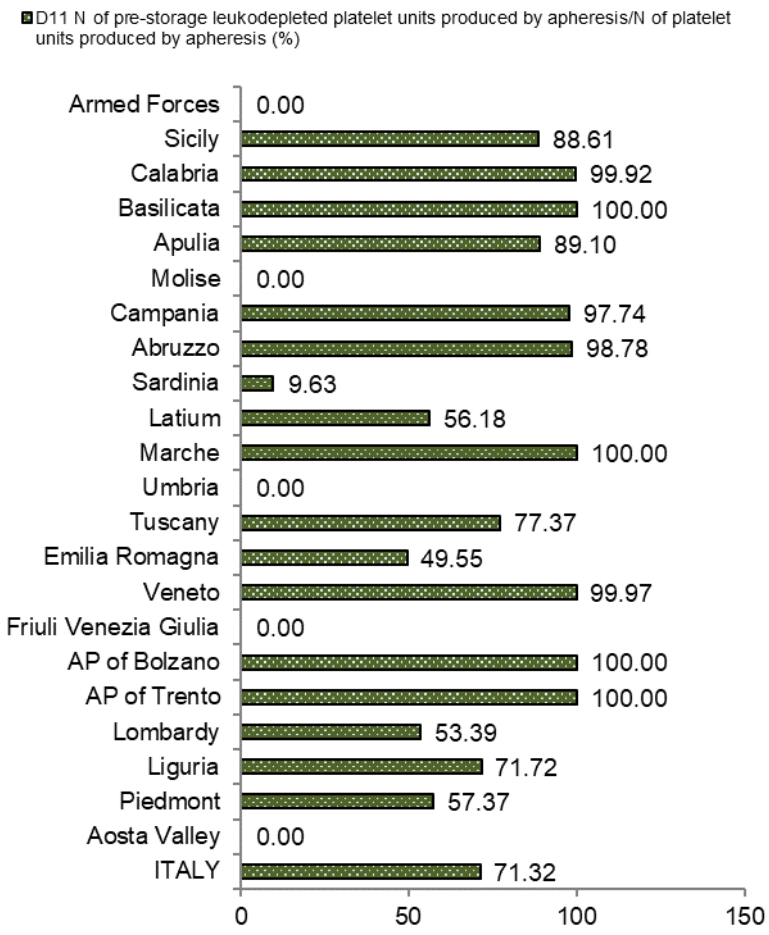
*Since six months after the the Ministerial Decree of 2nd November, 2015 (9) came into force, the production of platelet concentrates from whole blood units through the intermediate separation of platelet-rich plasma has not been allowed.



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

Figure A32. INDICATOR D10: N. of pre-storage leukodepleted* RBC units/N. of RBC units produced (%) (2020)

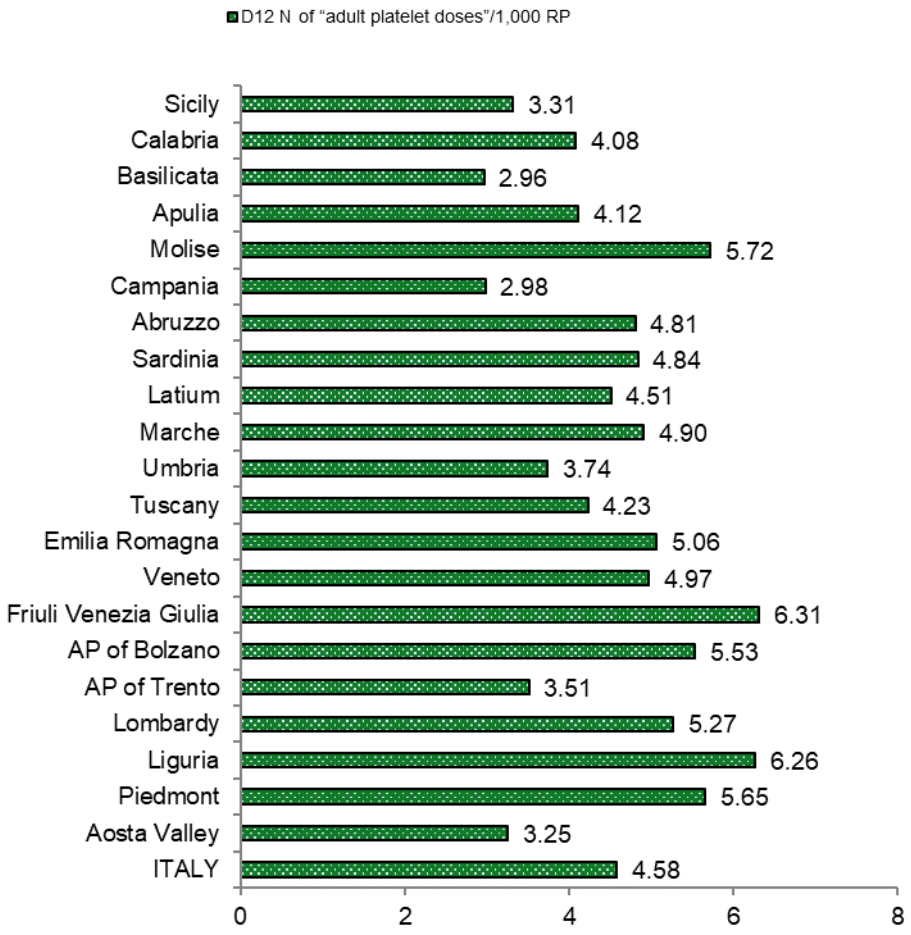
*: Since twelve months after the Ministerial Decree of 2nd November, 2015 (9) came into force, only the production of pre-storage leukodepleted blood components has been allowed.



N. number; AP Autonomous Province

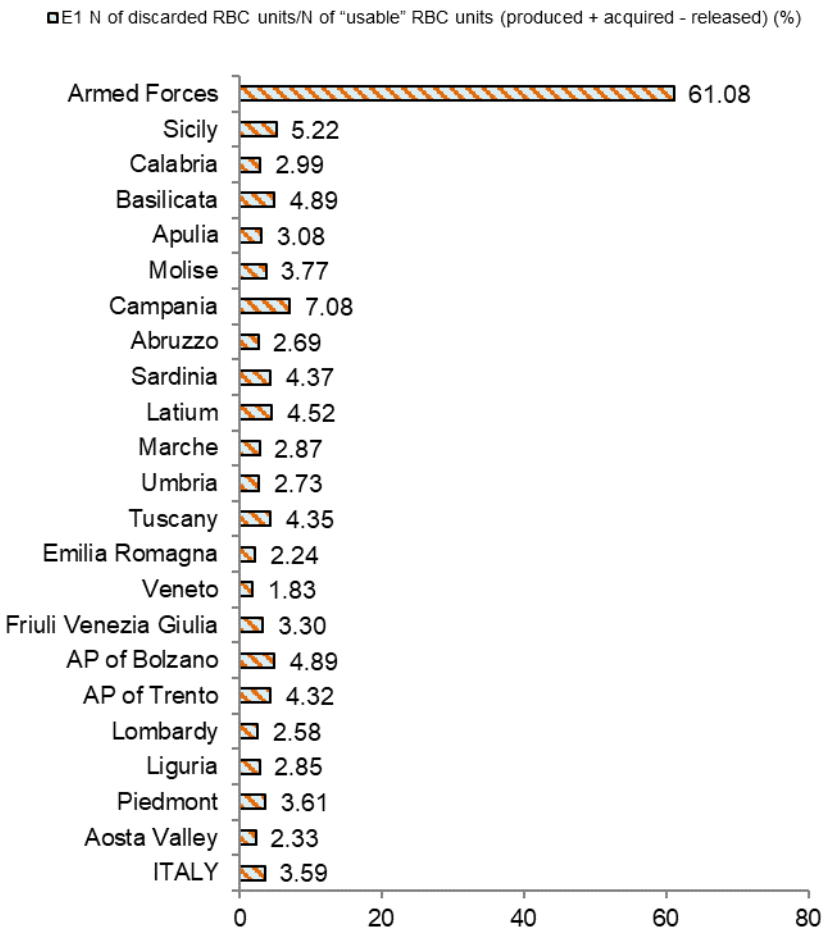
Figure A33. INDICATOR D11: N. of pre-storage leukodepleted platelet units produced by apheresis/N. of platelet units produced by apheresis (%) (2020)

*: Since twelve months after the Ministerial Decree of 2nd November, 2015 (9) came into force, only the production of pre-storage leukodepleted blood components has been allowed.



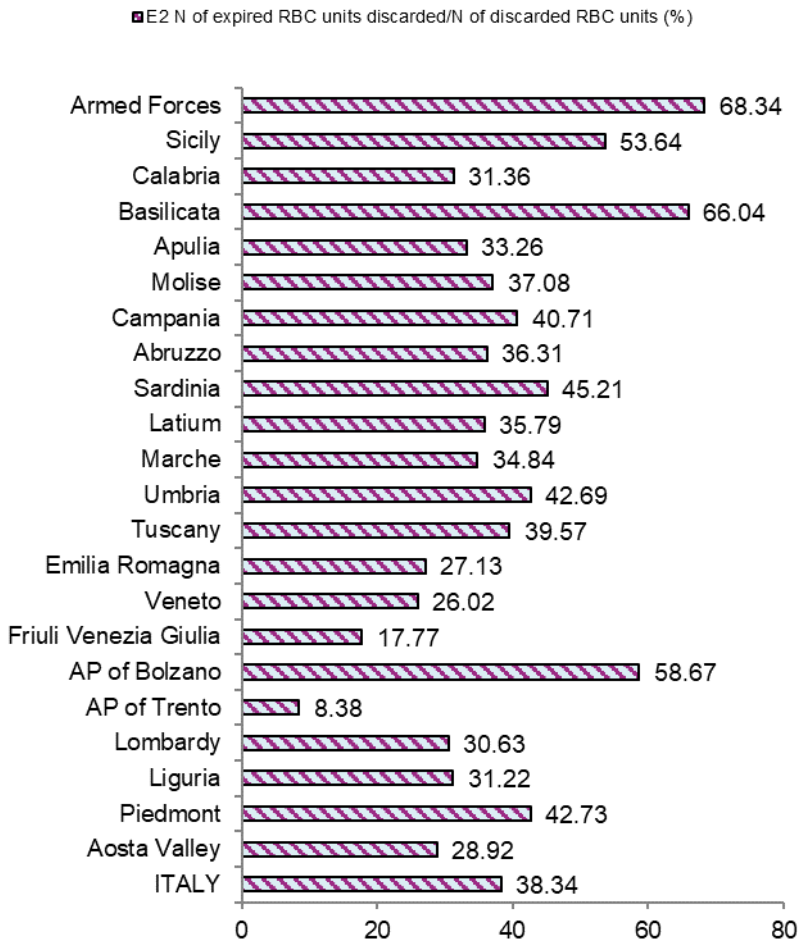
N. number; RP resident population; AP Autonomous Province

Figure A34. INDICATOR D12: N. of "adult platelet doses"/1,000 resident population (2020)



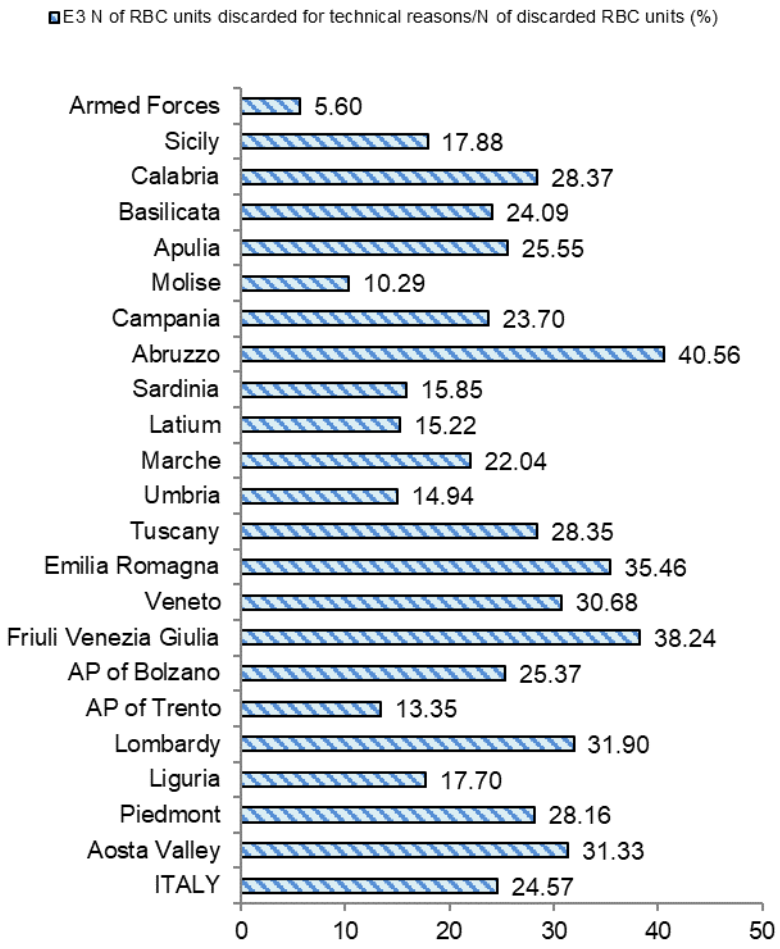
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A35. INDICATOR E1: N. of discarded RBC units/N. of "usable" RBC units (produced + acquired- released) (%) (2020)



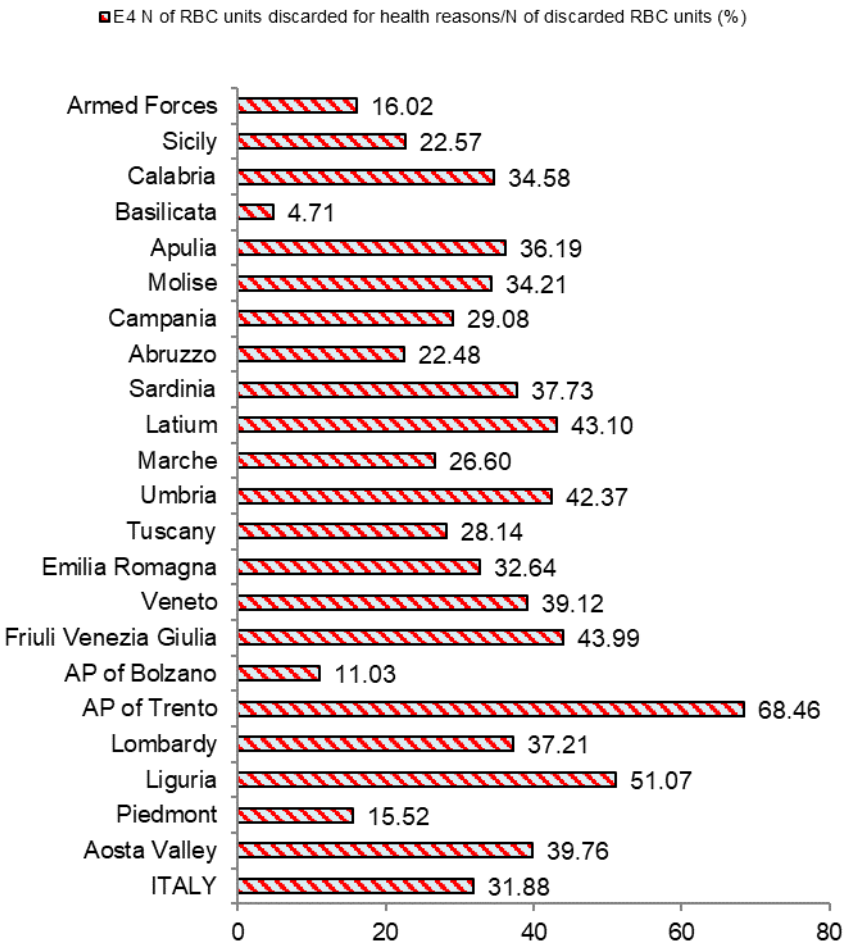
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A36. INDICATOR E2: N. of expired RBC units discarded/N. of discarded RBC units (%) (2020)



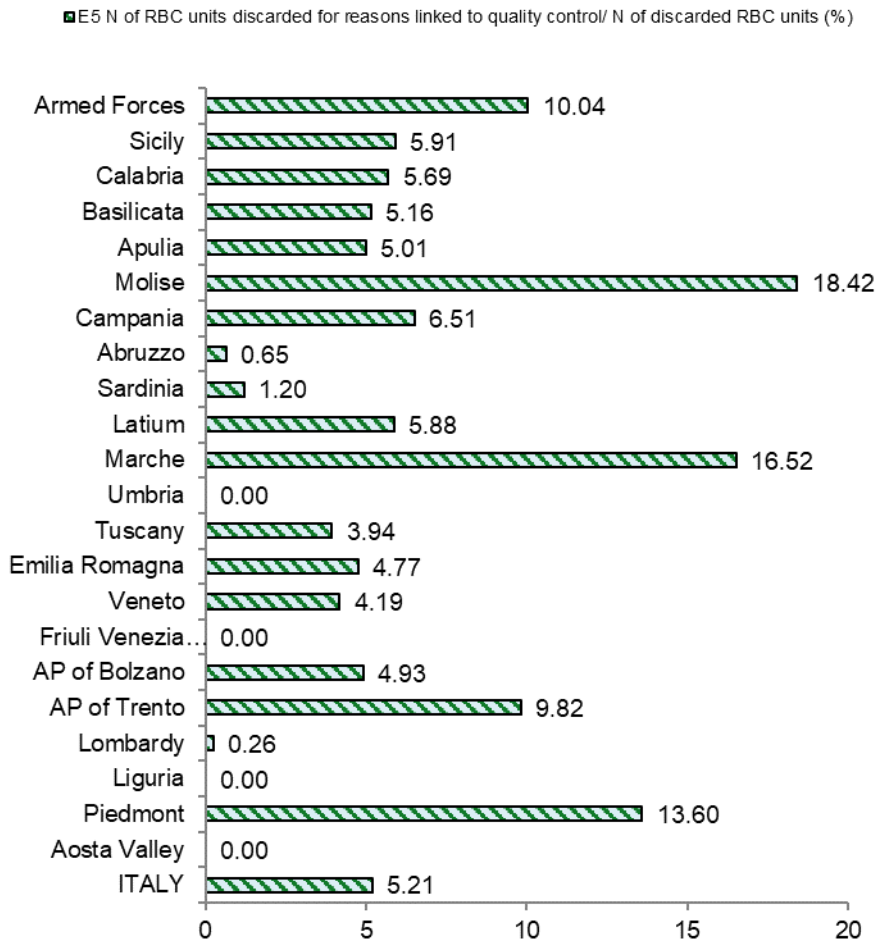
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A37. INDICATOR E3: N. of RBC units discarded for technical reasons/N. of discarded RBC units (%) (2020)



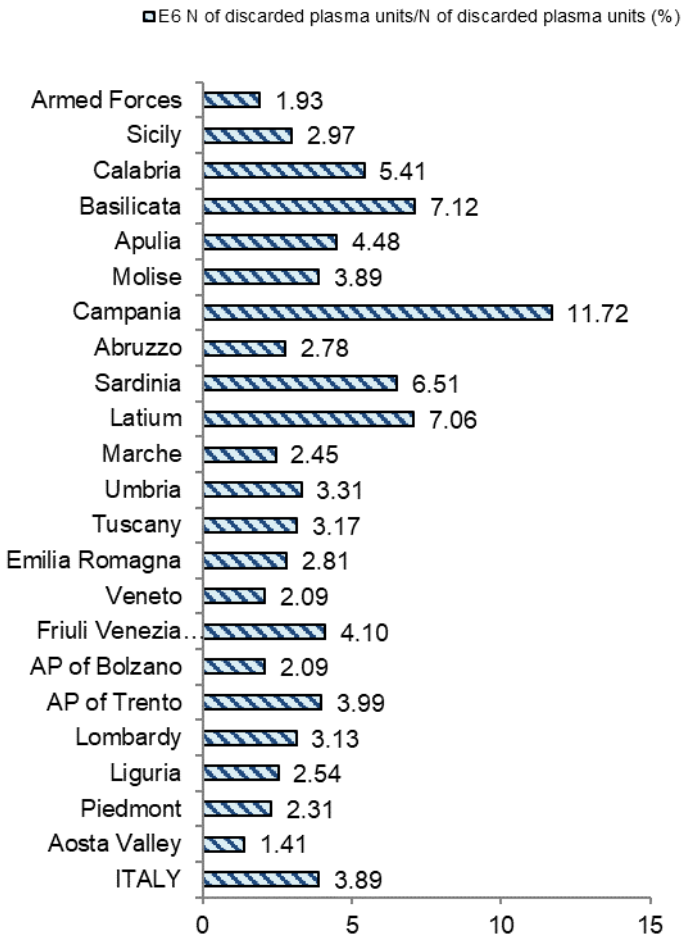
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A38. INDICATOR E4: N. of RBC units discarded for health reasons/N. of discarded RBC units (%) (2020)



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

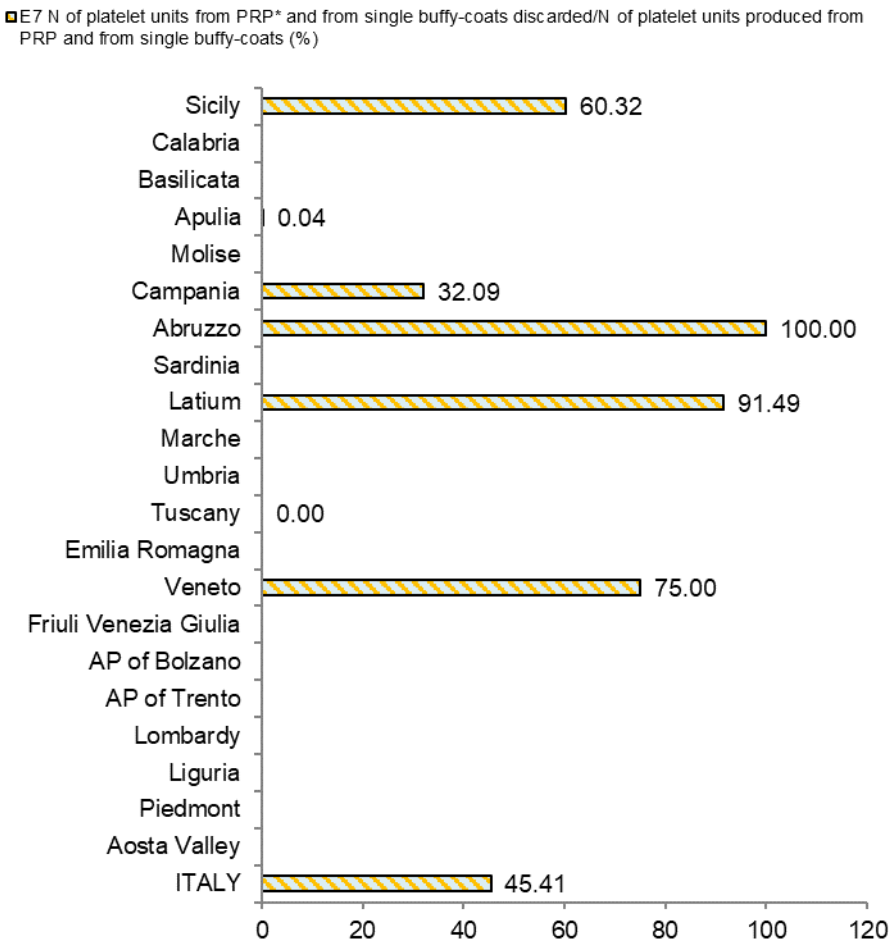
Figure A39. INDICATOR E5: N. of RBC units discarded for reasons linked to quality control/N. of discarded RBC units (%) (2020)



N. number; AP Autonomous Province

Figure A40. INDICATOR E6: N. of discarded plasma units /N. of produced plasma units (%) (2020)

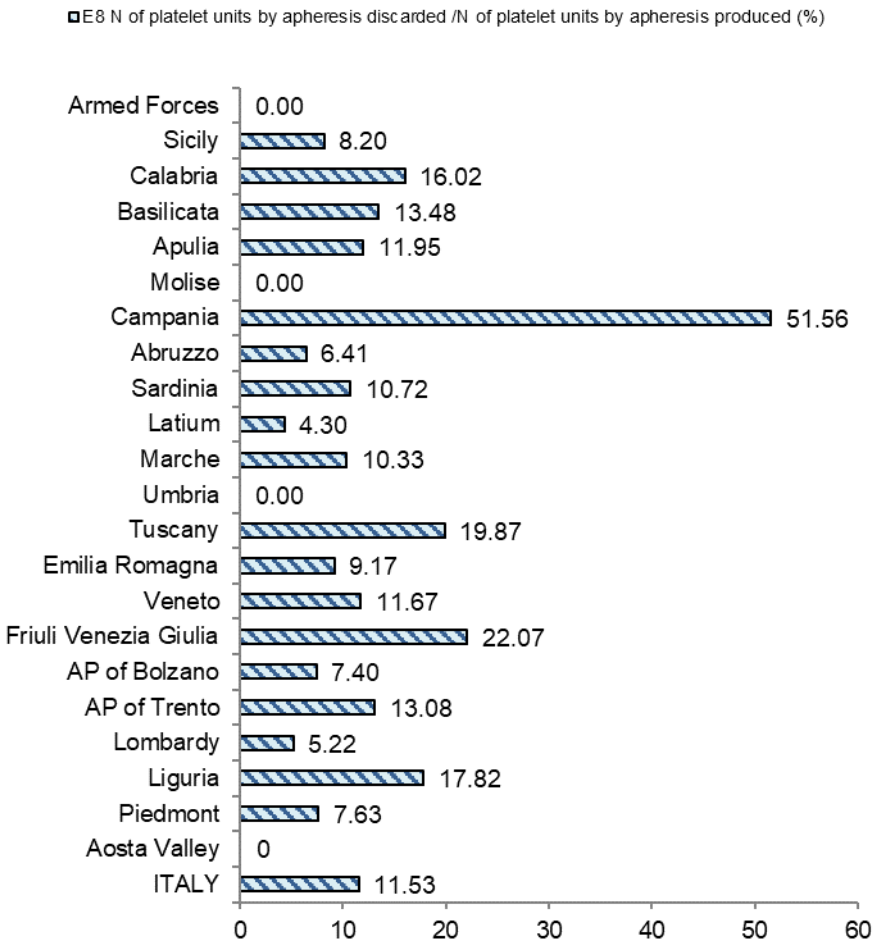
.



N. number; PRP platelet rich plasma; AP autonomous Province

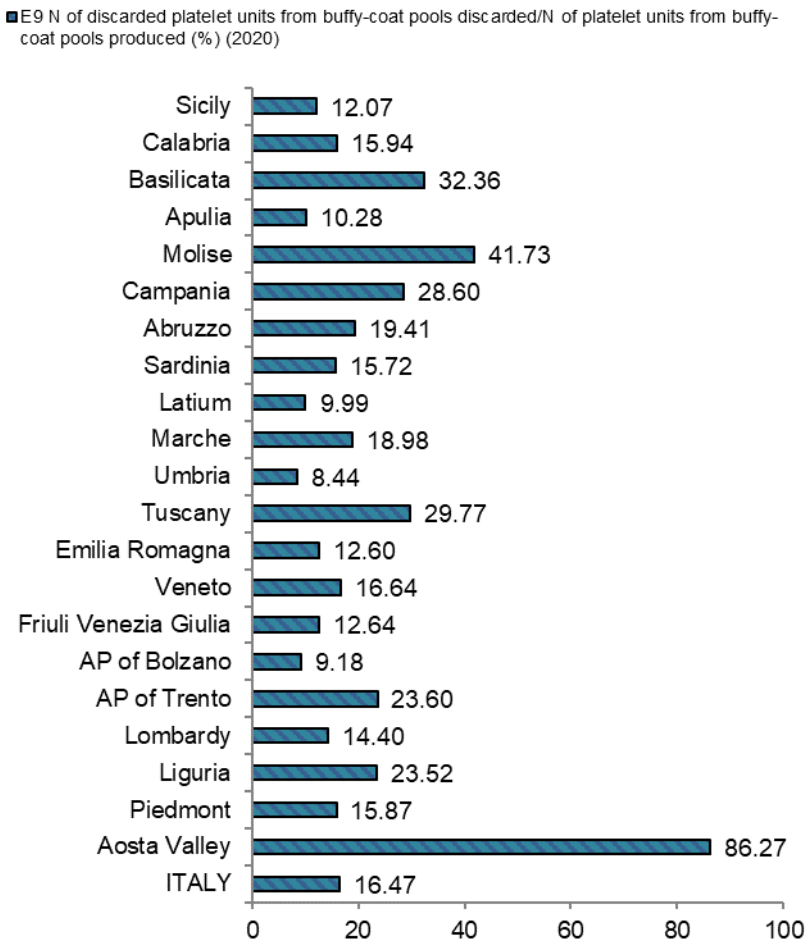
* Since six months after the Ministerial Decree of 2nd November, 2015 (9) came into force, the production of platelet concentrates from whole blood units through the intermediate separation of platelet-rich plasma has not been allowed.

Figure A41. INDICATOR E7: N. of platelet units from PRP* and from single buffy-coats discarded /N. of platelet units produced from PRP and from single buffy-coats (%) (2020)



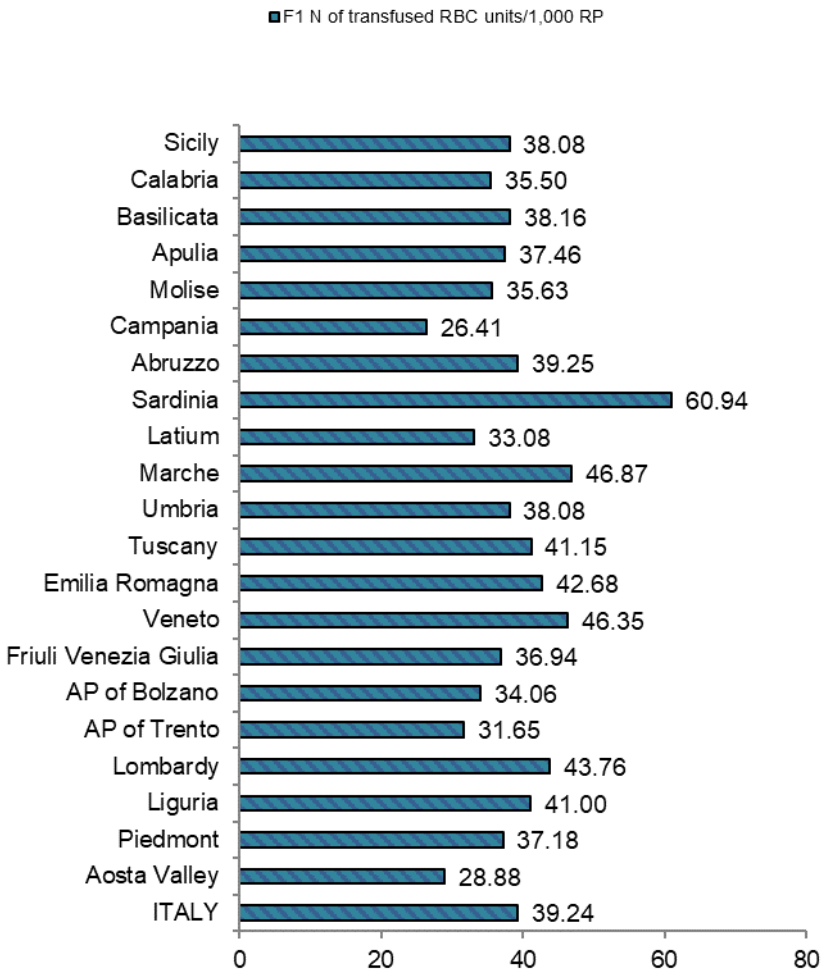
N. number; AP Autonomous Province

Figure A42. INDICATOR E8: N. of platelet units by apheresis discarded /N. of platelet units by apheresis produced (%) (2020)



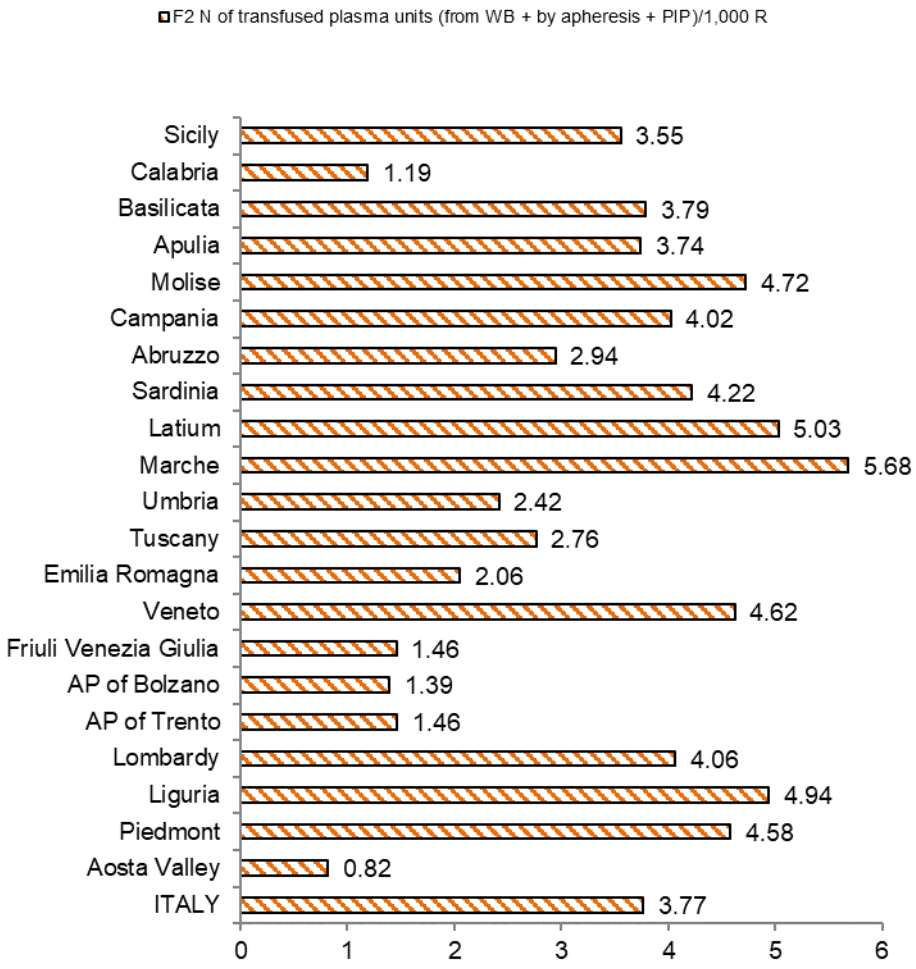
N. number; AP Autonomous Province

Figure A43. INDICATOR E9: N. of platelet units from buffy-coat pools discarded/N. of platelet units from buffy-coat pools produced (%) (2020)



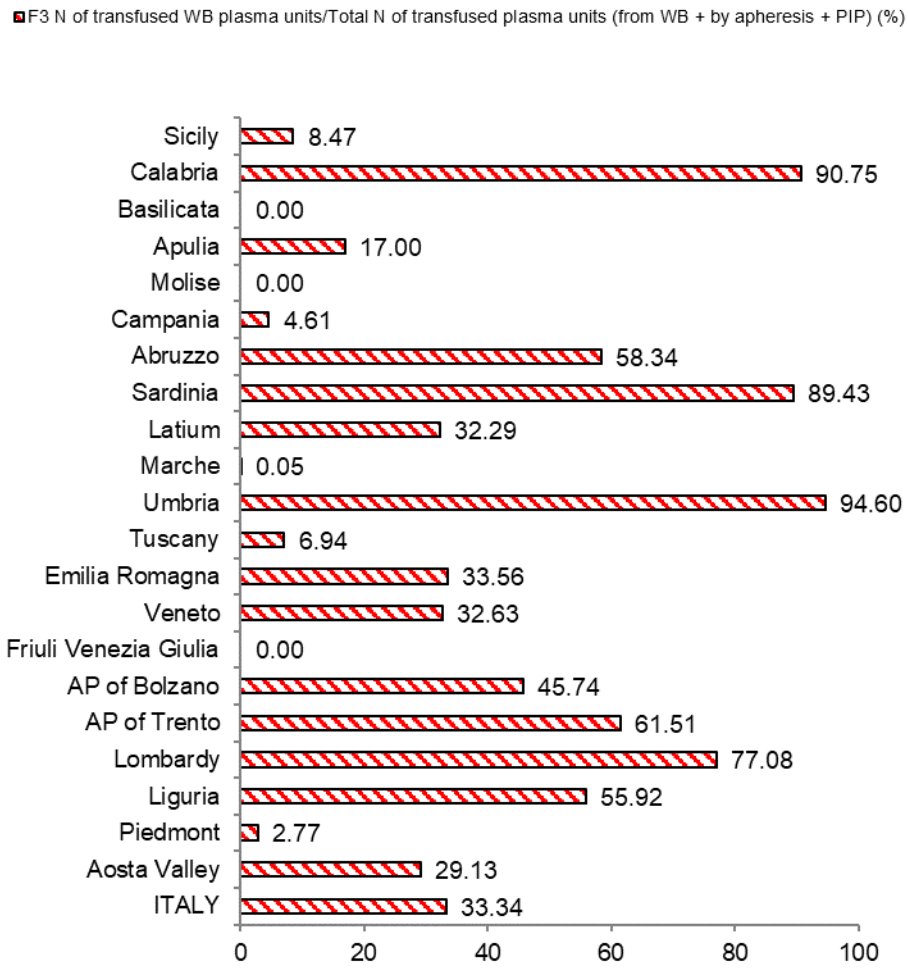
N. number; RBC Red Blood Cells; RP resident population; AP Autonomous Province

Figure A44. INDICATOR F1: N. of transfused RBC units/1,000 resident population (2020)



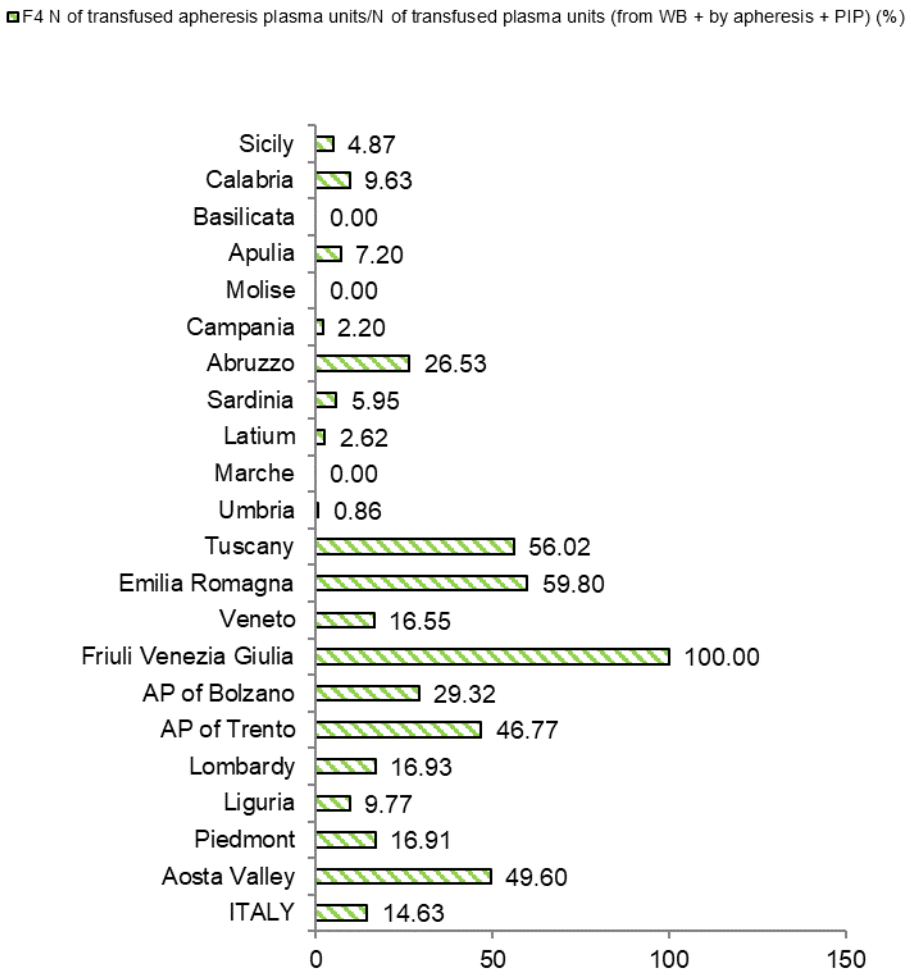
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; RP resident population; AP Autonomous Province

Figure A45. INDICATOR F2: N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma)/1,000 resident population (2020)



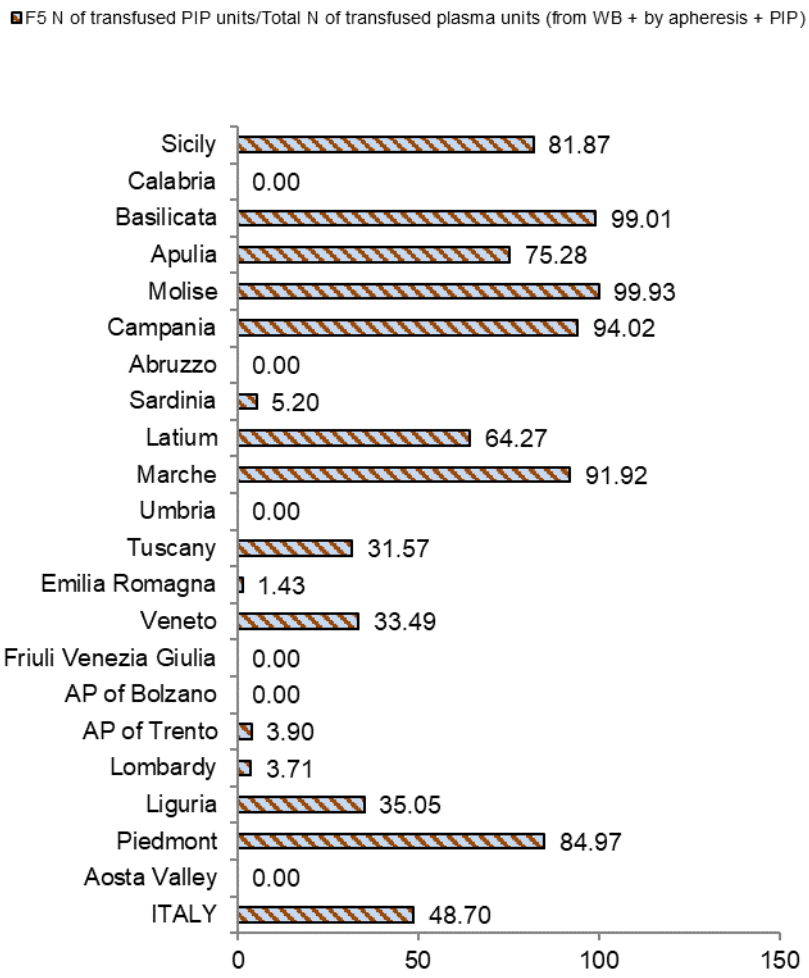
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A46. INDICATOR F3: N. of transfused whole blood plasma units/Total N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2020)



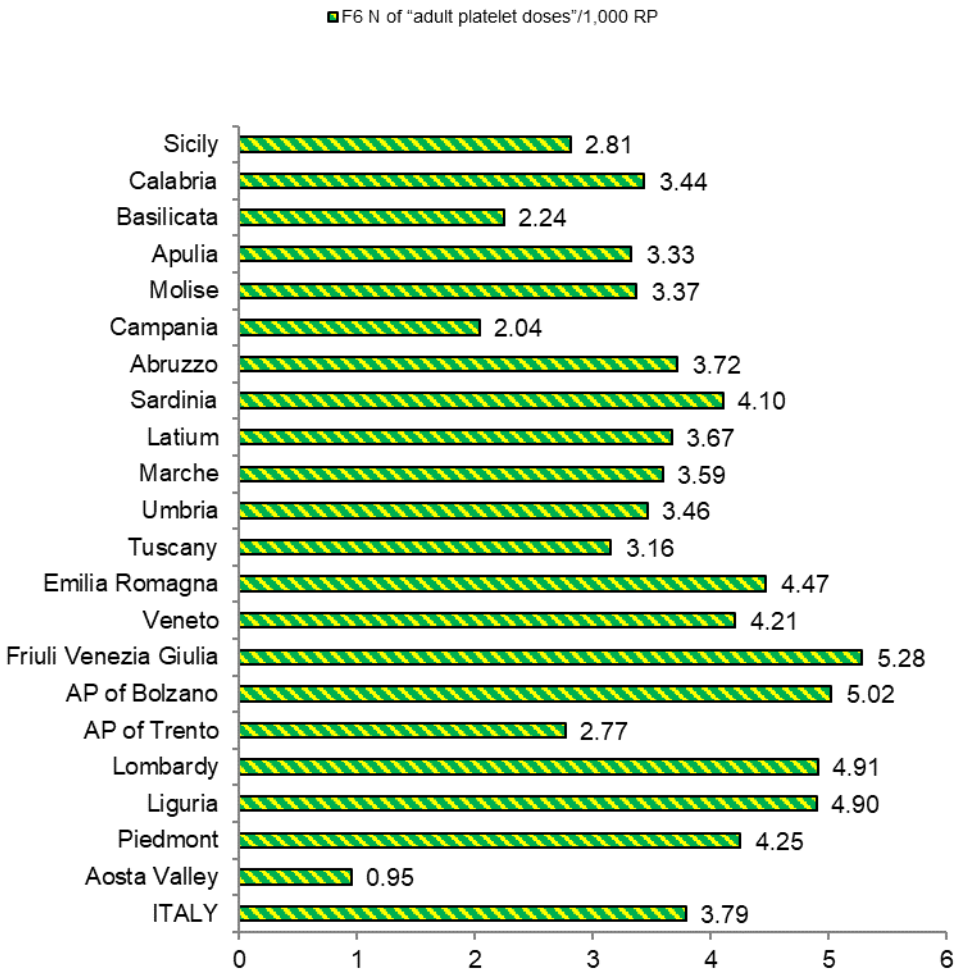
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A47. INDICATOR F4: N. of transfused apheresis plasma units/N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2020)



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

Figure A48. F5 INDICATOR: N. of transfused pharmaceutical virus-inactivated plasma units/Total N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2020)



N. number; RP resident population; AP Autonomous Province

Figure A49. INDICATOR F6: N. of "adult platelet doses"/1,000 resident population (2020)

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