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Italian Blood System 2018: activity data, haemovigilance and epidemiological surveillance Volume 1

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EPIDEMIOLOGIA E SANITA PUBBLICA

ISTITUTO SUPERIORE DI SANITÀ

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2019, iii, 104 p. Rapporti ISTISAN 19/27

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 2018.

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

Istituto Superiore di Sanità
Sistema trasfusionale italiano 2018: dati di attività, emovigilanza e sorveglianza epidemiologica. Volume 1.
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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 2018.

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

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

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)
CMV	Cytomegalovirus
CNS	Centro Nazionale Sangue (Italian National Blood Centre)
CT	Computed Tomography
ECG	Electrocardiogram
FT	First-time tested (donor)
FTE	Full-Time Equivalent
FIDAS	Federazione Italiana Associazioni Donatori di Sangue (Italian Federation of Voluntary Blood Donors Associations)
FNHTR	Febrile Non Haemolytic Transfusion Reaction
GDBS	Global Database on Blood Safety
HAV	Hepatitis A virus
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HLA	Human leukocyte antigen
HSC	Haematopoietic stem cells
IRC	Italian Red Cross
ISTAT	National Institute of Statistics
NAT	Nucleic Acid Amplification Technology
NSIS	Nuovo Sistema Informativo Sanitario (New Health Information System)
PDMP	Plasma-Derived Medicinal Product
PTP	Post Transfusion Purpura
RBCC	Regional Blood Coordination Centre
RT	Repeat tested (donor)
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 2018.

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

Through the anagraphic 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 2018 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 Annex to the Chapter, 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, 2018, available at http://demo.istat.it/ (last accessed May 2019).

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.

National data

In 2018, as in 2017, 278 BEs were validated by the RBCCs on SISTRA. By contrast there was a decrease in the number of peripheral organisational sites (-1.43%) 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). Likewise, the number of BCSs decreased by 21% compared to 2017 and in 2018, 1,281 (-3.39%) peripheral organisational sites were registered (Table 1). 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 1. BEs and BCSs with their respective peripheral organisational sites: Italy 2018 (2017-2018)

Blood facilities and population	2017	2018	Δ%
BEs	278	278	0.00
BEs peripheral organisational sites*	1,049	1,034	-1.43
BCS	267	211	-20.97
BCS peripheral organisational sites*	1,326	1,281	-3.39
Population	60,589,445	60,483,973	-0.17

BEs Blood Enstablishments, BCSs Blood Collection Sites (in Italy all BCSs are run by Voluntary Blood Donor Associations and Federations) Updated data 2018

Table 2. Professionals operating in BEs as of 31st December 2018* (2017-2018)

Staff	2017	2018	Δ%
Physicians	1,712.6	1,721.8	0.54
Graduates (biologist and other professionals with a PhD)	524.0	491.4	-6.22
Blood Technicians	2,973.3	3,005.8	1.09
Nurses	1,570.8	1,617.6	2.98
Health Operators	422.3	414.7	-1.80
Administrative Staff	304.7	288.2	-5.42
Total	**7,507.7**	**7,539.5**	0.42

* 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 2017, there was a very slight increase in the total number of donors and a slight increase in regular donors, while there was a decrease 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 first-time not pre-qualified donors (newly-registered donors who are screened and donate during their first visit)}. In 2018, more first-time pre-qualified donors re-donated than first-time not pre-qualified donors.

Table 3. Donors of blood and blood components (2017-2018)

Donors	2017	2018	Δ%
Prospective*	**186,264**	**187,548**	0.69
Those who did not donate in the period under examination	96,604	95,166	-1.49
First-time pre-qualified (A)	**119,684**	**123,944**	3.56
Those who re-donated at least once in the period under examination (A1)	42,759	42,874	0.27
First-time not pre-qualified (B)	**265,727**	**247,149**	-6.99
Those who re-donated at least once in the period under examination year of detection (B1)	38,194	36,879	-3.44
Total First-time (A+B)	**385,411**	**371,093**	-3.71
Those who re-donated in the period under examination	80,953	79,753	-1.48
Regular (R)	**1,375,688**	**1,391,384**	1.14
Those who re-donated at least once a year in the last 5 years	624,707	618,465	-1.00
Total ((A-A1)+(B-B1)+R)	**1,680,146**	**1,682,724**	0.15
Apheresis	205,738	202,509	-1.57
Those who donated only in apheresis	110,006	109,521	-0.44
Permanently deferred	48,195	45,354	-5.89
Members of VBDAs	**1,518,496**	**1,543,063**	1.62

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 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 4. Collection procedures carried out by BEs and BCSs (2017-2018)

Collection procedures	2017	2018	Δ%
Whole blood	**2,579,438**	**2,569,275**	**0.39**
Apheresis	**427,288**	**421,807**	**-1.28**
Monocomponent apheresis	*362,390*	*357,661*	*-1.30*
Multicomponent apheresis	*64,898*	*64,146*	*-1.16*
Total	**3,006,726**	**2,991,082**	**-0.52**
Type			
Plasmapheresis	348,486	346,778	-0.49
Plateletpheresis	9,507	9,201	-3.22
Single Donor Plasma-Platelet apheresis	2,445	0	-100.00
Stem Cells apheresis	1,601	1,353	-15.49
Granulocytapheresis	104	65	-37.50
Lymphocytapheresis	247	264	6.88
Red Blood Cell/Platelet apheresis	4,556	3,466	-23.92
Double Red Blood Cell unit apheresis	443	238	-46.28
Plasma/Platelet apheresis	43,626	46,860	7.41
Red Blood Cell/Plasma apheresis	14,179	11,555	-18.51
Double Platelet unit apheresis	1,224	1,021	-16.58
Red Blood Cell/Platelet/Plasma apheresis	870	1,006	15.63

Table 5. Percentage of collection procedures carried out by BCSs (2017-2018)

Region/AP	% 2017	% 2018	Δ%
Aosta Valley	0.00	0.00	
Piedmont	54.09	54.44	0.65
Liguria	42.96	38.13	-11.25
Lombardy	35.75	36.23	-1.33
AP of Trento	0.00	0.00	
AP of Bolzano	0.00	0.00	
Friuli Venezia Giulia	0.00	0.00	
Veneto	12.11	11.05	-8.77
Emilia Romagna	53.56	55.09	2.85
Tuscany	4.49	4.71	5.02
Umbria	0.00	0.00	
Marche	4.31	4.51	4.55
Latium	29.43	31.45	6.86
Sardinia	25.87	27.66	6.91
Abruzzo	6.88	10.43	51.67
Campania	50.46	41.65	-17.45
Molise	0.00	0.00	
Apulia	0.00	0.00	
Basilicata	73.06	72.99	-0.10
Calabria	73.00	75.76	3.77
Sicily	80.36	82.63	2.83
Armed Forces	0.00	0.00	
Italy	**33.04**	**33.07**	**0.10**

Table 6 shows the number of collections carried out by BCSs (total and by Association/Federation); 94% were carried out by the four Associations/Federations that go to form the Inter-associative Committee of Voluntary Italian Blood Donors Associations/Federations (CIVIS).

Table 6. Number of collections carried out by BCSs (2017-2018)

Association/Federation	2017	2018	Δ%
AVIS	830,575	813,662	-2.04
FIDAS	92,522	96,149	3.92
FRATRES	13,576	13,773	1.45
CRI	5,500	9,029	64.16
Other	50,965	56,764	11.38
Total	**993,138**	**989,377**	**-0.38**

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 shows data concerning the production of blood components. Compared to 2017, there was a slight drop in the total number of units of blood components produced.

Table 7. Blood component production (2017-2018)

Blood component	2017	2018	Δ%
Red Blood Cells	2,560,000	2,550,046	-0.39
Red Blood Cells from whole blood	*2,533,846*	*2,533,856*	0.00
Red Blood Cells by apheresis	*26,154*	*16,190*	-38.10
Platelets from single donors	45,455	20,043	-55.91
Platelet Pools	189,280	203,992	7.77
Platelets by apheresis	65,392	66,999	2.46
Plasma	**2,946,186**	**2,942,344**	**-0.13**
Recovered Plasma	2,535,264	2,534,728	-0.02
Source Plasma	349,967	348,504	-0.42
Source Plasma from multiple apheresis	60,955	59,112	-3.02
Total	**5,806,313**	**5,783,424**	**-0.39**

In 2018, 8,049 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 2017, there was:

a) an overall decrease in the total number of units of blood components discarded (Table 9);
b) an increase 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) an increase in the production of autologous blood components for non-transfusional use (Table 12);
e) a slight increase in the number of patients who predeposited blood components for autologous transfusion (Table 13);
f) an approximate 1% reduction of the number of transfused patients, including those transfused in BEs (day hospital) (Table 14).

Table 8. Transfused units of blood components (2017-2018)

Blood component	2017	2018	Δ%
Red Blood Cells	2,457,300	2,443,359	-0.57
Red Blood Cells from whole blood	2,437,982	2,428,264	-0.40
Red Blood Cells by apheresis	19,318	15,0958	-21.86
Platelets from single donors	29,028	8,447	-70.09
Platelets Pools	157,944	169,178	7.11
Platelets by apheresis	55,187	55,596	0.74
Plasma	284,406	268,349	-5.65
Recovered Plasma	*118,851*	*100,927*	*-15.08*
Source Plasma	*38,256*	*32,519*	*-15.00*
Source Plasma from multiple apheresis	*7,895*	*6,949*	*-11.98*
Pharmaceutical Inactivated Plasma	*119,404*	*127,954*	*7.16*
Total	**2,983,865**	**2,944,929**	**-1.30**

Table 9. Blood components discarded for reasons linked to health, technical issues, quality control and expiry dates (2017-2018)

Blood component	2017	2018	Δ%
Red Blood Cells	84,252	77,888	-7.55
Platelets from single donors	19,848	11,459	-42.27
Platelet Pools	30,936	31,365	1.39
Platelets by apheresis	7,931	6,767	-14.68
Plasma	131,652	128,494	-2.40
Recovered Plasma	*109,256*	*108,671*	*-0.547*
Source Plasma	*17,823*	*16,059*	*-9.90*
Source Plasma from multiple apheresis	*4,573*	*3,764*	*-17.69*
Total	**274,619**	**255,973**	**-6.79**

Table 10. Plasma for fractionation (2017-2018)

Blood component	2017	2018	Δ%
Plasma for fractionation (kg)	**819,114**	**843,716**	**3.00**

Data source: Pharmaceutical industry - year 2018 data updated to April 2019.

Table 11. Production and use of allogeneic blood components for non-transfusion use (2017-2018)

Blood component	2017	2018	Δ%
Platelet Gel			
Produced	7,280	9,574	31.51
*of which those that could be further evaluated**	*7,710*	*8,311*	*7.80*
Used	6,525	7,283	11.62
Not Used	1,185	1,028	-13.25
Fibrin Glue			
Produced	200	114	-43.00
*of which those that could be further evaluated**	*236*	*196*	*-16.95*
Used	202	185	-8.42
Not Used	34	11	-67.65

* 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 (2017-2018)

Blood component	2017	2018	Δ%
Platelet Gel			
Produced	21,460	26,836	25.05
*of which those that could be further evaluated **	*17,347*	*21,211*	*22.27*
Used	15,816	19,267	21.82
Not Used	1,531	1,944	26.98
Fibrin Glue			
Produced	96	228	137.50
*of which those that could be further evaluated **	*69*	*179*	*159.42*
Used	61	175	186.89
Not Used	8	4	-50.00

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

Table 13. Autologous donation and transfusion (2017-2018)

Patients and autologous donation activities	2017	2018	Δ%
Patients who predeposited blood components for autologous transfusion	15,012	15,236	1.49
Patients who underwent an autologous transfusion	13,252	12,656	-4.50

Table 14. Transfused patients (2017-2018)

Patients* transfused with:	2017	2018	Δ%
Whole Blood^	79	59	-25.32
Red Blood Cells	603,858	596,549	-1.21
Plasma	56,636	53,160	-6.14
Platelets	53,080	53,209	0.24
Other	2,902	3,324	14.54
Total**	**630,203**	**630,770**	**-1.01**

* 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 (Annex to the chapter).

Table 15. Quantitative indicators for transfusion activities in Italy (2018)

Indicators		Index
A. General		
A1	N. BE/1,000,000 RP	4.60
A2	N. of professionals operating in BE100,000 RP	12.47
A3	N. of professionals operating in BE/N. of BE	27.12
A4	N. of physicians operating in BE/Total of professionals operating in BE (%)	22.84
B. Donors		
B1	N. of donors/1,000 RP	27.82
B2	M/F ratio: female donors (%)	31.67
B3	N. of donors /1,000 RP in the 18-65 age bracket	44.60
B4	N. of donors in the 18-65 age bracket/1,000 RP	3.47
B5	N. of donors in the 18-25 age bracket /1,000 RP in the 18-65 age bracket	5.57
B6	N. of donors /1,000 RP	23.00
B7	N. of prospective donors /1,000 RP	3.10
B8	N. of first-time donors/1,000 RP	6.14
B9	N. of first-time not pre-qualified donors /1,000 RP	4.09
B10	N. of first-time pre-qualified donors/1,000 RP	2.05
B11	N. of prospective donors who did not donate/Total N. of prospective donors (%)	50.74
B12	N. of “regular” donors/1,000 RP	10.23
C. Donations		
C1	N. of donations (WB + apheresis)/1,000 RP	49.45
C2	N. of donations (WB + apheresis)/Total N. of donors (excluding prospective donors)	1.78
C3	N. of donations WB/1,000 RP	42.48
C4	N. of donations WB/N. of WB donors	1.63
C5	N. of donations in apheresis/1,000 RP	6.97
C6	N. of donations in apheresis/N. of apheresis donors	2.08
D. Production of blood components		
D1	N. of RBC units produced/1,000 RP	42.16
D2	N. of plasma units produced from WB and by apheresis/1,000 RP	48.65
D3	N. of plasma units produced from WB/1,000 RP	41.76
D4	N. of plasma units produced by apheresis (monocomponent or multicomponent)/1,000 RP	6.74
D5	Plasma for fractionation (kg)/1,000 RP	13.52
D6	Plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%)	26.46
D7	N. of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 RP	1.11
D8	N. of platelet units produced from buffy-coat pools/1,000 RP	3.37
D9	N. of platelet units produced from PRP and single buffy-coats/1,000 RP	0.33
D10	N. of pre-storage leukodepleted RBC units/N. of RBC units produced (%)	100.00
D11	N. of pre-storage leukodepleted platelet units produced by apheresis/ N. of platelet units produced by apheresis (%)	69.48
D12	N. of “adult platelet doses”/1,000 RP	4.55
E. Discarded blood components		
E1	N. of discarded RBC units/N. of “usable” RBC units (produced + acquired - released) (%)	3.05
E2	N. of expired RBC units discarded/N. of discarded RBC units (%)	30.88
E3	N. of RBC units discarded for technical reasons/N. of discarded RBC units (%)	29.02
E4	N. of RBC units discarded for health reasons/N. of discarded RBC units (%)	33.71
E5	N. of RBC units discarded for reasons linked to QC/ N. of discarded RBC units (%)	6.39
E6	N. of discarded plasma units /N. of produced plasma units (%)	4.37
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 (%)	57.17
E8	N. of platelet units by apheresis discarded /N. of platelet units by apheresis produced (%)	10.10
E9	N. of platelet units from buffy-coat pools discarded / N. of platelet units from buffy-coat pools produced (%)	15.38

F. Transfused blood components		
F1	N. of transfused RBC units / 1,000 RP	40.40
F2	N. of transfused plasma units (from WB + by apheresis + PIP) / 1,000 RP	4.44
F3	N. of transfused WB plasma units / Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	37.61
F4	N. of transfused apheresis plasma units / N. of transfused plasma units (from WB + by apheresis + PIP) (%)	14.71
F5	N. of transfused PIP units / Total N. of transfused plasma units (from WB + by apheresis + PIP) (%)	47.68
F6	N. of "adult platelet doses"/1,000 RP	3.74

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 2018, 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 2017, a slight increase in the number of employees operating in BEs was noted.

Although there was a very slight rise in the total number of donors of blood and blood components (0.15%), especially regular donors (1.14%), the national self-sufficiency was ensured. In 2018, an overall drop in the number of transfused units of blood components (-1.30%) was noted, and was more marked particularly for plasma for clinical use compared to the previous year (-5.65%). Data showed a slight reduction in the overall production of blood components from apheresis and of platelets from single units while there was a 3.0% increase in the quantity of plasma for fractionation compared to the previous year. This increase was due to the provisions set out in the Ministry of Health Decree of 2nd November, 2015 (9), which authorised the collection of higher volumes of plasma from apheresis.

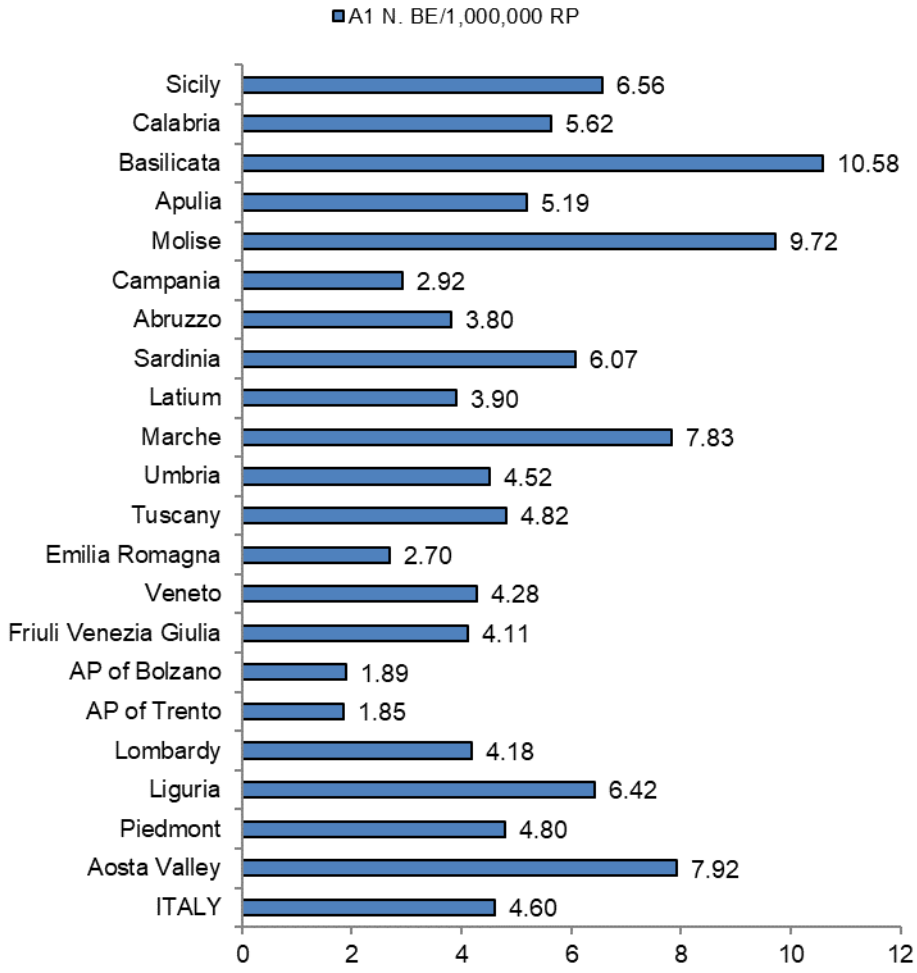
A high percentage of donors who redonated during 2018 were first-time pre-qualified donors (35%).

Compared to 2017 the slight reduction of the use of RBCs shows that the Patient Blood Management strategies and techniques (7-9), first specified in the Italian national blood and blood products self-sufficency plans dating back to 2012 (see the latest Italian self-sufficiency plan 2018 (10)), 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 2018, an increase in the production of homologous platelet gel (approx. +31%) and a decrease in the production of homologous fibrin glue (-43%) was noted.

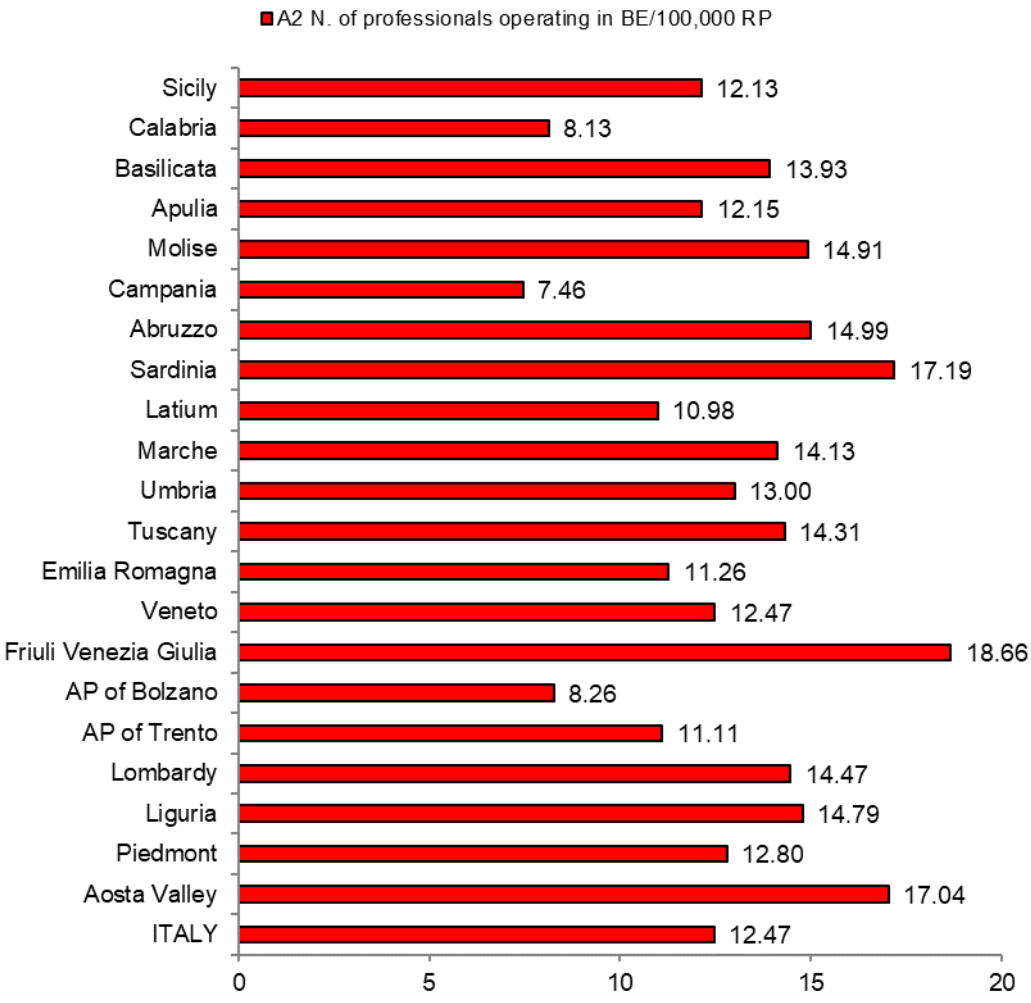
Annex to the chapter

Regional and national indicators 2018



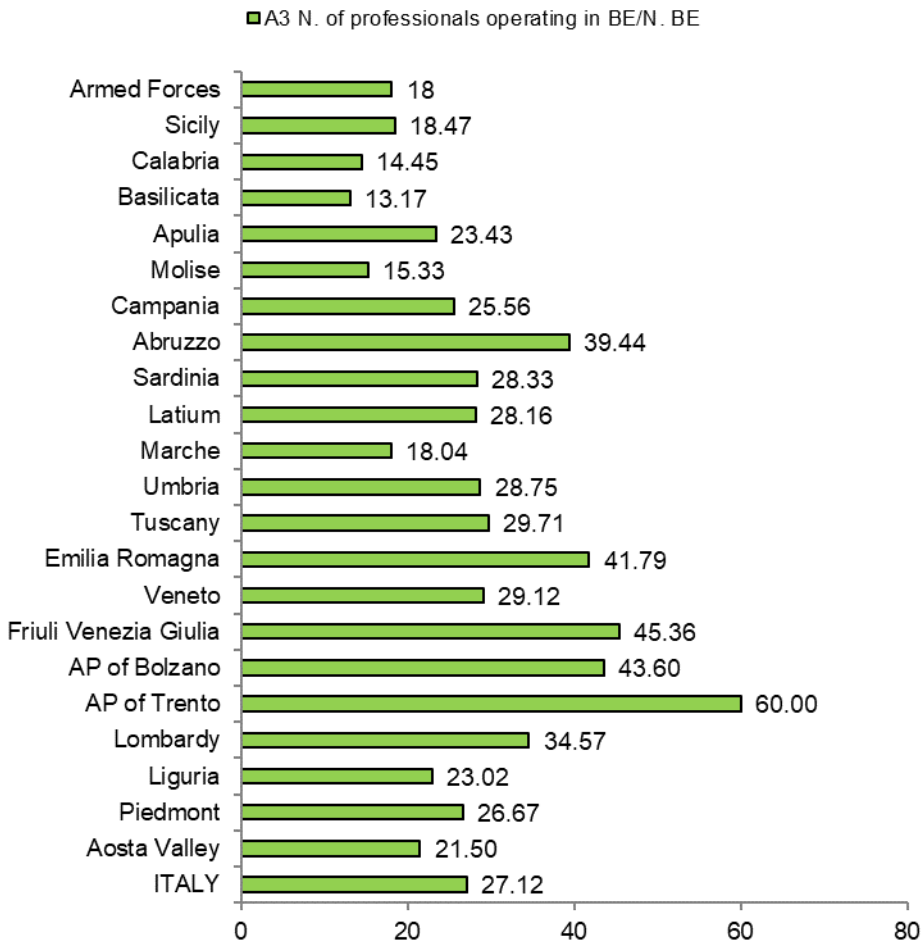
N. number; BE blood establishment/s; RP resident population; AP Autonomous Province

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 (2018)



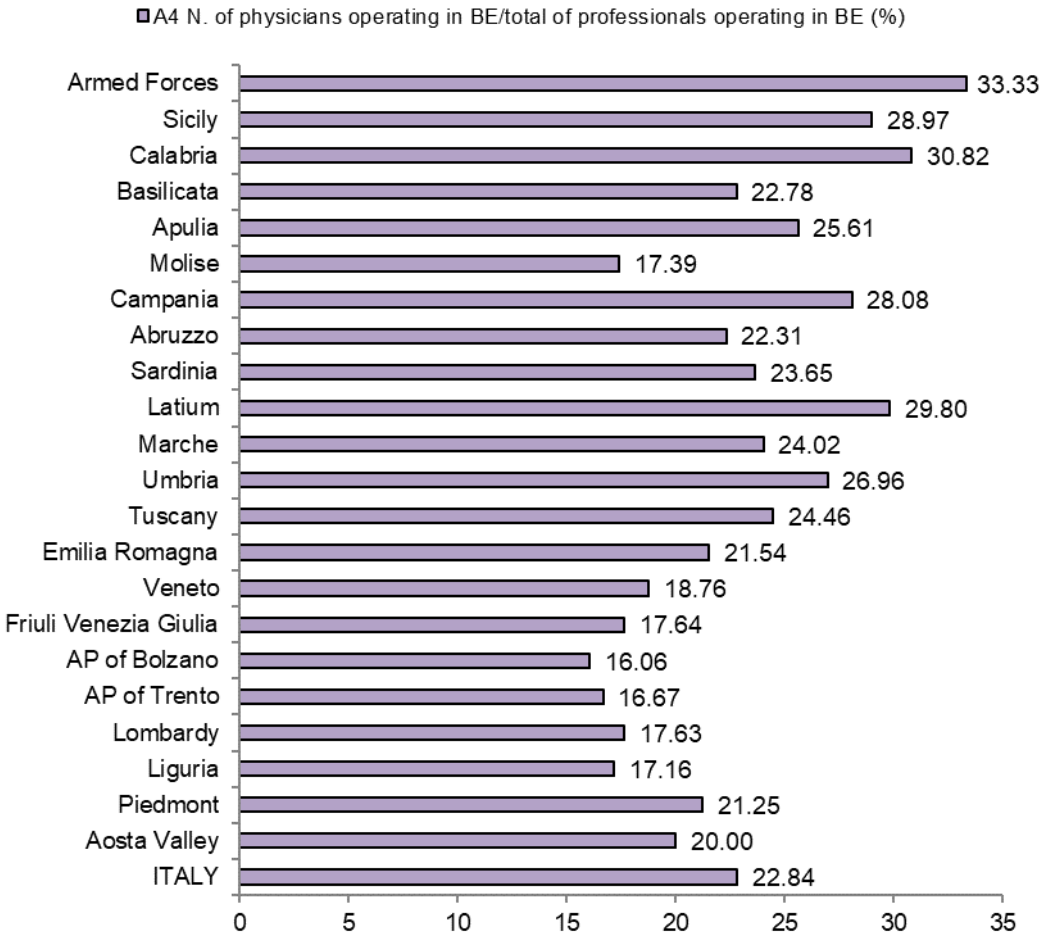
N. number; BE blood establishment/s; RP resident population; AP Autonomous Province

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 (2018)



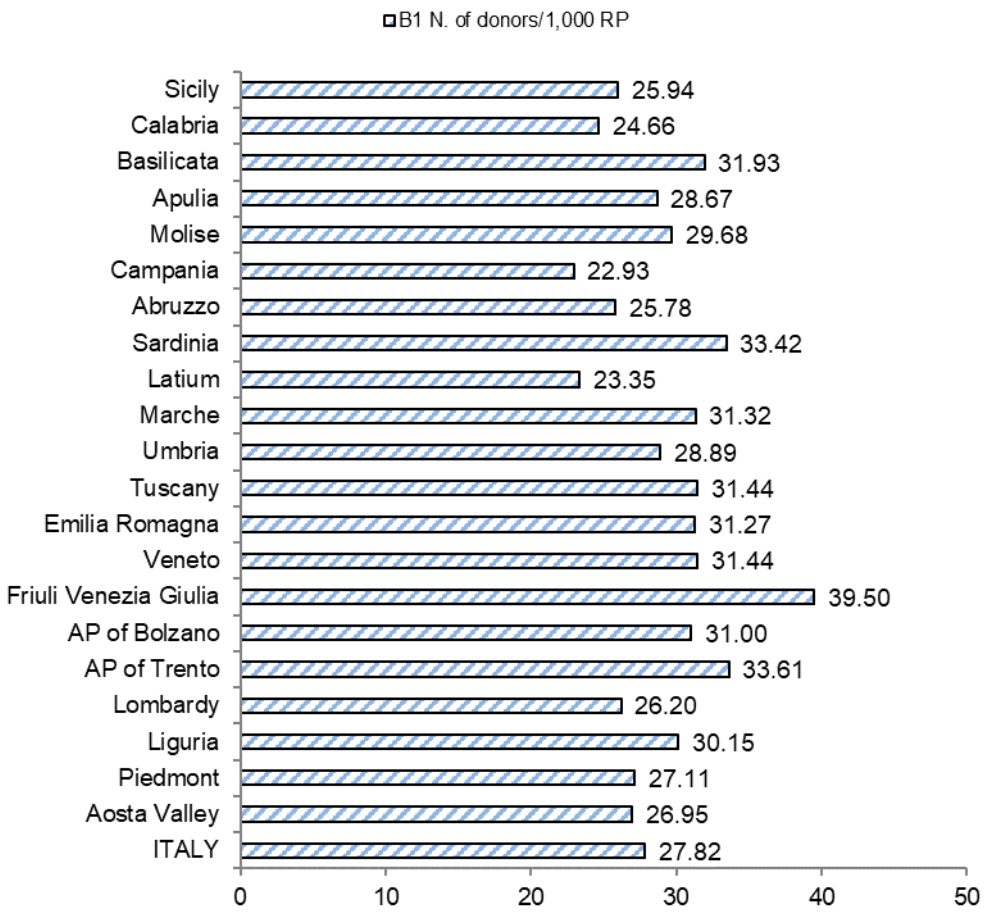
N. number; BE blood establishment/s; AP Autonomous Province

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 (2018)



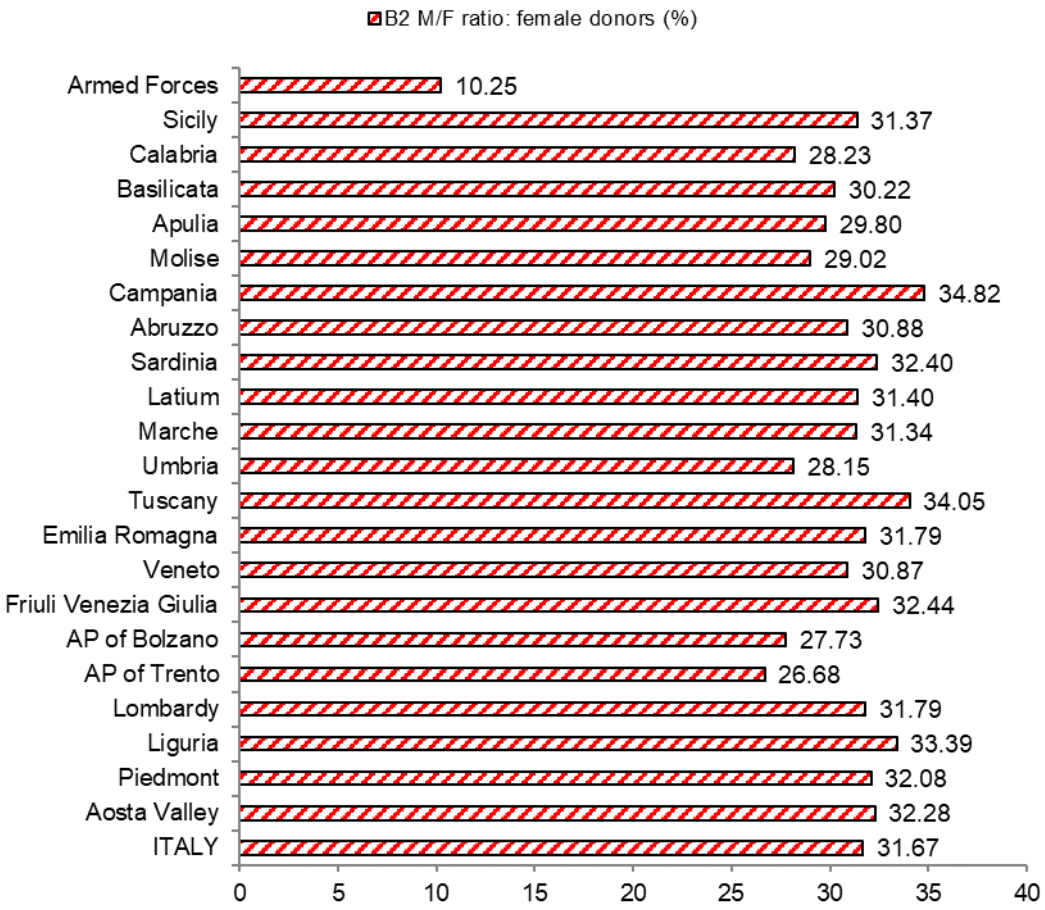
N. number; BE blood establishment/s; AP Autonomous Province

Figure A4. INDICATOR A4: N. of physicians operating in BEs/Total of professionals operating in BEs (%) (excluding physicians operating in BCSs) (2018)



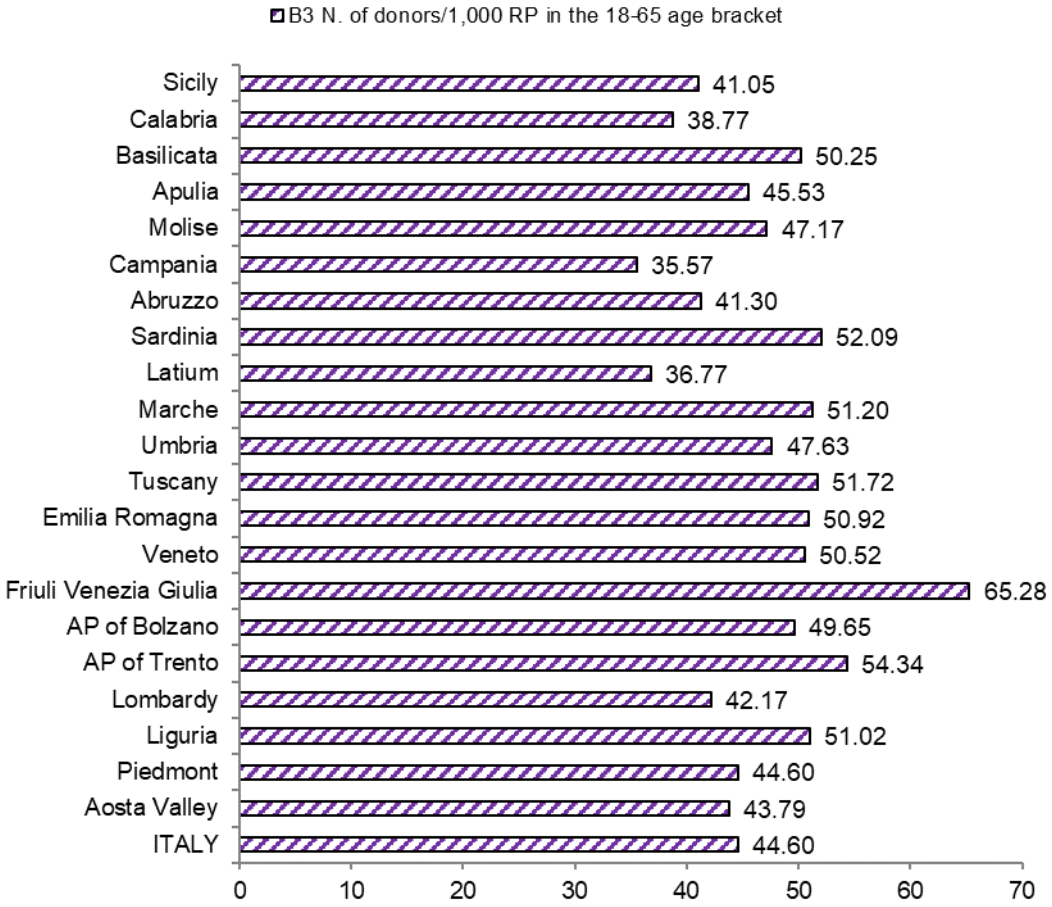
N. number; RP resident population; AP Autonomous Province

Figure A5. INDICATOR B1: Regional blood donors distribution/1,000 resident population (2018)



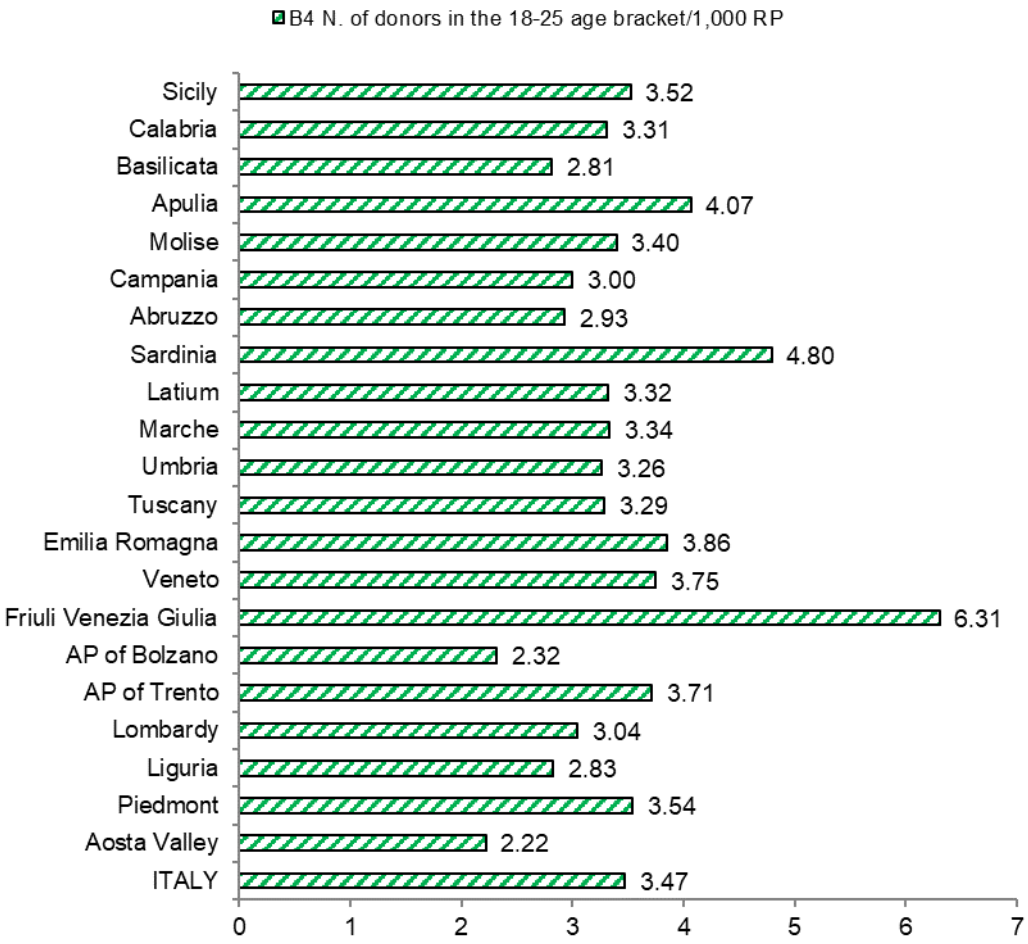
AP Autonomous Province; M male; F Female

Figure A6. INDICATOR B2: M/F ratio, female donors percentage (2018)



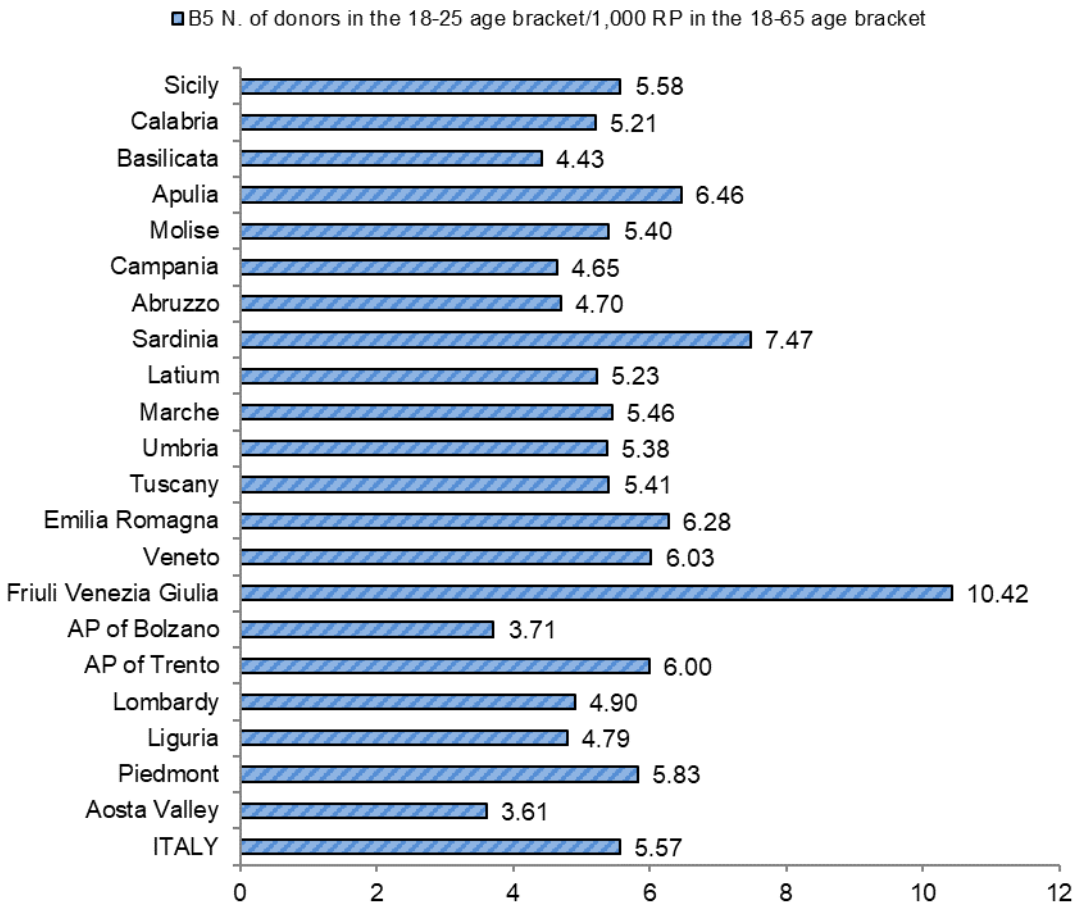
N. number; RP resident population; AP Autonomous Province

Figure A7. INDICATOR B3: N. of donors/1,000 resident population in the 18-65 age bracket (2018)



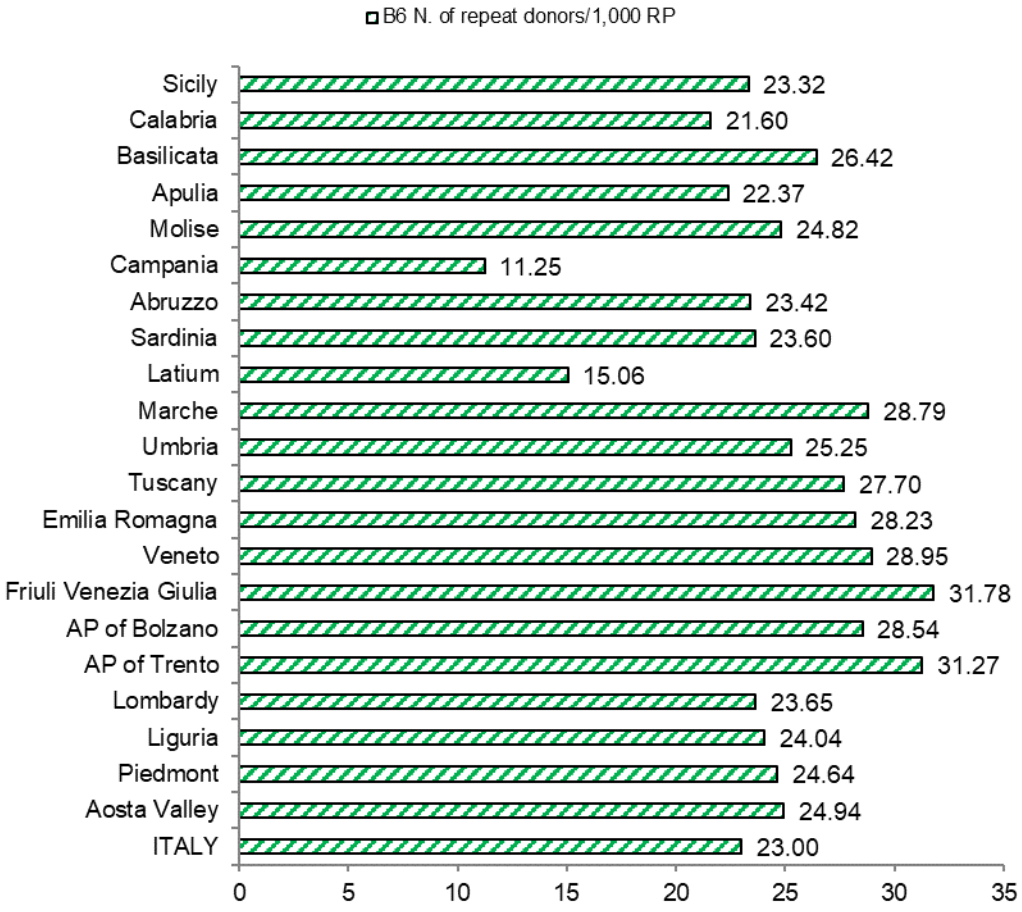
N. number; RP resident population; AP Autonomous Province

Figure A8. INDICATOR B4: N. of donors in the 18-25 age bracket/1,000 resident population (2018)



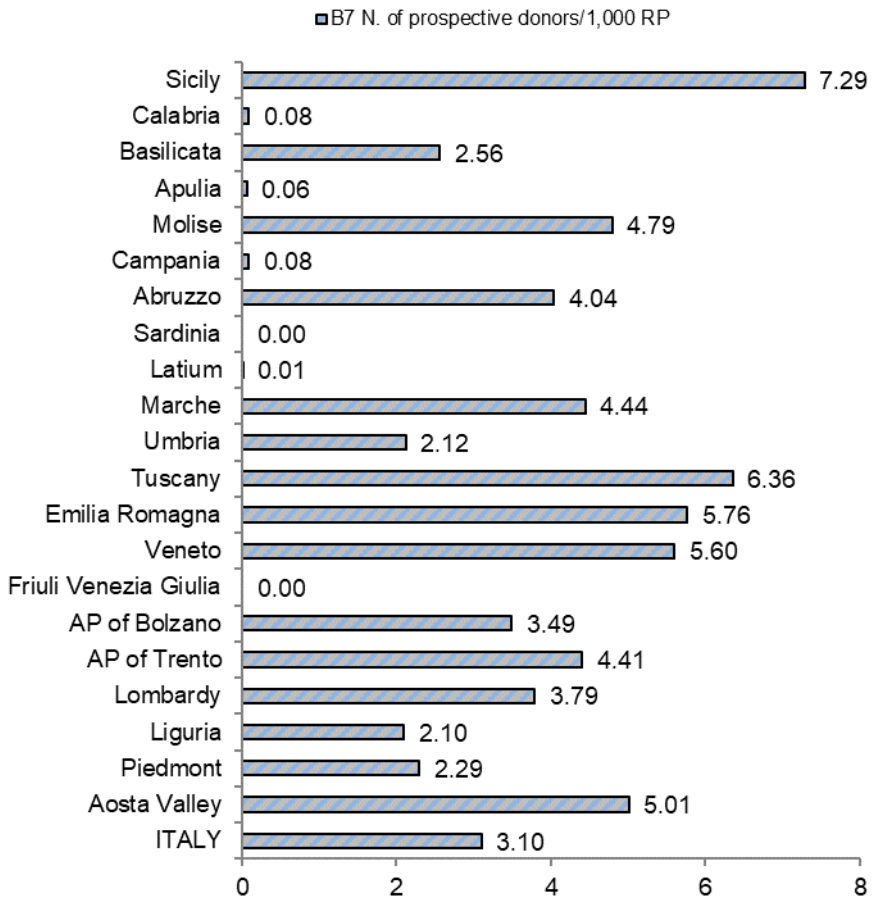
N. number; RP resident population; AP Autonomous Province

Figure A9. INDICATOR B5: N. of donors in the 18-25 age bracket/1,000 resident population in the 18-65 age bracket (2018)



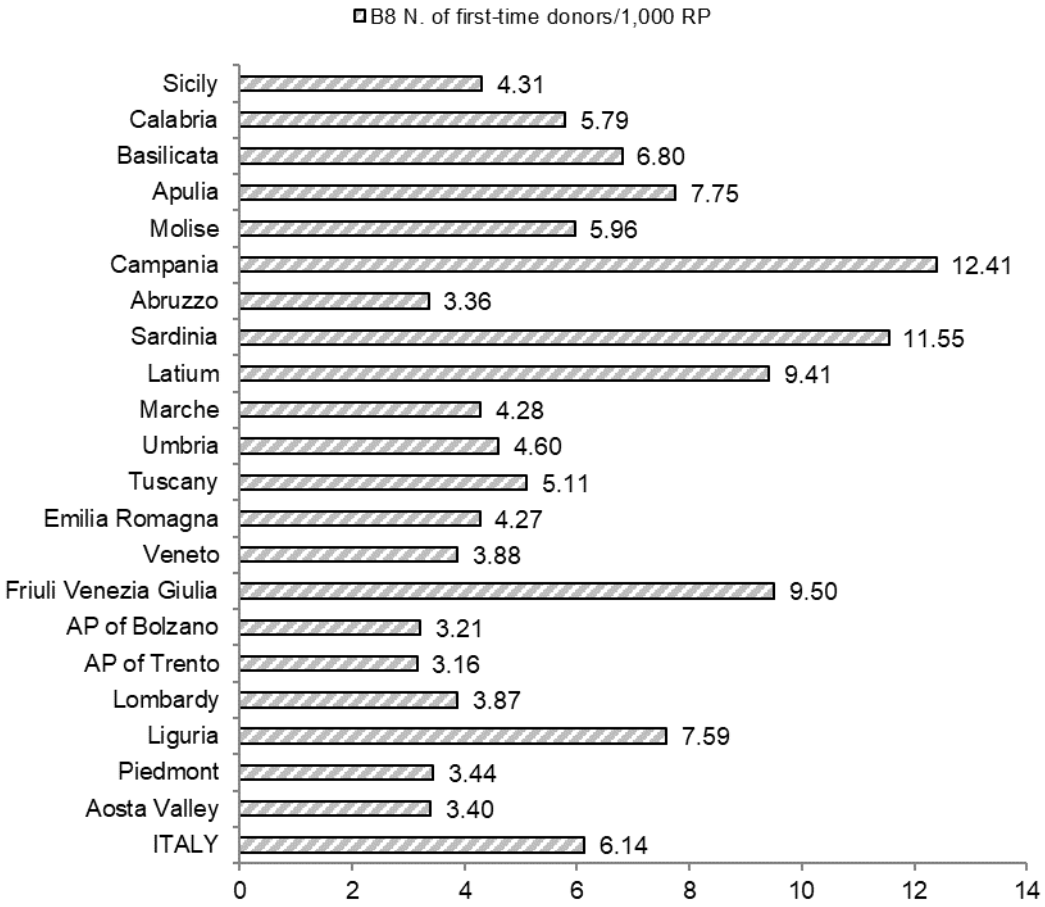
N. number; RP resident population; AP Autonomous Province

Figure A10. INDICATOR B6: N. of repeat donors/1,000 resident population (2018)



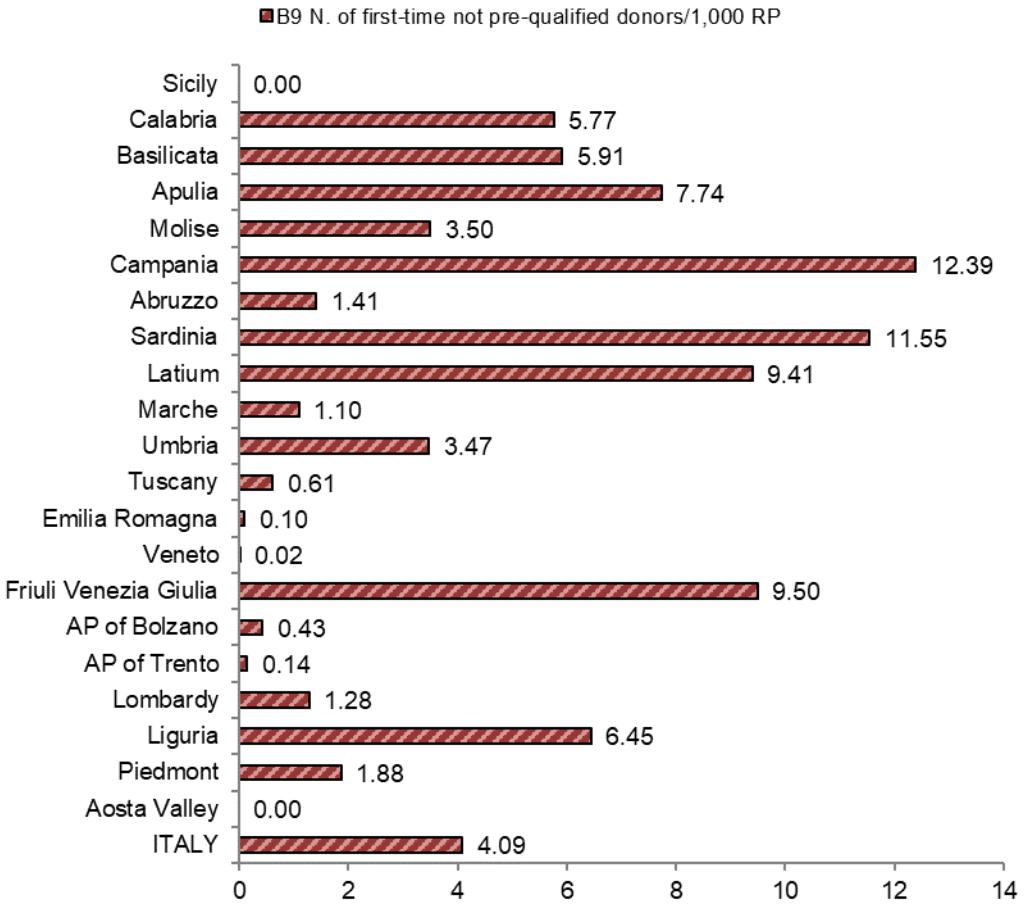
N. number; RP resident population; AP Autonomous Province

Figure A11. INDICATOR B7: N. of prospective donors/1,000 resident population (2018)



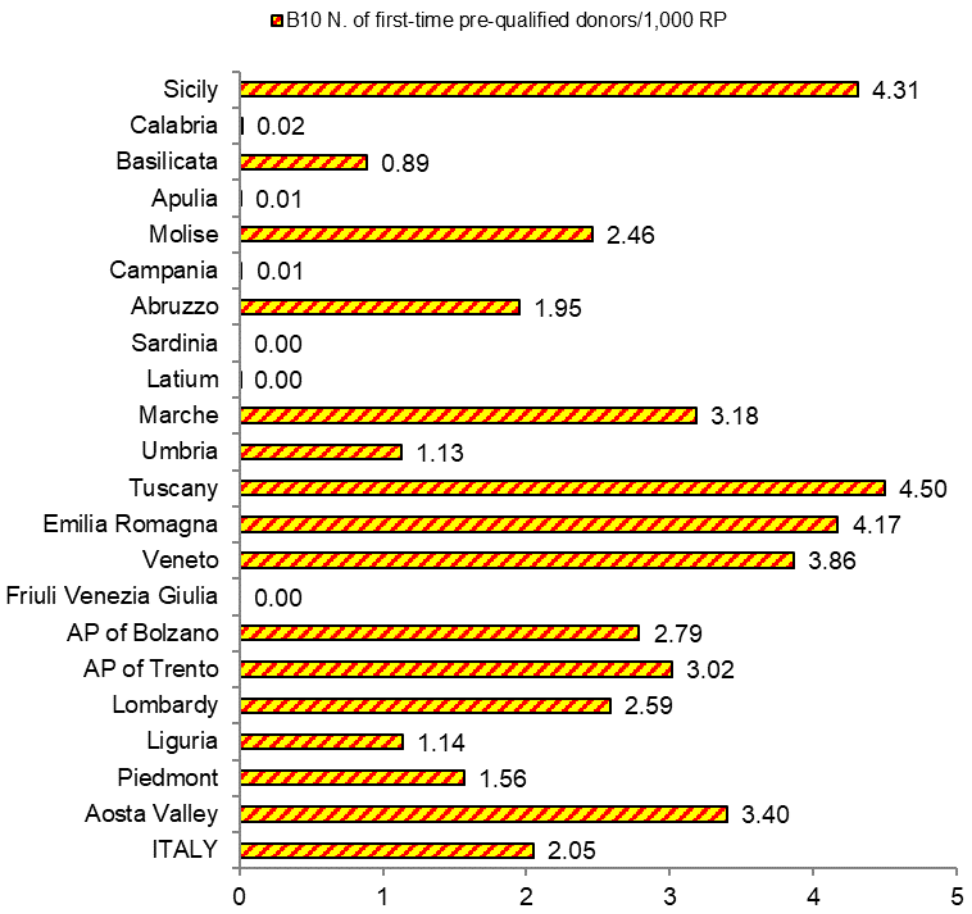
N. number; RP resident population; AP Autonomous Province

Figure A12. INDICATOR B8: N. of first-time donors/1,000 resident population (2018)



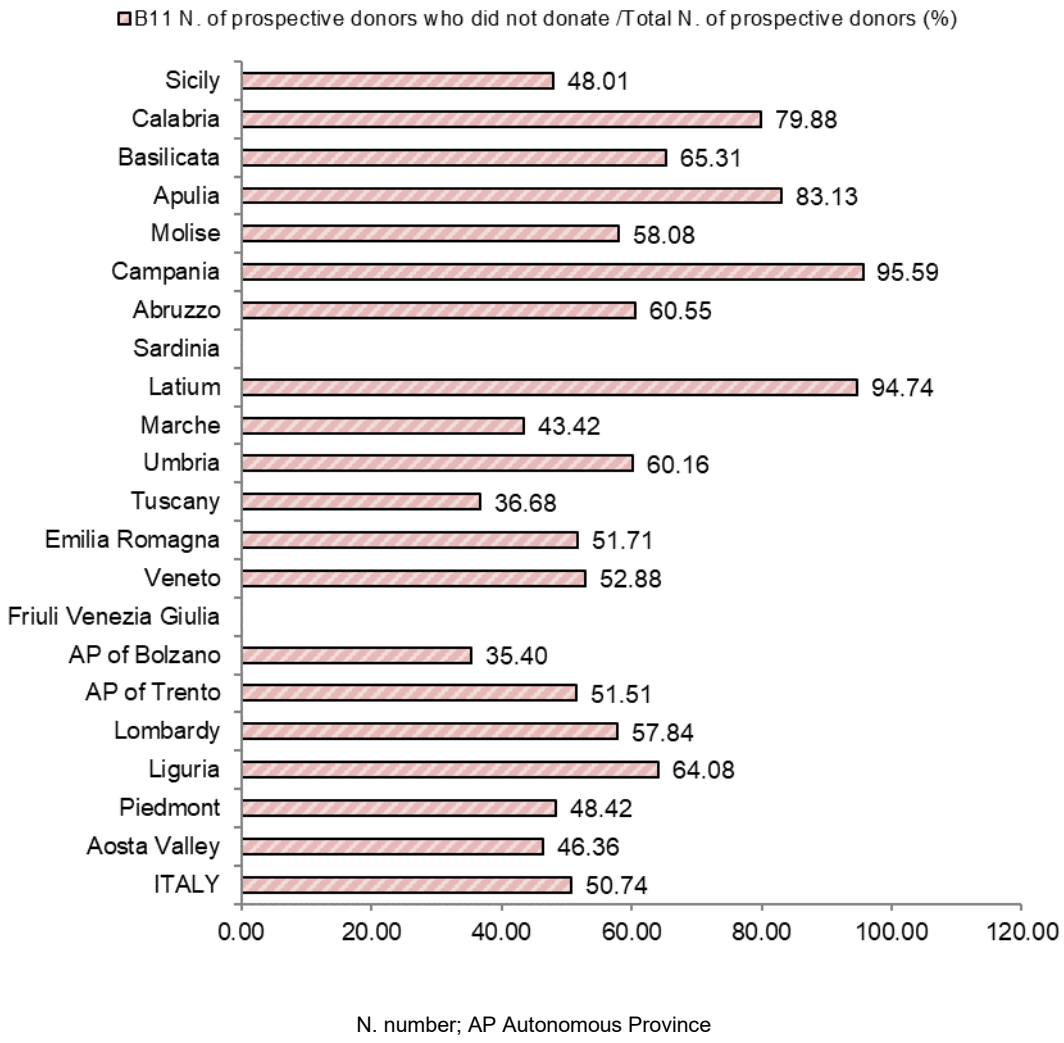
N. number; RP resident population; AP Autonomous Province

Figure A13. INDICATOR B9: N. of first-time not pre-qualified donors/1,000 resident population (2018)



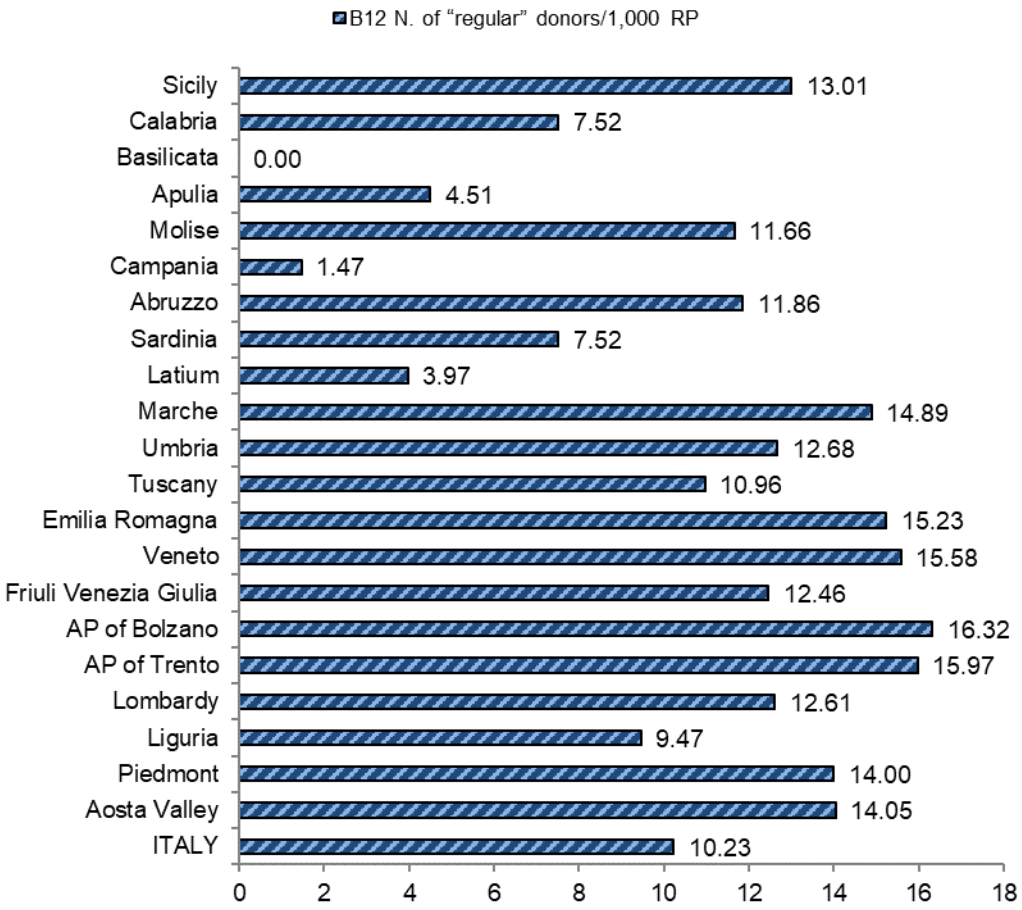
N. number; RP resident population; AP Autonomous Province

Figure A14. INDICATOR B10: N. of first-time pre-qualified donors/1,000 resident population (2018)



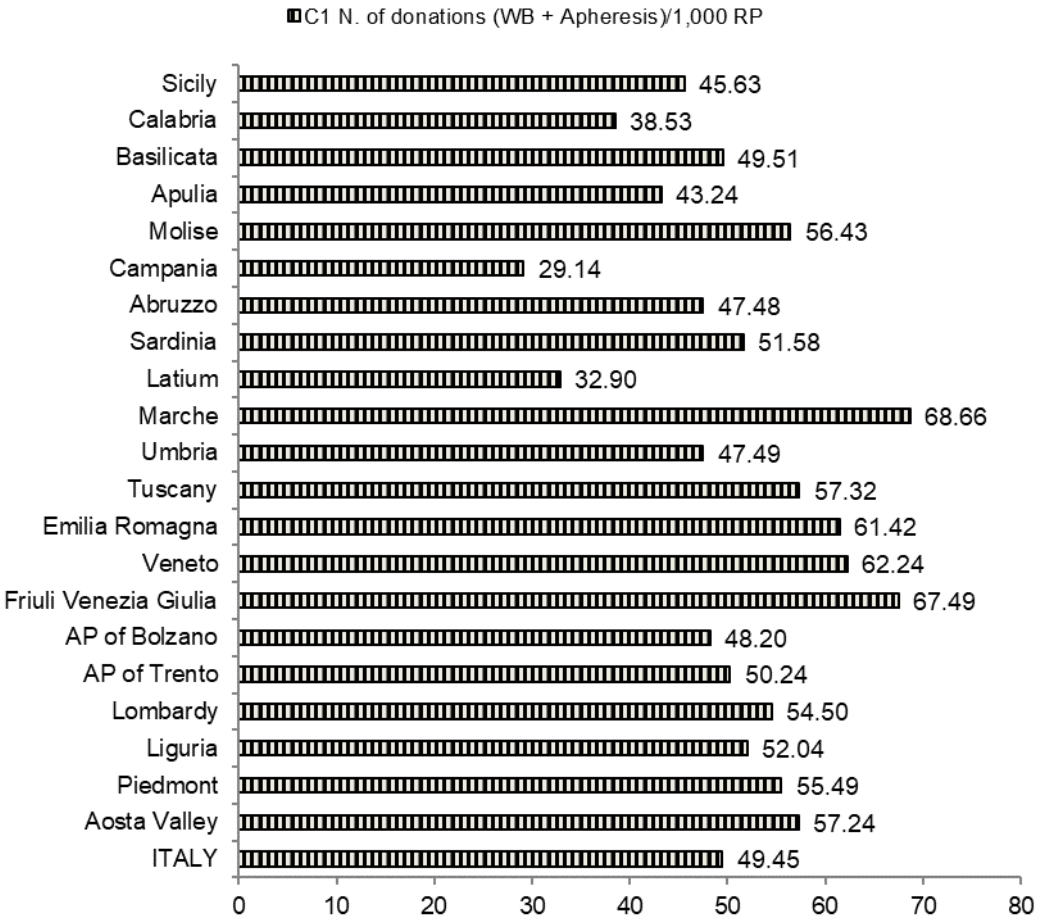
N. number; AP Autonomous Province

Figure A15. INDICATOR B11: N. of prospective donors who did not donate/Total N. of prospective donors (%) (2018)



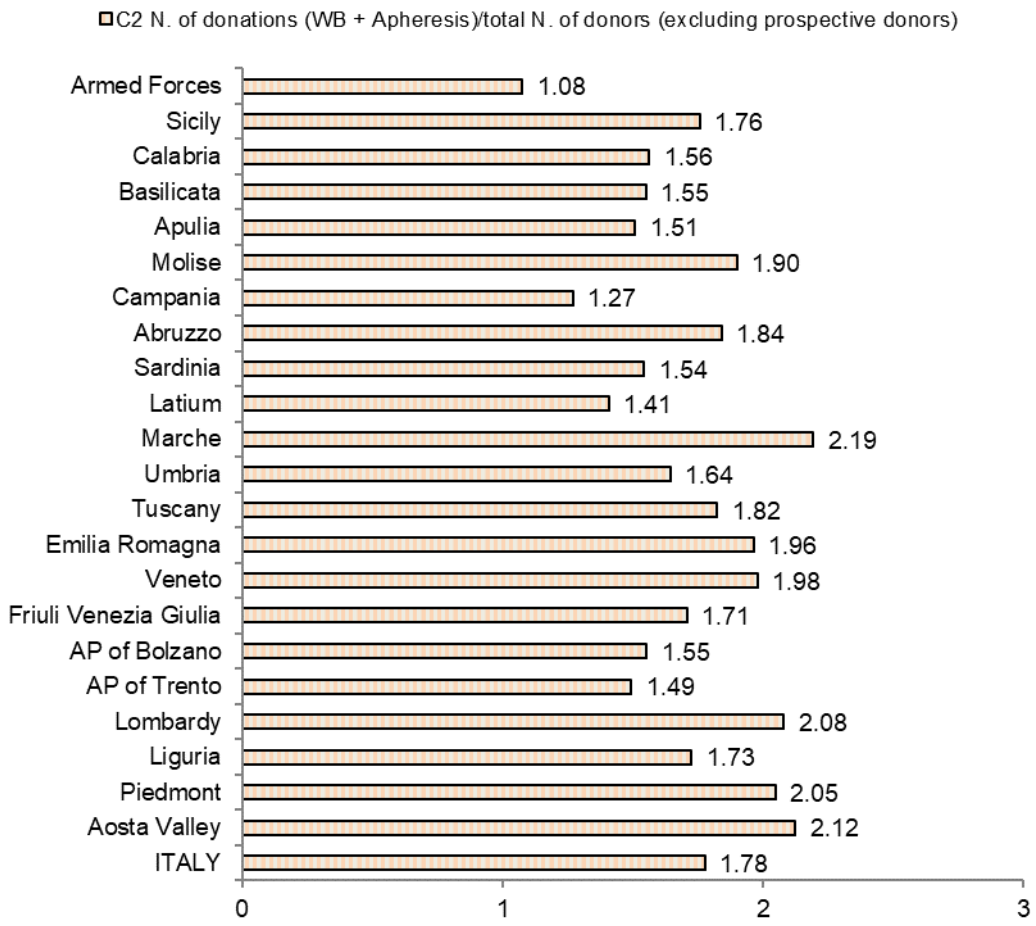
N. number; RP resident population; AP Autonomous Province

Figure A16. INDICATOR B12: N. of "regular" donors/1,000 resident population (2018)



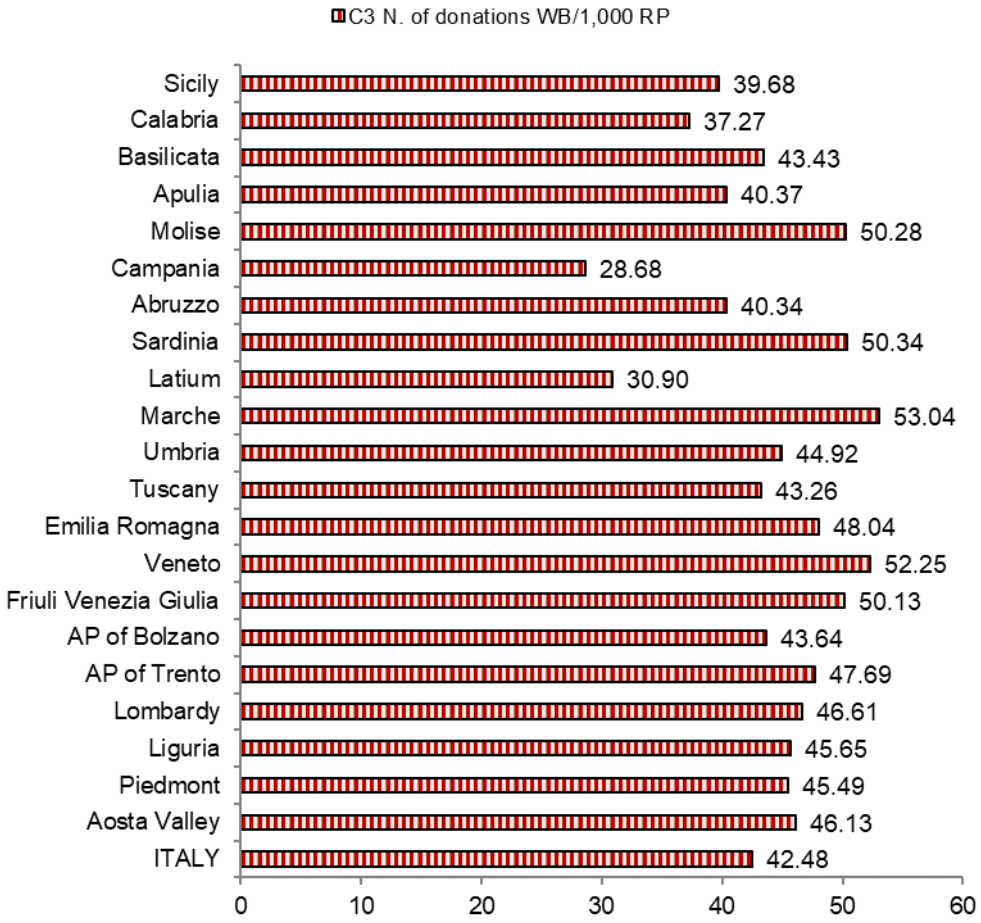
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A17. INDICATOR C1: N. of whole blood and apheresis donations/1,000 resident population (2018)



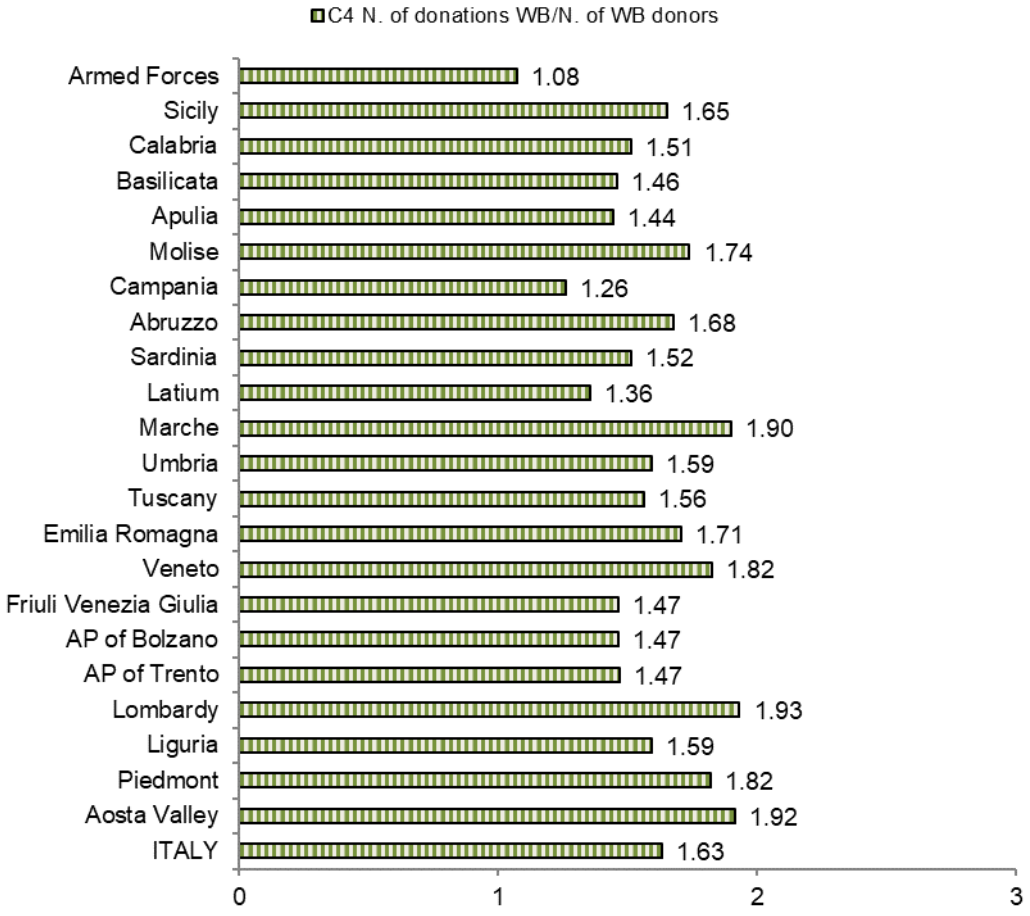
N. number; AP Autonomous Province; WB whole blood

Figure A18. INDICATOR C2: N. of whole blood and apheresis donations/Total N. of donors (excluding prospective donors) (2018)



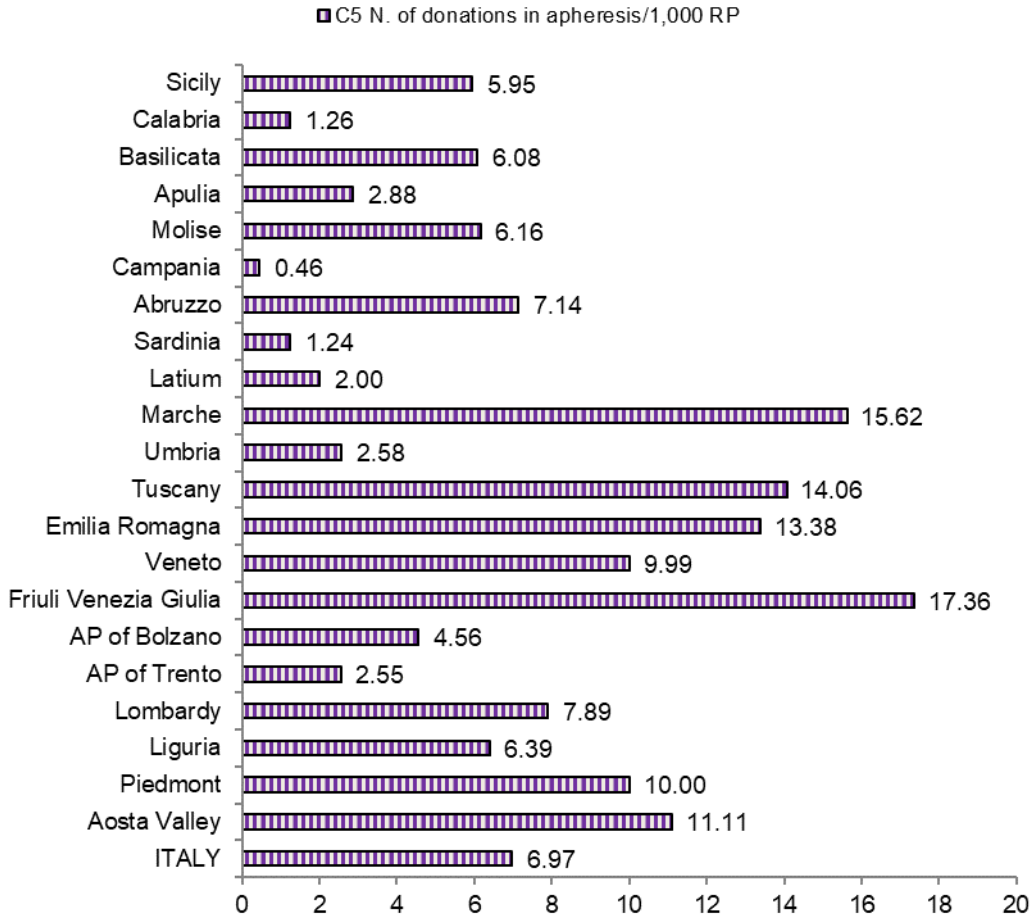
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A19. INDICATOR C3: N. of whole blood donations/1,000 resident population (2018)



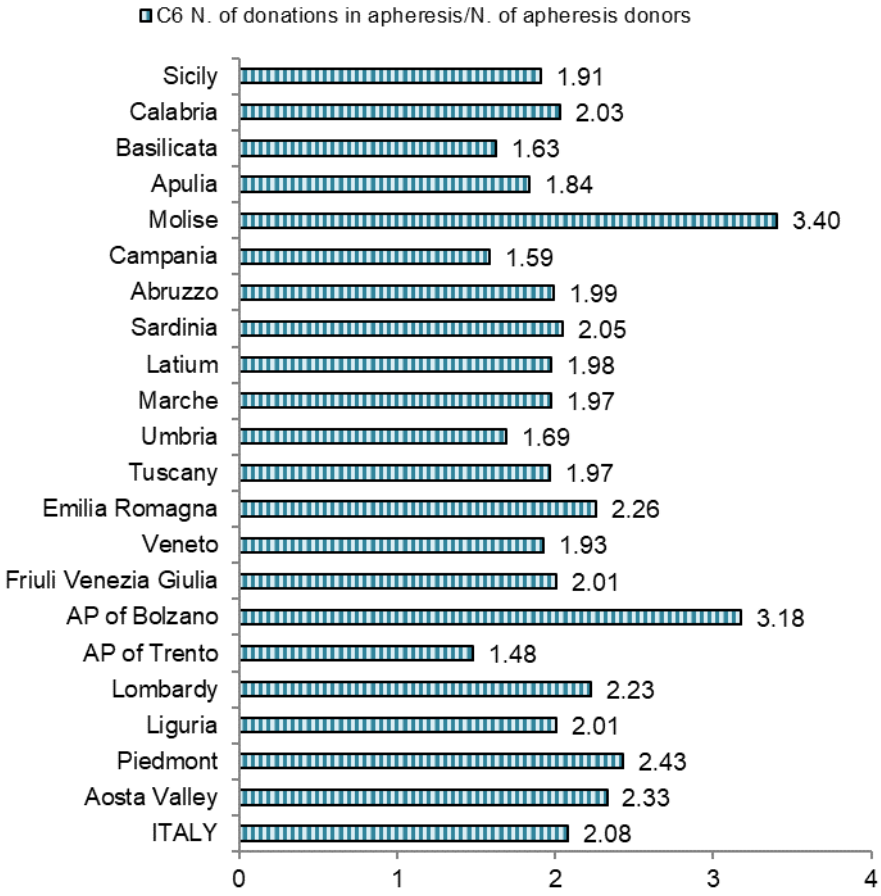
N. number; AP Autonomous Province; WB whole blood

Figure A20. INDICATOR C4: N. of whole blood donations/N. of whole blood donors (2018)



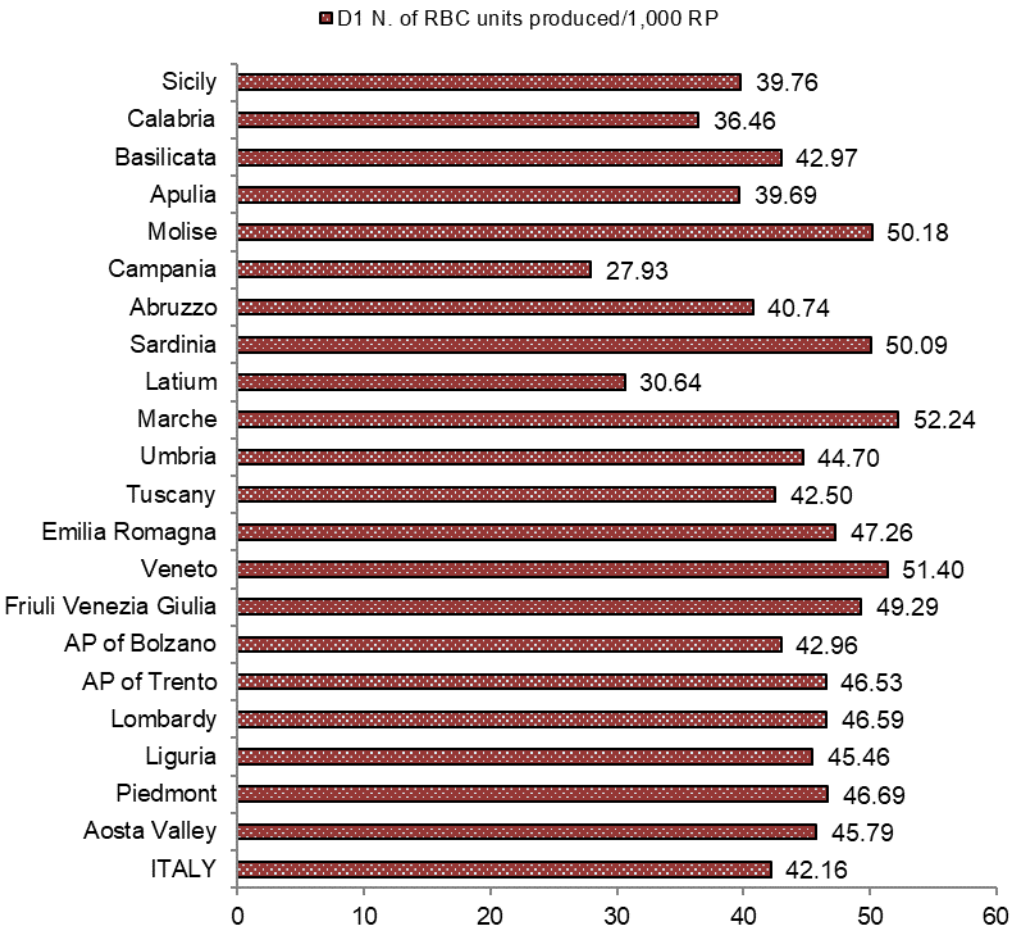
N. number; RP resident population; AP Autonomous Province

Figure A21. INDICATOR C5: N. of donations in apheresis/1,000 resident population (2018)



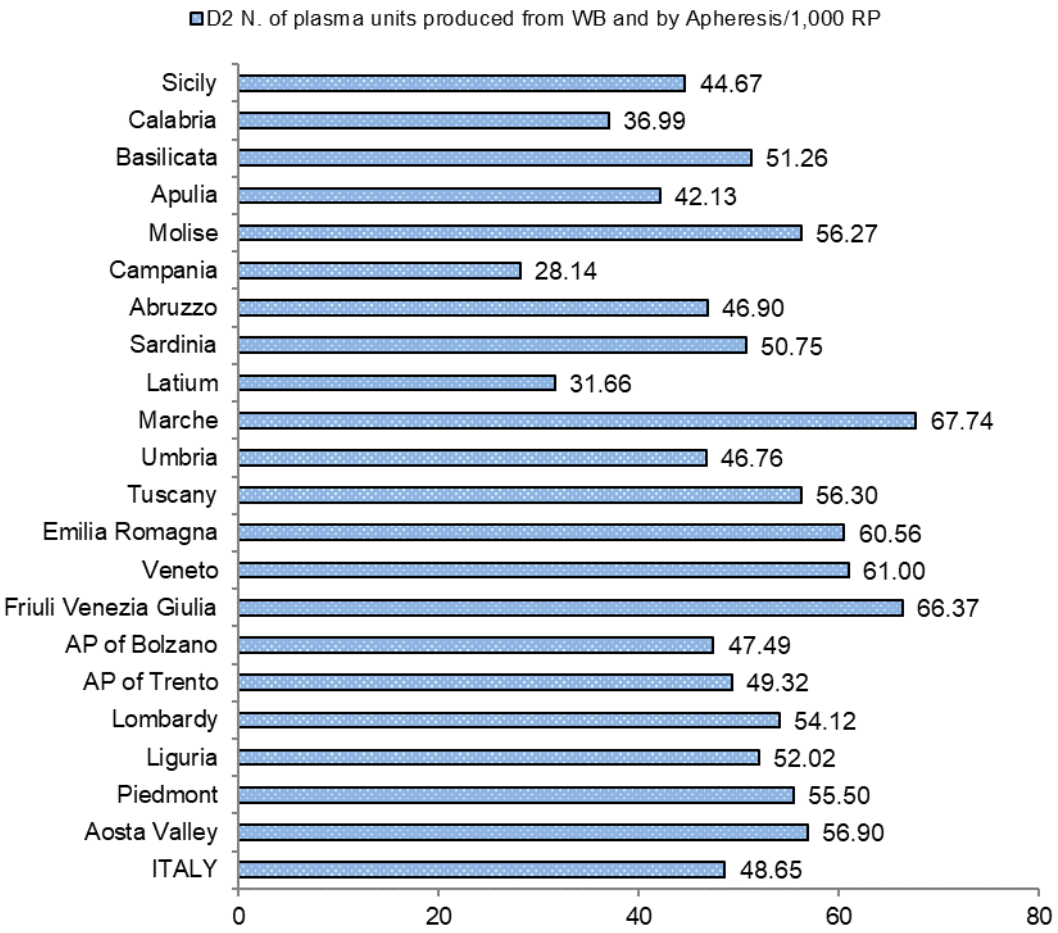
N. number; AP Autonomous Province

Figure A22. INDICATOR C6: N. of donations in apheresis/N. of apheresis donors (2018)



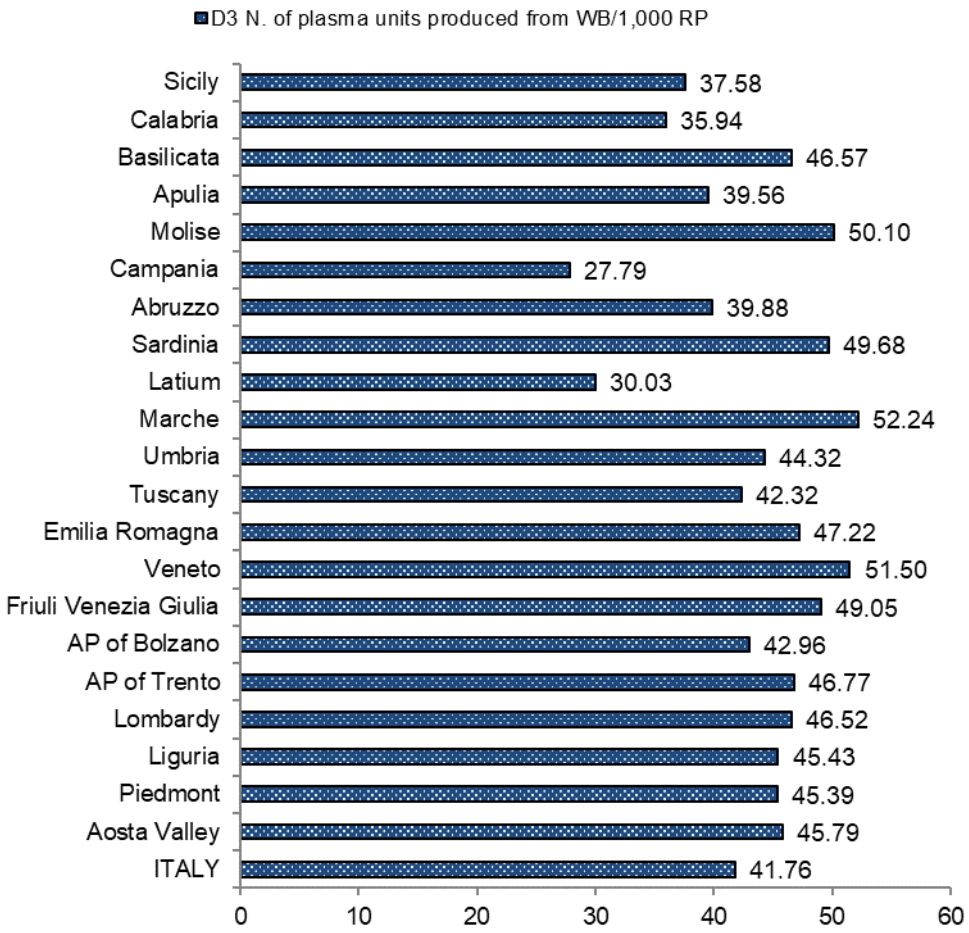
N. number; RP resident population; AP Autonomous Province

Figure A23. INDICATOR D1: RBC units produced/1,000 resident population (2018)



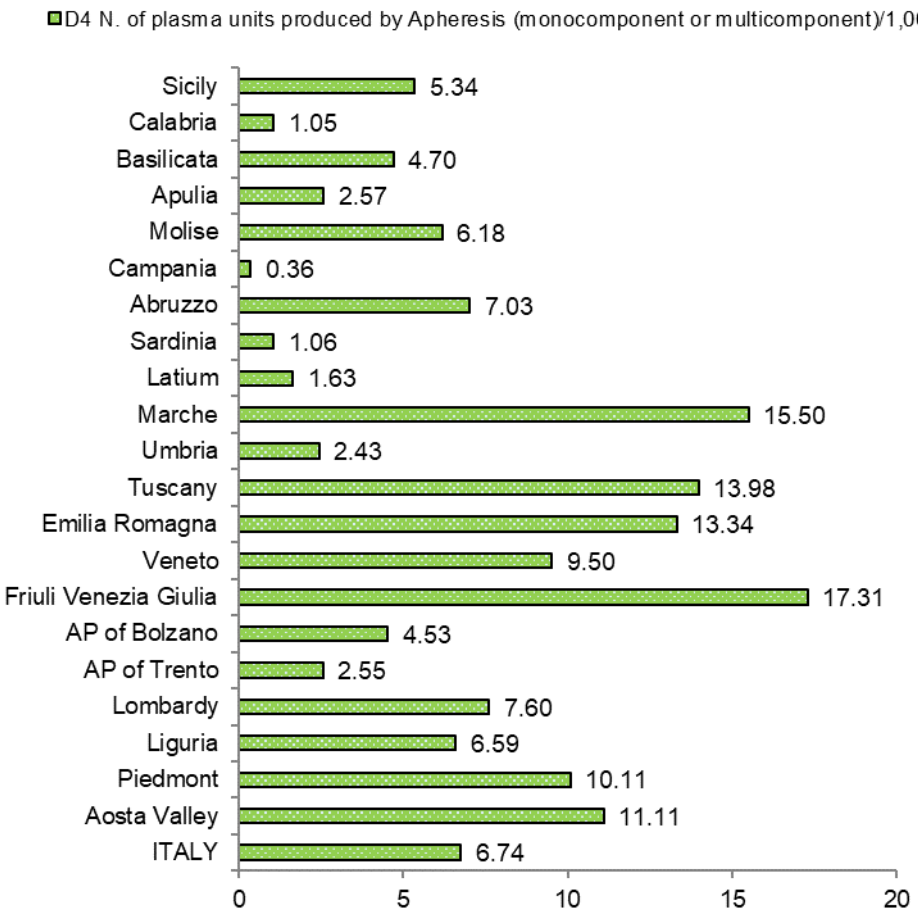
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A24. INDICATOR D2: N. of plasma units produced from whole blood and by apheresis/1,000 resident population (2018)



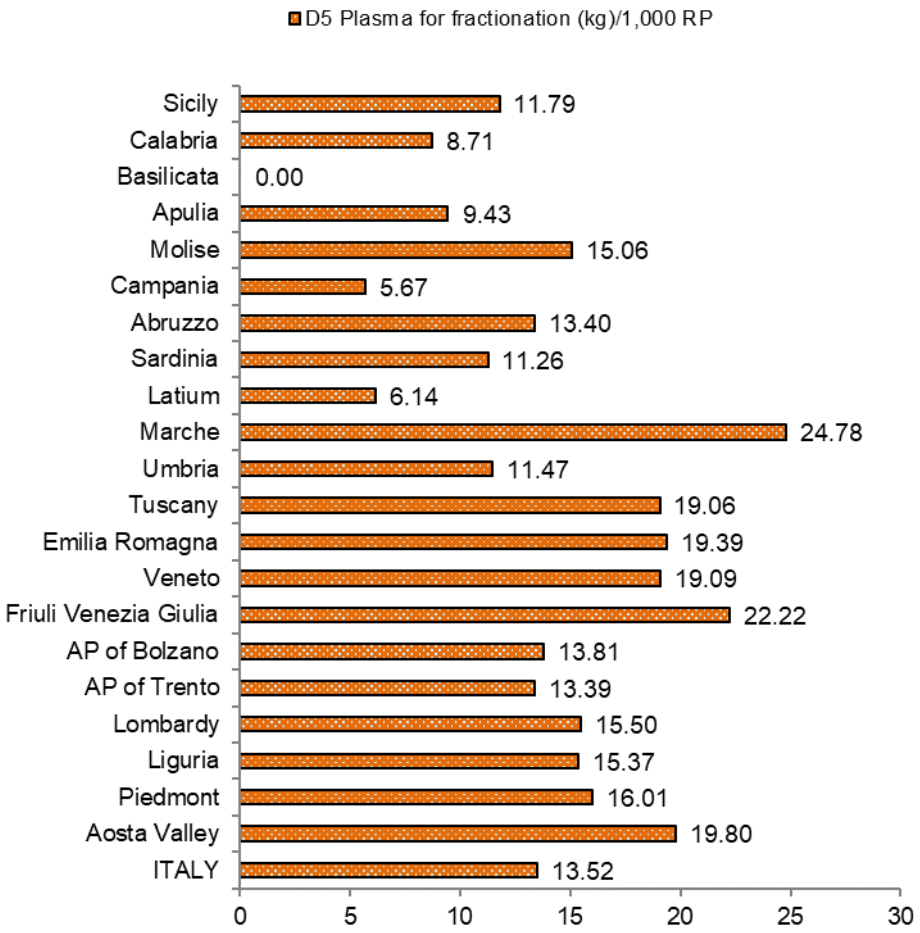
N. number; RP resident population; AP Autonomous Province; WB whole blood

Figure A25. INDICATOR D3: N. of plasma units produced from whole blood/1,000 resident population (2018)



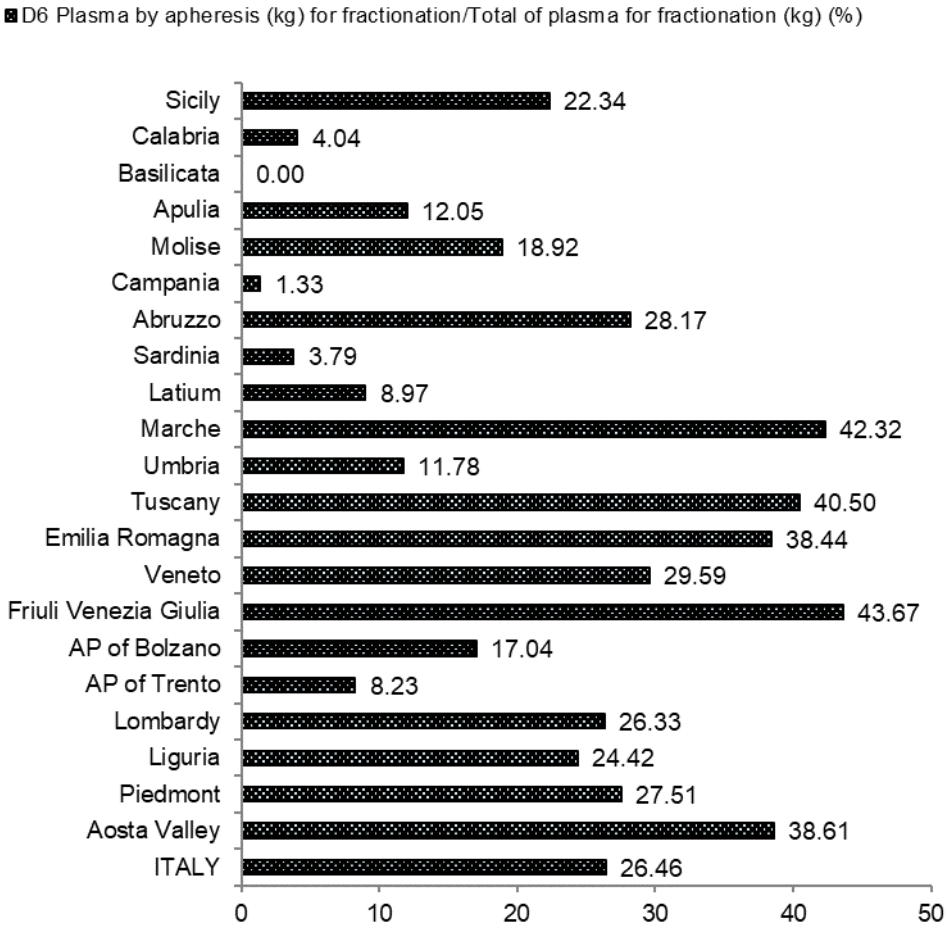
N. number; RP resident population; AP Autonomous Province

Figure A26. INDICATOR D4: N. of plasma units produced from apheresis (monocomponent + multicomponent)/1,000 resident population (2018)



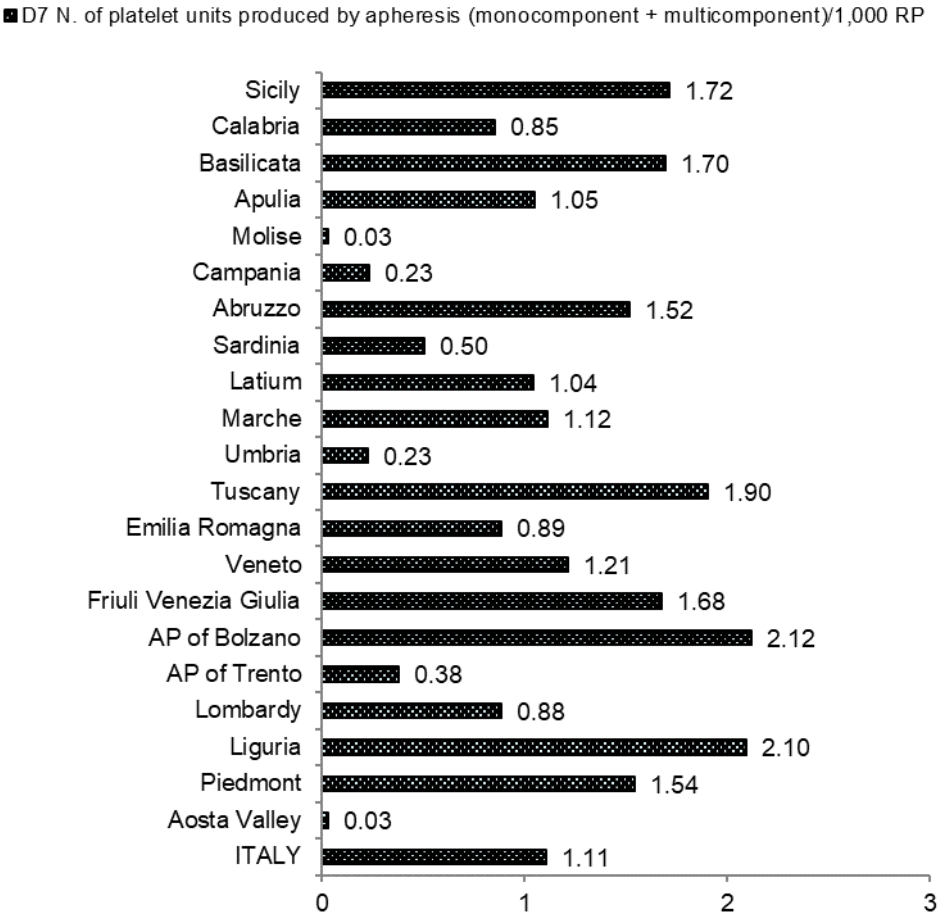
kg kilograms; RP resident population; AP Autonomous Province

Figure A27. INDICATOR D5: plasma (kg) for fractionation/1,000 resident population (from SISTRA) (2018)



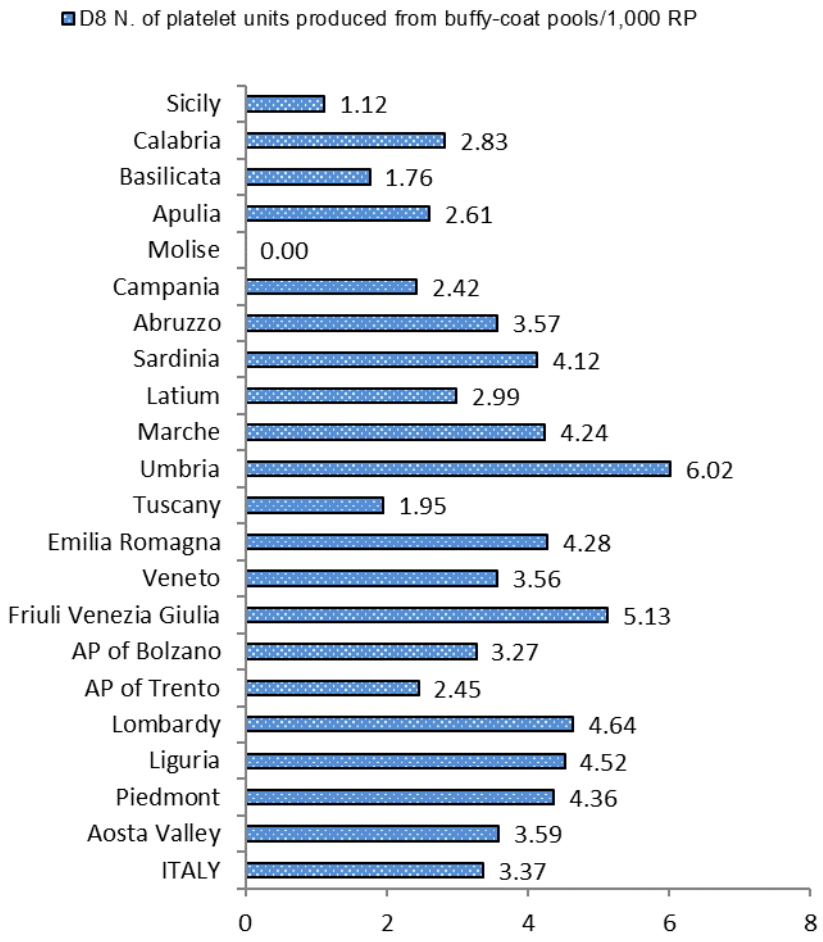
kg kilograms; AP Autonomous Province

Figure A28. INDICATOR D6: plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%) (2018)



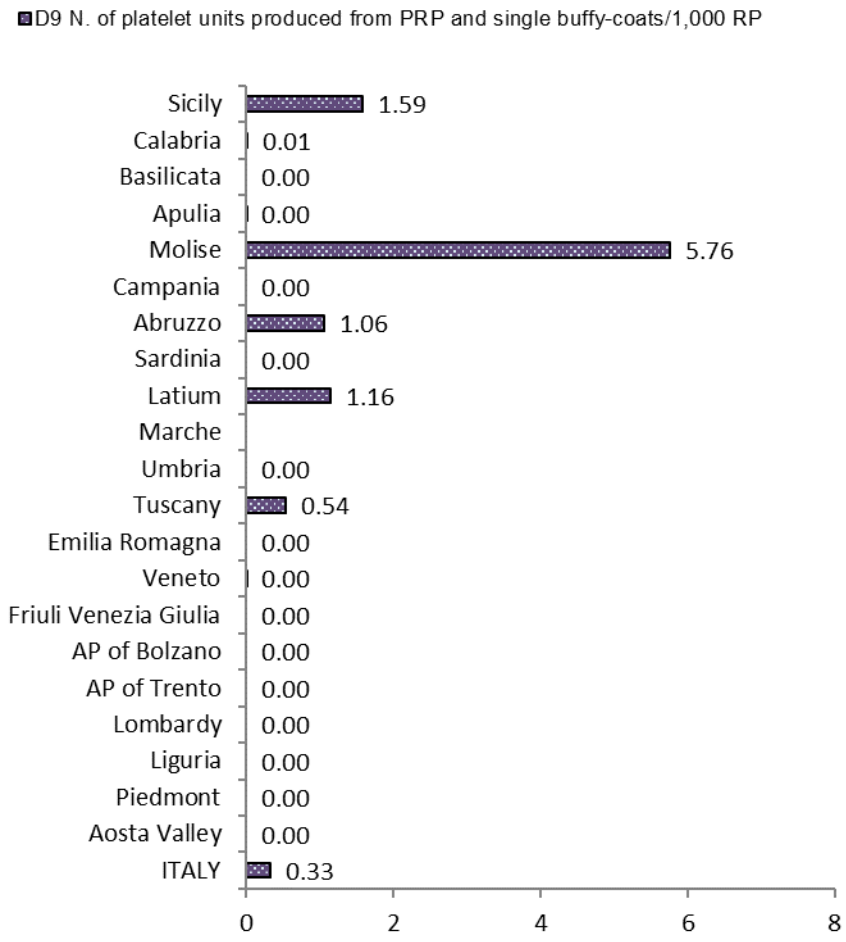
N. number; RP resident population; AP Autonomous Province

Figure A29. INDICATOR D7: N. of platelet units produced by apheresis (monocomponent + multicomponents)/1,000 resident population (2018)



N. number; RP resident population; AP Autonomous Province

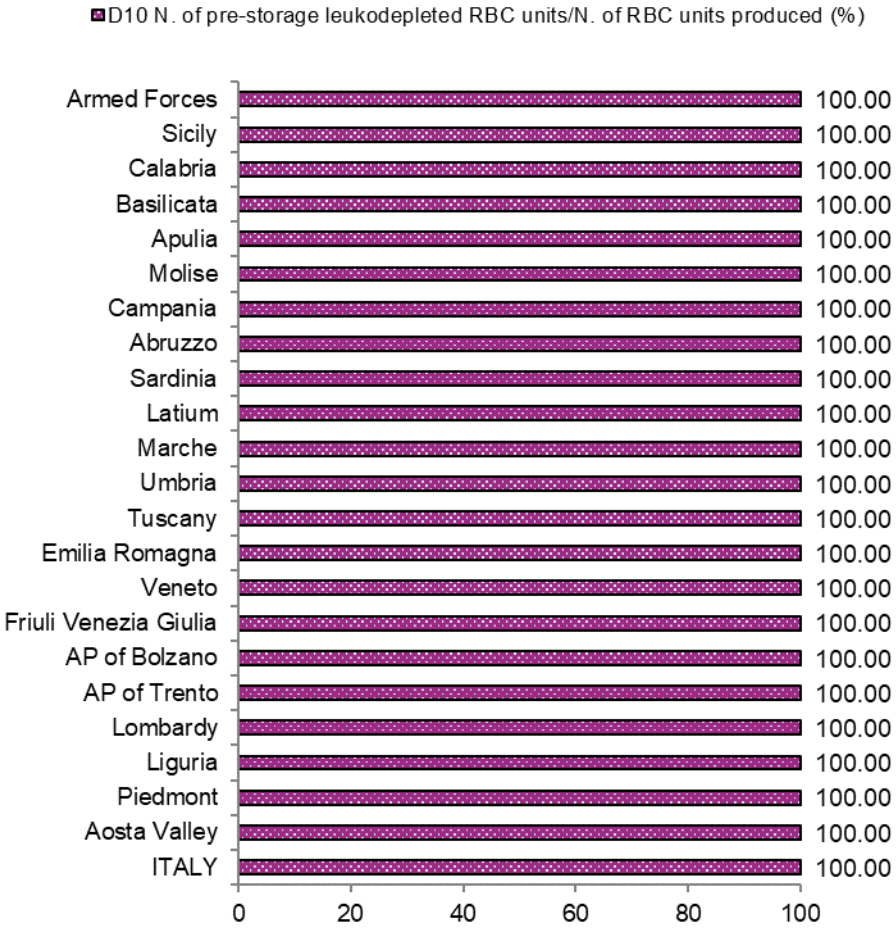
Figure A30. INDICATOR D8: N. of platelet units produced from buffy-coat pools/1,000 resident population (2018)



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 (2018)

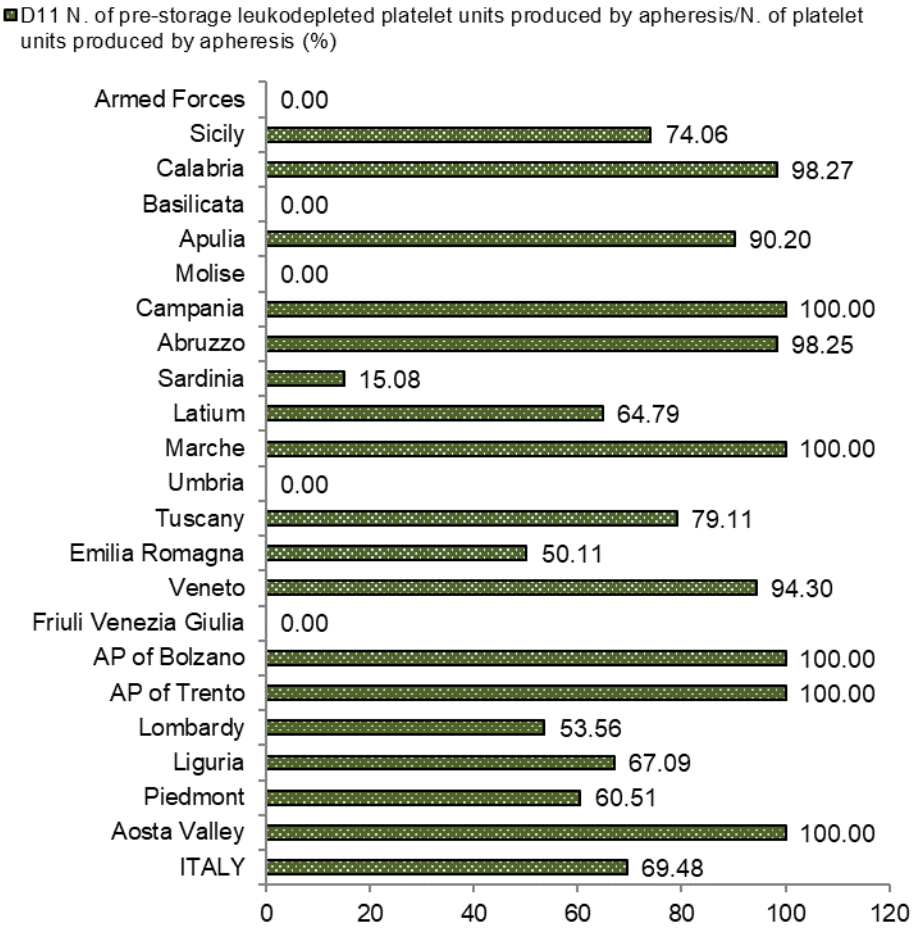
*: Since six months after the the Ministerial Decree of 2nd November, 2015 (9) came into force, the production of platelet concentrates from whole blood units through the intermediate separation of platelet-rich plasma has not been allowed.



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 (%) (2018)

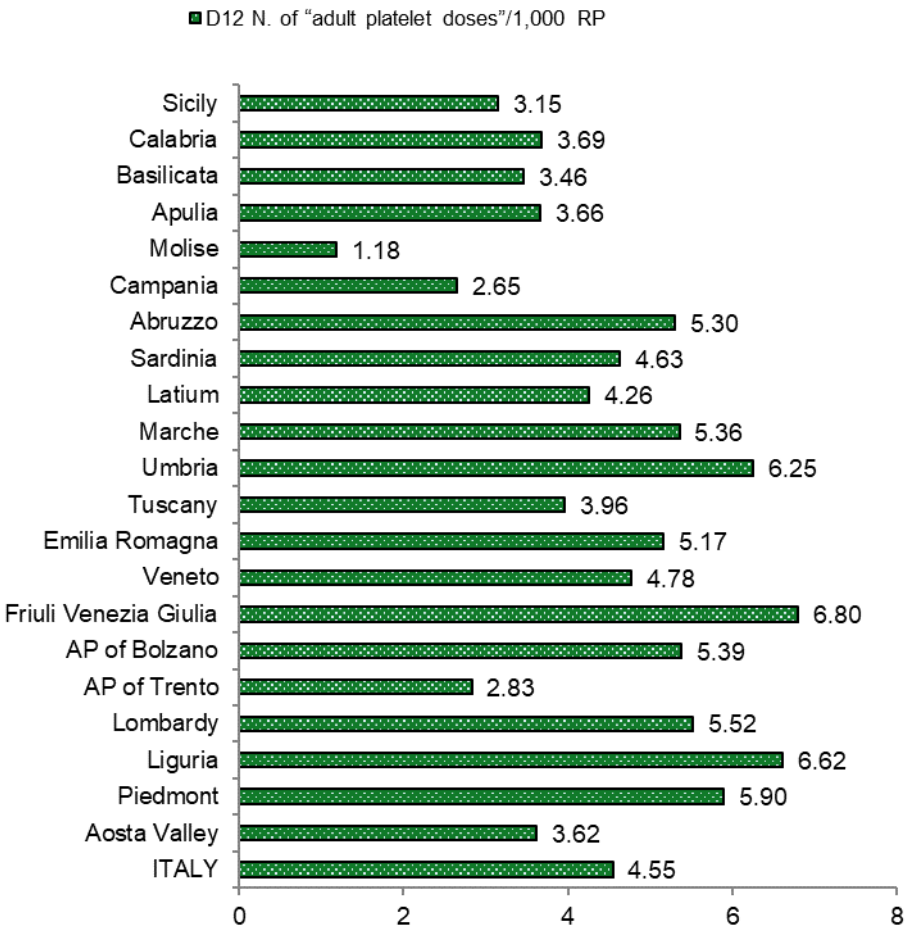
*: Since twelve months after the Ministerial Decree of 2nd November, 2015 (9) came into force, only the production of pre-storage leukodepleted blood components has been allowed.



N. number; AP Autonomous Province

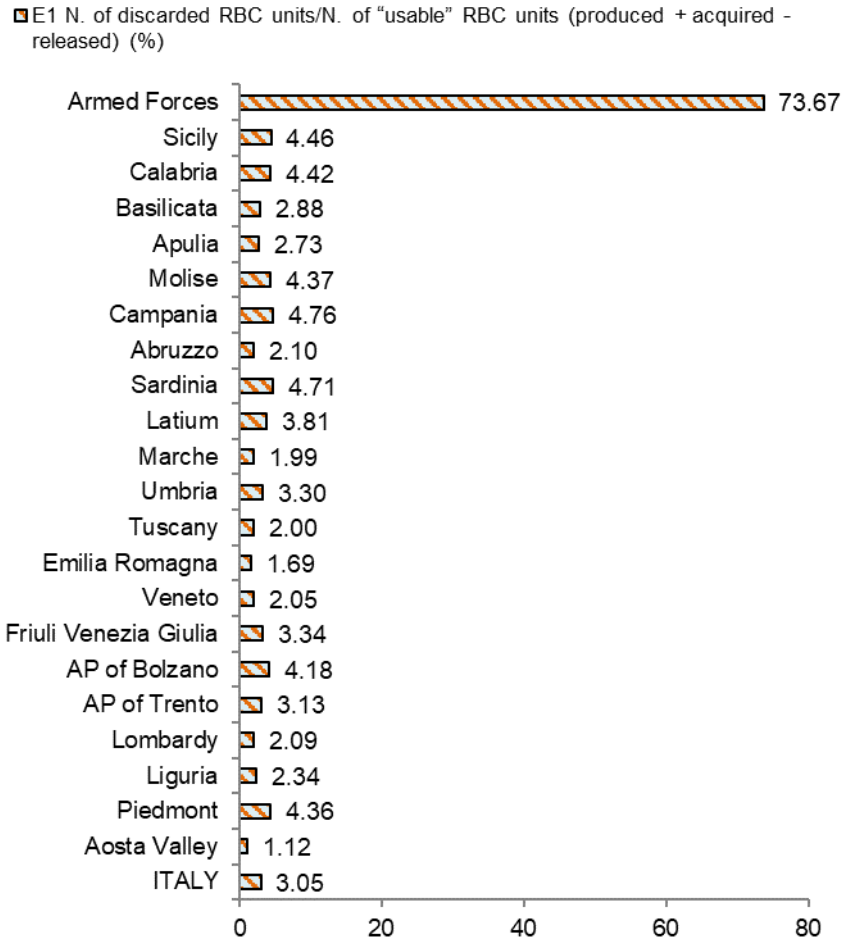
Figure A33. INDICATOR D11: N. of pre-storage leukodepleted platelet units produced by apheresis/N. of platelet units produced by apheresis (%) (2018)

*: 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.



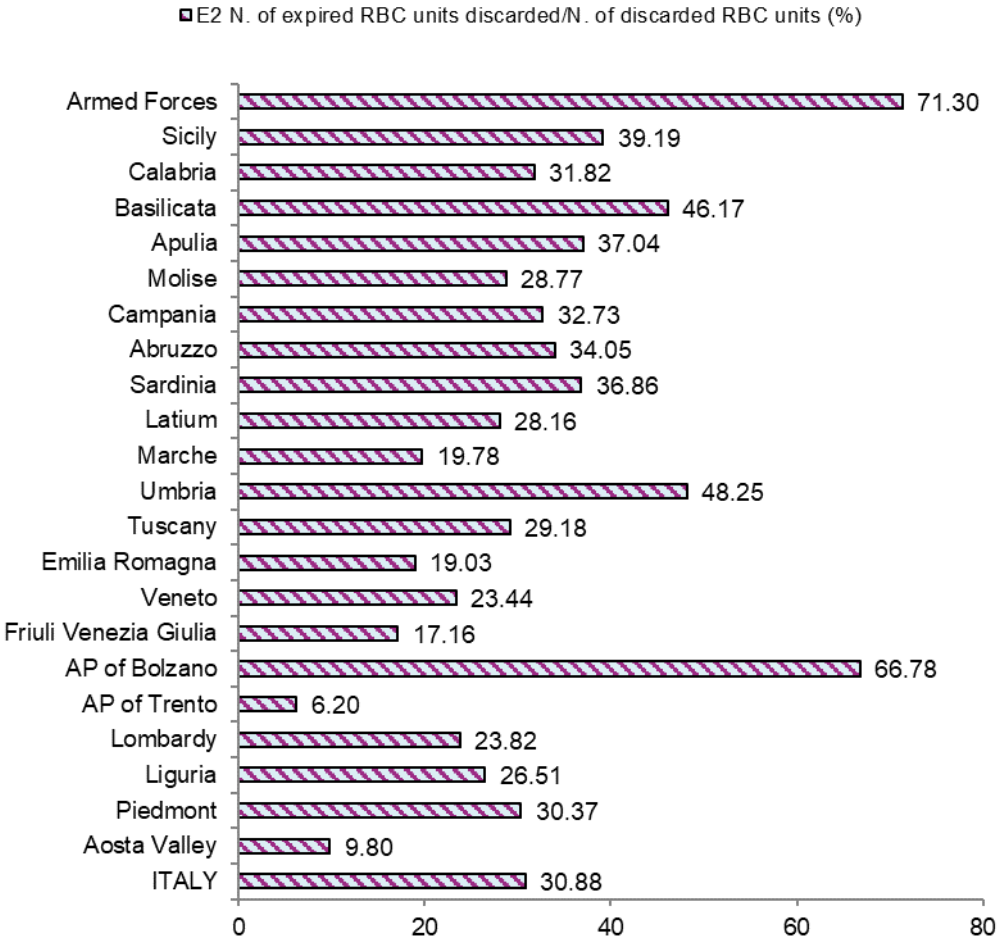
N. number; RP resident population; AP Autonomous Province

Figure A34. INDICATOR D12: N. of "adult platelet doses"/1,000 resident population (2018)



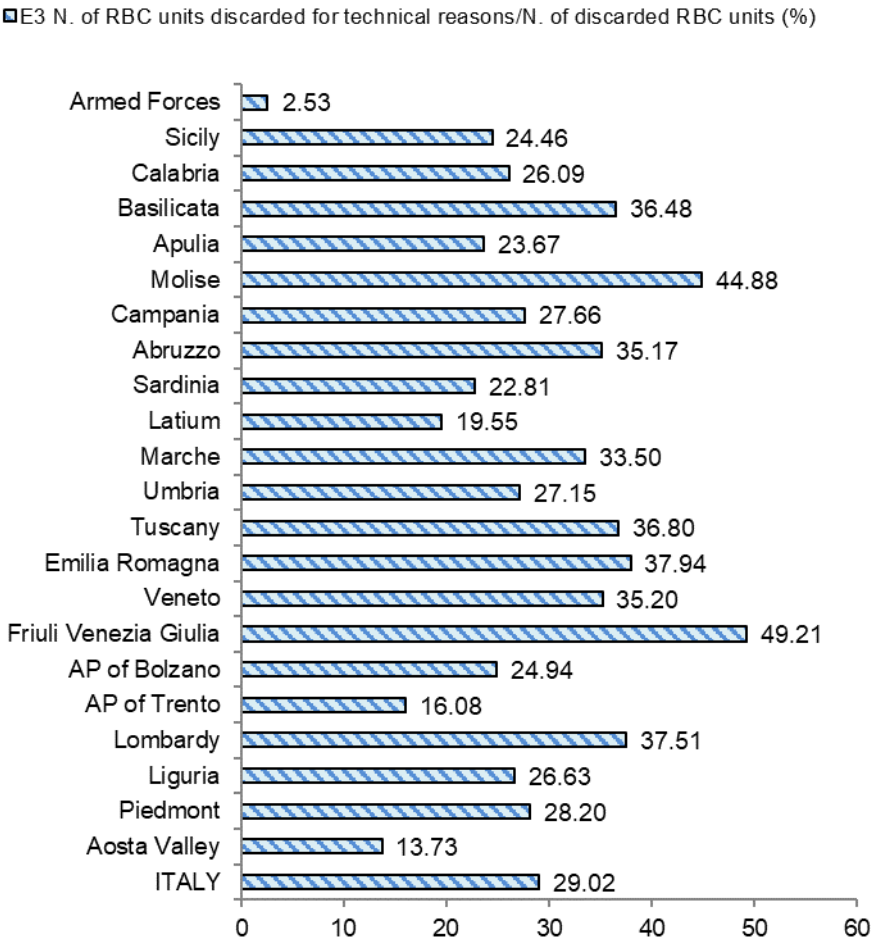
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A35. INDICATOR E1: N. of discarded RBC units/N. of "usable" RBC units (produced + acquired- released) (%) (2018)



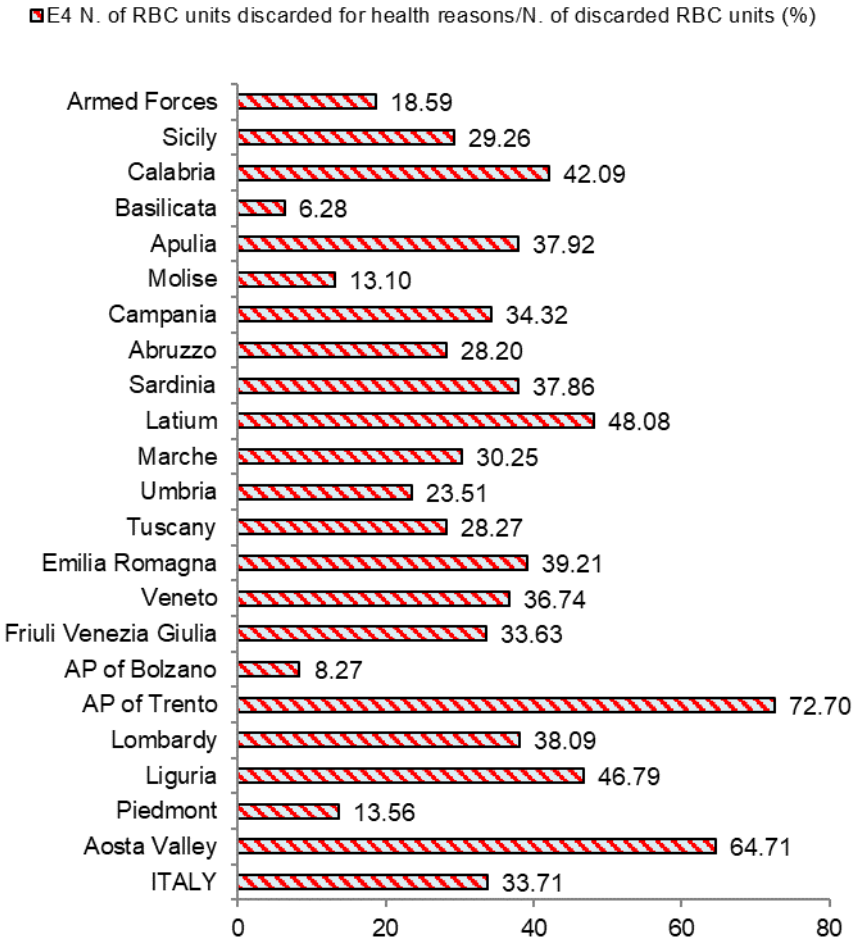
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A36. INDICATOR E2: N. of expired RBC units discarded/N. of discarded RBC units (%) (2018)



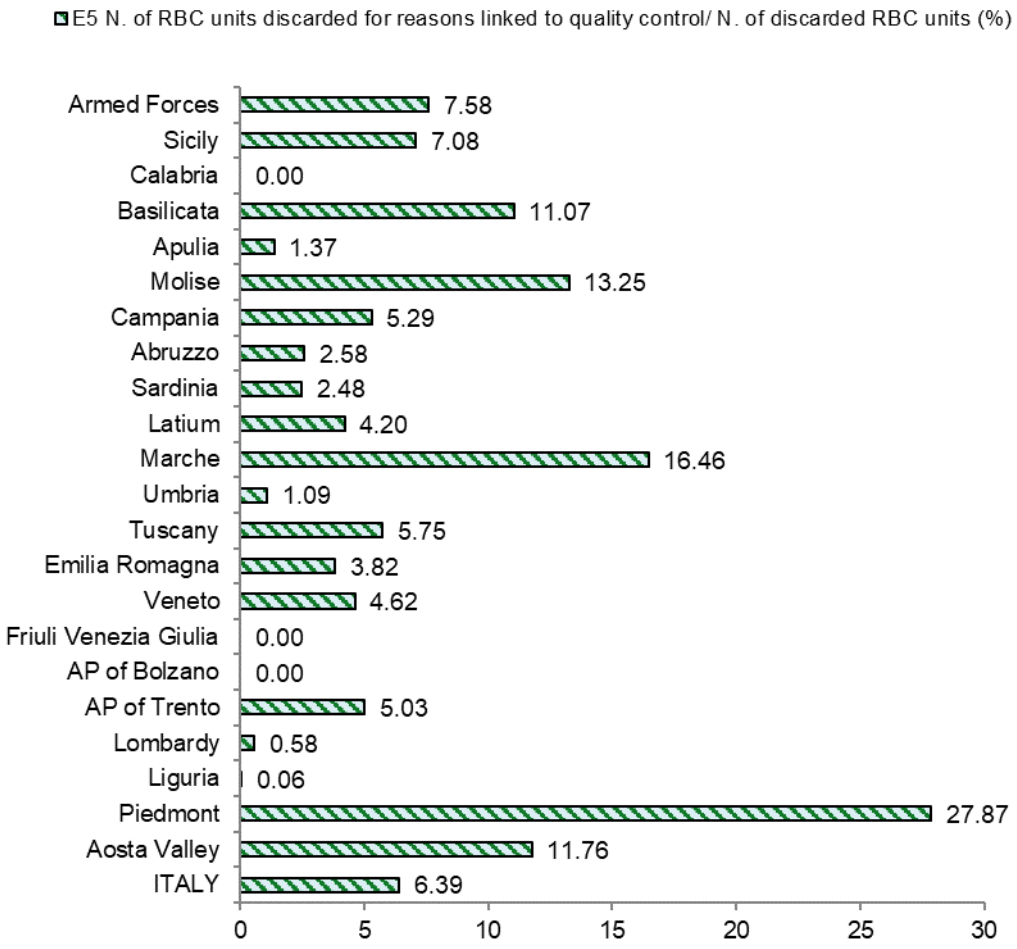
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A37. INDICATOR E3: N. of RBC units discarded for technical reasons/N. of discarded RBC units (%) (2018)



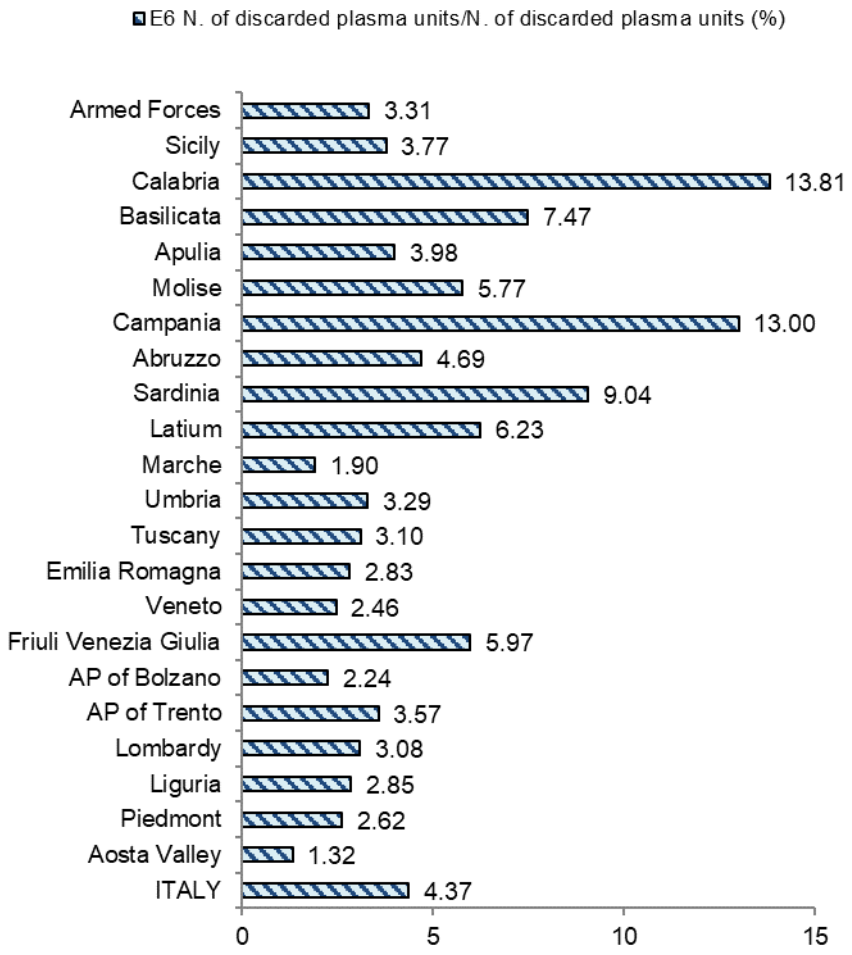
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A38. INDICATOR E4: N. of RBC units discarded for health reasons/N. of discarded RBC units (%) (2018)



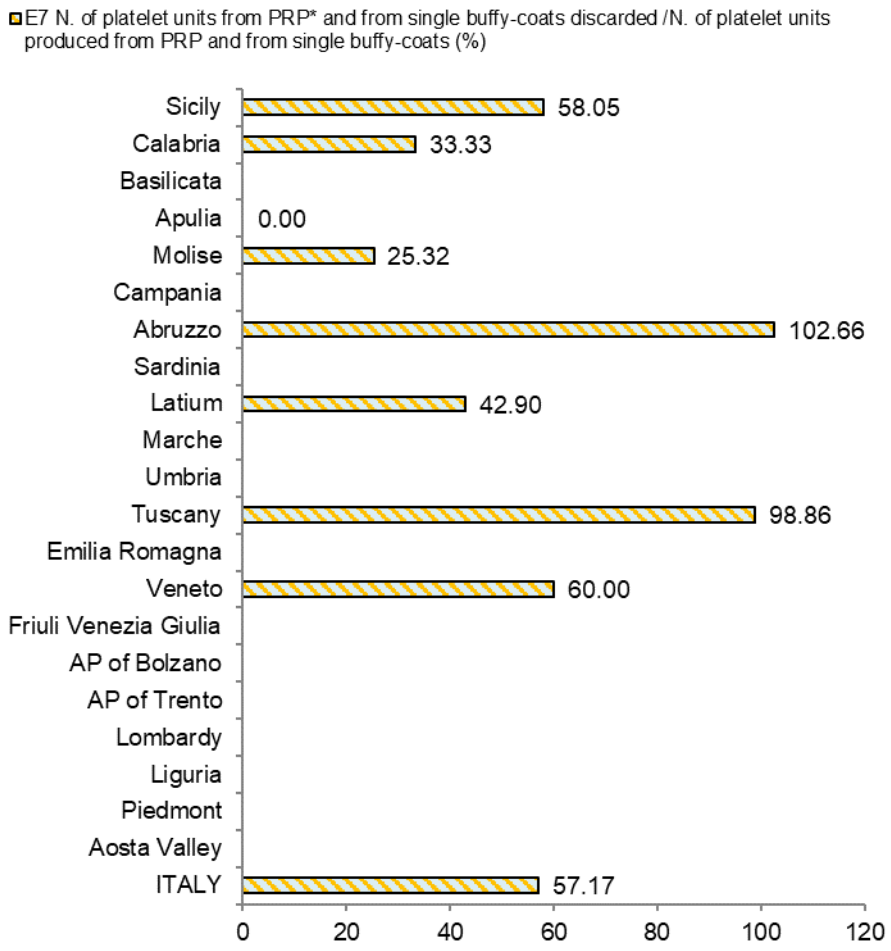
N. number; RBC Red Blood Cells; AP Autonomous Province

Figure A39. INDICATOR E5: N. of RBC units discarded for reasons linked to quality control/N. of discarded RBC units (%) (2018)



N. number; AP Autonomous Province

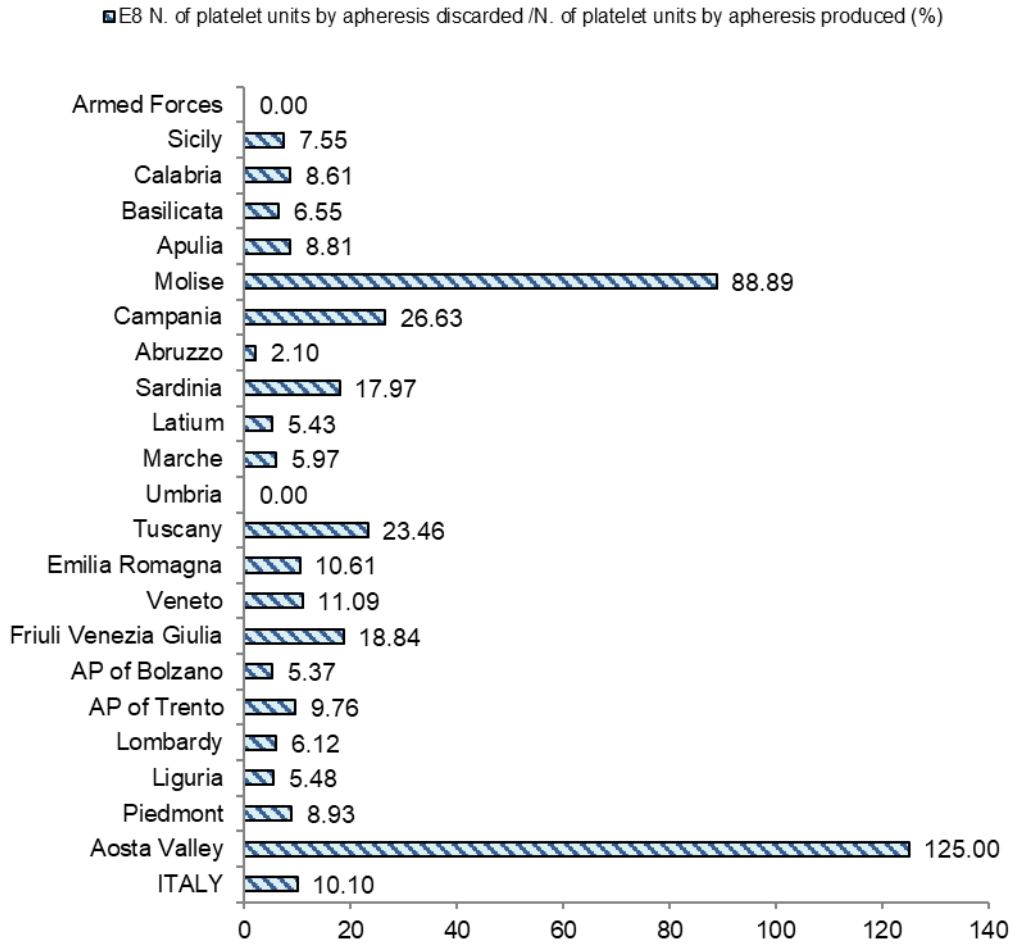
Figure A40. INDICATOR E6: N. of discarded plasma units /N. of produced plasma units (%) (2018)



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

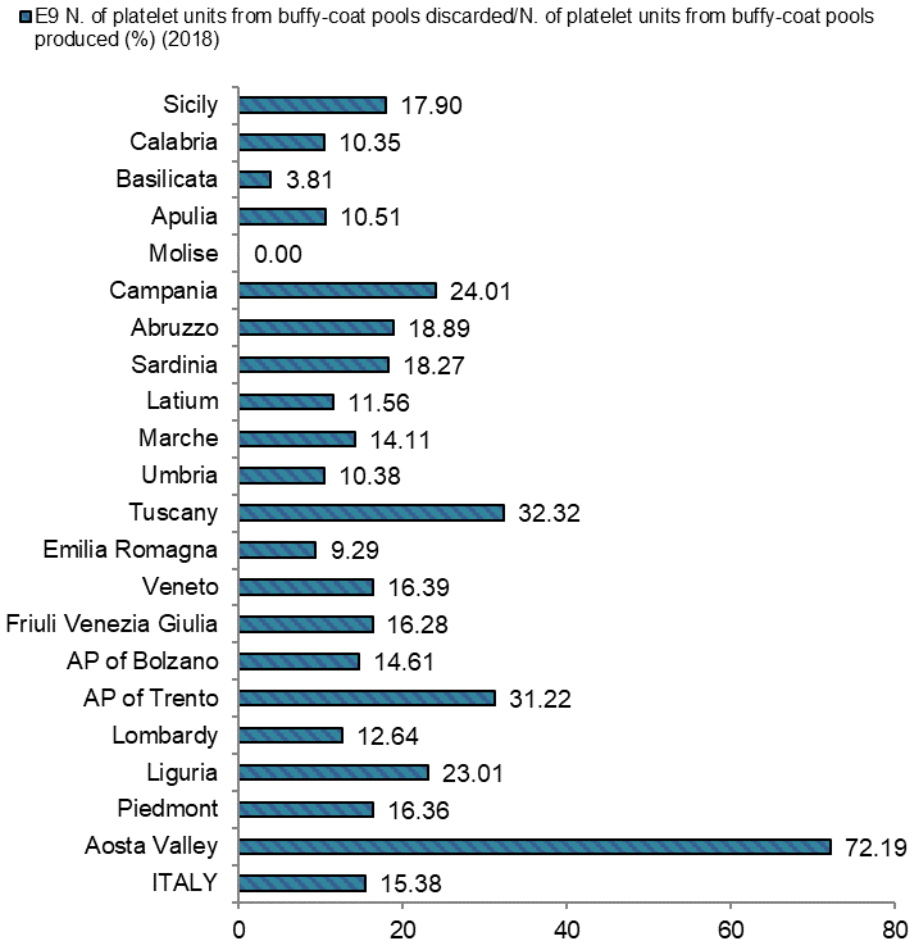
Figure A41. INDICATOR E7: N. of platelet units from PRP* and from single buffy-coats discarded /N. of platelet units produced from PRP and from single buffy-coats (%) (2018)

*: 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.



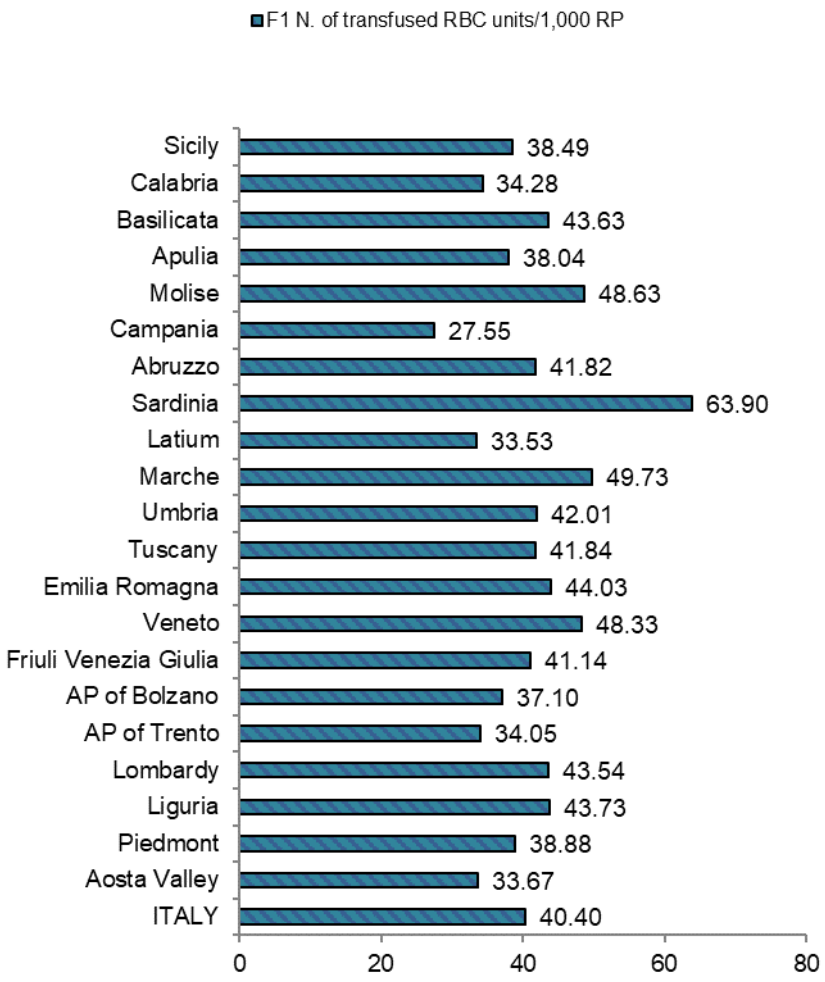
N. number; AP Autonomous Province

Figure A42. INDICATOR E8: N. of platelet units by apheresis discarded /N. of platelet units by apheresis produced (%) (2018)



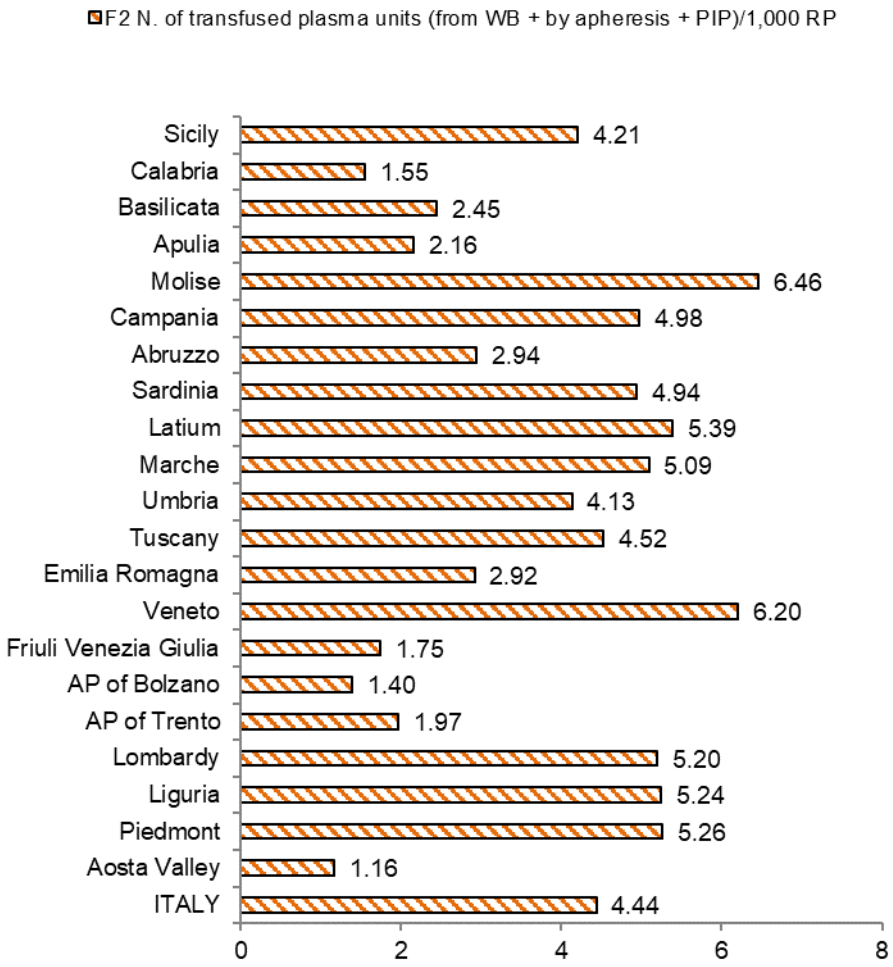
N. number; AP Autonomous Province

Figure A43. INDICATOR E9: N. of platelet units from buffy-coat pools discarded/N. of platelet units from buffy-coat pools produced (%) (2018)



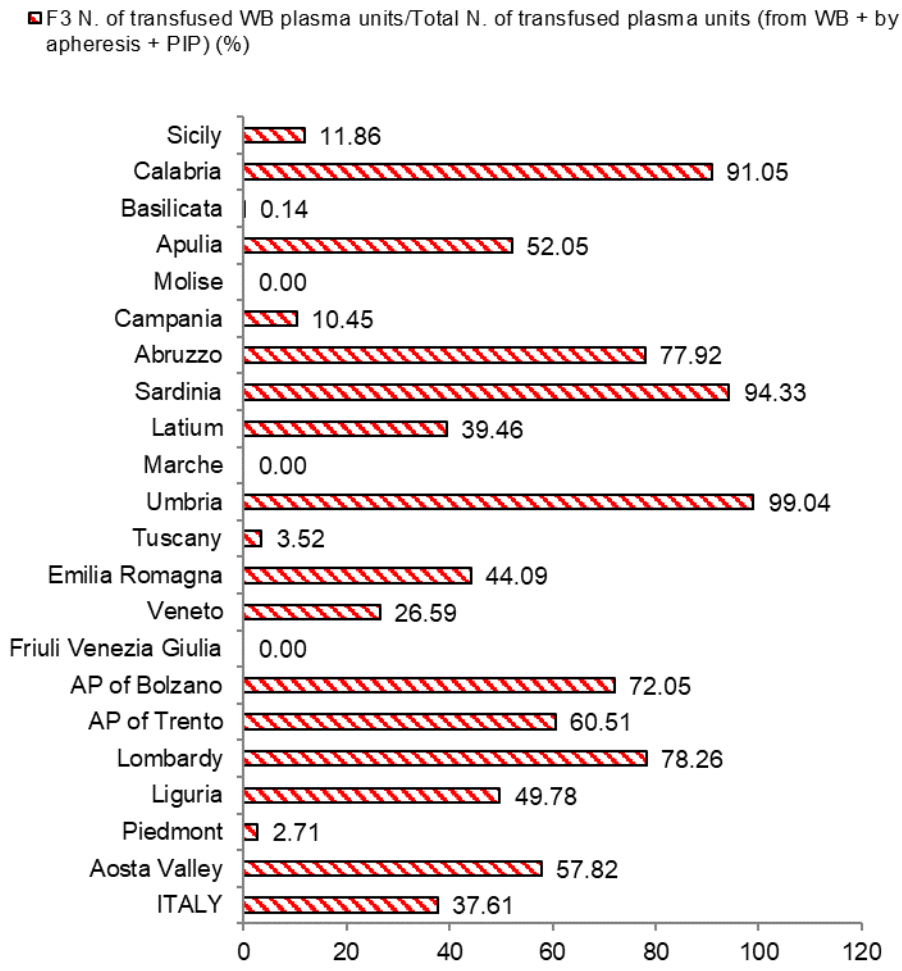
N. number; RBC Red Blood Cells; RP resident population; AP Autonomous Province

Figure A44. INDICATOR F1: N. of transfused RBC units/1,000 resident population (2018)



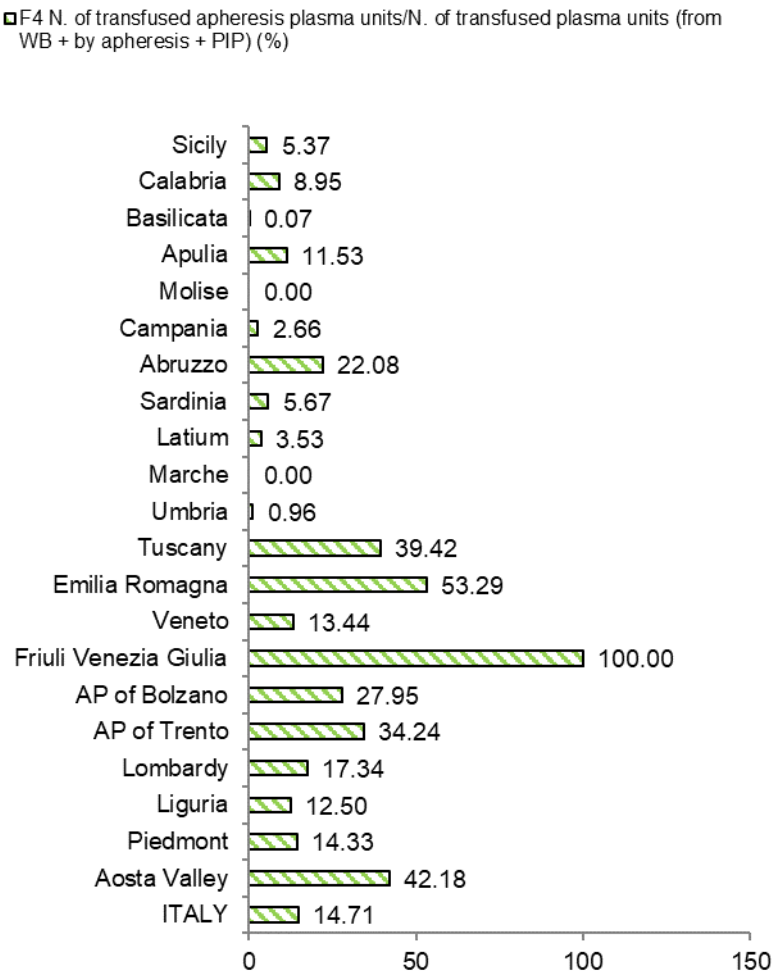
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; RP resident population; AP Autonomous Province

Figure A45. INDICATOR F2: N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma)/1,000 resident population (2018)



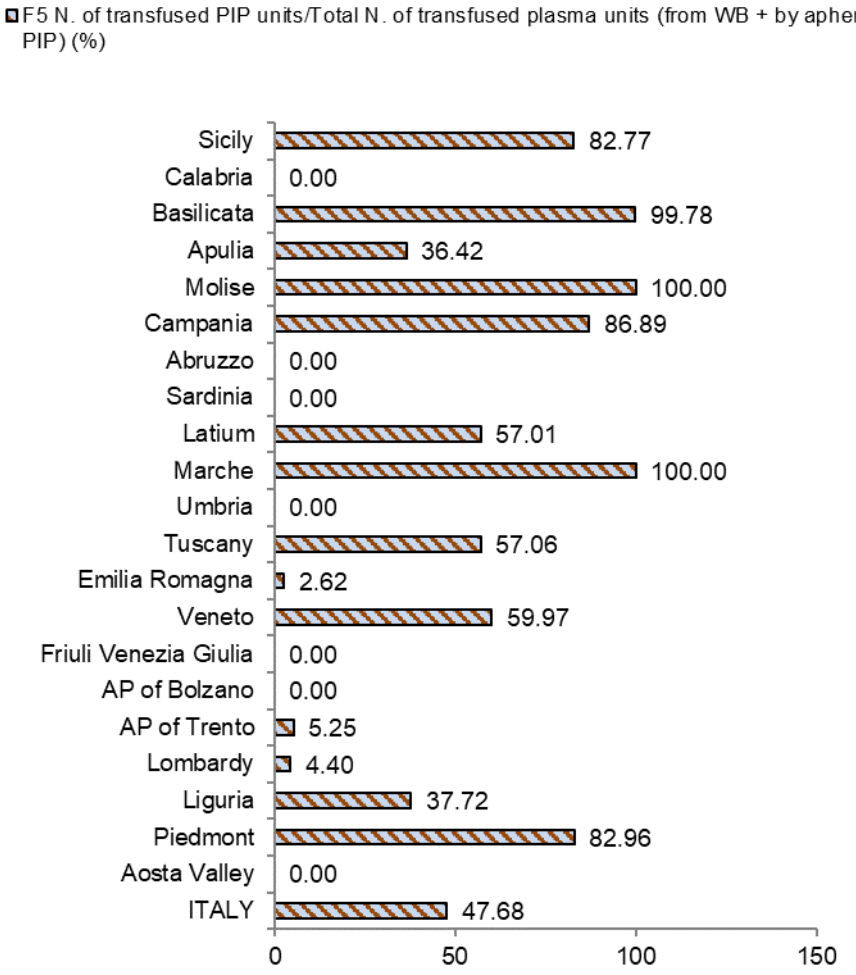
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

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) (%) (2018)



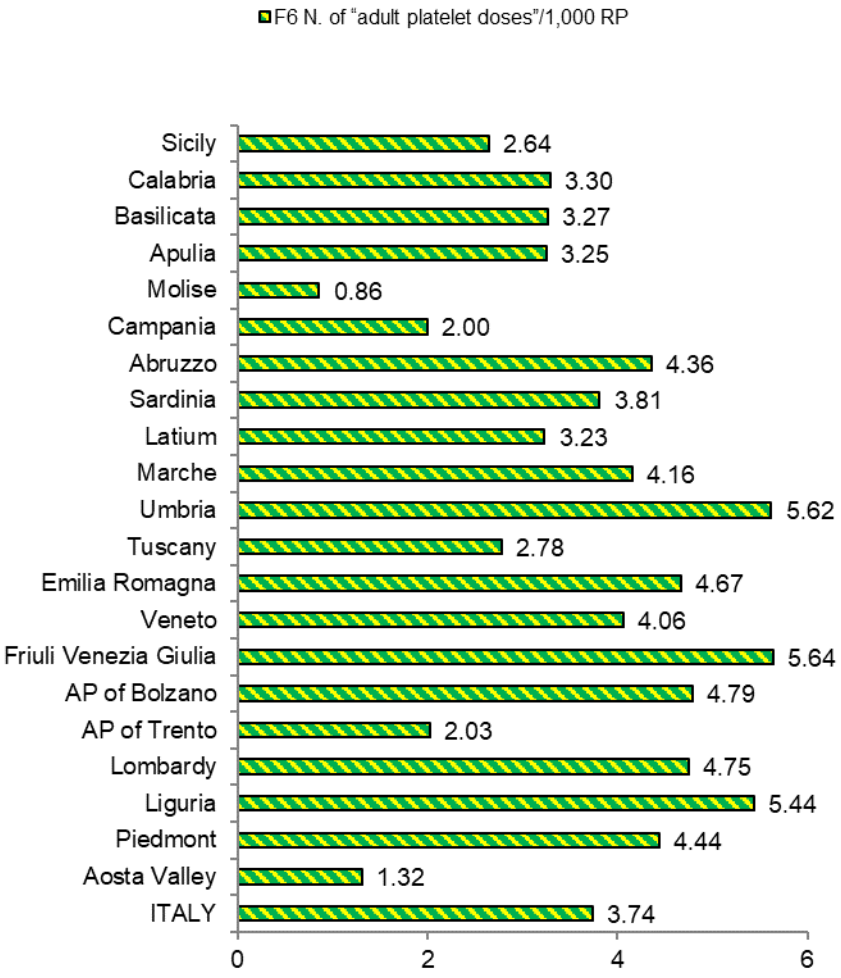
N. number; WB whole blood; PIP pharmaceutical virus-inactivated plasma; AP Autonomous Province

Figure A47. INDICATOR F4: N. of transfused apheresis plasma units/N. of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2018)



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) (%) (2018)



N. number; RP resident population; AP Autonomous Province

Figure A49. INDICATOR F6: N. of "adult platelet doses"/1,000 resident population (2018)

HAEMOVIGILANCE IN ITALY

Haemovigilance is a set of surveillance procedures covering the monitoring, reporting, investigation and analysis of serious adverse reactions in recipients, serious adverse events, serious adverse reactions in donors as well as the epidemiological surveillance of donors and the surveillance of medical devices used in transfusion activities (Italian Ministry of Health Decree n. 69/2015) (9). Haemovigilance systems are regulated by specific national laws and by European Directives (11, 12), transposed into national laws (13, 14), which state the procedures that must be adopted for the reporting of serious 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 serious 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.

Information flow

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 serious adverse reactions in recipients and serious 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.

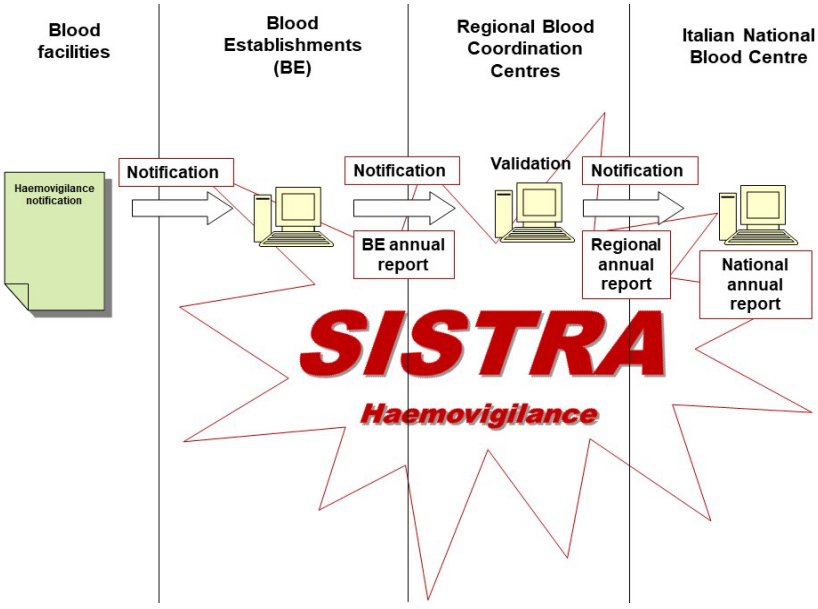


Figure 1. Haemovigilance information flow in SISTRA

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

Serious adverse reactions in recipients, serious adverse events, serious adverse reactions in donors

In 2018, validated data from each RBCC was sent until March 30th, 2019; an extension for data consolidation and validation was allowed. All essential data relative to 2018 related to serious adverse reactions in recipients, serious adverse events in blood transfusion, and serious adverse reactions in donors are shown below.

Materials and methods

For the purpose of this report, also in compliance with the Ministry of Health n. 69/2015 (9), 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 table below shows the levels of severity and imputability of serious adverse reactions in recipients, adopted in accordance with the European Directives and reported in the Legislative Decree n. 207/2007 (13).

Level		Description
Severity		
0		No symptoms
1		Mild symptoms (no therapeutic intervention)
2		Symptoms requiring therapeutic intervention
3		Severe symptoms requiring resuscitation procedures
4		Death
Imputability		
N.A.	Non assessable	When there are insufficient data to evaluate the imputability.
0	Excluded/unlikely	When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to alternative causes.
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.
2	Probable	When the available evidence is clearly in favour of attributing the adverse event to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt that the adverse reaction can be attributed to the blood or blood component.

Results

The information concerns 2,944,929 transfused blood components and 2,991,082 donations of blood and blood components. Participation in the haemovigilance system, expressed as number of notifications/year, appears to be generally increasing, especially in the number of blood donors' adverse reactions (Figure 2). As in the previous years (6,15), the number of notifications shows a significant regional variability (Figures 3-5).

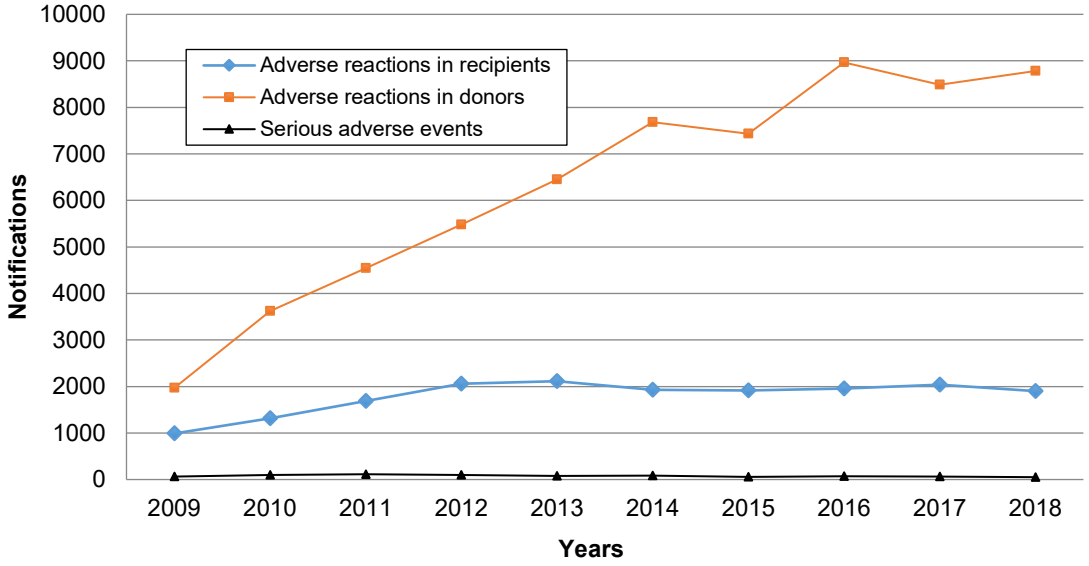


Figure 2. Number of haemovigilance notifications per year (2009-2018)

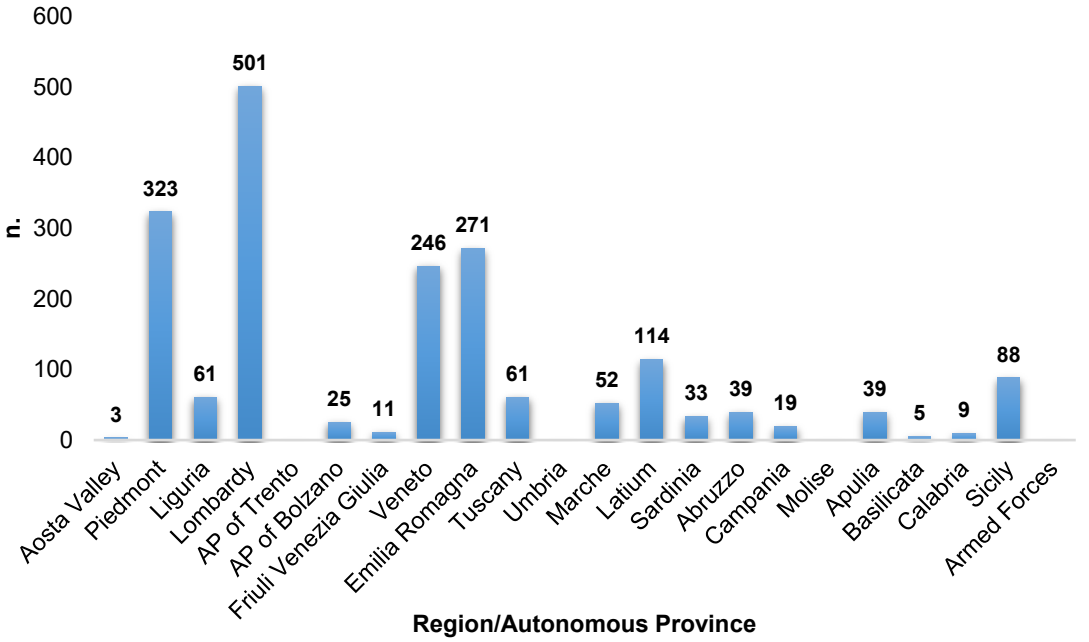


Figure 3. Serious adverse reactions in recipients notified by region (2018)

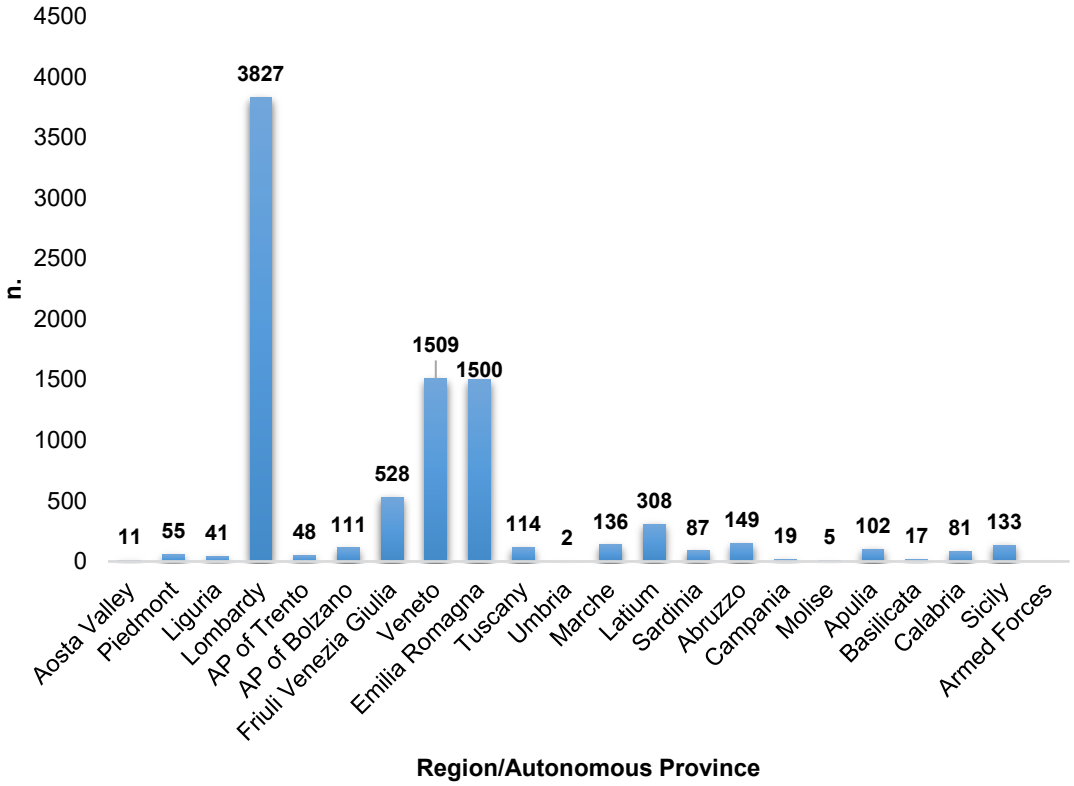


Figure 4. Serious adverse reactions in donors notified by region (2018)

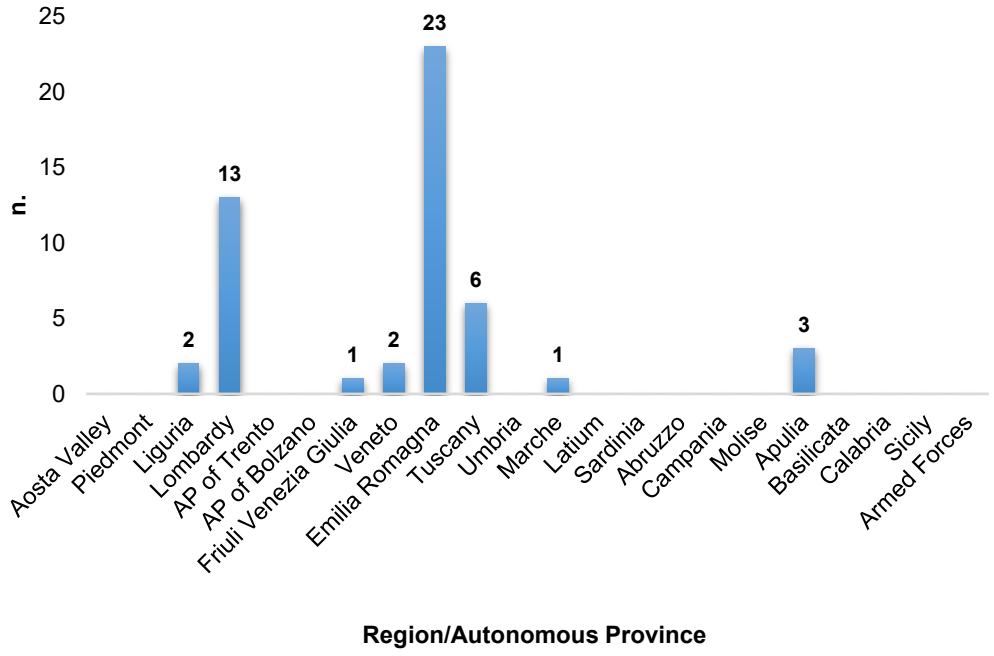


Figure 5. Serious adverse events notified by region (2018)

Adverse reactions in recipients

From January 1st to December 31st 2018, 1,900 adverse reactions were notified in recipients of blood components (one every 1,550 transfused units) (Table 16).

Table 16. Adverse reactions in recipients regardless of severity and imputability levels (2018)

Adverse reaction	n.	%
Alloimmunisation	17	0.9
Other bacterial infection	4	0.2
Other viral infection	2	0.1
Transfusion associated dyspnoea (TAD)	71	3.7
Transfusion-related acute lung injury (TRALI)	2	0.1
Non-immunological haemolysis - physical cause	2	0.1
Non-immunological haemolysis - mechanical cause	2	0.1
Hyperkalemia	1	0.1
Hypotensive transfusion reaction	43	2.3
Allergic reactions involving the respiratory and/or cardiovascular system	74	3.9
Allergic manifestations with only mucosal and cutaneous symptoms	552	29.1
Post transfusion purpura (PTP)	2	0.1
Acute haemolytic reaction due to ABO incompatible transfusion	6	0.3
Delayed haemolytic reaction due to ABO incompatible transfusion	1	0.1
Delayed haemolytic reaction due to Rh incompatible transfusion	1	0.1
Haemolytic transfusion reactions due to autoantibodies	1	0.1
Febrile non-haemolytic reaction (FNHTR)	663	34.9
Anaphylactic shock	6	0.3
Transfusion-associated circulatory overload (TACO)	56	2.9
Acute haemolytic transfusion reactions due to others blood group	4	0.2
Delayed haemolytic transfusion reactions due to others blood group	2	0.1
Incorrect Blood Component Transfused without reaction	4	0.2
Other	384	20.2
Total	**1,900**	**100**

TAD Transfusion associated dyspnoea; **TRALI** Transfusion related acute lung injury; **TACO** Transfusion associated circulatory overload.

Taking into account only adverse reactions that are probably or certainly imputable with a high level of severity (grade 3 and 4) the frequency is one every 588,986 transfused units. Table 16 shows adverse reactions in recipients by type, by absolute number and percentage. In 2018, the most frequently notified reactions were Febrile Non-Haemolytic Reactions (FNHTR) (34.9%) and allergic manifestations with only mucosal and cutaneous symptoms (29.1%), representing 64% of all notified adverse reactions in recipients.

Adverse reactions involving the respiratory and/or cardiovascular system

In 2018, 10.6% of all the notifications (202/1,900) were related to the respiratory system; 74 were allergic reactions involving the respiratory and/or cardiovascular system, 71 TAD, 56 TACO and 2 TRALI. The frequency of the aforementioned reactions per transfused blood components was 1 allergic reaction every 39,796, 1 TAD every 41,478, 1 TACO every 52,588, and 1 TRALI every 1,472,464. However, on the whole the notifications were unsatisfactory because of the 71 cases of TAD, 5.6% were certainly imputable, 21.1% probable, 49.3% possible, 15.5% excluded/unlikely, and 8.5% not evaluable; of the 56 cases of TACO, 8.9% were certainly imputable, 44.6% probable, 37.5% possible, 7.2% excluded/unlikely, and 1 case (1.8%) not evaluable.

The cases of TRALI were notified as follows:

– one case probably imputable to transfusion occurred in a 65-year-old female patient receiving two units of pre-storage leukodepleted RBCs for severe anaemia (major

bleeding). Onset of symptoms (dispnoea) within 6 hours of completion of transfusion. Bilateral infiltrates on frontal chest radiograph. Pharmacological therapy: intravenous Methylprednisolone 40 mg/die. Complete resolution within 2 months;
- one case possibly imputable to transfusion occurred in a 16-year-old female patient receiving one unit of pre-storage leukodepleted RBCs for severe anaemia. Onset of symptoms (dispnoea, hypoxemia, hypothermia, cough, and tachycardia) within 6 hours of completion of transfusion. Complete resolution within a few days.

Other viral/bacterial infections

In 2018, 2 cases of "Other viral infection" were notified as follows:

- Case 1v – Hepatitis A virus: (Severity: 2- symptoms requiring therapeutic intervention; Imputability: 1- excluded/unlikely)

  A female patient who had undergone haematopoietic stem cell transplantation for haematological disease was transfused with one unit of pre-storage leukodepleted RBCs. The patient did not develop any specific symptom related to HAV infection. In the month following transfusion an increase in transaminase was reported. In the same period, she presented a cytomegalovirus (CMV) reactivation. The patient's pre-transfusion serological status was Ab anti-HAV positive. The exams repeated the day after the transfusion were Ab anti-HAV positive, Ab anti-HAV IgM negative, HAV RNA negative. No information about HAV RNA genotypisation, in order to verify the homology between the donor's and the recipient's virus sequence, was provided. In the months after the transfusion, laboratory investigation confirmed that the fluctuations of the transaminases levels were due to CMV reactivations. On the basis of the above-mentioned results this event was evaluated as an excluded/unlikely HAV TTI.

- Case 2v – Hepatitis A virus: (Severity: 2- symptoms requiring therapeutic intervention; Imputability: 1- possible)

  A male patient with severe thrombocytopenia after abdominal surgery was transfused with a pooled platelet unit. The patient did not develop any specific symptom related to HAV infection. In the month following transfusion an increase in transaminases levels was reported. The patient's pre-transfusion serological status was not available. The exams carried out 3 weeks after the transfusion were Ab anti-HAV positive, Ab anti-HAV IgM positive. No information about HAV RNA genotypisation, in order to verify the homology between the donor's and the recipient's virus sequence, was provided. A decrease of the transaminases levels in the following 3 months was noted. On the basis of the above-mentioned results this event was evaluated as a possible HAV TTI.

Both patients (Case 1v and Case 2v) received blood components from the same donation. The donor in question (asymptomatic at the time of the donation) was hospitalised seven days later for hepatitis A. He said he had eaten raw mussels in South Italy on two different occasions, which could have been the source of infection.

In 2018, 4 cases of "Other bacterial infection" were notified as follows:

- Case 1b - *Campylobacter jejuni*
  (Severity: 2- symptoms requiring therapeutic intervention; Imputability: 0- excluded/unlikely)

  A male patient who was receiving supportive therapy for relapsed myeloproliferative disorder was transfused with one unit of pre-storage leukodepleted RBCs. A few hours following the transfusion he was suffering with diarroea, fever, nausea and vomiting. He

was treated with broad spectrum antibiotics with resolution of fever. Complete resolution of symptoms after a few days. Blood cultures and coprocultures were taken from the patient but tested negative. The symptoms resulted in the case being reported as a bacterial TTI although the symptoms may have been related to the patient's underlying condition. On the basis of the above-mentioned results this event was notified as an excluded/unlikely *Campylobacter jejuni* TTI.

- Case 2b - *Staphylococcus aureus*
  (Severity: 2- symptoms requiring therapeutic intervention; Imputability: 1- possible)
  A male patient with severe thrombocytopenia was transfused with one unit of pre-storage leukodepleted platelet concentrates from apheresis. The patient was receiving a cycle of chemotherapy for Acute Myeloid Leukaemia (AML). Within 1 hour of completion of the transfusion the patient developed fever and chills. The patient died from complications linked to the haematological disease. Blood cultures were taken from the patient and from the transfused unit and both tested *Staphylococcus aureus* positive. Blood cultures and skin cultures were taken from the donor but these were negative. On the basis of the above-mentioned results this event was notified as a possible *Staphylococcus aureus* TTI.
- Case 3b - *Staphylococcus aureus*
  (Severity: 2- symptoms requiring therapeutic intervention; Imputability: 0- excluded/unlikely)
  A male patient who had undergone haematopoietic stem cell transplantation was transfused with one pooled platelet unit for severe thrombocytopenia. After the completion of the transfusion the patient developed fever and lumbar pain. He was treated with antihistamines and corticosteroids with the complete resolution of the symptoms after a few hours. No isolation of *Staphylococcus aureus* in patient blood culture. Blood cultures were taken from the patient but these tested negative. The symptoms resulted in the case being reported as a bacterial TTI although the symptoms may have been related to the patient's underlying condition. On the basis of the above-mentioned results this event was notified as an excluded/unlikely *Staphylococcus aureus* TTI.
- Case 4b - *Rothia mucilaginosa*
  (Severity: 2- symptoms requiring therapeutic intervention; Imputability: 1- possible)
  A a male patient with severe anaemia of unknown origin was transfused with some units of pre-storage leukodepleted RBCs. During the infusion of the second RBC unit, the patient developed a fever, which disappeared after being treated with paracetamol. A broad spectrum antibiotics therapy was started and blood cultures and urinoculture were taken but tested negative. Moreover, a blood culture was taken from the transfused unit and tested positive. On the basis of the above-mentioned results this event was notified as a possible *Rothia mucilaginosa* TTI.

Tests and protocols for the quality control of blood components

The introduction of measures to reduce the risk of bacterial contamination of blood and blood components (9), such as the diversion of the first volume of blood collected and the application of a correct disinfection of the donor's skin, has contributed greatly to the improvement of transfusion safety; however, in literature, there are cases of bacterial sepsis related to the transfusion of contaminated blood components due to asymptomatic donor bacteraemia, contamination during the collection, processing and treatment of blood components. The implementation of quality controls on blood and blood components provides excellent information about the correct application of procedures aimed at reducing the bacterial contamination risk.

The CNS, in 2019, conducted a survey throughout the country, aimed at understanding the tests and protocols used at the BEs for the quality control of blood components, the positive results on microbiological testing detected for the year 2018 and the pathogens and blood components involved, as well as the procedures and methods used for the prevention of the bacterial contamination of blood components.

The survey shows that the blood components most involved in bacterial contamination are platelets (38%) and red blood cells (38%), followed by plasma (22%) and cryoprecipitate (2%). The amount of red blood cells tested, compared to the annual production, is generally equal to or less than 1%; the tests are conducted mainly on the expired blood component or during storage. The quantity of platelets tested, compared to the annual production, is generally equal to or less than 5%; for apheresis platelets or buffy-coat pools the tests are mainly conducted on the expired blood component and/or during storage. The amount of plasma tested for clinical use, compared to the annual production, is generally equal to or less than 1%; the tests are conducted after thawing and/or 24 hours after the preparation and/or the blood component expired. Finally, the cryoprecipitate is generally tested 24h after preparation or thawing.

The pathogens most implicated in the phenomena of bacterial contamination are Gram positive bacteria, generally belonging to the Staphylococcus genus (Figure 6).

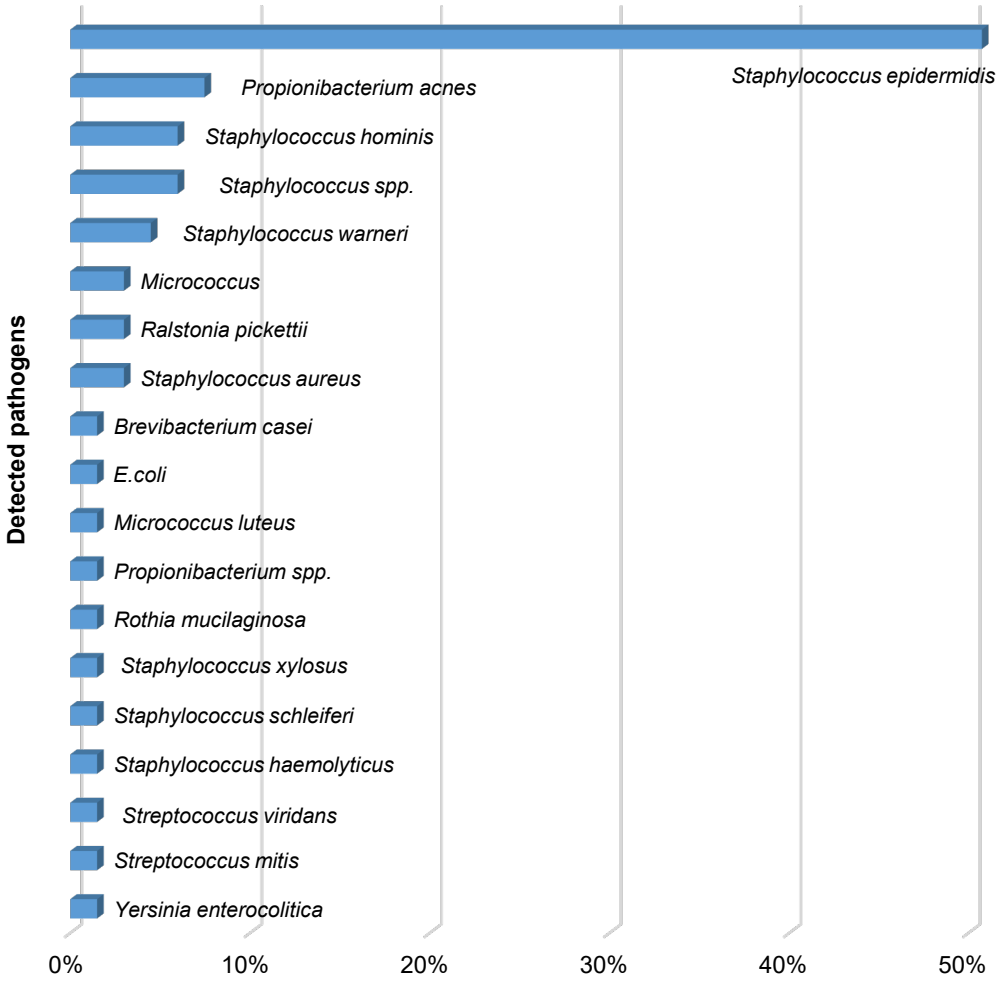


Figure 6. Percentage distribution of detected pathogens (2018)

The introduction in the transfusion practice of pathogen reduction technologies (PRTs), although still not available for RBCs, could contribute to the reduction of the risk of TTBI and, therefore, the achievement of high safety standards. However, more generally, it is noted that the pathogens detected are mainly commensal of human skin and mucosa and therefore any inactivation activity cannot disregard the correct application of the veni-puncture procedures for reducing the risk of bacterial contamination of blood and blood components.

ABO incompatible transfusions

In 2018, 14 cases of ABO-incompatible transfusions were notified as follows:
- 6 cases as "Acute haemolytic reaction";
- 1 case as "Delayed haemolytic reaction";
- 2 cases as "ABO-incompatible Blood Component Transfused without reaction";
- 5 cases as "Serious Adverse Events".

Incorrect blood components transfused and near misses

In 2018, 14 cases of ABO-incompatible transfusions were notified, of which 9 (64.2%) caused a reaction (Table 17). Moreover, 3 cases of ABO-compatible blood transfused to the wrong patient were notified but none caused reactions.

Table 17. Incorrect blood component transfused and near misses (2018)

Site of primary error	Transfused		Near miss (not transfused)
	with reaction	without reaction	
Wrong donor group label	1	-	-
Wrong recipient identification on unit	-	1	4
Wrong group of blood component	-	-	2
Wrong group of patient	-	-	2
Wrong name on tube	-	-	80
Wrong patient collected	-	-	75
ABO incompatible - Wrong recipient identification	8	1	21
ABO compatible - Wrong recipient identification	-	3	
Wrong product type	-	-	5

As reported in the EDQM "Guide to the preparation, use and quality assurance of blood components" (15), 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 2018, 189 near misses (the component was not transfused) were notified.

Most cases were "wrong name on tube" 80 (42.3%) while 75 (39.7%) were "wrong patient collected".

Severity and imputability levels

The severity of adverse reactions to transfusion required therapeutic intervention in 74.1% of the cases; no therapeutic intervention was required in 23.2% (Table 18 and Figure 7).

Table 18. Adverse reactions in recipients classified by severity level (2018)

Level	Severity	n.	%
0	No symptoms	28	1.5
1	Mild symptoms (no therapeutic intervention)	440	23.2
2	Symptoms requiring therapeutic intervention	1,408	74.1
3	Symptoms requiring resuscitation procedures	23	1.2
4	Death	1	0.1
	Total	**1,900**	**100**

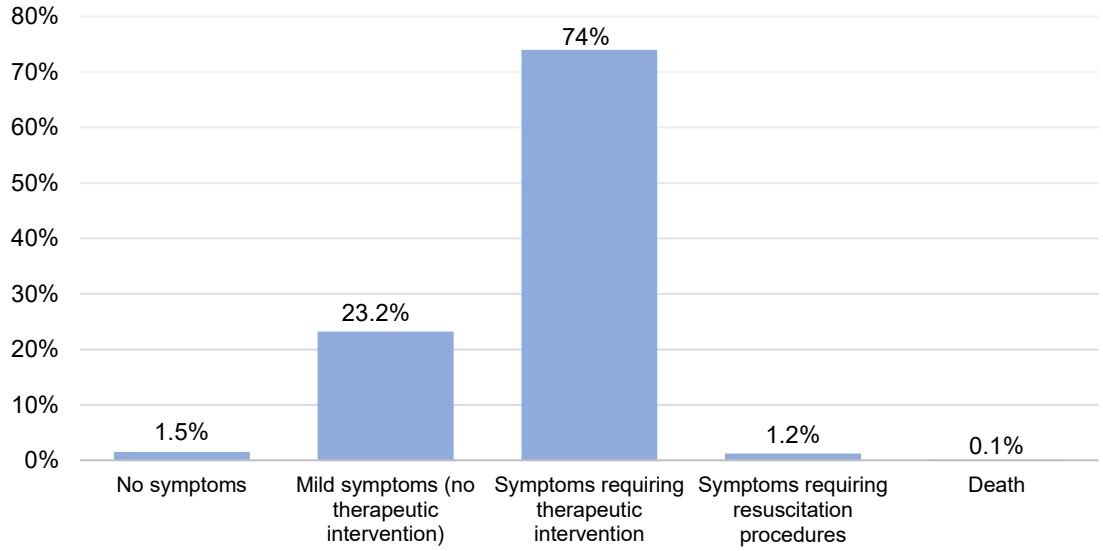


Figure 7. Severity level of adverse reactions in recipients (2018)

In 88.2% of adverse reactions the clinical resolution occurred in a few hours and only in 6 cases was a disease persistence within 6 months observed (Table 19).

Table 19. Adverse reactions in recipients by outcome (2018)

Outcome	n.	%
Resolution within a few hours	1,675	88.2
Resolution within a few days	37	1.9
Complete resolution within 6 months	3	0.2
Disease persistence within 6 months	6	0.3
Not assessable	179	9.4
Total	**1,900**	**100**

Concerning the imputability level, more than 42% of adverse reactions in recipients were possibly imputable, 12.7% were excluded/improbably related to the transfusion, and in 179 cases (9.4%) it was not assessable. Data show that 55.6% of adverse reactions in recipients were associated with low levels of imputabilty (Table 20 and Figure 8).

Table 20. Adverse reactions in recipients by imputability level (2018)

Level	Imputability	n.	%
0	Excluded/Improbable	242	12.7
1	Possible	816	42.9
2	Probable	573	30.2
3	Certain	107	5.6
N.A.	Not assessable	162	8.5
	Total	**1,900**	**100**

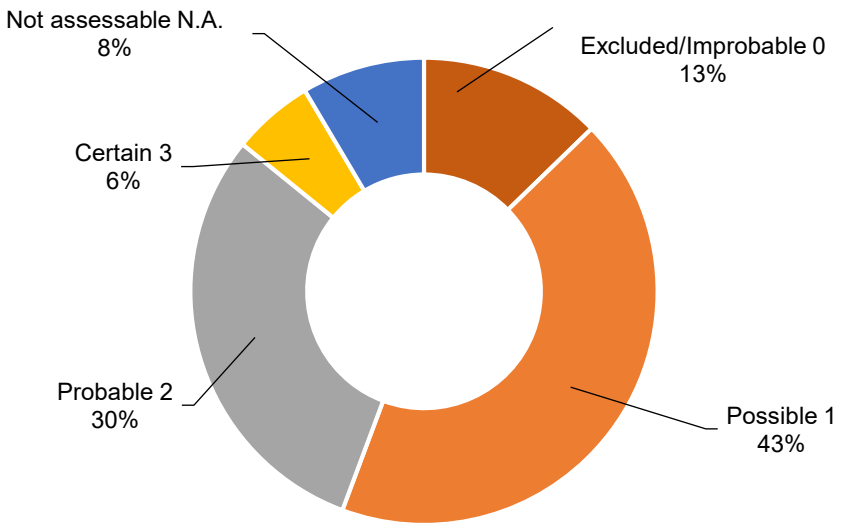


Figure 8. Adverse reactions in recipients linked to the imputability level expressed as a percentage (2018)

Transfusion sites

The majority of adverse reactions occurred in hospital ward (74.6%) or in day-hospital (9.6%) (Table 21 and Figure 9).

Table 21. Transfusion sites notifying adverse reactions (2018)

Transfusion site	n.	%
Hospital ward	1,418	74.6
Day hospital	182	9.6
Emergency/ICU	109	5.7
Blood establishment	74	3.9
Clinic	80	4.2
Operating theatre	21	1.1
Home	16	0.8
Total	**1,900**	**100**

ICU Intensive Care Unit

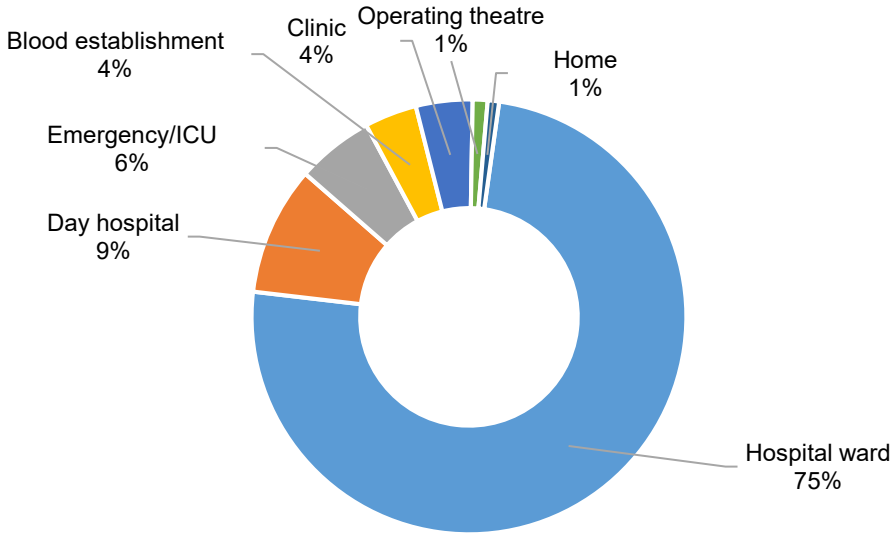


Figure 9. Adverse reactions by transfusion site as a percentage (2018)

Adverse reactions classified by transfused blood component

Among the notified 1,900 adverse reactions in recipients, most were related to RBC transfusion (63.2%). In 18 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 22).

Table 22. Adverse reactions in recipients classified by transfused blood component (2018)

Blood component	n.	%
Red Blood Cells	1,201	63.2
Platelets	452	23.8
Plasma*	192	10.1
Pharmaceutical Inactivated Plasma	25	1.3
More than one blood component transfused**	18	0.9
Cryoprecipitate	1	0.1
Haemopoietic Stem Cells	10	0.5
Lymphocytes from apheresis	1	0.1
Total	**1,900**	**100**

* Pharmaceutical inactivated plasma excluded.
** 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 every 1,000 units of transfused blood components, the highest incidence is found in platelet concentrate transfusions (Table 23).

In addition, 25 adverse reactions resulting from infused pharmaceutical virus-inactivated plasma equal to 1.3 adverse reactions every 1,000 transfused units were notified (*see* Table 22).

Table 23. Adverse reactions/1,000 transfused units grouped by blood component regardless of the imputability and severity levels (2018)

Blood component	Transfused units	Adverse reactions	Adverse reactions/ 1,000 transfused units
Red Blood Cells	2,443,359	1,201	0.49
Plasma*	268,349	217	0.80
Platelets	233,221	452	1.94

* Plasma includes Pharmaceutical Inactivated Plasma (Transfused units 127,954 with 25 adverse reactions)

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

In 2018, among the 1,900 adverse events to transfusion 7 were serious with a high imputability level (imputability level 2-3 and severity level 3-4). Table 24 shows the type of adverse reaction by transfused blood component.

Table 24. Adverse reactions to transfusion classified by transfused blood component with an imputability level 2-3 and a severity level 3-4 (2018)

Adverse reactions	RBCs	Platelets	Plasma	Total
Anaphylactic shock	-	1	2	3
ABO acute haemolytic reaction	2	-	-	2
Transfusion-associated circulatory overload (TACO)	1	-		1
Other (Dyspnoea)	1	-	-	1
Total	**4**	**1**	**2**	**7**

Deaths

In 2018, 1 case of death was notified.

The case of death was an ABO acute haemolytic reaction: the case was certainly imputable to transfusion due to wrong recipient identification. Two ABO incompatible units of RBCs were transfused. The adverse reaction occurred in a 90-year-old female patient receiving two units of pre-storage leukodepleted RBCs for severe anaemia.

Adverse reactions in donors

In 2018, 8,716 adverse reactions to allogeneic donation were notified (1 every 343 donations) (Table 25); 787 of these reactions were severe (1 every 3,800 donations). Autologous donations were excluded from the analysis. Another reason for exclusion was miscoded reaction category (4 citrate reactions recorded after whole blood donation).

Table 25 shows the number of adverse reactions in donors classified by type and the related percentage.

Table 26 shows adverse reactions to donations classified by severity level and the related percentage.

In 2018, of all notified reactions, 6,374 (73.1%) were mild, 1,555 (17.9%) moderate, and only 787 (9%) severe (Table 26). The most frequent type of notified reaction was immediate vasovagal reaction (78.3%) (Table 25), of which only 3.28% (224/6,826) severe.

Table 25. Adverse reactions in donors (2018)

Adverse reaction	n.	%
Immediate vasovagal reaction	6,826	78.32
Immediate vasovagal reaction with complications	16	0.2
Delayed vasovagal reaction	890	10.21
Delayed vasovagal reaction with complications	7	0.1
Haematoma	596	6.84
Citrate paraesthesia/tingling	2	0.02
Arterial puncture	24	0.3
Cold/shivers	12	0.14
Thrombophlebitis	5	0.05
Incidents tied to vasovagal syndrome	2	0.02
Nerve injury	9	0.1
Citrate reactions	143	1.61
Haemolysis	11	0.13
Nerve injury due to a haematoma	1	0.01
Tightness in the chest	6	0.1
Systemic allergic reaction	3	0.02
Acute neurologic deficit	1	0.01
Thrombocytopenia	2	0.02
Other incidents	18	0.2
Other	142	1.6
Total	**8,716**	**100**

Table 26. Adverse reactions to donations classified per severity level (2018)

Adverse reaction	Mild		Moderate		Severe	
	n.	%	n.	%	n.	%
Immediate vasovagal reaction	5,390	61.8	1,212	13.9	224	2.6
Immediate vasovagal reaction with complications	7	0.08	6	0.07	3	0.03
Delayed vasovagal reaction	555	6.4	249	2.9	86	0.99
Delayed vasovagal reaction with complications	3	0.03	-	0	4	0.05
Haematoma	142	1.6	38	0.4	416	4.8
Citrate paraesthesia/tingling	1	0.01	-	0	1	0.01
Arterial puncture	-	0	22	0.25	2	0.02
Cold/shivers	9	0.1	-	0	3	0.03
Thrombophlebitis	-	0	-	0	5	0.06
Incidents tied to vasovagal syndrome	-	0	-	0	2	0.02
Nerve injury	5	0.06	4	0.05	-	0
Citrate reactions	121	1.39	6	0.07	16	0.2
Haemolysis	-	0	-	0	11	0.13
Nerve injury due to a haematoma	-	0	1	0.01	-	0
Tightness in the chest	6	0.07	-	0	-	0
Systemic allergic reaction	-	0	-	0	3	0.03
Acute neurologic deficit	-	0	-	0	1	0.01
Thrombocytopenia	2	0.02	-	0	-	0
Other incidents	15	0.17	1	0.01	2	0.02
Other	118	1.35	16	0.2	8	0.09
Total	**6,374**	**73.1**	**1,555**	**17.9**	**787**	**9.0**

If the absolute number of adverse reactions are compared to the total number of donation procedures, there are more adverse reaction related to whole blood donations than to apheresis donations (6,564 against 2,152). Nevertheless, if we normalise the figures to 1,000 donation procedures, the highest incidence is linked to apheresis donation (5.1 against 2.55/1,000 donations) (Table 27). These figures are in line with those of previous years.

Table 27. Donors with adverse reactions to donations classified per donation procedure (2018)

Donation procedure			Donors with adverse reactions			Donors with adverse reactions/ 1,000 donation procedures		
whole blood	***apheresis***	***total***	***whole blood***	***apheresis***	***total***	***whole blood***	***apheresis***	***total***
2,569,275	421,807	2,991,082	6,564	2,152	8,716	2.55	5.10	2.91

Considering the 6,564 adverse reactions related to whole blood donations (Table 28), the most frequent types of notified reactions were immediate vasovagal reaction (82.32%) and delayed vasovagal reaction (11.33%). Considering only the 2,152 adverse reactions related to apheresis donations (Table 29), the most frequent types of notified reactions were immediate vasovagal reaction (65.9%) and haematoma (16.2%).

Table 28. Adverse reactions related to whole blood donations (2018)

Adverse reaction	n.	%
Immediate vasovagal reaction	5,407	82.3
Immediate vasovagal reaction with complications	16	0.2
Delayed vasovagal reaction	744	11.3
Delayed vasovagal reaction with complications	6	0.09
Haematoma	248	3.8
Arterial puncture	22	0.3
Cold/shivers	3	0.05
Thrombophlebitis	3	0.05
Nerve injury	8	0.1
Nerve injury due to a haematoma	1	0.02
Tightness in the chest	4	0.06
Acute neurologic deficit	1	0.02
Other incidents	11	0.2
Other	90	1.4
Total	**6,564**	**100**

Table 29. Adverse reactions related to apheresis donations (2018)

Adverse reaction	n.	%
Immediate vasovagal reaction	1,419	65.9
Delayed vasovagal reaction	146	6.8
Delayed vasovagal reaction with complications	1	0.01
Haematoma	348	16.2
Citrate paraesthesia/tingling	2	0.1
Arterial puncture	2	0.1
Cold/shivers	9	0.4
Thrombophlebitis	2	0.1
Incidents tied to vasovagal syndrome	2	0.1
Nerve injury	1	0.01
Citrate tetany	143	6.6
Haemolysis	11	0.5
Tightness in the chest	2	0.1
Systemic allergic reaction	3	0.1
Thrombocytopenia	2	0.1
Other incidents	7	0.3
Other	52	2.4
Total	**2,152**	**100**

In 2018, the majority of adverse reactions to donation (54.7%) occurred in BEs and 29.7% in BCSs (Table 30).

Table 30. Donor adverse reaction classified by donation site (2018)

Donation site	n.	%
BE peripheral organisational site	1,222	14.0
In Itinere	137	1.6
BEs	4,769	54.7
BCSs	2,588	29.7
Total	**8,716**	**100**

BEs Blood establishments; BCSs Blood collection Sites.

Serious adverse events

In 2018, 51 serious adverse events were notified; the majority was due to human error (Table 31 and Figure 10). Six of them (11.8%) were notified as "Other" (Table 31).

Table 31. Cause of adverse events (2018)

Cause	n.	%
Transfusional product defect	1	2.0
Material defect	4	7.8
Equipment malfunction	1	2.0
Human error	30	58.8
Organisational error	9	17.6
Other	6	11.8
Total	**51**	**100**

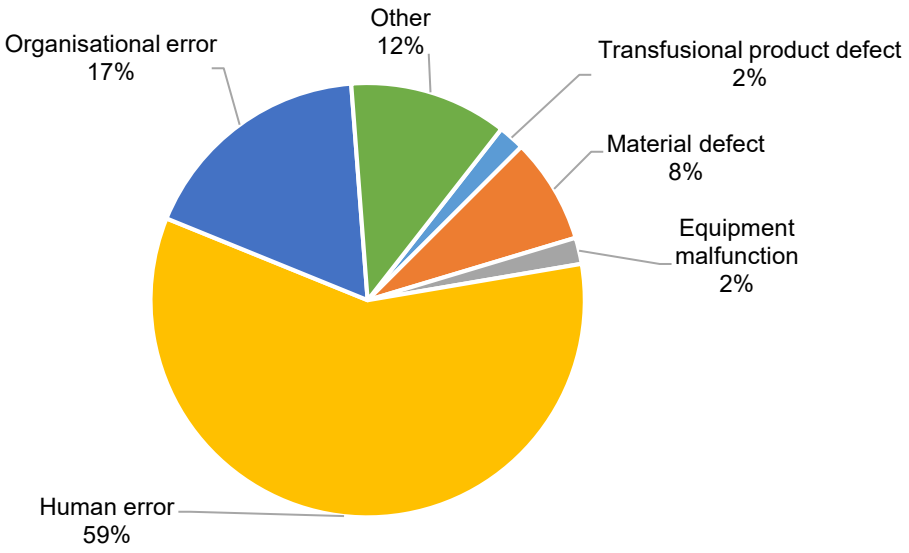


Figure 10. Cause of adverse events (2018)

For the majority of serious adverse events (56.9%) the phase was not reported and they were notified as "Other" (Table 32 and Figure 11).

Table 32. Phases in which serious adverse events occurred (2018)

Phase	n.	%
Collection	8	15.7
Processing	1	2.0
Distribution	13	25.5
Other	29	56.9
Total	**51**	**100**

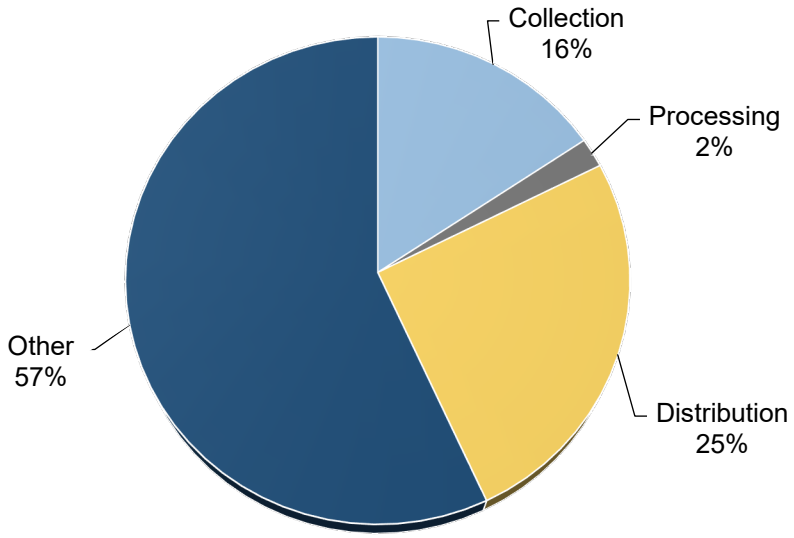


Figure 11. Phases in which serious adverse events occurred (2018)

In 2018, the majority of adverse events (62.7%) occurred in clinical wards and 27.5% in BEs (Table 33 and Figure 12).

Table 33. Adverse events classified by site of the occurrence (2018)

Donation site	n.	%
BE peripheral organisational site	3	5.9
During the blood units transportation	2	3.9
BE	14	27.5
Clinical ward	32	62.7
Total	**51**	**100**

BEs Blood establishments

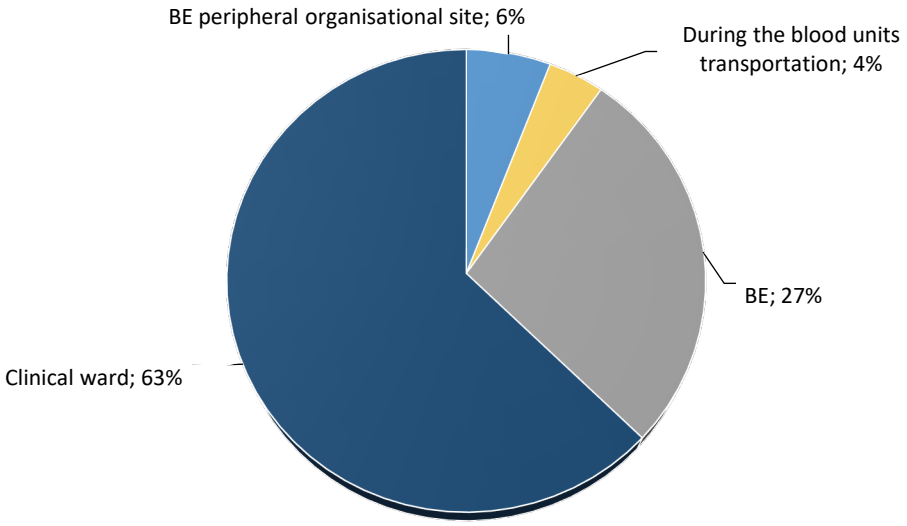


Figure 12. Site in which serious adverse events occurred (2018)

Comments and recommendations

The analysis of the 2018-haemovigilance data confirms that, as in previous years (6,16), the most frequent adverse reactions to transfusion, considering all imputability and severity levels, are FNHTR (34.9%) and allergic manifestations with only mucosal and cutaneous symptoms (29.1%).

There were only 7 adverse reactions with probable or certain imputability requiring resuscitation procedures, including one case of death related to an ABO acute haemolytic reaction.

There were 14 cases of ABO-incompatible transfusion, 6 of which were notified as "acute haemolytic reaction", 1 as "delayed haemolytic reaction", "5 as "serious adverse event", and 2 as "ABO-incompatible Blood Component Transfused without reaction". The above-mentioned events are caused by an error or deviation from standard procedures or policies. Root cause analysis of these events should be carried out to highlight and resolve these system failures. Monitoring and reporting this type of event is important so suitable preventive measures can be adopted.

In 2018, reactions involving the respiratory system accounted for 10.6% of the notifications of which 74 were allergic reactions involving the respiratory and/or cardiovascular system, 71 TAD, 56 TACO and 2 TRALI. Of the 71 TAD cases only 5.6% were certainly imputable to transfusion.

Although data from scientific literature show variable frequency regarding these adverse reactions associated to several factors (utilised definitions, diagnostic criteria, studied populations and type of haemovigilance system adopted (active or passive)), the unsatisfactory quality of TACO or TRALI notifications on SISTRA and several notified cases of TAD with a low imputability level suggests that as far as haemovigilance is concerned obtaining useful data for a differential diagnosis is problematical. Further efforts are necessary to minimise the number of incomplete and low grade imputability notifications.

In 2018, 4 cases of transfusion-transmitted bacterial infection (TTBI) were notified. Despite the recognition of these adverse reactions in recipients, their true incidence is unknown as a result of underdetection and underreporting (17-19). An inaccurate and untimely reporting of suspected transfusion-associated adverse reactions (often carried out by unqualified personnel), in association with the complicated application of the criteria for their diagnosis (often these criteria broadly overlap with the diagnostic criteria for other noninfectious adverse reactions such as FNHTRs and hypotensive transfusion reactions) can lead to underreporting. Moreover, it should be noted that the above-mentioned 4 notified TTBI cases were associated with a low imputability level (2 cases possibly and 2 cases excluded/improbably imputable to transfusion) suggesting that obtaining useful data for a differential diagnosis and attribuition of imputability level is problematical. Further efforts are necessary to minimise the number of incomplete and low grade imputability notifications. The execution of quality controls on blood and blood components provides excellent information about the correct application of procedures aimed at reducing the bacterial contamination risk.

In 2018, 189 near misses were notified. Errors in patient samples (wrong group of patient, wrong name on tube, and wrong patient collected) 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. In general, an increase in near miss reports was noted - 189 in 2018, 136 in 2017, and 92 in 2016 - but they still seem to be underreported. Improving near miss reporting is important to support learning from near miss cases and so suitable preventive measures can be adopted.

As regards adverse reactions in donors, the increased number of notifications in 2018 were not related to a higher incidence of severe reactions but to an increased participation of the transfusion network in the national haemovigilance system. In fact, as can be seen in Table 25, although immediate vasovagal reactions were the most frequently notified (78.3%), only 3.28% were severe.

Moreover, there were more adverse reactions related to apheresis donation than to whole blood donation. Suggested recommendations are therefore:

More 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);

Adequate training and continuing education of the operators responsible for apheresis donations in order to:

- detect the donors at “high risk” of adverse reactions so suitable preventive measures can be adopted
- 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 observation concerns the low number of “serious adverse events” notified (overall 51) in which in most cases the specific phase in which the serious event occurred was not identified and was notified as “Other” on SISTRA. As in previous years (6,16), a limited capacity of reporting serious adverse events and classifying them 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 (13-14).

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

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

The collected information refers to donors who tested positive to the mandatory tests for the purpose of qualifying blood and blood components (9). The following serological tests are performed: hepatitis B virus surface antigen (HBsAg), anti-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 2018 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 (9) and are compliant with the document issued by the European Medicines Agency (EMA) “Guideline on epidemiological data on blood transmissible infections” (21).

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 (9).

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

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

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

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

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

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

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

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

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

General data

The data, 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 2018, out of a total of 1,907,151 blood donors, 1,661 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 (4.11‰), followed by Apulia (1.38‰) and Latium (1.25‰).

Table 34. Tested donors and positive donors to infectious markers at national and regional level (2018)

Region/AP (Autonomous Province)	Tested donors	Positive donors	
	n.	n.	‰
Aosta Valley	4,033	1	0.25
Piedmont	130,708	54	0.41
Liguria	51,955	42	0.81
Lombardy	303,740	125	0.41
AP of Trento	20,546	5	0.24
AP of Bolzano	18,242	1	0.05
Friuli Venezia Giulia	50,176	25	0.50
Veneto	181,698	48	0.26
Emilia Romagna	165,000	122	0.74
Tuscany	141,841	68	0.48
Umbria	27,991	25	0.89
Marche	55,378	24	0.43
Latium	144,362	181	1.25
Sardinia	57,927	45	0.78
Abruzzo	39,656	27	0.68
Campania	138,298	568	4.11
Molise	10,803	3	0.28
Apulia	122,179	168	1.38
Basilicata	20,189	2	0.10
Calabria	53,714	34	0.63
Sicily	167,049	93	0.56
Armed Forces	1,666	0	0.00
Italy	**1,907,151**	**1,661**	**0.87**

The data shown in Table 34 (positive donors per 1,000 tested donors (‰)) were the same as those shown in Figure 13.

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 0.95‰) in the 26-65 age bracket (Table 35).

Table 36 shows the distribution by age bracket and gender of the 1,661 positive donors; for all age brackets, the number of male positive donors appears to be on average 3 times higher than the number of female positive donors (Figure 14).

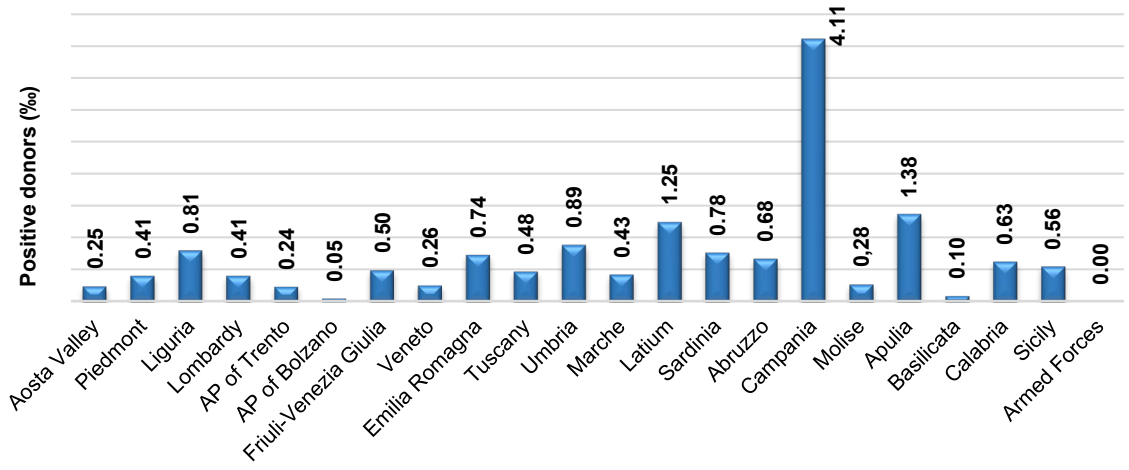


Figure 13. Positive donors per 1,000 tested donors (‰) by Italian Regions (2018)

Table 35. Positive donor by age bracket (2018)

Age bracket	Total donors		Positive donors		
	n.	%	n.	%	‰
18-25	280,083	14.7	125	7.5	0.45
26-35	343,986	18.0	310	18.7	0.90
36-45	475,491	24.9	457	27.5	0.96
46-55	529,871	27.8	506	30.5	0.95
56-65	258,662	13.6	255	15.4	0.99
over 65	19,058	1.0	8	0.5	0.42
Total	**1,907,151**	**100**	**1,661**	**100**	**0.87**

Table 36. Positive donors by age bracket and gender (2018)

Age bracket	Male				Female			
	donors		positive donors		donors		positive donors	
	n.	%	n.	%	n.	%	n.	%
18-25	149,700	11.8	99	8.1	130,383	20.5	26	5.9
26-35	220,862	17.4	240	19.6	123,124	19.4	70	16.0
36-45	329,946	25.9	336	27.5	145,545	22.9	121	27.6
46-55	372,678	29.3	369	30.2	157,193	24.8	137	31.3
56-65	184,633	14.5	173	14.1	74,029	11.7	82	18.7
over 65	14,842	1.2	6	0.5	4,216	0.7	2	0.5
Total	**1,272,661**	**100**	**1,223 (74%)**	**100**	**634,490**	**100**	**438 (26%)**	**100**

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 and 26-35 age brackets, while it was reduced in the 36-45 age bracket and was almost comparable in the 46-55, 56-65 and over 65 age brackets (Figure 15).

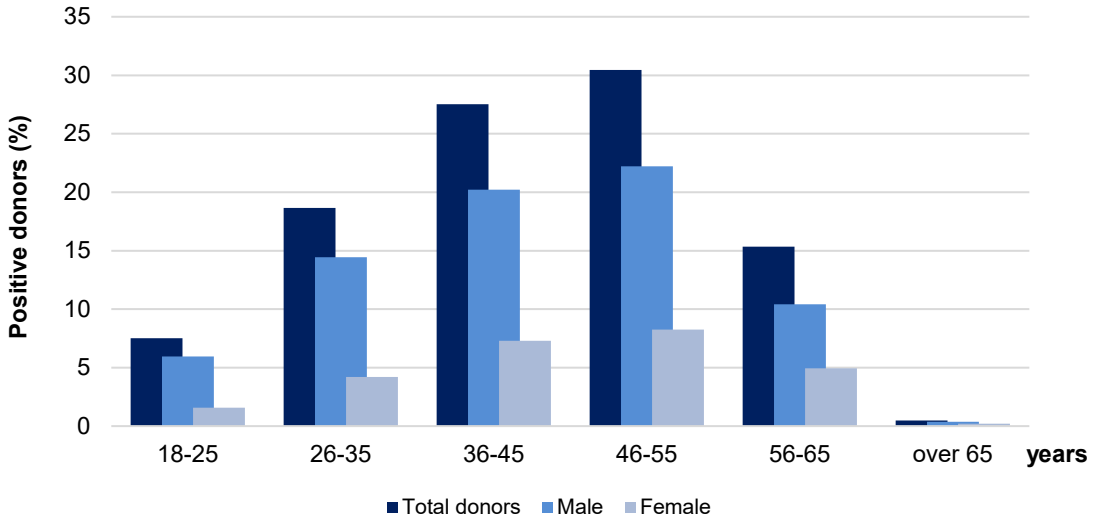


Figure 14. Positive donors (total, male and female donors) by age bracket (%) (2018)

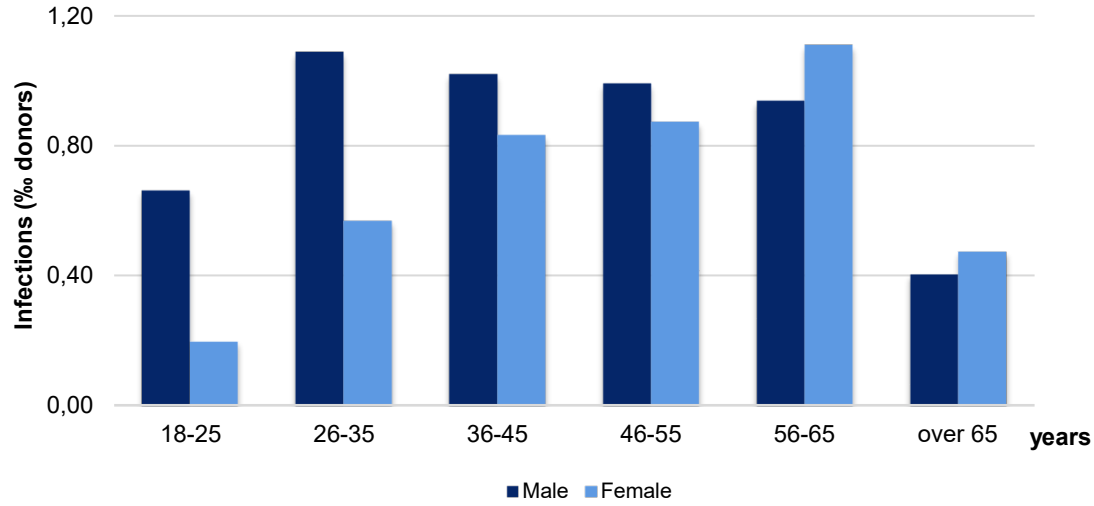


Figure 15. Positive donors by age bracket and gender (‰ total donors) (2018)

Figure 16 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 HIV, TP and HCV infections. HIV and TP infections are more frequent in the 26-35 age bracket; 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 bracket.

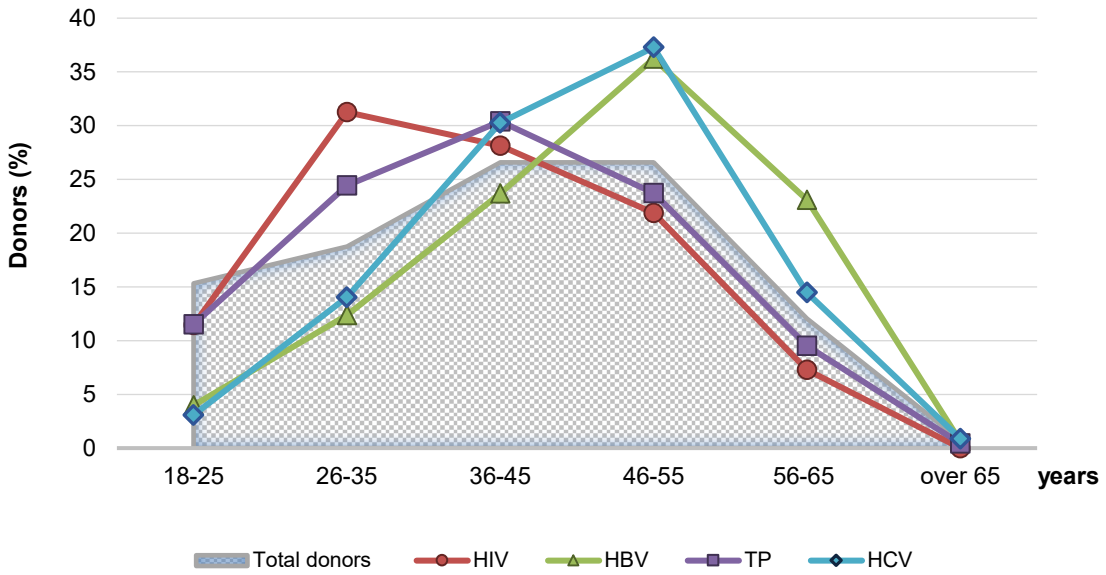


Figure 16. Total donors and HIV, HBV, HCV and TP positive donors by age bracket (2018)

The number of positive donors changed significantly also in relationship with the category (Table 37). In fact, it emerged that 3‰ of FT donors were positive to one of the infectious markers compared to 0.3‰ of RT donors (Table 38). Figure 17 shows the same data reported in Table 38.

Table 37. Positive donors by category (2018)

Donor category	Donors	Positive donors	
	n.	n.	%
First-time tested donors	**434,697**	**1,271**	**76.52**
Prospective donors (first screening without donation)	187,548	364	21.91
First-time not pre-qualified donors	247,149	907	54.60
Repeat tested donors	**1,472,454**	**390**	**23.48**
First-time pre-qualified donors	123,944	6	0.36
Regular donors	1,348,510	384	23.12
Total donors	**1,907,151**	**1,661**	**100**

Table 38. Positive donors per 1,000 (‰) tested donors: distribution by category (2018)

Donor category	Donors	Positive donors	
	n.	n.	(‰)
First-time tested donors	**434,697**	**1,271**	**2.92**
Prospective donors (first screening without donation)	187,548	364	1.94
First-time not pre-qualified donors	247,149	907	3.67
Repeat tested donors	**1,472,454**	**390**	**0.26**
First-time pre-qualified donors	123,944	6	0.05
Regular donors	1,348,510	384	0.28
Total donors	**1,907,151**	**1,661**	**0.87**

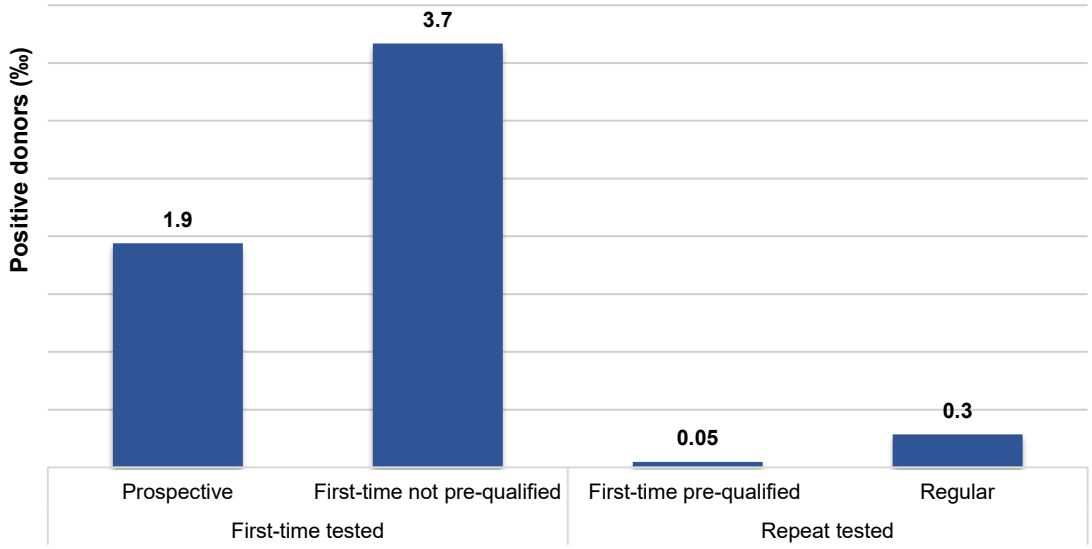


Figure 17. Categories of positive donors (2018)

Table 39 shows the number of FT and RT positive donors in Italy divided by Region. The Region with the highest number of FT (6.96‰) and RT (0.95‰) positive donors was Campania.

Table 39. FT and RT positive donors (total and per 1,000 (‰) tested donors) in Italy (2018)

Region/AP	Total of donors		Positive donors			
	FT	RT	FT	RT	FT (‰ FT)	RT (‰ RT)
Aosta Valley	632	3,401	1	0	1.58	0.00
Piedmont	18,251	112,457	34	20	1.86	0.18
Liguria	13,308	38,647	34	8	2.55	0.21
Lombardy	50,868	252,872	84	41	1.65	0.16
AP of Trento	2,457	18,089	3	2	1.22	0.11
AP of Bolzano	2,067	16,175	1	0	0.48	0.00
Friuli Venezia Giulia	11,548	38,628	13	12	1.13	0.31
Veneto	27,552	154,146	33	15	1.20	0.10
Emilia Romagna	26,076	138,924	87	35	3.34	0.25
Tuscany	26,043	115,798	50	18	1.92	0.16
Umbria	4,947	23,044	18	7	3.64	0.30
Marche	8,489	46,889	18	6	2.12	0.13
Latium	55,544	88,818	145	36	2.61	0.41
Sardinia	19,029	38,898	30	15	1.58	0.39
Abruzzo	7,177	32,479	16	11	2.23	0.34
Campania	72,690	65,608	506	62	6.96	0.95
Molise	2,559	8,244	0	3	0.00	0.36
Apulia	31,571	90,608	123	45	3.90	0.50
Basilicata	4,807	15,382	2	0	0.42	0.00
Calabria	11,451	42,263	24	10	2.10	0.24
Sicily	36,624	130,425	49	44	1.34	0.34
Armed Forces	1,007	659	0	0	0.00	0.00
Italy	**434,697**	**1,472,454**	**1,271**	**390**	**2.92**	**0.26**

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Figure 18 shows the percentage of positive donors by category (FT/RT). In general, with the exception of the Molise Region, more than 50% were FT.

The male/female ratio for FT positive donors was about 2:1. However, the male/female ratio for RT positive donors was about 3:1 (Figure 19).

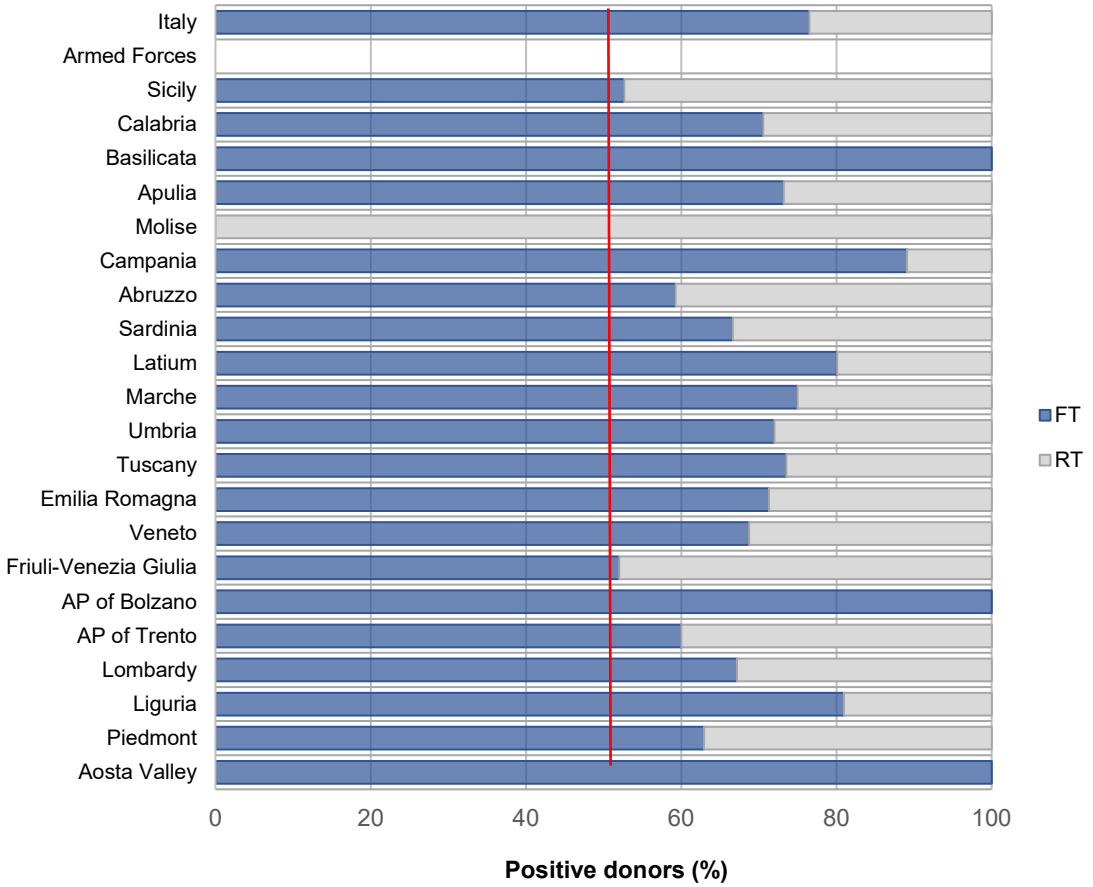


Figure 18. Positive donors by FT and RT category (%) at national and regional level (2018)

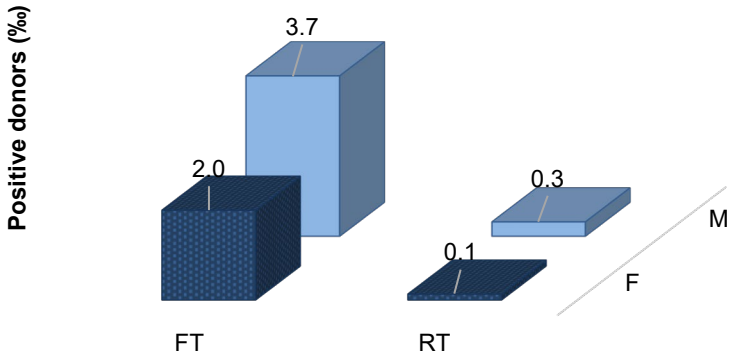


Figure 19. Positive donors by FT and RT category (‰ total male and female donors) and gender (2018)

Figure 20 shows the positive donor distribution at national and regional level for each infectious marker per 100,000 tested donors. The Region with the highest number of all infections was Campania (HIV: 20.2/100,000, HBV: 142.6/100,000, HCV: 57.8/100,000, and TP: 167.5/100,000 tested donors). These values were from 4 (HIV) to 4.8 times (HCV) higher compared to the national data.

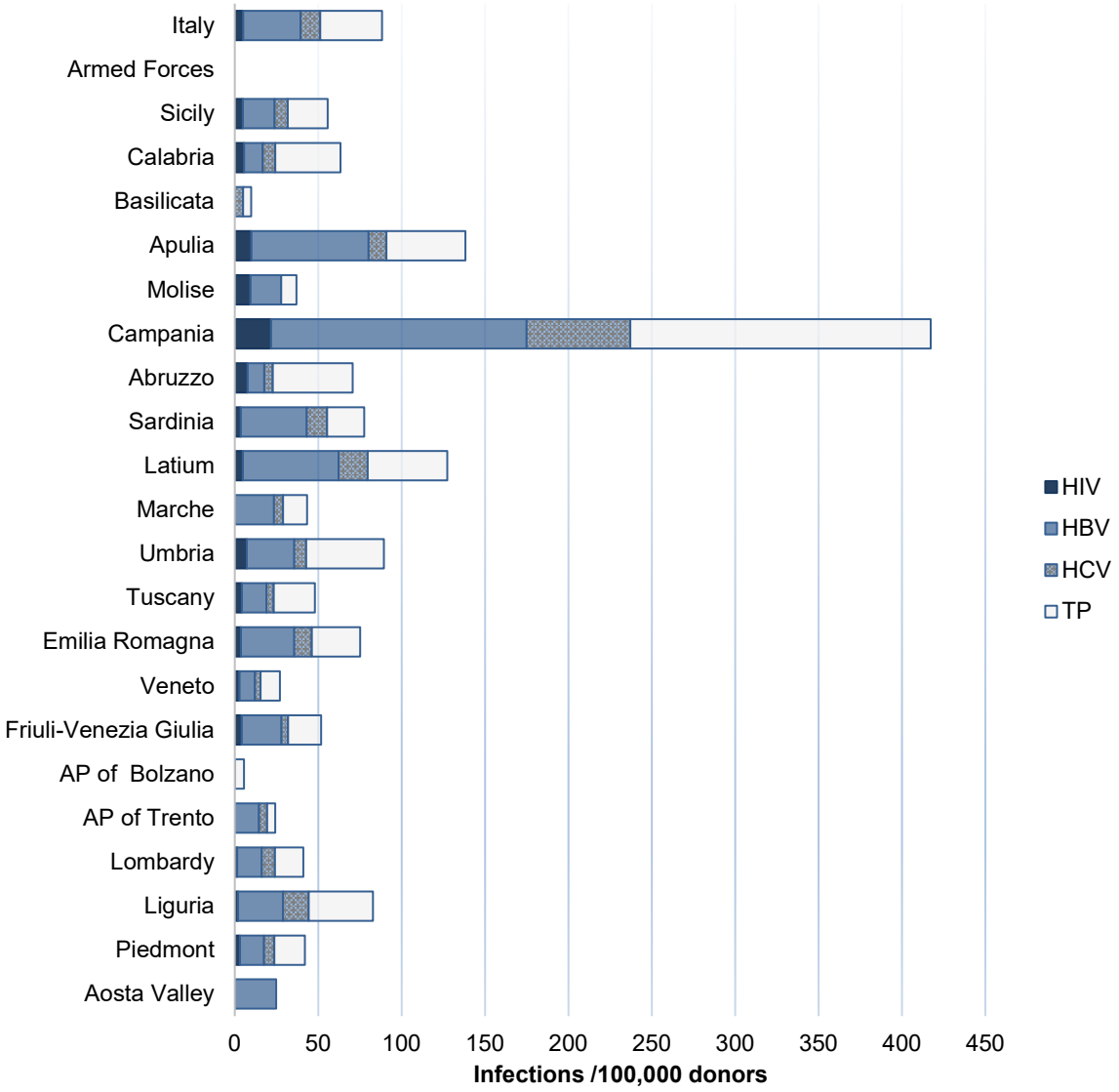
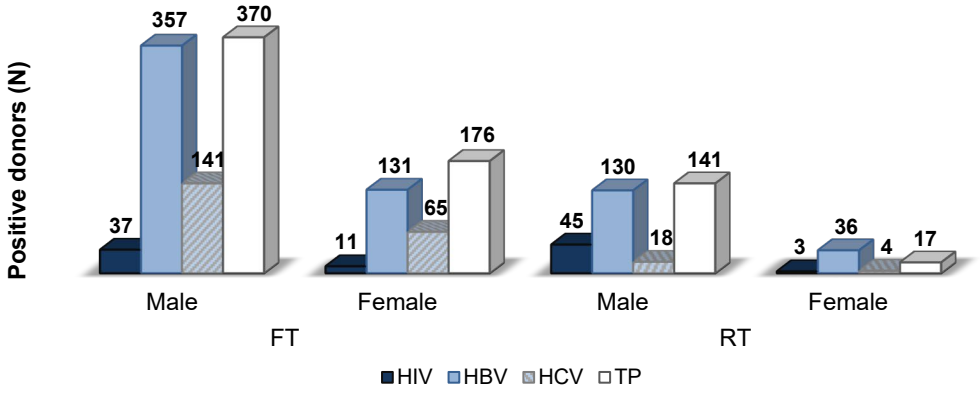


Figure 20. Number of positive donor distribution at national and regional level for each infectious marker per 100,000 donors (2018)

Figure 21 shows the distribution of infections by category (FT/RT), gender and infectious marker. 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 3:1 (HBV) to about 9:1 (HCV).



FT First time tested donors; RT Repeat tested donors

Figure 21. Infections by donor category (FT/RT), gender and infectious marker (2018)

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 TP (125.6/100,000 FT donors), followed by HBV (112.3/100,000 FT donors) (Table 40).

Table 40. Prevalence by infectious marker/100,000 FT donors (2018)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	158.2	0.0	0.0
Piedmont	11.0	71.2	43.8	65.8
Liguria	0.0	90.2	60.1	112.7
Lombardy	5.9	47.2	39.3	72.7
AP of Trento	0.0	40.7	40.7	40.7
AP of Bolzano	0.0	0.0	0.0	48.4
Friuli Venezia Giulia	0.0	43.3	8.7	60.6
Veneto	3.6	43.6	14.5	58.1
Emilia Romagna	3.8	134.2	53.7	149.6
Tuscany	11.5	69.1	19.2	92.2
Umbria	20.2	121.3	40.4	181.9
Marche	0.0	117.8	35.3	58.9
Latium	5.4	120.6	37.8	102.6
Sardinia	0.0	99.9	26.3	31.5
Abruzzo	13.9	41.8	13.9	167.2
Campania	34.4	243.5	115.6	315.0
Molise	0.0	0.0	0.0	0.0
Apulia	12.7	205.9	41.2	129.9
Basilicata	0.0	0.0	20.8	20.8
Calabria	0.0	34.9	34.9	139.7
Sicily	10.9	43.7	30.0	49.2
Armed Forces	0.0	0.0	0.0	0.0
Italy	**11.0**	**112.3**	**47.4**	**125.6**

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Similarly, the highest incidence value was for HBV (11.3/100,000 RT donors) and TP (10.7/100,000 RT donors) infections (Table 41).

Table 41. Incidence by infectious marker/100,000 RT donors (2018)

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	1.8	5.3	0.0	10.7
Liguria	2.6	5.2	0.0	12.9
Lombardy	0.4	8.3	1.6	5.9
AP of Trento	0.0	11.1	0.0	0.0
AP of Bolzano	0.0	0.0	0.0	0.0
Friuli Venezia Giulia	5.2	18.1	2.6	7.8
Veneto	2.6	3.2	1.3	3.2
Emilia Romagna	3.6	13.0	2.2	6.5
Tuscany	2.6	2.6	0.9	9.5
Umbria	4.3	8.7	0.0	17.4
Marche	0.0	6.4	0.0	6.4
Latium	4.5	18.0	4.5	13.5
Sardinia	5.1	10.3	5.1	18.0
Abruzzo	6.2	3.1	3.1	21.6
Campania	7.6	53.4	3.1	30.5
Molise	12.1	24.3	0.0	12.1
Apulia	8.8	23.2	0.0	18.8
Basilicata	0.0	0.0	0.0	0.0
Calabria	7.1	4.7	0.0	11.8
Sicily	3.1	12.3	1.5	16.9
Armed Forces	0.0	0.0	0.0	0.0
Italy	**3.3**	**11.3**	**1.5**	**10.7**

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Moreover, it is important to note that in 78% of cases no information on causes of missed deferral of donors positive to infectious markers was reported in SISTRA. When the cause of missed deferral was reported (22%), in most cases the donor "denied the risk factor" (Figure 22).

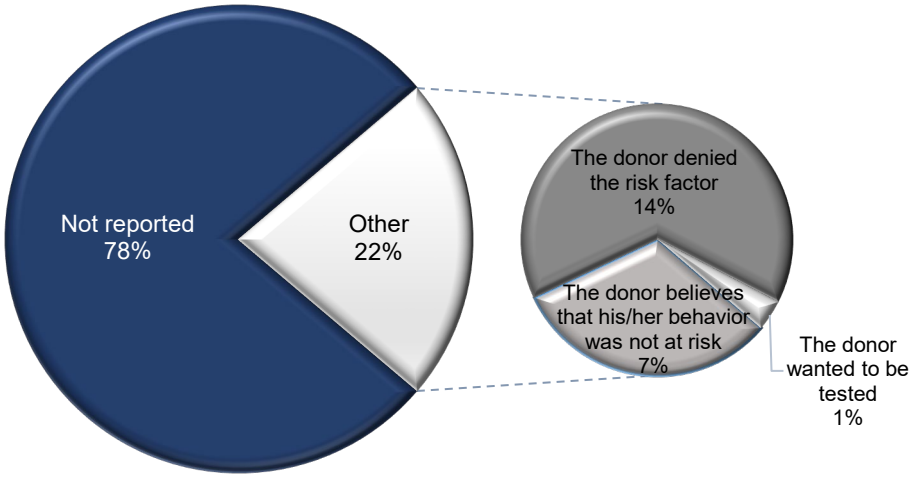

Figure 22. Causes of missed deferral of donor positive to infectious markers (2018)

Table 42 shows the number of donors positive to infectious markers by nationality and category.

Table 42. Positive donors to infectious markers by nationality and category (FT/RT) (2018)

Nationality	Positive donors		FT		RT	
	n.	%	n.	%	n.	%
Italians	1,251	75.3	883	69.5	368	94.4
Foreigners	410	24.7	388	30.5	22	5.6
Total	**1,661**	**100**	**1,271**	**100**	**390**	**100**

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 39 and Table 40 were the same as those shown in Figure 23.

Table 43. Positive donors to infectious markers by category (FT/RT) and by geographical area of birth (2018)

Geographical area of birth	FT	RT	Total
Africa	85	6	91
America	24	2	26
Asia	30	4	34
Europe	249	10	259
Italy	883	368	1,251
Total	**1,271**	**390**	**1,661**

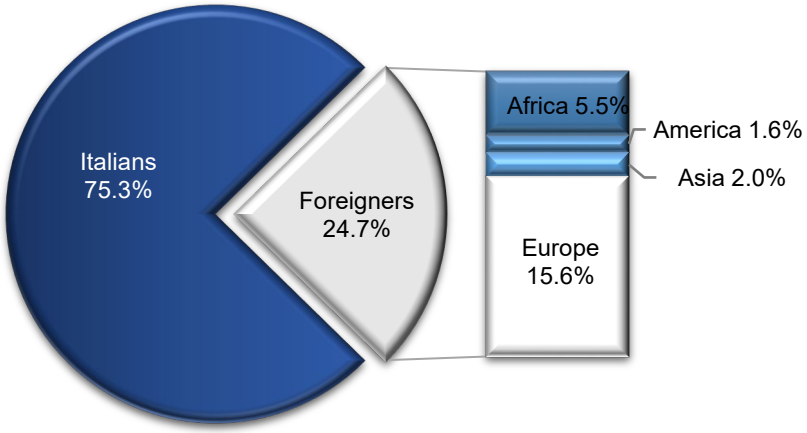

Figure 23. Positive donors to infectious markers by nationality (%) (2018)

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 2018, 96 HIV infections were reported, with a prevalence of 11.0 per 100,000 FT donors and an incidence of 3.3 per 100,000 RT donors. The highest number of HIV infections was found in the Campania Region (30 cases). The Region with the highest prevalence was Campania (34.4) while the Region with the highest incidence was Molise (12.1).

Table 44. Number, prevalence and incidence of HIV infections per 100,000 donors at national and regional level (2018)

Region/AP	HIV infections		
	n.	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	4	11.0	1.8
Liguria	1	0.0	2.6
Lombardy	4	5.9	0.4
AP of Trento	0	0.0	0.0
AP of Bolzano	0	0.0	0.0
Friuli-Venezia Giulia	2	0.0	5.2
Veneto	5	3.6	2.6
Emilia Romagna	6	3.8	3.6
Tuscany	6	11.5	2.6
Umbria	2	20.2	4.3
Marche	0	0.0	0.0
Latium	7	5.4	4.5
Sardinia	2	0.0	5.1
Abruzzo	3	13.9	6.2
Campania	30	34.4	7.6
Molise	1	0.0	12.1
Apulia	12	12.7	8.8
Basilicata	0	0.0	0.0
Calabria	3	0.0	7.1
Sicily	8	10.9	3.1
Armed Forces	0	0.0	0.0
Italy	**96**	**11.0**	**3.3**

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Figure 24 shows the distribution, expressed as a percentage, of HIV positive donors by nationality; 7.3% of all positive donors were foreigners.

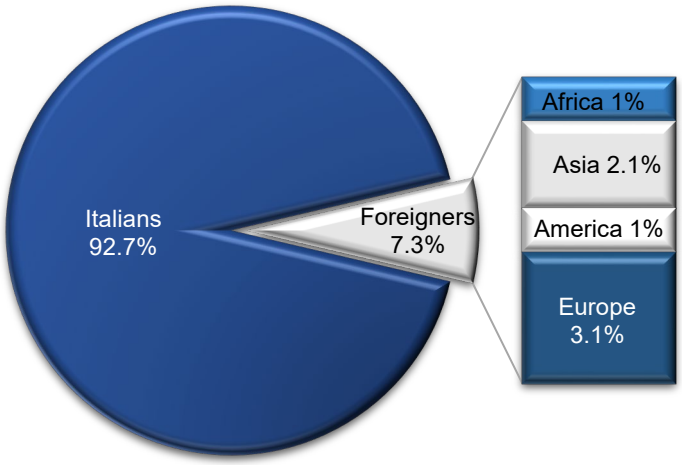

Figure 24. Distribution of HIV positive donors by nationality (%) (2018)

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

Table 45. HIV infections by geographical area of birth (2018)

Geographical area of birth	N. of infections
Africa	1
America	1
Asia	2
Europe	3
Italy	89
Total	**96**

In about 45% of the HIV positive donors (43/96) 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 heterosexual and homosexual/bisexual exposure (Figure 25).

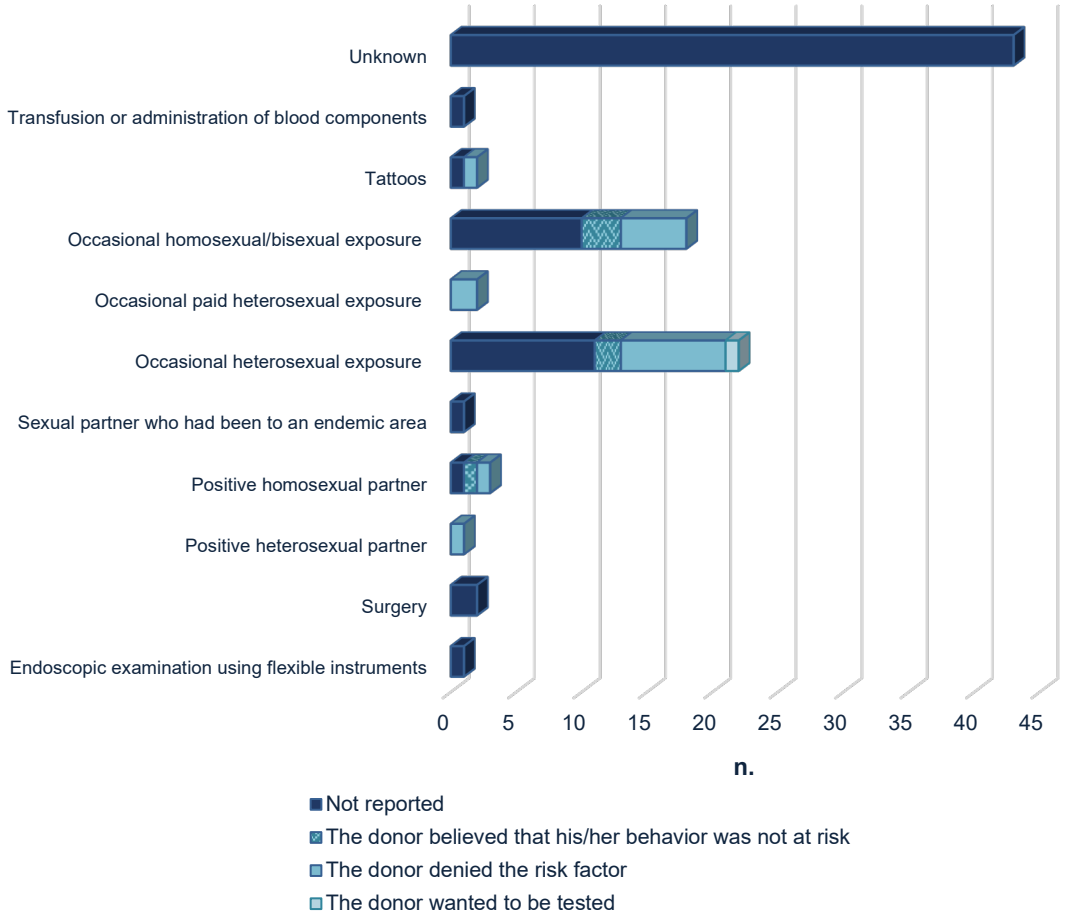

Figure 25. Causes of failed deferral and risk factors detected in HIV positive donors (2018)

Moreover, in most cases (81/96) the molecular (NAT) serological and confirmatory tests were positive; in 3 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 (2018)

Combinations of results			n. of infections
NAT	**SER**	**CONF**	
+	**+**	**+**	81
+	**+**	**+/-**	2
+	**-**	**-**	1
+	**-**		3
-	**+**	**+**	3
ND*	**+**	**+**	6
		Total	**96**

*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 2018, 228 HCV infections were reported, with a prevalence of 47.4 infections per 100,000 FT donors and an incidence of 1.5 infections per 100,000 RT donors. The highest number of HCV infections was found in the Campania Region (86). The Region with the highest prevalence was Campania (115.6), while the Region with the highest incidence was Sardinia (5.1).

Table 47. Number, prevalence and incidence of HCV infections per 100,000 donors at national and regional level (2018)

Region/AP	HCV nfections		
	n.	**prevalence**	**incidence**
Aosta Valley	0	0.0	0.0
Piedmont	8	43.8	0.0
Liguria	8	60.1	0.0
Lombardy	24	39.3	1.6
AP of Trento	1	40.7	0.0
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	2	8.7	2.6
Veneto	6	14.5	1.3
Emilia Romagna	17	53.7	2.2
Tuscany	6	19.2	0.9
Umbria	2	40.4	0.0
Marche	3	35.3	0.0
Latium	25	37.8	4.5
Sardinia	7	26.3	5.1
Abruzzo	2	13.9	3.1
Campania	86	115.6	3.1
Molise	0	0.0	0.0
Apulia	13	41.2	0.0
Basilicata	1	20.8	0.0
Calabria	4	34.9	0.0
Sicily	13	30.0	1.5
Armed Forces	0	0.0	0.0
Italy	**228**	**47.4**	**1.5**

AP Autonomous Province

Figure 26 shows the distribution, expressed as a percentage, of HCV positive donors by nationality; 16.2% of all positive donors were foreigners. Table 48 shows the distribution of HIV positive donors by geographical area of birth.

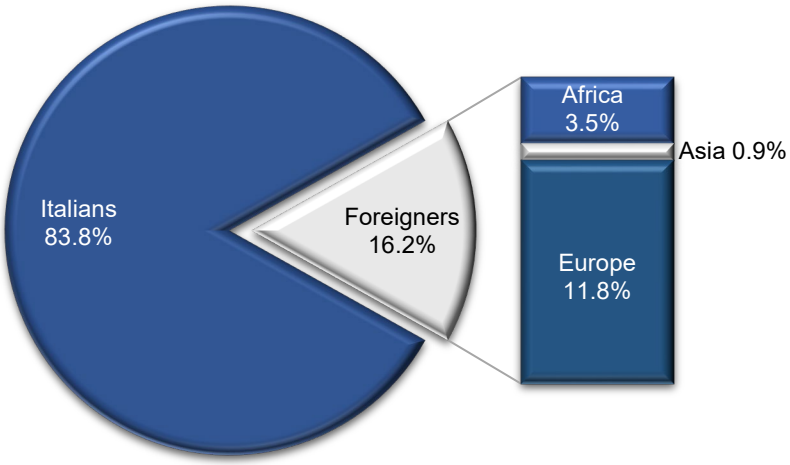

Figure 26. HCV positive donors by nationality (%) (2018)

Table 48. HCV infections by geographical area of birth (2018)

Geographical area of birth	N. of infections
Africa	8
Asia	2
Europe	27
Italy	191
Total	**228**

In most cases (118/228), the molecular (NAT), serological and confirmatory tests were positive; in 79 cases the molecular test was negative with a positive serological screening and confirmatory tests. In 3 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 (2018)

Combinations of results			N. of infections
NAT	**SER**	**CONF**	
+	**+**	**+**	118
+	**-**	**-**	3
-	**+**	**+**	79
-	**+/-**	**+**	1
ND*	**+**	**+**	27
	Total		**228**

* NAT unavailable because prospective donors only underwent serological screening tests

In about 74% of HCV positive donors (168/228) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern occasional heterosexual exposure, surgery and dental treatment (Figure 27).

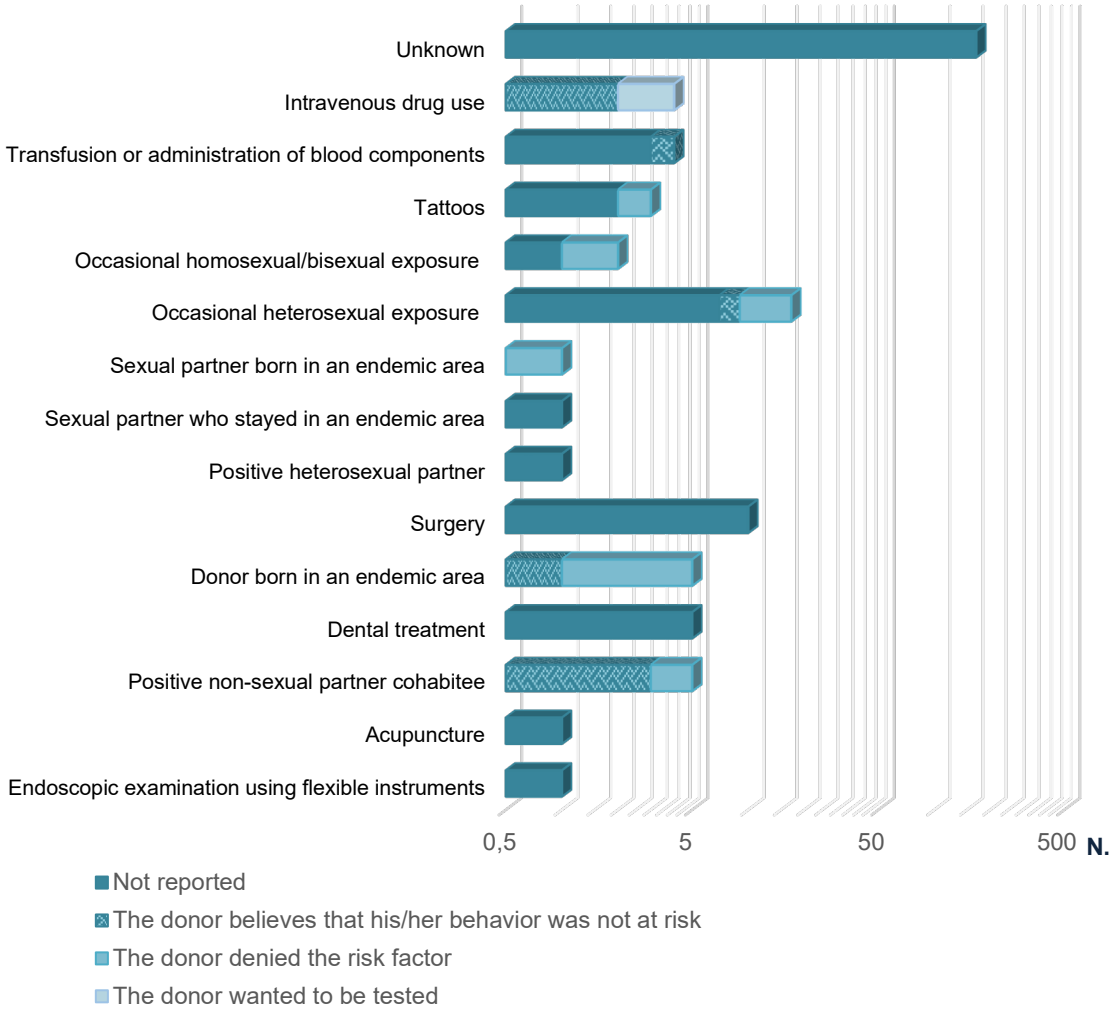

Figure 27. Causes of failed deferral and risk factors detected in HCV positive donors (values reported on a logarithmic scale) (2018)

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 2018, 654 HBV infections were reported, with a prevalence of 112.3 infections per 100,000 FT donors and an incidence of 11.3 infections per 100,000 RT donors. The highest number of HBV infections was found in the Campania Region (212). The Region with the highest prevalence (243.5) and incidence (53.4) was Campania.

Table 50. Number, prevalence and incidence of HBV infections per 100,000 donors at national and regional level (2018)

Region/AP	HBV infections		
	n.	prevalence	incidence
Aosta Valley	1	158.2	0.0
Piedmont	19	71.2	5.3
Liguria	14	90.2	5.2
Lombardy	45	47.2	8.3
AP of Trento	3	40.7	11.1
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	12	43.3	18.1
Veneto	17	43.6	3.2
Emilia Romagna	53	134.2	13.0
Tuscany	21	69.1	2.6
Umbria	8	121.3	8.7
Marche	13	117.8	6.4
Latium	83	120.6	18.0
Sardinia	23	99.9	10.3
Abruzzo	4	41.8	3.1
Campania	212	243.5	53.4
Molise	2	0.0	24.3
Apulia	86	205.9	23.2
Basilicata	0	0.0	0.0
Calabria	6	34.9	4.7
Sicily	32	43.7	12.3
Armed Forces	0	0.0	0.0
Italy	**654**	**112.3**	**11.3**

AP Autonomous Province

Figure 28 shows the distribution, expressed as a percentage, of HBV positive donors by nationality; 30.4% of all positive donors were foreigners.

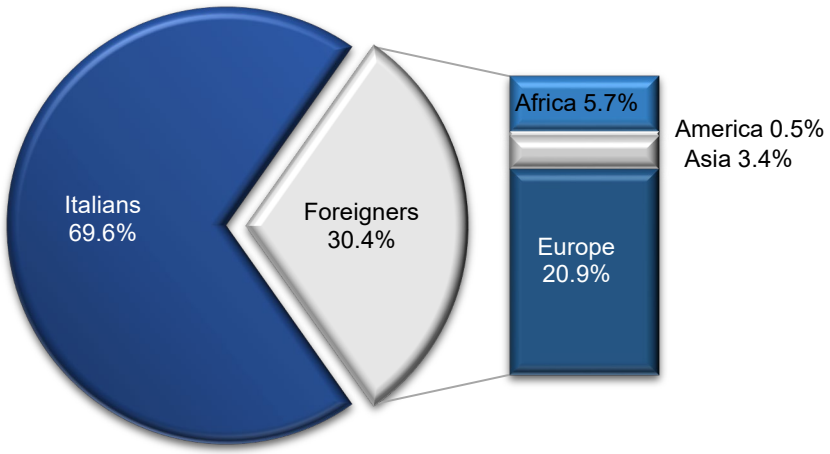

Figure 28. HBV positive donors by nationality (%) (2018)

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

Table 51. HBV infections by geographical area of birth (2018)

Geographical area of birth	N. of infections
Africa	37
America	3
Asia	22
Europe	137
Italy	455
Total	**654**

In about 71.5% of the HBV positive donors (468/654) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern occasional heterosexual exposure, surgery and dental treatment; the highest rates of behaviour considered unsafe were related to occasional heterosexual exposure (Figure 29). Moreover, in most cases (387/654), both the molecular test (NAT) and the serological tests were positive; in 208 cases the infection was detected exclusively by means of the NAT test (NAT only); in 58 cases the infection was detected exclusively by means of the serological and confirmatory tests (Table 52).

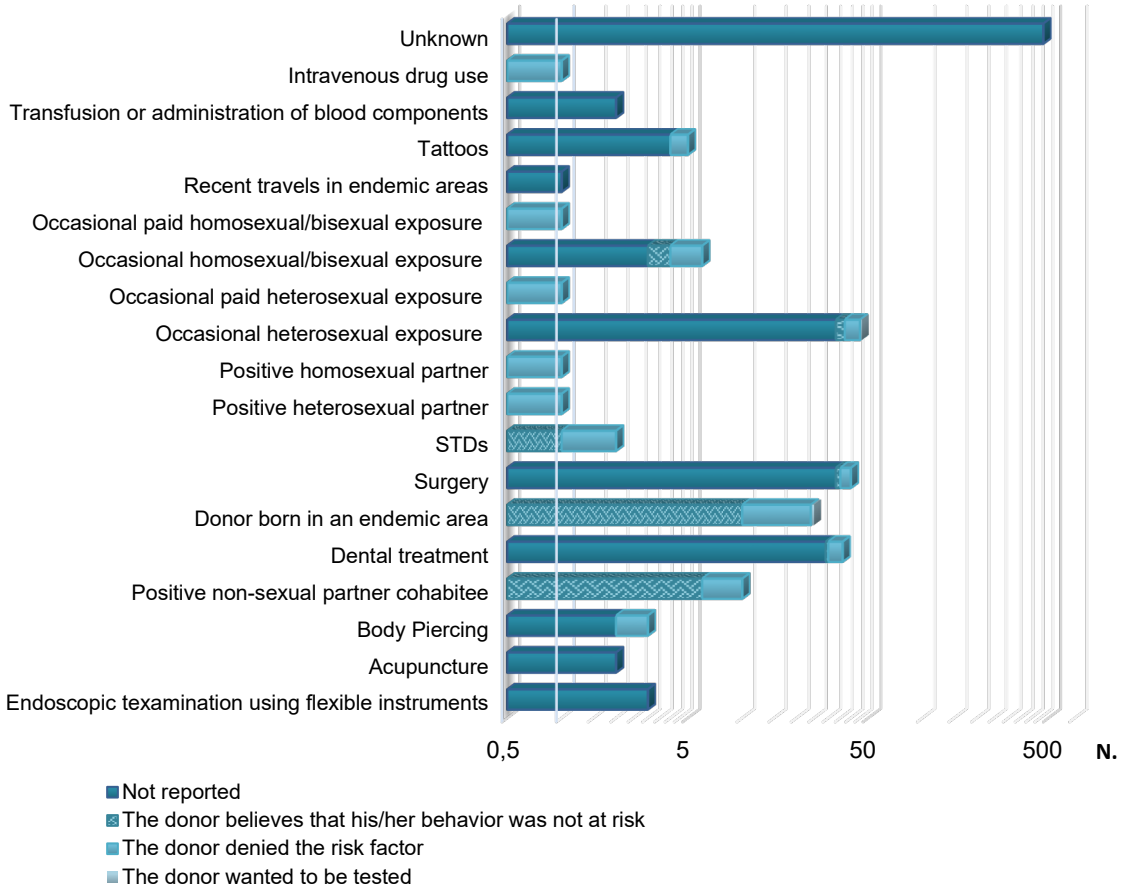

Figure 29. Causes of failed deferral and risk factors detected in HBV positive donors (values reported on a logarithmic scale) (2018)

Table 52. Number of HBV infections obtained from different combinations of the results of individual molecular and serological tests (2018)

Combinations of results			n. of infections
NAT	**SER**	**CONF**	
+	+	+	387
+	+	+/-	1
+	-	-	208
-	+	+	8
ND*	+	+	50
		Total	**654**

*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 2018, 704 TP infections were reported, with a prevalence of 125.6 infections per 100,000 FT donors and an incidence of 10.7 infections per 100,000 RT donors. The highest number of TP infections was found in the Campania Region (249). The Region with the highest prevalence (315.0) and incidence (30.5) was Campania.

Table 53. Number, prevalence and incidence of TP infections per 100,000 donors at national and regional level (2018)

Region/AP	TP infections		
	n.	**prevalence**	**incidence**
Aosta Valley	0	0.0	0.0
Piedmont	24	65.8	10.7
Liguria	20	112.7	12.9
Lombardy	52	72.7	5.9
AP of Trento	1	40.7	0.0
AP of Bolzano	1	48.4	0.0
Friuli Venezia Giulia	10	60.6	7.8
Veneto	21	58.1	3.2
Emilia Romagna	48	149.6	6.5
Tuscany	35	92.2	9.5
Umbria	13	181.9	17.4
Marche	8	58.9	6.4
Latium	69	102.6	13.5
Sardinia	13	31.5	18.0
Abruzzo	19	167.2	21.6
Campania	249	315.0	30.5
Molise	1	0.0	12.1
Apulia	58	129.9	18.8
Basilicata	1	20.8	0.0
Calabria	21	139.7	11.8
Sicily	40	49.2	16.9
Armed Forces	0	0.0	0.0
Italy	**704**	**125.6**	**10.7**

AP Autonomous Provinces

Figure 30 shows the distribution, expressed as a percentage, of the TP positive donors by nationality; 23% of all positive donors were foreigners.

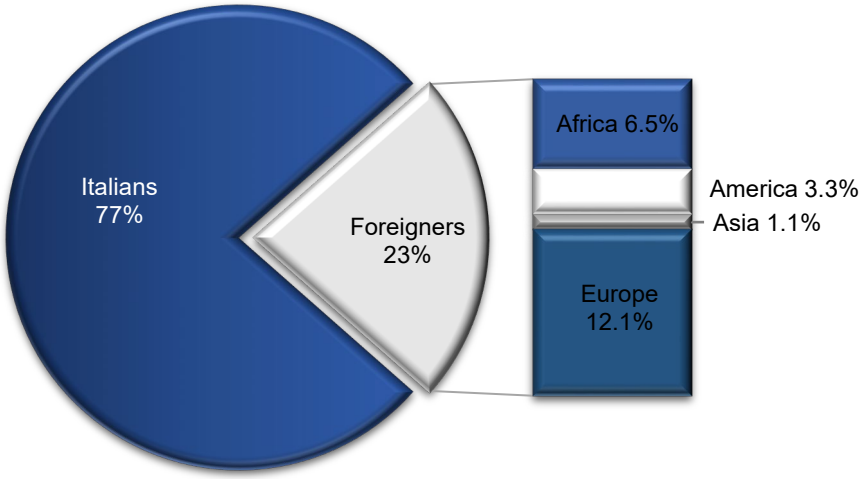

Figure 30. Distribution of TP positive donors by nationality (%) (2018)

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

Table 54. Number of TP infections by geographical area of birth (2018)

Geographical area of birth	N. of infections
Africa	46
America	23
Asia	8
Europe	85
Italy	542
Total	**704**

In about 61% of the TP positive donors (430/704) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern occasional heterosexual exposure, occasional homosexual/bisexual exposure and TP positive heterosexual partner; the highest percentages of behaviour not considered at risk refer to occasional heterosexual/homosexual/bisexual exposure. In 87 cases the donor denied the risk factor, especially occasional heterosexual/homosexual/bisexual exposure (Figure 31).

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

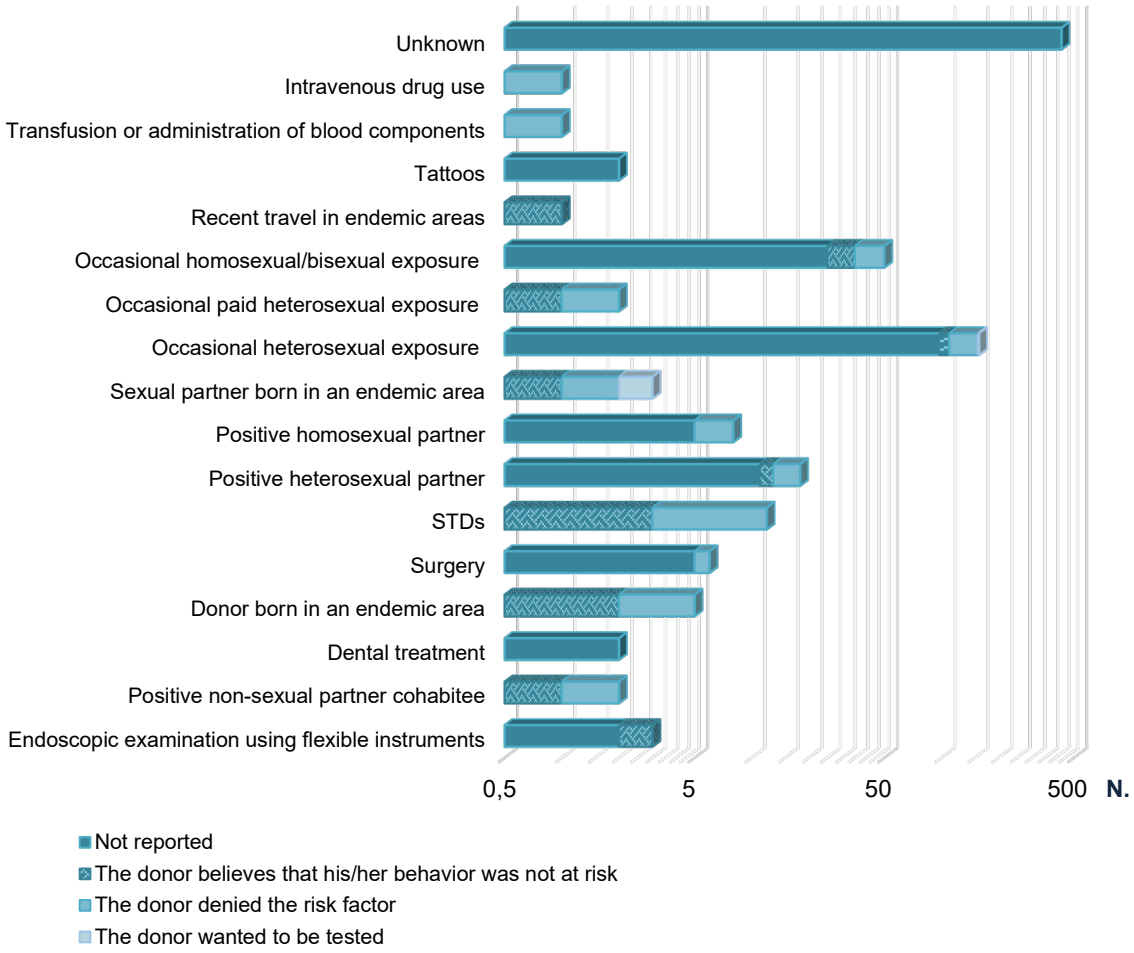

Figure 31. Causes of failed deferral and risk factors detected in TP positive donors (values reported on a logarithmic scale) (2018)

Table 55. Number of TP infections obtained from individual serological test (2018)

Results		n. of infections
SER	**CONF**	
+	**+**	703
+/-	**+**	1
Total		704

Coinfections

In this chapter, the authors want to provide more accurate epidemiological data on coinfection notifications regarding blood donors for the year 2018.

Figure 32 shows the number of coinfected donors by gender and type of coinfection diagnosed; of the 21 coinfections notified, 18 included TP. The majority of coinfected donors were males. In particular, in 1/3 of cases the coinfection was diagnosed in male donors in the 36-45 age bracket (Figure 33).

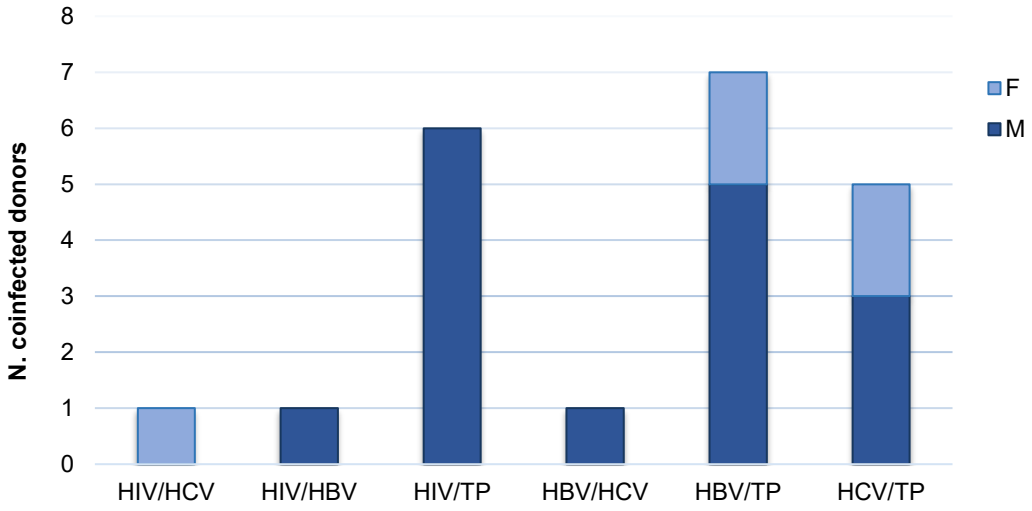

Figure 32. Number of coinfected donors by type of coinfection and by gender (2018)

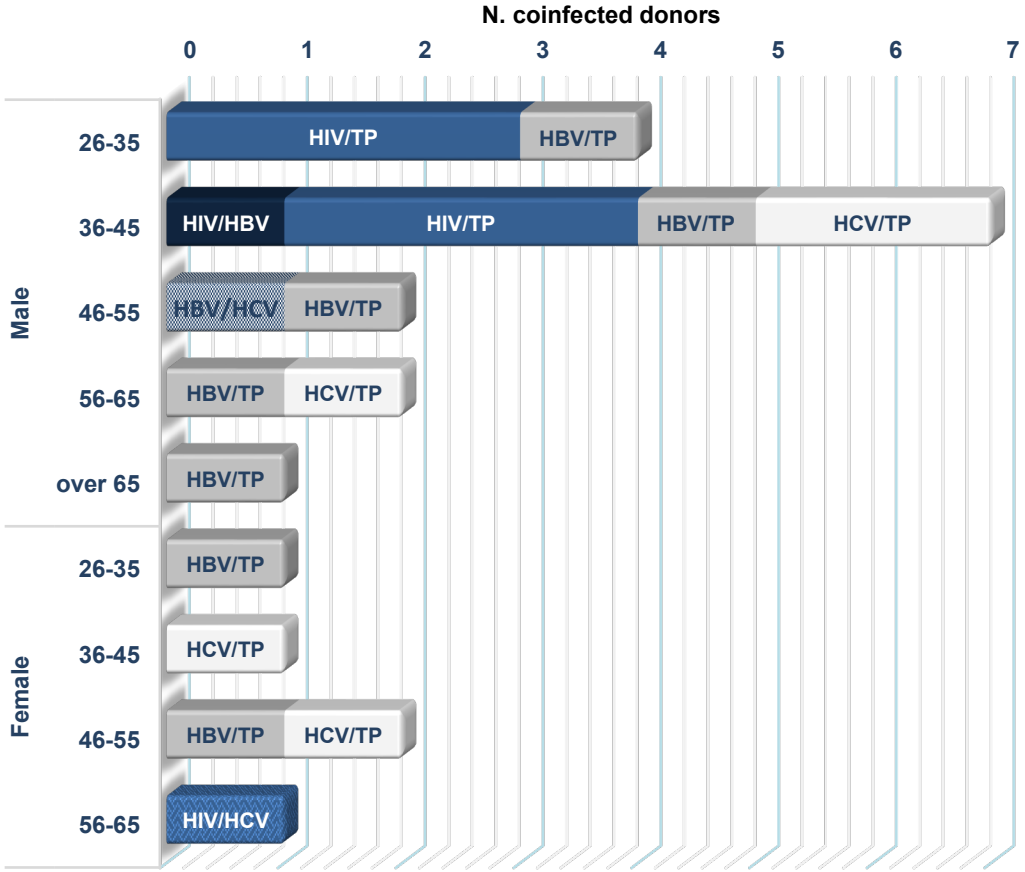

Figure 33. Number of coinfected donors by type of coinfection, age bracket and sex (2018)

For the majority of coinfected donors (HIV/TP, HBV/TP and HCV/TP) it was not possible to trace the reasons for missed deferral and the risk factors are not known. For 10 cases of coinfection the risk factors were identified and were generally due to high risk sexual behaviour; in the remaining 2 cases the risk factors were identified and were due to surgery and intravenous drug use (Figure 34).

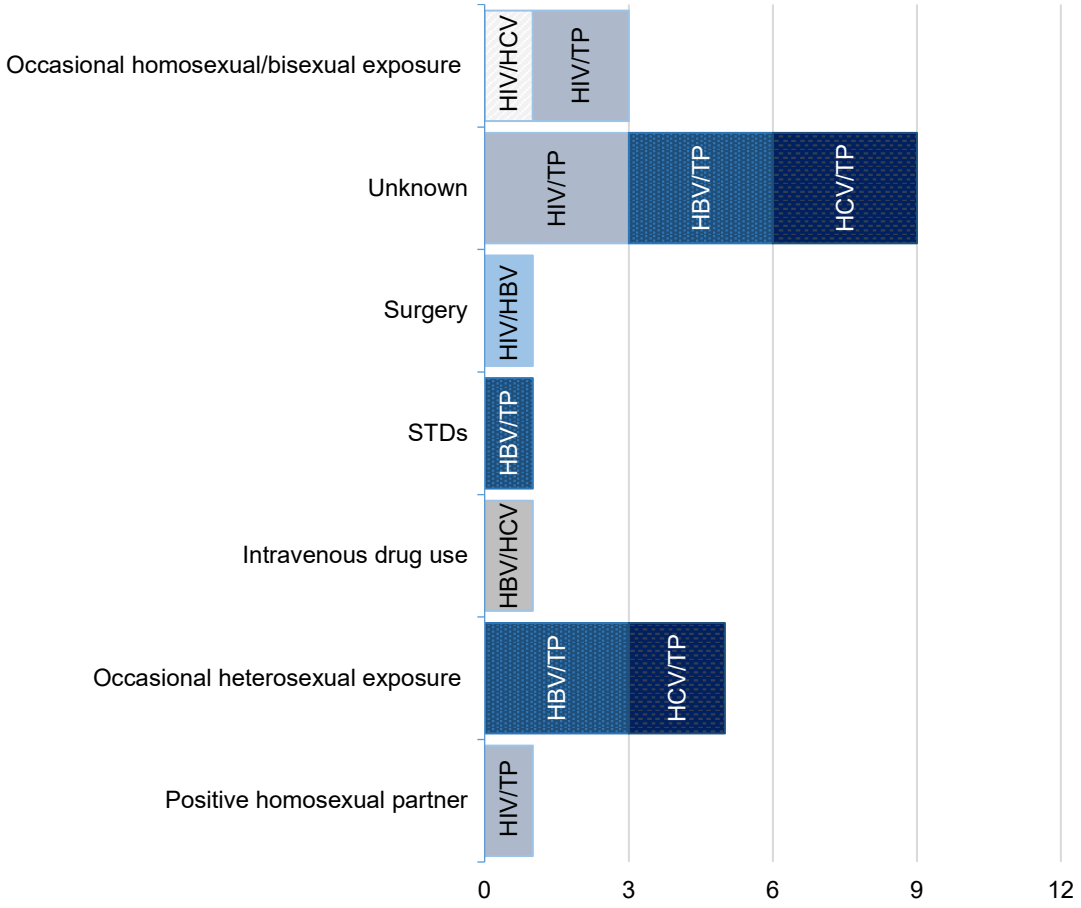

Figure 34. Number of coinfected donors by type of coinfection and risk factor (2018)

Comments and recommendations

As in previous years (6, 16), from the analysis of the notifications received in 2018 it emerged that the number of donors positive to transfusion-transmissible infectious markers varied greatly from one region to another.

About 75% of the positive donors were Italian, while the remaining 25% 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 (74%) and FT (76.5%).

In general, the highest number of positive donors were in the 26-65 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 year age bracket, while HBV and HCV infections were higher in the 46-65 year age brackets.

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

The analysis on coinfections showed that the majority of coinfected donors were TP positive. As in the previous years (6,16), many coinfected and monoinfected donors did not declare any risk factor. This phenomenon indicates a probable criticality in the collection of post-donation information. In order to optimise and standardise the collection of post-donation information, homogeneous *counselling* techniques across the country are recommended to make communication with donors more effective.

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