Italian Blood System 2019: activity data, haemovigilance and epidemiological surveillance

VOLUME 1

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CNS Report 1/2020

CENTRO NAZIONALE SANGUE

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Italian National Blood Centre
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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 2019.

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

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ACRONYMS

AP	Autonomous Province
AVIS	Associazione Volontari Italiani del Sangue (Association of Voluntary Italian BloodDonors)
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 VoluntaryBlood 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
HIV-1	Human immunodeficiency virus, type 1
HIV-2	Human immunodeficiency virus, type 2
HLA	Human leukocyte antigen
HNA	Human neutrophil 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 2019.

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 ST 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 2019 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, as the previous year[6]. In the Annex 1 - Supplemental figures, 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 "Systems, Applications and Products (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, 2019, available at http://demo.istat.it/ (last accessed May 2020).

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

a. The Veneto Region that supplied 7 figures from 21 operating BEs;
b. The Friuli Venezia Giulia Region that supplied 1 figure from 5 operating BEs;
c. The Latium Region that supplied 22 figures from 23 operating BEs;
d. The Sicily Region that supplied 25 figures from 33 operating BEs.

National data

In 2019, 279 BEs were reported on SISTRA. There was a decrease in the number of peripheral organisational sites (-0.10%) 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 9% compared to 2018 and in 2019, 1,271 (-0.78%) peripheral organisational sites were registered (Table I). To standardise the calculation of the number of employees in each single organisation, the professionals operating in BEs (Table II) are reported as Full-Time Equivalent (FTE), which corresponds to 8 hours per day per 218 days/year.

Table I - BEs and BCSs with their respective peripheral organisational sites: Italy 2019 (2018-2019).

Blood facilities and population	**2018**	**2019**	**Δ%**
BEs	278	279	0.36
BEs peripheral organisational sites	1,034	1,033	-0.10
BCS	211	191	-9.48
BCS peripheral organisational sites	1,281	1,271	-0.78
Population	60,483,973	60,359,546	-0.21

BEs: Blood Enstablishments; BCSs: Blood Collection Sites (in Italy all BCSs are run by Voluntary Blood Donor Associations and Federations). Updated data 2019.

Table II - Professionals operating in BEs as of 31st December 2019* (2018-2019).

Staff	**2018**	**2019**	**Δ%**
Physicians	1,721.8	1,697.8	-1.39
Graduates (biologist and other professionals with a PhD)	491.4	481.2	-2.08
Blood Technicians	3,005.8	3,021.3	0.52
Nurses	1,617.6	1,662.4	2.77
Health Operators	414.7	416.5	0.43
Administrative Staff	288.2	275.9	-4.27
Total	**7,539.5**	**7,555.1**	0.21

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

Table III shows data concerning donors of blood and blood components subdivided by type. Compared to 2018, 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 2019, more first-time pre-qualified donors re-donated than first-time not pre-qualified donors.

Table III - Donors of blood and blood components (2018-2019).

Donors	**2018**	**2019**	**Δ%**
Prospective*	**187,548**	**183,953**	-1.92
Those who did not donate in the period under examination	95,166	92,462	-2.84
First-time pre-qualified (A)	**123,944**	**121,536**	-1.94
Those who re-donated at least once in the period under examination (A1)	42,874	43,815	2.19
First-time not pre-qualified (B)	**247,149**	**241,065**	-2.46
Those who re-donated at least once in the period under examination year of detection (B1)	36,879	32,788	-11.09
Total First-time (A+B)	**371,093**	**362,601**	-2.29
Those who re-donated in the period under examination	79,753	76,603	-3.95
Regular (R)	**1,391,384**	**1,397,472**	0.44
Those who re-donated at least once a year in the last 5 years	618,465	626,521	1.30
Total ((A-A1)+(B-B1)+R)	**1,682,724**	**1,683,470**	0.04
Apheresis	202,509	202,476	-0.02
Those who donated only in apheresis	109,521	109,016	-0.46
Permanently deferred	45,354	50,406	11.14
Members of VBDAs	**1,543,063**	**1,516,155**	-1.74

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 IV shows the total number of collection procedures (carried out by both BEs and BCSs) subdivided by type. Table V 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 IV - Collection procedures carried out by BEs and BCSs (2018-2019).

Collection procedures	**2018**	**2019**	**Δ%**
Whole blood	**2,569,275**	**2,566,446**	-0.11
Apheresis	**421,807**	**429,818**	1.90
Monocomponent apheresis	*357,661*	*368,294*	2.97
Multicomponent apheresis	*64,146*	*61,524*	-4.09
Total	**2,991,082**	**2,996,264**	0.17
Type			
Plasmapheresis	346,778	357,610	3.12
Plateletpheresis	9,201	8,786	-4.51
Single Donor Plasma-Platelet apheresis	0	0	
Stem Cells apheresis	1,353	1,412	4.36
Granulocytapheresis	65	117	80.00
Lymphocytapheresis	264	369	39.77
Red Blood Cell/Platelet apheresis	3,466	3,182	-8.19
Double Red Blood Cell unit apheresis	238	673	182.77
Plasma/Platelet apheresis	46,860	45,625	-2.64
Red Blood Cell/Plasma apheresis	11,555	10,076	-12.80
Double Platelet unit apheresis	1,021	963	-5.68
Red Blood Cell/Platelet/Plasma apheresis	1,006	1,005	-0.10

BEs: Blood Enstablishments; BCSs: Blood Collection Sites.

Table V - Percentage of collection procedures carried out by BCSs (2018-2019).

Region/AP	**% 2018**	**% 2019**	**Δ%**
Aosta Valley	0.00	0.00	
Piedmont	54.44	53.61	-1.53
Liguria	38.13	43.93	15.21
Lombardy	36.23	36.20	-0.09
AP of Trento	0.00	0.00	
AP of Bolzano	0.00	0.00	
Friuli Venezia Giulia	0.00	0.00	
Veneto	11.05	11.08	0.26
Emilia Romagna	55.09	55.35	0.48
Tuscany	4.71	4.25	-9.82
Umbria	0.00	0.00	
Marche	4.51	4.51	-0.01
Latium	31.45	33.22	5.64
Sardinia	27.66	28.53	3.15
Abruzzo	10.43	10.47	0.38
Campania	41.65	52.41	25.82
Molise	0.00	0.00	
Apulia	0.00	0.00	
Basilicata	72.99	72.71	-0.38
Calabria	75.76	76.02	0.35
Sicily	82.63	82.31	-0.39
Armed Forces	0.00	0.00	
Italy	**33.07**	**33.89**	**2.47**

AP: Autonomous Province; BCSs: Blood Collection Sites.

Table VI 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 VI - Number of collections carried out by BCSs (2018-2019).

Association/Federation	**2018**	**2019**	**Δ%**
AVIS	813,662	831,728	2.22
FIDAS	96,149	94,659	-1.55
FRATRES	13,773	18,033	30.93
CRI	9,029	10,850	20.17
Other	56,764	60,106	5.89
Total	**989,377**	**1,015,376**	2.63

BCSs: Blood Collection Sites; 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 VII shows data concerning the production of blood components. Compared to 2018, there was a slight increase in the total number of units of blood components produced.

Table VII - Blood component production (2018-2019).

Blood component	**2018**	**2019**	**Δ%**
Red Blood Cells	**2,550,046**	**2,546,914**	-0.12
Red Blood Cells from whole blood	*2,533,856*	*2,527,426*	-0.25
Red Blood Cells by apheresis	*16,190*	*19,488*	20.37
Platelets from single donors	20,043	13,904	-30.63
Platelet Pools	203,992	213,522	4.67
Platelets by apheresis	66,999	66,059	-1.40
Plasma	**2,942,344**	**2,957,515**	0.52
Recovered Plasma	*2,534,728*	*2,525,372*	-0.37
Source Plasma	*348,504*	*368,653*	5.78
Source Plasma from multiple apheresis	*59,112*	*63,490*	7.41
Total	**5,783,424**	**5,797,918**	0.25

In 2019, 8,046 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 VIII). Moreover, compared to 2018, there was:

a) an overall decrease in the total number of units of blood components discarded (Table IX);
b) an increase in the quantity of plasma for fractionation (Table X);
c) an increase in the production of allogeneic and autologous fibrin glue and a decrease of allogeneic and autologous platelets gel for non-transfusional use (Table XI and Table XII);
d) a slight decrease in the number of patients who predeposited blood components for autologous transfusion (Table XIII);
e) an approximate 1% increase of the number of transfused patients, including those transfused in BEs (day hospital) (Table XIV).

Table VIII - Transfused units of blood components (2018-2019).

Blood component	**2018**	**2019**	**Δ%**
Red Blood Cells	**2,443,359**	**2,449,139**	0.24
Red Blood Cells from whole blood	2,428,264	2,435,651	0.30
Red Blood Cells by apheresis	15,095	13,488	-10.65
Platelets from single donors	8,447	5,360	-36.55
Platelets Pools	169,178	175,854	3.95
Platelets by apheresis	55,596	52,784	-5.06
Plasma	**268,349**	**253,367**	-5.58
Recovered Plasma	*100,927*	*93,091*	-7.76
Source Plasma	*32,519*	*30,555*	-6.04
Source Plasma from multiple apheresis	*6,949*	*6,731*	-3.14
Pharmaceutical Inactivated Plasma	127,954	123,367	-3.58
Total	**2,944,929**	**2,936,881**	-0.27

Table IX - Blood components discarded for reasons linked to health, technical issues, quality control and expiry dates (2018-2019).

Blood component	**2018**	**2019**	**Δ%**
Red Blood Cells	77,888	75,061	-3.63
Platelets from single donors	11,459	8,505	-25.78
Platelet Pools	31,365	33,640	7.25
Platelets by apheresis	6,767	6,449	-4.70
Plasma	**128,494**	**116,424**	-9.39
Recovered Plasma	*108,671*	*96,167*	-11.51
Source Plasma	*16,059*	*16,619*	3.49
Source Plasma from multiple apheresis	*3,764*	*3,638*	-3.35
Total	**255,973**	**240,079**	-6.21

Table X - Plasma for fractionation (2018-2019).

Blood component	**2018**	**2019**	**Δ%**
Plasma for fractionation (kg)	843,257	858,170	1.77

Data source: Pharmaceutical industry - year 2019 data updated to April 2020.

Table XI - Production and use of allogeneic blood components for non-transfusion use (2018-2019).

Blood component	**2018**	**2019**	**Δ%**
Platelet Gel			
Produced	9,574	9,288	-2.99
*of which those that could be further evaluated**	*8,311*	*8,364*	0.64
Used	7,283	7,644	4.96
Not Used	1,028	990	-3.70
Fibrin Glue			
Produced	114	188	64.91
*of which those that could be further evaluated**	*196*	*185*	-5.61
Used	185	174	-5.95
Not Used	11	25	127.27

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

Table XII - Production and use of autologous blood components for non-transfusion use (2018-2019).

Blood component	**2018**	**2019**	**Δ%**
Platelet Gel			
Produced	26,836	25,727	-4.13
*of which those that could be further evaluated **	*21,211*	*18,705*	-11.81
Used	19,267	17,086	-11.32
Not Used	1,944	1,619	-16.72
Fibrin Glue			
Produced	228	244	7.02
*of which those that could be further evaluated **	*179*	*203*	13.41
Used	175	202	15.43
Not Used	4	1	-75.00

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

Table XIII - Autologous donation and transfusion (2018-2019).

Patients and autologous donation activities	**2018**	**2019**	**Δ%**
Patients who predeposited blood components for autologous transfusion	15,236	14,613	-4.09
Patients who underwent an autologous transfusion	12,656	12,684	0.22

Table XIV - Transfused patients (2018-2019).

Patients* transfused with:	**2018**	**2019**	**Δ%**
Whole Blood^	59	53	-10.17
Red Blood Cells	596,549	599,782	0.54
Plasma	53,160	53,783	1.17
Platelets	53,209	53,679	0.88
Other	3,324	3,934	18.35
Total**	**630,770**	**638,131**	1.17

*: 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.

A total of 49 indicators, are presented at national level (Table XV) and regional level (Annex 1 - Supplemental figures).

Table XV - Quantitative indicators for transfusion activities in Italy (2019).

Indicators		Index
A. General		
A1	N BE/1,000,000 RP	4.62
A2	N of professionals operating in BE/100,000 RP	12.52
A3	N of professionals operating in BE/N of BE	27.08
A4	N of physicians operating in BE/Total of professionals operating in BE (%)	22.47
B. Donors		
B1	N of donors/1,000 RP	27.89
B2	M/F ratio: female donors (%)	31.98
B3	N of donors /1,000 RP in the 18-65 age bracket	44.77
B4	N of donors in the 18-65 age bracket/1,000 RP	3.54
B5	N of donors in the 18-25 age bracket /1,000 RP in the 18-65 age bracket	5.68
B6	N of donors /1,000 RP	23.15
B7	N of prospective donors /1,000 RP	3.05
B8	N of first-time donors/1,000 RP	6.01
B9	N of first-time not pre-qualified donors /1,000 RP	3.99
B10	N of first-time pre-qualified donors/1,000 RP	2.01
B11	N of prospective donors who did not donate/Total N of prospective donors (%)	50.26
B12	N of "regular" donors/1,000 RP	10.38
C. Donations		
C1	N of donations (WB + apheresis)/1,000 RP	49.64
C2	N of donations (WB + apheresis)/Total N of donors (excluding prospective donors)	1.78
C3	N of donations WB/1,000 RP	42.52
C4	N of donations WB/N of WB donors	1.63
C5	N of donations in apheresis/1,000 RP	7.12
C6	N of donations in apheresis/N of apheresis donors	2.12
D. Production of blood components		
D1	N of RBC units produced/1,000 RP	42.2
D2	N of plasma units produced from WB and by apheresis/1,000 RP	49
D3	N of plasma units produced from WB/1,000 RP	41.69
D4	N of plasma units produced by apheresis (monocomponent or multicomponent)/1,000 RP	7.16
D5	Plasma for fractionation (kg)/1,000 RP	14.04
D6	Plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%)	26.95
D7	N of platelet units produced by apheresis (monocomponent + multicomponent)/1,000 RP	1.09
D8	N of platelet units produced from buffy-coat pools/1,000 RP	3.54
D9	N of platelet units produced from PRP and single buffy-coats/1,000 RP	0.23
D10	N of pre-storage leukodepleted RBC units/N of RBC units produced (%)	100
D11	N of pre-storage leukodepleted platelet units produced by apheresis/ N of platelet units produced by apheresis (%)	69.42
D12	N of "adult platelet doses"/1,000 RP	4.68
E. Discarded blood components		
E1	N of discarded RBC units/N of "usable" RBC units (produced + acquired - released) (%)	2.95
E2	N of expired RBC units discarded/N of discarded RBC units (%)	32.02
E3	N of RBC units discarded for technical reasons/N of discarded RBC units (%)	29.23
E4	N of RBC units discarded for health reasons/N of discarded RBC units (%)	33.27
E5	N of RBC units discarded for reasons linked to QC/ N of discarded RBC units (%)	5.48
E6	N of discarded plasma units /N of produced plasma units (%)	3.94
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 (%)	61.15
E8	N of platelet units by apheresis discarded /N of platelet units by apheresis produced (%)	9.76
E9	N of platelet units from buffy-coat pools discarded / N of platelet units from buffy-coat pools produced (%)	15.75

F. Transfused blood components		
F1	N of transfused RBC units / 1,000 RP	40.58
F2	N of transfused plasma units (from WB + by apheresis + PIP) / 1,000 RP	4.20
F3	N of transfused WB plasma units / Total N of transfused plasma units (from WB + by apheresis + PIP) (%)	36.69
F4	N of transfused apheresis plasma units / N of transfused plasma units (from WB + by apheresis + PIP) (%)	14.69
F5	N of transfused PIP units / Total N of transfused plasma units (from WB + by apheresis + PIP) (%)	48.62
F6	N of "adult platelet doses"/1,000 RP	3.81

N: number; BE: Blood Enstablishment; RBC: red blood cells; 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" ≥ 2x1011 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 2019, 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 2018, a slight increase in the number of employees operating in BEs was noted.

There was a very slight rise in the total number of donors of blood and blood components (+0.04%), especially regular donors (+0.44%), and the national self-sufficiency was ensured. In 2019, the total number of transfused units of blood components was substantially stable (-0.27%), but a marked drop was noted particularly for plasma for clinical use compared to the previous year (-5.58%). Data showed an increase in the overall production of red blood cells (+20.37%) and source plasma from apheresis (5.78% and 7.41%) and a decrease of platelets from single donors (-30.63%) while there was an increase in the quantity of plasma for fractionation compared to the previous year (+1.77%). This increase was mainly 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 2019 were first-time pre-qualified donors (+36%).

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 2019, an increase in the production of homologous fibrin glue (approx. +65%) and a decrease in the production of homologous platelet gel (-3%) was noted.

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 (Ministry of Health Decree of 2nd November, 2015[7]). Haemovigilance systems are regulated by specific national laws and by European Directives[8,9], transposed into national laws[10,11], 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.

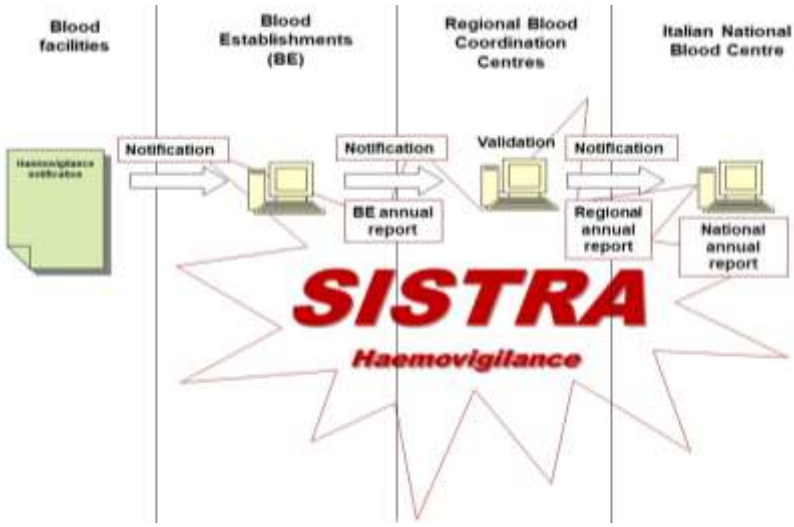

Figure 1 - Haemovigilance information flow in SISTRA.

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

For 2019-haemovigilance data, validated data from each RBCC was sent until March 30th, 2020; an extension for data consolidation and validation was allowed. All essential data relative to 2019 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 Decree of 2nd November, 2015[7], 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.

For the purpose of this report, 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[10], are classified as follows:

- ***Severity:***

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

– ***Imputability:***

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

Results

The information concerns 2,936,881 transfused blood components and 2,996,264 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[6,12], the number of notifications shows a significant regional variability (Figures 3-5).

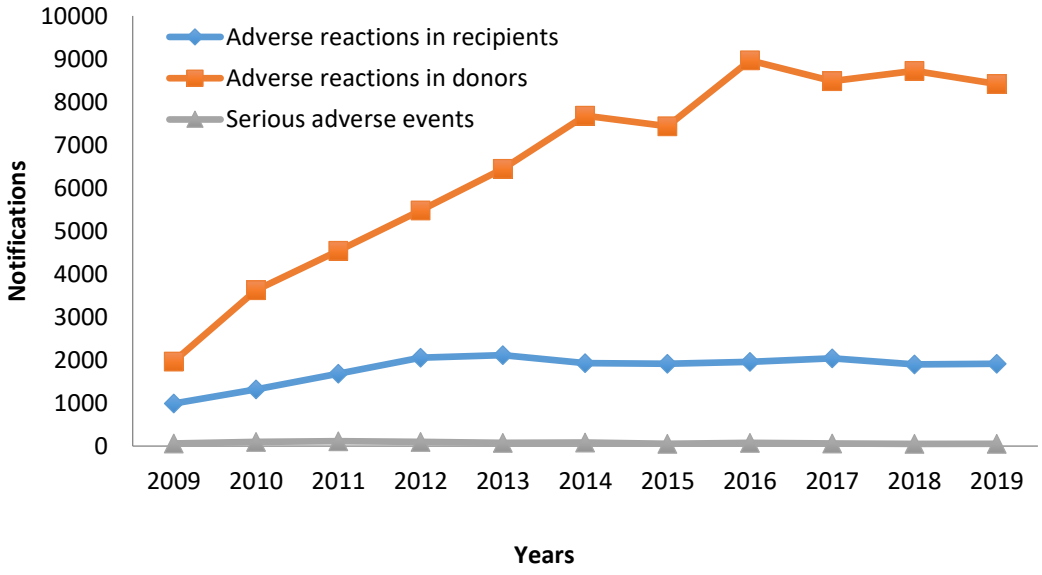

Figure 2 - Number of haemovigilance notifications per year (2009-2019).

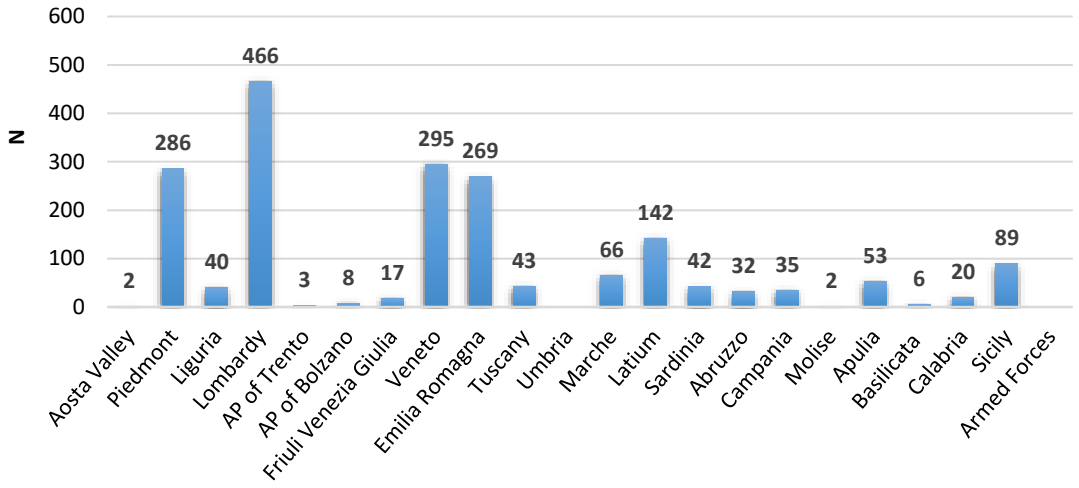

Figure 3 - Serious adverse reactions in recipients notified by region (2019).
N: number.

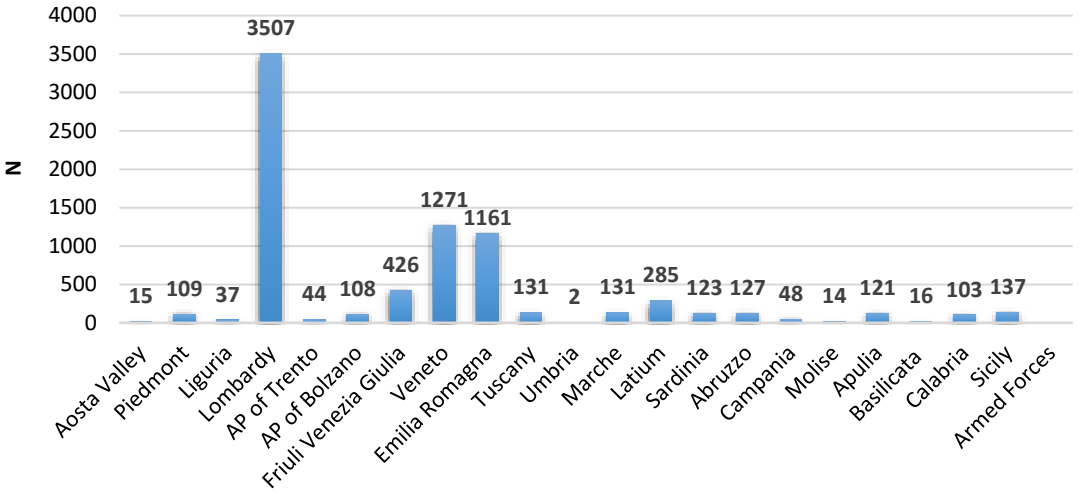

Figure 4 - Serious adverse reactions in donors notified by region (2019).
N: number.

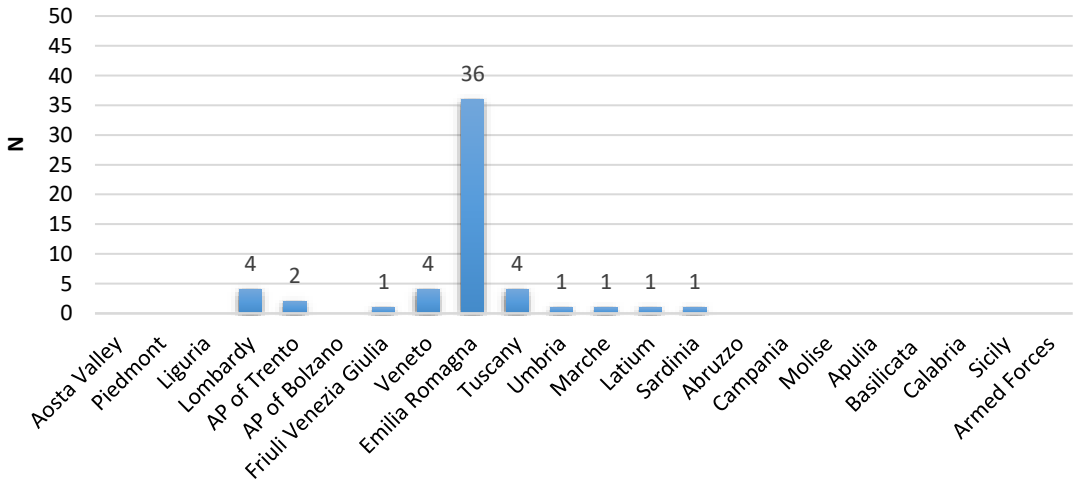

Figure 5 - Serious adverse events notified by region (2019).
N: number.

Adverse reactions in recipients

From January 1st to December 31st 2019, 1,916 adverse reactions were notified in recipients of blood components (one every 1,533 transfused units) (Table XVI).

Table XVI - Adverse reactions in recipients regardless of severity and imputability levels (2019).

Adverse reaction	N	%
Alloimmunisation	12	0.6
Transfusion associated dyspnoea (TAD)	70	3.7
Transfusion-related acute lung injury (TRALI)	3	0.2
Transfusion-associated circulatory overload (TACO)	52	2.7
Non-immunological haemolysis - physical cause	2	0.1
Hyperkalemia	1	0.1
Hypotensive transfusion reaction	35	1.8
Allergic reactions involving the respiratory and/or cardiovascular system	81	4.2
Allergic manifestations with only mucosal and cutaneous symptoms	542	28.3
Post-transfusion purpura	4	0.2
Acute haemolytic reaction due to ABO incompatible transfusion	5	0.3
Delayed haemolytic transfusion reactions due to others blood group	2	0.1
Delayed haemolytic transfusion reactions due to Rh	1	0.1
Haemolytic transfusion reactions due to autoantibodies	4	0.2
Febrile non-haemolytic reaction (FNHTR)	742	38.7
Anaphylactic shock	3	0.2
Other bacterial infections[#]	1	0.1
Suspected Transfusion Transmitted Malaria[¤]	1	0.1
Incorrect Blood Component Transfused without reaction	3	0.2
Other	352	18.4
Total	**1,916**	**100**

N: number; TAD: Transfusion associated dyspnoea; TRALI: Transfusion related acute lung injury; TACO: Transfusion associated circulatory overload. [#] Staphylococcus aureus infection (Severity: 2 - symptoms requiring therapeutic intervention; Imputability: 3 - Certain; Resolution within a few days). [¤] Suspected Transfusion Transmitted Malaria (Severity: 2 - symptoms requiring therapeutic intervention; Imputability: 0 - Excluded/unlikely; Complete resolution within 6 months), Adverse Event notified late. The analysis of the case is still ongoing.

Table XVI shows adverse reactions in recipients by type, by absolute number and percentage. In 2019, the most frequently notified reactions were Febrile Non-Haemolytic Reactions (FNHTR) (38.7%) and allergic manifestations with only mucosal and cutaneous symptoms (28.3%), representing 67% of all notified adverse reactions in recipients.

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 326,320 transfused units.

Adverse reactions involving the respiratory and/or cardiovascular system

In 2019, 10.8% of all the notifications (206/1,916) were related to the respiratory system; 81 were allergic reactions involving the respiratory and/or cardiovascular system, 70 TAD, 52 TACO and 3 TRALI. The frequency of the aforementioned reactions per transfused blood components was 1 allergic reaction every 36,205, 1 TAD every 41,894, 1 TACO every 56,396, and 1 TRALI every 977,531. However, on the whole the notifications were unsatisfactory because of the 70 cases of TAD, 1.4% were certainly imputable, 22.9% probable, 57.1% possible, 11.4% excluded/unlikely, and 7.1% not evaluable; of the 52 cases of TACO, 5.8% were certainly imputable, 34.6% probable, 40.4% possible, 13.5% excluded/unlikely, and 5.8% not

evaluable; of the 3 cases of TRALI one case was certainly imputable, one case was probable, and one case was excluded/unlikely.

The case of TRALI certainly imputable occurred in a 76-year-old female patient receiving one unit of pre-storage leukodepleted RBCs for anaemia after surgery. Onset of symptoms (dyspnoea, hypertension, and tachycardia) within 6 hours of completion of transfusion. Complete resolution within a few days.

ABO incompatible transfusions

There were 10 ABO-incompatible red cell transfusions reported in 2019, notified as follows:

- 2 cases as “Acute haemolytic reaction”;
- 3 cases as “Acute haemolytic reaction” , also notified as “Serious Adverse Events”;
- 3 cases as “ABO-incompatible Blood Component Transfused without reaction”, also notified as “Serious Adverse Events”;
- 2 cases as “Serious Adverse Events”.

One case of fatal ABO-incompatible red cell transfusion was reported.

Incorrect blood components transfused and near misses

In 2019, 10 cases of ABO-incompatible transfusions were notified, of which 5 (50%) caused a reaction (Table XVII). Moreover, 5 cases of ABO-compatible blood transfused to the wrong patient were notified but none caused reactions.

Table XVII - Incorrect blood component transfused and near misses (2019).

Site of primary error	Transfused		Near miss (not transfused)
	with reaction	without reaction	
Wrong donor group label	1	-	-
Wrong recipient identification on unit	-	-	3
Wrong group of blood component	-	-	1
Wrong group of patient	1	-	5
Wrong name on tube	-	-	66
Wrong patient collected	-	-	78
ABO incompatible - Wrong recipient identification	3	5	16
Wrong product type	-	-	6

As reported in the EDQM “Guide to the preparation, use and quality assurance of blood components”[13], 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 2019, 175 near misses (the component was not transfused) were notified.

Most cases were “Wrong patient collected” 78 (44.5%) while 66 (37.7%) were “Wrong name on tube”.

Analysis of near miss data shows that these could represent the base of a pyramid (especially taking into account their under-reporting). Data from 2019 show that although there were 10 ABO-incompatible red cell transfusions there were 175 near misses which could have resulted in incompatible transfusions. These errors, which could have had lethal outcomes, demonstrate the importance of the groupcheck policy, correct patient identification at the time of sampling, and the correct recipient identification.

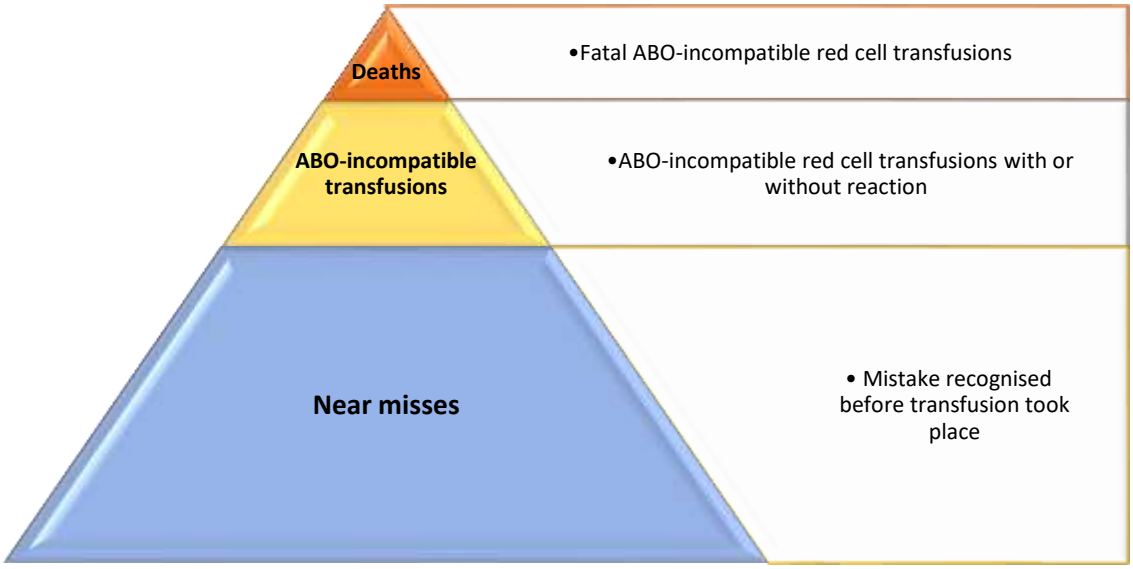

Figure 6 - ABO-incompatible red cell transfusions and near misses (2019).

Severity and imputability levels

The severity of adverse reactions to transfusion required therapeutic intervention in 71.1% of the cases; no therapeutic intervention was required in 26.8% (Table XVIII and Figure 7).

In 89.1% of adverse reactions the clinical resolution occurred in a few hours and only in 1 case a persistence of symptoms within 6 months was observed (Table XIX).

Table XVIII - Adverse reactions in recipients classified by severity level (2019).

Level	Severity	N	%
0	No symptoms	18	0.9
1	Mild symptoms (no therapeutic intervention)	513	26.8
2	Symptoms requiring therapeutic intervention	1,363	71.1
3	Symptoms requiring resuscitation procedures	21	1.1
4	Death	1	0.1
	Total	**1,916**	**100**

N: number.

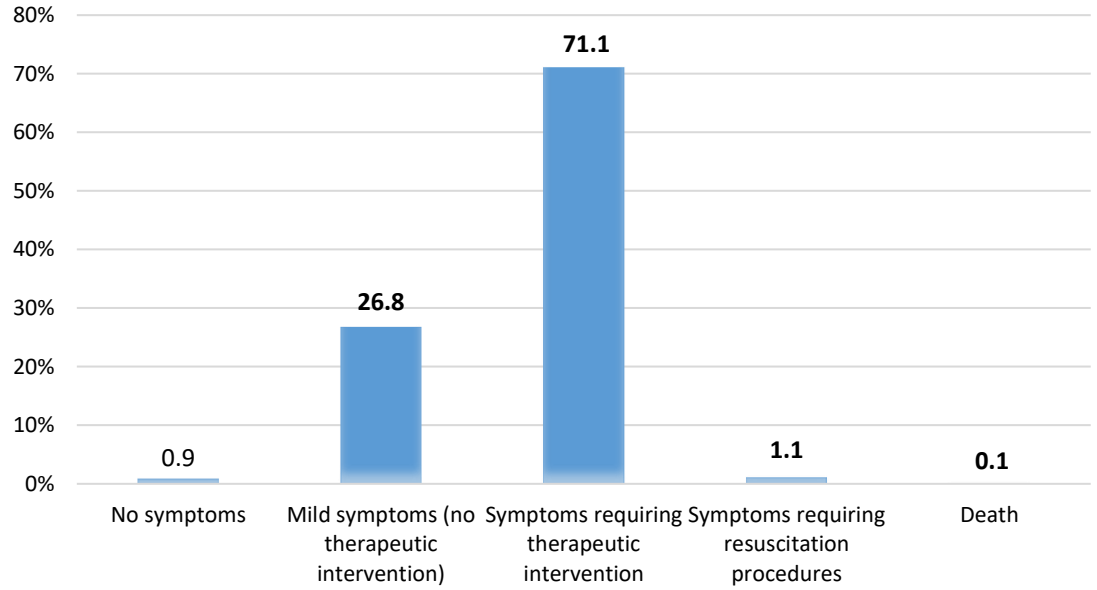

Figure 7 - Severity level of adverse reactions in recipients expressed as a percentage (2019).

Table XIX - Adverse reactions in recipients by outcome (2019).

Outcome	**N**	**%**
Resolution within a few hours	1,708	89.1
Resolution within a few days	40	2.1
Complete resolution within 6 months	1	0.1
Not assessable	167	8.7
Total	**1,916**	**100**

N: number.

Concerning the imputability level, more than 44.8% of adverse reactions in recipients were possibly imputable, 11% were excluded/improbably related to the transfusion, and in 128 cases (6.7%) it was not assessable. Data show that 55.8% of adverse reactions in recipients were associated with low levels of imputabilty (Table XX and Figure 8).

Table XX - Adverse reactions in recipients by imputability level (2019).

Level	**Imputability**	**N**	**%**
0	Excluded/Improbable	210	11.0
1	Possible	859	44.8
2	Probable	603	31.5
3	Certain	116	6.1
N.A.	Not assessable	128	6.7
	Total	**1,916**	**100**

N: number.

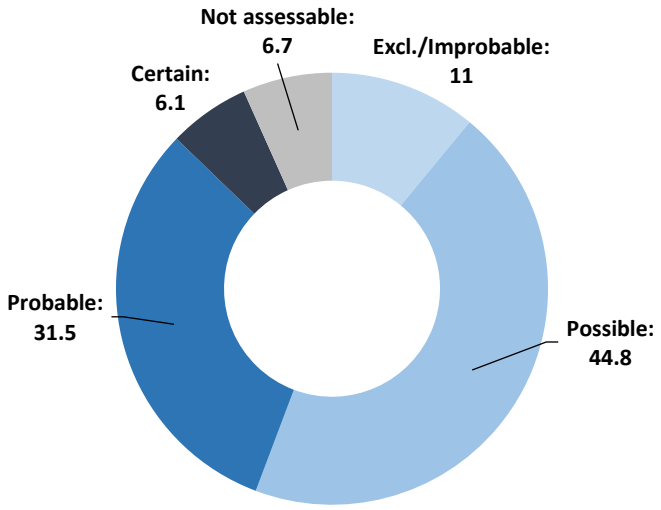

Figure 8 - Adverse reactions in recipients linked to the imputability level expressed as a percentage (2019).

Transfusion sites

The majority of adverse reactions occurred in hospital ward (77%) or in day-hospital (7.7%) (Table XXI and Figure 9).

Table XXI - Transfusion sites notifying adverse reactions (2019).

Transfusion site	**N**	**%**
Hospital ward	1,476	77
Day hospital	148	7.7
Emergency/ICU	109	5.7
Blood establishment	68	3.5
Clinic	66	3.4
Operating theatre	30	1.6
Home	19	1
Total	**1,916**	**100**

ICU: Intensive Care Unit.

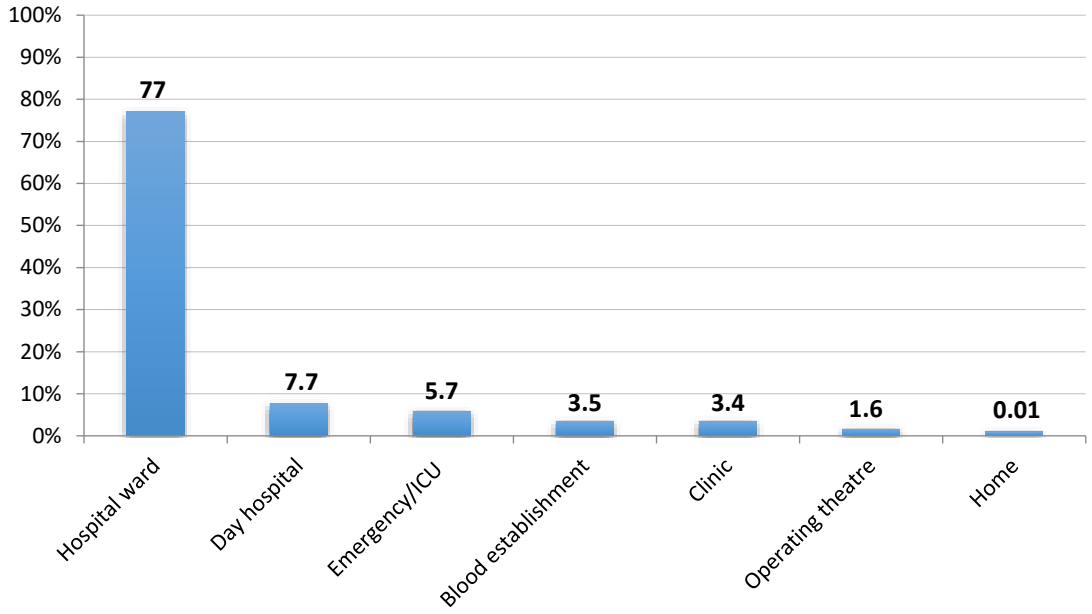

Figure 9 - Adverse reactions by transfusion site as a percentage (2019).
ICU: Intensive Care Unit.

Adverse reactions classified by transfused blood component

Among the notified 1,916 adverse reactions in recipients, most were related to RBC transfusion (64.9%). In 9 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 XXII). In addition, 14 adverse reactions resulting from infused pharmaceutical virus-inactivated plasma were notified (*see* Table XXII).

Table XXII - Adverse reactions in recipients classified by transfused blood component (2019).

Blood component	**N**	**%**
Red Blood Cells	1,243	64.9
Platelets	438	22.9
Plasma*	197	10.3
Pharmaceutical Inactivated Plasma	14	0.7
More than one blood component transfused**	9	0.5
Cryoprecipitate	1	0.1
Haemopoietic Stem Cells	12	0.6
Lymphocytes from apheresis	2	0.1
Total	**1,916**	**100**

N: number.
*: 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 XXIII).

Table XXIII - Adverse reactions/1,000 transfused units grouped by blood component regardless of the imputability and severity levels (2019).

Blood component	Transfused units	Adverse reactions	Adverse reactions/ 1,000 transfused units
Red Blood Cells	2,449,139	1,243	0.51
Plasma*	253,744	211	0.83
Platelets	233,998	438	1.87

*: Plasma includes Pharmaceutical Inactivated Plasma (Transfused units 123,367 with 14 adverse reactions).

Adverse reactions to transfusion classified by transfused blood component with an imputability level 2-3 (Probable, Certain) and a severity level 3-4 (Severe symptoms requiring resuscitation procedures, Death)

In 2019, among the 1,916 adverse events to transfusion 9 were serious with a high imputability level (imputability level 2-3 and severity level 3-4). Table XXIV shows the type of adverse reaction by transfused blood component.

Table XXIV - Adverse reactions to transfusion classified by transfused blood component with an imputability level 2-3 and a severity level 3-4 (2019).

Adverse reaction	RBCs	Platelets	Plasma	HSCs	Total
Anaphylactic shock		1		1	**2**
ABO acute haemolytic reaction	2				**2**
Transfusion-associated circulatory overload (TACO)	2				**2**
Hypotensive transfusion reaction	1				**1**
Transfusion-related acute lung injury (TRALI)		1			**1**
Febrile non-haemolytic reaction (FNHTR)		1			**1**
Total	**5**	**3**	**-**	**1**	**9**

RBCs: Red Blood Cells; HSCs: Haemopoietic Stem Cells.

Deaths

In 2019, 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 85-year-old female patient receiving one unit of pre-storage leukodepleted RBCs for anaemia after orthopaedic surgery.

Adverse reactions in donors

In 2019, 8.416 adverse reactions to allogeneic donation were notified (1 every 356 donations) (Table XXV); 482 of these reactions were severe (1 every 6,216 donations). Autologous donations were excluded from the analysis. Another reason for exclusion was miscoded reaction category (1 citrate reaction recorded after whole blood donation).

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

Table XXV - Adverse reactions in donors regardless of severity level (2019).

Adverse reaction	**N**	**%**
Immediate vasovagal reaction	6,340	75.33
Immediate vasovagal reaction with complications	17	0.20
Delayed vasovagal reaction	869	10.33
Delayed vasovagal reaction with complications	3	0.04
Haematoma	758	9.01
Arteriovenous fistula	1	0.01
Arterial puncture	36	0.43
Cold/shivers	25	0.30
Thrombophlebitis	4	0.05
Cerebrovascular accident (TIA, stroke)	1	0.01
Nerve injury	10	0.12
Citrate reactions	65	0.77
Haemolysis	4	0.05
Nerve injury due to a haematoma	3	0.04
Tightness in the chest	3	0.04
Systemic allergic reaction	2	0.02
Local allergic reaction	4	0.05
Myocardial infarction	1	0.01
Deep venous thrombosis	2	0.02
Other incidents	22	0.26
Other	246	2.92
Total	**8,416**	**100**

N: number; TIA: transient ischemic attack.

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

In 2019, of all notified reactions, 6,281(74.6%) were mild, 1,653 (19.7%) moderate, and only 482 (5.3%) severe (Table XXVI). The most frequent type of notified reaction was immediate vasovagal reaction (75.3%) (Table XXV), of which only 3.27% (275/6,340) severe.

Table XXVI - Adverse reactions to donations classified per severity level (2019).

Adverse reaction	Mild	%	Moderate	%	Severe	%
Immediate vasovagal reaction	4,782	56.8	1,283	15.24	275	3.27
Immediate vasovagal reaction with complications	1	0.01	12	0.14	4	0.05
Delayed vasovagal reaction	561	6.67	225	2.67	83	0.99
Delayed vasovagal reaction with complications	-	-	1	0.01	2	0.02
Haematoma	608	7.2	63	0.75	87	1.03
Arteriovenous fistula	-	-	-	-	1	0.01
Arterial puncture	-	-	35	0.42	1	0.01
Cold/shivers	24	0.29	-	-	1	0.01
Thrombophlebitis	-	-	-	-	4	0.05
Cerebrovascular accident (TIA, stroke)	-	-	-	-	1	0.01
Nerve injury	6	0.07	4	0.05	0	0.00
Citrate reactions	46	0.55	9	0.11	10	0.12
Haemolysis	-	0.00	-	-	4	0.05
Nerve injury due to a haematoma	2	0.02	1	0.01	-	-
Tightness in the chest	3	0.04	-	-	-	-
Systemic allergic reaction	0	0.00	-	-	2	0.02
Local allergic reaction	4	0.05	-	-	-	-
Myocardial infarction	-	-	-	-	1	0.01
Deep venous thrombosis	-	-	-	-	2	0.02
Other incidents	17	0.20	4	0.05	1	0.01
Other	227	2.70	16	0.19	**3**	0.04
Total	**6,281**	**74.6**	**1,653**	**19.7**	**482**	**5.7**

TIA: transient ischemic attack.

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 (6,308 against 2,108). Nevertheless, if we normalise the figures to 1,000 donation procedures, the highest incidence is linked to apheresis donation (4.9 against 2.46/1,000 donations) (Table XXVII). These figures are in line with those of previous years.

Table XXVII - Donors with adverse reactions to donations classified per donation procedure (2019).

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***
2,566,446	429,818	2,996,264	6,308	2,108	8,416	2.46	4.9	2.81

Considering the 6,308 adverse reactions related to whole blood donations (Table XXVIII), the most frequent types of notified reactions were immediate vasovagal reaction (79.84%) and delayed vasovagal reaction (11.45%).

Table XXVIII - Adverse reactions related to whole blood donations (2019).

Adverse reaction	**N**	**%**
Immediate vasovagal reaction	5,036	79.84
Immediate vasovagal reaction with complications	13	0.21
Delayed vasovagal reaction	722	11.45
Delayed vasovagal reaction with complications	1	0.02
Haematoma	278	4.41
Arteriovenous fistula	1	0.02
Arterial puncture	32	0.51
Cold/shivers	2	0.03
Thrombophlebitis	4	0.06
Cerebrovascular accident (TIA, stroke)	1	0.02
Nerve injury	7	0.11
Nerve injury due to a haematoma	3	0.05
Tightness in the chest	1	0.02
Local allergic reaction	2	0.03
Myocardial infarction	1	0.02
Deep venous thrombosis	1	0.02
Other incidents	16	0.25
Other	187	2.96
Total	**6,308**	**100**

N: number; TIA: transient ischemic attack.

Considering the 2,108 adverse reactions related to apheresis donations (Table XXIX), the most frequent types of notified reactions were immediate vasovagal reaction (61.86%) and haematoma (22.77%).

Table XXIX - Adverse reactions related to apheresis donations (2019).

Adverse reaction	**N**	**%**
Immediate vasovagal reaction	1,304	61.86
Immediate vasovagal reaction with complications	4	0.19
Delayed vasovagal reaction	147	6.97
Delayed vasovagal reaction with complications	2	0.09
Haematoma	480	22.77
Arterial puncture	4	0.19
Cold/shivers	23	1.09
Nerve injury	3	0.14
Citrate reactions	65	3.08
Haemolysis	4	0.19
Tightness in the chest	2	0.09
Systemic allergic reaction	2	0.09
Local allergic reaction	2	0.09
Deep venous thrombosis	1	0.05
Other incidents	6	0.28
Other	59	2.80
Total	**2,108**	**100**

N: number.

In 2019, the majority of adverse reactions to donation (53.2%) occurred in BEs and 29.1 % in BCSs (Table XXX).

Table XXX - Donor adverse reaction classified by donation site (2019).

Donation site	N	%
BE peripheral organisational site	1,366	16.2
In Itinere	119	1.4
BEs	4,480	53.2
BCSs	2,451	29.1
Total	**8,416**	**100**

N: number; BEs: Blood establishments; BCSs: Blood collection Sites.

Serious adverse events

In 2019, 55 serious adverse events were notified; the majority (67.3%) was due to human error and 20% was due to organisational error (Table XXXI and Figure 10). One of them (1.8%) was notified as "Other" (Table XXXI).

Table XXXI - Cause of adverse events (2019).

Cause	N	%
Transfusional product defect	2	3.6
Material defect	1	1.8
Equipment malfunction	3	5.5
Human error	37	67.3
Organisational error	11	20
Other	1	1.8
Total	**55**	**100**

N: number.

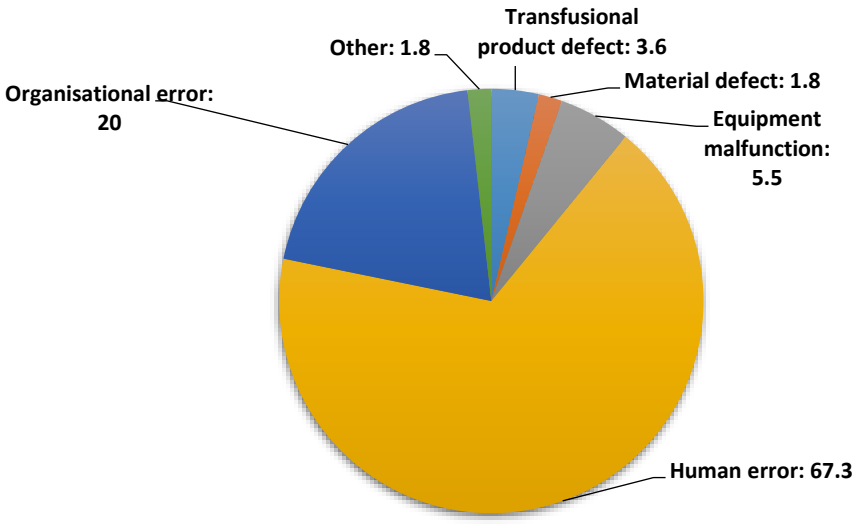

Figure 10 - Cause of adverse events (2019).

For the majority of serious adverse events (65.5%) the phase was not reported and they were notified as "Other" (Table XXXII and Figure 11).

Table XXXII - Phases in which serious adverse events occurred (2019).

Phase	**N**	**%**
Collection	7	12.7
Materials	1	1.8
Distribution	9	16.4
Storage	2	3.6
Other	36	65.5
Total	**55**	**100**

N: number.

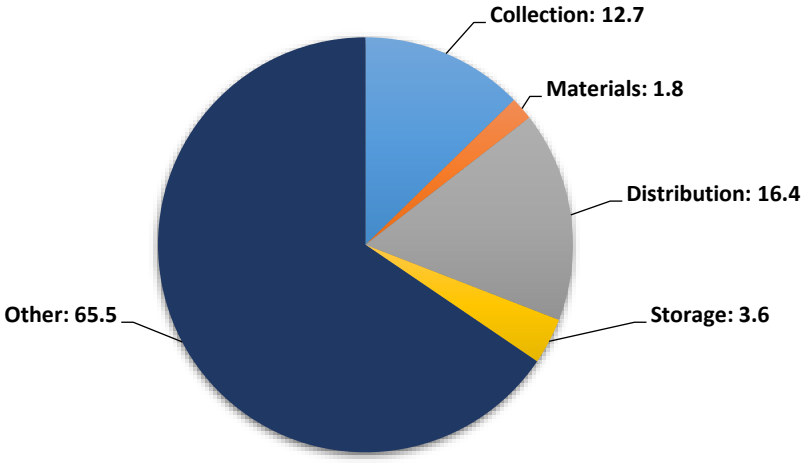

Figure 11 - Phases in which serious adverse events occurred (2019).

In 2019, the majority of adverse events (72.7%) occurred in clinical wards and 21.8% in BEs (Table XXXIII and Figure 12).

Table XXXIII - Adverse events classified by site of the occurrence (2019).

Donation site	**N**	**%**
BE peripheral organisational site	2	3.6
BCS	1	1.8
BE	12	21.8
Clinical ward	40	72.7
Total	**55**	**100**

N: number; BE: Blood establishment; BCS: Blood collection Site.

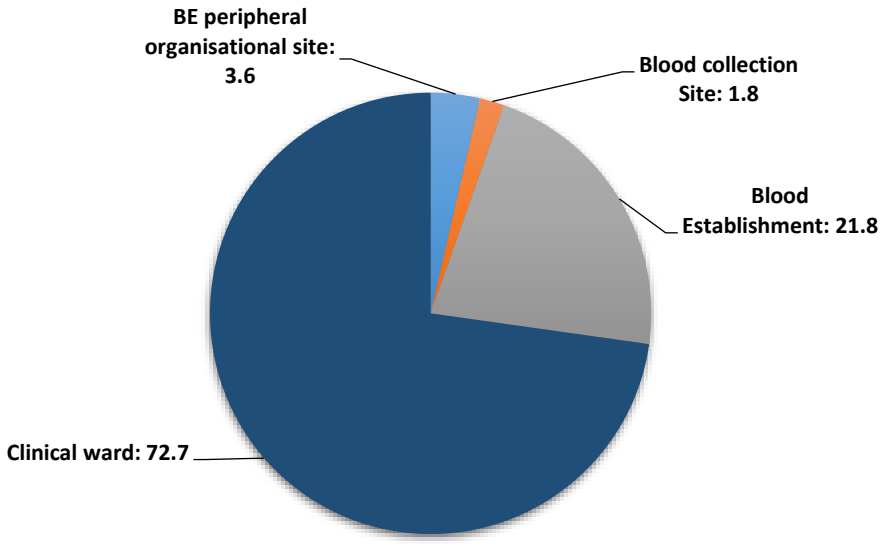

Figure 12 - Site in which serious adverse events occurred (2019).

Comments and recommendations

The analysis of the 2019-haemovigilance data confirms that, as in previous years[6,12], the most frequent adverse reactions to transfusion, considering all imputability and severity levels, are FNHTR (38.7%) and allergic manifestations with only mucosal and cutaneous symptoms (28.3%).

There were only 9 adverse reactions with probable or certain imputability requiring resuscitation procedures, including one case of death related to an ABO acute haemolytic reaction.

There were 10 cases of ABO-incompatible transfusion, 2 cases as "Acute haemolytic reaction", 3 cases as "Acute haemolytic reaction" , also notified as "Serious Adverse Events", 3 cases as "ABO-incompatible Blood Component Transfused without reaction", also notified as "Serious Adverse Events", and 2 cases only as "Serious Adverse Events".

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 2019, reactions involving the respiratory system accounted for 10.8% of the notifications of which 81 were allergic reactions involving the respiratory and/or cardiovascular system, 70 TAD, 52 TACO and 3 TRALI. Of the 71 TAD cases only 1.4% were certainly imputable to transfusion. Of the 3 cases of TRALI one case was certainly imputable, one case was probable, and one case was excluded/unlikely.

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 this regard, the utilisation of the tools "Algorithm for the differencial diagnosis of TACO and TRALI" and "Supplementary form for data collection about the adverse reactions related to

the respiratory system", that are available on the section "Download Files" of SISTRA, is recommended.

In 2019, 175 near misses were notified. Errors in patient samples (wrong name on tube, wrong name on tube, and wrong recipient identification) were commonly reported. The above-mentioned near misses are errors or deviations from standard procedures or policies and often resulted from underlying poor practices. Root cause analysis of near miss events should be carried out to highlight and resolve these system failures. Improving near miss reporting (they still seem to be underreported) is important to support learning from near miss cases and so suitable preventive measures can be adopted.

As regards adverse reactions in donors, the number of notifications in 2019 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 XXV, although immediate vasovagal reactions were the most frequently notified (75.3%), only 3.27% 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 remark concerns the low number of "Serious Adverse Events" notified (overall 55) 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[6,12], 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[10,11].

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[7]. 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 2019 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[7] and are compliant with the document issued by the European Medicines Agency (EMA) “Guideline on epidemiological data on blood transmissible infections”[13].

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[7].

- *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 2019, out of a total of 1,900,211 blood donors, 1,396 tested positive for the currently mandatory infectious disease markers.

Table XXXIV 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 (3.2‰), followed by Apulia (1.08‰) and Latium (0.96‰).

Table XXXIV - Tested donors and positive donors to infectious markers at national and regional level (2019).

Region/AP	Tested donors	Positive donors	
	N	N	‰
Aosta Valley	3,796	0	0.00
Piedmont	129,437	53	0.41
Liguria	49,498	20	0.40
Lombardy	297,179	109	0.37
AP of Trento	20,460	5	0.24
AP of Bolzano	16,602	1	0.06
Friuli Venezia Giulia	50,330	37	0.74
Veneto	179,985	49	0.27
Emilia Romagna	164,008	100	0.61
Tuscany	140,382	81	0.58
Umbria	28,679	12	0.42
Marche	55,783	28	0.50
Latium	143,743	138	0.96
Sardinia	58,073	44	0.76
Abruzzo	40,317	12	0.30
Campania	140,773	451	3.20
Molise	12,595	0	0.00
Apulia	121,728	131	1.08
Basilicata	20,031	7	0.35
Calabria	52,300	29	0.55
Sicily	173,288	89	0.51
Armed Forces	1,224	0	0.00
Italy	**1,900,211**	**1,396**	**0.73**

N: number; AP: Autonomous Province.

The data shown in Table XXXIV (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 (average value equal to 0.8‰) in the 26-65 age bracket (Table XXXV).

Table XXXVI shows the distribution by age bracket and gender of the 1,396 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).

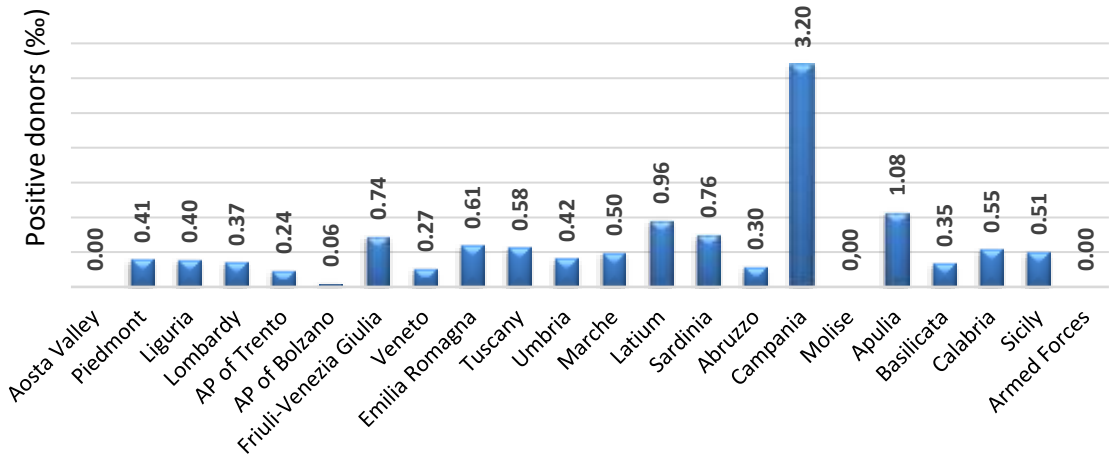

Figure 13 - Positive donors per 1,000 tested donors (‰) by Italian Regions (2019).

Table XXXV - Positive donor by age bracket (2019).

Age bracket	Total donors		Positive donors		
	N	%	N	%	‰
18-25	282,434	14.9	103	7.4	0.36
26-35	338,591	17.8	248	17.8	0.73
36-45	456,732	24.0	372	26.6	0.81
46-55	530,943	27.9	439	31.4	0.83
56-65	270,784	14.3	224	16.0	0.83
over 65	20,727	1.1	10	0.7	0.48
Total	**1,900,211**	**100**	**1,396**	**100**	**0.73**

N: number.

Table XXXVI - Positive donors by age bracket and gender (2019).

Age bracket	Male				Female			
	donors		positive donors		donors		positive donors	
	N	%	N	%	N	%	N	%
18-25	150,012	11.9	84	8.4	132,422	20.8	19	4.8
26-35	215,463	17.1	189	18.9	123,128	19.3	59	14.9
36-45	316,095	25.0	255	25.5	140,637	22.1	117	29.5
46-55	371,631	29.4	304	30.4	159,312	25.0	135	34.0
56-65	193,690	15.3	158	15.8	77,094	12.1	66	16.6
over 65	16,122	1.3	9	0.9	4,605	0.7	1	0.3
Total	**1,263,013**	**100**	**999 (72%)**	**100**	**637,198**	**100**	**397 (28%)**	**100**

N: number.

Considering the number of infections detected in the total number of donors (‰ tested donors) for each age bracket, the biggest difference in the number of infections between

males and females was found in the 18-25, 26-35 and over 65 age brackets, while it was almost comparable in the 36-45, 46-55 and 56-65 age brackets (Figure 15).

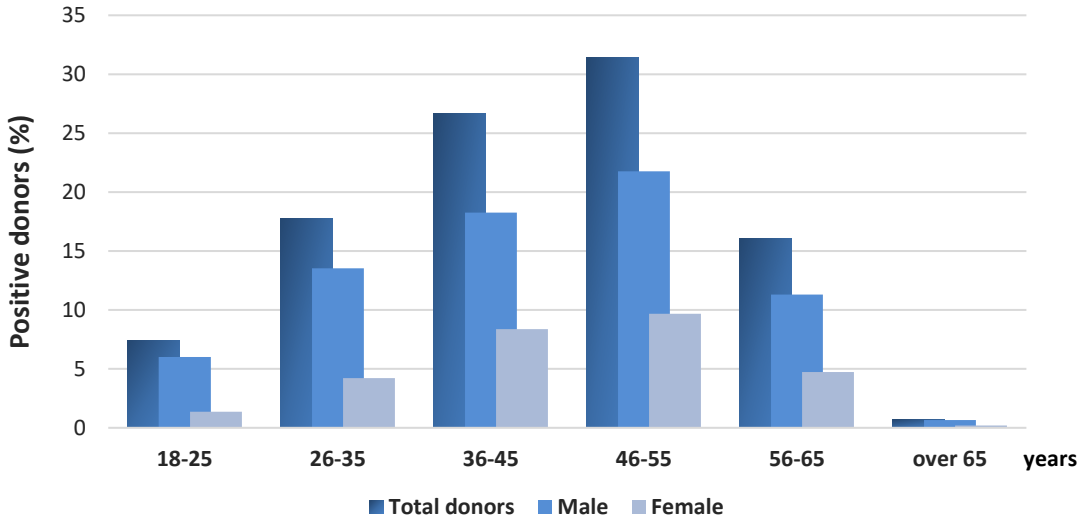

Figure 14 - Positive donors (total, male and female donors) by age bracket (%) (2019).

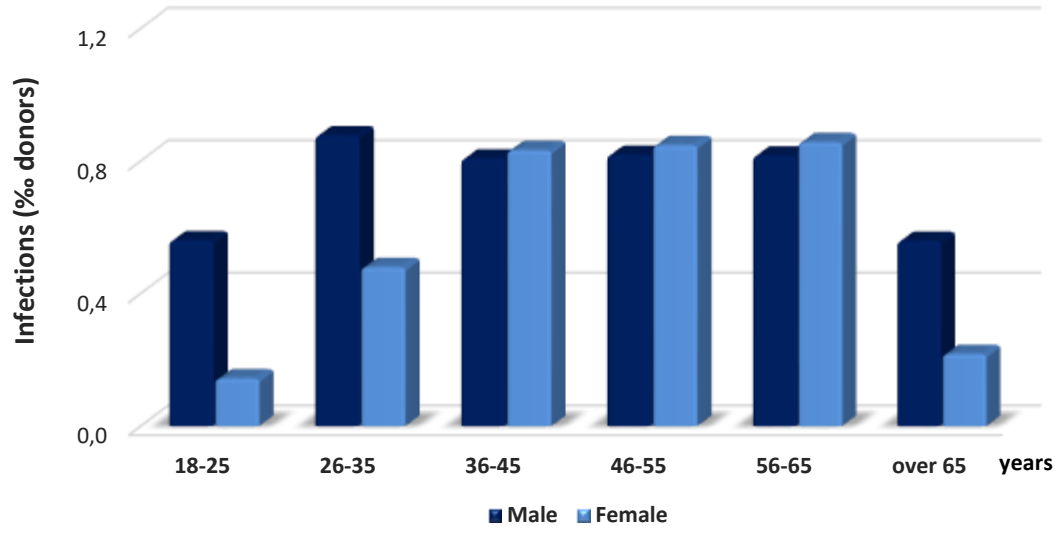

Figure 15 - Positive donors by age bracket and gender (‰ total donors) (2019).

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 between the trend of distribution of tested donors and that of the positive donors for each marker of HBV, TP and HCV infections. HIV infections are more frequent in age brackets under 46 years; TP infections are more frequent in 26-35 and 36-45 age brackets; on the contrary, HCV infections are more frequent in the 36-45 and 46-55 age brackets and HBV infections in the 46-55 and 56-65 age brackets.

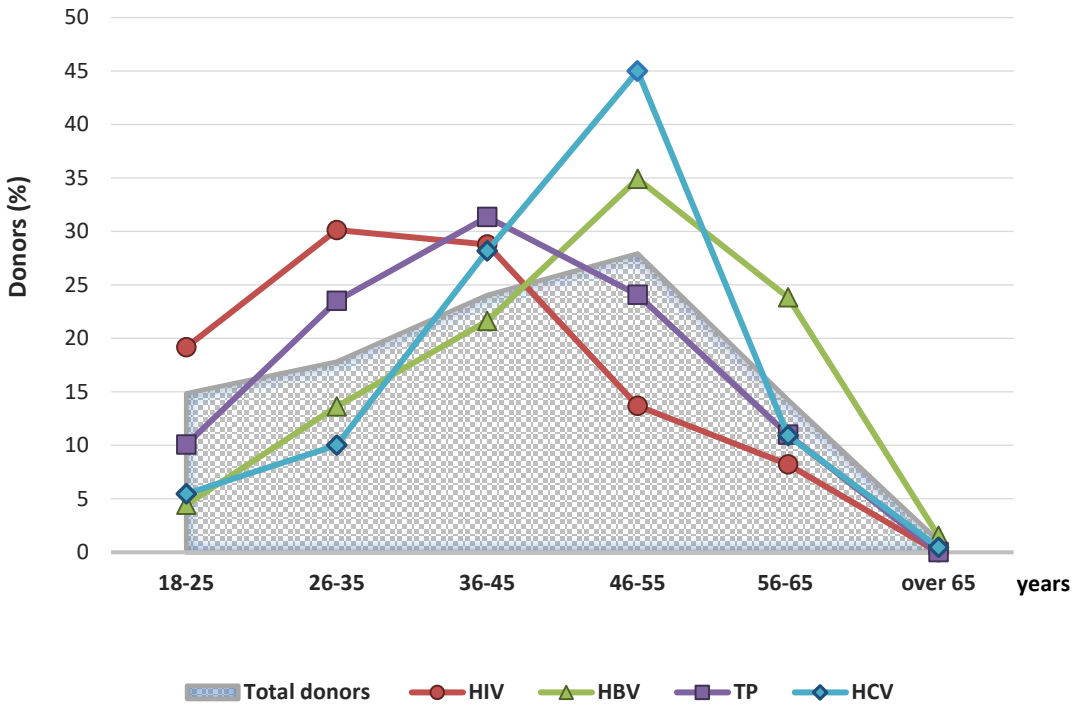

Figure 16 - Total donors and HIV, HBV, HCV and TP positive donors by age bracket (2019).
HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; TP: *Treponema pallidum;* HCV: Hepatitis C virus.

The number of positive donors changes significantly also in relationship with the membership category (Table XXXVII). In fact, it emerged that 2,4‰ of FT donors were positive to one of the infectious markers compared to 0.2‰ of RT donors (Table XXXVIII). Figure 17 shows the same data reported in Table XXXVIII.

Table XXXVII - Positive donors by category (2019).

Donor category	Donors	Positive donors	
	N	N	%
First-time tested donors	**425,018**	**1,036**	**74.21**
Prospective donors (first screening without donation)	183,953	336	24.07
First-time not pre-qualified donors	241,065	700	50.14
Repeat tested donors	**1,475,193**	**360**	**25.79**
First-time pre-qualified donors	77,721	7	0.50
Regular donors	1,397,472	353	25.29
Total donors	**1,900,211**	**1,396**	**100**

N: number.

Table XXXVIII - Positive donors per 1,000 (‰) tested donors: distribution by category (2019).

Donor category	Donors	Positive donors	
	N	N	(‰)
First-time tested donors	**425,018**	**1,036**	**2.44**
Prospective donors (first screening without donation)	183,953	336	1.83
First-time not pre-qualified donors	241,065	700	2.90
Repeat tested donors	**1,475,193**	**360**	**0.24**
First-time pre-qualified donors	77,721	7	0.09
Regular donors	1,397,472	353	0.25
Total donors	**1,900,211**	**1,396**	**0.73**

N: number.

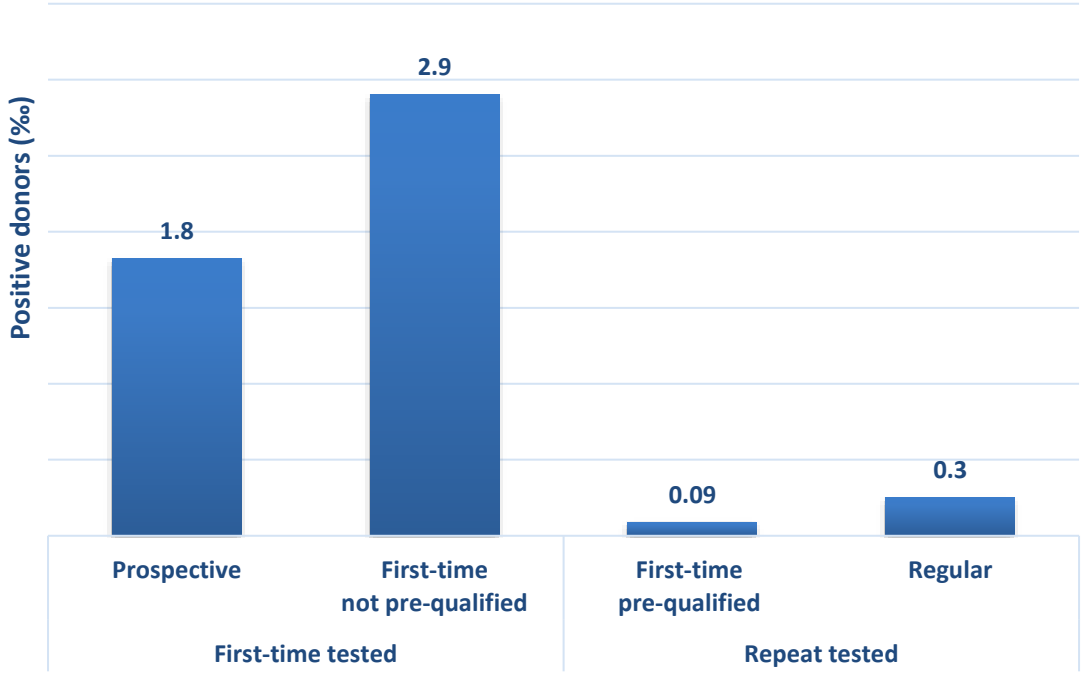

Figure 17 - Categories of positive donors (2019).

Table XXXIX shows the number of FT and RT positive donors in Italy divided by Region. The Region with the highest number of FT (5.35‰) and RT (0.80‰) positive donors was Campania.

Table XXXIX - FT and RT positive donors (total and per 1,000 (‰) tested donors) in Italy (2019).

Region/AP	Total of donors		Positive donors			
	FT	RT	FT	RT	FT (‰ FT)	RT (‰ RT)
Aosta Valley	571	3,225	0	0	0.00	0.00
Piedmont	18,703	110,734	40	13	2.14	0.12
Liguria	11,453	38,045	11	9	0.96	0.24
Lombardy	48,731	248,448	68	41	1.40	0.17
AP of Trento	2,376	18,084	3	2	1.26	0.11
AP of Bolzano	1,449	15,153	0	1	0.00	0.07
Friuli Venezia Giulia	11,772	38,558	17	20	1.44	0.52
Veneto	27,013	152,972	36	13	1.33	0.08
Emilia Romagna	26,073	137,935	70	30	2.68	0.22
Tuscany	27,226	113,156	60	21	2.20	0.19
Umbria	5,571	23,108	10	2	1.80	0.09
Marche	8,589	47,194	24	4	2.79	0.08
Latium	55,106	88,637	114	24	2.07	0.27
Sardinia	18,245	39,828	34	10	1.86	0.25
Abruzzo	7,159	33,158	6	6	0.84	0.18
Campania	74,389	66,384	398	53	5.35	0.80
Molise	2,834	9,761	0	0	0.00	0.00
Apulia	25,527	96,201	76	55	2.98	0.57
Basilicata	4,886	15,145	5	2	1.02	0.13
Calabria	10,551	41,749	18	11	1.71	0.26
Sicily	36,578	136,710	46	43	1.26	0.31
Armed Forces	216	1,008	0	0	0.00	0.00
Italy	**425,018**	**1,475,193**	**1,036**	**360**	**2.44**	**0.24**

FT: First-time tested donors; RT: Repeat tested donors; AP: Autonomous Province.

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

The male/female ratio for FT positive donors was about 1.6:1. However, the male/female ratio for RT positive donors was about 3:1 (Figure 19).

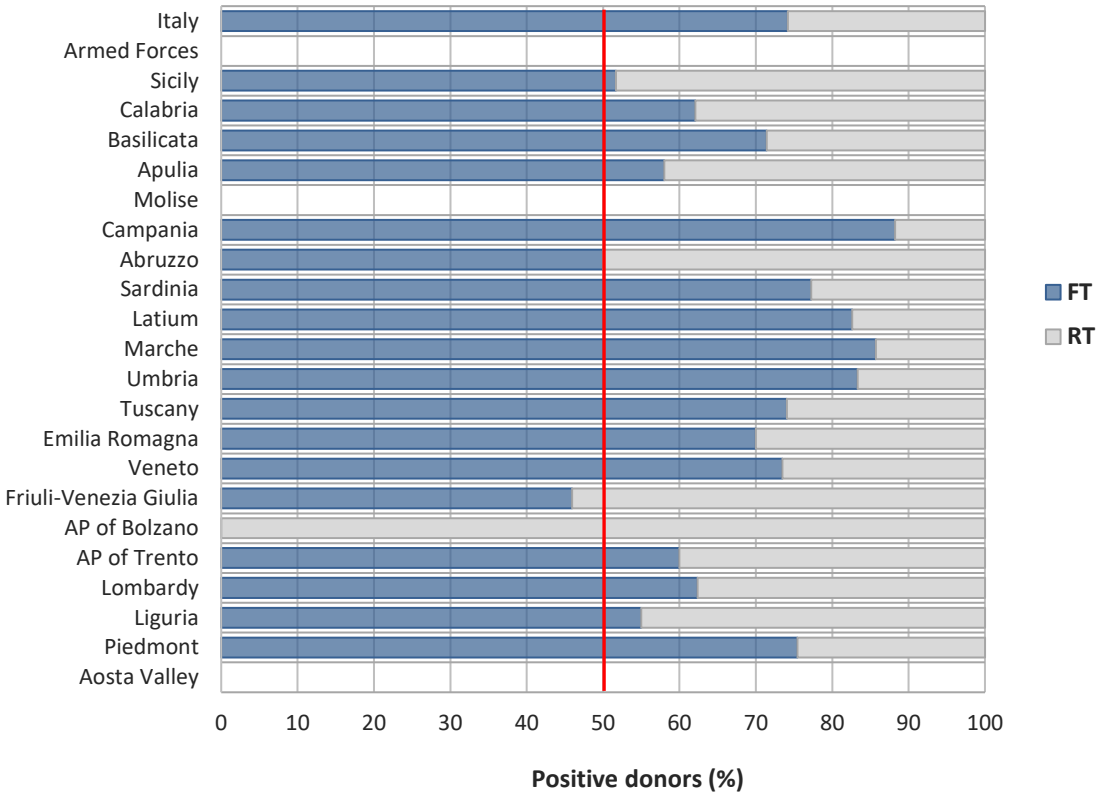

Figure 18 - Positive donors by FT and RT category (%) at national and regional level (2019).
FT: First-time tested donors; RT: Repeat tested donors.

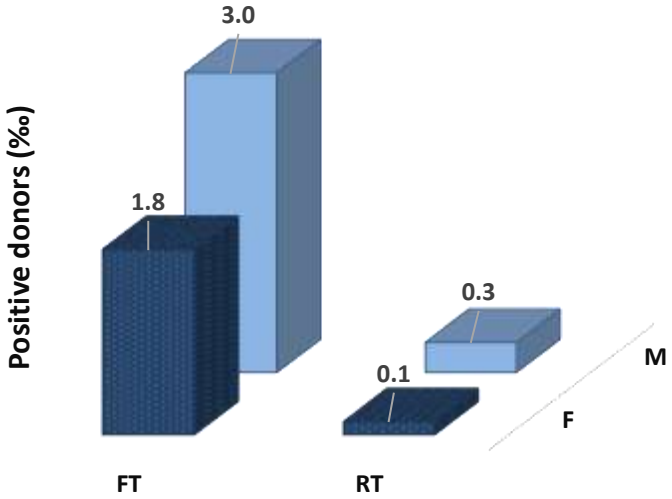

Figure 19 - Positive donors by FT and RT category (‰ total male and female donors) and gender (2019).
FT: First-time tested donors; RT: Repeat tested donors.

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: 17.8/100,000, HBV: 138.5/100,000, HCV: 54.7/100,000, and TP: 115.8/100,000 tested donors). These values were from 4.1 (TP) to 4.7 times (HCV) higher compared to the national data.

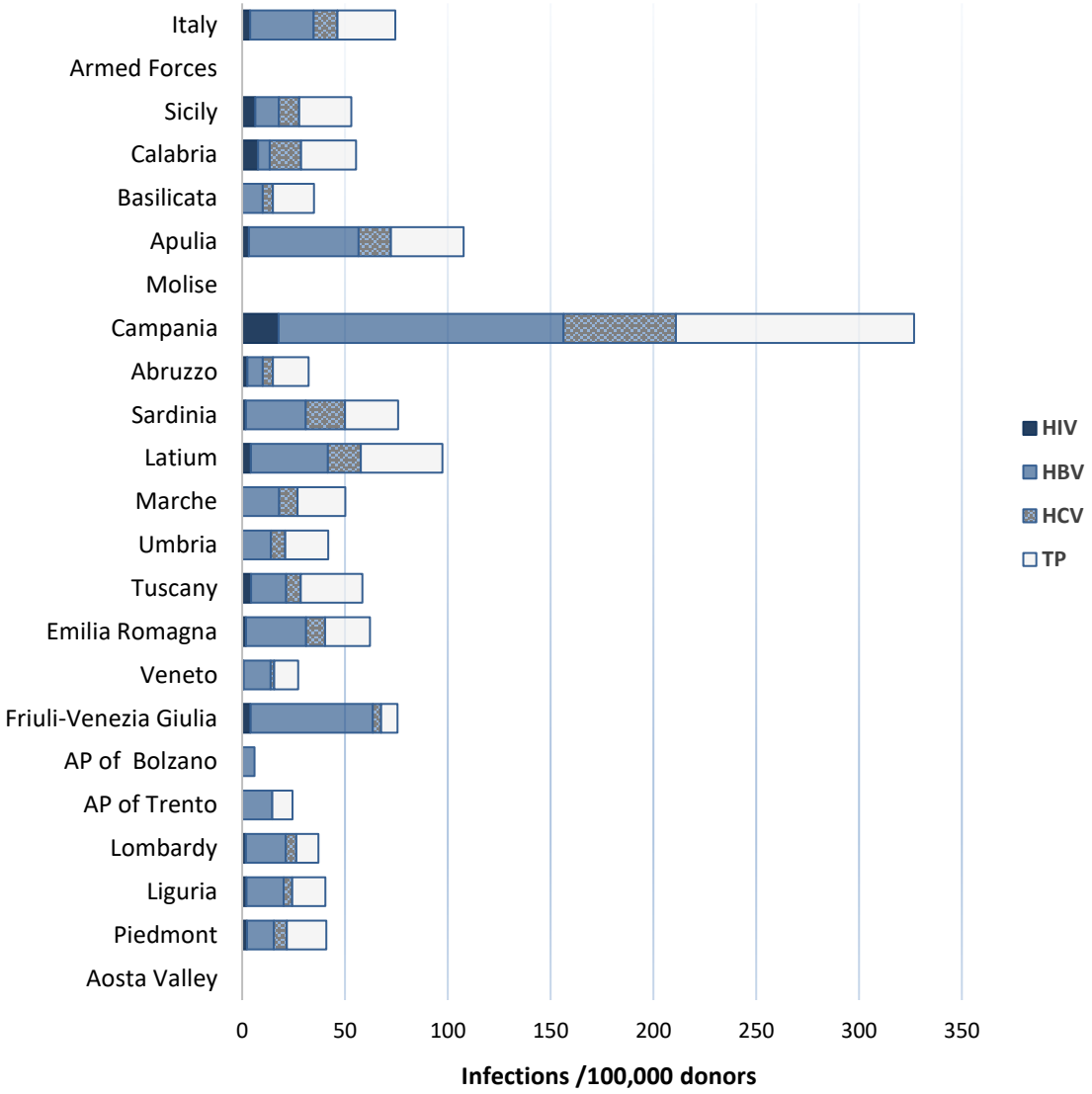

Figure 20 - Number of positive donor distribution at national and regional level for each infectious marker per 100,000 donors (2019).
HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; TP: *Treponema pallidum;* HCV: Hepatitis C virus.

Figure 21 shows the distribution of infections by category (FT/RT), gender and infectious marker. All infectious markers 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 2:1 (HIV) to about 11:1 (HCV).

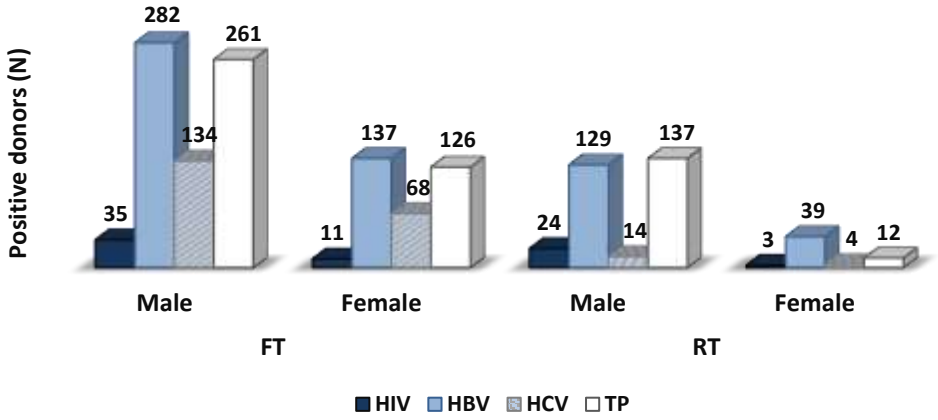

Figure 21 - Infections by donor category (FT/RT), gender and infectious marker (2019).
FT:First-time tested donors; RT: Repeat tested donors; HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; TP: *Treponema pallidum;* HCV: Hepatitis C virus.

In Tables XL and XLI data on HIV, HBV, HCV and TP prevalence and incidence at national and regional level are reported. At national level, the highest prevalence value was for HBV (98.6/100,000 FT donors), followed by TP (91.1/100,000 FT donors) (Table XL).

Table XL - Prevalence by infectious marker/100,000 FT donors (2019).

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	5.4	69.5	37.4	101.6
Liguria	8.7	43.7	17.5	26.2
Lombardy	4.1	69.8	26.7	41.0
AP of Trento	0.0	84.2	0.0	42.1
AP of Bolzano	0.0	0.0	0.0	0.0
Friuli Venezia Giulia	0.0	101.9	17.0	25.5
Veneto	3.7	66.6	11.1	51.8
Emilia Romagna	3.8	122.7	46.0	103.6
Tuscany	11.0	88.2	33.1	91.8
Umbria	0.0	71.8	35.9	71.8
Marche	0.0	116.4	58.2	104.8
Latium	9.1	74.4	41.7	85.3
Sardinia	5.5	76.7	54.8	49.3
Abruzzo	0.0	14.0	27.9	55.9
Campania	30.9	220.5	103.5	192.2
Molise	0.0	0.0	0.0	0.0
Apulia	7.8	121.4	58.8	109.7
Basilicata	0.0	40.9	20.5	40.9
Calabria	9.5	19.0	47.4	94.8
Sicily	13.7	27.3	38.3	51.9
Armed Forces	0.0	0.0	0.0	0.0
Italy	**10.8**	**98.6**	**47.5**	**91.1**

HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; HCV: Hepatitis C virus; TP: *Treponema pallidum;* FT: First-time tested donors; AP: Autonomous Province.

Similarly, the highest incidence value was for HBV (11.4/100,000 RT donors) and TP (10.1/100,000 RT donors) infections (Table XLI).

Table XLI - Incidence by infectious marker/100,000 RT donors (2019).

Region/AP	HIV	HBV	HCV	TP
Aosta Valley	0.0	0.0	0.0	0.0
Piedmont	1.8	3.6	0.9	5.4
Liguria	0.0	10.5	0.0	13.1
Lombardy	1.2	9.7	0.8	4.8
AP of Trento	0.0	5.5	0.0	5.5
AP of Bolzano	0.0	6.6	0.0	0.0
Friuli Venezia Giulia	5.2	46.7	0.0	2.6
Veneto	0.0	3.9	0.0	4.6
Emilia Romagna	1.5	11.6	2.2	6.5
Tuscany	2.7	0.0	0.9	15.0
Umbria	0.0	0.0	0.0	8.7
Marche	0.0	0.0	0.0	8.5
Latium	1.1	14.7	0.0	11.3
Sardinia	0.0	7.5	2.5	15.1
Abruzzo	3.0	6.0	0.0	9.1
Campania	3.0	46.7	0.0	30.1
Molise	0.0	0.0	0.0	0.0
Apulia	2.1	35.3	4.2	15.6
Basilicata	0.0	0.0	0.0	13.2
Calabria	7.2	2.4	7.2	9.6
Sicily	4.4	7.3	2.2	18.3
Armed Forces	0.0	0.0	0.0	0.0
Italy	**1.8**	**11.4**	**1.2**	**10.1**

HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; HCV: Hepatitis C virus; TP: *Treponema pallidum;* RT: Repeat tested donors; AP: Autonomous Province.

Moreover, it is important to note that in 85% 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 (15%), in most cases the donor "denied the risk factor" (Figure 22).

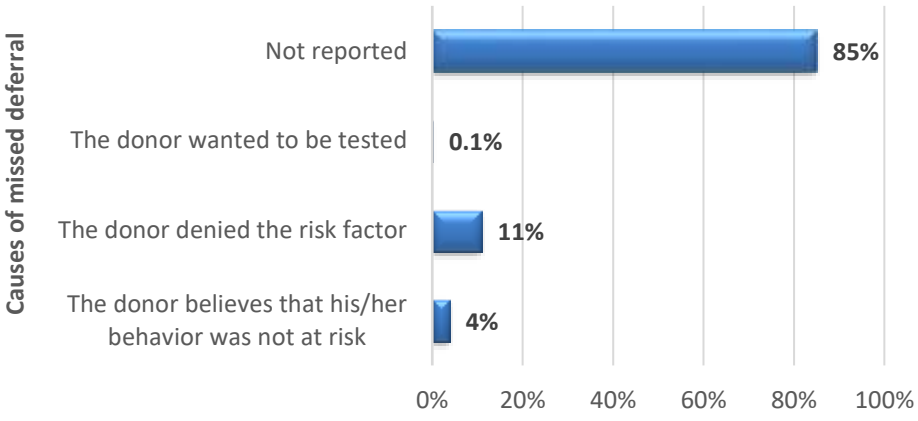

Figure 22 - Causes of missed deferral of donor positive to infectious markers (2019).

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

Table XLII - Positive donors to infectious markers by nationality and category (FT/RT) (2019).

Nationality	Positive donors		FT		RT	
	N	%	N	%	N	%
Italians	1.065	76.3	730	70.5	335	93.1
Foreigners	331	23.7	306	29.5	25	6.9
Total	**1,396**	**100**	**1,036**	**100**	**360**	**100**

FT: First-time tested donors; RT: Repeat tested donors; N: number.

Table XLIII shows the distribution of positive donors to infectious markers by geographical area of birth and category (FT/RT). The data shown in Table XLII and Table XLIII were the same as those shown in Figure 23.

Table XLIII - Positive donors to infectious markers by category (FT/RT) and by geographical area of birth (2019).

Geographical area of birth	FT	RT	Total
Africa	59	3	62
America	15	4	19
Asia	35	2	37
Europe	197	16	213
Italy	730	335	1,065
Total	**1,036**	**360**	**1,396**

FT: First-time tested donors; RT: Repeat tested donors.

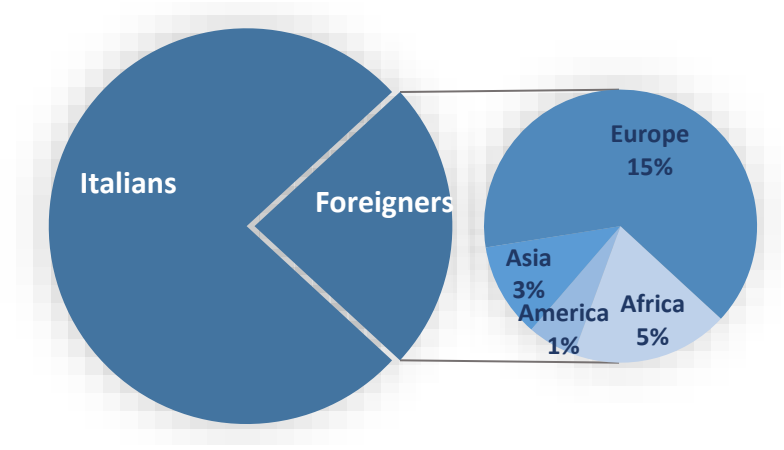

Figure 23 - Positive donors to infectious markers by nationality (%) (2019).

HIV surveillance data

Table XLIV reports the number of HIV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2019, 73 HIV infections were reported, with a prevalence of 10.8 per 100,000 FT donors and an incidence of 1.8 per 100,000 RT donors. The highest number of HIV infections was found in the Campania Region (25 cases). The Region with the highest prevalence was Campania (30.9) while the Region with the highest incidence was Calabria (7.2).

Table XLIV - Number, prevalence and incidence of HIV infections per 100,000 donors at national and regional level (2019).

Region/AP	HIV infections		
	N	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	3	5.4	1.8
Liguria	1	8.7	0.0
Lombardy	5	4.1	1.2
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	1	3.7	0.0
Emilia Romagna	3	3.8	1.5
Tuscany	6	11.0	2.7
Umbria	0	0.0	0.0
Marche	0	0.0	0.0
Latium	6	9.1	1.1
Sardinia	1	5.5	0.0
Abruzzo	1	0.0	3.0
Campania	25	30.9	3.0
Molise	0	0.0	0.0
Apulia	4	7.8	2.1
Basilicata	0	0.0	0.0
Calabria	4	9.5	7.2
Sicily	11	13.7	4.4
Armed Forces	0	0.0	0.0
Italy	**73**	**10.8**	**1.8**

HIV: Human immunodeficiency virus; N: number; AP: Autonomous Province.

Figure 24 shows the distribution, expressed as a percentage, of HIV positive donors by nationality; 10% of all positive donors were foreigners.

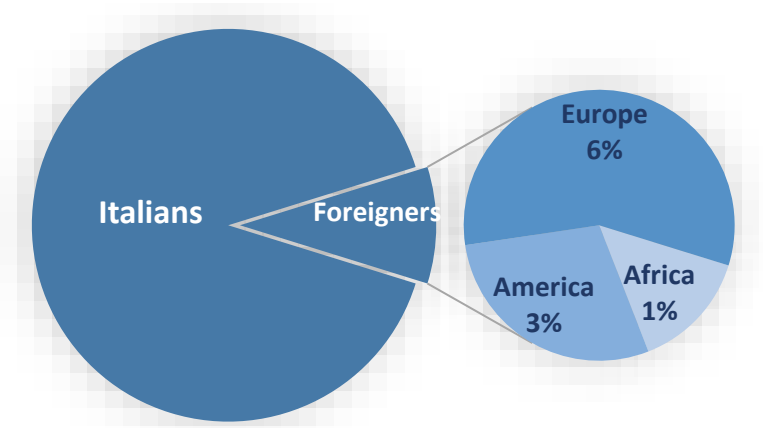

Figure 24 - Distribution of HIV positive donors by nationality (%) (2019).
HIV: Human immunodeficiency virus.

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

Table XLV - HIV infections by geographical area of birth (2019).

Geographical area of birth	N of infections
Africa	1
America	2
Europe	4
Italy	66
Total	**73**

HIV: Human immunodeficiency virus; N: number.

In about 50% of the HIV positive donors (37/73) it was not possible to identify the risk factor; in the remaining 50%, 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 "donor's sexual behaviour at risk" (Figure 25).

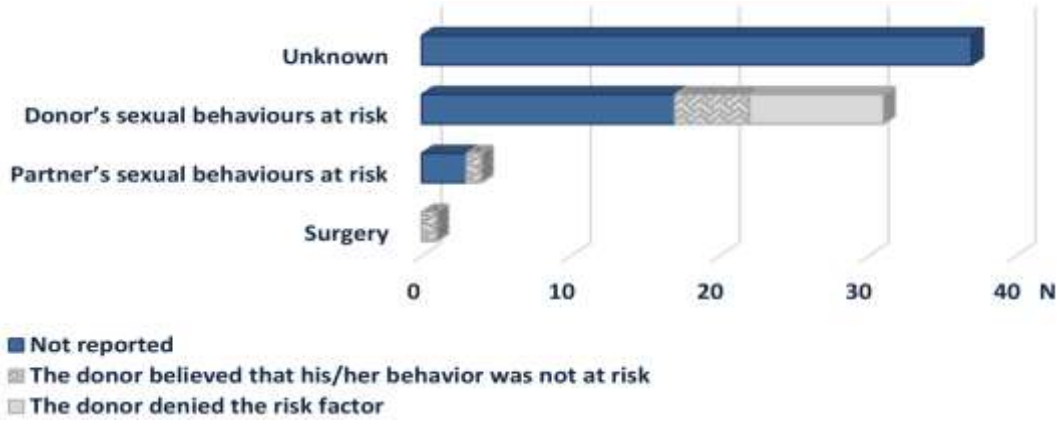

Figure 25 - Causes of failed deferral and risk factors detected in HIV positive donors (2019).
N: number.

Moreover, in most cases (63/73) the molecular (NAT) serological and confirmatory tests were positive; in 3 cases the molecular test was negative with positive serological and confirmatory tests (Table XLVI).

Table XLVI - HIV infections obtained from the different combinations of the results of the individual molecular and serological tests (2019).

Combinations of results			N of infections
NAT	**SER**	**CONF**	
+	**+**	**+**	63
-	**+**	**+**	3
NP*	**+**	**+**	7
		Total	**73**

HIV: Human immunodeficiency virus; N: number; NAT: Nucleic Acid Test; SER: serological tests; CONF: confirmatory tests; NP: not performed.
*: NAT unavailable because prospective donors only underwent serological screening tests.

HCV surveillance data

Table XLVII reports the number of HCV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2019, 220 HCV infections were reported, with a prevalence of 47.5 infections per 100,000 FT donors and an incidence of 1.2 infections per 100,000 RT donors. The highest number of HCV infections was found in the Campania Region (77). The Region with the highest prevalence was Campania (103.5), while the Region with the highest incidence was Calabria (7.2).

Table XLVII - Number, prevalence and incidence of HCV infections per 100,000 donors at national and regional level (2019).

Region/AP	HCV infections		
	N	**prevalence**	**incidence**
Aosta Valley	0	0.0	0.0
Piedmont	8	37.4	0.9
Liguria	2	17.5	0.0
Lombardy	15	26.7	0.8
AP of Trento	0	0.0	0.0
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	2	17.0	0.0
Veneto	3	11.1	0.0
Emilia Romagna	15	46.0	2.2
Tuscany	10	33.1	0.9
Umbria	2	35.9	0.0
Marche	5	58.2	0.0
Latium	23	41.7	0.0
Sardinia	11	54.8	2.5
Abruzzo	2	27.9	0.0
Campania	77	103.5	0.0
Molise	0	0.0	0.0
Apulia	19	58.8	4.2
Basilicata	1	20.5	0.0
Calabria	8	47.4	7.2
Sicily	17	38.3	2.2
Armed Forces	0	0.0	0.0
Italy	**220**	**47.5**	**1.2**

HCV: Hepatitis C virus; N: number; AP: Autonomous Province.

Figure 26 shows the distribution, expressed as a percentage, of HCV positive donors by nationality; 18% of all positive donors were foreigners. Table XLVIII shows the distribution of HCV positive donors by geographical area of birth.

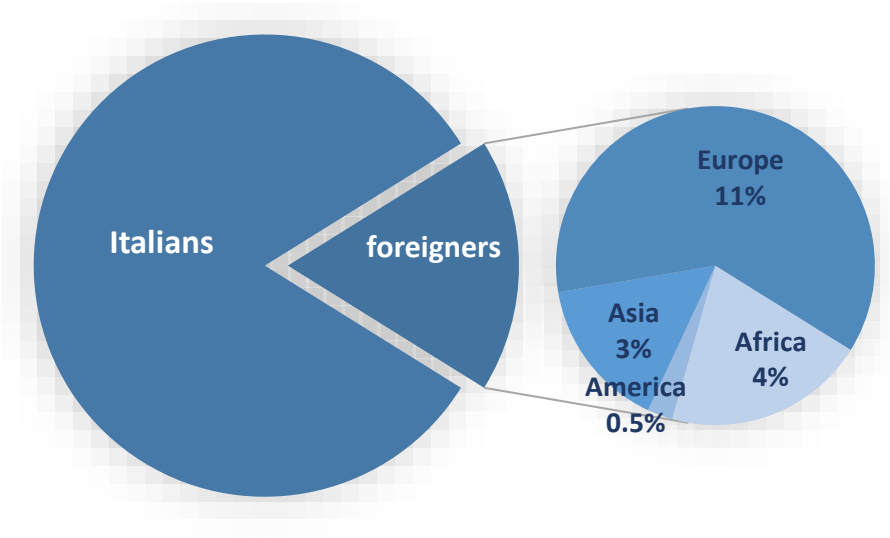

Figure 26 - HCV positive donors by nationality (%) (2019).
HCV: Hepatitis C virus.

Table XLVIII - HCV infections by geographical area of birth (2019).

Geographical area of birth	N of infections
Africa	8
America	1
Asia	6
Europe	24
Italy	181
Total	**220**

HCV: Hepatitis C virus; N: number.

In about 74% of HCV positive donors (162/220) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern donor's sexual behaviours at risk and dental treatment (Figure 27).

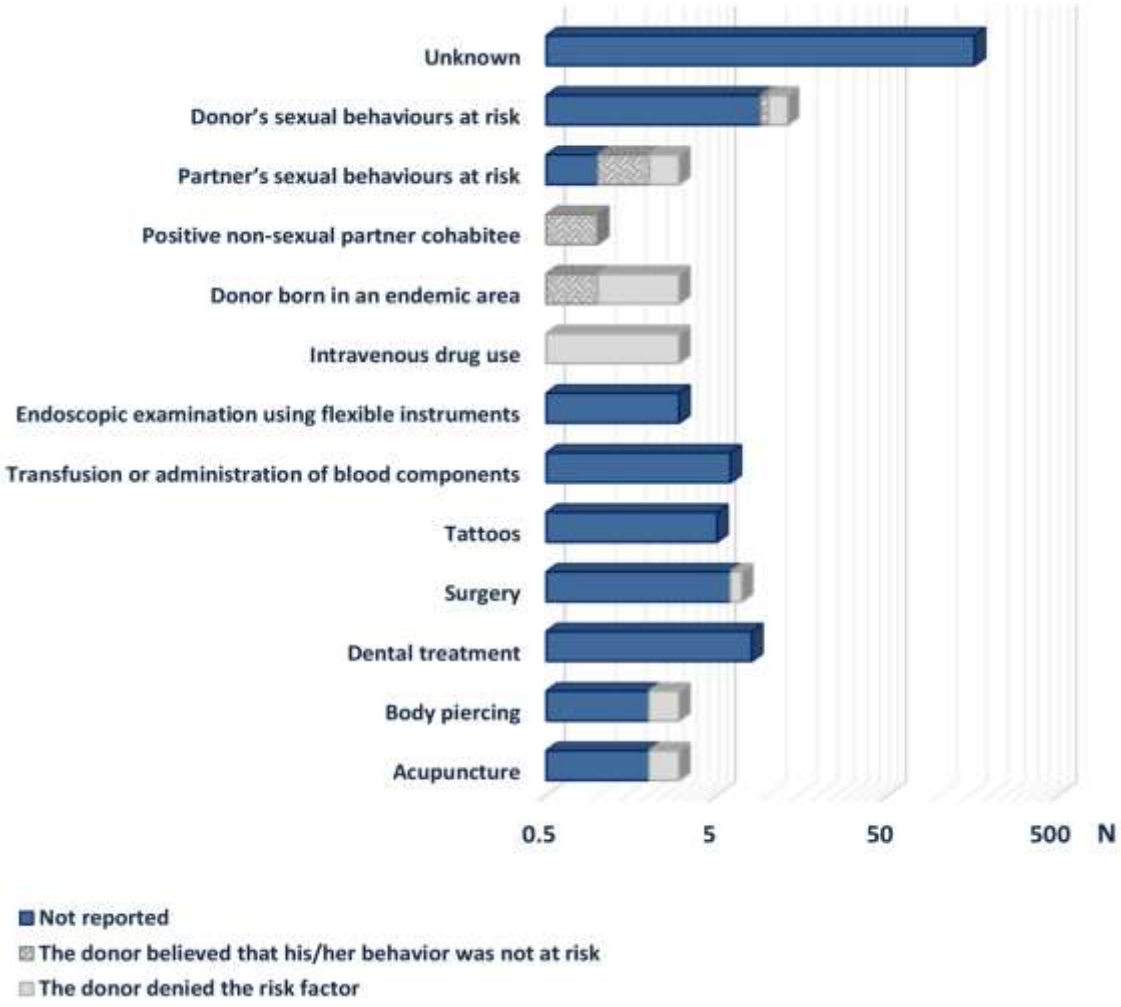

Figure 27 - Causes of failed deferral and risk factors detected in HCV positive donors (values reported on a logarithmic scale) (2019).
N: number.

In most cases (101/220), the molecular (NAT), serological and confirmatory tests were positive; in 85 cases the molecular test was negative with a positive serological screening and confirmatory tests. In 1 case the infection was detected exclusively by means of the NAT test (NAT only) (Table XLIX).

Table XLIX - HCV infections obtained from the different combinations of the results of the individual molecular and serological tests (2019).

Combinations of results			N of infections
NAT	**SER**	**CONF**	
+	+	+	101
+	-	**NP**	1
-	+	+	85
NP*	+	+	32
Total			**220**

HCV: Hepatitis C virus; N: number; NAT: Nucleic Acid Test; SER: serological tests; CONF: confirmatory tests; NP: not performed.
*: NAT unavailable because prospective donors only underwent serological screening tests.

HBV surveillance data

Table L reports the number of HBV positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2019, 587 HBV infections were reported, with a prevalence of 98.6 infections per 100,000 FT donors and an incidence of 11.4 infections per 100,000 RT donors. The highest number of HBV infections was found in the Campania Region (195). The Region with the highest prevalence (220.5) was Campania, while the Regions with the highest incidence were Friuli Venezia Giulia and Campania (46.7).

Table L - Number, prevalence and incidence of HBV infections per 100,000 donors at national and regional level (2019).

Region/AP	HBV infections		
	N	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	17	69.5	3.6
Liguria	9	43.7	10.5
Lombardy	58	69.8	9.7
AP of Trento	3	84.2	5.5
AP of Bolzano	1	0.0	6.6
Friuli Venezia Giulia	30	101.9	46.7
Veneto	24	66.6	3.9
Emilia Romagna	48	122.7	11.6
Tuscany	24	88.2	0.0
Umbria	4	71.8	0.0
Marche	10	116.4	0.0
Latium	54	74.4	14.7
Sardinia	17	76.7	7.5
Abruzzo	3	14.0	6.0
Campania	195	220.5	46.7
Molise	0	0.0	0.0
Apulia	65	121.4	35.3
Basilicata	2	40.9	0.0
Calabria	3	19.0	2.4
Sicily	20	27.3	7.3
Armed Forces	0	0.0	0.0
Italy	**587**	**98.6**	**11.4**

HBV: Hepatitis B virus; N: number; AP: Autonomous Province.

Figure 28 shows the distribution, expressed as a percentage, of HBV positive donors by nationality; 31% of all positive donors were foreigners.

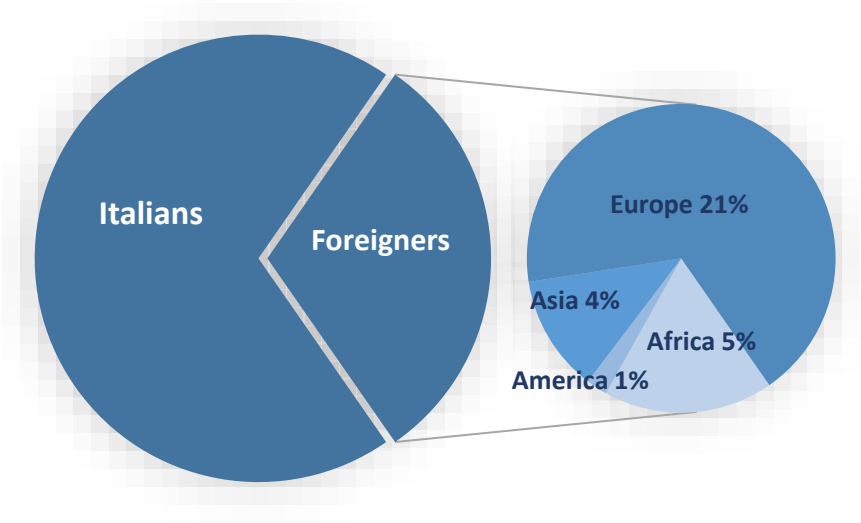

Figure 28 - HBV positive donors by nationality (%) (2019).
HBV: Hepatitis B virus.

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

Table LI - HBV infections by geographical area of birth (2019).

Geographical area of birth	N of infections
Africa	32
America	4
Asia	22
Europe	122
Italy	407
Total	**587**

HBV: Hepatitis B virus; N: number.

In about 71% of the HBV positive donors (415/587) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern donor's sexual behaviours at risk, tattoos and dental treatment; the highest rates of behaviour considered unsafe were related to donor born in an endemic area (Figure 29).

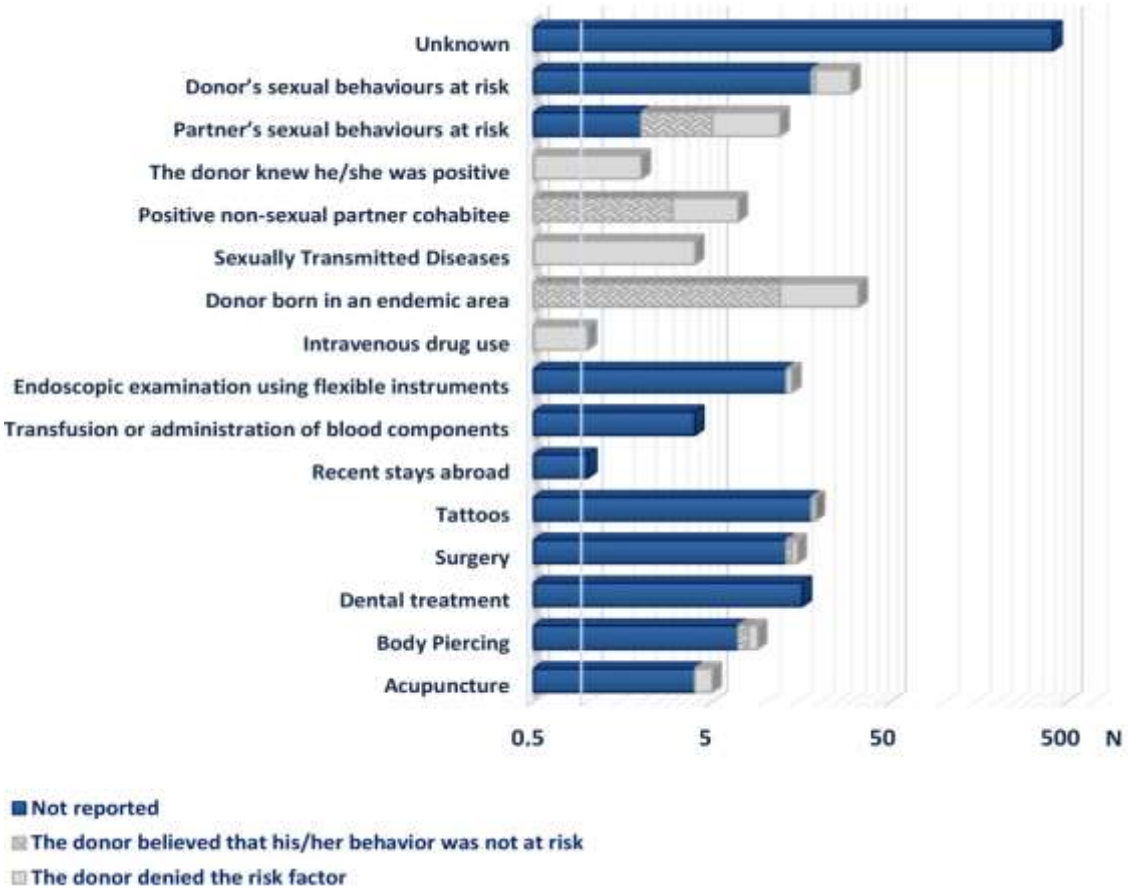

Figure 29 - Causes of failed deferral and risk factors detected in HBV positive donors (values reported on a logarithmic scale) (2019).
N: number.

Moreover, in most cases (317/587), both the molecular test (NAT) and the serological tests were positive; in 213 cases the infection was detected exclusively by means of the NAT test (NAT only); in 56 cases the infection was detected exclusively by means of the serological and confirmatory tests (Table LII).

Table LII - Number of HBV infections obtained from different combinations of the results of individual molecular and serological tests (2019).

Combinations of results			N of infections
NAT	**SER**	**CONF**	
+	+	+	317
+	+	-	1
+	-	-	213
-	+	+	12
NP*	+	+	44
	Total		**587**

HBV: Hepatitis B virus; N: number; NAT: Nucleic Acid Test; SER: serological tests; CONF: confirmatory tests; NP: not performed.
*: NAT unavailable because prospective donors only underwent serological screening tests.

TP surveillance data

Table LIII reports the number of TP positive donors and the incidence and prevalence by Italian Region and in Italy. In Italy, in 2019, 536 TP infections were reported, with a prevalence of 91.1 infections per 100,000 FT donors and an incidence of 10.1 infections per 100,000 RT donors. The highest number of TP infections was found in the Campania Region (163). The Region with the highest prevalence (192.2) and incidence (30.1) was Campania.

Table LIII - Number, prevalence and incidence of TP infections per 100,000 donors at national and regional level (2019).

Region/AP	TP infections		
	N	prevalence	incidence
Aosta Valley	0	0.0	0.0
Piedmont	25	101.6	5.4
Liguria	8	26.2	13.1
Lombardy	32	41.0	4.8
AP of Trento	2	42.1	5.5
AP of Bolzano	0	0.0	0.0
Friuli Venezia Giulia	4	25.5	2.6
Veneto	21	51.8	4.6
Emilia Romagna	36	103.6	6.5
Tuscany	42	91.8	15.0
Umbria	6	71.8	8.7
Marche	13	104.8	8.5
Latium	57	85.3	11.3
Sardinia	15	49.3	15.1
Abruzzo	7	55.9	9.1
Campania	163	192.2	30.1
Molise	0	0.0	0.0
Apulia	43	109.7	15.6
Basilicata	4	40.9	13.2
Calabria	14	94.8	9.6
Sicily	44	51.9	18.3
Armed Forces	0	0.0	0.0
Italy	**536**	**91.1**	**10.1**

TP: *Treponema pallidum*; N: number; AP: Autonomous Provinces.

Figure 30 shows the distribution, expressed as a percentage, of the TP positive donors by nationality; 21% of all positive donors were foreigners.

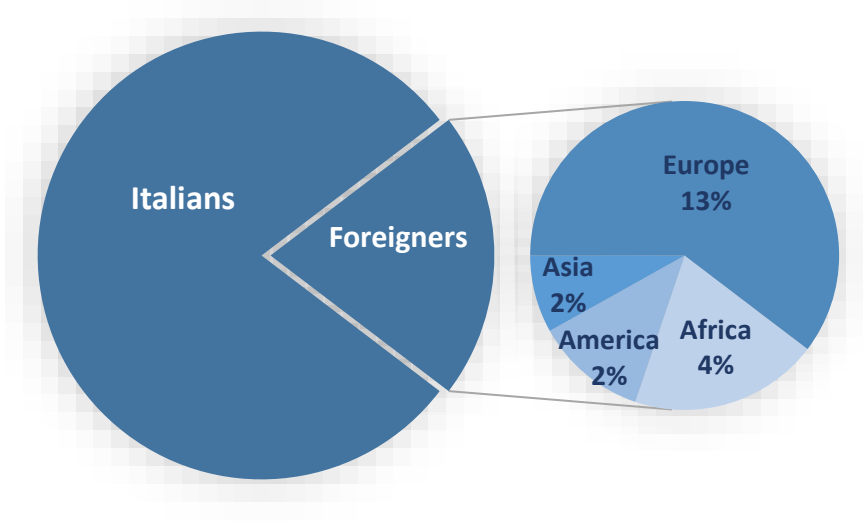

Figure 30 - Distribution of TP positive donors by nationality (%) (2019).
TP: *Treponema pallidum*.

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

Table LIV - Number of TP infections by geographical area of birth (2019).

Geographical area of birth	N of infections
Africa	22
America	13
Asia	9
Europe	67
Italy	425
Total	**536**

TP: *Treponema pallidum*; N: number.

In about 57% of the TP positive donors (303/536) it was not possible to identify the risk factor. The highest percentages relative to the "not reported" data mainly concern donor's sexual behaviours at risk; the highest percentages of behaviour not considered at risk refer to sexual behaviours at risk of the donor and partner (Figure 31).

Except for two cases (negative/indeterminate screening test and positive confirmatory test), both the serological tests (screening and confirmatory) were positive (Table LV).

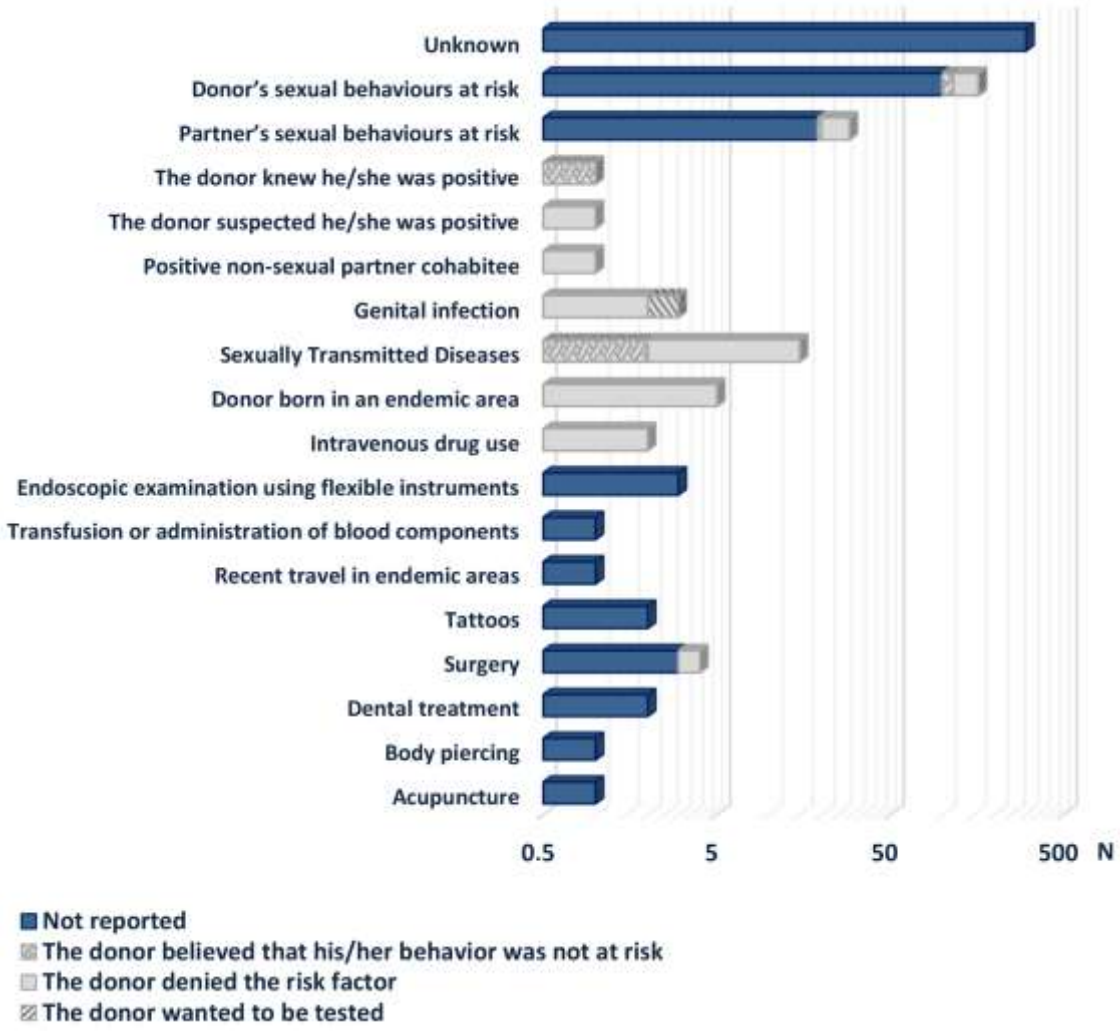

Figure 31 - Causes of failed deferral and risk factors detected in TP positive donors (values reported on a logarithmic scale) (2019).

Table LV - Number of TP infections obtained from individual serological test (2019).

Results		N of infections
SER	**CONF**	
+	+	534
+/-	+	1
-	+	1
Total		**536**

TP: *Treponema pallidum*; N: number; SER: serological tests; CONF: confirmatory tests.

Coinfections

In this chapter, the authors want to provide more accurate epidemiological data on coinfection notifications regarding blood donors for the year 2019.

Figure 32 shows the number of coinfected donors by gender and type of coinfection diagnosed; of the 20 coinfections notified, 16 included TP. The majority of coinfected donors were males. In particular, in 1/4 of cases the coinfection was diagnosed in male donors in the 36-45 age bracket (Figure 33).

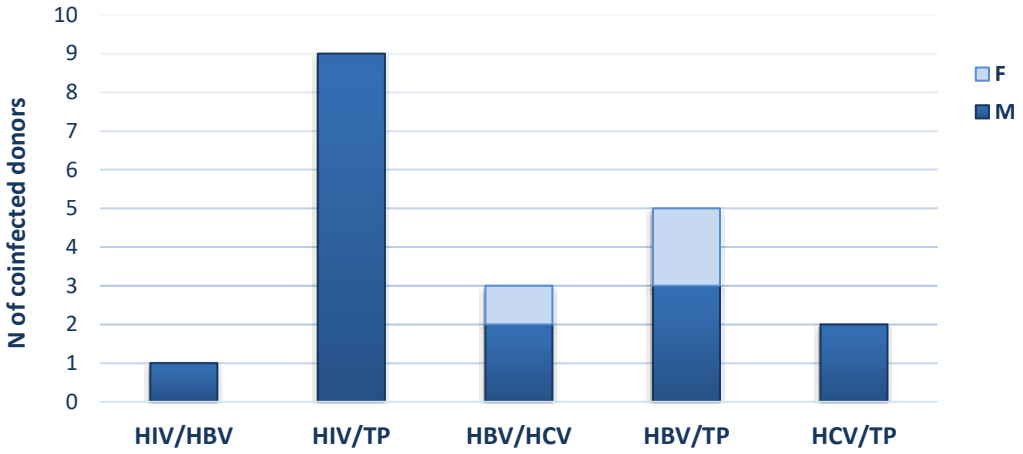

Figure 32 - Number of coinfected donors by type of coinfection and by gender (2019).
N: number; M: male; F: female; HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; TP: *Treponema pallidum;* HCV: Hepatitis C virus.

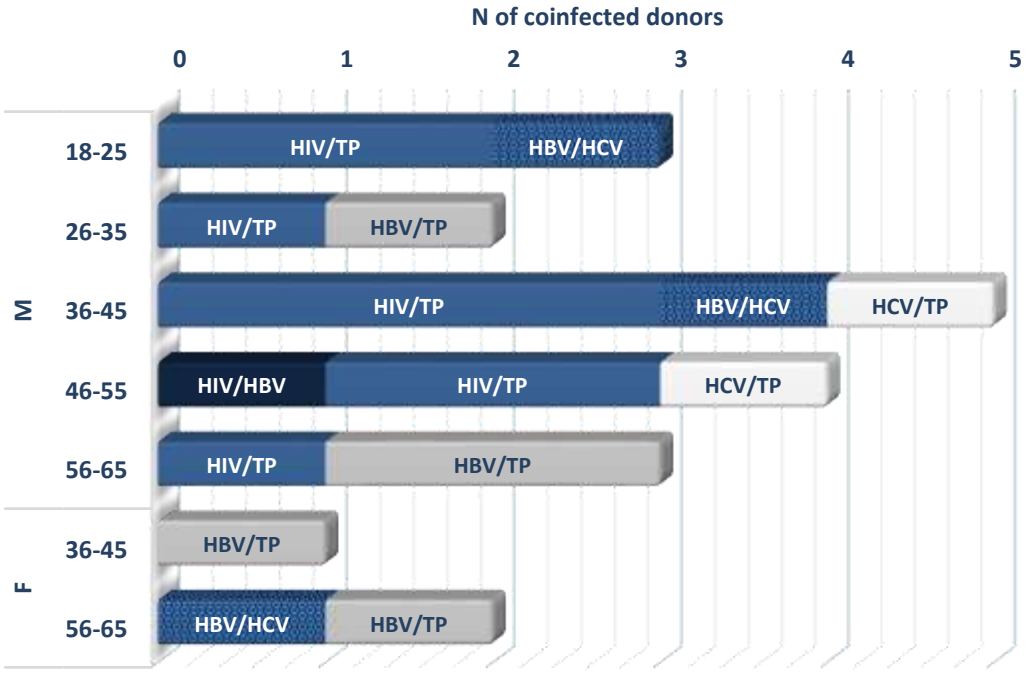

Figure 33 - Number of coinfected donors by type of coinfection, age bracket and sex (2019).
N: number; M; male; F: female; HIV: Human immunodeficiency virus; HBV: Hepatitis B virus; TP: *Treponema pallidum;* HCV: Hepatitis C virus.

For the majority of coinfected donors (12) it was not possible to trace the reasons for missed deferral and the risk factors are not known. For 5 cases of coinfection the risk factors were identified and were generally due to donor's sexual behaviour at risk; in the remaining two cases the risk factors were identified and were due to surgery and endoscopic examination using flexible instruments (Figure 34).

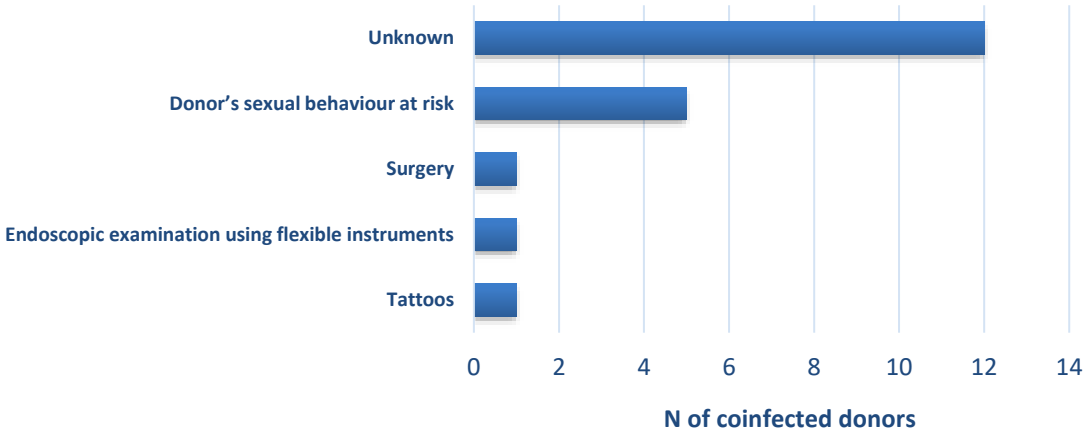

Figure 34 - Number of coinfected donors by risk factor (2019).
N: number.

Comments and recommendations

As in previous years[6,12], from the analysis of the notifications received in 2019 it emerged that the number of donors positive to transfusion-transmissible infectious markers varied greatly from one region to another.

About 76% of the positive donors were Italian, while the remaining 24% 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 (72%) and FT (74%).

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 26-45 year age brackets, while HBV and HCV infections were higher in the 46-55 year age bracket.

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

The analysis on coinfections showed that the majority of coinfected donors were TP positive. As in the previous years[6,12], 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.

REFERENCES

1. Ministry of Health Decree of 21th December, 2007 "*Establishment of the National Blood Information System blood transfusion services information system*" (Official Journal General Series n. 13 of 16th January, 2008).

2. Decree of the Prime Minister of 1st April, 2008 "*Technical and security rules for the operation of the Public Connectivity System provided for by Article 71, paragraph 1-bis of Legislative Decree n. 82 of 7th March, 2005, containing the Digital Administration Code*" (Official Journal General Series n. 144 of 21th June, 2008).

3. Legislative Decree "*Digital Administration Code n. 82 of 7th March, 2005*" (Ordinary Supplement n. 112 of Official Journal of 21th June, 2008).

4. Legislative Decree n. 235 of 30th December, 2010 "*Amendments and additions to Legislative Decree n. 82 of 7 March, 2005, containing the Digital Administration Code, pursuant to article 33 of Law n. 69 of 18 June, 2009"* (Ordinary Supplement n. 8 of Official Journal of 10th January, 2011).

5. Italian Organization for Standardization. [UNI 10529. *"Medicina trasfusionale. Scambio di informazioni tra le strutture del sistema trasfusionale"].* Milan,,1996.

6. Catalano L, Piccinini V, Pati I, et al. *Italian Blood System 2018: activity data, haemovigilance and epidemiological surveillance. Volume 1*. Volume 1. Roma: Istituto Superiore di Sanità; 2019. (Rapporti ISTISAN 19/27).

7. Ministry of Health Decree of 2nd November, 2015 "*Provisions relative to quality and safety standards of blood and blood components*" (Ordinary Supplement n. 300 of Official Journal of 28th December, 2015)

8. European Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. (Official Journal of European Union L33 of 8th February, 2003).

9. European Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events. (Official Journal of European Union L256 of 1st October, 2005).

10. Legislative Decree of 9th November, 2007, n. 207 "*Implementation of Directive 2005/61/EC, implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events*". (Ordinary Supplement n. 228 of Official Journal of n. 261 of 9th November, 2007).

11. Legislative Decree of 20th December, 2007, n. 261. "*Revision of Legislative Decree of 19th August, 2005, n. 191, implementing Directive 2002/98/EC setting standards of*

quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components". (Official Journal General Series n. 19 of 23th January, 2008).

12. Catalano L, Piccinini V, Pati I, et al. *Sistema trasfusionale italiano 2017: dati di attività, emovigilanza e sorveglianza epidemiologica. Volume 1/ Italian Blood System 2017: activity data, haemovigilance and epidemiological surveillance. Volume 1*. Roma: Istituto Superiore di Sanità; 2019. (Rapporti ISTISAN 19/6).
13. European Directorate for the Quality of Medicines. Guide to the preparation, use and quality assurance of blood components - Recommendation No. R (95) 15, 20th Edition,2020. Available at: https://www.edqm.eu/en/blood-guide Accessed on 01/06/2020.
14. European Medicines Agency. Committee for Medicinal Products for Human Use. *Guideline on epidemiological data on blood transmissible infections*. London, 2016. (EMA/CHMP/BWP/548524/2008 rev 1).
    Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-epidemiological-data-blood-transmissible-infections-revision-1_en.pdf.
    Accessed on 01/06/2020.

ANNEX 1 - SUPPLEMENTAL FIGURES

Activities of the italian blood system - regional and national indicators (2019)

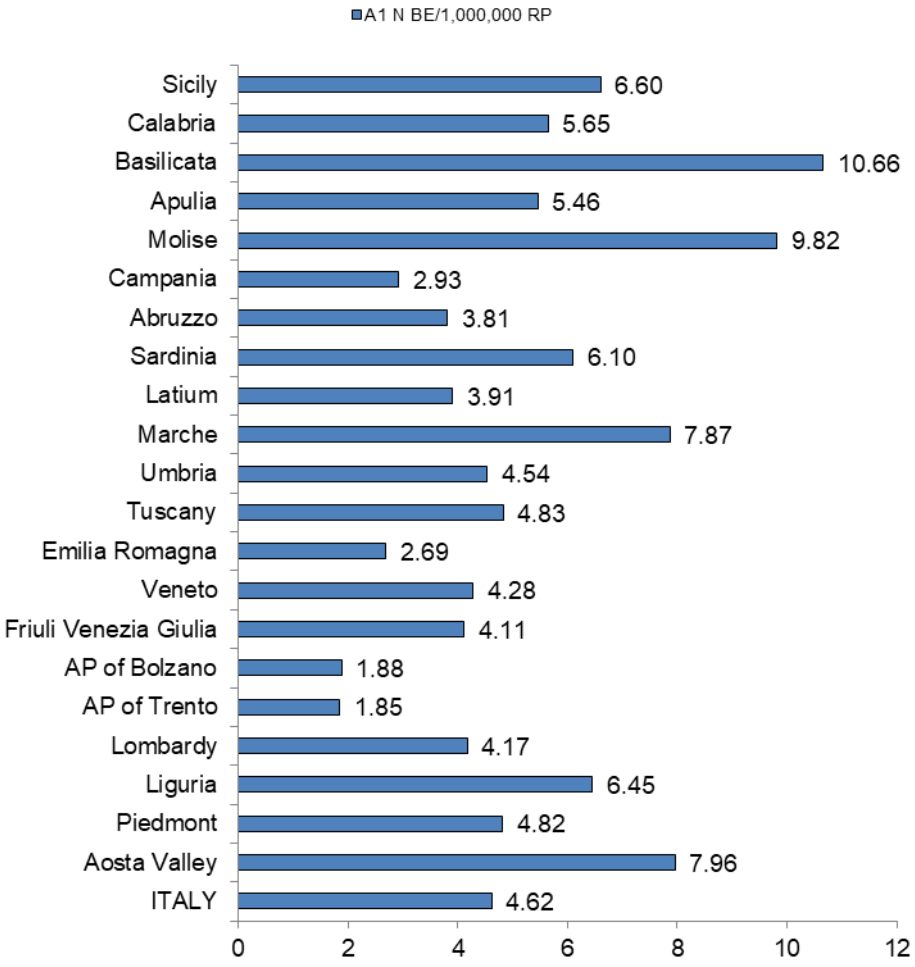

Figure A1 - INDICATOR A1: N of BEs (as stated by ex Art. 2, paragraph 1, letter e of Legislative Decree 261/2007) /1,000,000 resident population (2019).
N: number; BE: blood establishment/s; RP: resident population; AP: Autonomous Province.

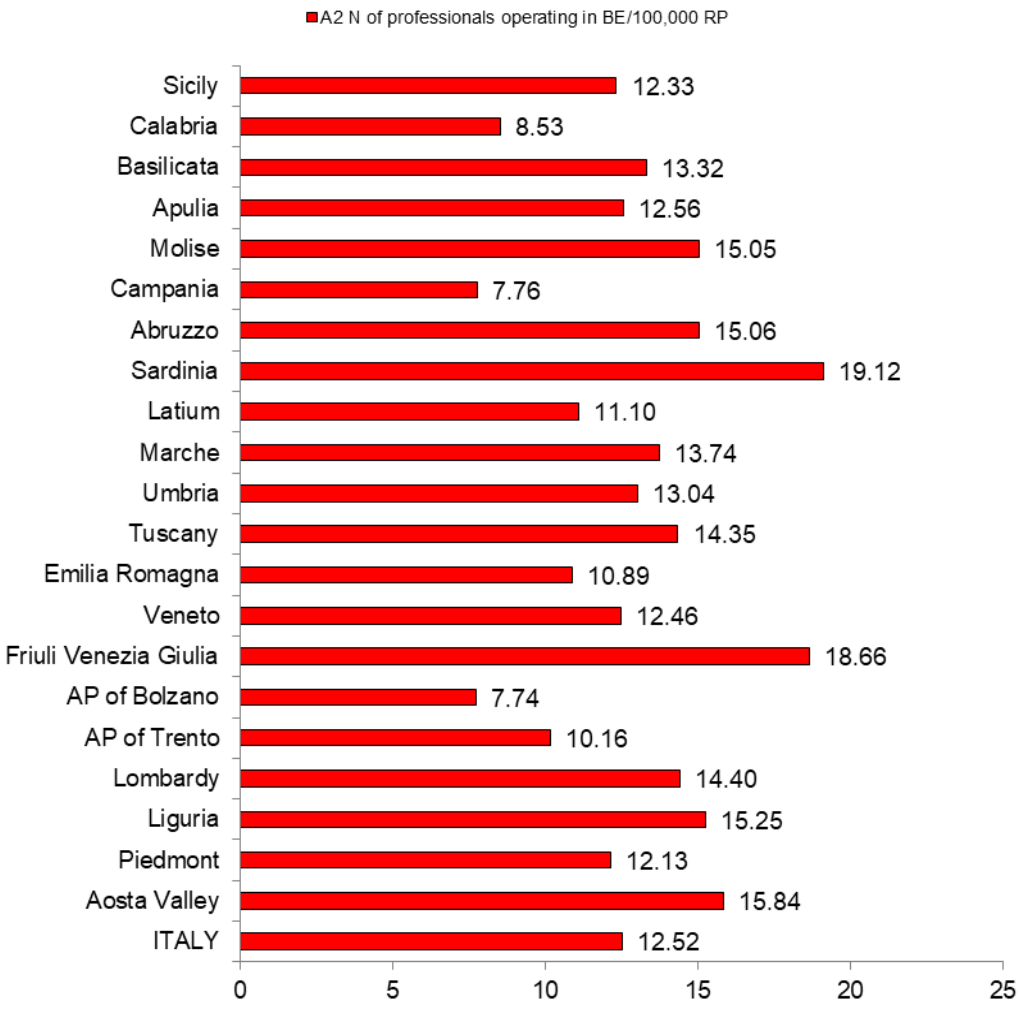

Figure A2 - INDICATOR A2: N of professionals operating in BEs (as stated by ex Art. 2, paragraph 1, letter e of Legislative Decree 261/2007) /100,000 resident population (2019).
N: number; BE: blood establishment/s; RP: resident population; AP: Autonomous Province.

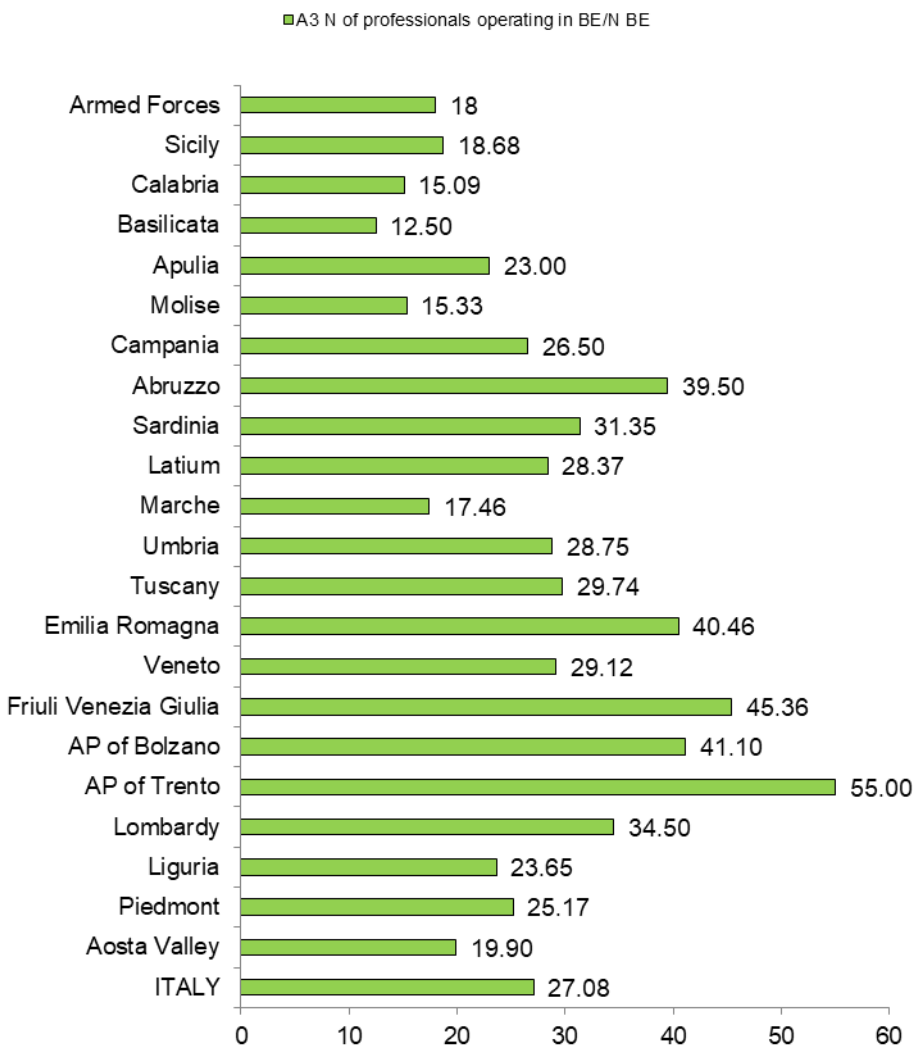

Figure A3 - INDICATOR A3: N of professionals operating in BEs (as stated by ex Art. 2, paragraph 1, letter e of Legislative Decree 261/2007)/N of BE reported in SISTRA (2019).
N: number; BE: blood establishment/s; AP: Autonomous Province.

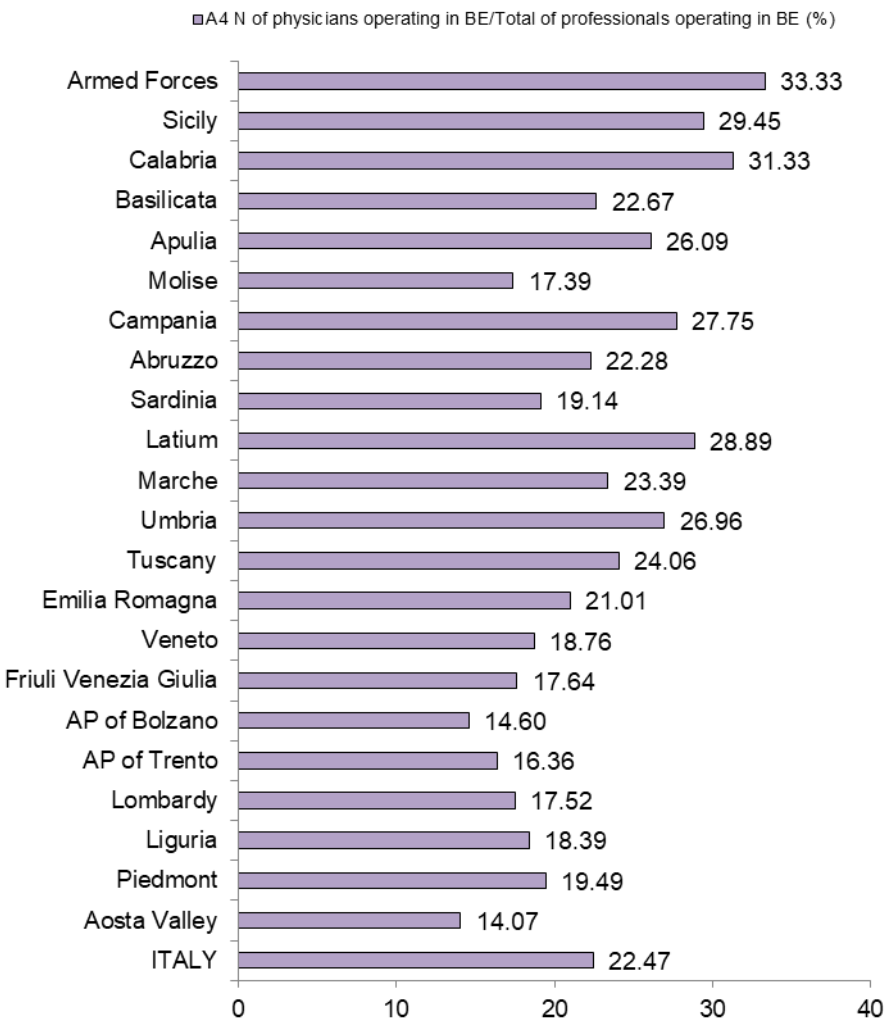

Figure A4 - INDICATOR A4: N of physicians operating in BEs/Total of professionals operating in BEs (%) (excluding physicians operating in BCSs) (2019).
N: number; BE: blood establishment/s; AP: Autonomous Province.

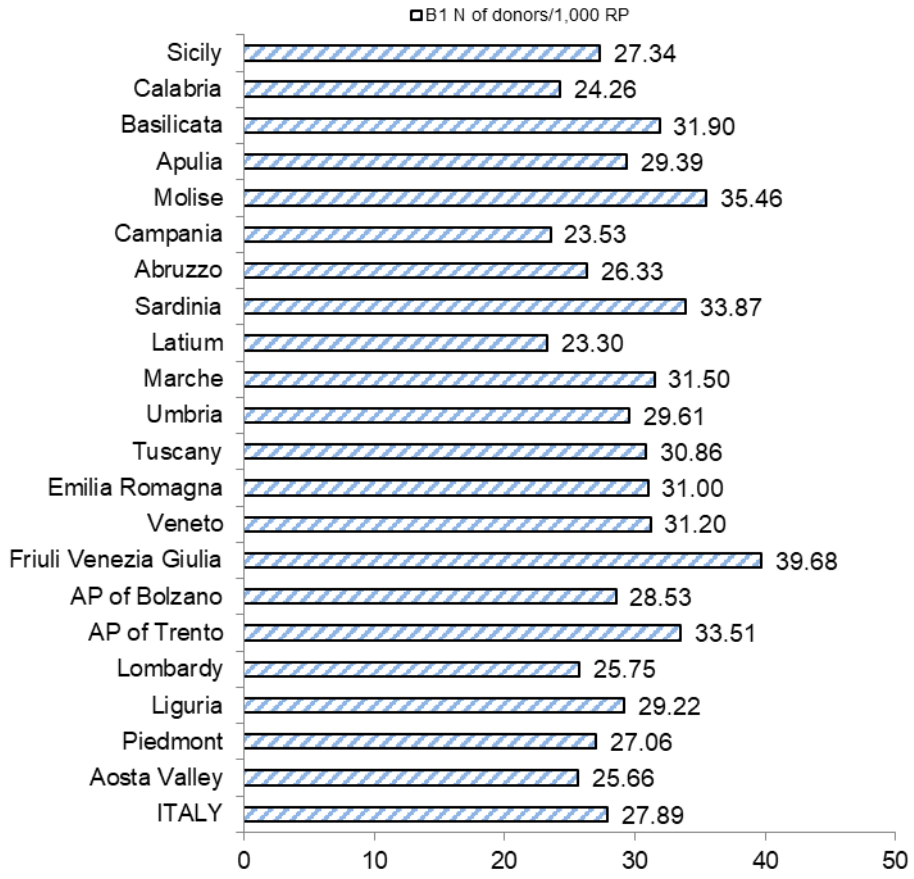

Figure A5 - INDICATOR B1: Regional blood donors distribution/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

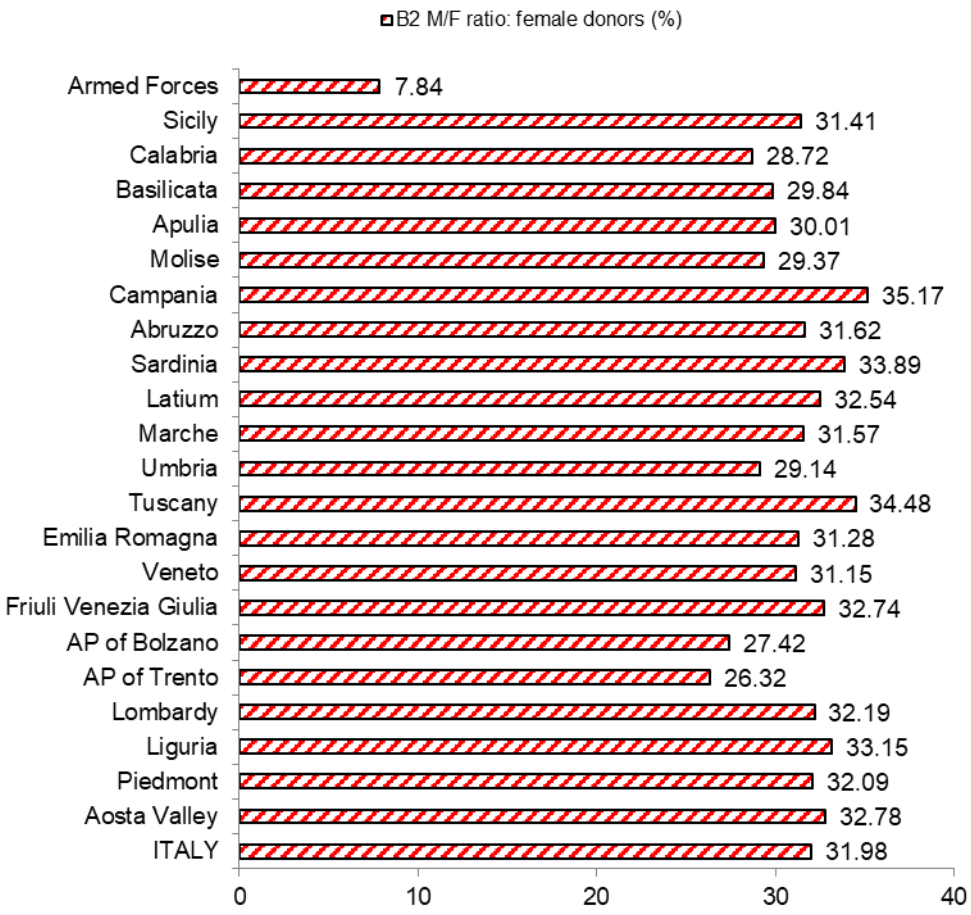

Figure A6 - INDICATOR B2: M/F ratio, female donors percentage (2019).
AP: Autonomous Province; M: male; F: Female.

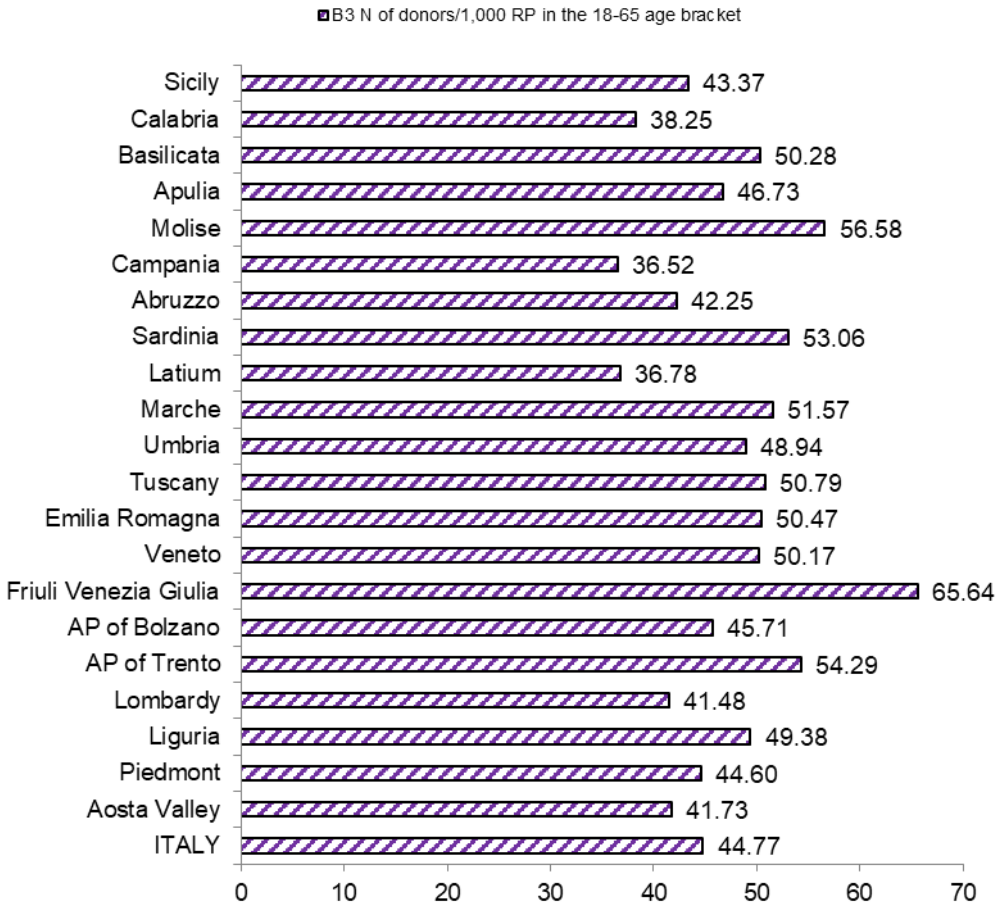

Figure A7 - INDICATOR B3: N of donors/1,000 resident population in the 18-65 age bracket (2019).
N: number; RP: resident population; AP: Autonomous Province.

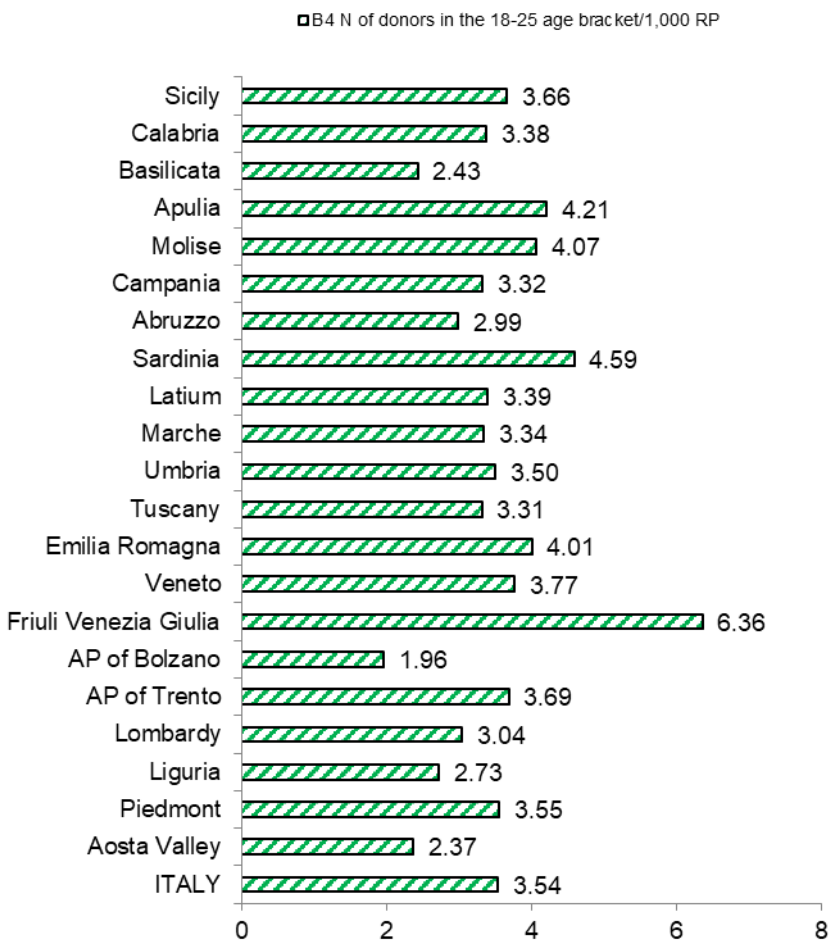

Figure A8 - INDICATOR B4: N of donors in the 18-25 age bracket/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

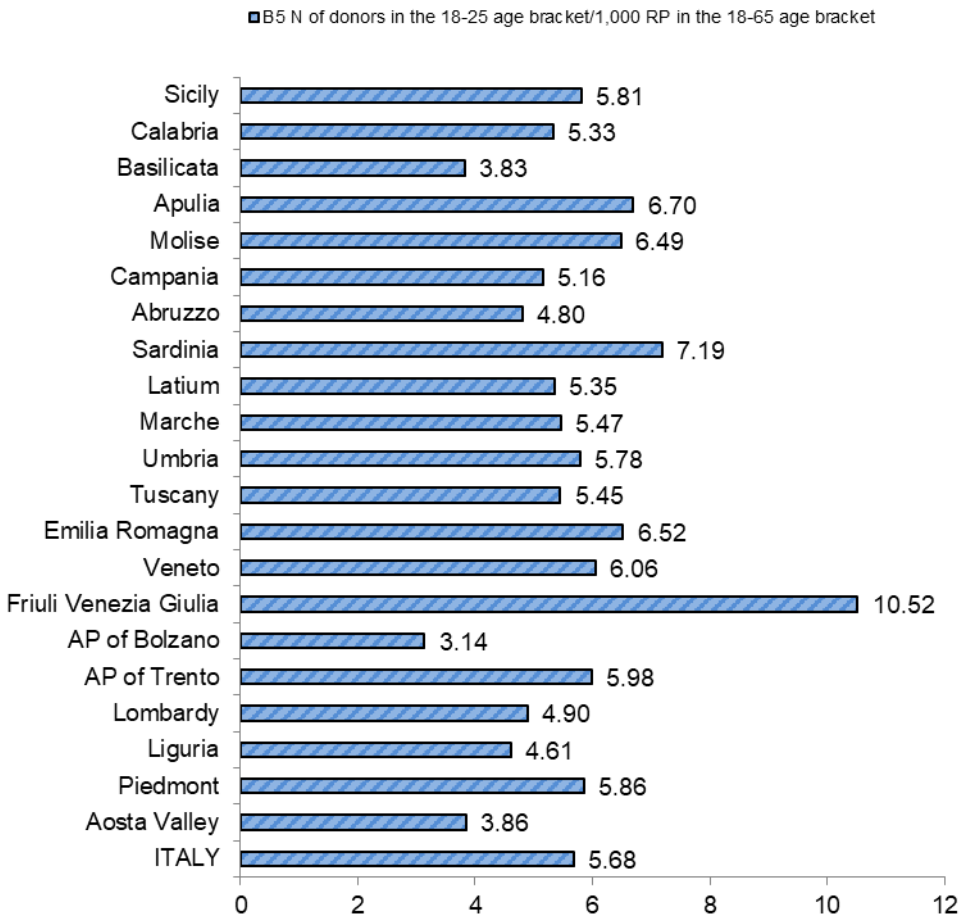

Figure A9 - INDICATOR B5: N of donors in the 18-25 age bracket/1,000 resident population in the 18-65 age bracket (2019).
N: number; RP: resident population; AP: Autonomous Province.

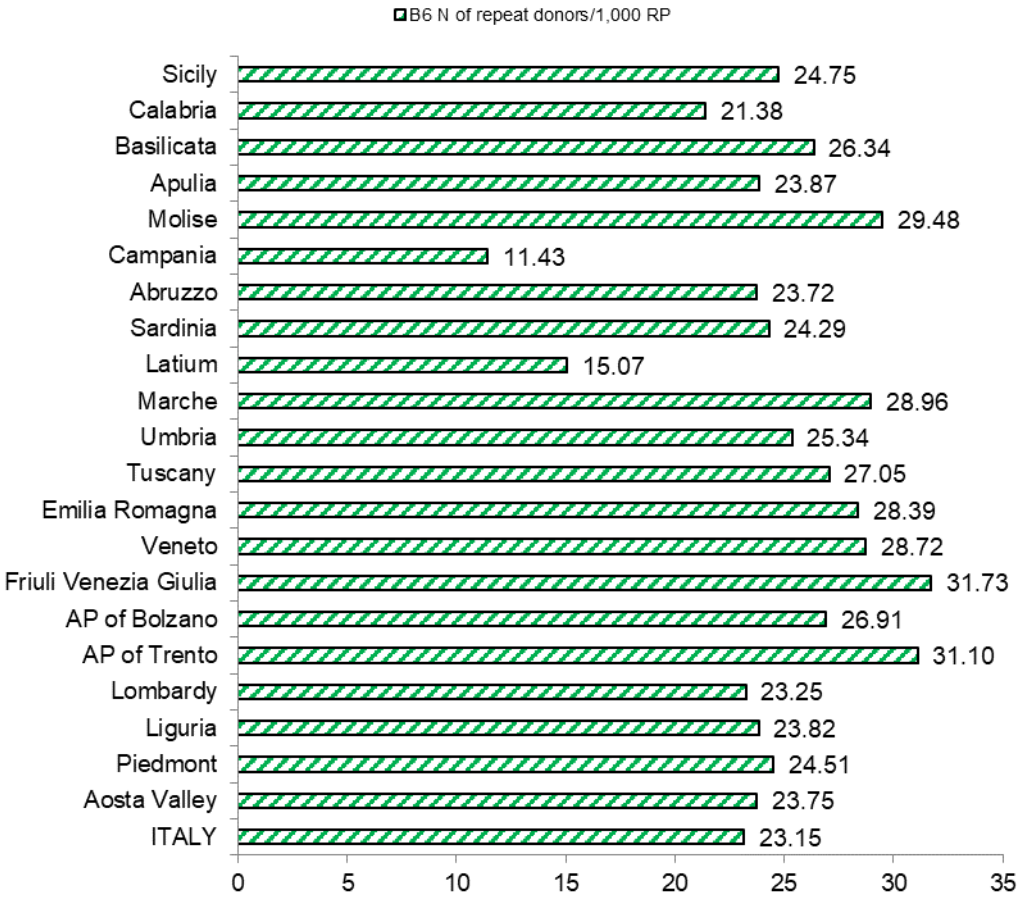

Figure A10 - INDICATOR B6: N of repeat donors/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

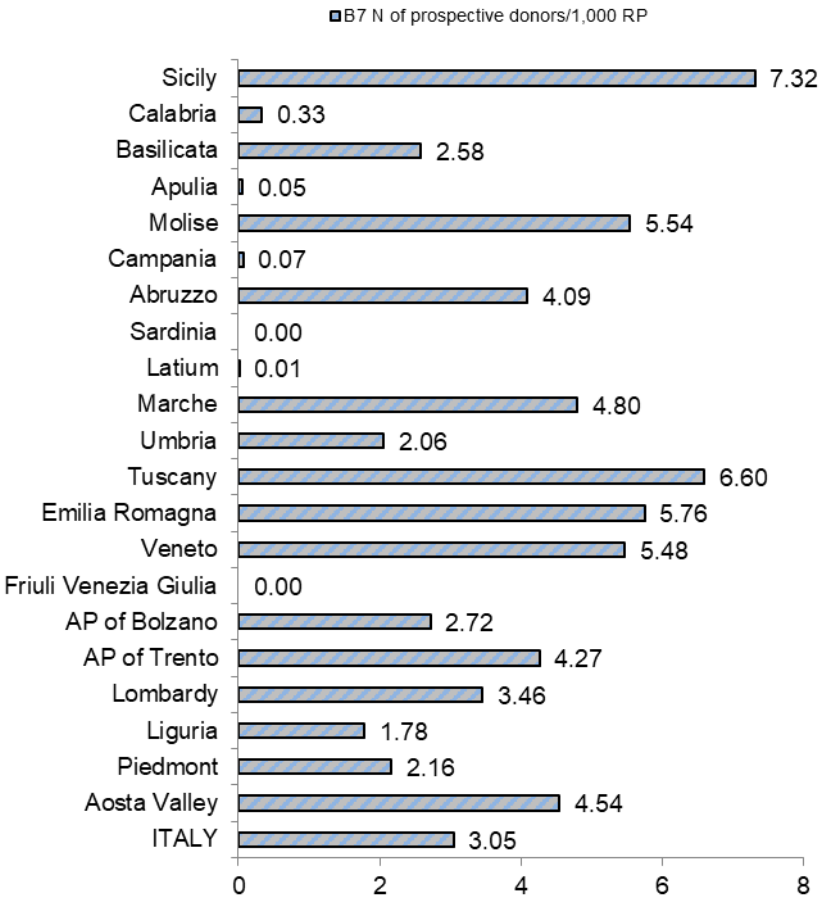

Figure A11 - INDICATOR B7: N of prospective donors/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

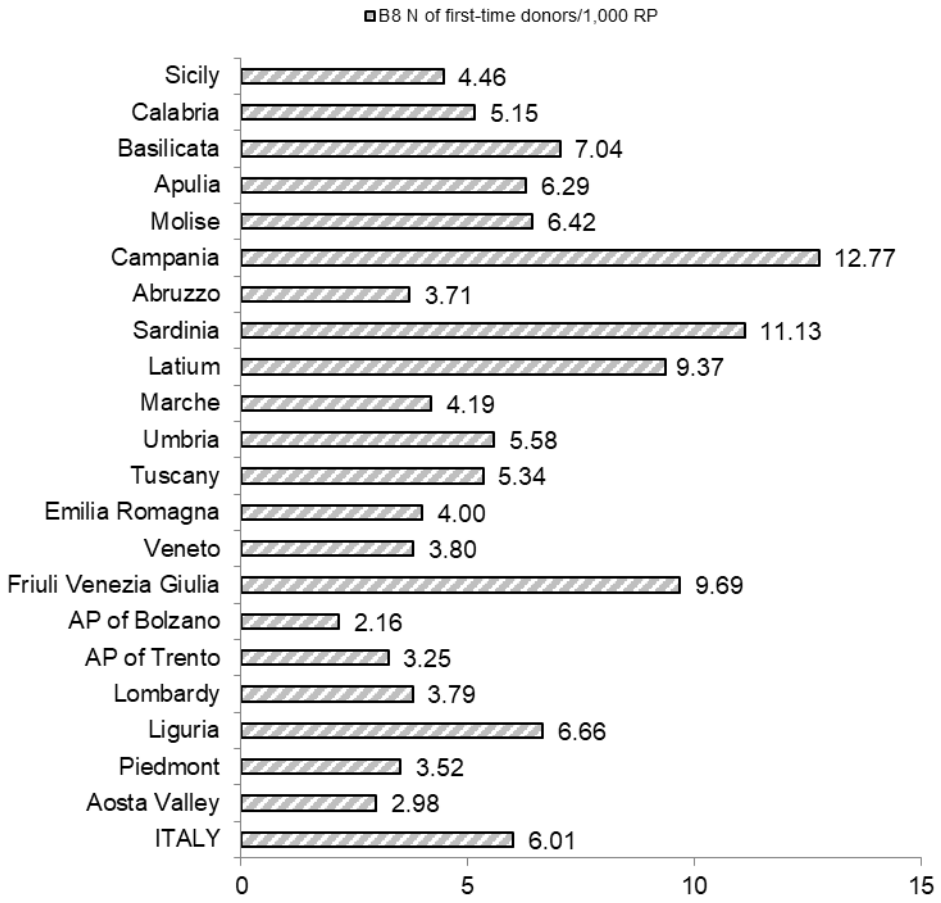

Figure A12 - INDICATOR B8: N of first-time donors/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

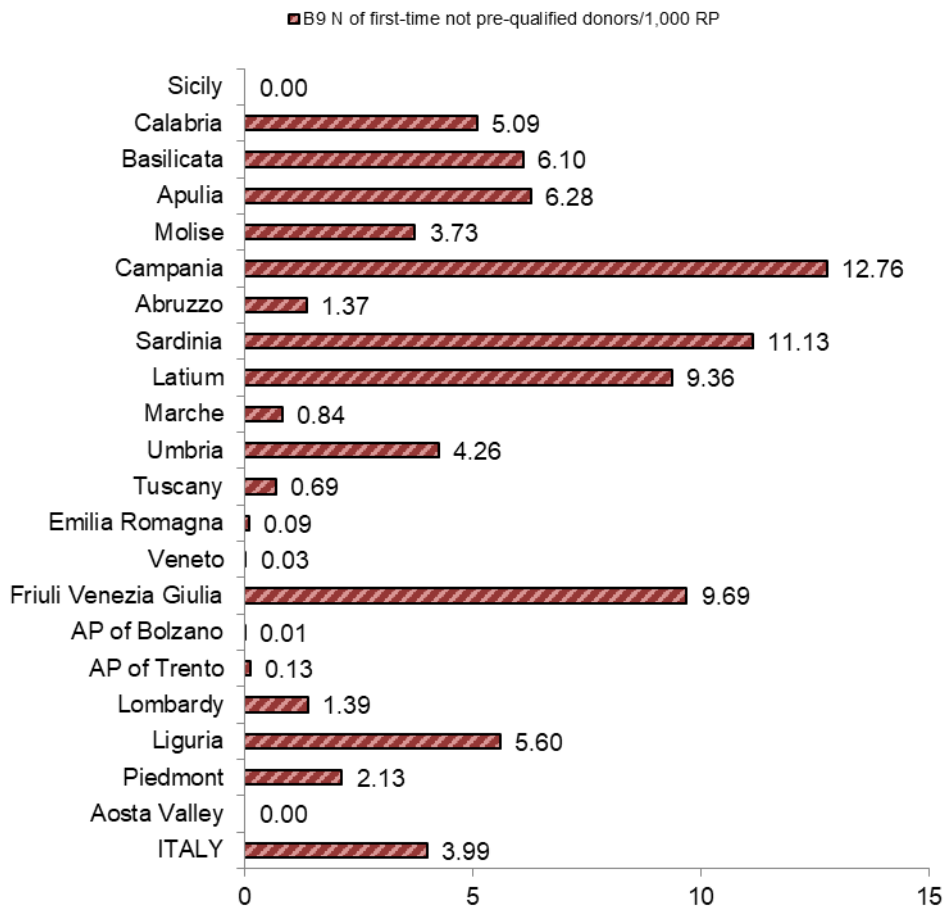

Figure A13 - INDICATOR B9: N of first-time not pre-qualified donors/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

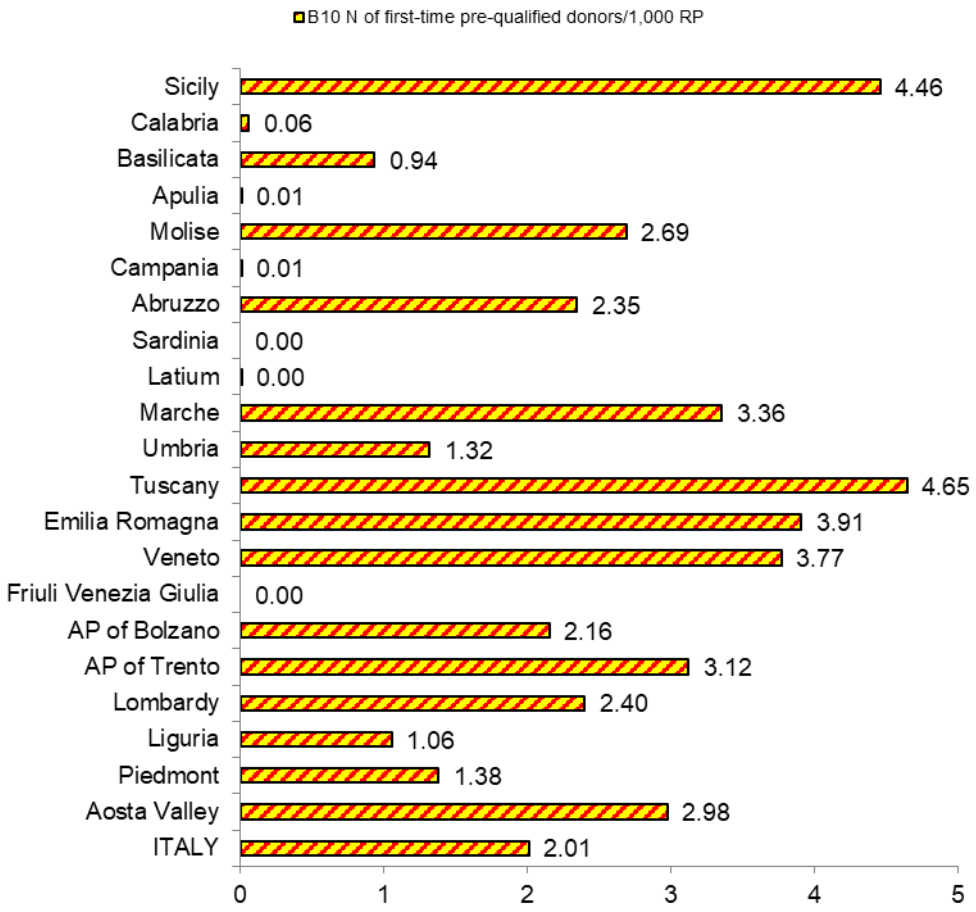

Figure A14 - INDICATOR B10: N of first-time pre-qualified donors/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

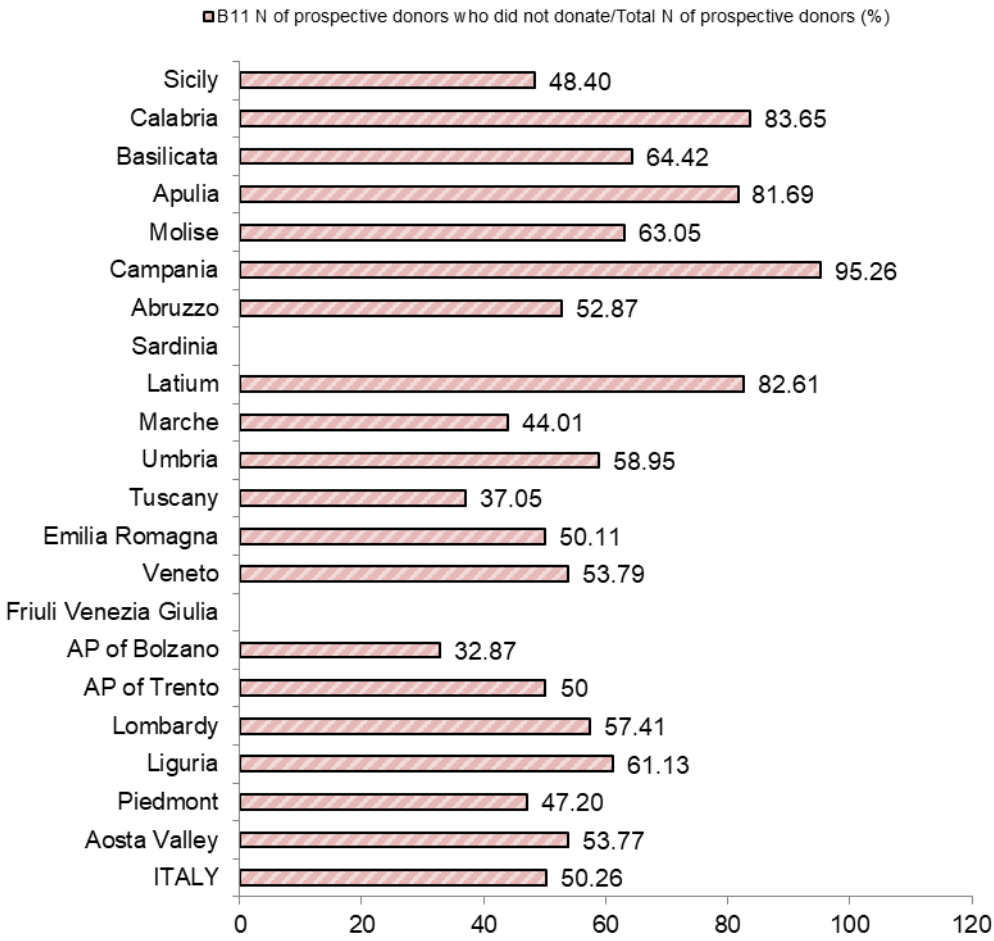

Figure A15 - INDICATOR B11: N of prospective donors who did not donate/Total N of prospective donors (%) (2019).
N: number; AP: Autonomous Province.

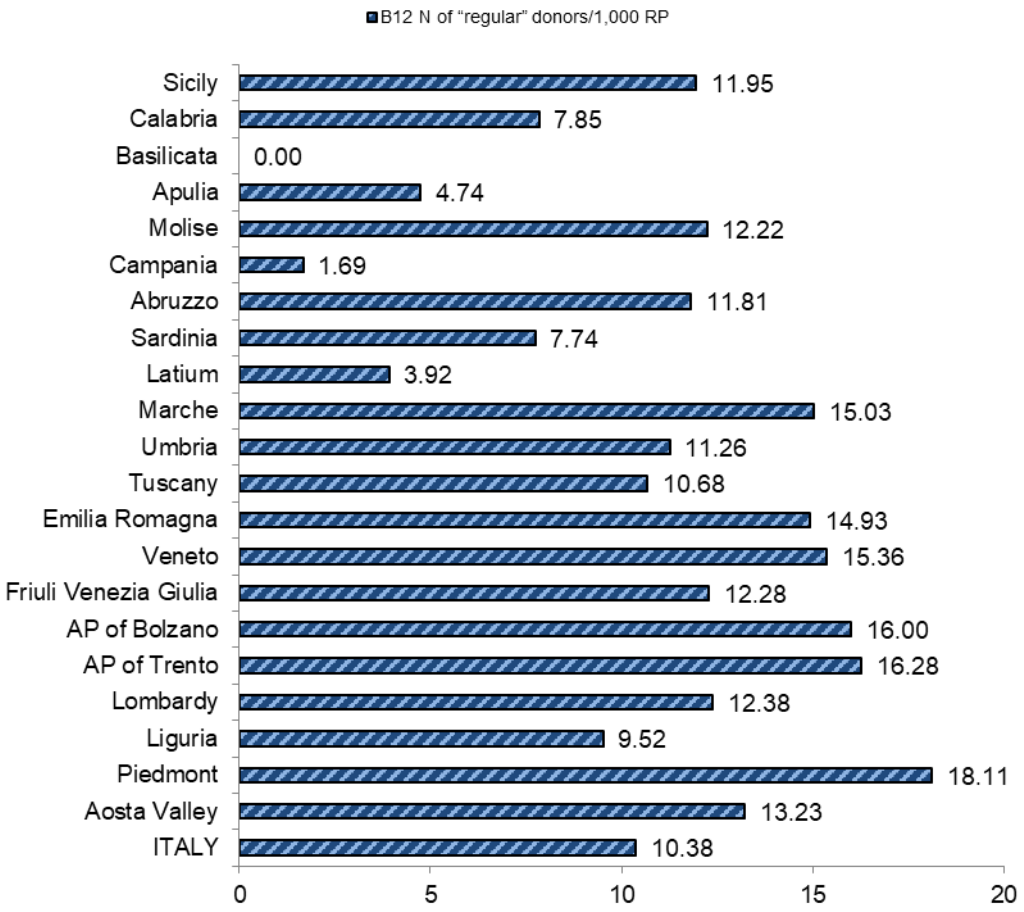

Figure A16 - INDICATOR B12: N of "regular" donors/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

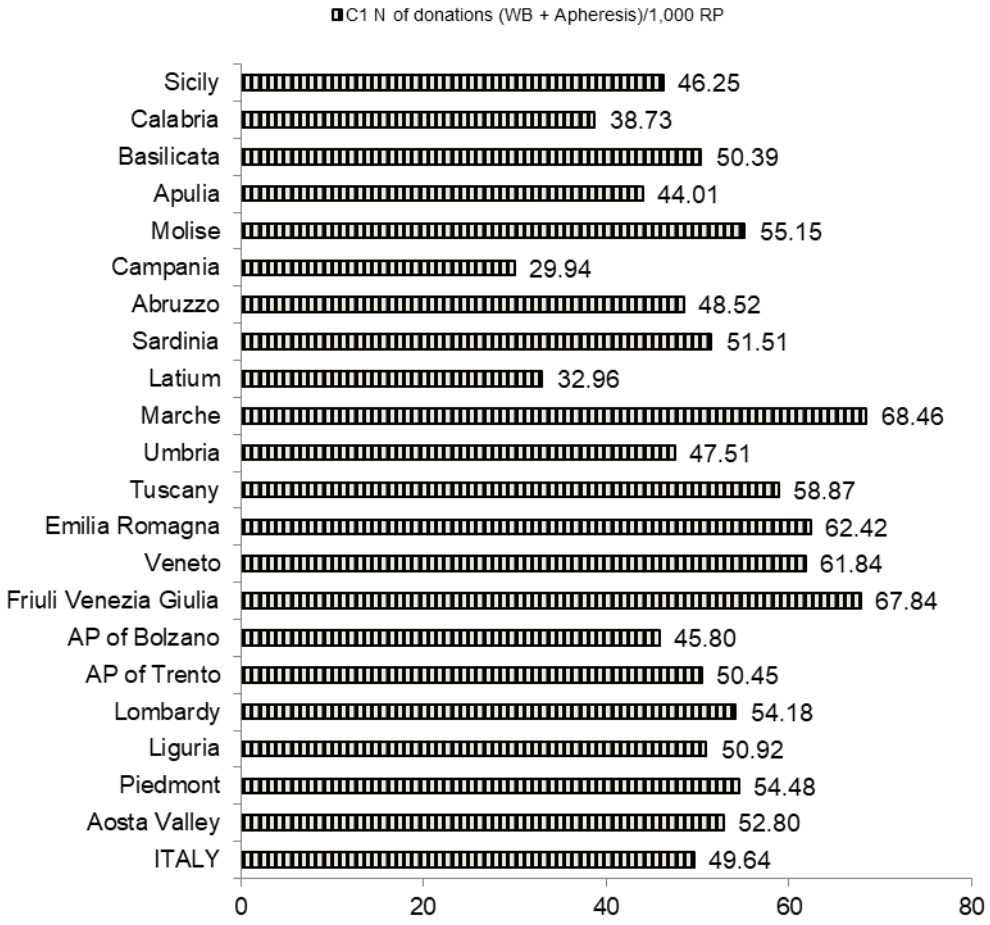

Figure A17 - INDICATOR C1: N of whole blood and apheresis donations/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province; WB: whole blood.

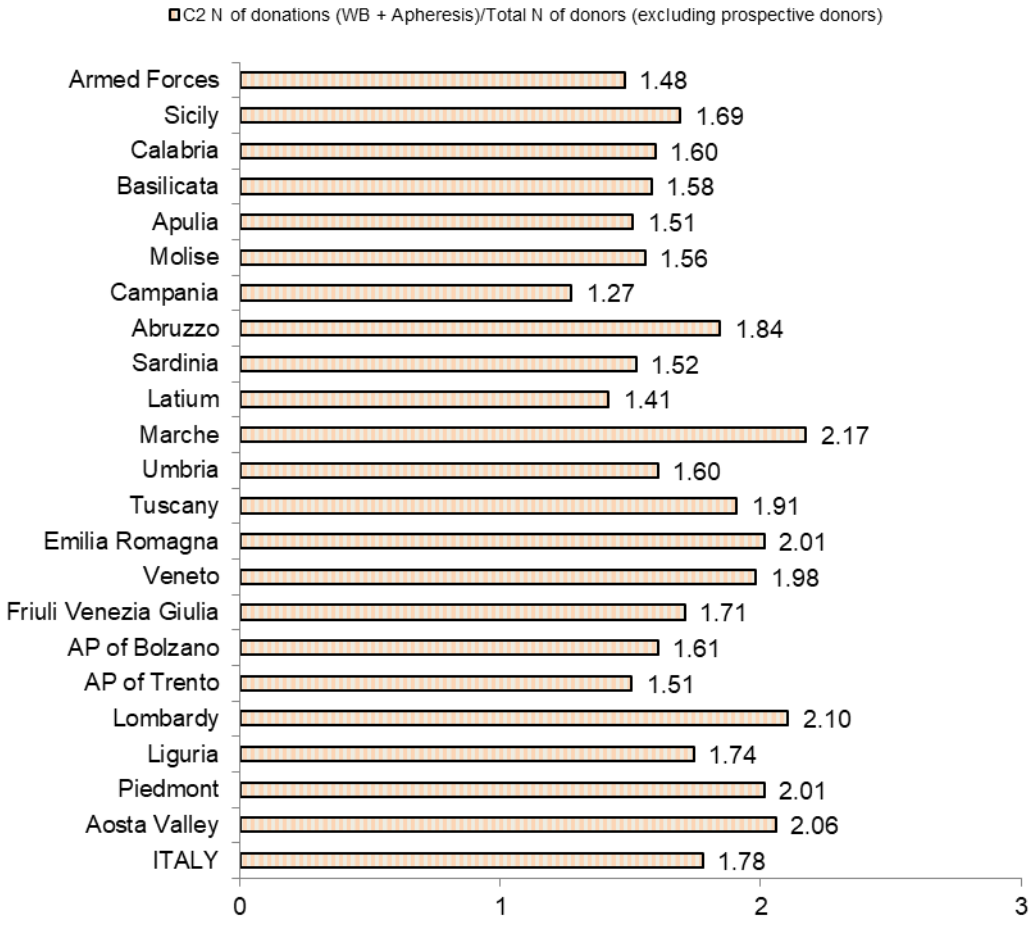

Figure A18 - INDICATOR C2: N of whole blood and apheresis donations/Total N of donors (excluding prospective donors)(2019).
N: number; AP: Autonomous Province; WB: whole blood.

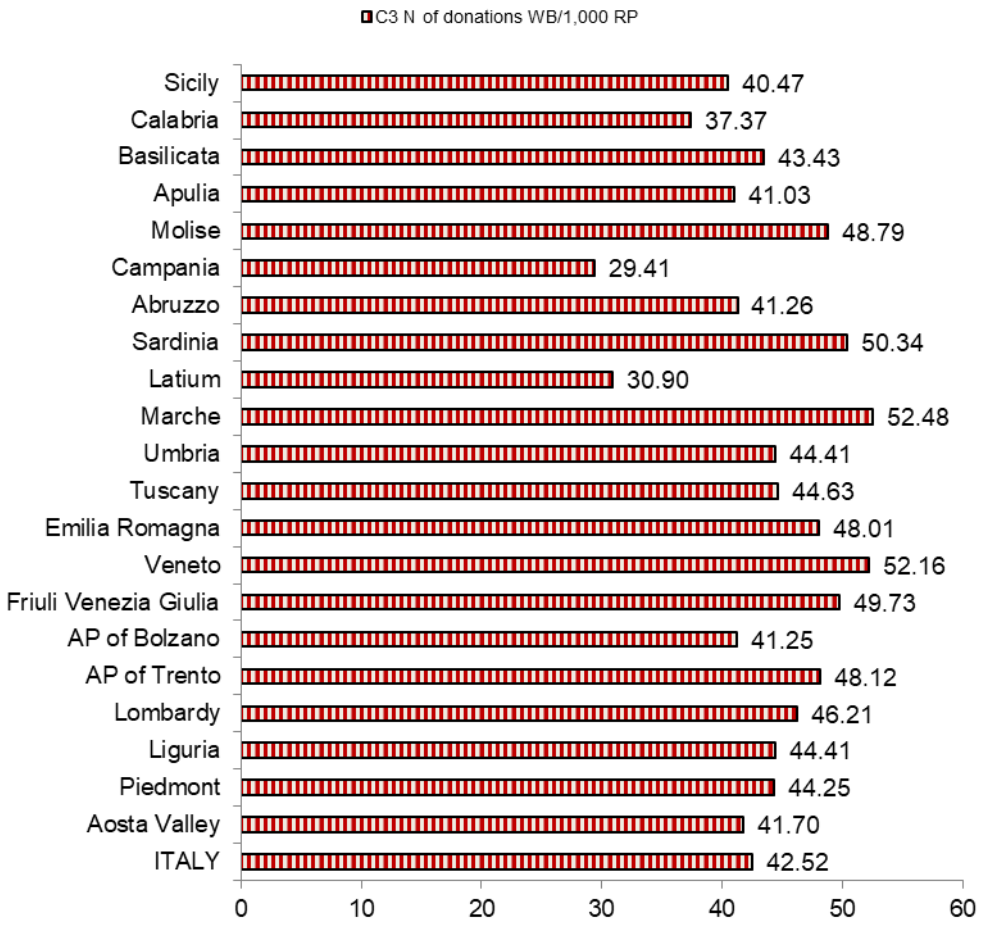

Figure A19 - INDICATOR C3: N of whole blood donations/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province; WB: whole blood.

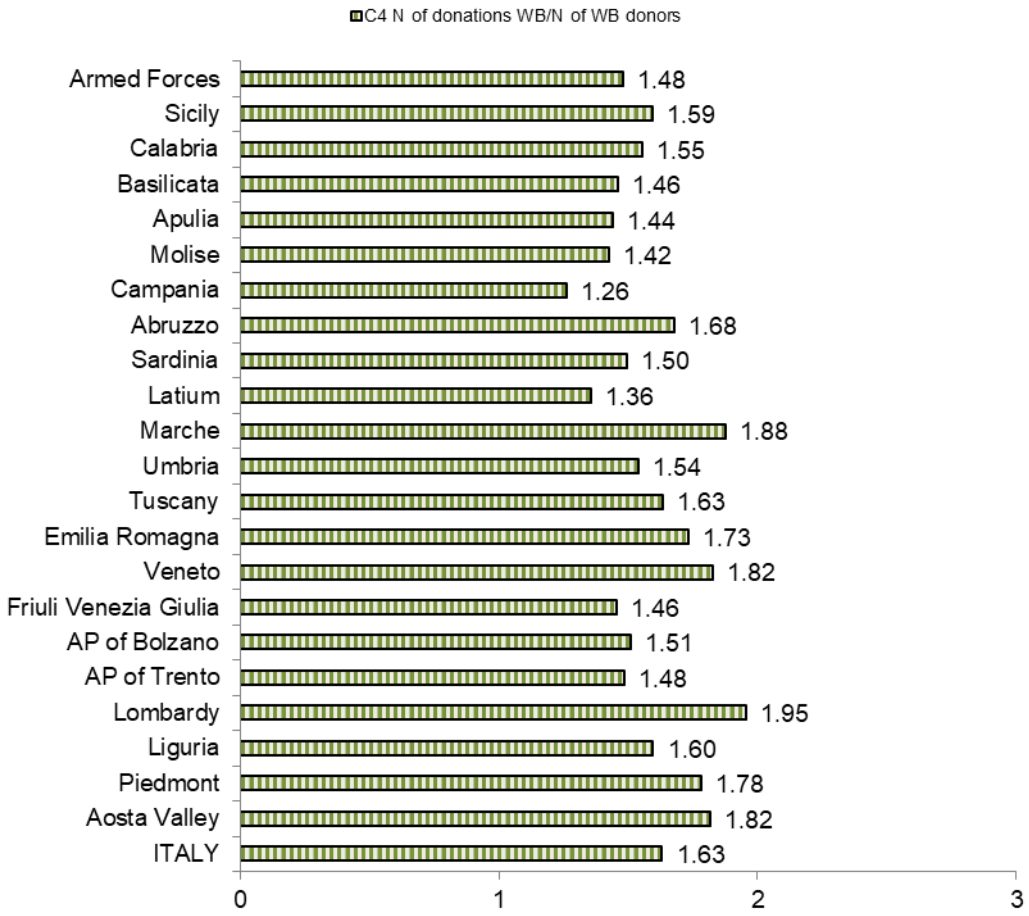

Figure A20 - INDICATOR C4: N of whole blood donations/N of whole blood donors (2019).
N: number; AP: Autonomous Province; WB: whole blood.

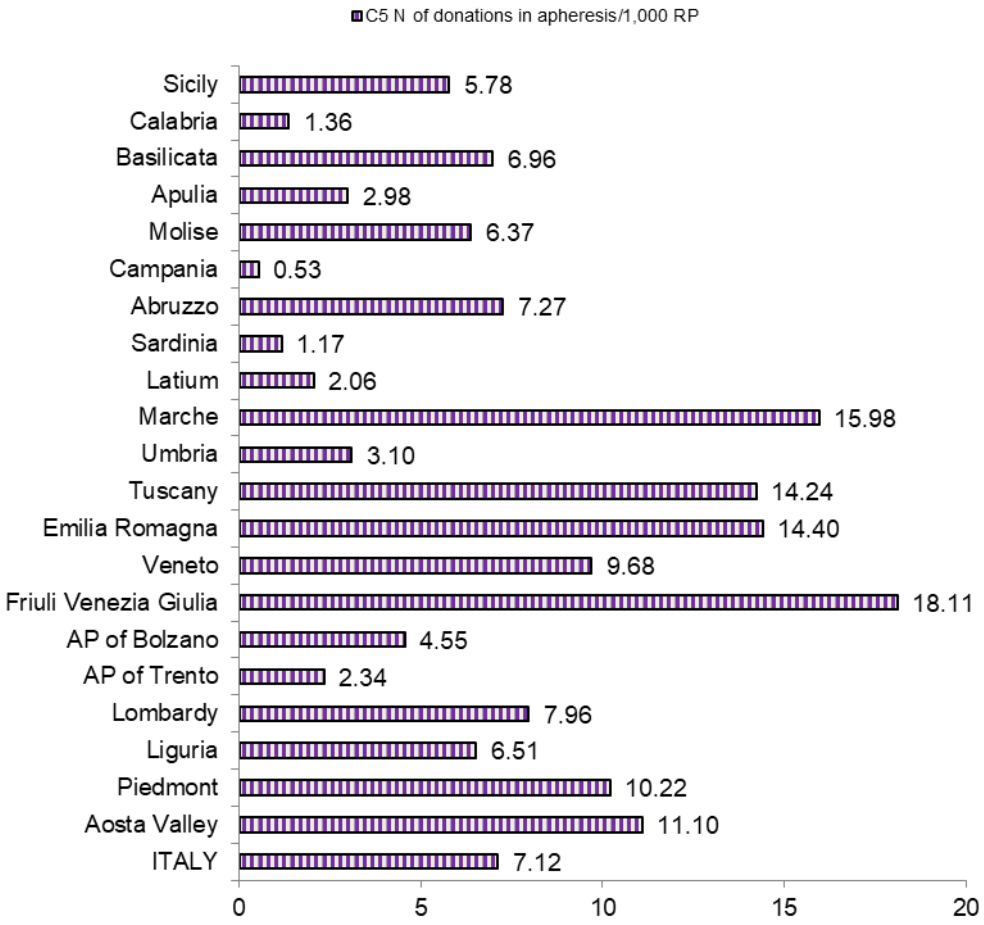

Figure A21 - INDICATOR C5: N of donations in apheresis/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

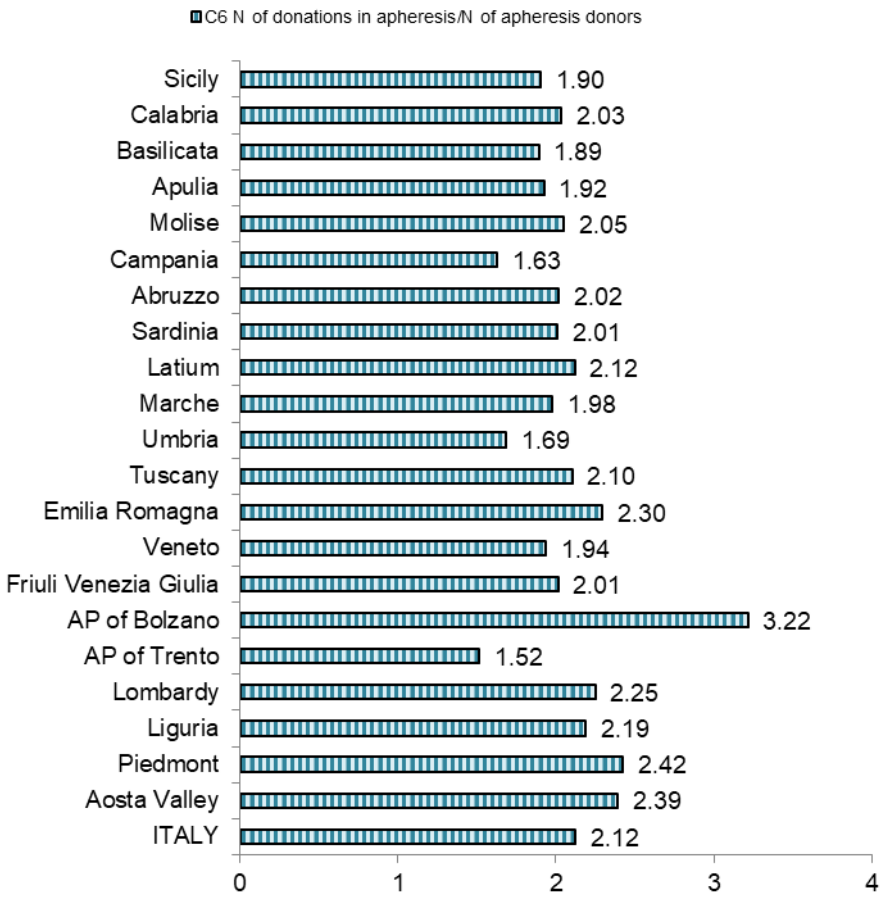

Figure A22 - INDICATOR C6: N of donations in apheresis/N of apheresis donors (2019).
N: number; AP: Autonomous Province.

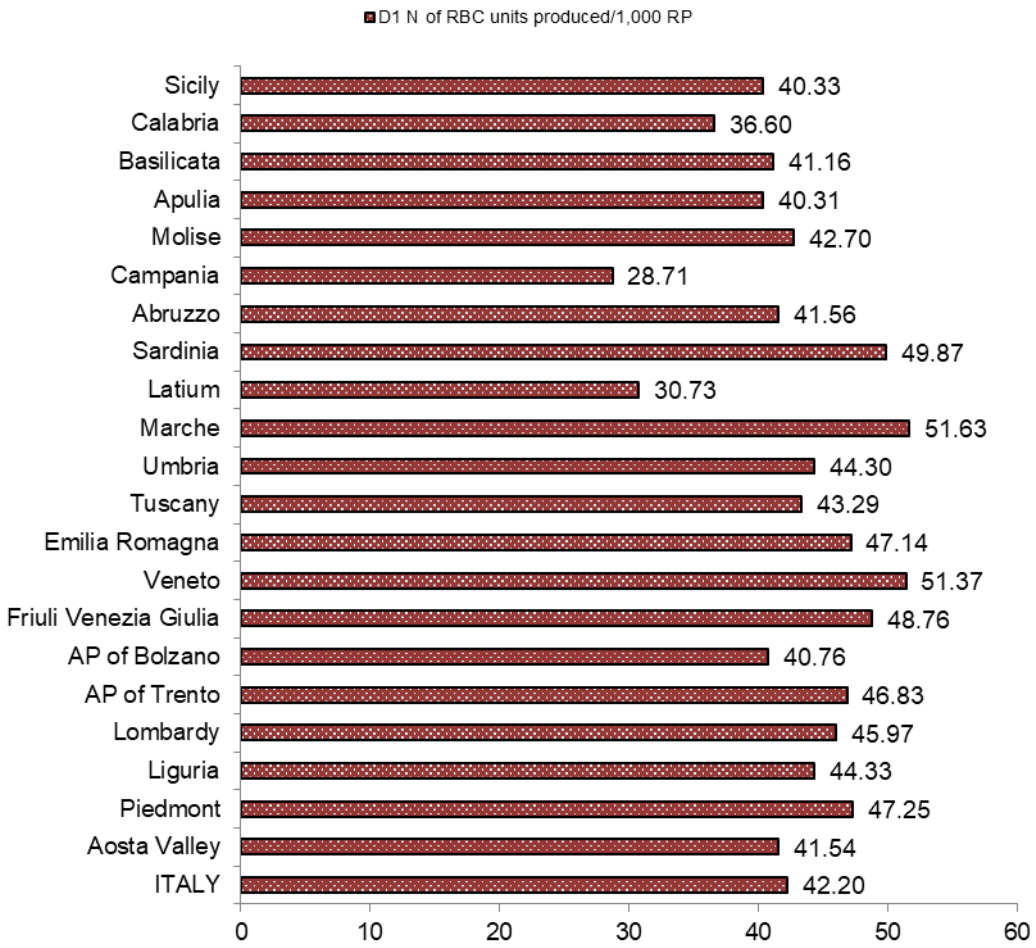

Figure A23 - INDICATOR D1: RBC units produced/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

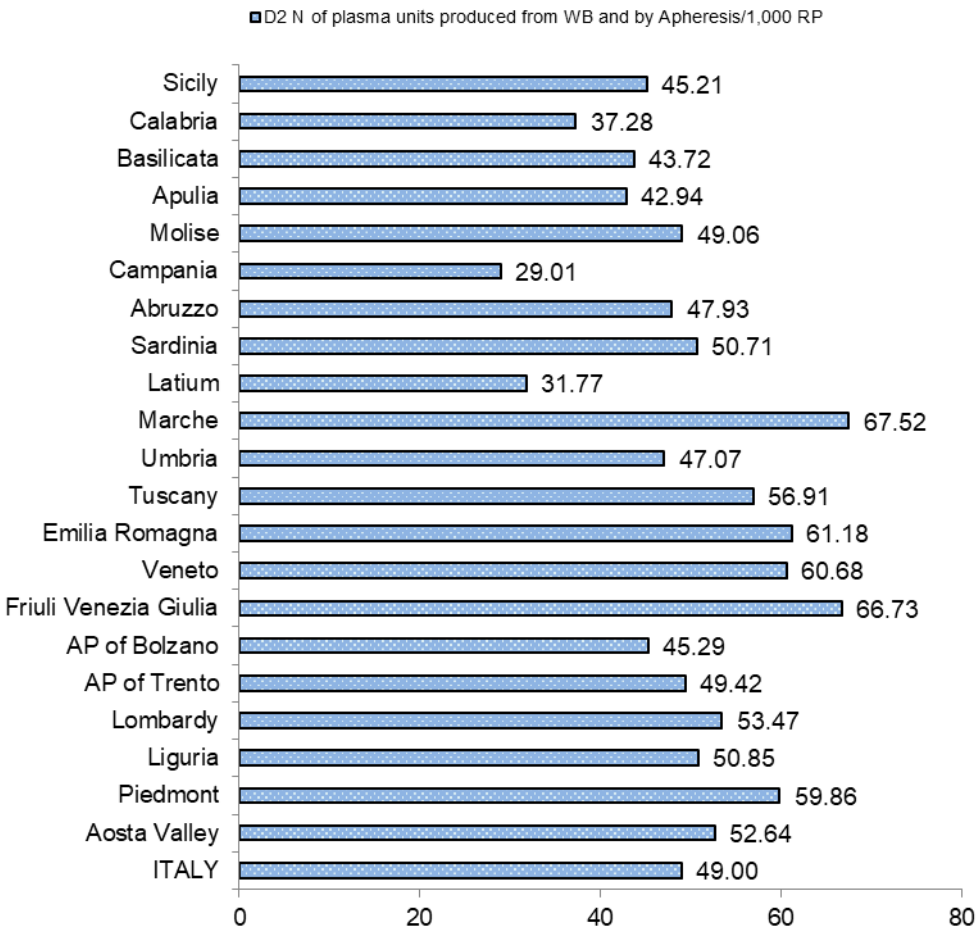

Figure A24 - INDICATOR D2: N of plasma units produced from whole blood and by apheresis/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province; WB: whole blood.

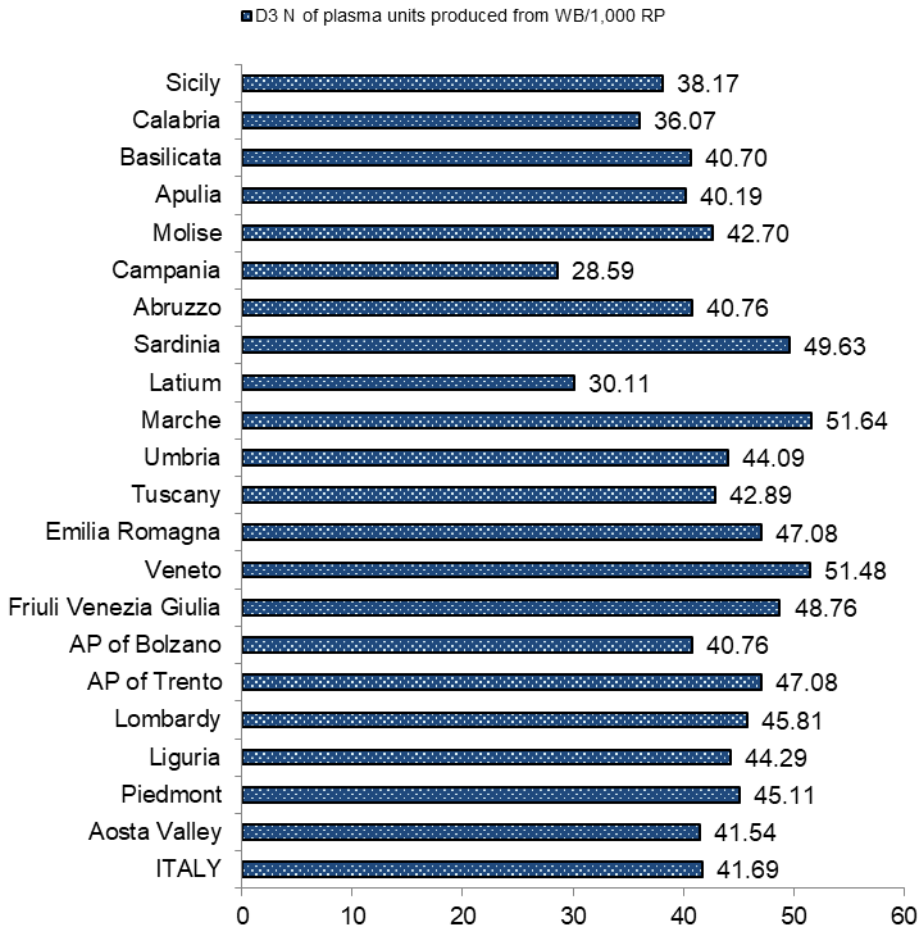

Figure A25 - INDICATOR D3: N of plasma units produced from whole blood/1,000 resident population (2019). N: number; RP: resident population; AP: Autonomous Province; WB: whole blood.

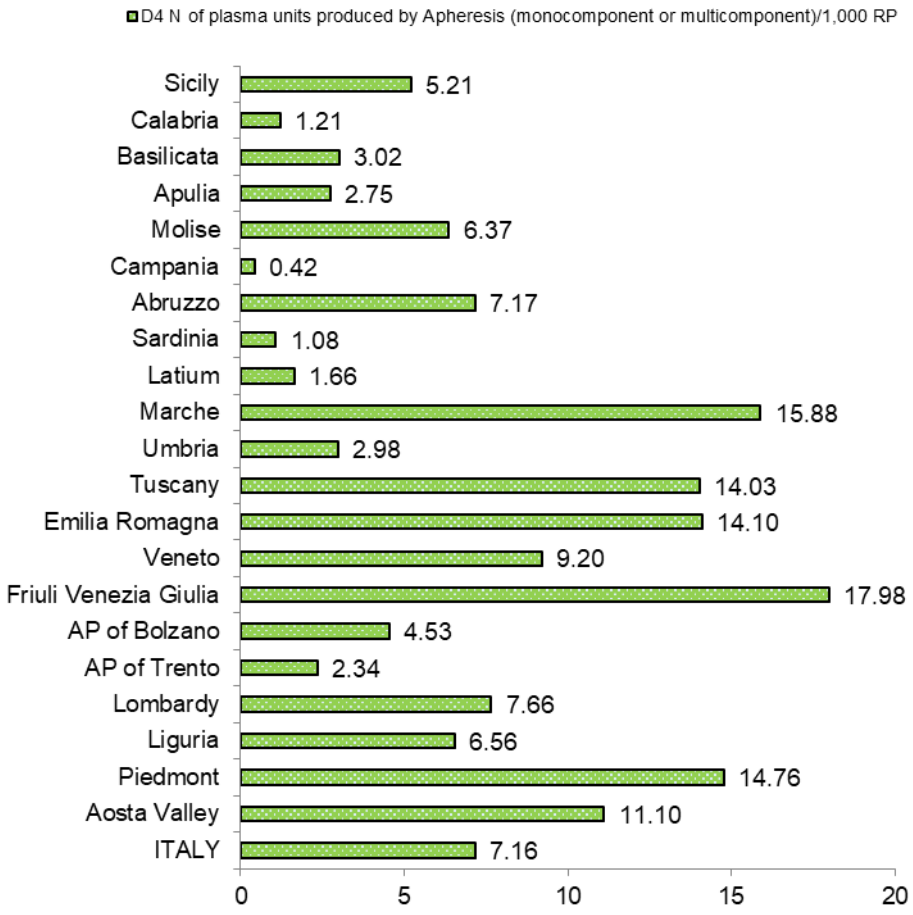

Figure A26 - INDICATOR D4: N of plasma units produced from apheresis (monocomponent + multicomponent)/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

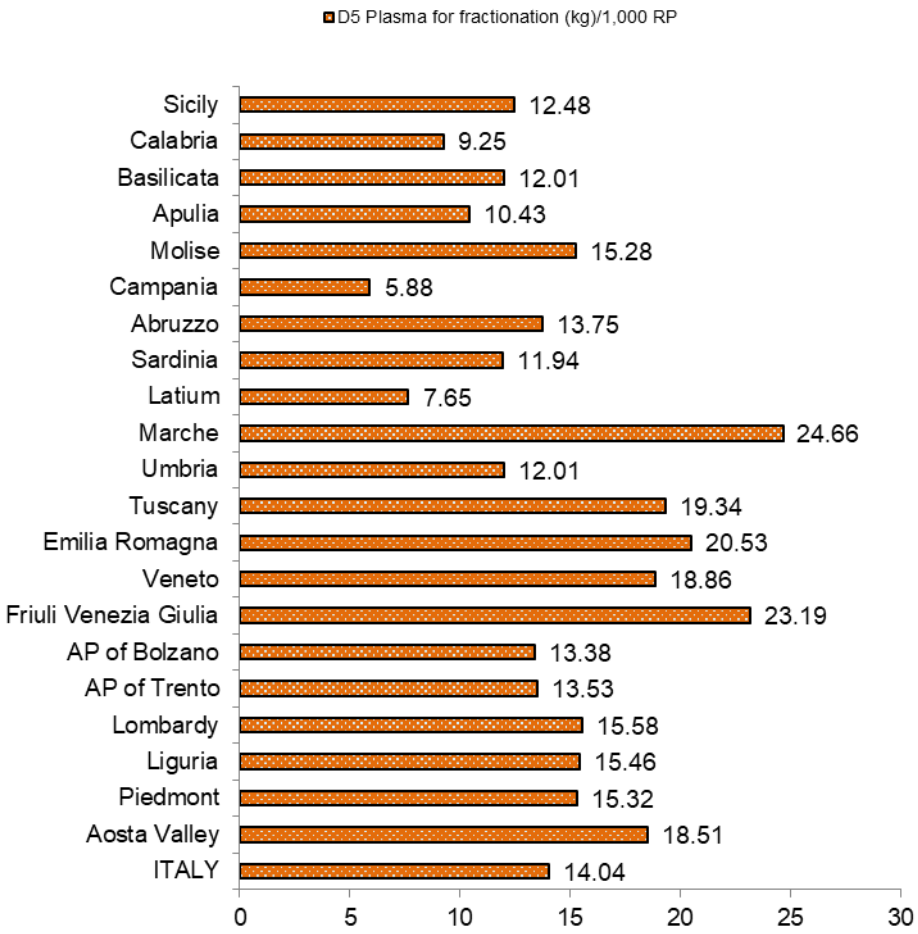

Figure A27 - INDICATOR D5: plasma (kg) for fractionation/1,000 resident population (from SISTRA) (2019). Kg: kilograms; RP: resident population; AP: Autonomous Province.

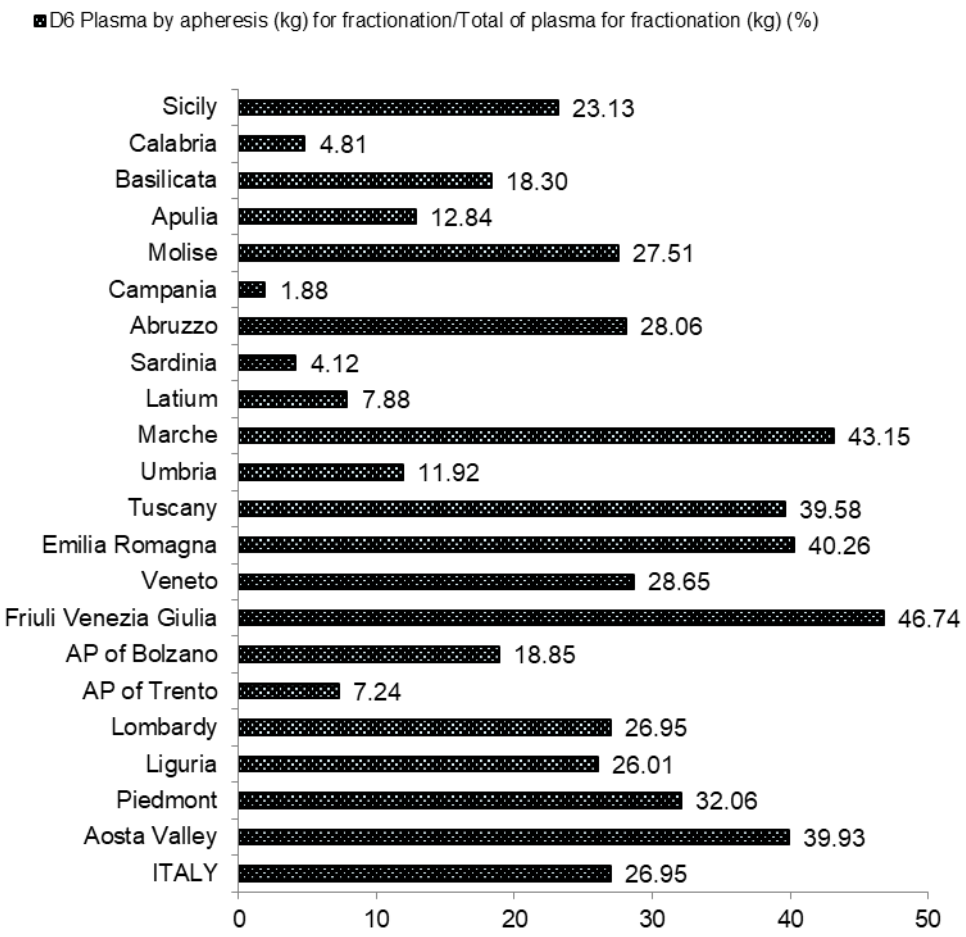

Figure A28 - INDICATOR D6: plasma by apheresis (kg) for fractionation/Total of plasma for fractionation (kg) (%) (2019).
Kg: kilograms; AP: Autonomous Province.

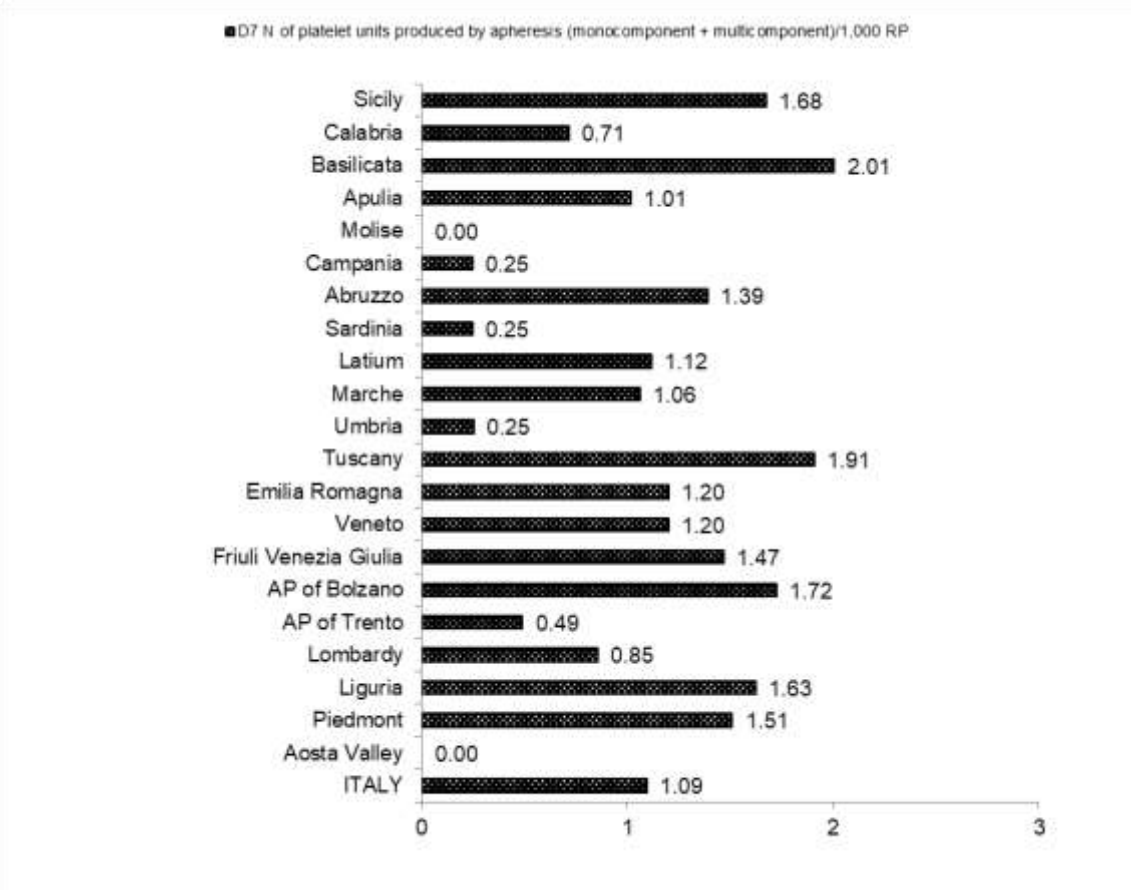

Figure A29 - INDICATOR D7: N of platelet units produced by apheresis (monocomponent + multicomponents)/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

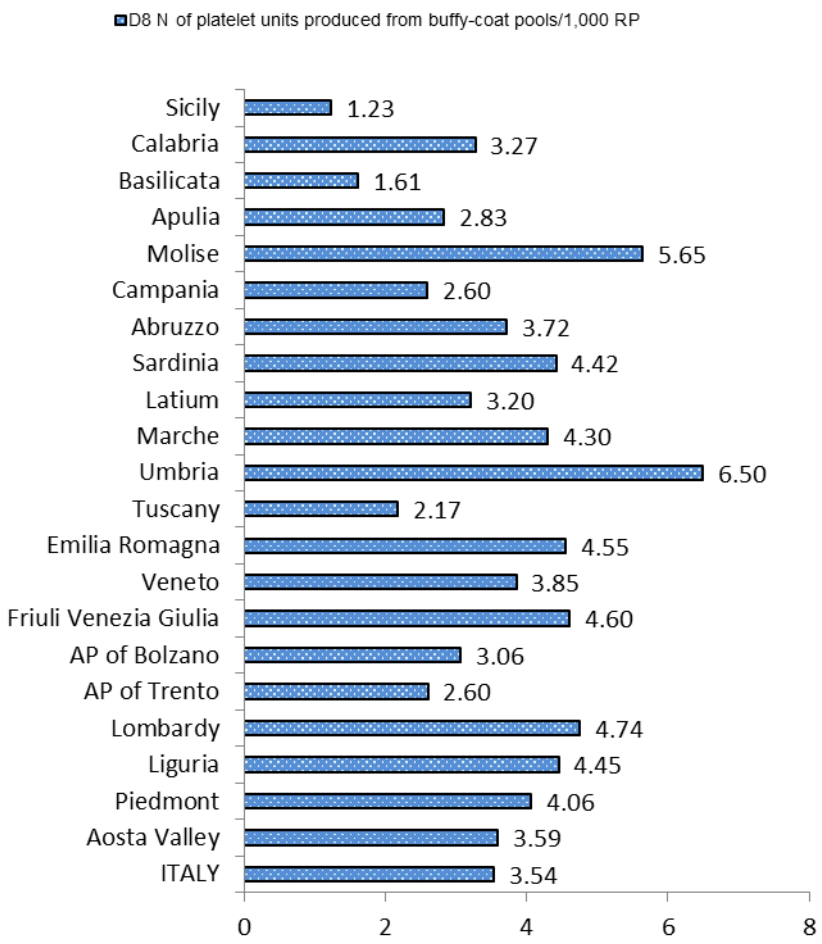

Figure A30 - INDICATOR D8: N of platelet units produced from buffy-coat pools/1,000 resident population (2019). N: number; RP: resident population; AP: Autonomous Province.

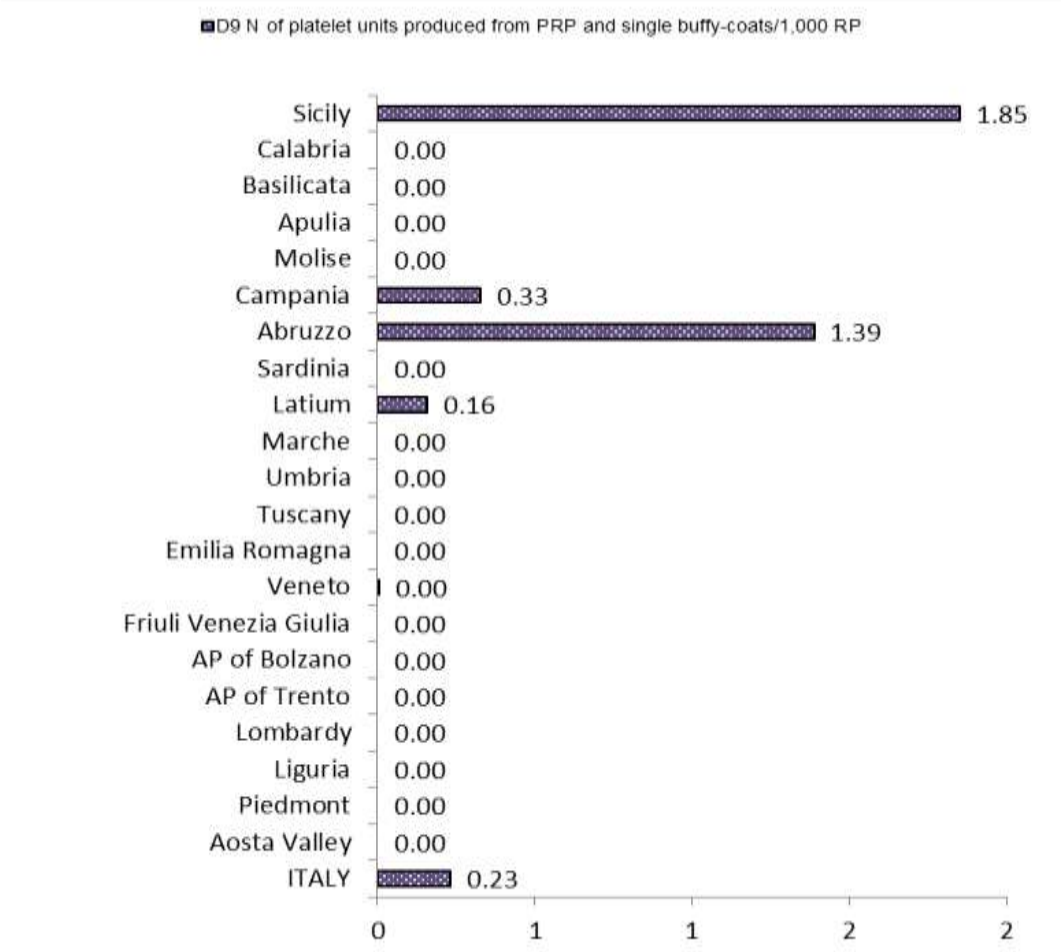

Figure A31 - INDICATOR D9: N of platelet units produced from PRP* and single buffy-coats/1,000 resident population (2019).
N: number; RP: resident population; PRP: patelet rich plasma; AP: Autonomous Province.
*: Since six months after the the Ministerial Decree of 2nd November, 2015 came into force, the production of platelet concentrates from whole blood units through the intermediate separation of platelet-rich plasma has not been allowed.

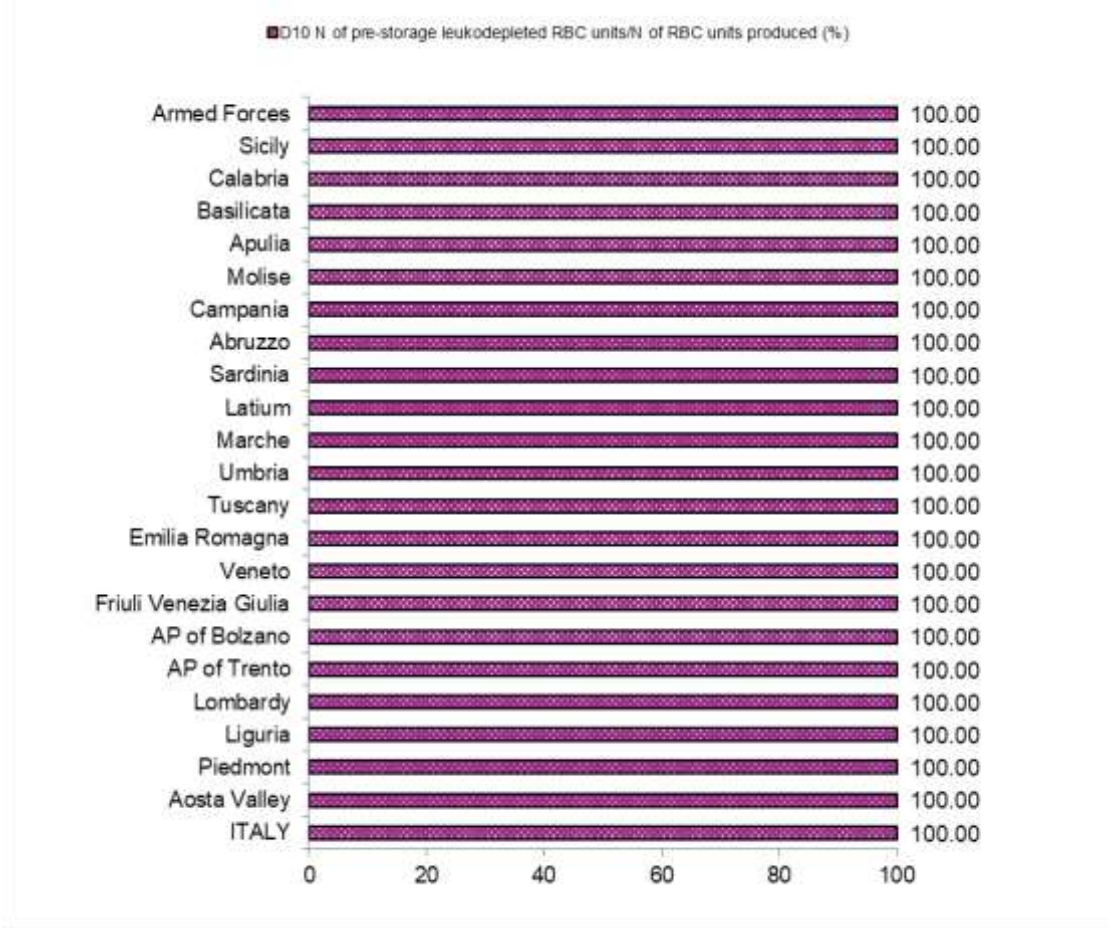

Figure A32 - INDICATOR D10: N of pre-storage leukodepleted* RBC units/N of RBC units produced (%) (2019).
N: number; RBC: Red Blood Cells; AP: Autonomous Province.
*: Since twelve months after the Ministerial Decree of 2nd November, 2015 came into force, only the production of pre-storage leukodepleted blood components has been allowed.

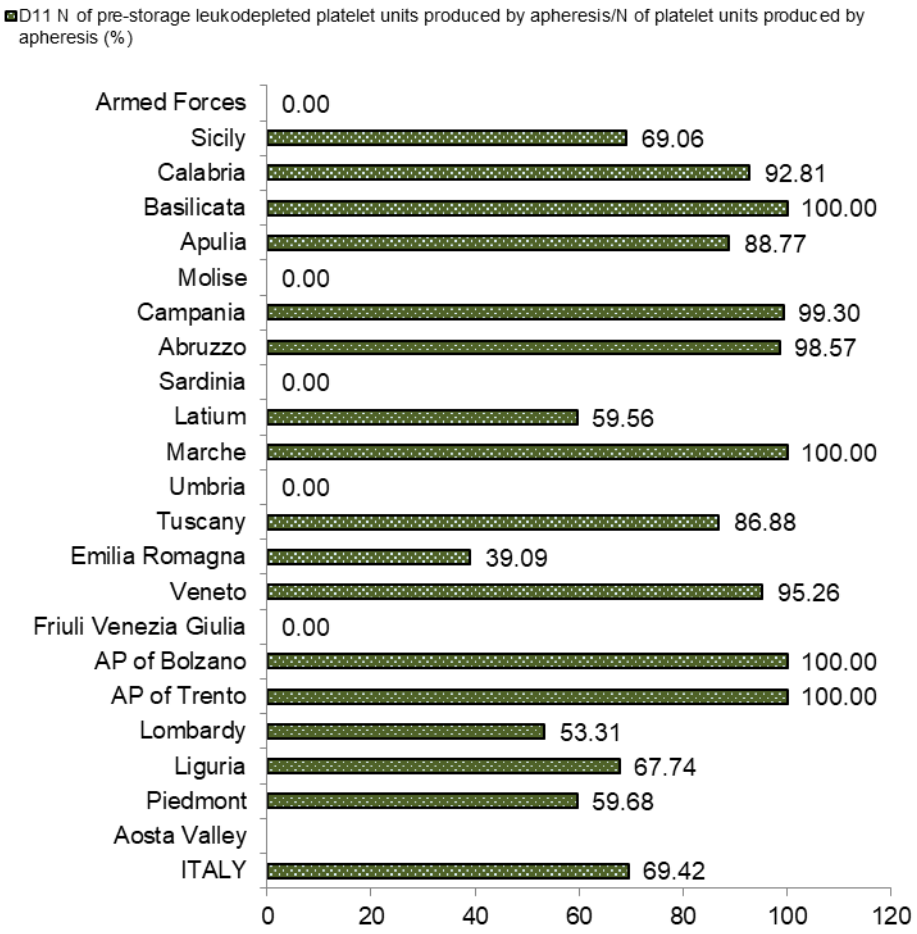

Figure A33 - INDICATOR D11: N of pre-storage leukodepleted platelet units produced by apheresis/N of platelet units produced by apheresis (%) (2019).
N: number; AP: Autonomous Province.
*: Since twelve months after the Ministerial Decree of 2nd November, 2015 came into force, only the production of pre-storage leukodepleted blood components has been allowed.

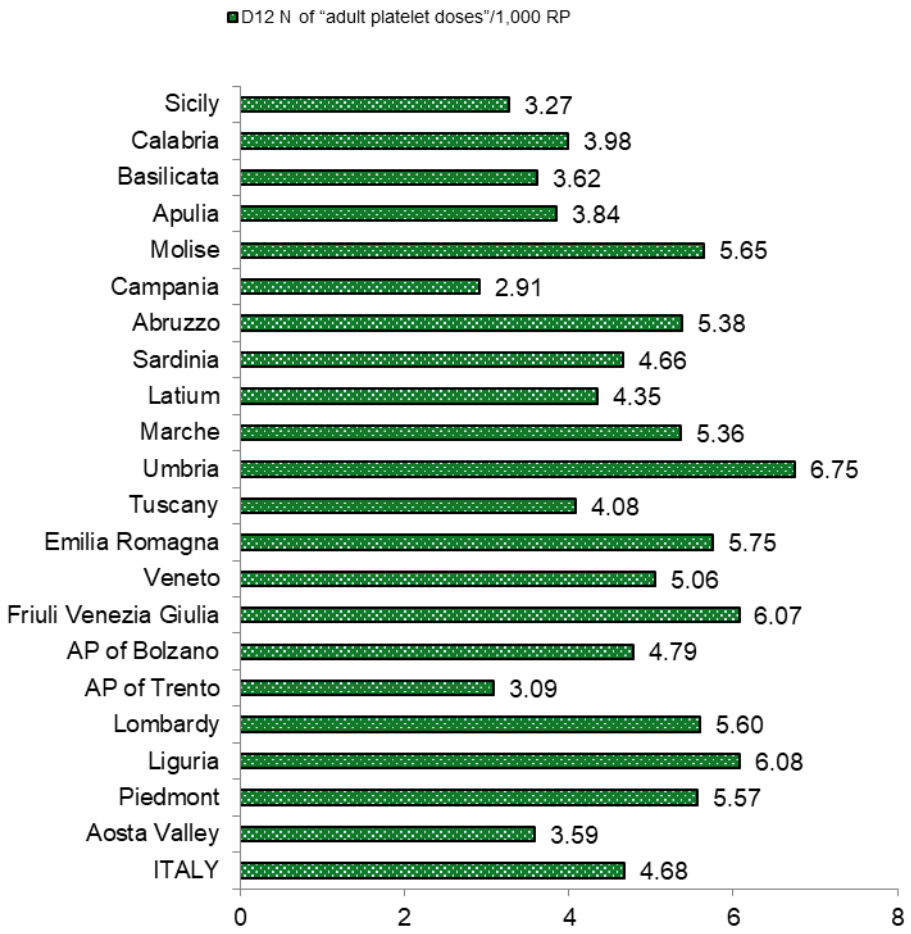

Figure A34 - INDICATOR D12: N of "adult platelet doses"/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

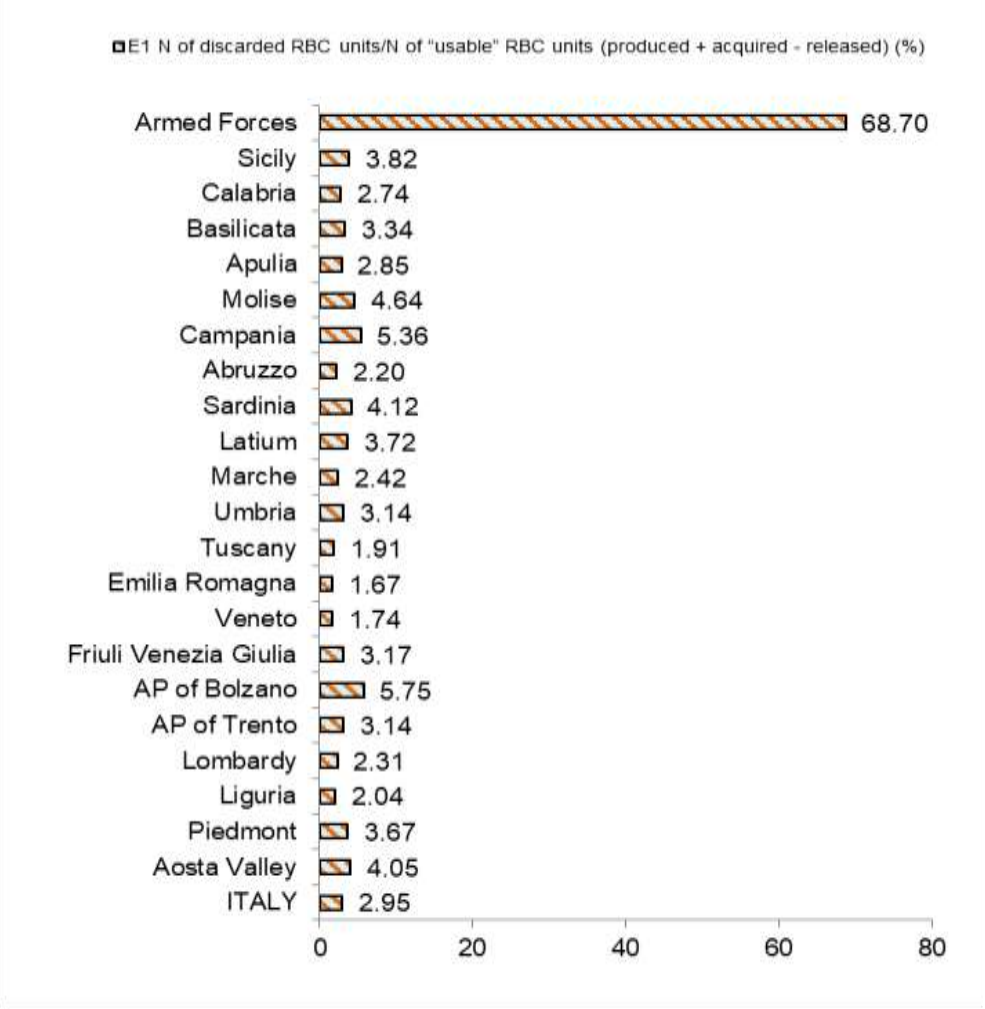

Figure A35 - INDICATOR E1: N of discarded RBC units/N of "usable" RBC units (produced + acquired- released) (%) (2019).
N: number; RBC: Red Blood Cells; AP: Autonomous Province.

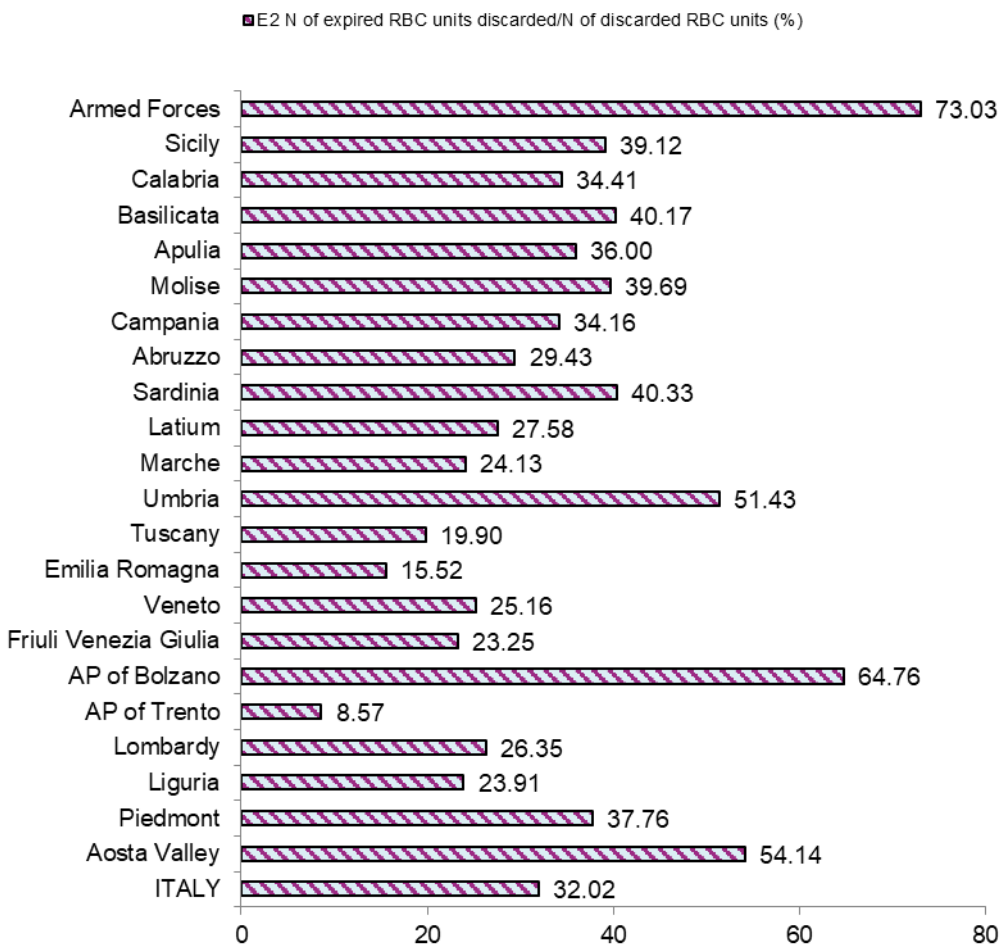

Figure A36 - INDICATOR E2: N of expired RBC units discarded/N of discarded RBC units (%) (2019).
N: number; RBC: Red Blood Cells; AP: Autonomous Province.

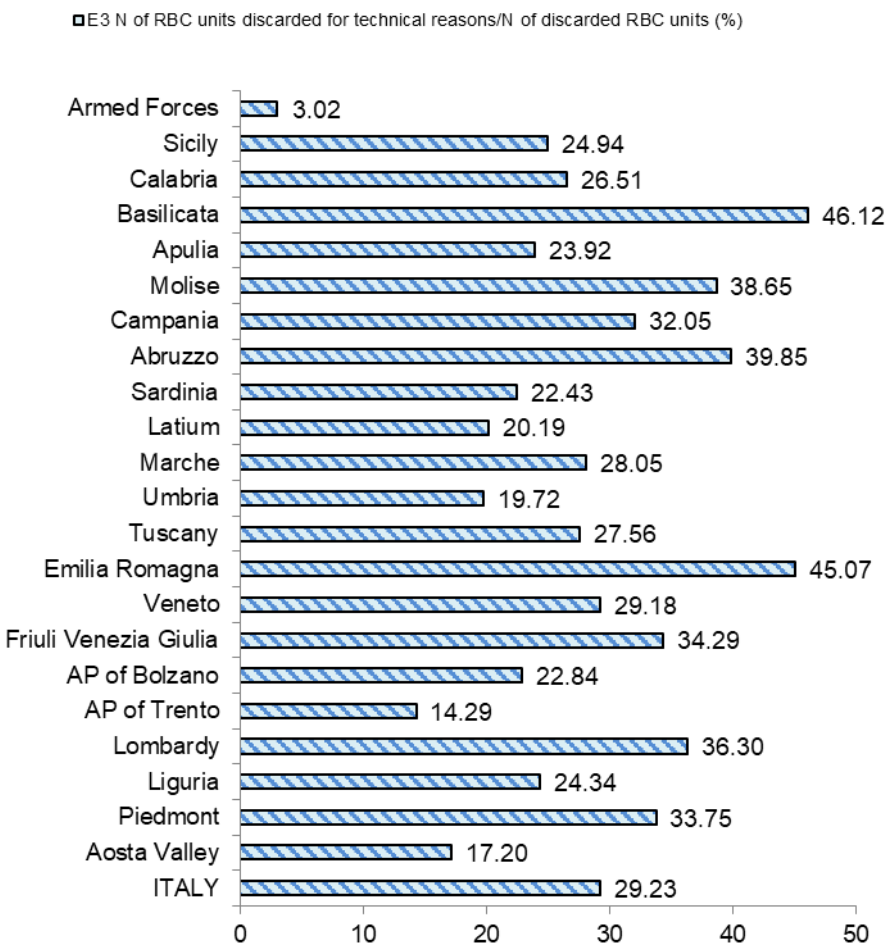

Figure A37 - INDICATOR E3: N of RBC units discarded for technical reasons/N of discarded RBC units (%) (2019). N: number; RBC: Red Blood Cells; AP: Autonomous Province.

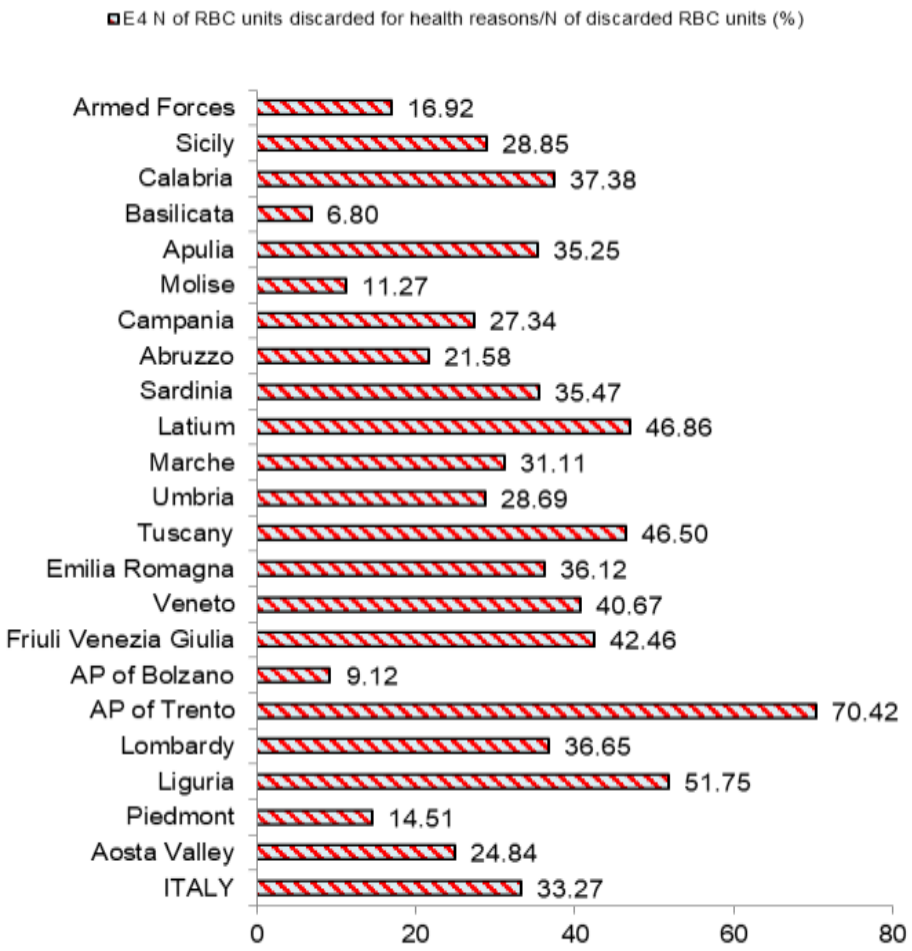

Figure A38 - INDICATOR E4: N of RBC units discarded for health reasons/N of discarded RBC units (%) (2019). N: number; RBC: Red Blood Cells; AP: Autonomous Province.

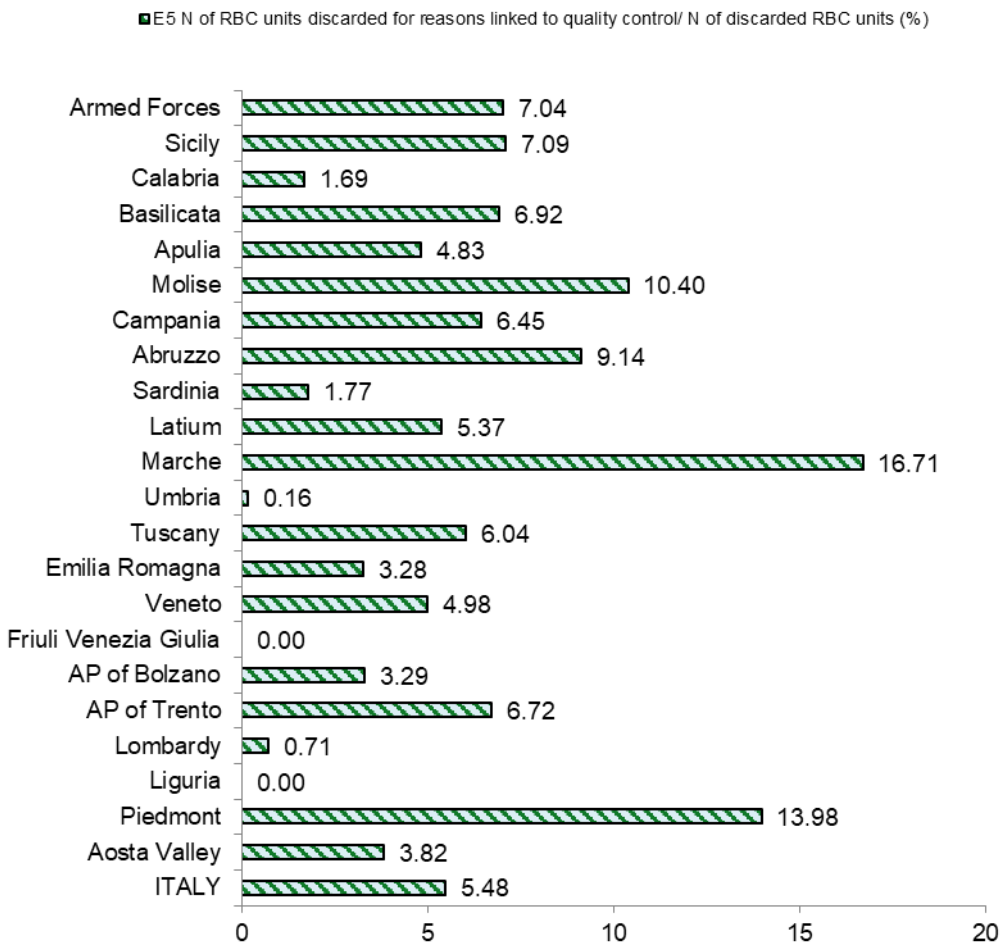

Figure A39 - INDICATOR E5: N of RBC units discarded for reasons linked to quality control/N of discarded RBC units (%) (2019).
N: number; RBC: Red Blood Cells; AP: Autonomous Province.

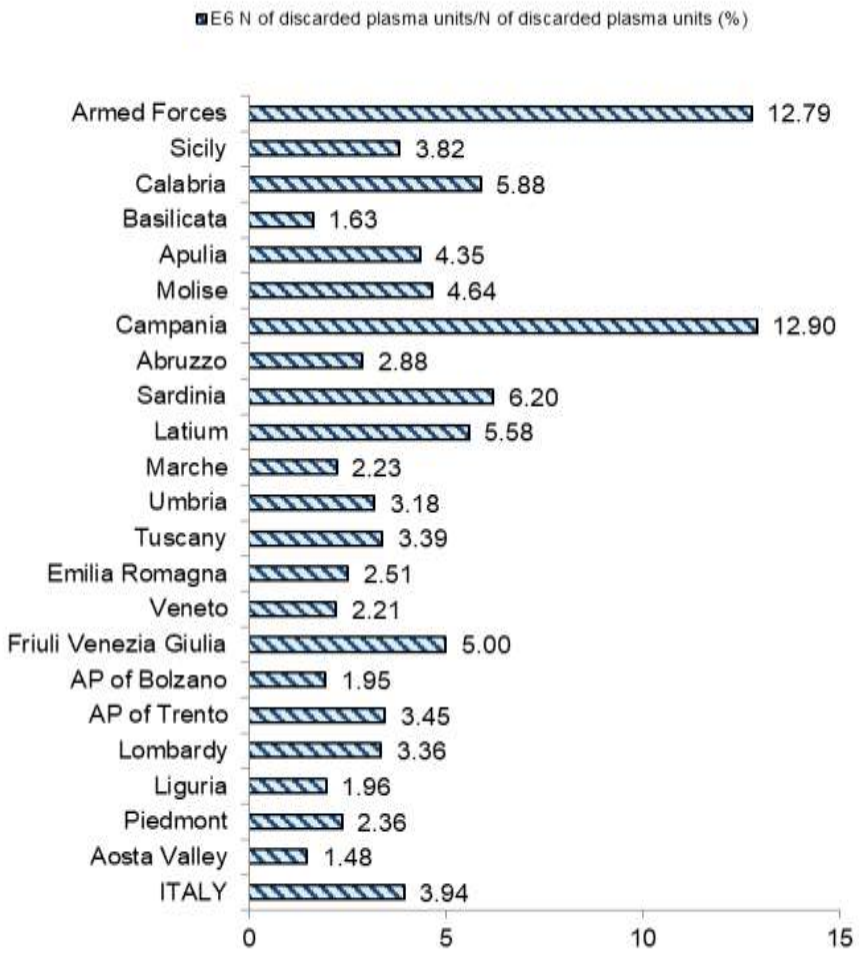

Figure A40 - INDICATOR E6: N of discarded plasma units /N of produced plasma units (%) (2019). N: number; AP: Autonomous Province.

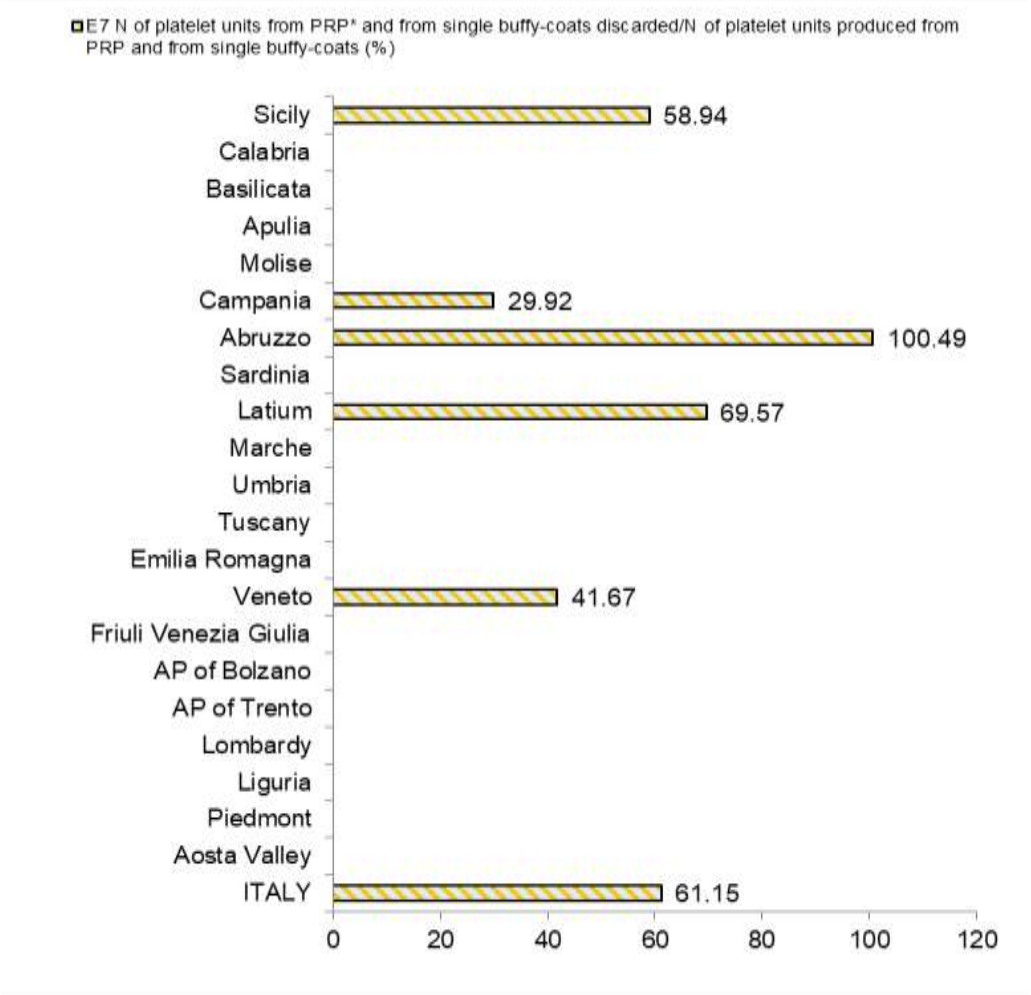

Figure A41 - **INDICATOR E7:** N of platelet units from PRP* and from single buffy-coats discarded /N of platelet units produced from PRP and from single buffy-coats (%) (2019).
N: number; PRP: platelet rich plasma; AP: autonomous Province.
*: Since six months after the Ministerial Decree of 2nd November, 2015 came into force, the production of platelet concentrates from whole blood units through the intermediate separation of platelet-rich plasma has not been allowed.

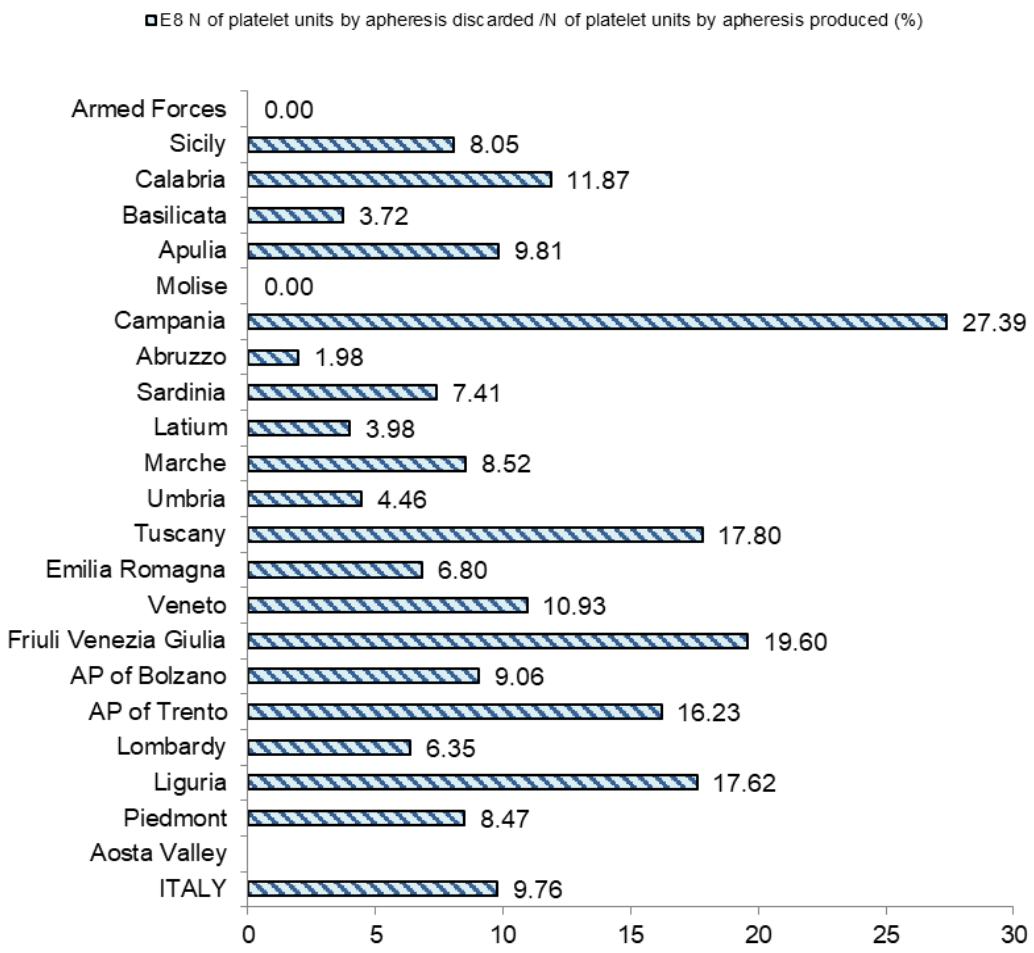

Figure A42 - INDICATOR E8: N of platelet units by apheresis discarded /N of platelet units by apheresis produced (%) (2019).
N: number; AP: Autonomous Province.

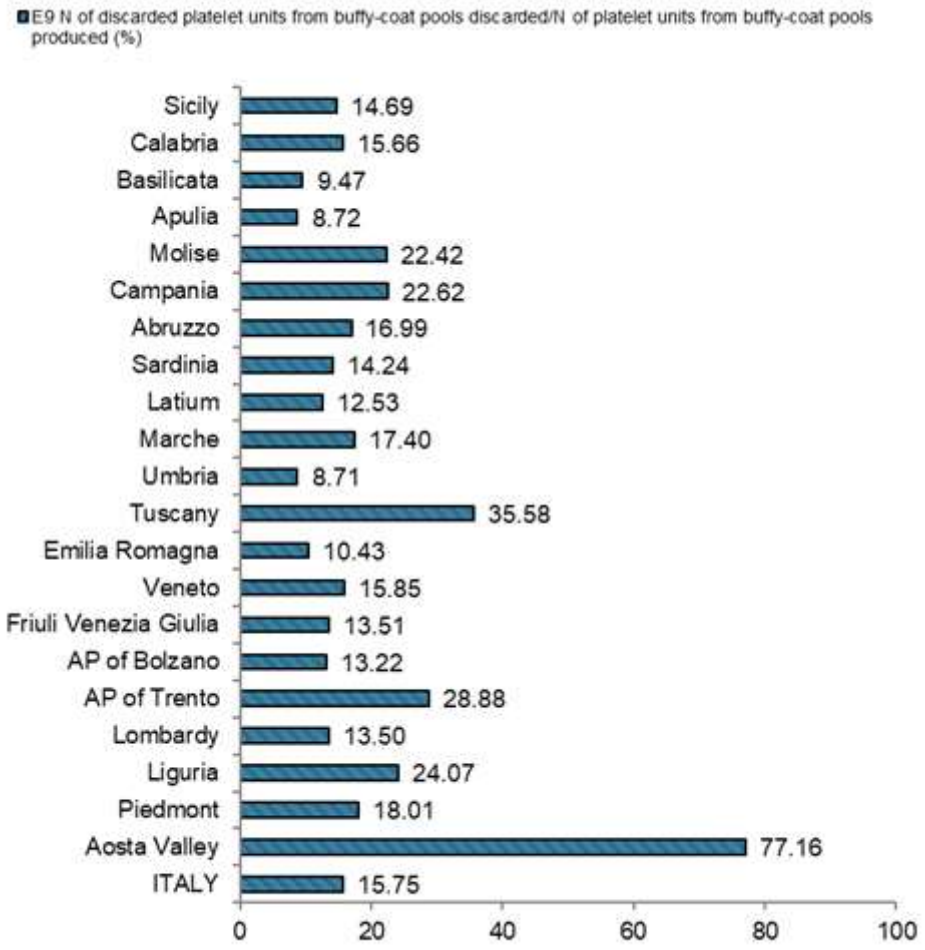

Figure A43 - INDICATOR E9: N of platelet units from buffy-coat pools discarded/N of platelet units from buffy-coat pools produced (%) (2019).
N: number; AP: Autonomous Province.

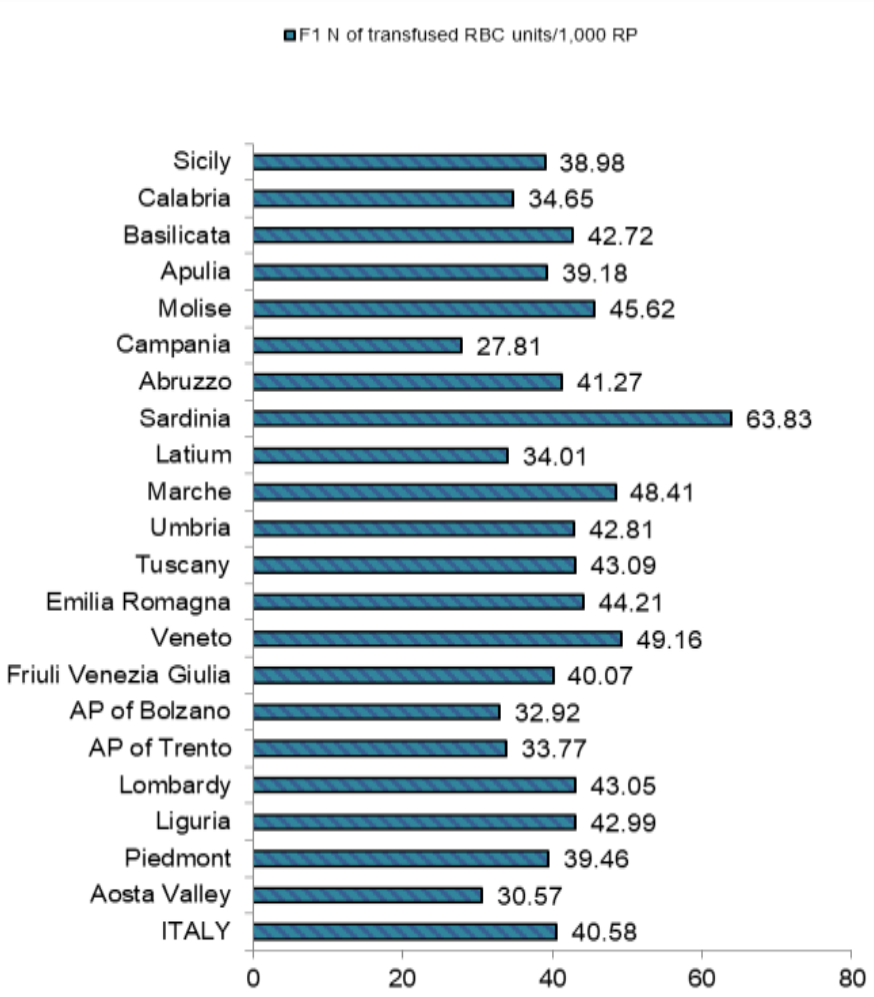

Figure A44 - INDICATOR F1: N of transfused RBC units/1,000 resident population (2019).
N: number; RBC: Red Blood Cells; RP: resident population; AP: Autonomous Province.

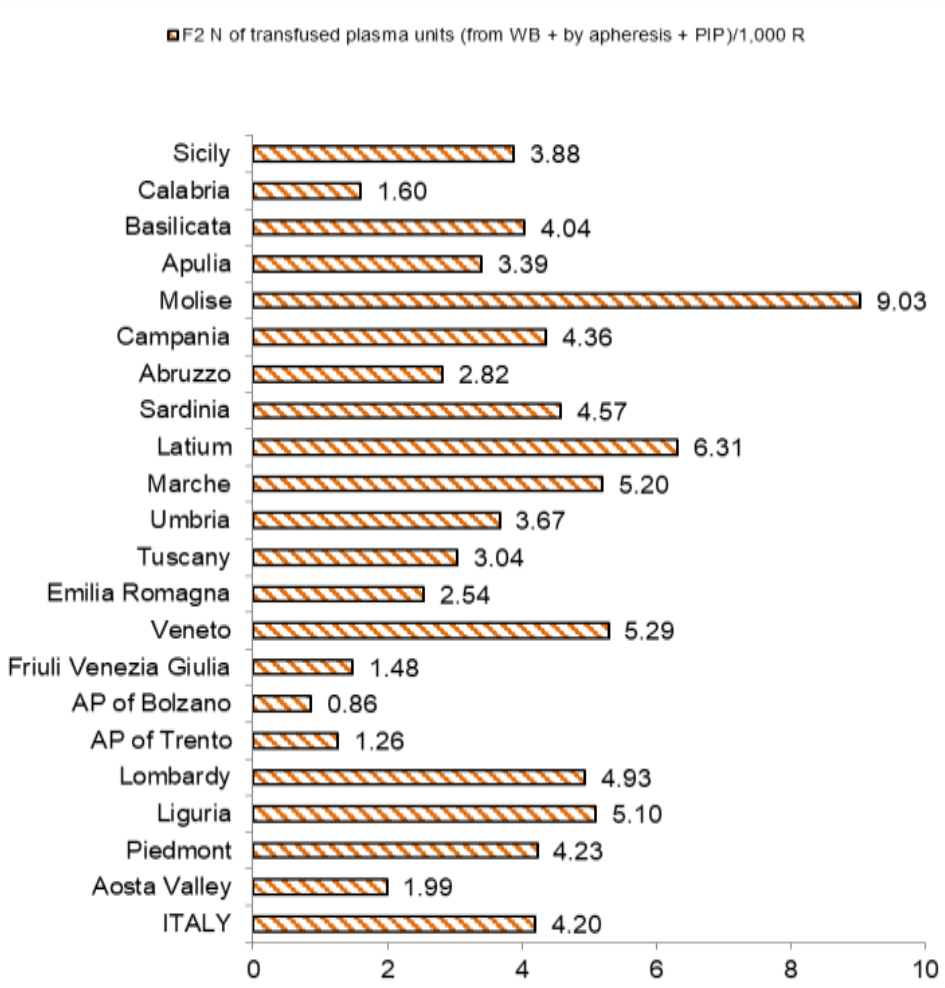

Figure A45 - INDICATOR F2: N of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma)/1,000 resident population (2019).
N: number; WB: whole blood; PIP: pharmaceutical virus-inactivated plasma; RP: resident population; AP: Autonomous Province.

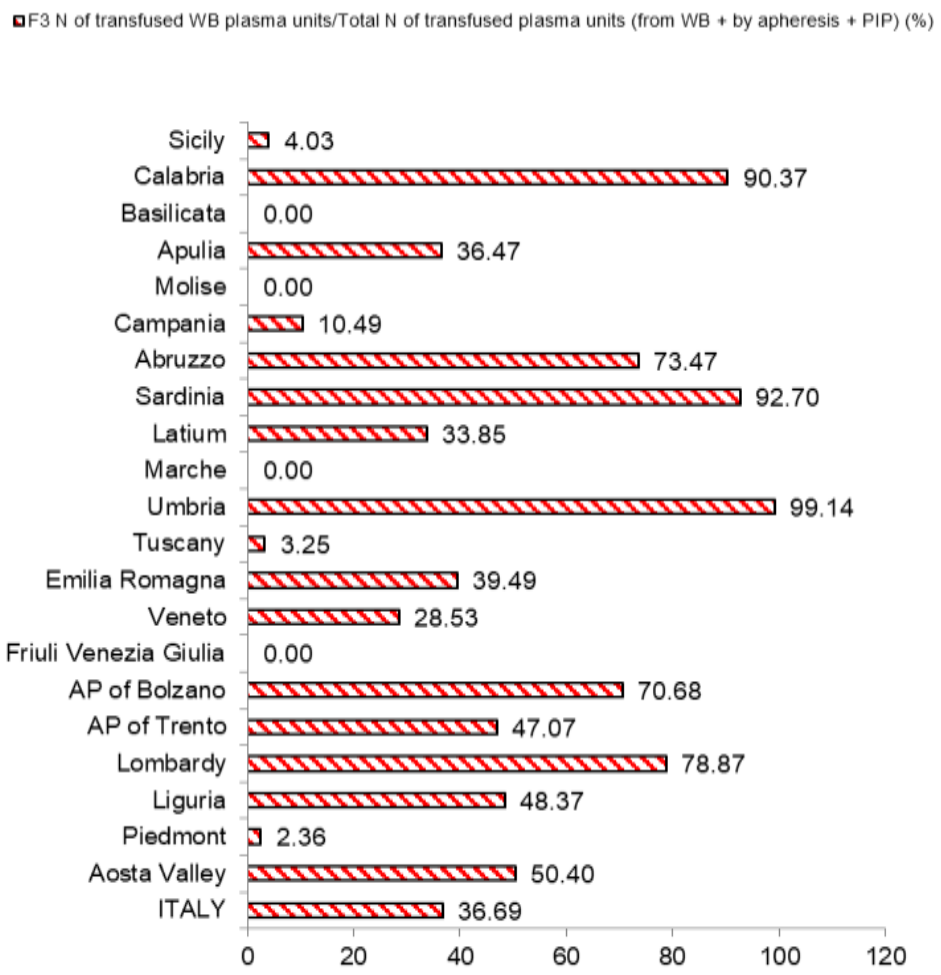

Figure A46 - INDICATOR F3: N of transfused whole blood plasma units/Total N of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2019).
N: number; WB: whole blood; PIP: pharmaceutical virus-inactivated plasma; AP: Autonomous Province.

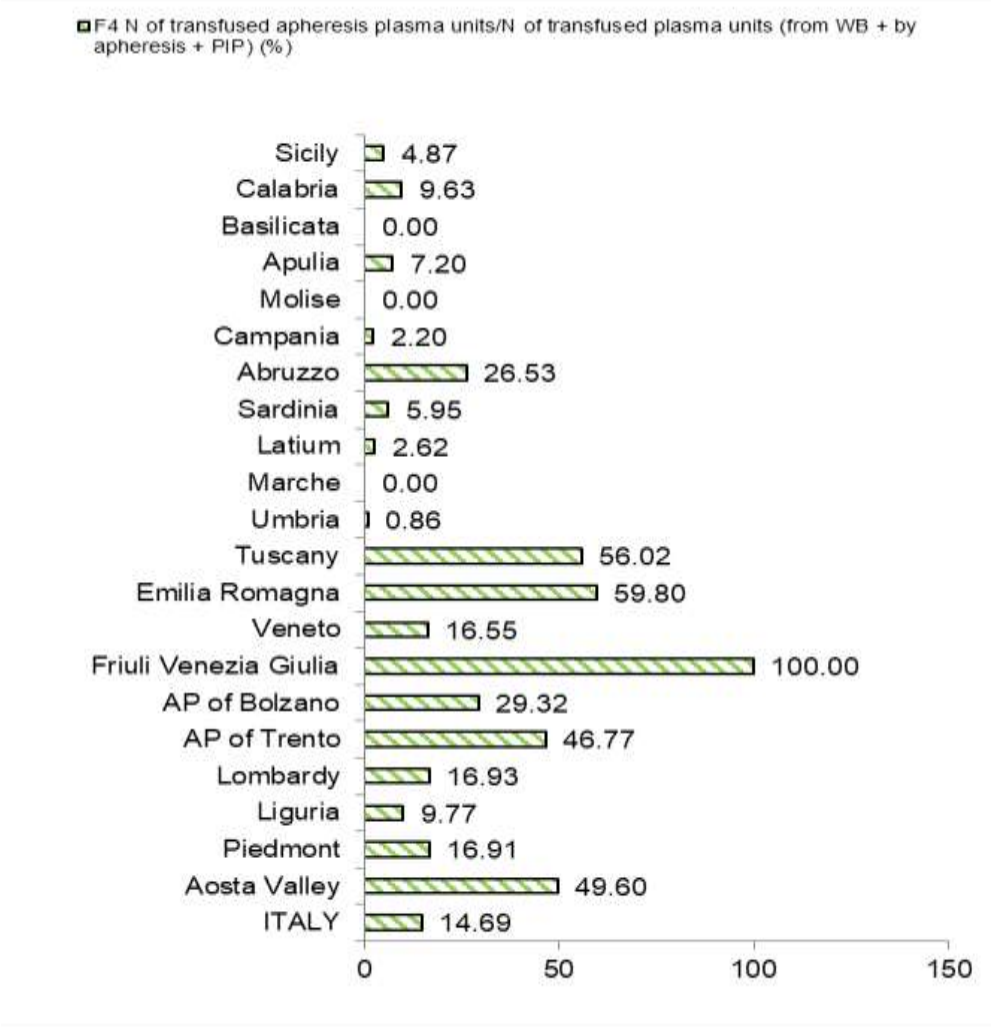

Figure A47 - INDICATOR F4: N of transfused apheresis plasma units/N of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2019).
N: number; WB: whole blood; PIP: pharmaceutical virus-inactivated plasma; AP: Autonomous Province.

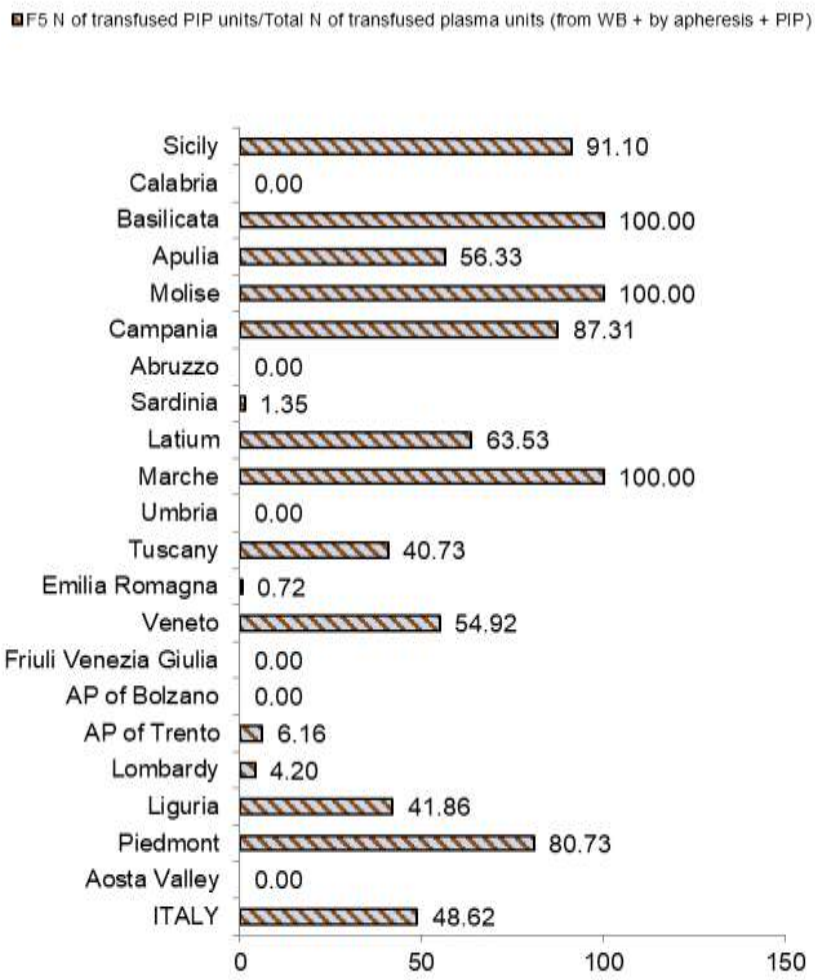

Figure A48 - F5 INDICATOR: N of transfused pharmaceutical virus-inactivated plasma units/Total N of transfused plasma units (from whole blood + by apheresis + pharmaceutical virus-inactivated plasma) (%) (2019).
N: number; WB: whole blood; PIP: pharmaceutical virus-inactivated plasma; AP: Autonomous Province.

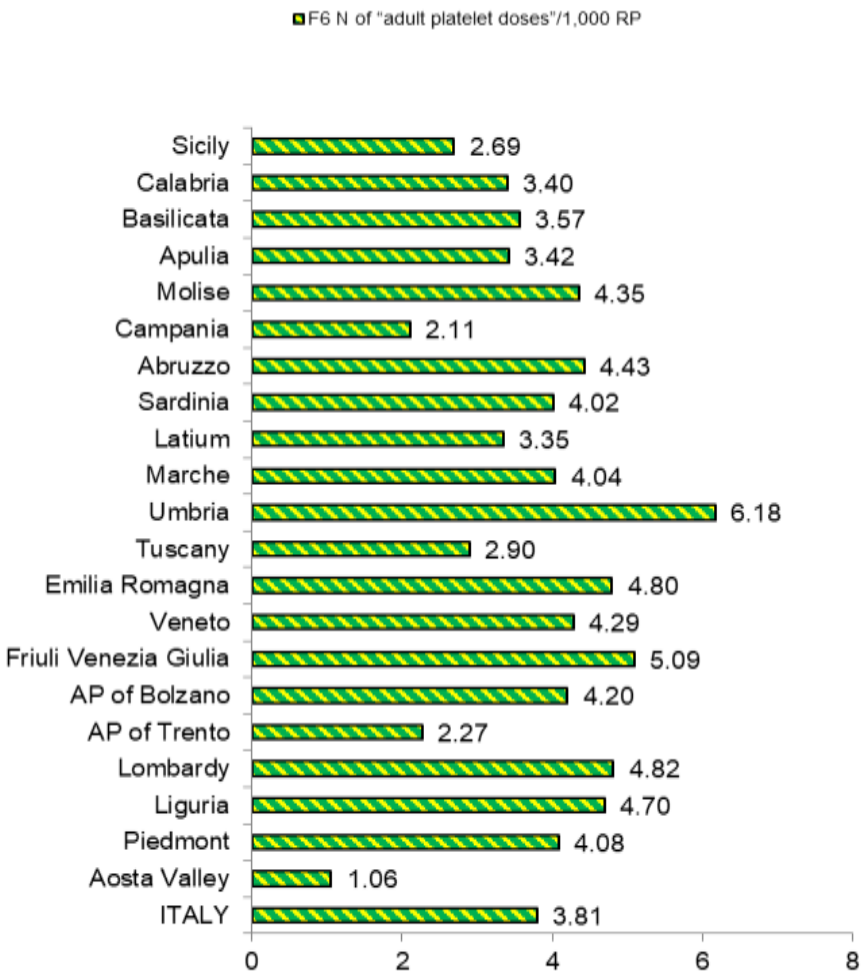

Figure A49 - INDICATOR F6: N of "adult platelet doses"/1,000 resident population (2019).
N: number; RP: resident population; AP: Autonomous Province.

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 2019.

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