



SAVE THE DATE  
**WORLD BLOOD DONOR DAY  
GLOBAL EVENT**  
Rome  
13 and 14 June 2020

**CENTRO  
NAZIONALE  
SANGUE**

Istituto Superiore di Sanità



## **Facilities and logistics International experiences - Italy**

**Giancarlo Maria Liumbruno**

Director General

Italian National Blood Centre

Rome, Italy

— IPFA/EBA WORKSHOP ON —  
**PLASMA  
COLLECTION**  
—

**Amsterdam, January 15, 2020**

# Disclosure

I hereby declare that I have neither financial nor non-financial relationships related to any of the products or services described, reviewed, evaluated or compared in this presentation.

# Agenda

- Founding principles and main figures
- Italy's self-sufficiency
- Plasma collection in Italy

# Italy's Blood System: founding principles



## Blood components collected in 2018

**2,991,082 donations**

49.5 per 1,000 pop

**2,569,275 whole blood donations**

85.9% of total of donations

42.5 per 1,000 pop

**421,087 apheresis: 107,198 in Blood Collection Sites**

**346,778 plasmapheresis**

14.1% of total donations

7 per 1,000 pop

**Donors: 1,682,724 (93% members of a Donor Association)**

**Apheresis donors: 202,509**

**Only apheresis donor: 109,521**

**1.6 WB donations/donor/year**

**2.1 plasma donations/donor/year**

**1.8 donations/donor/year**

## Blood components transfused in 2018

**2,936,445 units**

48.5 per 1,000 pop

**2,443,359 units of RBC**

40.4 per 1,000 pop

(100% leucodepleted)

**224,747 units of platelets \***

3.7 per 1,000 pop - (24.5% apheresis)

**268,349 units of plasma**

(S/D plasma + FFP)

**4.4 per 1,000 pop** - (of which 127,954 virus-inactivated plasma)

**8,045 blood components transfused per day**

**1 donation every 10 seconds guarantees transfusion therapy for 1,728 patients per day  
(630,770/year)**

\* Adult therapeutic dose \*\* Apheresis + WB

# Agenda

- Founding principles and main figures
- Italy's self-sufficiency
- Plasma collection in Italy

# The annual national self-sufficiency programme

**Self-sufficiency** of blood and blood products, including PDMPs, is a **national supra-regional strategic goal**, i.e. independent of the regionalised organization of health-care delivery.



The Minister of Health, on the basis of the indications provided by the National Blood Center in accordance with Regions, **annually defines the national self-sufficiency programme**, which identifies:

- the historical consumption,
- the **real needs**,
- the **production levels required**,
- the resources,
- the criteria for financing the system,
- the **organisational methods and the tariff references for the compensation** between the regions,
- the levels of import and export that may be needed.

Since 2008, 12 annual national **self-sufficiency programmes** have been published and became **law**

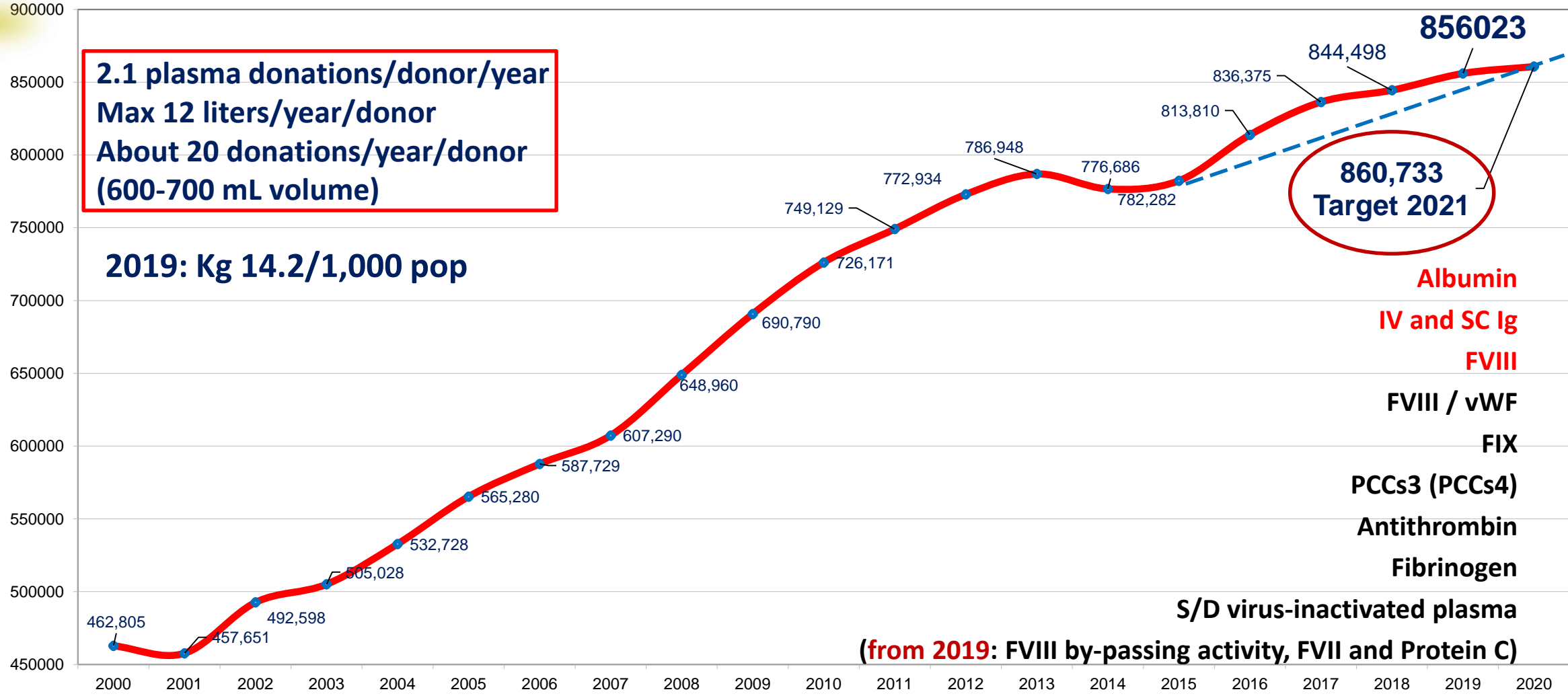


# Plasma for fractionation 2000 - 2019 and plasma national plan target (2017-)2021 (total kilograms)

Kg

2.1 plasma donations/donor/year  
Max 12 liters/year/donor  
About 20 donations/year/donor  
(600-700 mL volume)

2019: Kg 14.2/1,000 pop



- Albumin
- IV and SC Ig
- FVIII
- FVIII / vWF
- FIX
- PCCs3 (PCCs4)
- Antithrombin
- Fibrinogen
- S/D virus-inactivated plasma

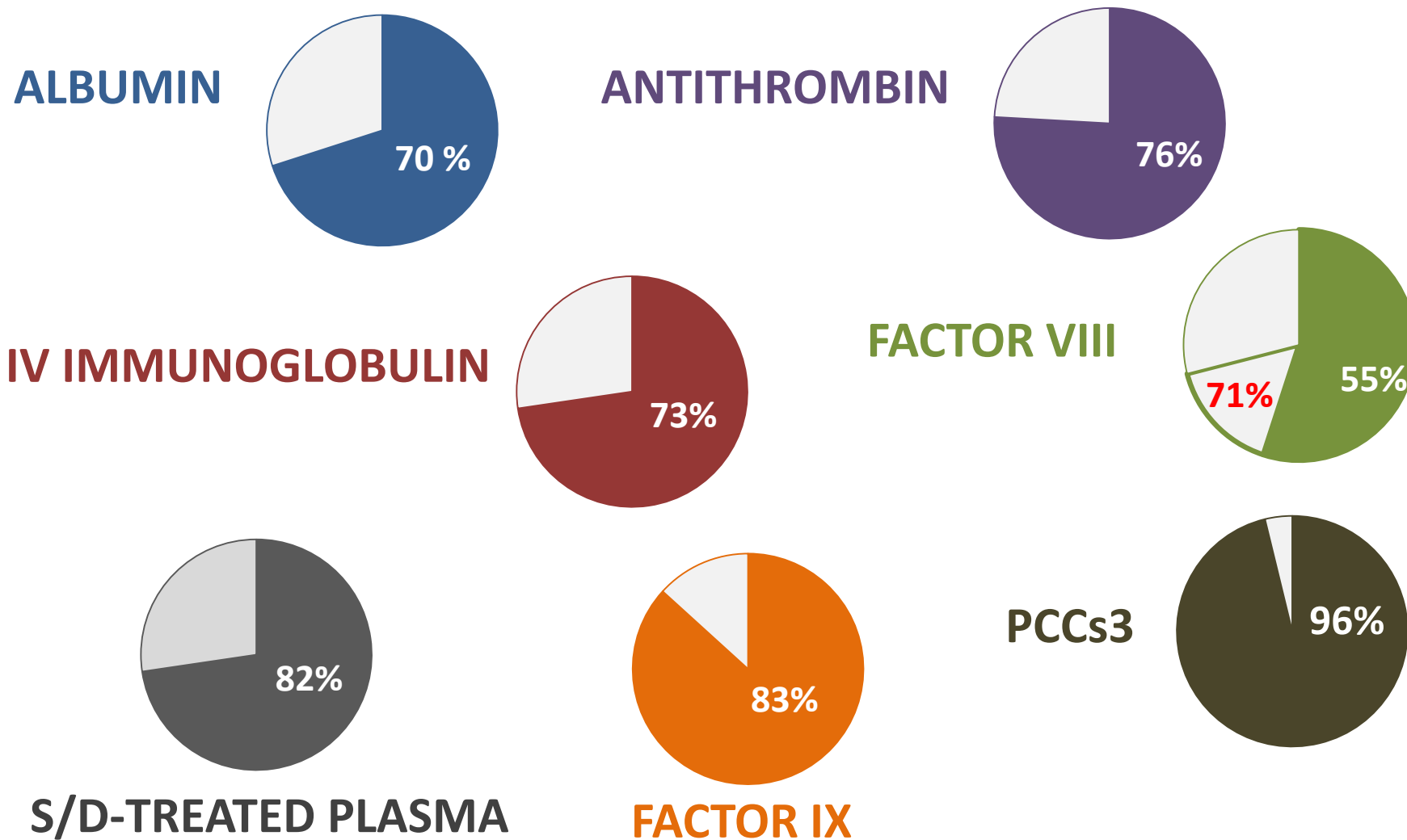
(from 2019: FVIII by-passing activity, FVII and Protein C)

Data sources:  
- Official Journal of the Italian Republic no. 9 January 12th. 2017. Ministerial Decree 2 December 2016.  
- Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2020

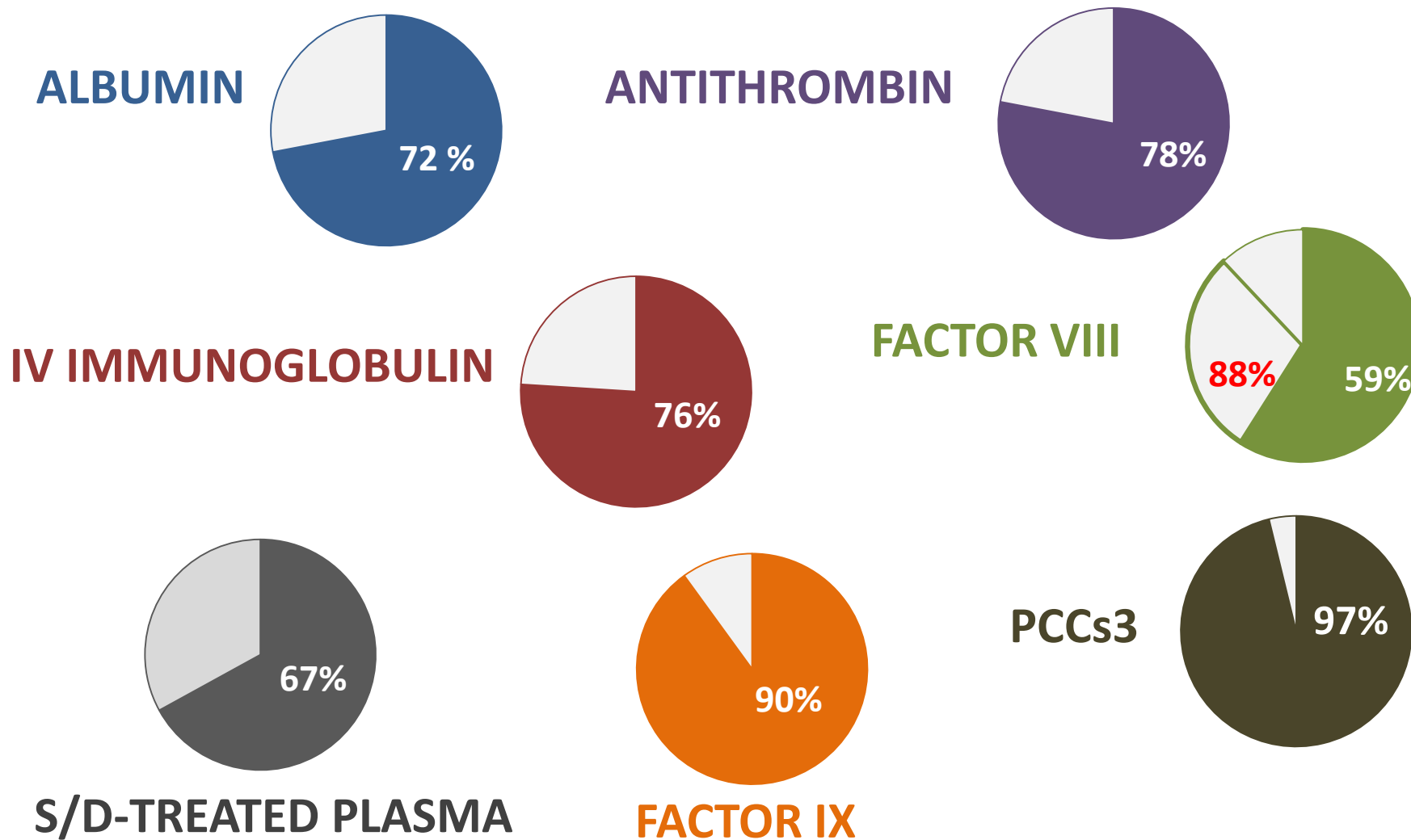




# Italy's self-sufficiency in 2017



# Italy's self-sufficiency in 2018



# Agenda

- Founding principles and main figures
- Italy's self-sufficiency
- Plasma collection in Italy



# The Italian Blood Network (*January 2020*)

★ Regional Blood Coordinating Centre (CRS)

★ Italian National Blood Centre (CNS)

Blood Establishments (BEs)	279	} (Public) Hospital based
BEs peripheral organisational sites	1,291	

Blood Collection Sites (BCSs)*	189	} Government funded NGO*
BCSs peripheral organisational sites*	1,255	

BEs ( <b>centralised</b> processing)	42
BEs ( <b>centralised</b> testing)	44

BEs ( <u>not centralised processing</u> )	134
BEs (not centralised testing)	25



**\*in Italy all BCSs are run by qualified blood donor Associations and Federations specifically licensed and accredited**



# N. of plasmapheresis/cell separator/year per Region

A.P. Bolzano: 398.33

A.P. Trento: 229.67

280.40

281.11

352.76

430.72

135.88

311.22

279.93

143.87

274.91

131.68

33.53

115.21

83.75

82.12

46.63

217.52




Range:

from **33.53** (Campania Region)  
to **430.72** (Emilia-Romagna Region)

Average:

**212.74**

*preliminary data*

-  Complete data
-  Partial data
-  Pending data



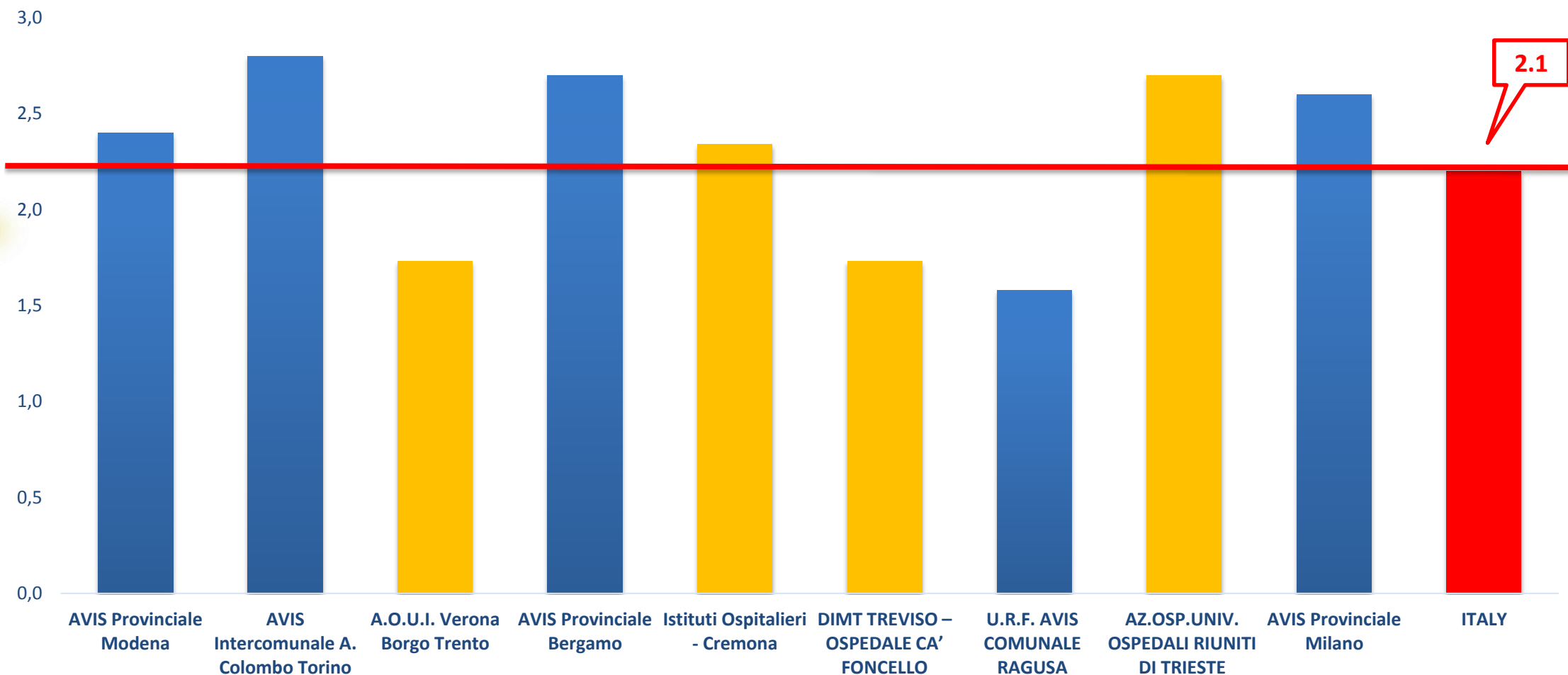
## The top 9 plasma collection centres: main data (I)

CENTRE	Total N. of apheresis procedures (114,047/421,087)	Plasma Donation Index	Mean volume of plasma units collected by monocomponent apheresis (mL)	Mean volume of plasma units collected by multicomponent apheresis (mL)
AZ.OSP.UNIV. OSPEDALI RIUNITI DI TRIESTE	21,062	2.7	700	N.A.
UdR AVIS Provinciale Modena - AVIS	17,067	2.4	700	550
AVIS INTERCOMUNALE A.COLOMBO TORINO - AVIS	17,426	2.8	690	500
AOUI VERONA BORGO TRENTO	11,571	1.73	615	450
AVIS Provinciale Bergamo - AVIS	12,139	2.7	660	450
U.R.F. AVIS COMUNALE RAGUSA - AVIS	9,673	1.58	670	480
OSPEDALE CA' FONCELLO	8,726	1.73	700	550
ISTITUTI OSPITALIERI - CREMONA	8,413	2.34	680	N.A.
AVIS Provinciale Milano - AVIS	7,970	2.6	600	N.A.

(Plasma production: kg 159,338)

N.A.: Data not available

# The top 9 plasma collection centres: Plasma Donation Index\*



Public BE



Blood collection site run by qualified blood donor Association specifically licensed and accredited

\* Plasma donations/donor/year



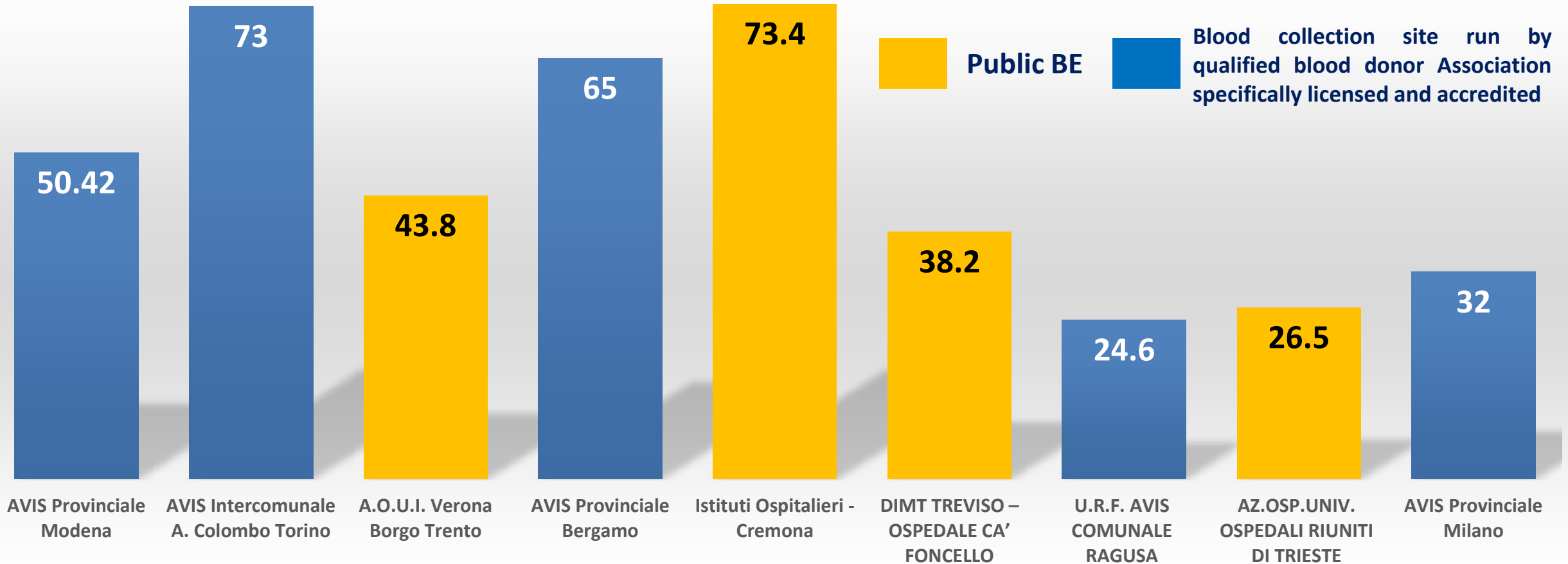
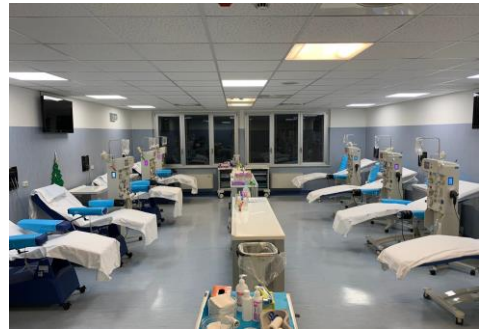
## The top 9 plasma collection centres: main data (II)

CENTRE	Total N. of cell separators	N. of cell separators dedicated to plasmapheresis procedures	N. of backup cell separators
AZ.OSP.UNIV. OSPEDALI RIUNITI DI TRIESTE	9	7	0
U d R AVIS Provinciale Modena - AVIS	30	30	7
AVIS INTERCOMUNALE A.COLOMBO TORINO - AVIS	22	20	2
AOUI VERONA BORGO TRENTO	26	22	0
AVIS Provinciale Bergamo - AVIS	21	20	1
U.R.F. AVIS COMUNALE RAGUSA - AVIS	39	32	7
OSPEDALE CA' FONCELLO	21	17	N.A.
ISTITUTI OSPITALIERI - CREMONA	8	8	0
AVIS Provinciale Milano - AVIS	21	21	2

N.A.: Data not available



# The top 9 plasma collection centres: N. of plasmapheresis/cell separator/month

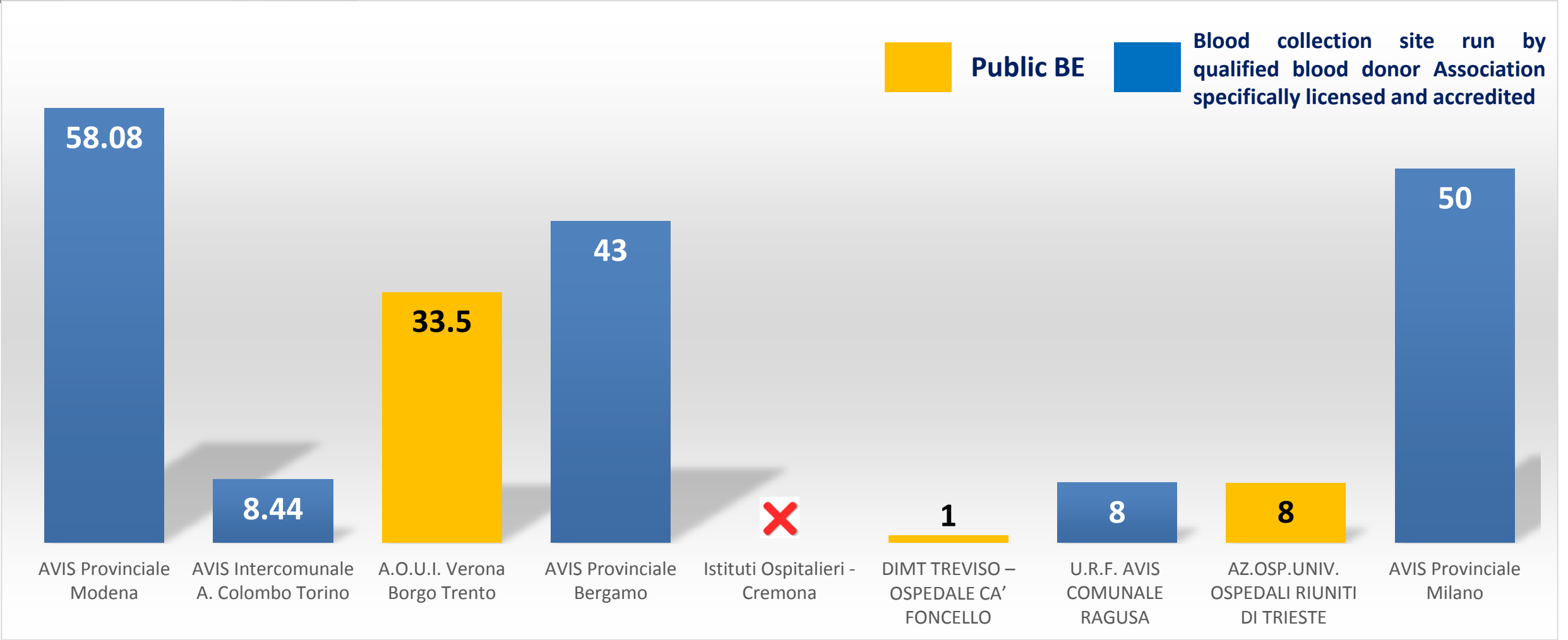


## The top 9 plasma collection centres: main data (III)

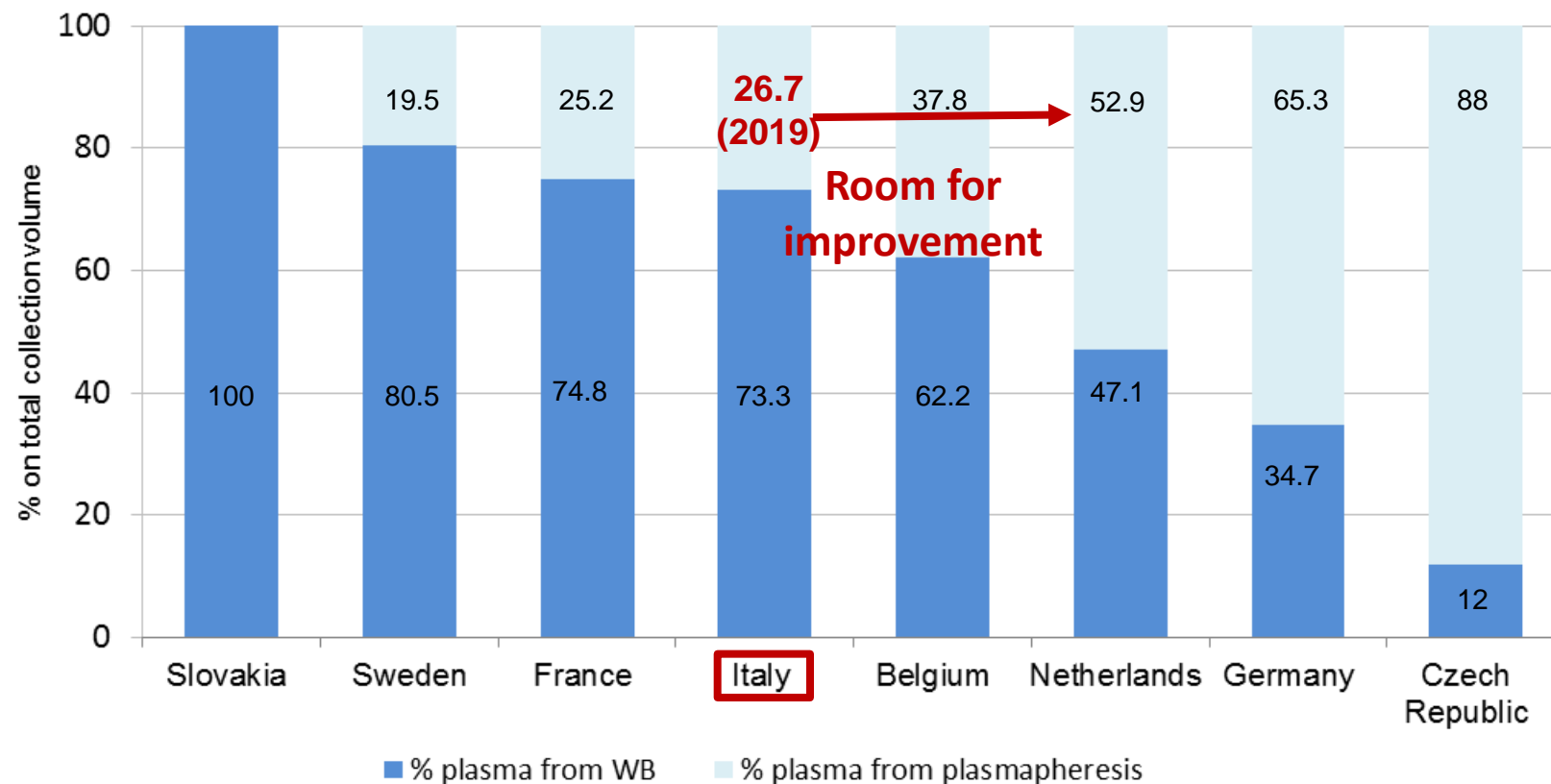
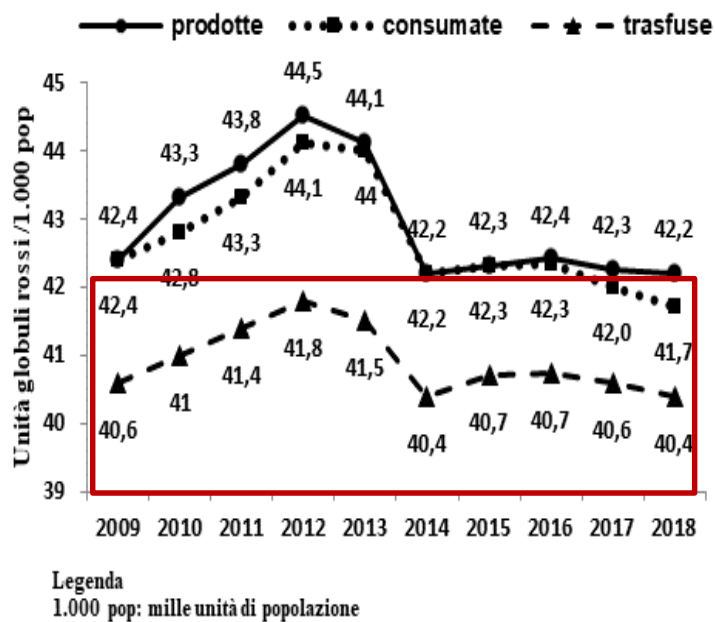
CENTRE	DAYS	OPENING HOURS	DAYS	OPENING HOURS
		A.M.		P.M.
AZ.OSP.UNIV. OSPEDALI RIUNITI DI TRIESTE	Mon-Sat	Mon-Fri 8:00-13:00 Sat 8:00-12:00	NO	---
U d R AVIS Provinciale Modena - AVIS	Mon-Sun	7:00-12:30	Thu	14:30-17:30
AVIS INTERCOMUNALE A.COLOMBO TORINO - AVIS	Mon-Sun	7:30-12:00	Mon-Fri	12:00-17:00
AOUI VERONA BORGO TRENTO	Mon-Sun	8:00-11:00	NO	---
AVIS Provinciale Bergamo - AVIS	Mon-Sat	7:30-10:30	NO	---
U.R.F. AVIS COMUNALE RAGUSA - AVIS	Mon-Sun	7:30-11:30	Tue-Thu	15:00-17:30
OSPEDALE CA' FONCELLO	Mon-Sun	7:30-10:30	Wed	15:00-18:00
ISTITUTI OSPITALIERI - CREMONA	Mon-Fri	7:00-12:00	NO	---
AVIS Provinciale Milano - AVIS	Fri-Mon	7:00-12:00	NO	---



# The top 9 plasma collection centres: Average apheresis procedures on Saturday/Sunday/Holidays



# Improvement of the efficiency of plasma collection, with particular regard to apheresis plasma procedures



# Conclusions

## Areas of improvement [included in the (2017-2021) Italian Plasma and PDMP plan]

- A way forward to intensify plasmapheresis: increase of plasma donation rate combined with an increasing efficiency of plasmapheresis machines
- Changes needed in the organisation of the plasma collection system (longer opening hours in collection centres and flexible working hours for staff)
- Strong action needed to change the widespread belief that plasma donations are second-class donations
- Educational programmes to promote plasma donation by apheresis

## Increase of awareness that

- Currently, **71% of the world's source plasma is collected in the United States** (The Source, Fall 2019)
- Plasma itself is a **strategic resource** as “raw material” for the production of life-saving medicinal products
- Achieving the self-sufficiency(/balance between domestic supply and importation) in PDMPs based on VNR(P)BD is **POSSIBLE and**
- **A EU Plasma and PDMP self-sufficiency plan based on VNRDs** could have a key role
- **PDMP self-sufficiency based on VNRDs** could/should be a **common European strategic objective**



SAVE THE DATE  
WORLD BLOOD DONOR DAY  
GLOBAL EVENT  
Rome  
13 and 14 June 2020

CENTRO  
NAZIONALE  
SANGUE

Istituto Superiore di Sanità



*Thanks for your  
attention!*

