

45°

**Convegno Nazionale
di Studi di Medicina Trasfusionale**

Rimini | 29-31 maggio 2024



**Il sistema trasfusionale italiano:
sfide aperte e future**

Vincenzo De Angelis

Direttore Centro Nazionale Sangue - Roma

Il sottoscritto, in qualità di Relatore
dichiara che

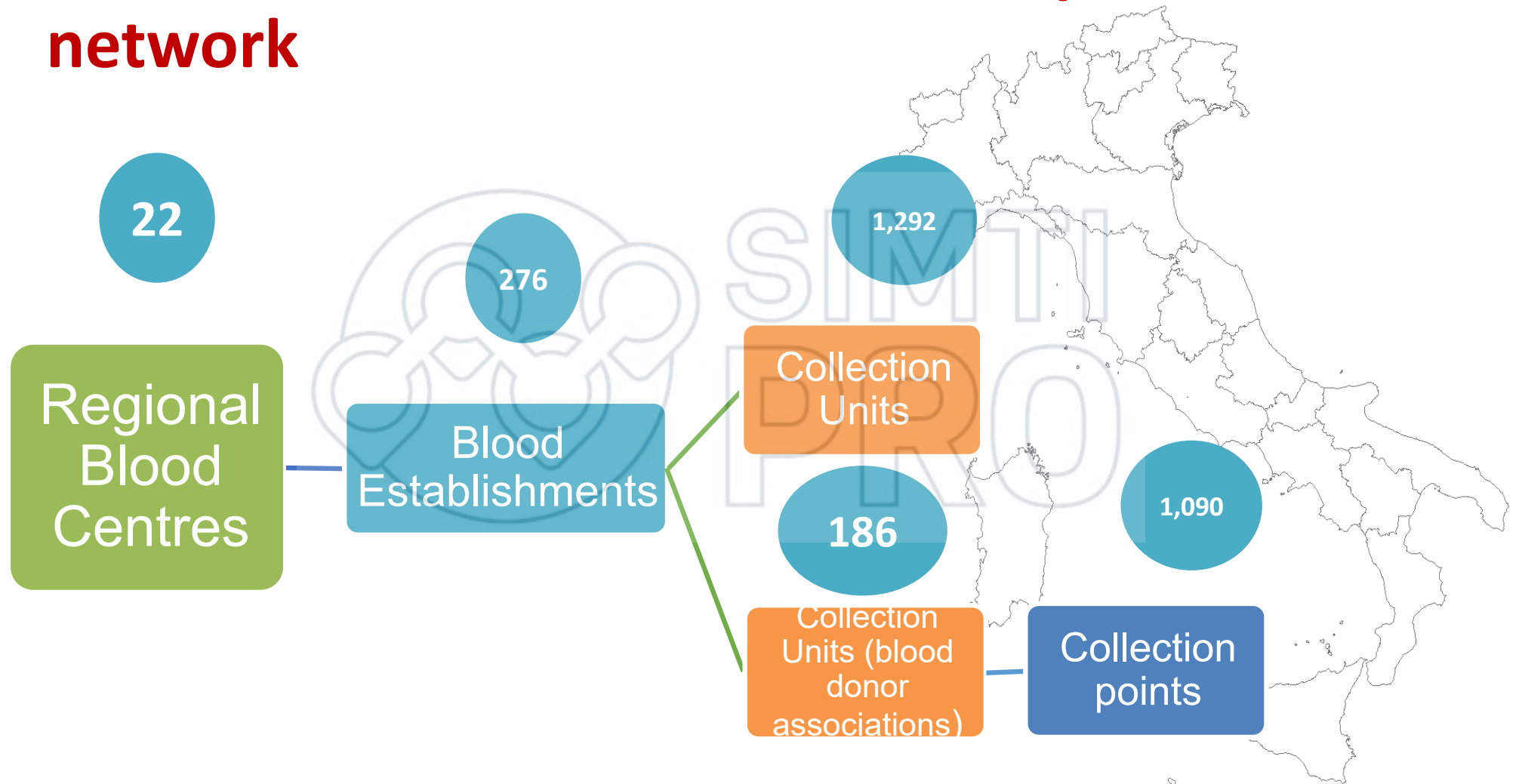
nell'esercizio della Sua funzione e per l'evento in oggetto, NON È in alcun modo portatore di interessi commerciali propri o di terzi; e che gli eventuali rapporti avuti negli ultimi due anni con soggetti portatori di interessi commerciali non sono tali da permettere a tali soggetti di influenzare le sue funzioni al fine di trarne vantaggio.



Principles and social values of the Italian blood system

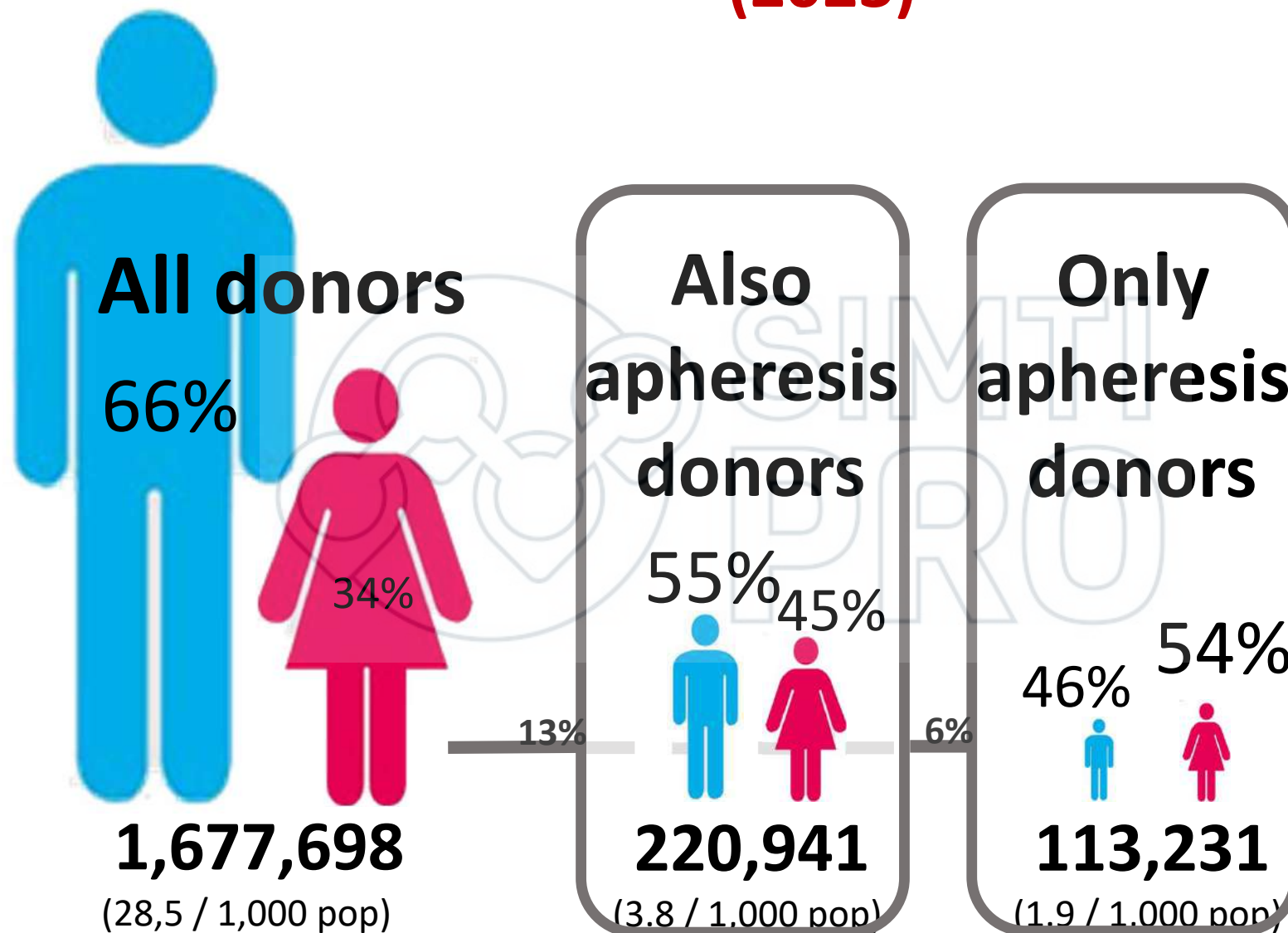


Overview of the Italian national operational network



Data sources: BEs Informatin System (Sistema informativo dei Servizi TRAsfusionali) – Last access 30/06/2022

Overview of the Italian national blood system (2023)



Data sources: BEs Information System (Sistema informativo dei Servizi TRASfusionali) – Last access 04/04/2022

Italian transfusion system- data 2023

Production of labile components

RBC (units): **2.506.415**
units / 1.000 pop: **42,6‰**
(100% leukodepleted)

Platelets (units *): **295.488**
units / 1.000 pop: **5,0‰**
(19,5 % apheresis)

Plasma (units **): **2.966.653**
units / 1.000 pop: **50,4‰**
[data from fractionation companies]: **880.193 Kg** (15,2 Kg/1000 pop)]

* Adult therapeutic dose (ATD = 200-450 *10⁹)
** recovered and apheresis

Transfusion of labile components

RBC (units): **2.392.289**
units / 1.000 pop: **40,7‰**
(100% leukodepleted)

Platelets (units *): **248.718**
units / 1.000 pop: **4,2‰**
(19,0% apheresis)

Plasma (units **): **196.795**
Unità / 1.000 pop **3,3‰**
[101.518 (51,6%) SD-plasma]

Total: **2.837.802**
Units/ 1.000 pop: **48,1‰**

* Adult therapeutic dose (ATD = 200-450 *10⁹)
** recovered and apheresis



Self sufficiency in blood components

Near 70 % sufficiency in PDMPs

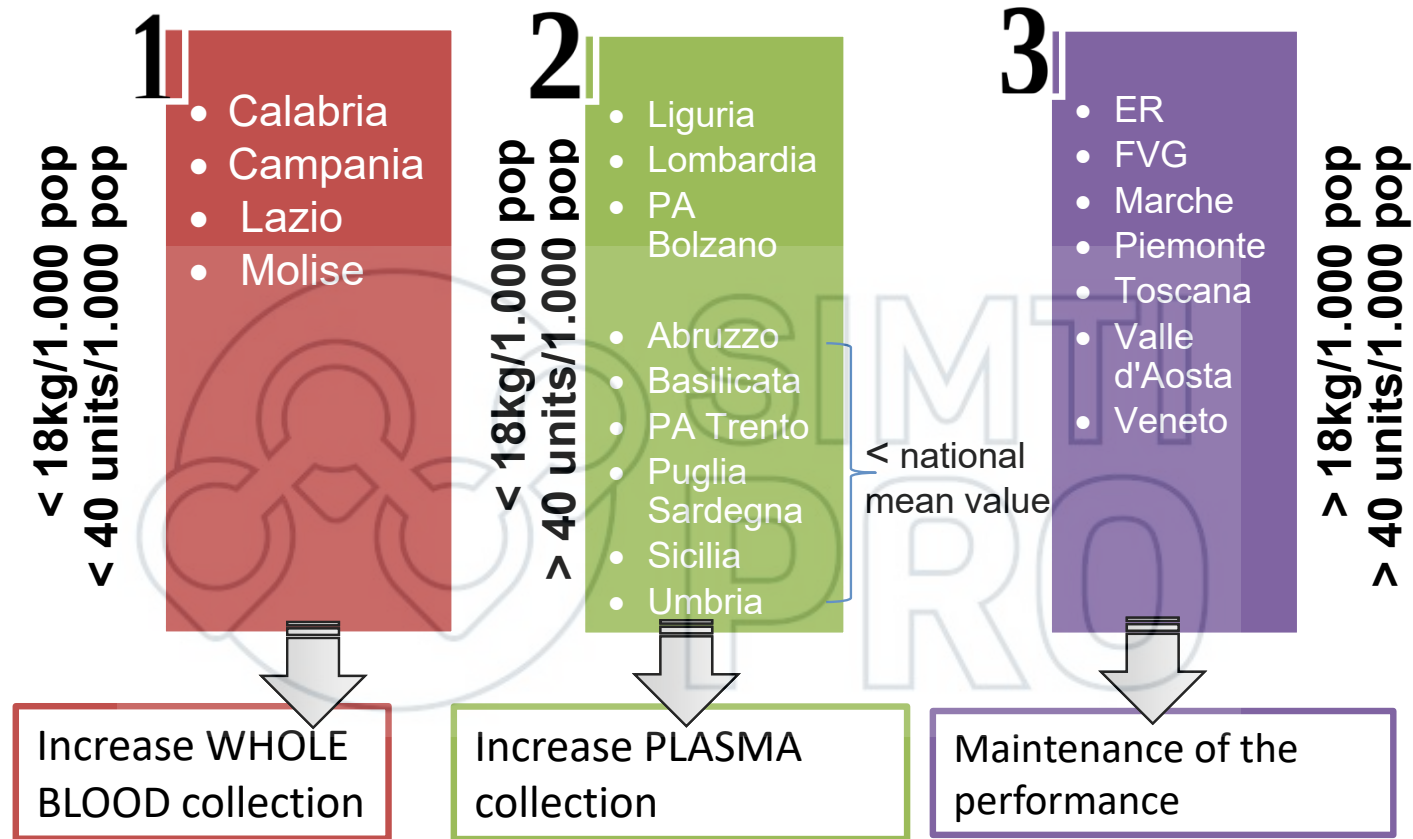
Dati donatori aggiornati al 14 marzo 2024

Challenges in Transfusion Medicine in Italy *(and in the rest of the world too...)*



- Challenge of **self sufficiency & appropriateness**
 - **Organizational** Challenge
 - Challenge of **plasma**
 - **Technology** Challenge
 - **Scientific** Challenge

National goals

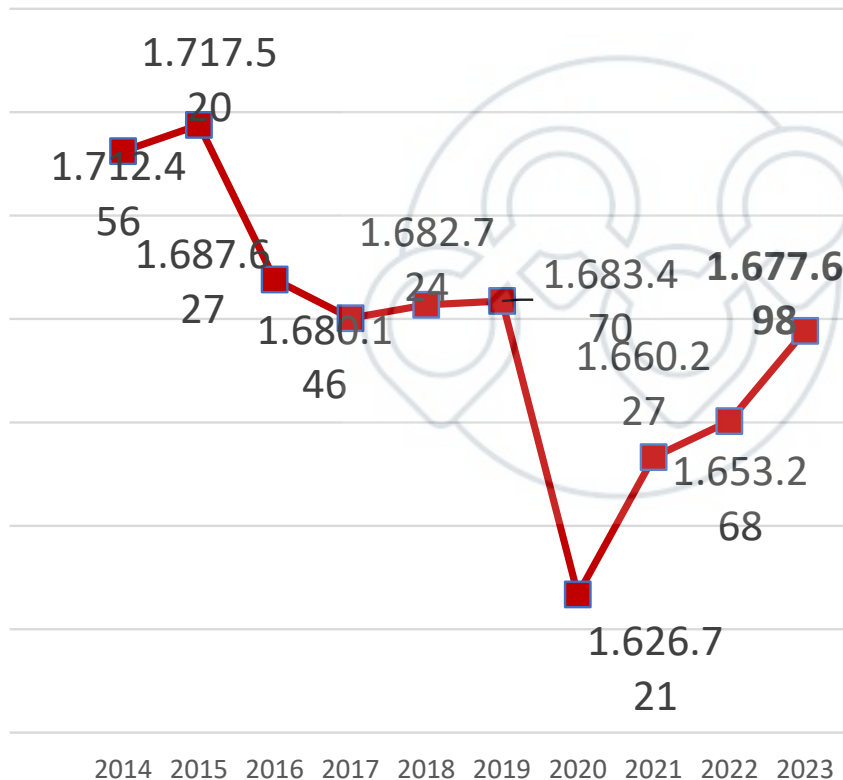


40 WB Units /1000 pop/year

18 Kg plasma/1000 pop/year



Blood donors: 2014-2023 trend



Total donors percentage variation: ten years trend

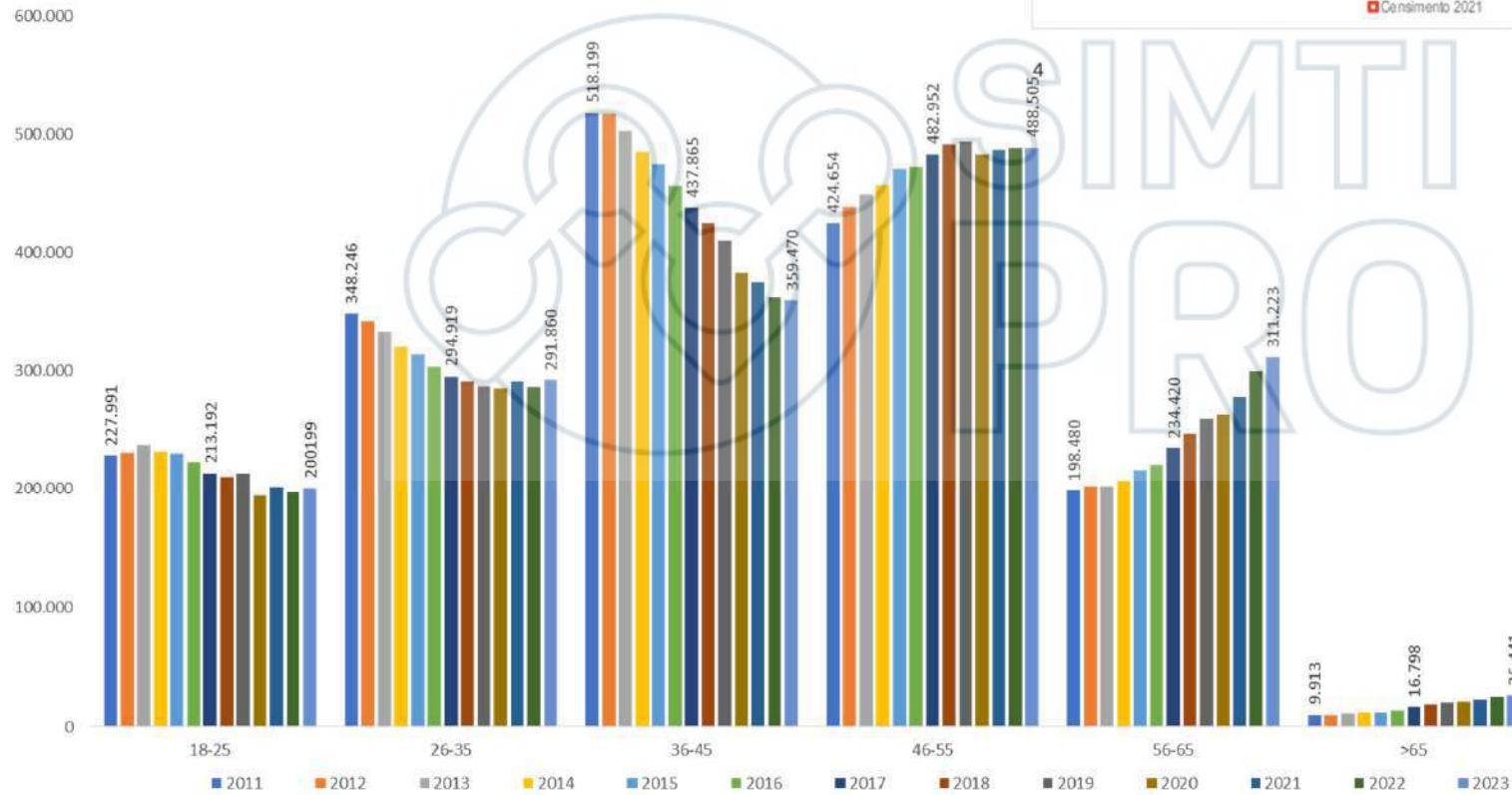
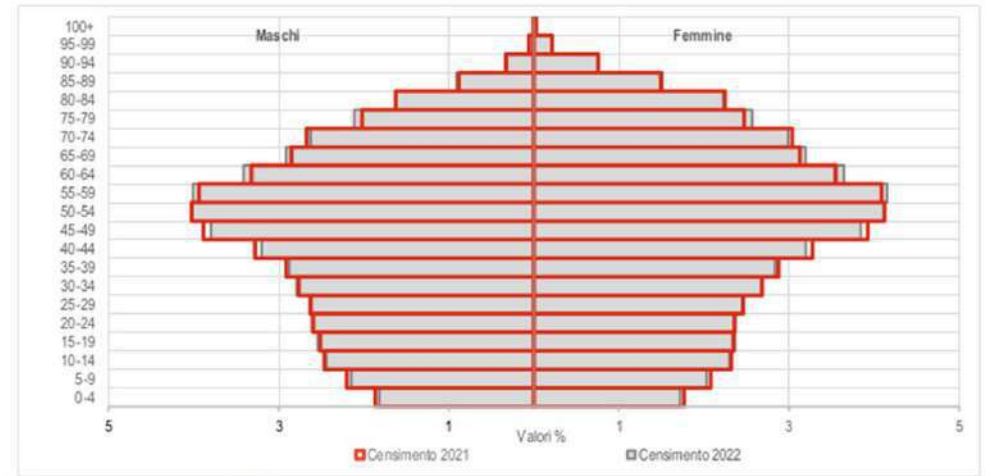
SIMTI
PRO -2%

Total donors percentage variation 2019 (pre-Covid)-2023:

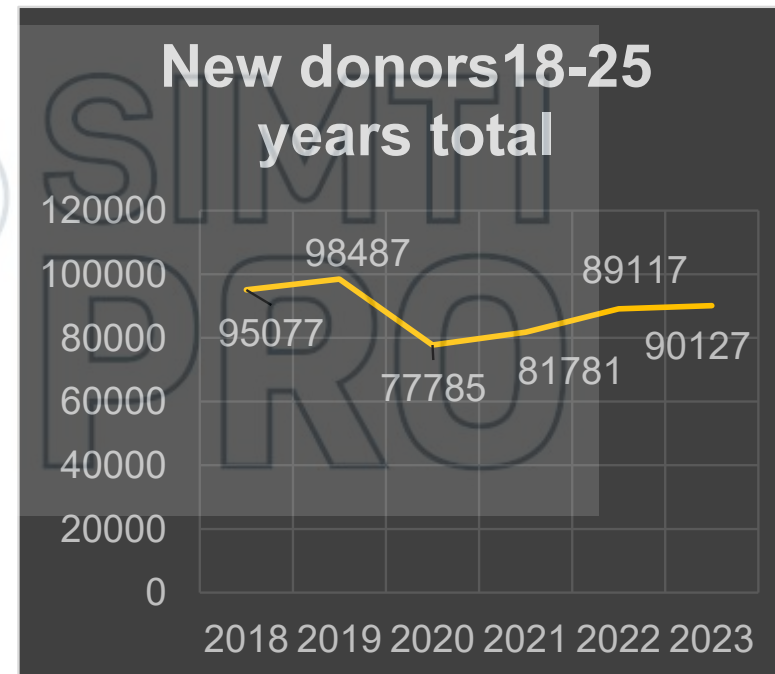
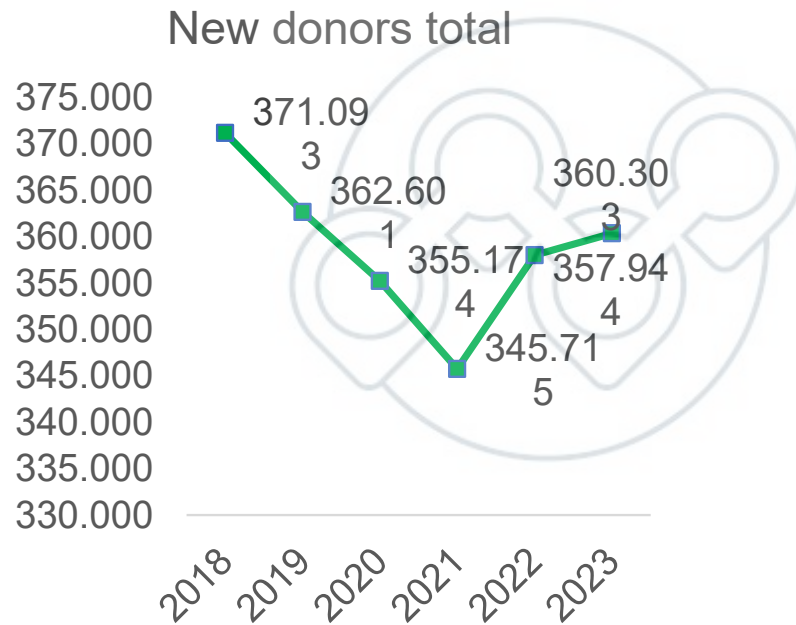
-0,3%

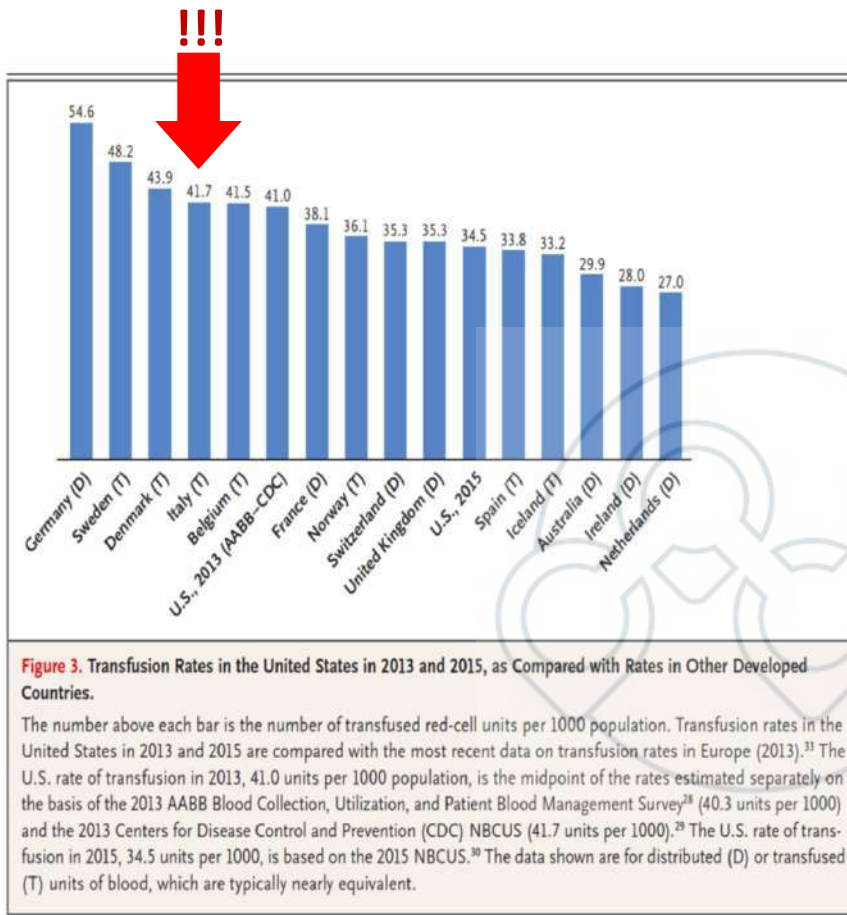
Italian blood donors (age brackets) 2011 – 2023

FIGURA 1. PIRAMIDE DELLA POPOLAZIONE RESIDENTE NEGLI ANNI 2022 E 2021



First time donors

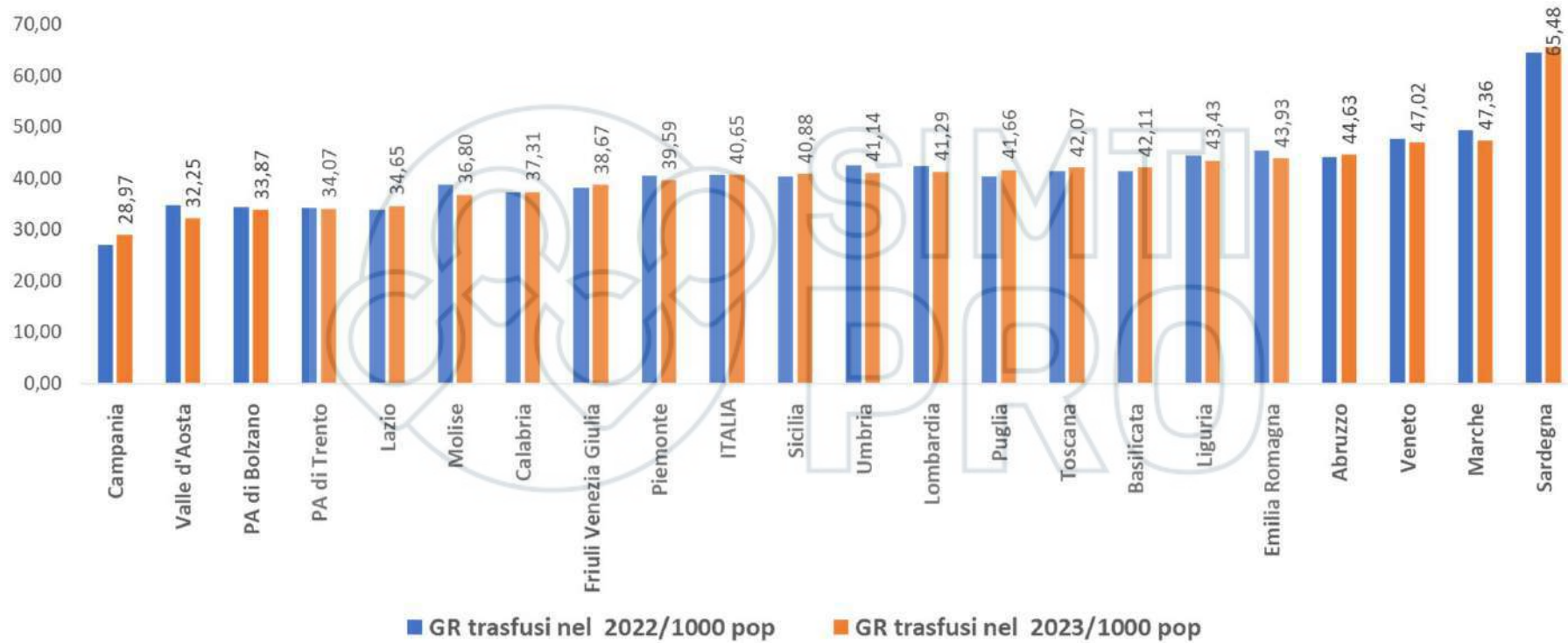




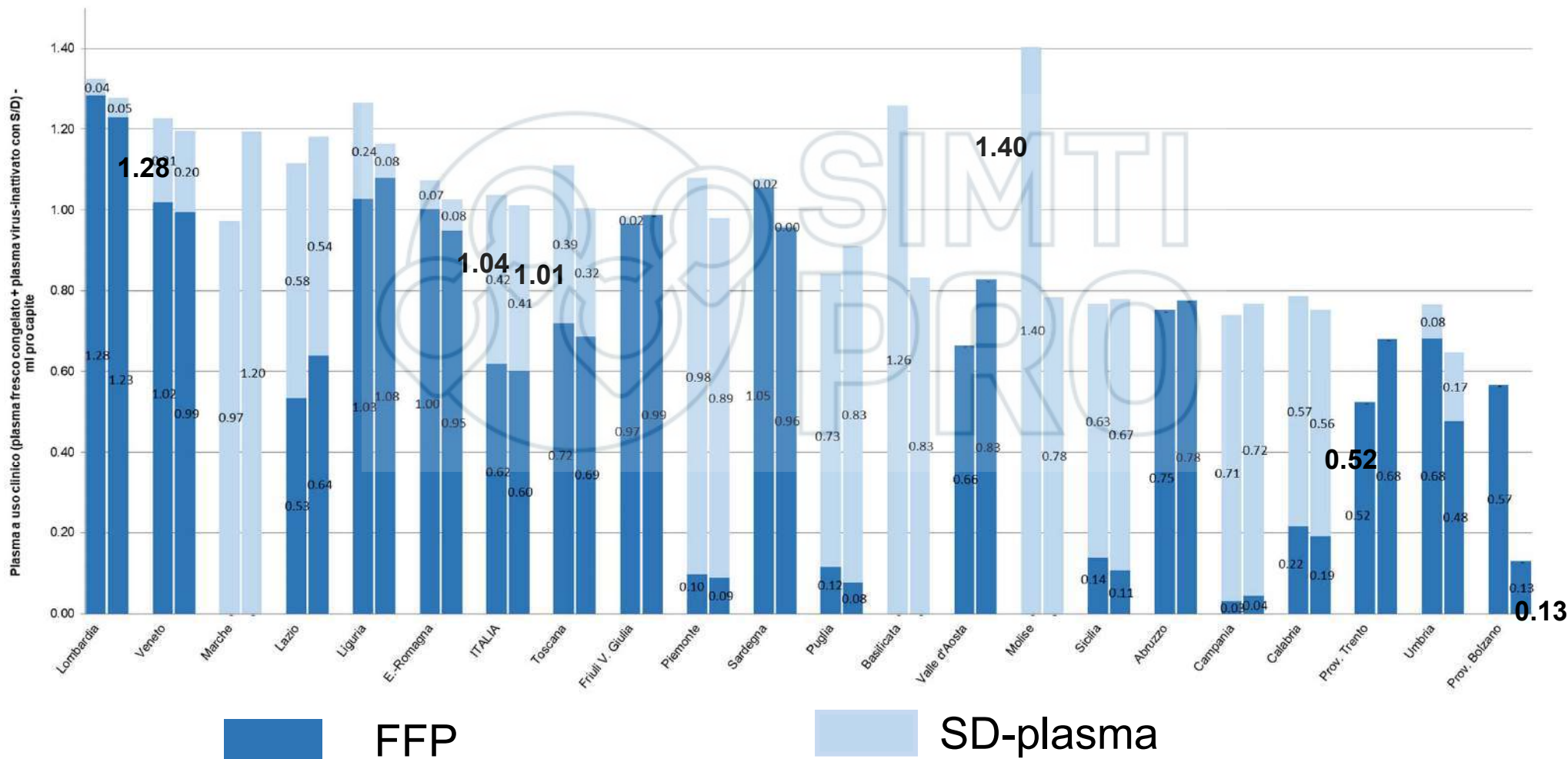
Carson, J. L., Triulzi, D. J. & Ness, P. M. Indications for and Adverse Effects of Red-Cell Transfusion. *N. Engl. J. Med.* 2017; 377: 1261–1272.

numero di unità di GR trasfuse. L'Italia si colloca tra i paesi con un indice di trasfusione elevato e probabilmente ciò è dovuto al fatto che il nostro Paese non ha ancora diffusamente adottato soglie trasfusionali "restrittive" né i programmi di Patient Blood Management sono stati estesamente attuati sul territorio.

RBC Transfusion /1.000 pop.



Plasma for clinical use in Italy 2022-2023 (L/1000 pop.)



A national study of plasma use in critical care: clinical indications, dose and effect on prothrombin time

Simon J Stanworth^{1*}, Timothy S Walsh², Robin J Prescott³, Robert J Lee³, Douglas M Watson⁴, Duncan Wyncoll⁵ and for the Intensive Care Study of Coagulopathy (ISOC) investigators

Prospective, multicentre observational study in 29 adult UK ICUs

12.7% received FFP for

- Bleeding 48%
- Preprocedural prophylaxis **15%**
- Prophylaxis without planning procedure **36%**



Efficacy of a strict surveillance policy towards inappropriateness of plasma transfusion

Ivo Beverina^{*}, Chiara Novelli, Arianna Gatti, Alessandro Aloni, Chiara Grassi, Stefania Latella, Rita Scalvini, Cinzia Gatti, Bruno Brando

Blood Transfusion Center, Legnano General Hospital, Legnano, Milano, Italy

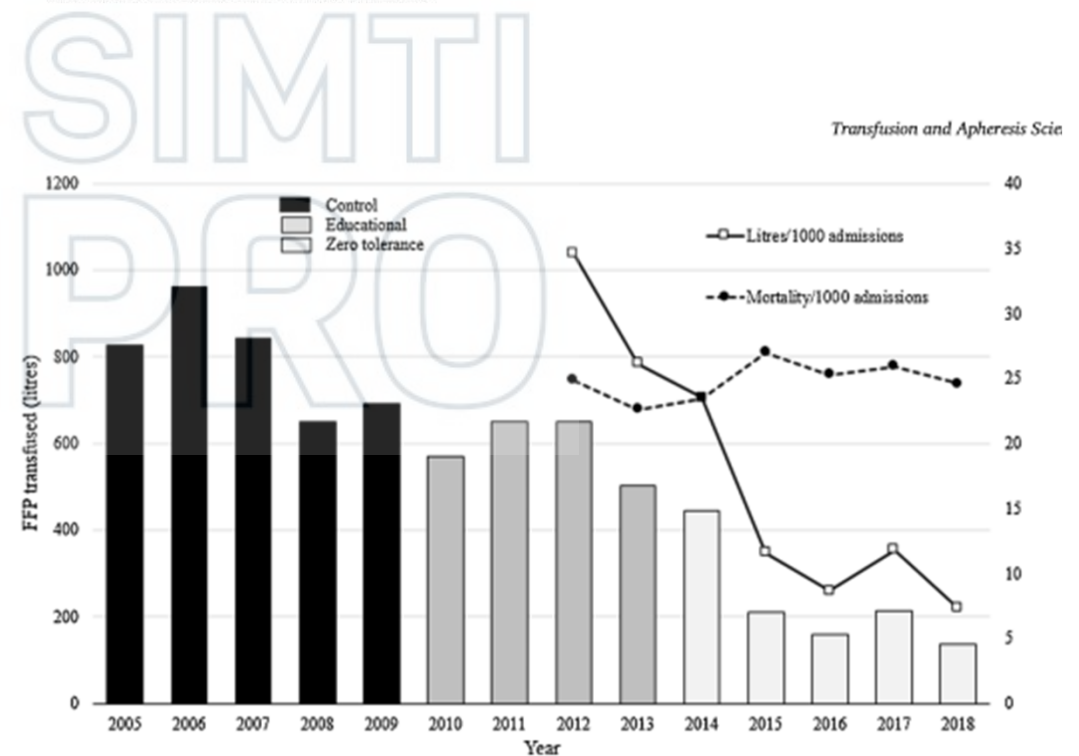


Fig. 1. Plasma transfusion by year and phase.

Coming soon !!

	Progetto	Rev. Data: Pag. 1 di 9
---	-----------------	---

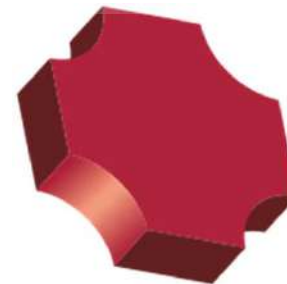
SEZIONE 1 – ANAGRAFICA PROGETTO

1.1 Titolo progetto

Definizione e sperimentazione di un modello trasferibile per la valutazione dell'appropriatezza della richiesta trasfusionale e della trasfusione evitabile.



Società Italiana di Medicina Trasfusionale e
Immunoematologia



ANMDO

Associazione Nazionale dei Medici
delle Direzioni Ospedaliere

Challenges in Transfusion Medicine in Italy *(and in the rest of the world too...)*

- Challenge of **self sufficiency & appropriateness**
 - • **Organizational Challenge**
 - Challenge of **plasma**
 - **Technology Challenge**
 - **Scientific Challenge**

Blood

Donor

Selection

**Guidelines on Assessing
Donor Suitability for
Blood Donation**



The responsibility for donor selection and care lies with **a physician or registered nurse** in attendance at the donation session.

Staff involved in donor selection should be appropriately qualified, well-trained and skilled.

The key skills, knowledge and competencies required for staff involved in donor selection include:

- Understanding of the donor selection criteria
- Pre-donation information and counselling
- Interview and assessment based on a standardized donor questionnaire
- Ability to explain questions in the donor questionnaire, ensure understanding and allay donors' apprehensions
- Basic health check, including haemoglobin screening
- Counselling of deferred donors
- Post-donation advice and care.



Donor selection & attendance

CONFIDENTIAL REPORT - TO BE USED ONLY WITHIN YOUR ORGANISATION

 EUROPEAN
BLOOD
ALLIANCE

EBA Consultation REPORT S2206_ Qualification of collection staff

Summary report EBA S2206_ Qualification of collection staff

Main findings

We have received 11 answers from our colleagues. You can read below our takeaways for each position.

Supervision of collection:

Only Portugal requires a more specific specialty (transfusion medicine) for apheresis procedures.

In 5 countries, a physician must necessarily supervise the collection. In the other 6 countries, nurses may do so, or even a biomedical analyst or nurse's aide (in Sweden).

Pre-donation interview:

In 6 countries, interviews are performed exclusively by doctors or nurses.

In Sweden, other accepted qualifications are: technicians, paramedics, biomedical analysts.

In 4 countries, in-house training allows anyone, even without medical training, to perform interviews.

Denmark is the only country to have a digital tool to help with data entry and decision making during the interview.

Clinical Practice
Discussion
Blood transfusion

Keywords Nursing roles/History/Blood transfusion/Better Blood Transfusion

This article has been
double-blind peer reviewed

In this article...

- Developing the role of the nurse in blood transfusion practice
- Government introduction of the Better Blood Transfusion initiative
- Non-medical authorisation of blood components

Exploring blood transfusion 2: the role of the nurse in clinical practice

Today in the UK there are hundreds of nurses working in roles directly related to blood transfusion (NHS Blood and Transplant, nd). These include blood donor nurses, transfusion practitioners, apheresis nurses, as well as roles within haemovigilance organisations (Serious Hazards of Transfusion, 2022). However, most blood transfusions are administered by non-specialist

Conclusion

In the last 100 or so years the nurse's role has developed from that of the humble doctor's assistant to one in which they can potentially extend their role to become an independent authoriser of blood and blood components. Learning about the history of nursing can be beneficial for many reasons.

NHSBT: Do you know what a nurse working in the Blood Donation Directorate does?

Senior sister/charge nurse (band 7)

Manages collection team, overseeing the clinical safety and effectiveness of the team, as well as the operational needs to ensure the sessions run smoothly

Session nurse (band 6)

Each donation session has at least one session nurse, who is responsible for leading and managing the session

Donor care supervisors (band 4)

Each donation session usually has at least one donor carer supervisor. They are donor carers who have the additional responsibility of helping to manage the team of donor carers and the donation session

- Nurses in blood donation are responsible for leading blood donation sessions, delivering high-quality care for donors and ensuring that the blood supply is safe for patients.
- They are the first step in providing safe blood components to patients in need.
- To put things in perspective, **NHSBT nurses collect around 5000 donations every day across England.**

Severe adverse events in donors: UK vs Italy

Table 6.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2022

	NHSBT	SNBTS	WBS	NIBTS
Whole blood donations	1,452,709	149,395	82,678	39,922
Apheresis donations	77,655	7,548	2,665	3,619
Total donations	1,530,364	156,943	85,343	43,541
Total number of SAED in the calendar year 2022	41	11	3	0
Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation'	33	9	1	0
Rate of total SAED per 10,000 donations in UK for 2022 (all submitted reports irrespective of imputability)		0.30		
Rate of SAED per 10,000 donations in UK for 2022 excluding those with imputability of 'unlikely' or 'not related to donation'		0.24		

Total donations and total numbers of SAED* in Italy (2022)

	Italy 2022
Whole Blood donations	2,555,886
Apheresis donations	426,738
Total donations	2,982,624
Mild, moderate and severe SAED	8,626
Severe SAED only	308
Rate of all SAED per 10,000 donations	28.92
Rate of severe SAED per 10,000 donations	1.03

* Imputability grading not applied.

The distribution of SAR imputability 1-3 and 2-3 by country and by blood component is represented in Figures 10 & 11.

It appears that there is no relationship between professionals involved in donor selection AND number of reported SARs

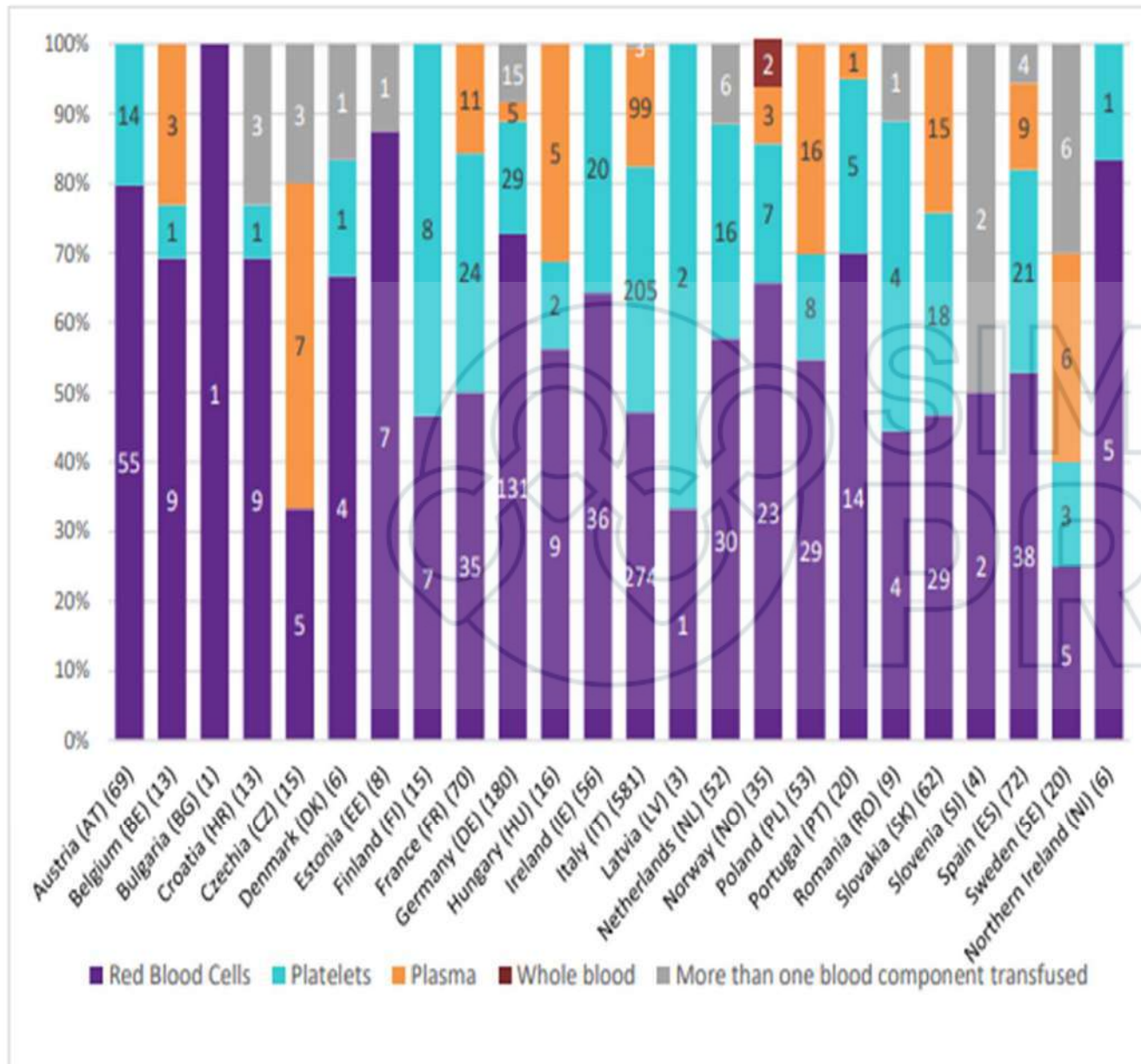


Figure 11. Number of SAR of imputability level 2-3 by country and type of blood component; data 2021

Article 50

Physician

1. *Each SoHO establishment shall appoint a physician who carries out their tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:*

(a) possession of formal qualification as a physician; and

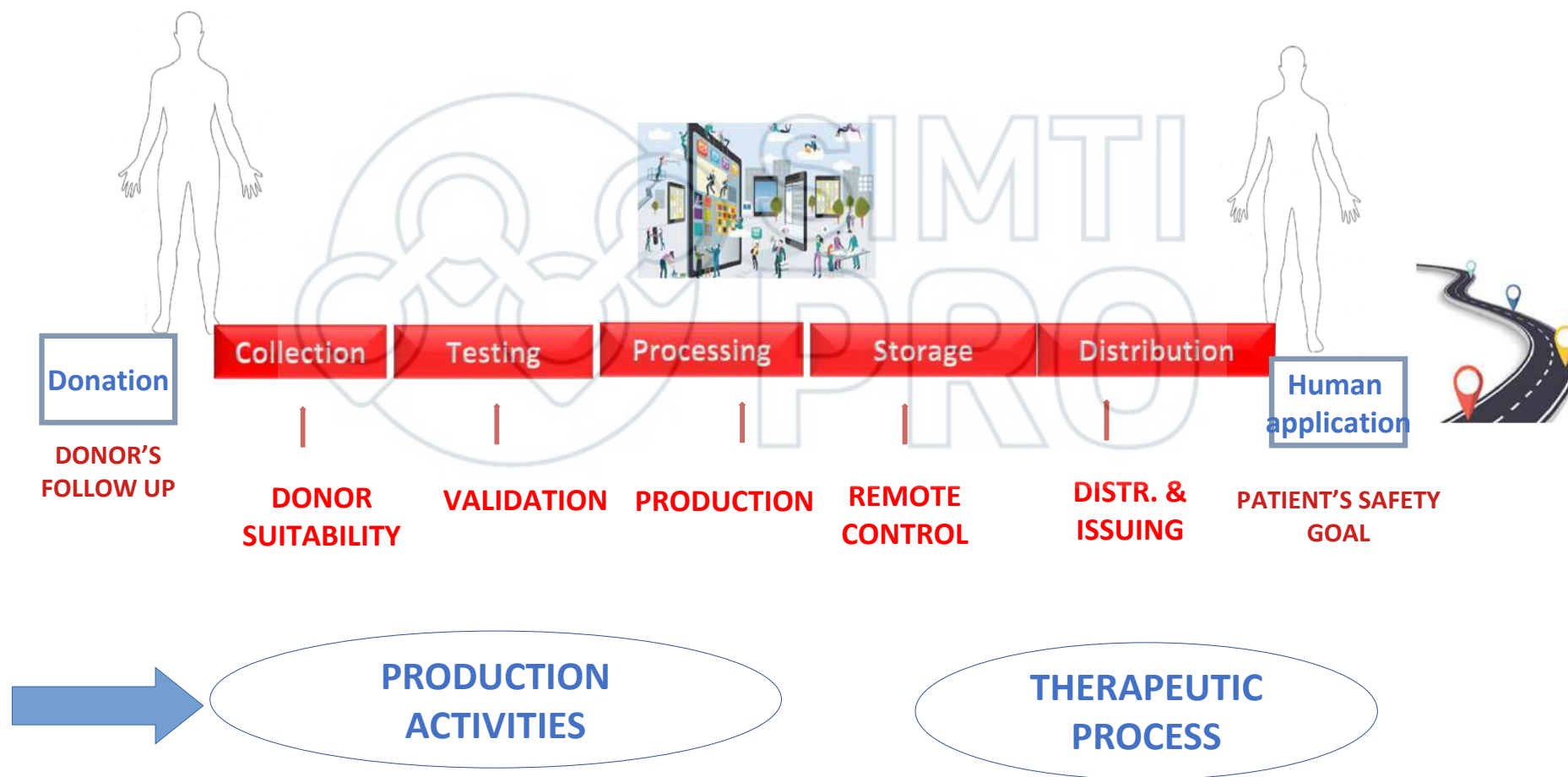
(b) at least 2 years' practical experience in the relevant field.

2. *The physician referred to in paragraph 1 shall be responsible for at least the following tasks:*

(a) development, review and approval of procedures for establishing and applying SoHO donor eligibility criteria, procedures for SoHO collection and criteria for the allocation of SoHO;

(b) supervision of the implementation of procedures referred to in point (a) when they are carried out by SoHO entities contracted by the SoHO establishment

Transfusion chain from vein-to-vein

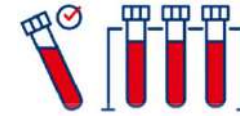
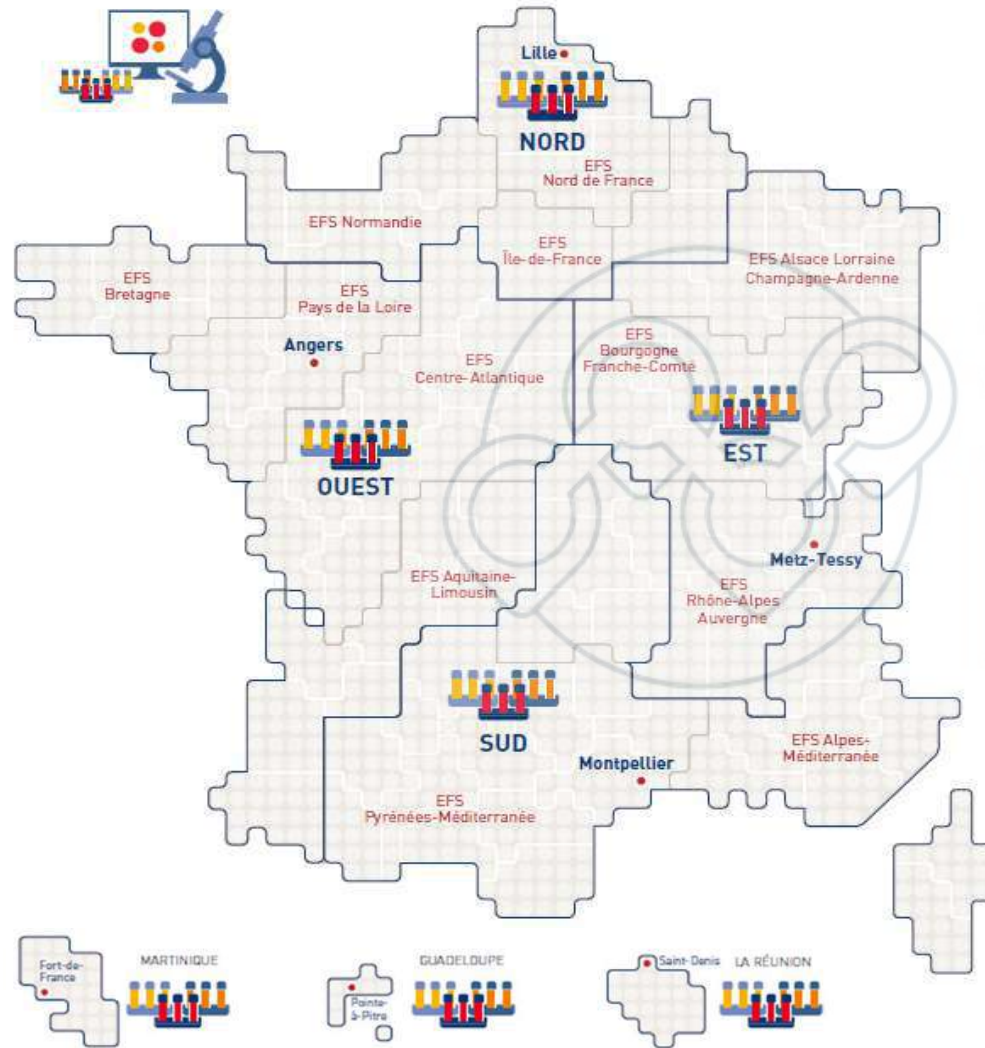


Organization of blood processing: Italy vs France

REGIONE	N° centri che effettuano lavorazione emocomponenti	Centro di Lavorazione con N.A.T.*		Totale unità sangue intero lavorate/anno		Centro di lavorazioni con Sierologia		Totale unità sangue intero lavorate/anno	
		NO	SI	Centri senza N.A.T.	Centri con N.A.T.	NO	SI	Centri senza Sierologia	Centri con Sierologia
ABRUZZO	4	-	4	-	55.581	-	4	-	55.581
BASILICATA	2	1	1	3.229	20.353	-	2	-	23.582
CALABRIA	3	2	1	37.518	31.564	2	1	37.518	31.564
CAMPANIA	17	14	3	109.749	53.895	14	3	109.749	53.895
EMILIA ROMAGNA	6	2	4	32.995	178.485	2	4	32.995	178.485
FRIULI-VENEZIA GIULIA	1	-	1	-	55.697	-	1	-	55.697
LAZIO	13	11	2	142.337	38.751	11	2	142.337	38.751
LIGURIA	2	1	1	24.569	44.808	1	1	24.569	44.808
LOMBARDIA	9	1	8	37.258	407.042	1	8	37.258	407.042
MARCHE	1	-	1	-	75.738	-	1	-	75.738
MOLISE	3	2	1	11.314	-	2	1	11.314	-
PIEMONTE	14	8	6	49.529	137.112	7	7	43.132	143.509
P.A. BOLZANO	1	-	1	-	22.506	-	1	-	22.506
P.A. TRENTO	1	-	1	-	24.939	-	1	-	24.939
PUGLIA	18	15	3	115.534	45.644	15	3	115.534	45.644
S.T. FORZE ARMATE	1	1	-	578	-	-	1	-	578
SARDEGNA	10	8	2	41.747	39.738	-	10	-	81.485
SICILIA	24	21	3	149.668	47.164	21	3	149.668	47.164
TOSCANA	9	6	3	78.123	74.289	6	3	78.123	74.289
UMBRIA	2	-	2	-	36.898	-	2	-	36.898
VALLE D'AOSTA	1	-	1	-	5.453	-	1	-	5.453
VENETO	7	2	5	27.837	212.822	2	5	27.837	212.822
Totale risultato	149	95	54	861.985	1.608.479	84	65	810.034	1.660.430

Data from SISTRA, CNS 2024

Organization of blood processing: Italy vs France



7 Qualification sites

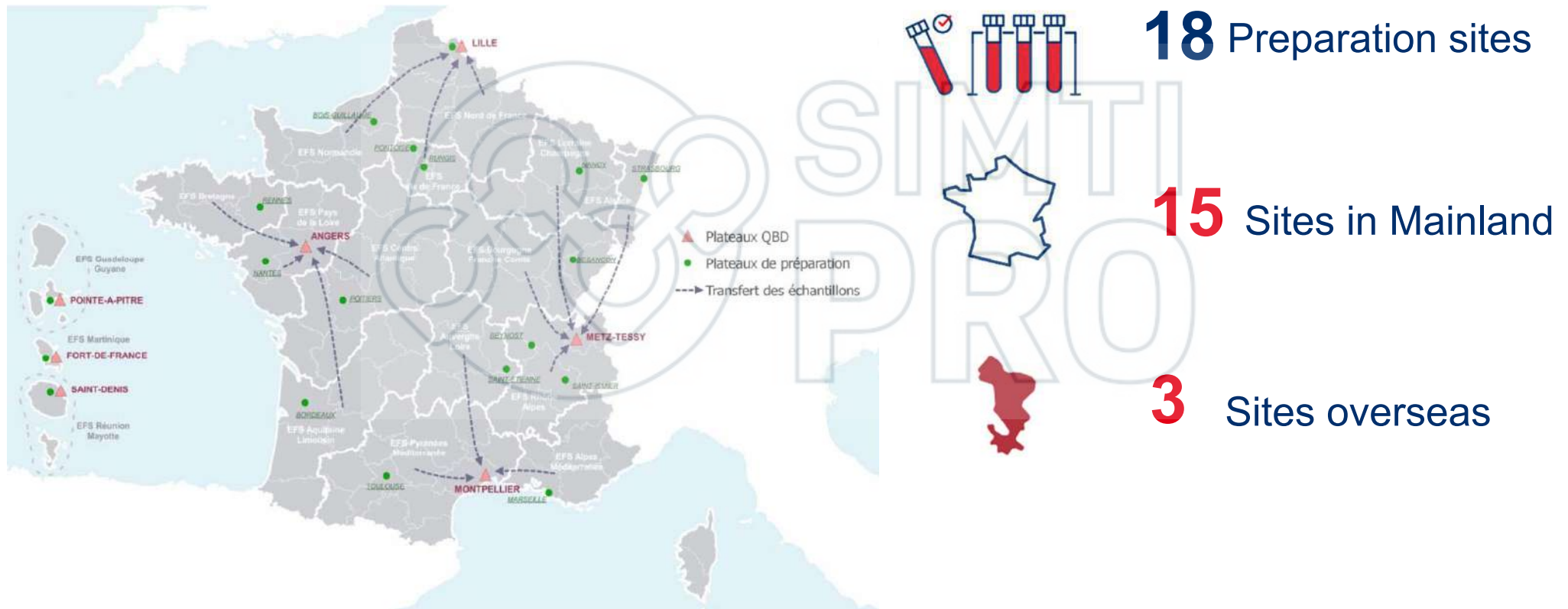


4 Sites in Mainland

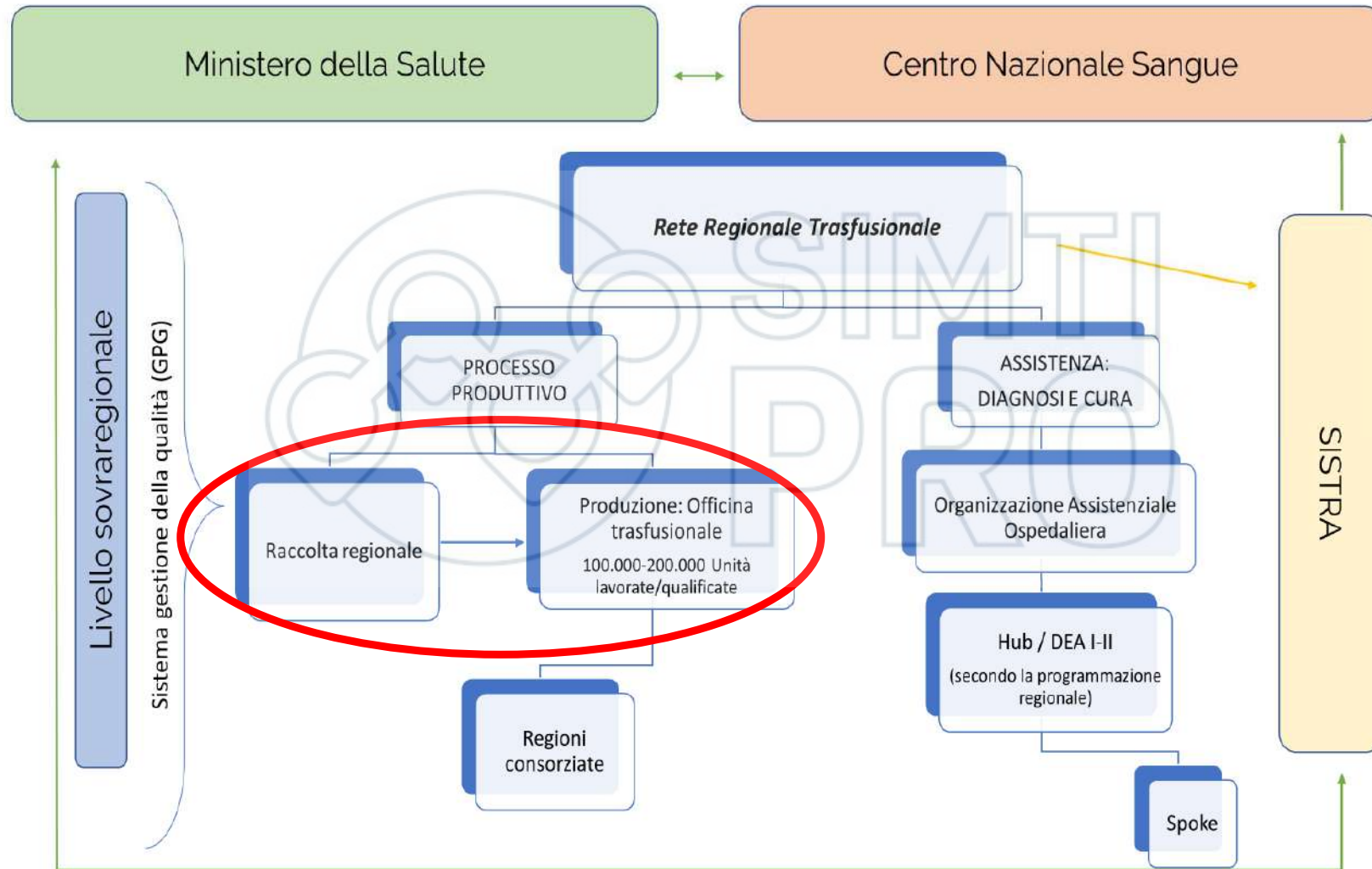


3 Sites overseas


Organization of blood processing: Italy vs France



Challenge for transfusion network in Italy

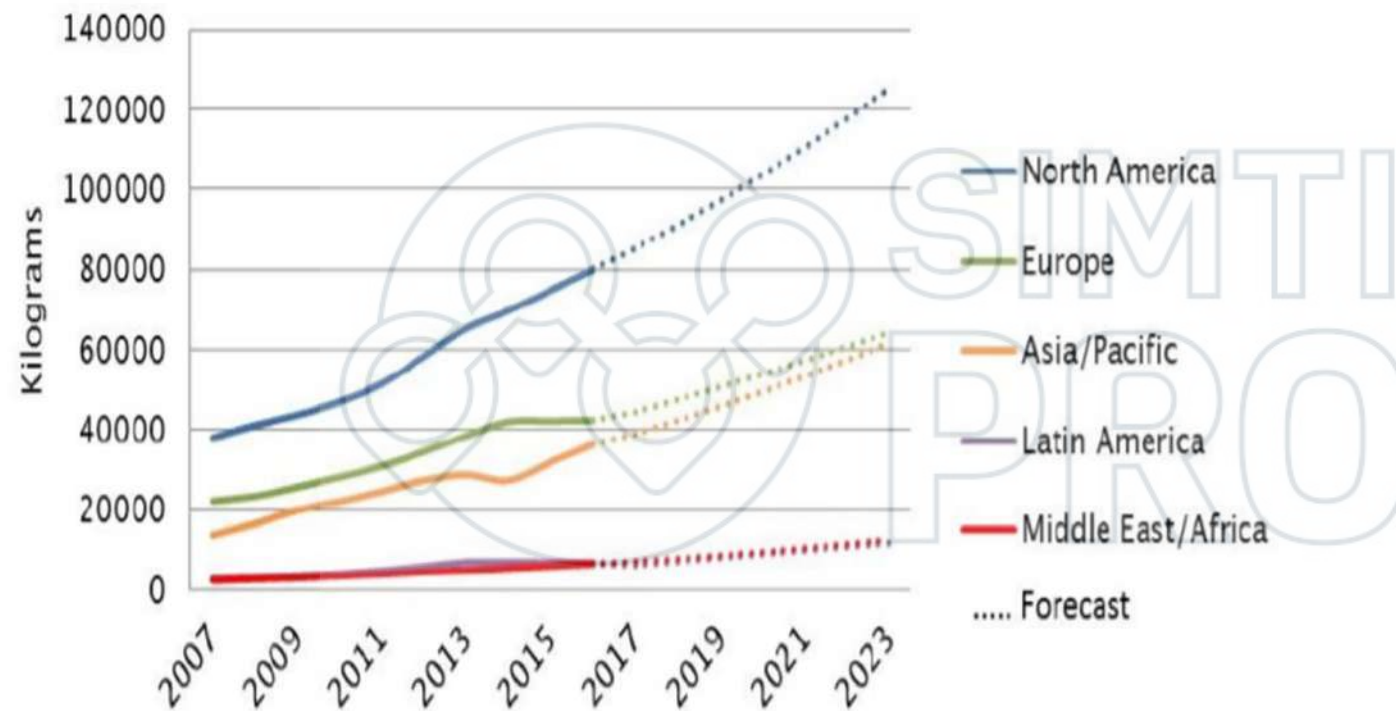


Challenges in Transfusion Medicine in Italy *(and in the rest of the world too...)*

- Challenge of **self sufficiency & appropriateness**
 - **Organizational** Challenge
 - Challenge of **plasma**
 - **Technology** Challenge
 - **Scientific** Challenge
- 

Domanda globale di immunoglobuline

Trend e prospettive



FARMINDUSTRIA

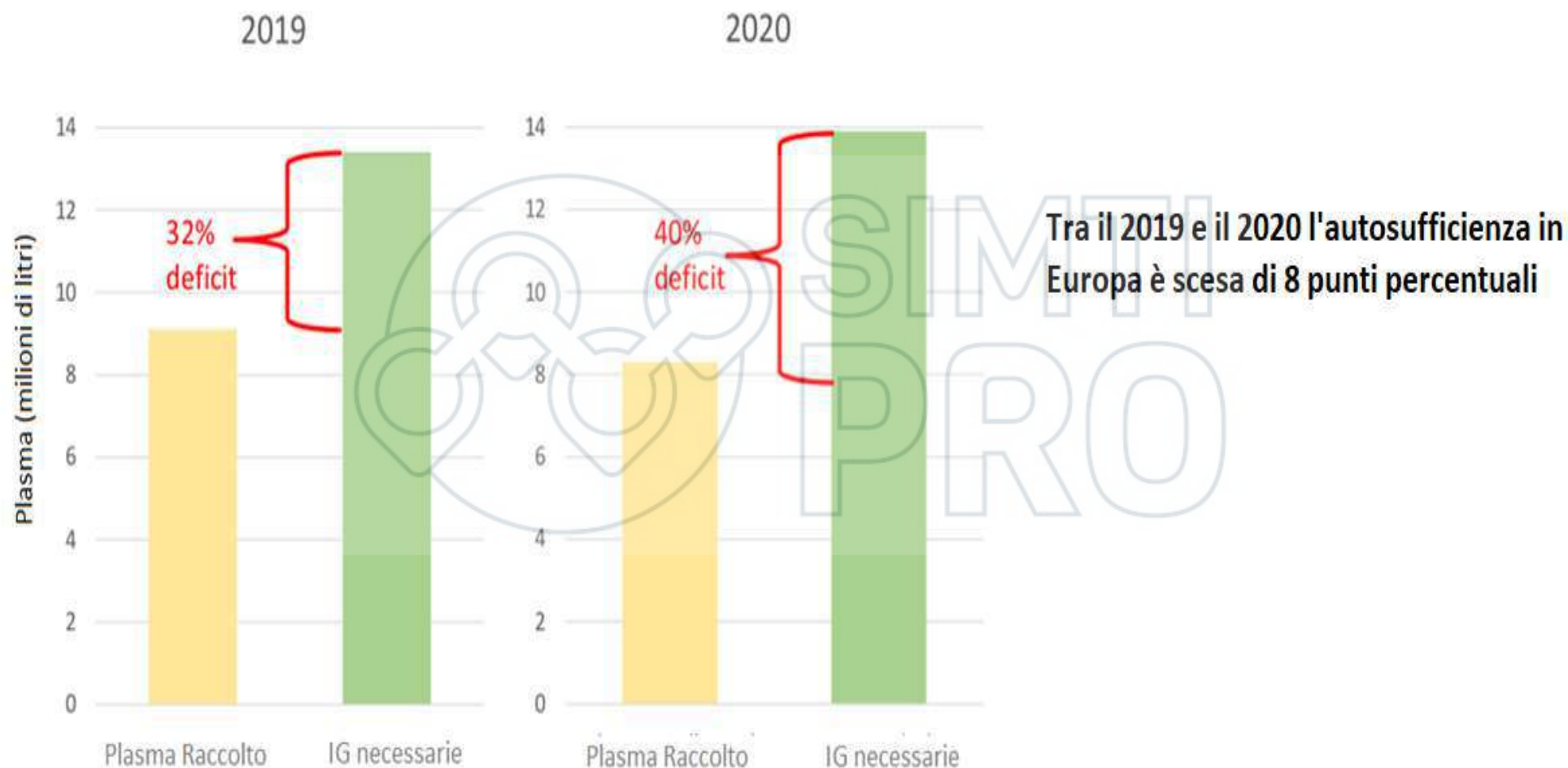
Fonte: Protecting access to immune globulins for Canadians. Final Report, Maggio 2018

14

Courtesy of: D. Medica on behalf of GAEF – Gruppo Aziende Emoderivati Farindustria adapted from P.Robert «Dans un Marché Mondialisé, Quel Accès des Patients Français aux Médicaments Dérivés du Plasma »?, 11 novembre 2020

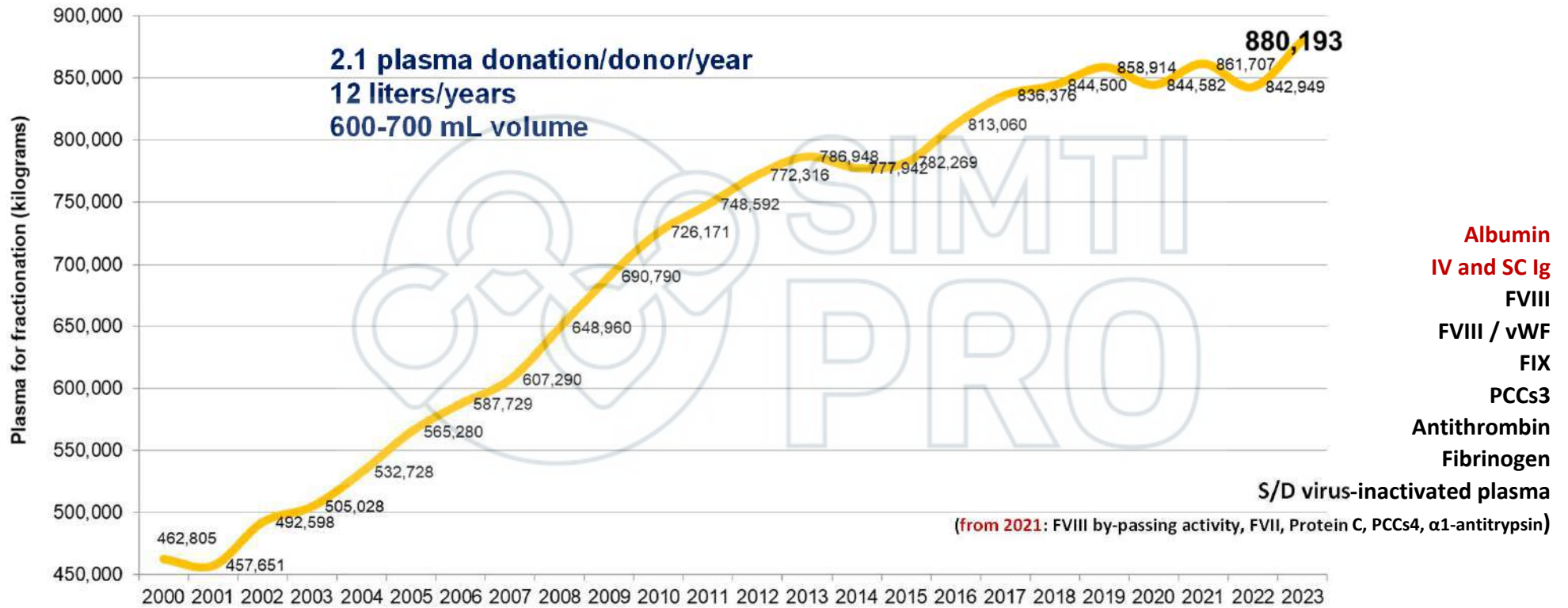


2019 e 2020: squilibrio tra raccolta del plasma e fabbisogno di IG in Europa



*Assumere una resa media di 4,5 grammi IG per litro di plasma

Plasma for fractionation 2000 - 2023 (total kilograms)



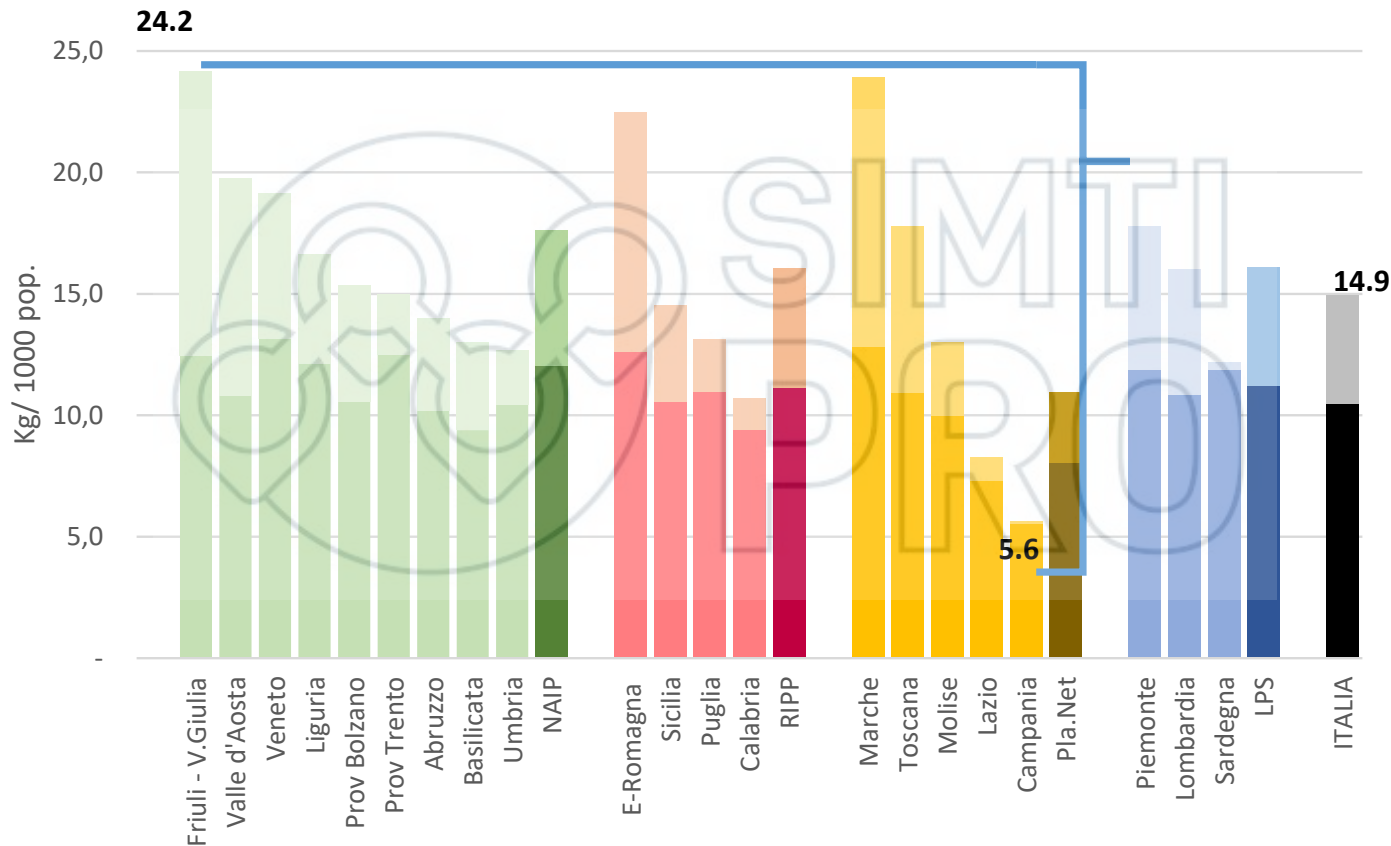
Donations needed for the treatment of 1 patient for 1 year:

- Primary immunodeficiency: 130**
- Alpha-1 antitrypsin deficiency: 900**
- Haemophilia: 1,200**

Data sources: - Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024

DATI
PROVISORI

PLASMA TO FRACTIONATION (BY REGION AND AGREEMENT). YEAR 2023 (kg/1.000 pop)



Data sources: - Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024

45°

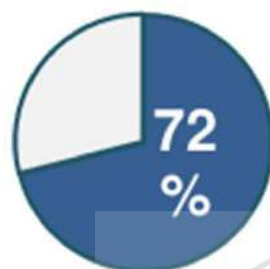
Convegno Nazionale di Studi di Medicina Trasfusionale

Rimini, 29-31 maggio 2024

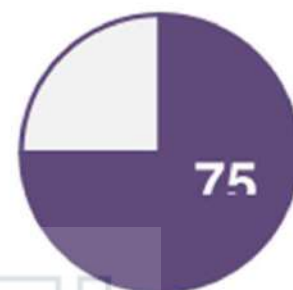


PDMPs self sufficiency in Italy in 2022

ALBUMIN



ANTITHROMBIN



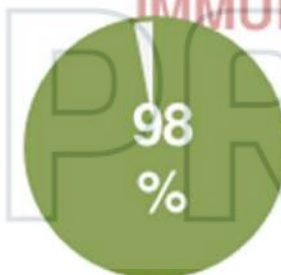
IV IMMUNOGLOBULIN**



SC IMMUNOGLOBULIN



FVIII*



FIX+3F-PCCs

(only 3F-PCCs self-sufficiency=91% only FIX self-sufficiency=75%)



FIBRINOGEN



FVIII/vWF



° on the total demand for contract-manufactured products

*100% of total demand for contract-manufactured products

** The value not includes Pentaglobin™

Data sources: adapted by the CNS on data from the Traceability information flow

45° | Convegno Nazionale di Studi di Medicina Trasfusionale

Rimini, 29-31 maggio 2024

SELF-SUFFICIENCY NATIONAL PROGRAMME (2023)

Plasma for fractionation to '18 kg / 1.000 pop'

$$18 \text{ kg / 1.000 pop} \rightarrow 1.093.800 \text{ kg} \rightarrow = 241.200 \text{ kg}$$

*Δ Plasma required vs Plasma planned 2023**

Plasma for fractionation = '90% Ig demand'

$$1.329.200 \text{ kg} \rightarrow \Delta \text{ Plasma required vs Plasma planned 2023}^* \rightarrow = 473.432 \text{ kg}$$


Plasma for fractionation = '90% Albumin demand'

$$1.359.500 \text{ kg} \rightarrow \Delta \text{ Plasma required vs Plasma planned 2023}^* \rightarrow = 520.376 \text{ kg}$$

*Obiettivo DM 01/08/2023 - Programma nazionale di autosufficienza 2023= 859.860 kg

Data source: Programma di autosufficienza nazionale del sangue e dei suoi prodotti, anno 2023

Challenges in Transfusion Medicine in Italy *(and in the rest of the world too...)*

- Challenge of **self sufficiency & appropriateness**
 - **Organizational** Challenge
 - Challenge of **plasma**
- 
- **Technology** Challenge
 - **Scientific** Challenge

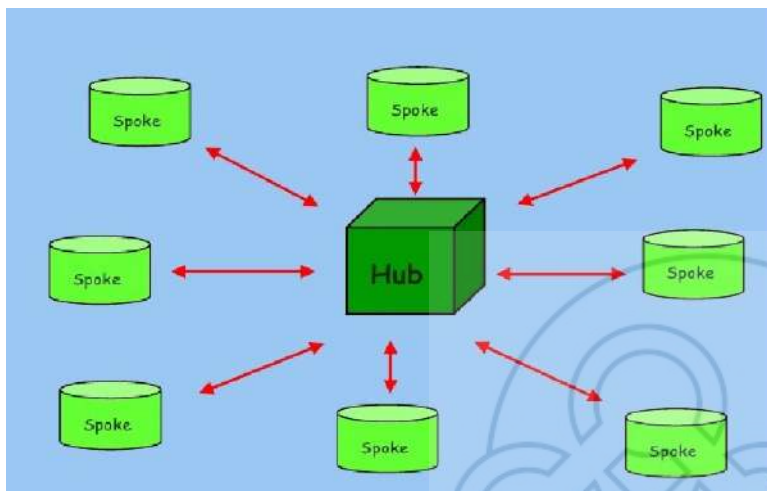
Artificial Intelligence and Transfusion Medicine

Transfusion Medicine is a medical discipline that supports a large number of medical specialties almost on a daily basis. The field represents a promising challenge for the introduction of AI through *deep learning* and *machine learning*.



The use of **Artificial Intelligence** can significantly improve the efficiency and effectiveness of blood donation management, allowing demand to be predicted and met more precisely and reducing the risk of transfusion errors.

Telemedicine in transfusion medicine: advantages



- ❖ Reshaping the structural and organizational models of transfusion activities
- ❖ Promote support between distant structures (structured exchange)
- ❖ Promote and improve traceability through connectivity of technologies



Short report

Connectivity in transfusion medicine: Challenges, benefits, and goals

Aspen King^{a,1}, Guillem Beltran Arroyos^{b,1}, Nicolas Cellier^{c,1}, Steve Durgacharan^{d,1},
Maria Kerr^{d,1}, Luis Larrea^{e,*}, Marcia Cardoso^{a,1}

Telemedicine in transfusion medicine: applications

DONORS

nell'interazione tra servizi trasfusionali (ST) e Unità di raccolta (UdR) associative da un lato e il donatore dall'altro nel processo di gestione dei donatori di sangue ed emocomponenti (promozione, programmazione della raccolta del sangue e degli emocomponenti, accertamento dell'idoneità del donatore di sangue ed emocomponenti e suo follow-up);

PRODUCTS

nella gestione del processo di produzione, qualificazione biologica e validazione degli emocomponenti, distribuzione degli stessi e cessione del plasma per la lavorazione industriale finalizzata alla produzione di medicinali emoderivati;

PATIENTS

nella gestione del processo complessivo che conduce a rendere assegnabili i prodotti trasfusionali (costituito da un insieme di procedure che includono la valutazione di appropriatezza della richiesta, la selezione delle unità rispondenti ai criteri di assegnabilità, le indagini pre-trasfusionali per la valutazione della compatibilità degli emocomponenti ad uso trasfusionale e la consegna dei prodotti);
nelle attività clinico-assistenziali e nelle prestazioni di diagnosi e cura proprie della medicina trasfusionale

Décrets, arrêtés, circulaires

TEXTES GÉNÉRAUX

MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ

Arrêté du 27 juin 2019 fixant les modalités de communication entre les infirmiers ou infirmières chargés de la surveillance du déroulement du prélèvement et de l'entretien préalable au don de sang total et le médecin mentionné à l'article R. 1222-17-II-1° du code de la santé publique

NOR : SSAP1918822A

Art. 2. – Les collectes de sang total en l'absence d'un médecin sur le site ne peuvent être organisées que dans les zones qui bénéficient d'une couverture de réseau internet ou de téléphonie mobile suffisante pour garantir la qualité des échanges qui se tiennent par l'intermédiaire du moyen de communication prévu à l'article 1^{er}.

Avant toute collecte, l'Etablissement français du sang évalue la bonne qualité du réseau dans la salle dédiée aux prélèvements et l'ensemble des locaux dédiés à la collecte en vérifiant par un appel test la connexion avec le médecin joignable à distance mentionné au premier article.

Art. 3. – En l'absence d'un médecin sur le site de collecte, l'Etablissement français du sang s'assure qu'un médecin est joignable durant les horaires d'ouverture de chaque collecte, et le cas échéant, jusqu'au départ du dernier donneur. Il organise la continuité et la permanence de la réponse.

Art. 4. – Chaque appel au médecin mentionné à l'article 3 fait l'objet d'une traçabilité visant à quantifier et

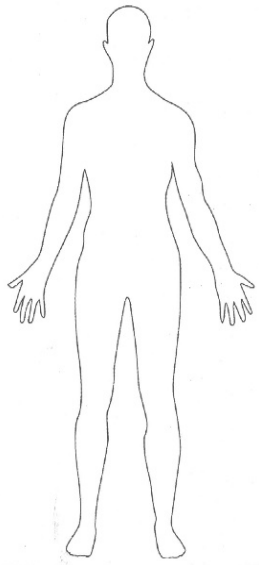
Indice

1. Premessa	3
2. Scopo e campo di applicazione	4
3. Glossario	4
3.1 Definizioni	4
3.2 Acronimi/abbreviazioni	5
4. Riferimenti tecnico-scientifici	6
5. Ruolo della telemedicina nel percorso trasfusionale	6
6. Indicazione delle condizioni per l'erogazione in telemedicina	8
7. Analisi di flusso per i principali ambiti di applicazione delle prestazioni sanitarie trasfusionali in telemedicina	10
7.1 Selezione del donatore e follow up della donazione	10
7.2 Preparazione, validazione e conservazione emocomponenti	12
7.3 Richiesta trasfusionale e selezione delle unità, Conservazione, Gestione delle emoteche e Distribuzione	13
7.4 Terapia Trasfusionale	15
7.4.1 Sicurezza al letto del paziente	15
7.4.2 Supporto al Patient Blood Management	16



Progetto CCM 2021 -2023

CONNECTIVITY IN DONOR SELECTION PROCESS



Donor



Donation

Availability of a self-assessment questionnaire, accessible through an app dedicated for smartphone or other mobile device, to be filled in by the donor no more than 48 hours before the date scheduled for presentation to the donor facility.

Aims

Production and validation of interactive software to assist the donor in pre-donation self-assessment(Computer Assisted Donor Self-Interviewing, CASI)

Improvement of the blood donor selection process through the optimization of TAT

Improve the reliability of the information provided by the donor (confidentiality, guided answers) and improvement of donor appreciation

Further aims

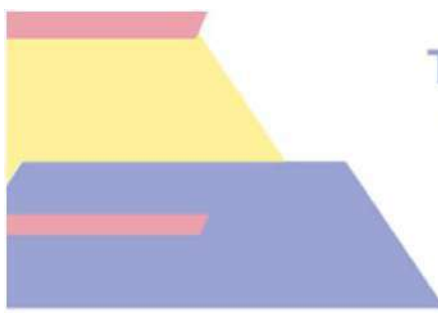
Reduce the donor's waiting time before donating

Strengthen the donor's attitude to booking the donation



Transfusion Medicine & ATMPs

- The rapid development of cellular therapy continues to surprise the entire medical field, including transfusion medicine, which has been actively involved in cellular therapies
- **The growth of cell therapies in the context of transfusion medicine continued** with various products of hematopoietic stem cells, granulocytes and lymphocytes, as well as cryopreservation of both cells and tissues, in some cases also preparations of chondrocytes and mesenchymal cells.
- Blood establishments have faced challenges in the field of advanced therapy medicinal products (ATMPs) and have demonstrated their suitability in providing starting materials for research and production, managing donors, using existing quality and traceability frameworks, product logistics strategies and good manufacturing practices, as well as in producing ATMPs. **The expansion of advanced treatment within transfusion institutions is expected to continue.**



TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023
High Level Meeting



American Journal of Transplantation xxx (xxxx) xxx

Santander statement

On November 9-10, the Organización Nacional de Trasplantes convened in Santander, Spain, for a Global Summit entitled “Towards Global Convergence in Transplantation: Sufficiency, Transparency, and Oversight.”¹ Paving the way for the next decade of global action in transplantation, the summit covered the following topics:

1. Improvement in patient care
2. Progress toward sufficiency in transplantation
3. Ensuring transparency and oversight of practices
4. Strengthening the prevention of human trafficking and organ trafficking in Substances of Human Origin
5. Fostering responsible innovation in the clinical use of Substances of Human Origin

- actively supporting and funding efforts to overcome the research and economic challenges in developing sustainable innovation;
- mandating the demonstration of quality, safety, and effectiveness of SoHO-based therapies before permitting them to be incorporated into healthcare systems;
- ensuring that human organs, tissues and cells do not become marketable;
- ensuring transparency in costs, pricing, and profits from all SoHO-based therapies, and making such therapies affordable to patients;
- promoting social responsibility in public-private collaboration in the development of SoHO-based therapies.

FUTURE???



Conclusions of the Evaluation - 2019

The legislation had increased the safety and quality of blood, tissues and cells across the EU. However, 5 gaps/shortcomings were identified:



1. Patients are not fully protected from avoidable risks

EU safety and quality requirements are incomplete and have failed to remain up to date with frequently changing scientific and epidemiological developments. The outdated provisions are technical in nature



2. Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos

Donor adverse reactions (including serious ones) are not systematically reported and the requirements for testing egg and sperm donors for genetic conditions are limited.



3. Divergent approaches to oversight cause unequal levels of safety and quality and barriers to the exchange of BTC across the EU

Lack of general principles, provisions for verification of effective implementation of inspection, authorisation, vigilance.



4. BTC legislation lags behind innovation

Limited clinical data on safety and efficacy of new ways of processing donations. Difficulties in defining the borderlines for novel BTC with other regulatory frameworks



5. EU vulnerable to interruptions in supply of some BTC

High dependence on plasma import. Lack of supply monitoring for crisis management.





Council of the
European Union

Brussels, 30 April 2024
(OR. en)

9239/24

Interinstitutional File:
2022/0216(COD)

P9_TA(2024)0353

Standards of quality and safety for substances of human origin intended for human application

European Parliament legislative resolution of 24 April 2024 on the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))

Scope: Regulation covers all steps for all SoHO (some limited provisions for autologous SoHO), unless processing or application steps fall under scope of other EU frameworks (art 2.3) – then SoHO regulation is restricted to certain relevant activities

Publication obligations – national security or defence

PROCESSING / APPLICATION

SoHO – transfusion, transplantation, assisted reproduction

DONATION / COLLECTION



Borderline criteria are not set in this proposal. They are set in the other legislative acts (pharma, medical devices) – **FUTURE PROOFING**

Medical devices

Medicinal products

Breast milk for own child

- Organs
- Tissue donations
- Autologous bedside (closed systems)



Article 1 Subject matter

This Regulation establishes measures that set high standards of quality and safety for all substances of human origin (SoHO) intended for human application and for activities related to those substances. It ensures a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction, including by strengthening the continuity of supply of critical SoHO.

Article 3 Definitions

(2) 'critical SoHO' means a SoHO for which an insufficient supply will result in serious harm or risk of serious harm to recipients' health or in a serious interruption in the manufacture of products regulated by other Union legislation...(omissis)... where an insufficient supply of such products will result in serious harm or risk of serious harm to human health;

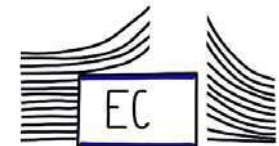
Implementation of high level standards through technical guidelines – staying up-to-date with the science in an agile way

SoHO entities shall follow the highest available levels of standards (Art. 56 & 59):

Level 1

Commission Implementing Legislation

“where the Commission deems necessary”



If none:

Technical Guidance on the EU SoHO Platform

Published & updated by ECDC/EDQM

Inspectors shall deem the standards to be met

Level 2

OR:

“Equivalent” Guidance

Deemed by CAs to achieve equivalent standards

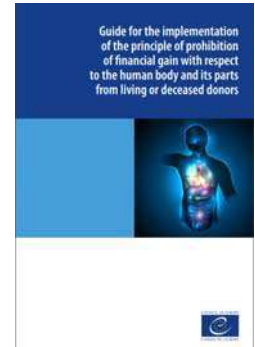
MS shall demonstrate compliance with standards – **may do so** by demonstrating equivalence to ECDC and EDQM

If none:

Level 3

Other guidelines or methods based on international standards or scientific evidence

Entities shall demonstrate equivalence to inspectors – **may do so** by demonstrating equivalence to ECDC and EDQM



- EU's ambition to build a stronger European Health Union, so as to:
 - **better protect the health of our citizens (including patients, donors and offspring);**
 - equip the EU and its Member States to better prevent and address future pandemics (surveillance, data analysis, risk assessment, early warning and response);
 - **improve the resilience of EU health systems (sufficient supply of SoHOs).**

Wkh#unsofnded#ixqgdp hqwd#sub#f#son#q#k#l#thp d#q#k#h#
unfux#lp hqwd#q#h#h#q#w#r#q#i#y#r#x#q#w#u#|#r#q#0#h#p#x#q#h#u#h#g#r#q#r#w

• Alice: *“ Would you tell me, please, which way I ought to go from here? ”*

The Cheshire Cat: *“That depends a good deal on where you want to get to”.*

Alice: *“I don't much care where“.*

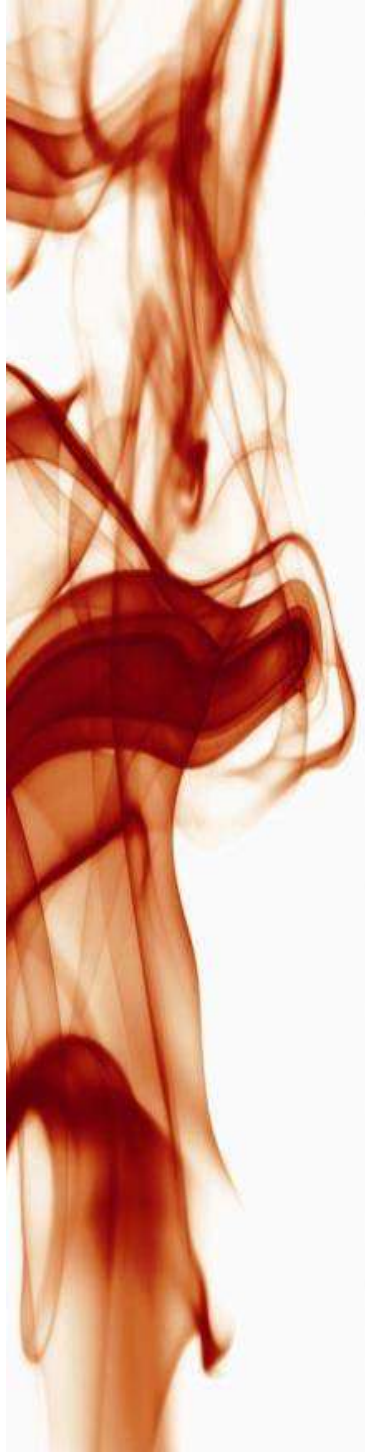
The Cheshire Cat: *“Then it doesn't much matter which way you go”.*

Alice: *“...So long as I get somewhere”.*

The Cheshire Cat: *“Oh, you're sure to do that, if only you walk long enough.”*

Lewis Carroll, Alice in Wonderland





Istituto Superiore di Sanità



*Grazie per
l'attenzione!*

