

# EDQM Blood Conference

Innovation in Blood  
Establishment Processes

14-15 January 2025 | Strasbourg, France



Co-funded  
by the European Union



EUROPEAN UNION

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Co-funded and implemented  
by the Council of Europe



COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

# Welcome address

**Petra Doerr**, Director of the EDQM

**Laurent Mallet**, Head of Intergovernmental Committees and Networks Department (ICND), EDQM

**Stefaan van der Spiegel**, European Commission / DG SANTE

# European Directorate for the Quality of Medicines & HealthCare

Council  
of Europe





# Council of Europe

- ★ Established in **1949**
- ★ **46 member states**
- ★ Based in **Strasbourg**
- ★ **Three main values: human rights, democracy and the rule of law**



Committee  
of Ministers



Parliamentary  
Assembly



Congress of Local  
and Regional  
authorities



European Court of  
Human Rights



Commissioner of  
Human Rights



Conference  
of INGOs





# SoHO activities - Guiding principles

## COMMITTEES

### CD-P-TO and CD-P-TS



Developing legal instruments,  
technical standards, policies

Monitoring data and best practices

Operational activities supporting  
SoHO establishments in  
implementing CoE standards  
& EU legislation

## ACTIVITIES



## PRINCIPLES

Non-commercialisation of  
substances of human origin

Mutual assistance

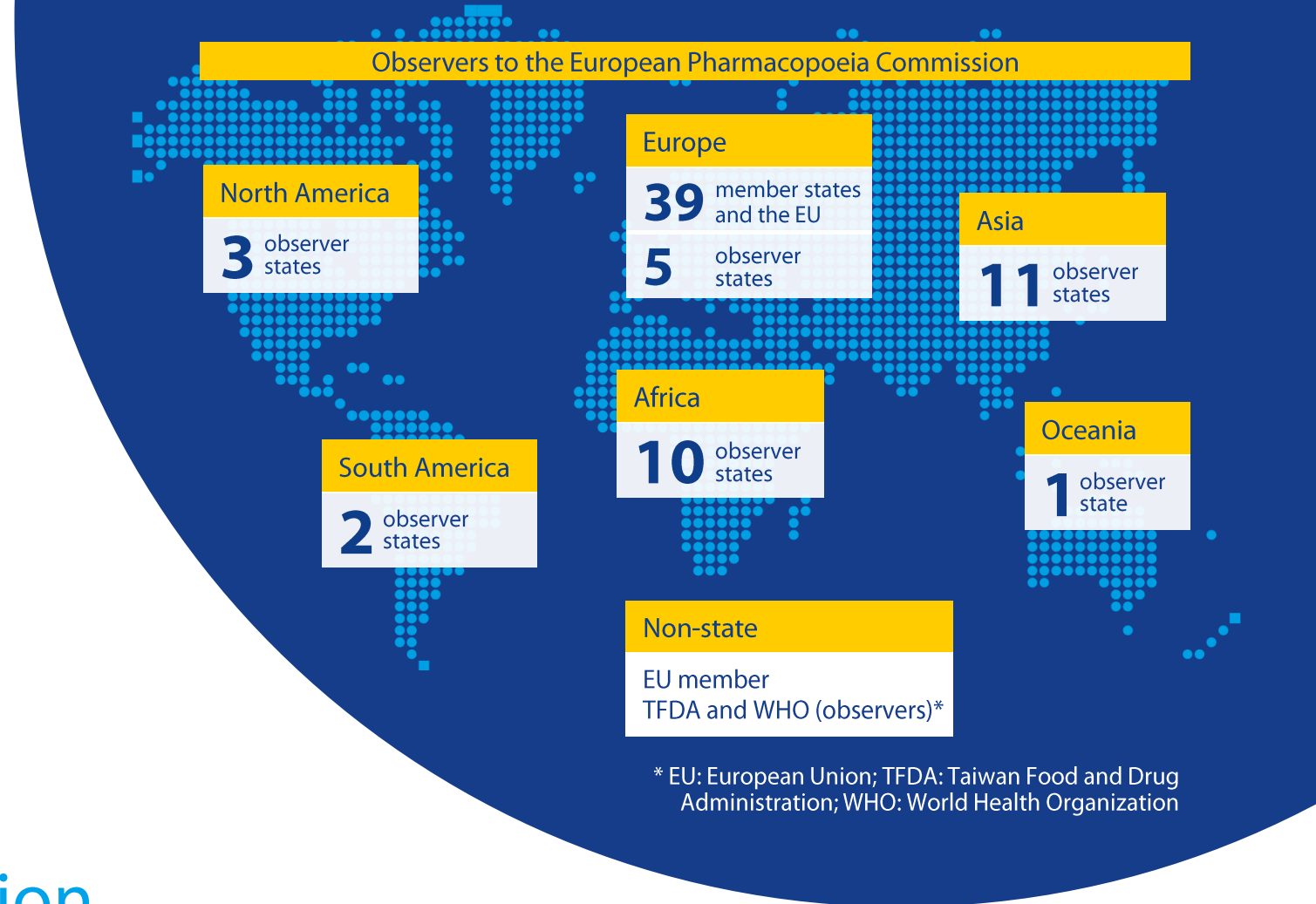
Protection of donors & recipients

# EDQM

- ★ Founded in **1964**
- ★ Partial Agreement (39 members & the EU + 34 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities

Our vision  
**Together for  
better health,  
for all**

Our mission  
To contribute to public health protection  
by engaging with an international  
community of experts and stakeholders



# Four policy areas & a wide portfolio of activities



## Medicinal products

Official standards for manufacture and quality control of pharmaceuticals

**European Pharmacopoeia (documentary & reference standards), Biological Standardisation Programme**

Certificates of suitability confirming compliance with European Pharmacopoeia and GMP inspections

**Certification of suitability**

Control of medicines  
**Network of Official Medicines Control Laboratories (OMCL)**



## Pharmaceutical care

Policies & model approaches for the safe use of medicines

Co-operation to combat falsification of medical products



## Consumer health

Safety standards for cosmetics, tattoos and food contact materials

Control of cosmetics  
**Network of Official Cosmetics Control Laboratories (OCCL)**



## Substances of human origin

Quality & safety standards

Data collection

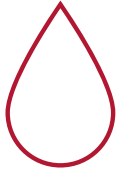
Improving quality systems / capacity building of blood and tissues & cells establishments



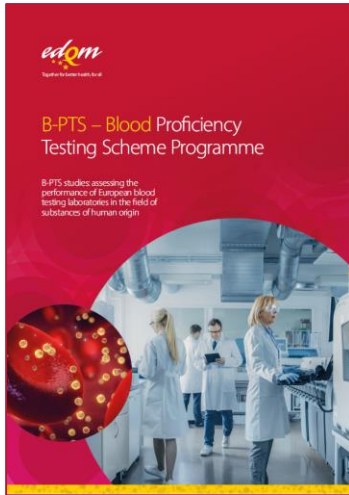
# CD-P-TS

## Blood transfusion

### Main objective



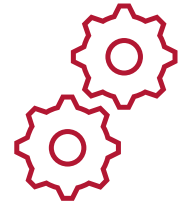
Ensures quality and safety of blood and blood components and application of ethical principles



### Activities

#### Standard setting

- Resolutions & recommendations
- Technical standards: Blood Guide



Blood Guide referred to in the new EU SoHO legislation

**Monitoring data and practices:** annual data collection on use of SoHO and vigilance



#### Capacity-building activities

- Blood Quality Management (B-QM)
- Blood Proficiency Testing Scheme (B-PTS)

## PUBLIC HEALTH IMPACT

- Improves clinical outcomes
- Protects donors and patients

# EDQM and EU today: a strategic and agile co-operation

## The EDQM, a regulatory and technical partner of the EU

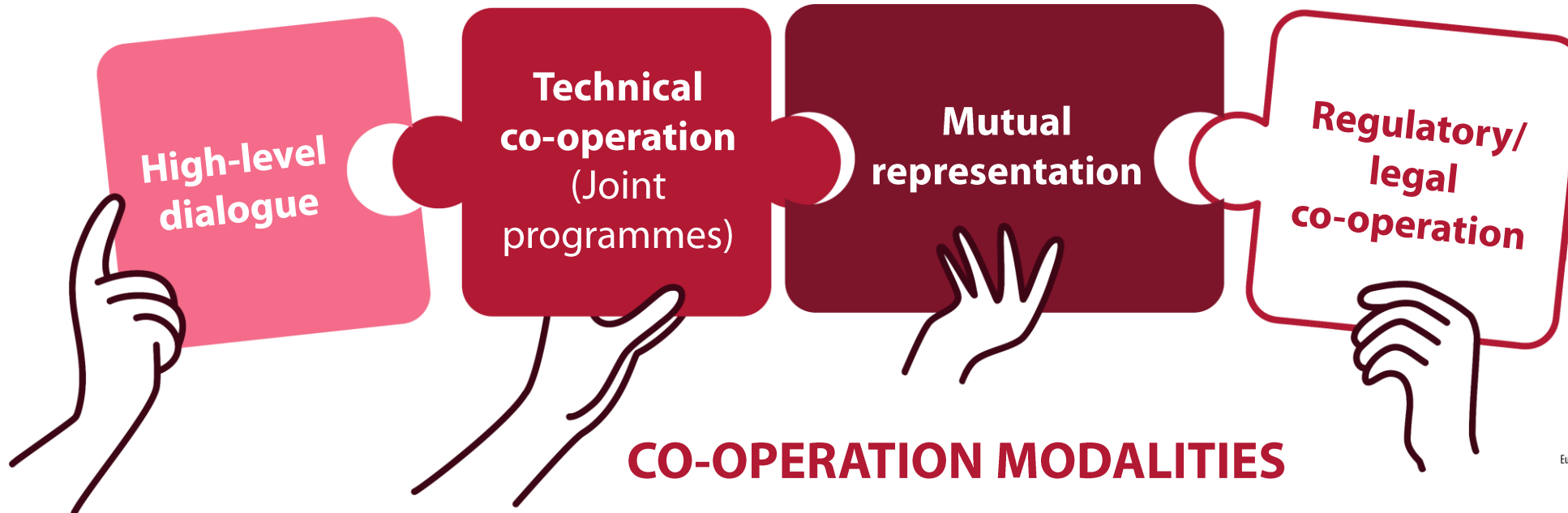
- 60 years of collaboration in the field of medicinal products
- 15 years of collaboration in the field of SoHO

Regular  
**meetings**  
since 2018

More than  
**40 agreements**  
signed since 1991

**Representation**  
in respective  
committees

A number of EDQM standards  
and activities **referred**  
**into the EU legislation**



# Blood Conference – The scientific committee

Margarida Amil

Alex Aquilina

Nigar Ertuğrul Örüç

Tor Hervig

Ína Björg Hjálmarsdóttir

Lene Holm Harritshøj

Luca Mascaretti

Simonetta Pupella

Harald Schennach

Stephen Vardy

Tomislav Vuk





# Blood Conference – Moderators

Johannes Blümel

Johanna Castrén

Ryan Evans

Tor Hervig

Jenny Mohseni Skoglund

Peter O'Leary

Joanne Pink

Stephen Vardy

Hans Vrielink



# EDQM Blood Conference

Innovation in Blood Establishment Processes

14-15 January 2025  
Strasbourg, France

Session A1 (part 1):

## Challenges for blood supply, donor recruitment & retention

(9:15 – 10:15)

Moderators: **Joanne Pink**, Australian Red Cross Lifeblood, Australia  
**Rada M. Grubovic Rastvorceva**, SoHO Standards Section, EDQM

Speakers: **Hans Vrielink**, Sanquin Blood Supply Foundation, the Netherlands  
**Betina Samuelsen Sørensen**, Aalborg University Hospital Department of Clinical Immunology, Denmark

*Please note:*

- *Food and drink are not permitted in the conference rooms*
- *Photography & filming during the presentations are strictly forbidden*
- *Photos and videos may only be taken by Council of Europe staff members*
- *The session will be recorded for internal purposes only*



# Challenges for the blood supply in Europe

*Hans Vrielink, MD, PhD  
Sanquin Blood Supply Foundation, The Netherlands*



[hansvrielink@hotmail.com](mailto:hansvrielink@hotmail.com)

***For Life.***





# Disclosures

No conflict of interest / no disclosures







# European Union







# European Union

The European Union (EU) is a political and economic union of 27 member states that are party to the EU's founding treaties, and thereby subject to the privileges and **obligations of membership**



# Article 288 (Treaty on the Functioning of the EU)

## Article 288

To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions.

|  |   |  |
|--|---|--|
|  |   | ISSN 1977-091X                             |
|  |   | doi:10.3000/1977091X.C_2012.326.eng        |
| <b>Official Journal</b>  |   | <b>C 326</b>                               |
| of the European Union  |   |  |
|  |   |  |
| English edition  | Information and Notices   |  |
|  |   | <b>Volume 55</b><br><b>26 October 2012</b> |
| <u>Notice No</u>   | Contents  | page                                       |
| 2012/C 326/1   | Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union | 1  |
|  | Consolidated version of the Treaty on European Union  | 13   |
|  | Consolidated version of the Treaty on the Functioning of the European Union                                   | 47   |
|  | Protocols   | 201  |



# Article 288 (Treaty on the Functioning of the EU)

A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.

A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.

A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them.

Recommendations and opinions shall have no binding force..



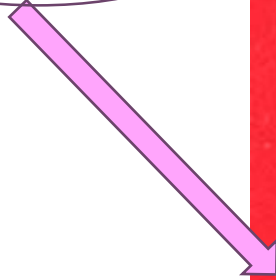
# Article 288 (Treaty on the Functioning of the EU)

## Binding

- Regulations
- Directives
- Decisions

## Non-binding

- Recommendations
- Opinions







# Blood needed



<https://en.wikipedia.org/wiki/Childbirth>



<https://aoav.org.uk/2015/blood-streets-boston-reviewing-response-april-2013-marathon-bombings/>



<https://www.alamy.com/stock-photo/underwent.html>



<https://www.ncei.noaa.gov/news/calculating-cost-weather-and-climate-disasters>





# Blood needed



<https://www.healthline.com/health-news/world-blood-donor-day-highlights-desperate-need-for-donations-061415#1>



# Safe blood needed

Safe for

Donors → blood donation

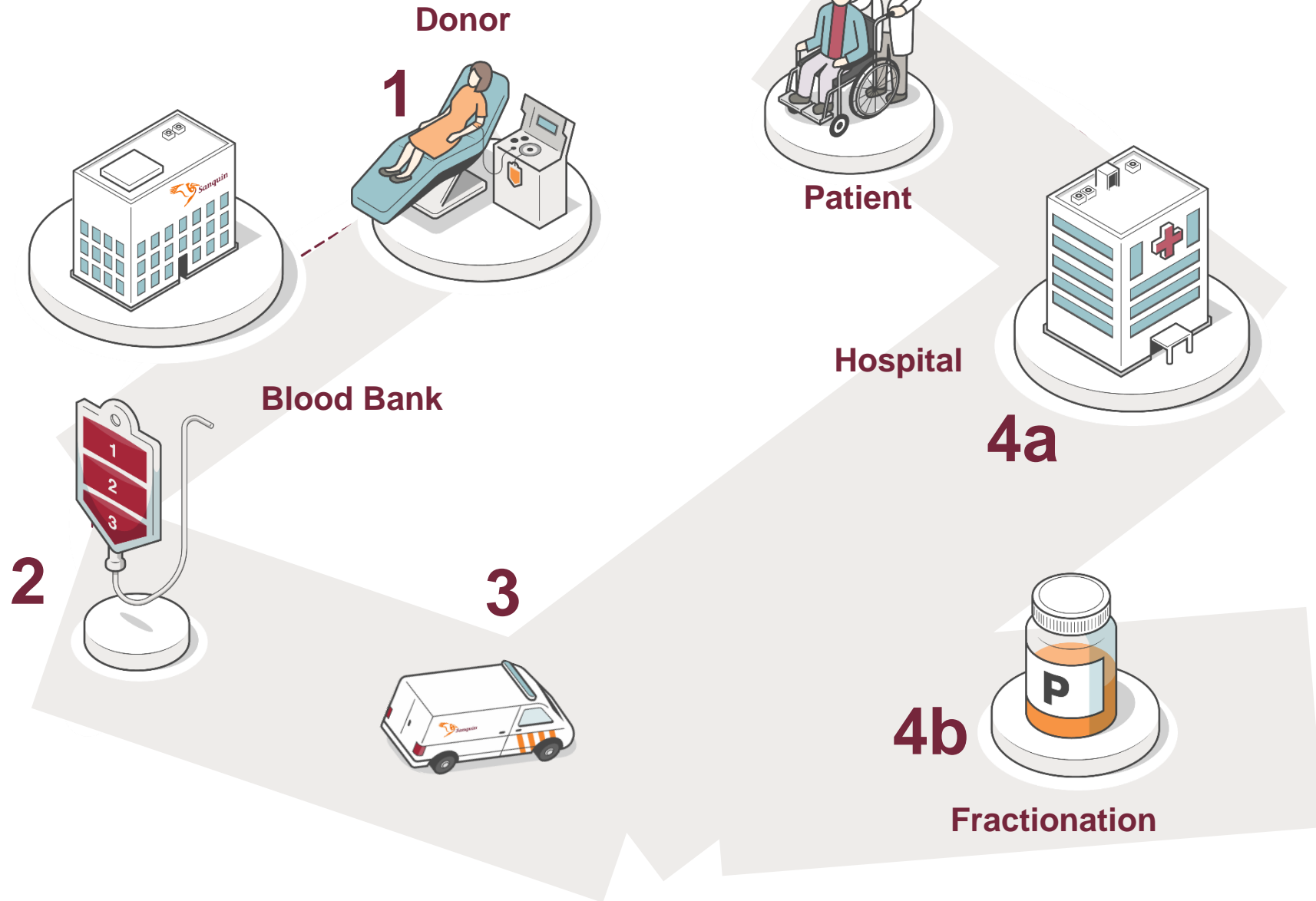
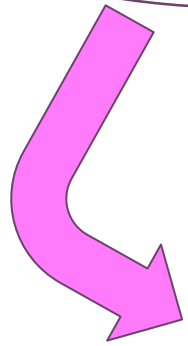
Patients → adequate quality of blood components

Donor questionnaire

Avoid transmittable medication with negative effects for patients

Test on TTI (Transmittable diseases)

Patient blood management → adequate use





# Influences on the blood system

Global (pharmaceutical regulation)  
European Union



## Directives

- 2002/98/EC
- 2004/33/EC
- 2005/61/EC
- 2005/62/EC
- 2011/38/EC
- 2016/1214/EC



## Article 288 (Treaty on the Functioning of the EU)

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# Influences on the blood system

Global (pharmaceutical regulation)

European Union

## Directives

- 2002/98/EC
- 2004/33/EC
- 2005/61/EC
- 2005/62/EC
- 2011/38/EC
- 2016/1214/EC

**Guide to the preparation,  
use and quality assurance  
of blood components**

Recommendation No. R (95) 15

21st Edition

European Directorate for the Quality of Medicines & HealthCare

Guide to the  
preparation, use and  
quality assurance of  
**BLOOD  
COMPONENTS**



**European Committee  
(Partial Agreement)  
on Blood Transfusion  
(CD-P-TS )**

**EDQM**  
21st Edition  
2023

**edqm**  
European Directorate  
for the Quality  
of Medicines  
& HealthCare

COUNCIL OF EUROPE  
  
CONSEIL DE L'EUROPE

Guide to the preparation,  
use and quality assurance  
of blood components

Appendix to Recommendation No. R (95) 15

GOOD PRACTICE GUIDELINES

for standards and specifications  
for implementing the quality  
system in blood establishments  
and hospital blood banks

Introductory note

Good Practice Guidelines (GPG) have been developed through an ad hoc co-operation between the European Commission and the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe.

GPG were first published in the 19th edition of the *Guide to the preparation, use and quality assurance of blood components*. Appendix to Recommendation No. R (95) 15 of the Committee of Ministers on the preparation, use and quality assurance of blood components, and are revised with each subsequent edition.

EU member states shall ensure, according to Directive 2005/62/EC, that the quality system in place in all blood establishments complies with the standards and specifications set out in the Annex to that Directive.

In order to implement the standards and specifications set out in the Annex to Directive 2005/62/EC, its Article 2, as amended by Directive (EU) 2016/1214, is replaced by the following:

*Member States shall ensure that, in order to implement the standards and specifications set out in the Annex to this Directive, there are good practice guidelines available to and used by all blood establishments, in their quality system, good practice guidelines which take fully into account, where relevant for blood establishments, the detailed principles and guidelines of good manufacturing practice, as referred to in the first subparagraph of Article 47 of Directive 2001/83/EC. In doing so, Member States shall take into account the Good Practice Guidelines jointly developed by the Commission and the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe and published by the Council of Europe.*

Council of Europe member states should take the necessary measures and steps to implement the GPG published in this 21st edition of the *Guide to the preparation, use and quality assurance of blood components*. The GPG are published within this edition of the *Guide* and have no separate glossary. Regarding terminology used in the GPG, reference is therefore made to the common definitions and abbreviations sections of the *Guide*.

GPG published in the *Guide* provide standards and specifications of quality systems that Member States shall ensure are in place in blood establishments and hospital blood banks. When referring to the EU directives the term 'must' reflects the legal status of

Manufacturing practice (GMP) is defined in the *Guide* as a set of requirements identified in the *Guide* that are not specific on how this is done. It is also replicated

DIRECTIVE



# Influences on the blood system

Global (pharmaceutical regulation)

Europe

Directives

Country

Laws / Medical authority

Climate / Geography / possibilities on disasters

Hospitals

Patient (associations)

Fractionator

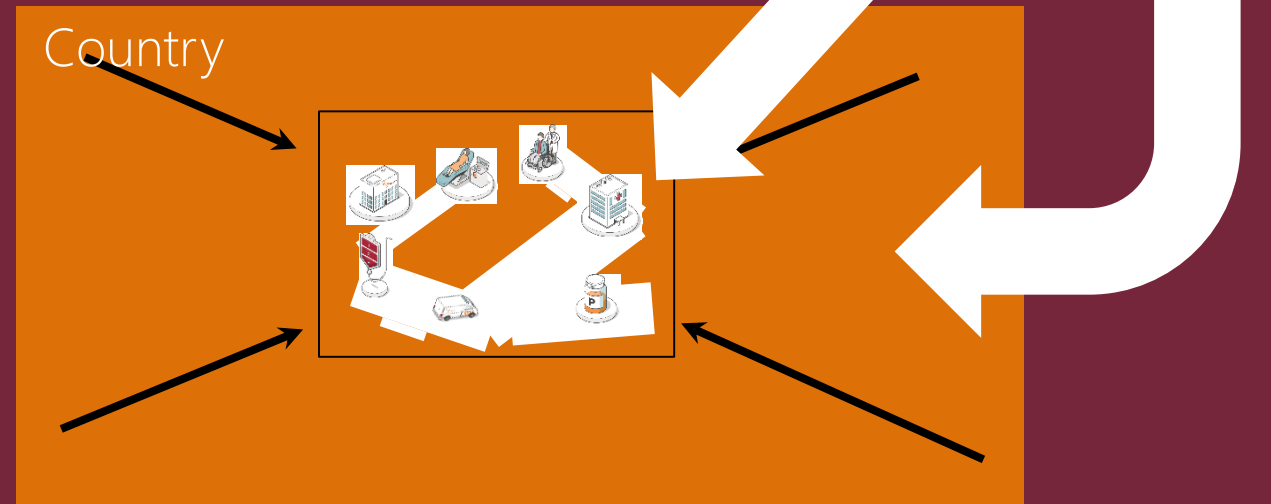
Donors

Blood center

Location

Building / architectural structure

BoD - Management – other personnel



WHO (June 2023)

"... every country's national health care policy and infrastructure...."

"... coordinated at the national level ..... national blood system ....."

<https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability>



# Influences on the blood system

Global (pharmaceutical regulation)

Europe

- Directives

Country

- Laws / Medical authority

- Climate / Geography / possibilities on disasters

- Hospitals

- Patient (associations)

Fractionator

Donors

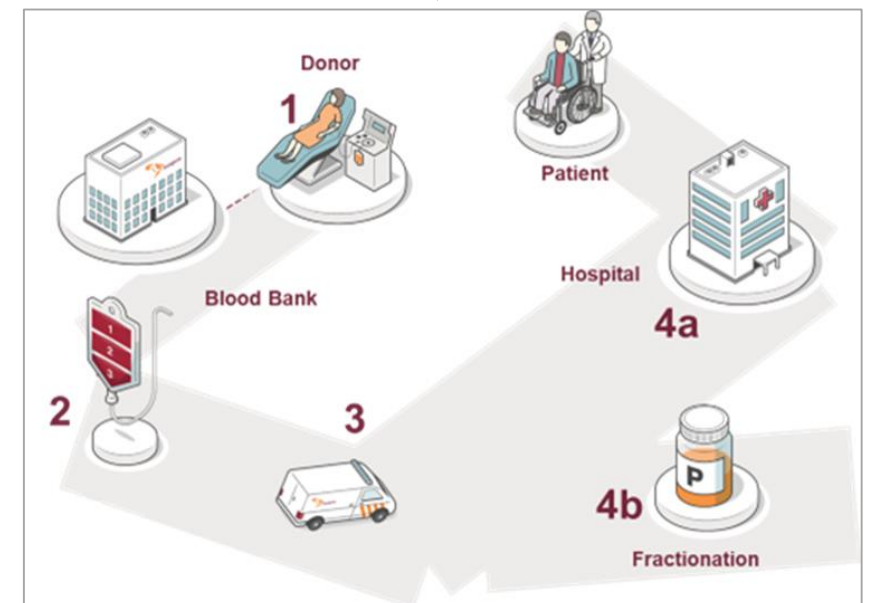
Blood center

- Location

- Building / architectural structure

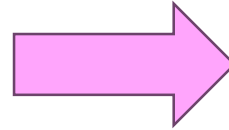
- BoD - Management – other personnel

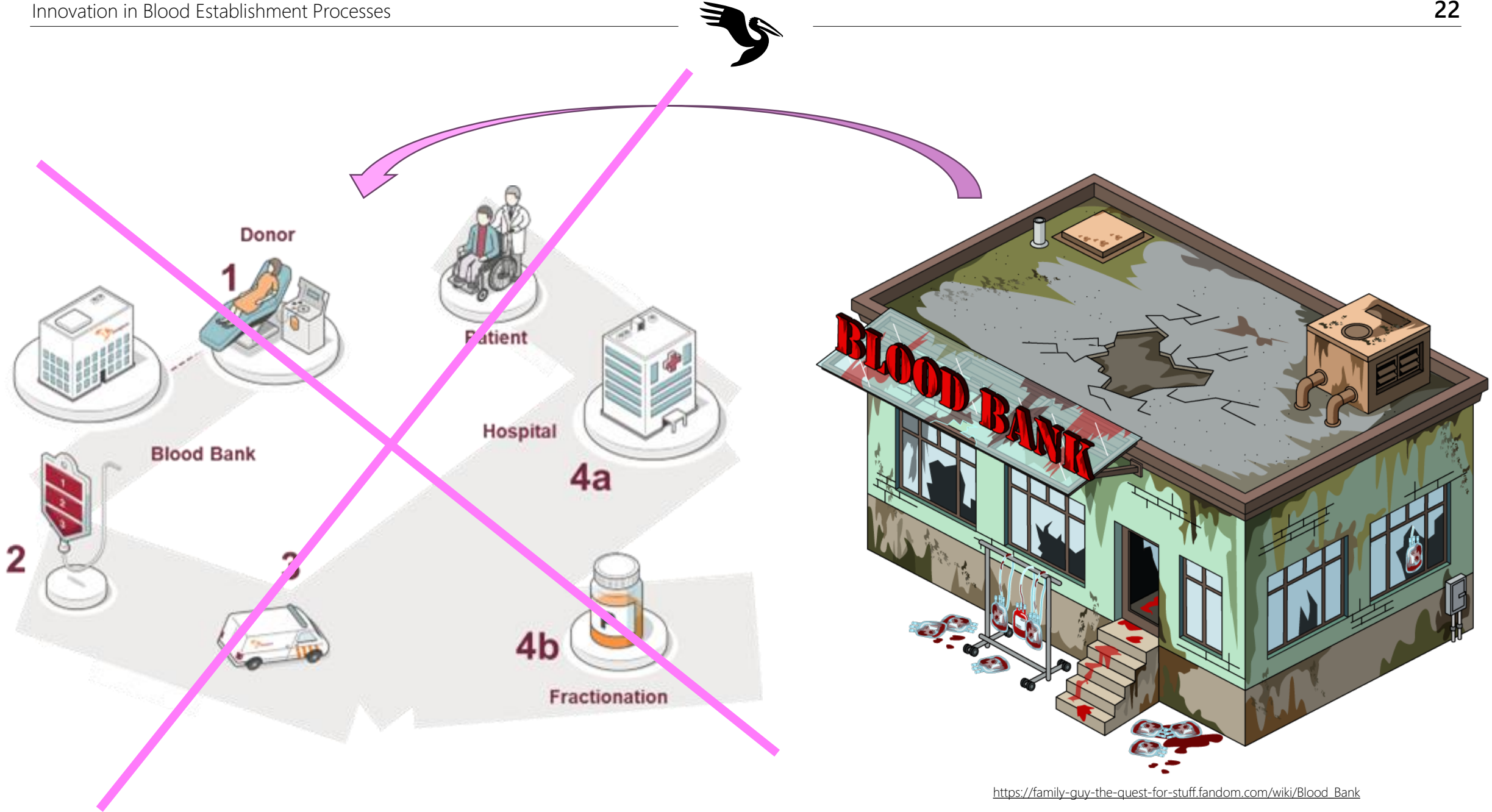
















# Influences on the blood system

Global (pharmaceutical regulation)

Europe

Directives

**Country**

Laws / Medical authority

Climate / Geography / possibilities on disasters

Hospitals

Patient (associations)

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Building / architectural structure

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≠

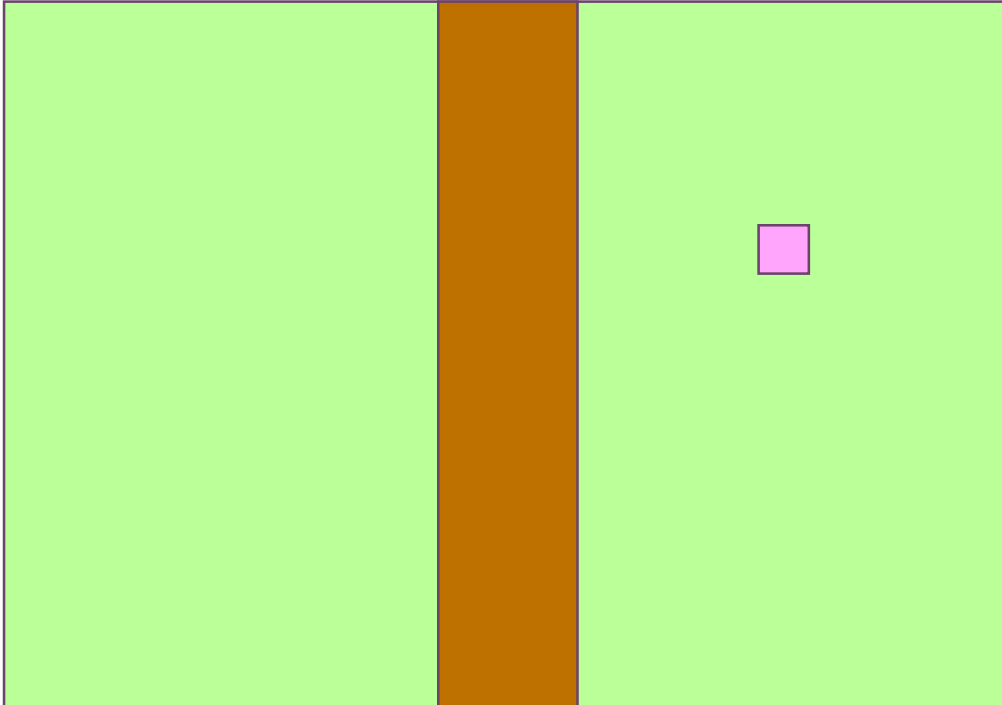




Hight pf mountains  
Climate  
Road conditions  
National finances  
Population density



# Challenges in the blood system



Country A

Population 4 million

Density 37 / km<sup>2</sup>

Capital country A

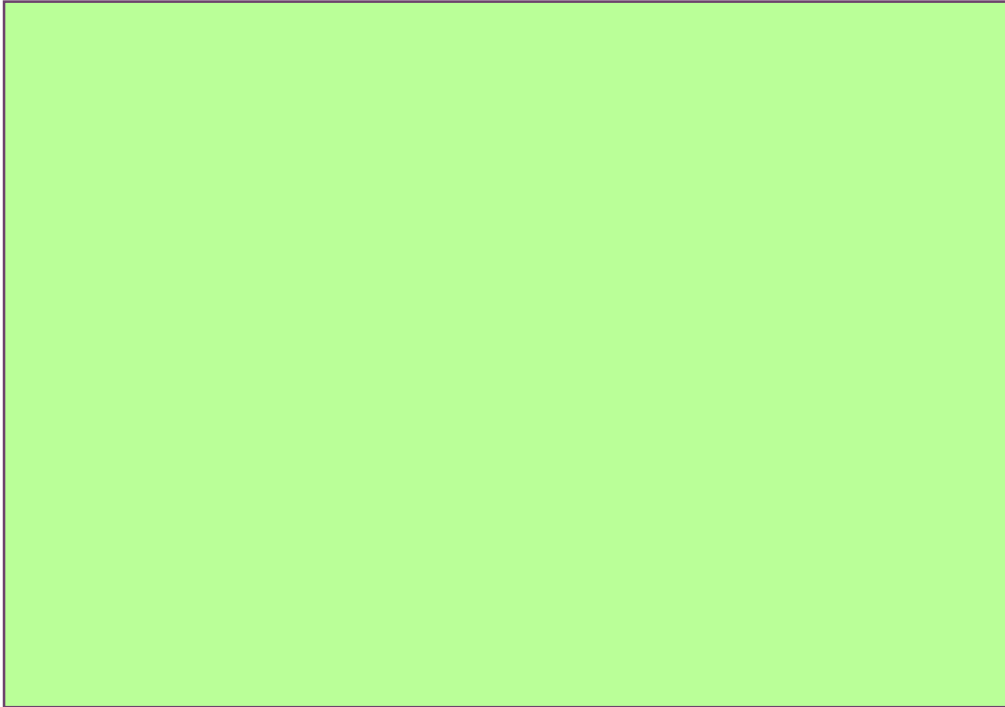
Population 1.4 million

Density 2800 / km<sup>2</sup>





# Challenges in the blood system



- 40 different blood establishments
- 2,000 – 20,000 donations per year
  - No or limited cooperation
  - Influence of BE heads
  - Influence politics / national government

INNOVATIONS







# Influences on the blood system

Global (pharmaceutical regulation)

Europe

Directives

Country

Laws / Medical authority

Climate / Geography / possibilities on disasters

Hospitals

Patient (associations)

Fractionator

**Donors**

Blood center

Location

Building / architectural structure

BoD - Management – other personnel



# Blood donors

Paid donors

Family donors / Replacement donors

Voluntary non-remunerated donors



## 2.1.1. Principle of voluntary non-remunerated donation

### STANDARD

- 2.1.1.1. Measures must be taken to promote the collection of blood and blood components from voluntary non-remunerated donations



### Voluntary non-remunerated blood donation

The safest blood donors are voluntary, non-remunerated blood donors from low-risk populations. The World Health Organization's goal is for all countries to obtain all their blood supplies through voluntary unpaid donors, in accordance with World Health Assembly resolution 28.72, which was adopted back in 1975.





# Blood needed



<https://en.wikipedia.org/wiki/Childbirth>



<https://aoav.org.uk/2015/blood-streets-boston-reviewing-response-april-2013-marathon-bombings/>



<https://www.alamy.com/stock-photo/underwent.html>



<https://www.ncei.noaa.gov/news/calculating-cost-weather-and-climate-disasters>

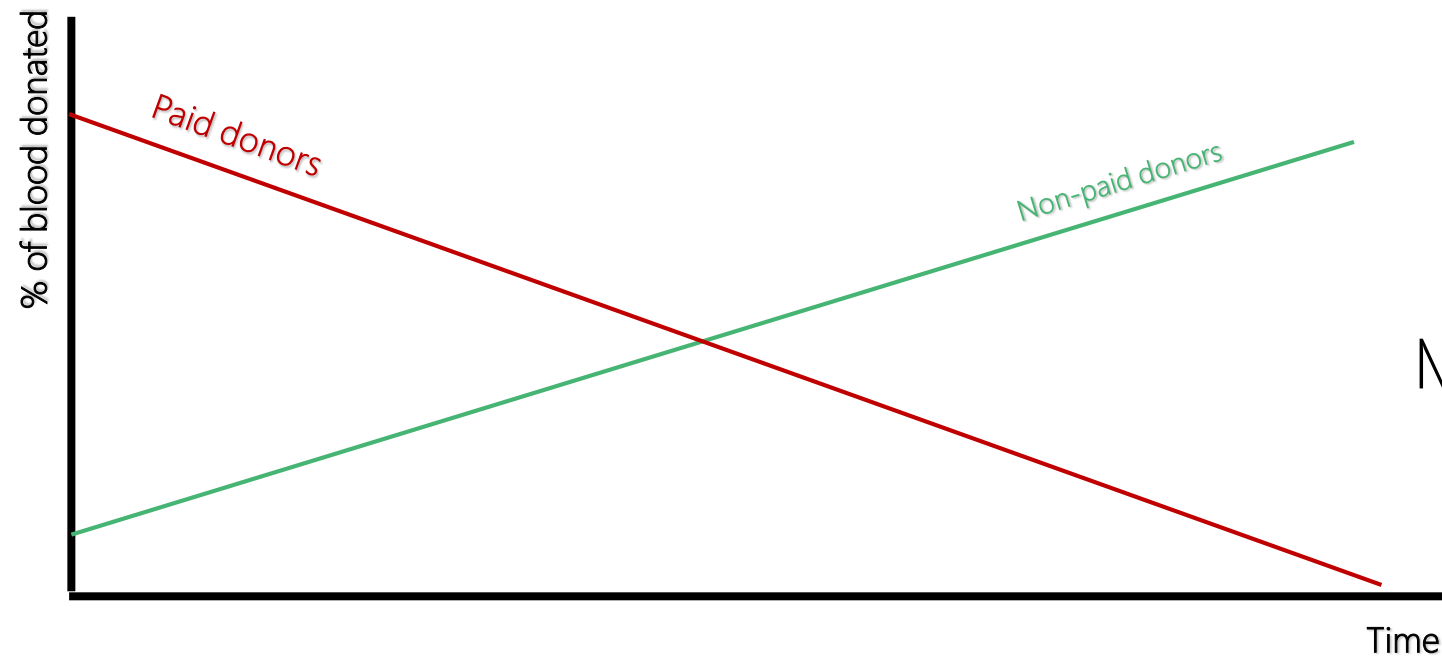


# Blood donors

Paid donors

Family donors / Replacement donors

Voluntary non-remunerated donors



Many first-time donors !





# Donors

New  
Repeat



<https://www.123rf.com/visual/search/61461259>





# Donors

New  
Repeat



<https://healthyfuturesva.com/11-blood-donation-effects/>





# Donors





<http://thefurthereducator.ie/teaching-strategies-all-you-need-to-know/>



# Strategies

How to achieve new donors  
How to keep existing donors



<https://www.midas-recruitment.nl/>



[How to Write Selection Criteria](https://www.wikihow.com/Write-Selection-Criteria)

<https://www.wikihow.com/Write-Selection-Criteria>



Reforming a blood establishment







# Blood donors

Paid donors

Family donors / Replacement donors

Voluntary non-remunerated donors



## 2.1.1. Principle of voluntary non-remunerated donation

### STANDARD

- 2.1.1.1. Measures must be taken to promote the collection of blood and blood components from voluntary non-remunerated donations



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# Family / replacement donors

Can we do without them?



# Family / replacement donors

We need



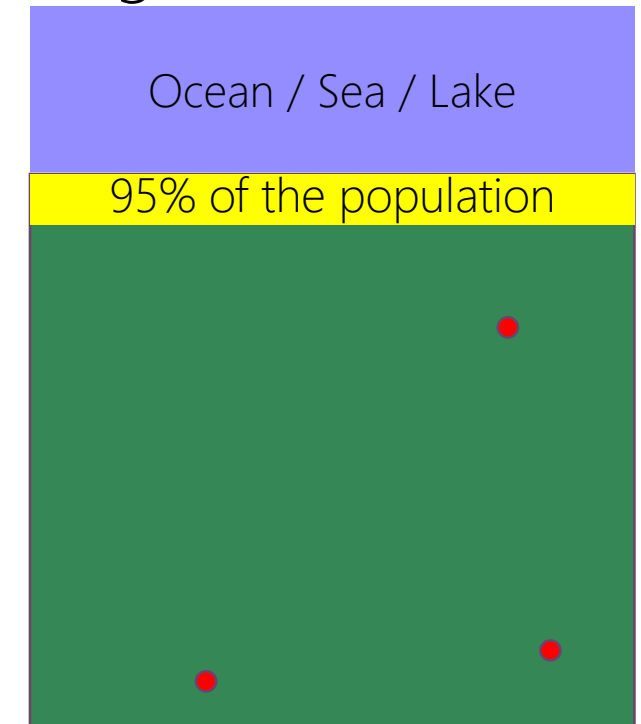


# Family / replacement donors

Can we do without them?

Depending on availability and size pool VNRD, amongst others

- Sufficient antigen typing (RBC / platelets)
- Stock
- Transport - Geography country







# Blood donors

## Paid donors

Family donors / Replacement donors  
Voluntary non-remunerated donors



### 2.1.1. Principle of voluntary non-remunerated donors

#### STANDARD

- 2.1.1.1. Measures must be taken to promote the collection of blood and blood components from voluntary non-remunerated donations

What is a "paid donor"

### Voluntary non-remunerated blood donation

The safest blood donors are voluntary, non-remunerated blood donors from all populations. The World Health Organization's goal is for all countries to obtain all their blood supplies through voluntary unpaid donors, in accordance with World Health Assembly resolution 28.72, which was adopted back in 1975.

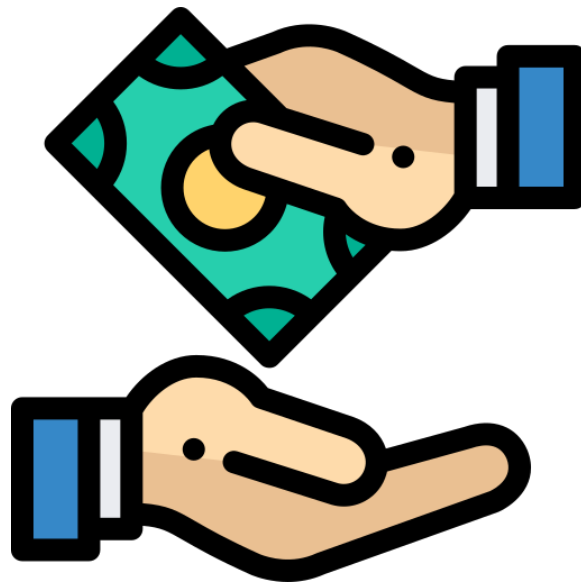




# Blood donors

Rights of blood donors are incorporated into the national law, e.g.

- Rights in specific shops
- Public transport
- Monthly compensation after retirement



<https://www.flaticon.com/free-icon/>



<https://www.ketr.org/news/>



# To summarize / conclude

Innovate / Reforming a blood service / system

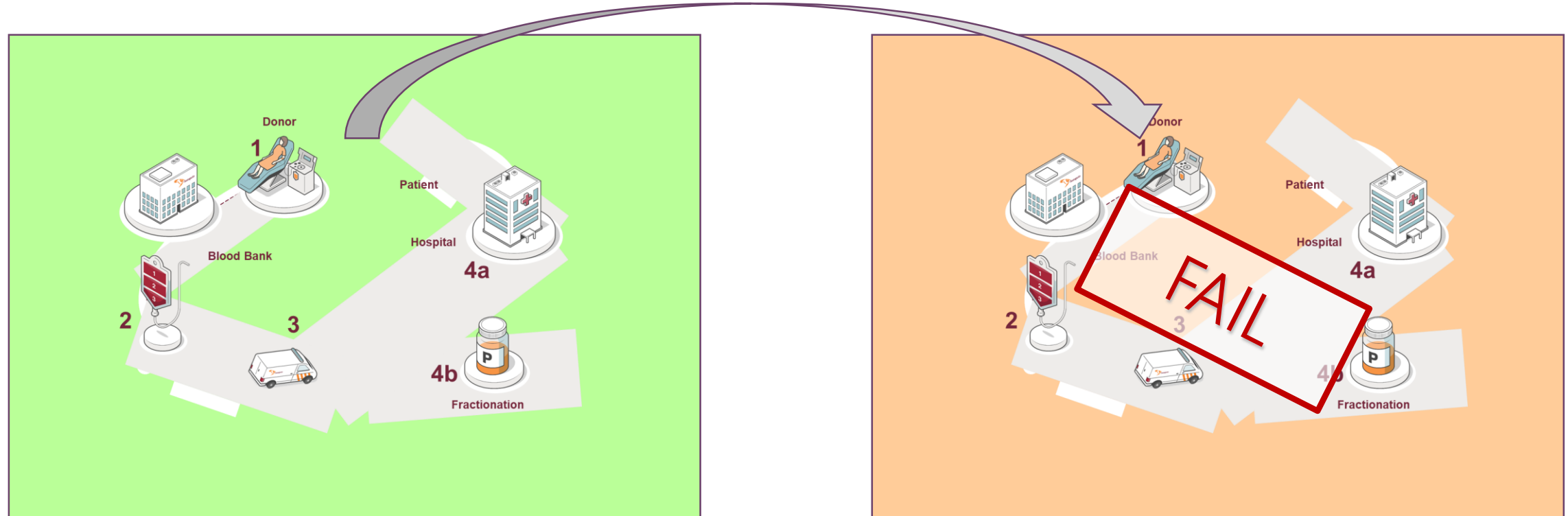


<https://steemit.com/life/@possibilities/how-do-you-see-challenges>



# To summarize / conclude

Innovate / Reforming a blood service / system







# To summarize / conclude

Innovate / Reforming a blood service / system



<https://steemit.com/life/@possibilities/how-do-you-see-challenges>



<https://stock.adobe.com/>



# To summarize / conclude

## Innovate / Reforming a blood service / system

Assessment needed

What is the exact question?

Nationally?

Regionally?

Locally?

- Solely the blood center?

- Also costumers?

Present situation in all sections



<https://stock.adobe.com/>

In cooperation with local leaders



# To summarize / conclude

Innovate / Reforming a blood service / system

Based on local request, we can support others to innovate their blood supply system with our knowledge





The background of the slide is a solid dark red color. It is decorated with several concentric circles of varying sizes and shades of red, creating a layered, organic effect. These circles are scattered across the slide, with some appearing as simple outlines and others as filled-in gradients.

# **Donor vigilance and challenges for blood supply**

**Betina S. Sørensen** M.D. MPG

Aalborg University Hospital



# Conflict of interest

The presenter has no conflict of interest

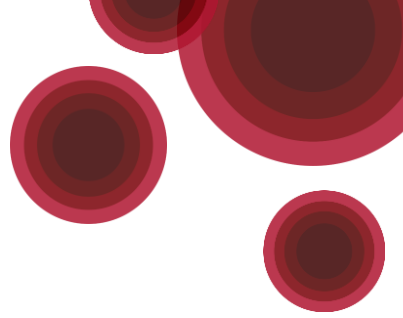
# What is donor vigilance?

- Donor vigilance is part of haemovigilance
  - Haemovigilance means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors<sup>1</sup>
  - The goal of haemovigilance is continuous quality improvement of the transfusion chain from donation of blood to transfusion of components, through corrective and preventive actions to ensure donor and patient safety, improve transfusion appropriateness and reduce wastage<sup>1</sup>
- Donor vigilance is protection of the individual donor
  - Surveillance of adverse reactions (complications)
  - Systematic recording and analysis of errors
  - Handling of post-donation information

1: 22nd Edition of the Guide to the preparation, use and quality assurance of blood components

# Donor vigilance

- Can donor vigilance also include a surveillance of challenges for the blood supply?
- Vigilance means watchfulness or readiness for danger





# Donor vigilance in the past years

- Donor adverse reactions and events have been giving more and more awareness in the last 20 years
- It is recommended that all blood services adopt a systematic approach to monitoring the rates of donor adverse reactions, in the interest of improving donor care
- Many publications and reports on advances in monitoring and studying the occurrence and prevention of complications of blood donations have been published and made awareness on the safety of the donor
- Protection of the individual donor is still important and a priority

# Donor vigilance

- ISBT-IHN-AABB definitions
  - The essence of donor haemovigilance is the recognition, management and prevention of donor adverse events.
- The latest version is from 2014 and a revision of the first edition from 2008
- Adverse reactions and events with a temporal relation to a blood donation – long term not captured e.g. iron depletion
- Focus is whole blood donations
- Validated by the users in 2018 (Land K et al, Transfusion 2018)
  - For severity it is recommended to use severity tool developed by AABB (ISBT and IHN)



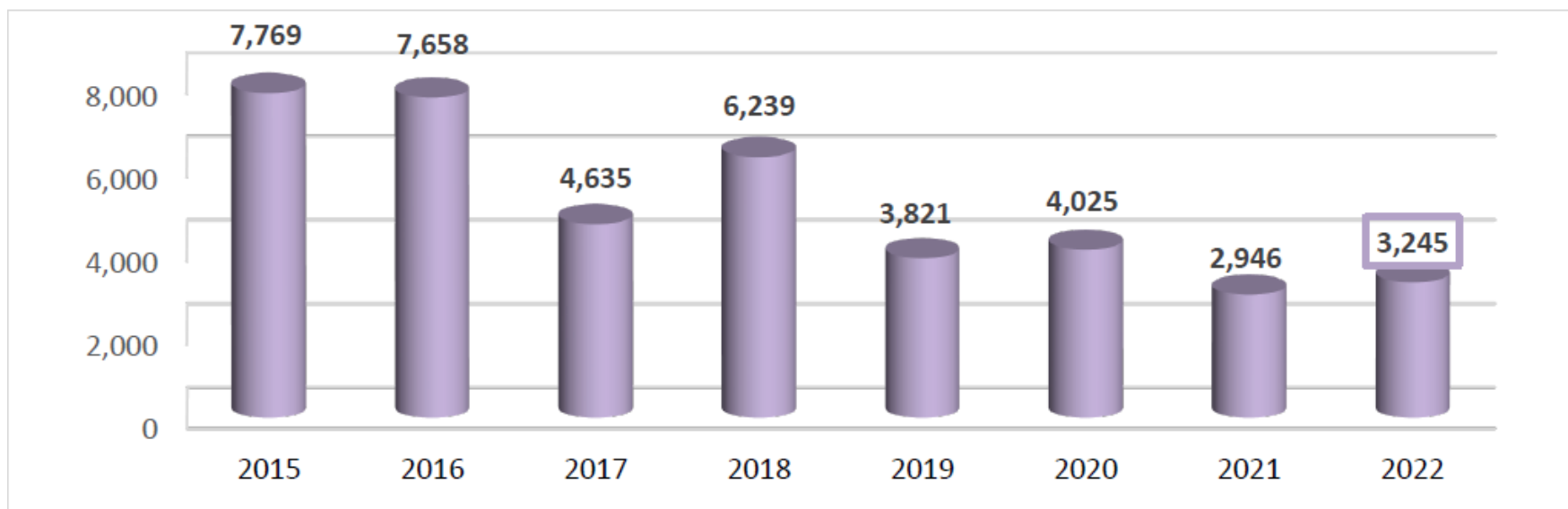
**Standard for Surveillance of  
Complications Related to Blood Donation**

*Working Group on Donor Vigilance  
of the  
International Society of Blood Transfusion  
Working Party on Haemovigilance*

# Donor vigilance and EU

- Severe adverse reaction (SAR)
  - SAR is "an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity." (*Article 3(h) of Directive 2002/98/EC*)
  - SARs in donors are not mandatory to report unless they impact on the quality and safety of the blood components (*Article 5 of Directive 2005/61/EC*)
  - Some member states collect SAR in donors regardless of the impact of the component
  - SAR in donors are reported to EU if
    - Only imputability level 2 or 3 (*likely/probable or certain* ) should be reported.
    - For donor fatalities all cases should be reported (imputability 1, 2 and 3)
  - It is recommended to use ISBT-IHN-AABB classification and the severity tool developed by AABB (ISBT and IHN)

# EU SARE report 2023 (2022 data)



*Figure 24. SAR in donors (absolute numbers): 2015-2022 comparative data*

Rate of SAR in donors in 2022: 20.8 per 100.000 donations

# EU SARE report 2023 (2022 data)

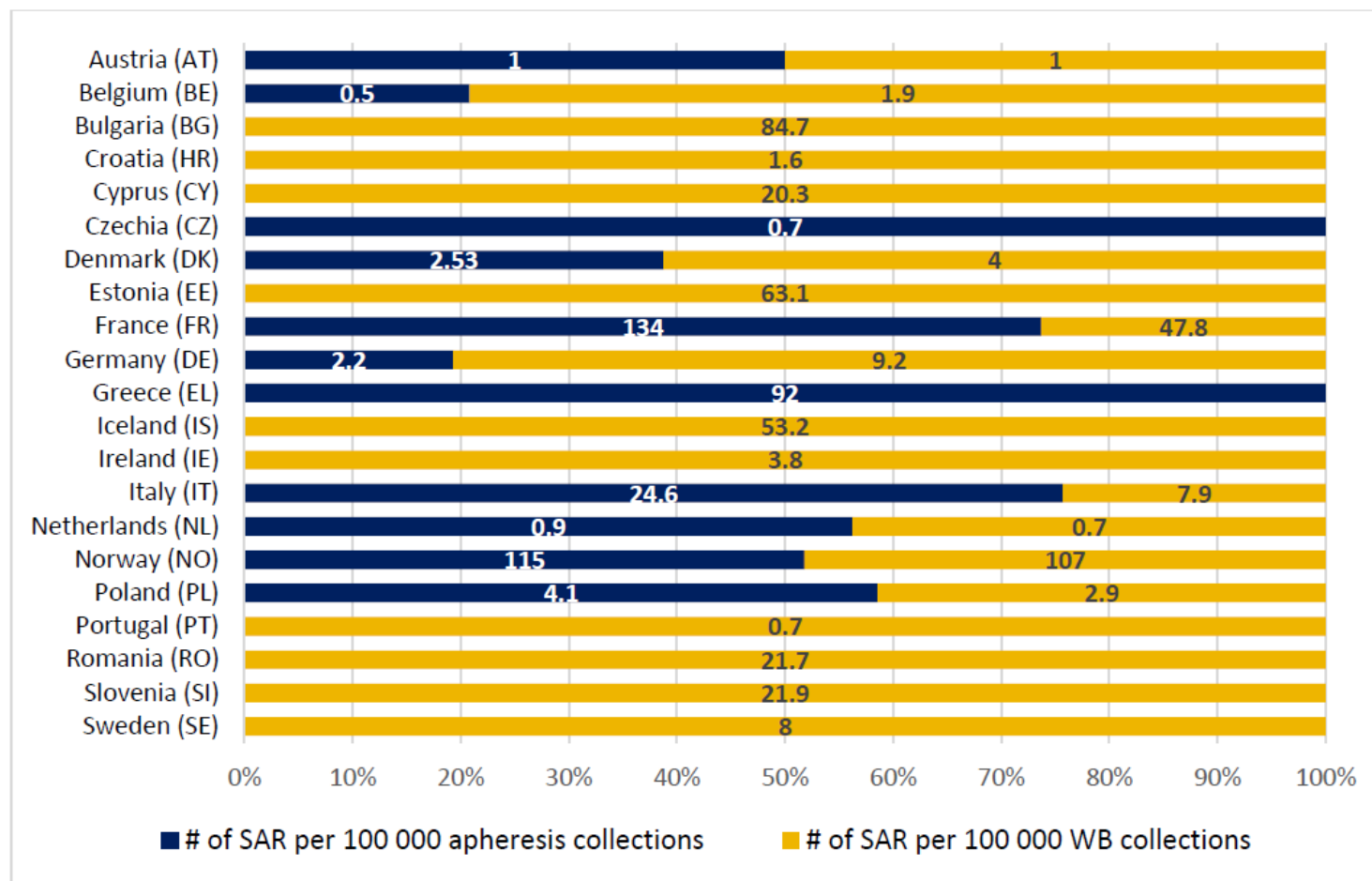


Figure 25. Incidence of SAR in donors per 100 000 collections (absolute numbers); data 2022



# EU SARE report 2023 (2022 data)

| SAR                               | Rate per 100,000 whole blood collections* |
|-----------------------------------|---|
| Vasovagal reaction                | 12  |
| Nerve injury/irritation           | 1   |
| Cardiovascular event (or death)** | 0.05                                      |
| Other                             | 1.5                                       |
| All                               | 14.5                                      |

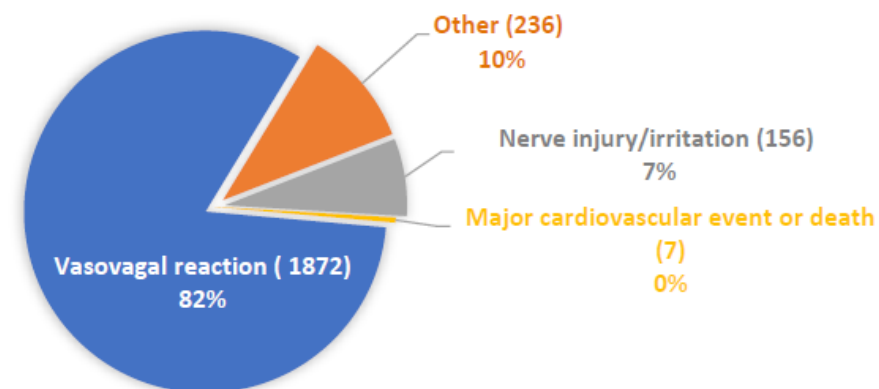


Figure 26. SAR in donors during whole blood collection (absolute numbers and percentages); data 2022

\*15 576 875 whole blood collections in 2022, 2271 SAR in whole blood

\*\* no deaths recorded

# EU SARE report 2023 (2022 data)

| SAR                               | Rate per 100,000 apheresis collections* |
|-----------------------------------|---|
| Vasovagal reaction                | 7.9                                     |
| Citrate reaction                  | 0.3                                     |
| Cardiovascular event (or death)** | 0.1                                     |
| Allergic reaction                 | 0.09                                    |
| Other                             | 1.7                                     |
| All                               | 10.4                                    |

\* 6 376 960 apheresis collections in 2022, 664 SAR in donors following apheresis collection

\*\* no deaths recorded

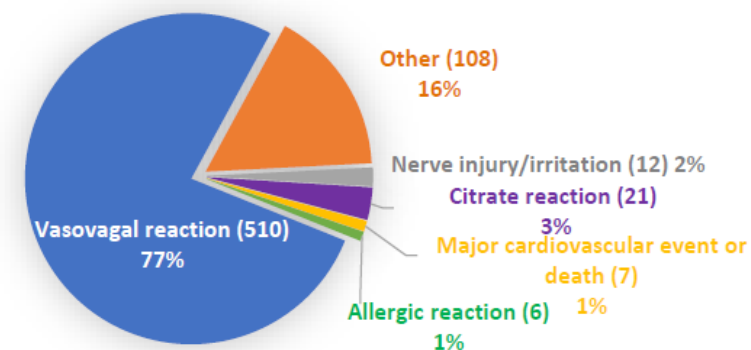
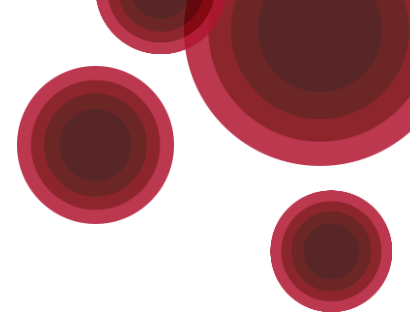


Figure 27. SAR in donors during apheresis collection (absolute numbers and percentages); data 2022

# Donor vigilance – what have we learned?



- It is difficult to collect standardised and comparable data between different countries
  - One size does not fit all?
  - Does it add value to compare data between countries, if countries are not comparable?
- It is safe to donate blood or plasma
  - All publications on donor SAR report on low incidence
- The most used classification is last updated in 2014
  - Is it sufficient today and in the future?
- The current donor vigilance is essential to protect the individual donor
  - is it suitable for protection of the blood supply?

# Donor vigilance in 2025

- The system needs to be able *to forecast tomorrows haemovigilance*<sup>1</sup>
  - The world changes
  - Much lower use of blood, much higher use of PMDPs – shift from whole blood to apheresis
  - New therapies
  - Pandemic, war, cyber security, climate changes
  - New generation of donors – what motivates?



1: Wood E et al. How we forecast tomorrow's haemovigilance? Transfusion clinique et biologique 2024, Vol.31(2), p.114-118

# Challenges for the blood supply

- Key challenge is to sustain a sufficient pool of donors to meet the demands of the health care system
  - **Blood and plasma**
- Need to ensure a large donor pool
  - Increase the number of donors
  - Increase the retention of donors
- In order of the safety of the donor and recipient, need to ensure VNRD





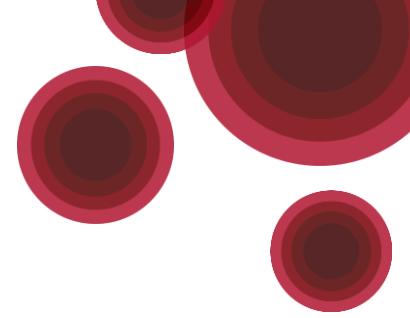
# Donor vigilance and donor retention

- Low donor retention is a danger for the blood supply
- Vigilance means readiness for danger
- Monitoring donor retention would be important in donor vigilance
- The goal of donor vigilance could be expanded

Protection of the donor  
*and*  
protection of the blood supply



# Donor retention



- Some factors shown to influence donor retention
  - Temporary deferral has an impact on donor retention<sup>1</sup>
    - Low haemoglobin
    - Medical reasons
    - First-time or reactivated donors
  - Motivations, intentions and behaviour
    - Feeling an identity as a donor<sup>2</sup>
  - Adverse reactions
    - VVR<sup>3</sup>

1: Spekman MLC et al, Transfusion 2019, Volume 59, Issue 12

2: Edwards A R-A et al. Journal of Health Psychology 2024

3: Thijsen A et al. Transfusion 2019, Volume 59

# Motivations, intentions and behaviour

- To increase the rate of blood donation, blood services need to adopt a multifaceted approach that involves a better understanding of donor motivations and the use of effective behavioral interventions
  - Understanding donor motivations is essential for developing effective and targeted interventions for different categories of donors
  - The use of behavioural interventions
  - The effects of technology advancements, applications and donor management technology



# Donor vigilance in the future?

- Haemovigilance means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, the epidemiological follow-up of donors and the availability of the donors
- The goal of haemovigilance is continuous quality improvement of the transfusion chain from donation of blood to transfusion of components, through corrective and preventive actions to ensure donor and patient safety, ensure donor retention, improve transfusion appropriateness and reduce wastage
- What should be reported? – the absolute numbers? The trend? Interventions that has been implemented and the results?

The background of the slide is a solid red color. It is decorated with several concentric circles of varying sizes and shades of red, creating a subtle pattern. The circles are scattered across the slide, with some appearing as thin outlines and others as more solid, darker red shapes.

# Thank you

Betina S. Sørensen M.D., MPG  
Aalborg University Hospital, Denmark  
[Betina.soerensen@rn.dk](mailto:Betina.soerensen@rn.dk)



# EDQM Blood Conference

Innovation in Blood Establishment Processes

14-15 January 2025  
Strasbourg, France

Session A1 (part 2):

## Challenges for blood supply, donor recruitment & retention

(10:45 – 12:15)

Moderators: **Joanne Pink**, Australian Red Cross Lifeblood, Australia  
**Rada M. Grubovic Rastvorceva**, SoHO Division, EDQM

Speakers: **Nigar Ertuğrul Örüç**, Blood Transfusion Center, University of Health Sciences Diskapı Yildirim Beyazit  
Training and Research Hospital, Türkiye  
**Rodica Popa**, European Blood Alliance, Belgium  
**Norbert Niklas**, Red Cross Transfusion Service for Upper Austria, Austria

*Please note:*

- *Food and drink are not permitted in the conference rooms*
- *Photography & filming during the presentations are strictly forbidden*
- *Photos and videos may only be taken by Council of Europe staff members*
- *The session will be recorded for internal purposes only*

# Recruitment and retention of blood donors

Nigar ERTUĞRUL ÖRÜÇ

Medical Director of Blood Transfusion Center  
University of Health Sciences Dışkapı Yıldırım Beyazıt Training  
and Research Hospital



# **DISCLOSURE**

**I declare that I have no conflict of interest.**

# Introduction



- Blood and blood component transfusion is a lifesaver for the patients not only in emergency and surgery, but also in certain medical treatments.
- A safe and adequate blood supply for transfusion is an essential component of every country's national health care policy and infrastructure.

# Introduction



- Blood safety starts with the donor since the major component of safe blood transfusion is based on safe blood collection.
- Voluntary non-remunerated blood donors (VNRBD) are the resource of a safe and sustainable blood supply.
- Self-sufficiency in blood and blood components provided from VNRBD at national level is essential.

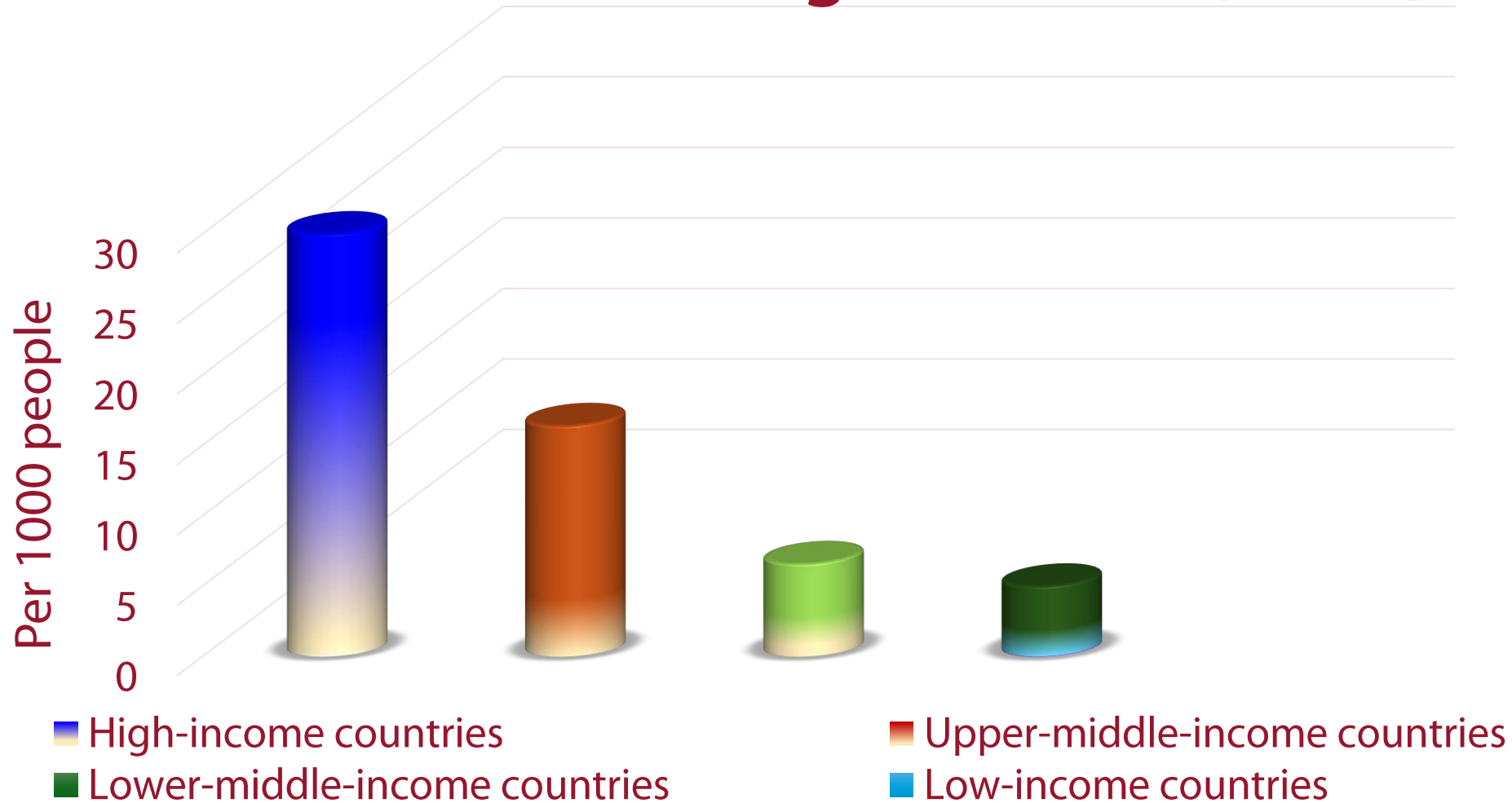


# Background



- Countries have to obtain their safe and adequate blood supplies through voluntary unpaid donors in accordance with World Health Assembly resolution 28.72.
- Encouragement and recruitment of voluntary non-remunerated blood donation is of vital importance.

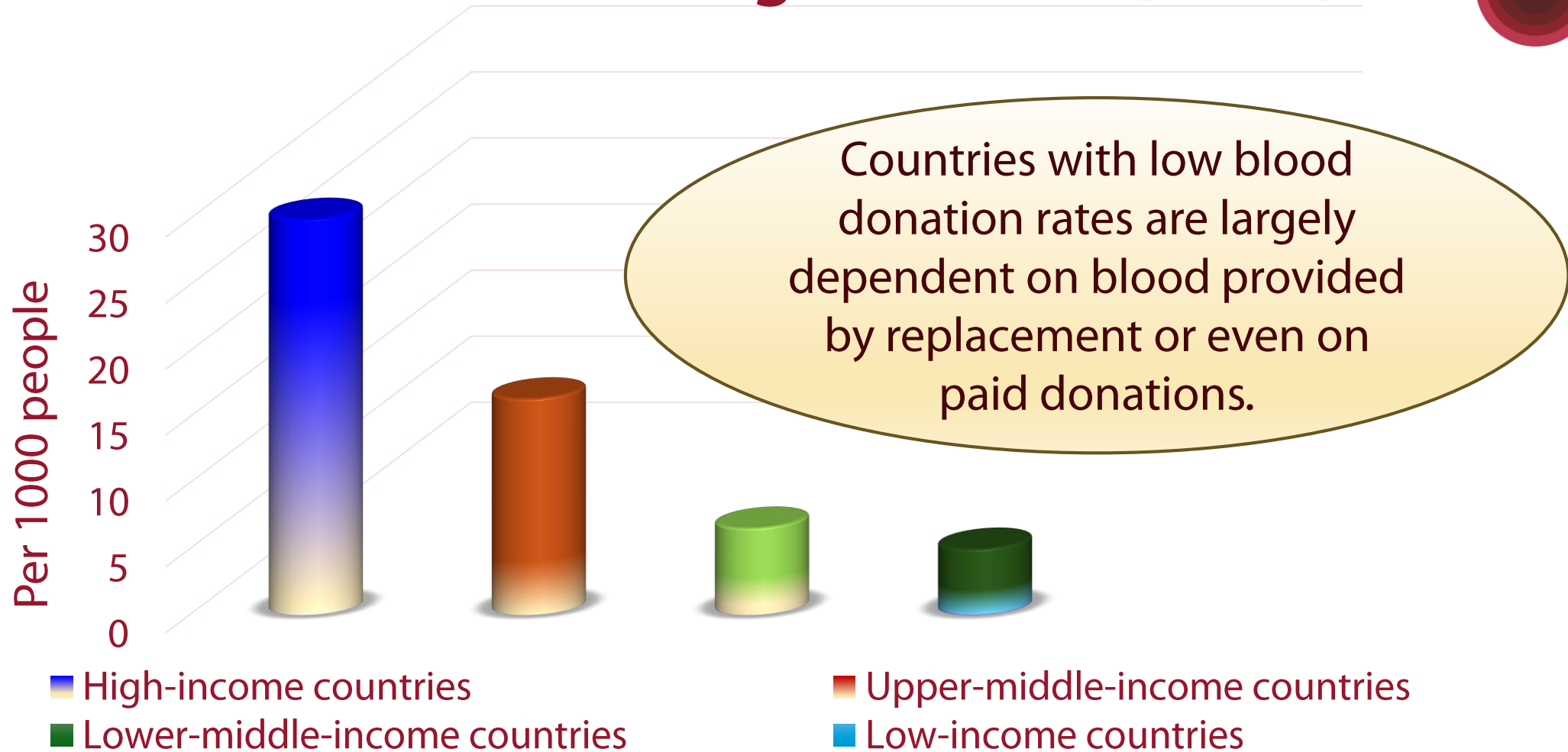
# Blood donation rate among countries (2018)



*World Health Organization: Global status report on blood safety and availability 2021.*

*World Health Organization; 2022 Jun 30.*

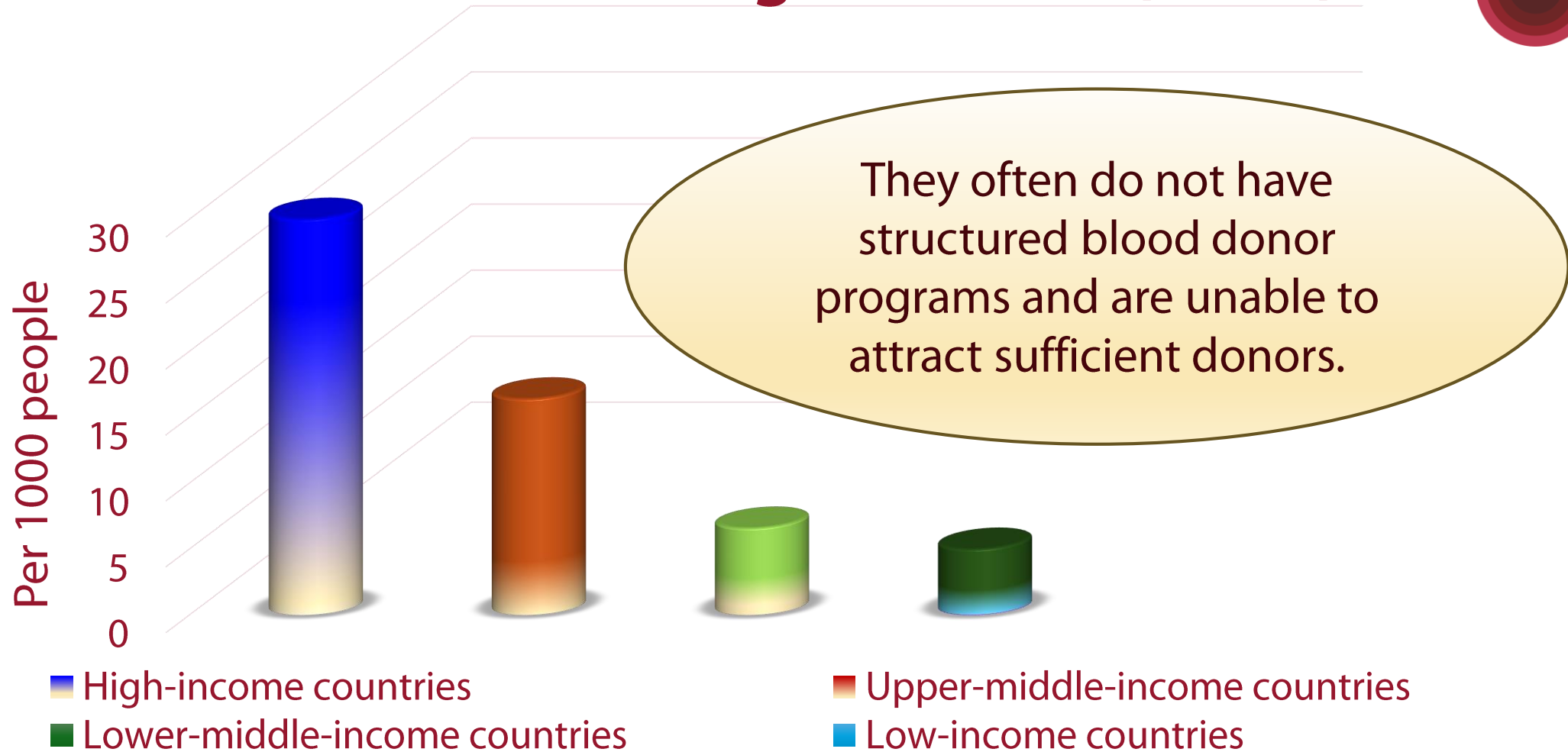
# Blood donation rate among countries (2018)



*World Health Organization: Global status report on blood safety and availability 2021.*

*World Health Organization; 2022 Jun 30.*

# Blood donation rate among countries (2018)

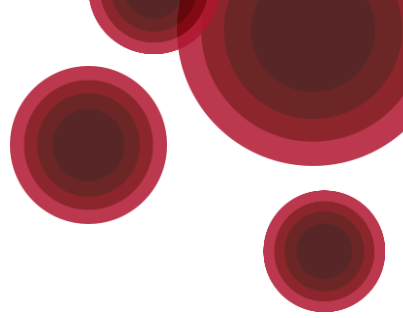


*World Health Organization: Global status report on blood safety and availability 2021.*

*World Health Organization; 2022 Jun 30.*

# Development of a regulatory framework

- National legislation with specific implementation
- National policy
- National strategy and action plan
- Recruitment and retention program
- Promotional and educational activities
- Financial support
- Adequate donor database





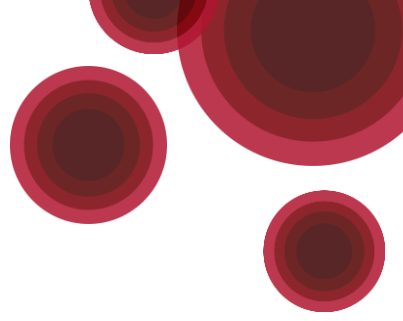
# Key Operators



- Although to ensure an adequate and safe blood supply is the responsibility of a country's government, many corporations and national societies play an important role in the promotion of VNRBD.
- Corporations and national societies should be involved in blood-related activities for systematic recruitment of blood donors.

# Development of recruitment activities

- Raising public awareness
- Effective communication methods
- Use of media (social & scientific)
- Educating potential donors
- Youth and school programmes
- Use of information technology



# Development of recruitment activities

- Extra efforts should be made to develop good recruitment strategies that are socially acceptable to the population concerned
  - ✓ the need for blood donation
  - ✓ the importance of voluntary donation
  - ✓ the importance of regular donation

# Donor recruitment

- To raise public awareness
  - ✓ Clear objectives
  - ✓ Knowing communities
  - ✓ What motivates people
  - ✓ Keeping in mind that ethical issues are important

# Donor recruitment

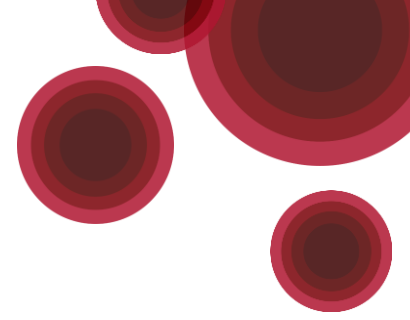
- The younger generation are the most important resources and the ideal target in the blood donation program.
- They are healthier and able to donate more regularly if dedicated.
- They can be motivated to become a regular donor.



# Donor recruitment and retention

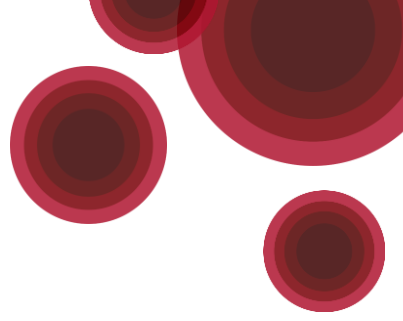
- Adequate and qualified staff must be appointed with good organizational, marketing and communication skills responsible for managing blood donation.
- To maintain safe and adequate blood supply, it is important to induct first-time blood donors and enable repeat donors to continue to donate.

# Donor recruitment and retention



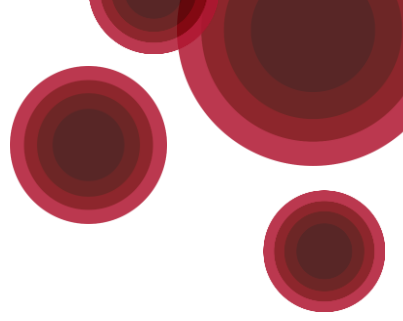
- Positive attitudes are the key issues to create a safe and relaxed environment, diminishing anxiety and fear during blood collection.
- The overall atmosphere with welcoming, kind, respectful and attentive professional staff acknowledging donors and their donations is perceived positive.

# Donor recruitment and retention



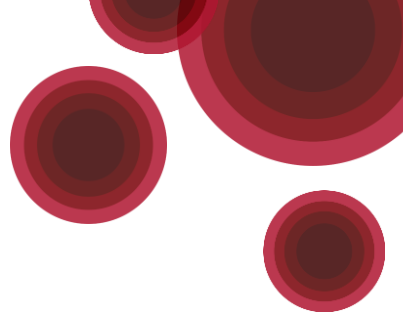
- First time donors should be followed-up with appreciation and reminders to stimulate their willingness to donate again.
- The longer the time lapsed from the last donation, the more likely this group of donors will not come back for donation.

# Donor recruitment and retention



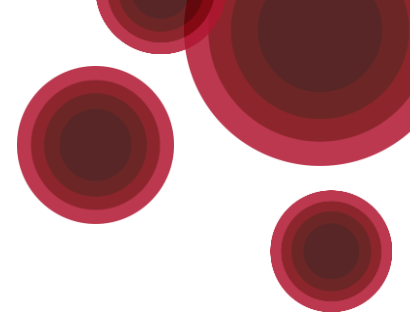
- Invitation or convocation messages can facilitate the donors' return.
- Regular donors should be followed within the same approach to continue their positive feelings for being able to help someone in need with the donation.

# Donor recruitment and retention



- Retention of previous donors is substantial for achieving safer blood which is not an easy task.
- It is important to create their spiritual satisfaction to continue to donate.

# Blood supply in Türkiye



## General information

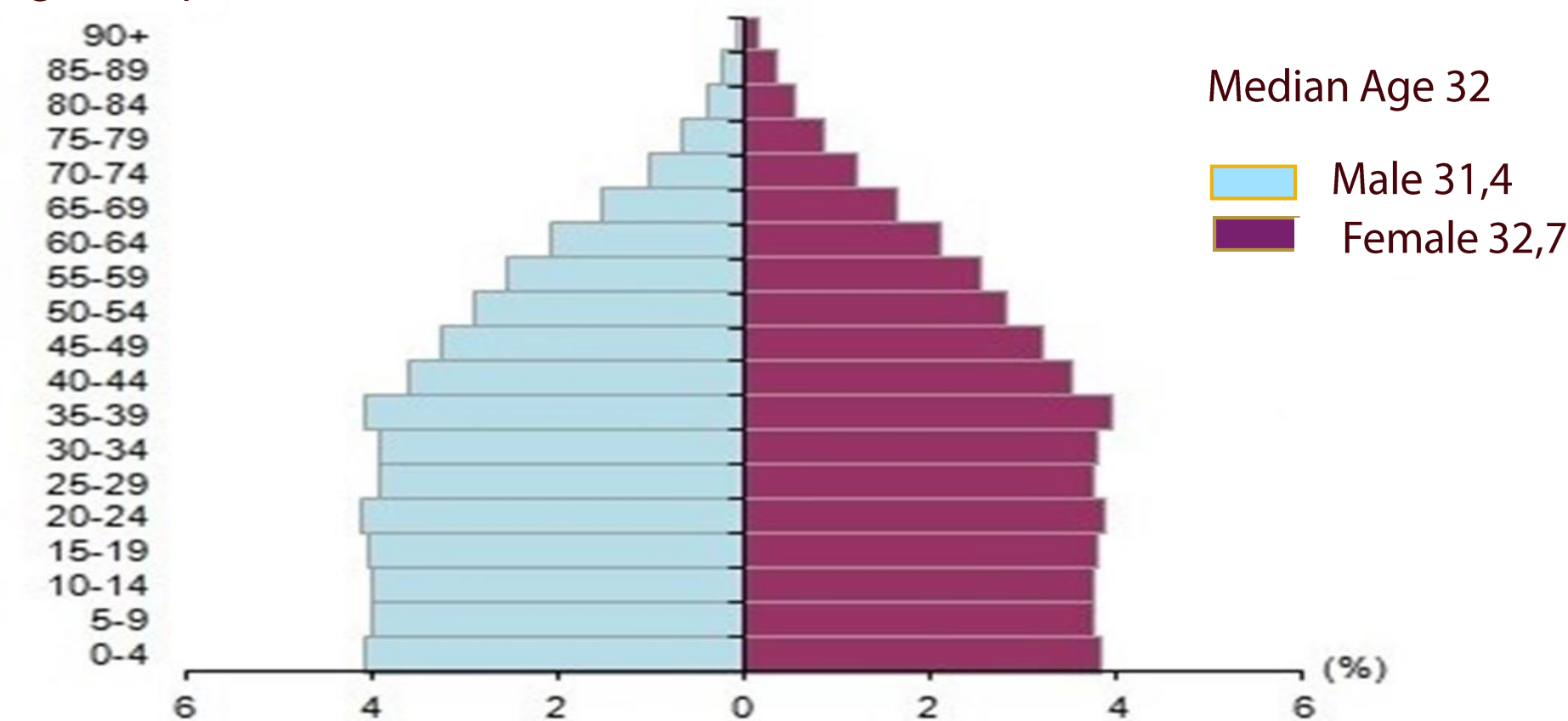
|                   |                         |
|-------------------|-------------------------|
| Surface:          | 783,562 km <sup>2</sup> |
| Population:       | 85 million              |
| Birth rate:       | 15,3 births/1,000       |
| Death rate:       | 5,2 deaths/1,000        |
| Number of donors: | ≈ 3 million             |



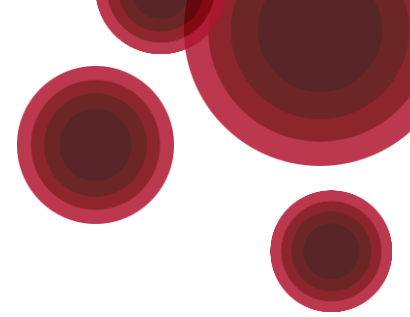
# Blood supply in Türkiye

## General Information of Population

Age Group



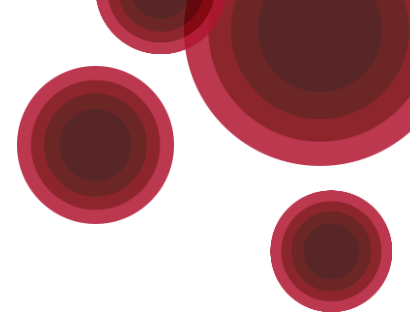
# Blood supply in Türkiye



## Legal framework

- New law on blood and blood products  
(Law No: 5624, OJ No: 26510, 02.05.2007)
- Implementing regulation on blood and blood products  
(December 2008)

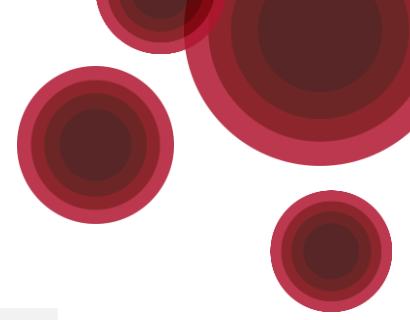
# Legal framework



National guides on

- Standards for blood services
- Quality Management in blood services
- Preparation, use and quality assurance of blood and blood components
- Haemovigilance
- Standards for certification in blood banking and transfusion medicine

# Blood establishments in Türkiye



|   | PUBLIC | OTHER |
|---|--------|-------|
| Regional blood centers of Turkish Red Cross (TRC) | -      | 18*   |
| Testing laboratory                                | -      | 4     |
| Blood collection center                           | -      | 68    |
| Temporary blood center                            | 13     | -     |
| Transfusion center                                | 1136   | -     |

# Donor recruitment activities of TRC

- A protocol was signed between the TRC and the Ministry of National Education in 2006 on “Activities for the Training and Recruitment of VNRBD”
- Training sessions are provided to teachers, student’s parents, and other staff in Provincial and District Directorates of National Education across the country
- Activities are ongoing with a slogan, “Kan”Panya Var”.

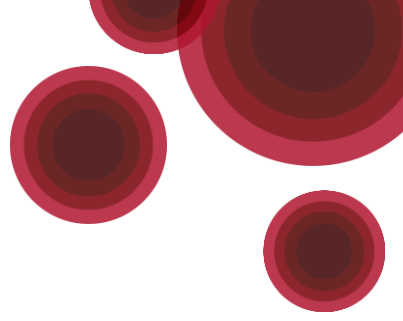
# Donor recruitment activities of TRC

- An international movement, Project Club-25 was adopted in 2006 and named as “Target-25” (Hedef-25)
  - ✓ to mobilize young people of up to 25 years by raising awareness to donate
  - ✓ to recruit intended voluntary regular donors and transfer this attitude to the next generation.



# Scope of Target-25

- Training of young people
- Donation campaigns for universities
- Design of promotional projects and advertisements



## Scope of Target-25

- 100 voluntary students from approximately 70 universities, have participated in workshops.
- These participants organized:
  - ✓ At least two donation campaigns in their universities in cooperation with the local blood donation center, to support donor recruitment activities,
  - ✓ Interactive trainings on their university campus with the contribution of local students and the staff from the local donation center to generate awareness for donation.

# Scope of Target-25

- 10 students who organized the top ten most successful campaigns are rewarded during the regular yearly Target-25 workshop meeting.
- The biggest support to reach the target number of donations is rewarded with the Target-25 Cup.
- The Target-25 Cup ceremony is turned into a tradition.

# Social promotions



- June 14: World Blood Donor Day Medal Delivery Ceremony.
- One Blood One Sapling Afforestation Project  
Between the Ministry of Forestry, Water Affairs and the TRC.
- “Turkish Blood Donation League Project” was launched with the slogan “Let’s Be a Fan of Benevolence, Sportsmanlike Conduct, Friendship, Blood Donation”

# Social promotions



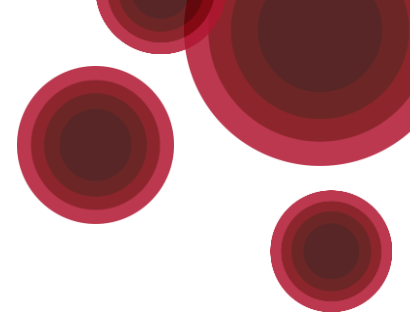
## ➤ Institutional blood donation collaborations

Protocols were signed with 176 organisations to carry out blood donation campaigns and awareness activities.

## ➤ "We Love Kindness" project

In November 2023 a loyal blood donor pool was created for patients with thalassemia in Adana Province.

# TRC Mobile Blood Donation Application



- Online appointment system
  - ✓ Creating/updating profile
  - ✓ Donation information
  - ✓ Nearest blood donation point
  - ✓ Online blood appointment
  - ✓ Directions to the blood collection team with an appointment
  - ✓ Creating a blood group card
  - ✓ Questionnaire
  - ✓ Contact form
  - ✓ Notification



# TRC Mobile Blood Donation Application

- Online appointment system
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  - ✓ Directions to the blood collection team with an appointment
  - ✓ Creating a blood group card
  - ✓ Questionnaire
  - ✓ Contact form
  - ✓ Notification

➤ 39.776 applications

➤ 9.676 online appointments

# Donor recruitment activities at governance level



- An EU funded Project on "Technical Assistance for Recruitment of Future Blood Donors" to supply the safest blood and to ensure national self-sufficiency was conducted between 2014 and 2016.

Ministry of Health (MoH)

Ministry of Education (MoE)

Turkish Red Crescent (TRC)

# Recruitment of future blood donors

Knowledge of primary and secondary school students regarding blood donation was increased in 500 pilot schools.





# Recruitment of future blood donors

Blood Donatin Clups were established in pilot schools.



# Recruitment of future blood donors

Materials about the importance of blood donation were developed and distributed to students and teachers.





# Recruitment of future blood donors

Family members of the students were motivated for VNRB donation





# Recruitment of future blood donors



Trainings, based on the responsibilities regarding blood donation, were provided to 688 staff of TRC, MoH and MoE.

# Recruitment of future blood donors

4399 school principals and 3218 hospital blood transfusion center employees in 81 provinces were informed on the importance of VNRB donation and project activities.





# Recruitment of future blood donors

Blood collection teams of TRC were trained in communication techniques and blood donor recruitment.



# Recruitment of future blood donors

Four animated cartoons raising awareness on VNRB donation were prepared and distributed.



**Deli Dumrul-  
Crazy Dumrul**



**Pamuk Prenses-Snow  
White and 7 Dwarfs**



**Kel Oğlan-Bald Boy**

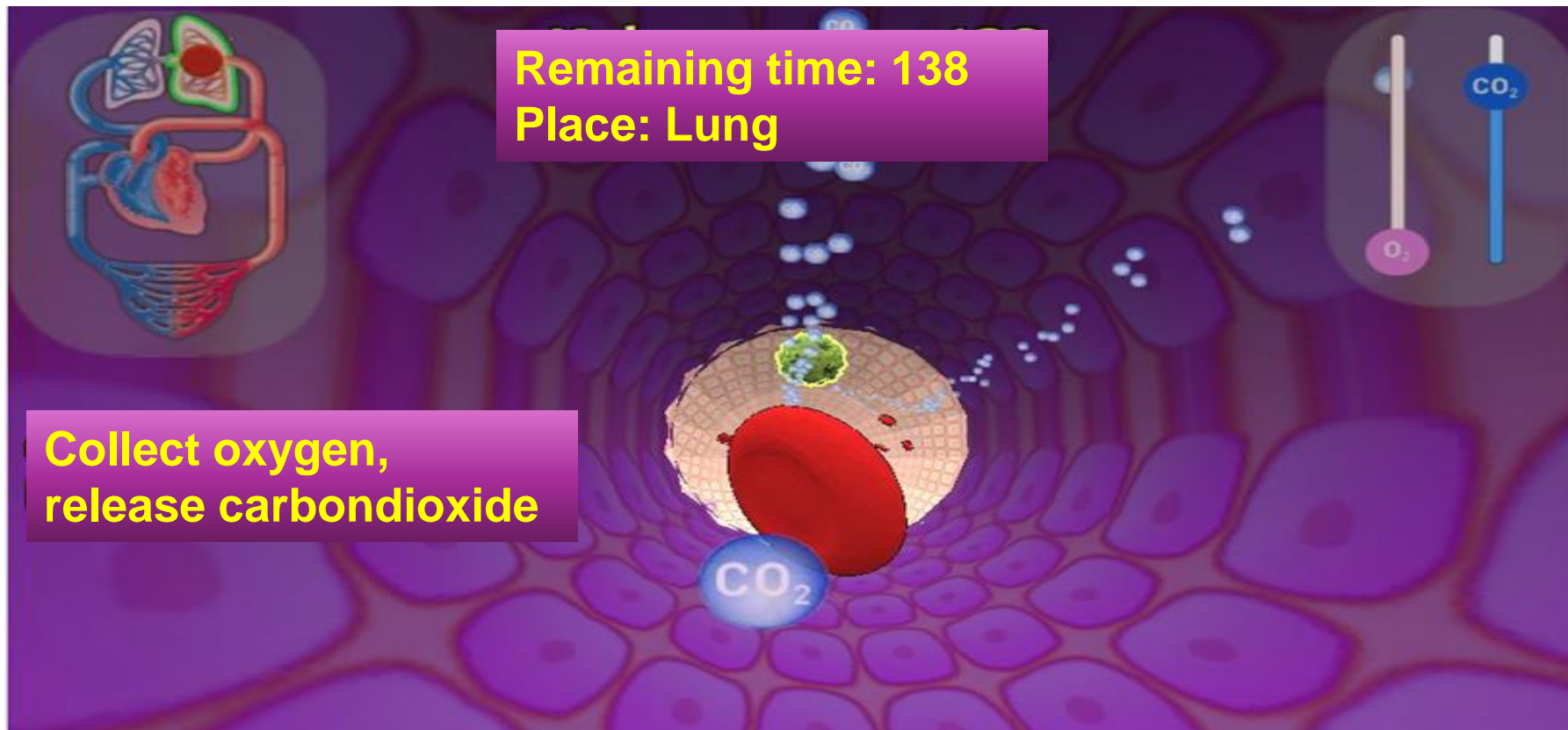


**Alaaddin Siharli Lambası-  
Aladdin's magical lamp**



# Recruitment of future blood donors

Three different computer games targeting different age groups were developed and distributed in pilot schools.



# Recruitment of future blood donors

Public awareness of blood donation through media and bilboards was created.



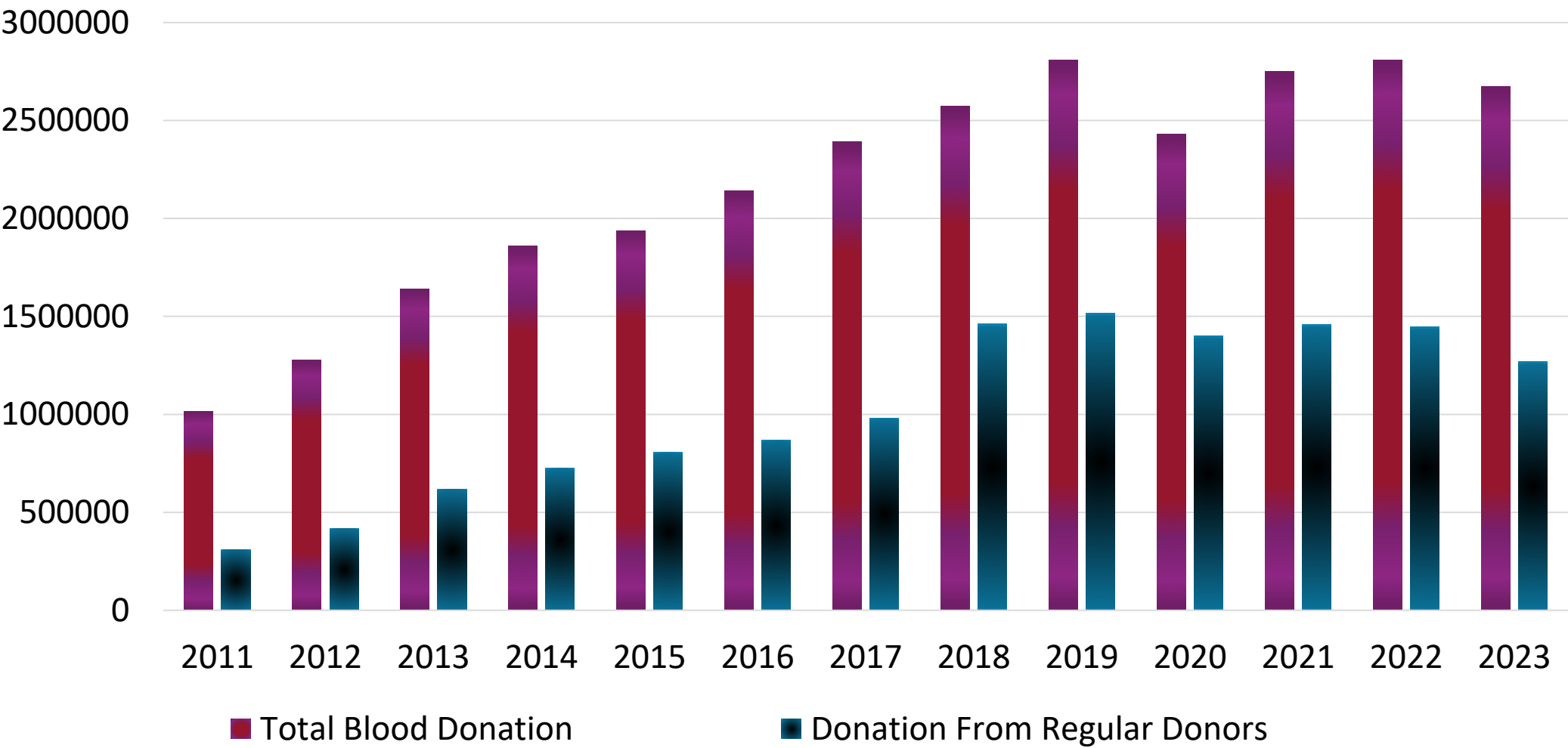


# Recruitment of future blood donors

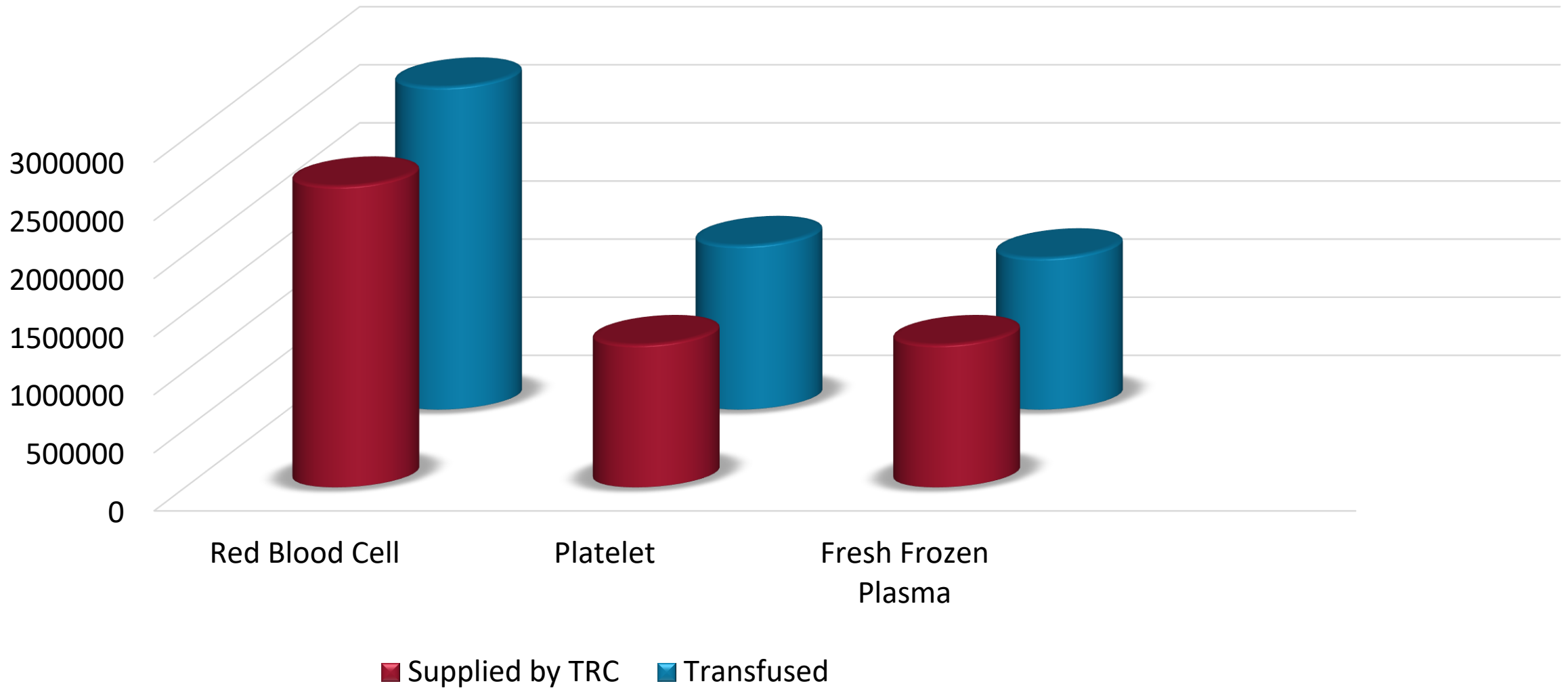
During the campaigns, 28.310 units of blood were received with the contributions of blood donation club members in pilot schools.



# VNRBD to Turkish Red Crescent over the years



# Annual need supplied by TRC in 2023



## In conclusion

- Donor recruitment and retention is not an easy task to undergo.
- Development and implementation of national and local strategies for donor recruitment and retention is essential.
- Active involvement of governmental and non-governmental institutions, organisations and societies in donor education, recruitment and retention programmes is essential.



A large Turkish flag with a white crescent and star on a red field is shown waving in the wind. The flag is positioned diagonally across the frame. In the background, a bright sun is setting or rising over a body of water, creating a golden glow and reflecting on the water's surface. The sky is filled with soft, colorful clouds. The overall scene is peaceful and patriotic.

**THANK YOU FOR YOUR ATTENTION!**



# Mapping Of Artificial Intelligence Initiatives And Challenges In Europe

## EBA Survey

Presenter: Rodica Popa, European Blood Alliance

**Authors:**

Mart Janssen (Sanquin), Rodica Popa (EBA),  
Mikko Arvas (FRCBS), Ólafur Eysteinn Sigurjónsson (Icelandic Blood Bank)



No conflicts of interest to declare



## EUROPEAN BLOOD ALLIANCE

Representing Non-profit blood establishments across Europe

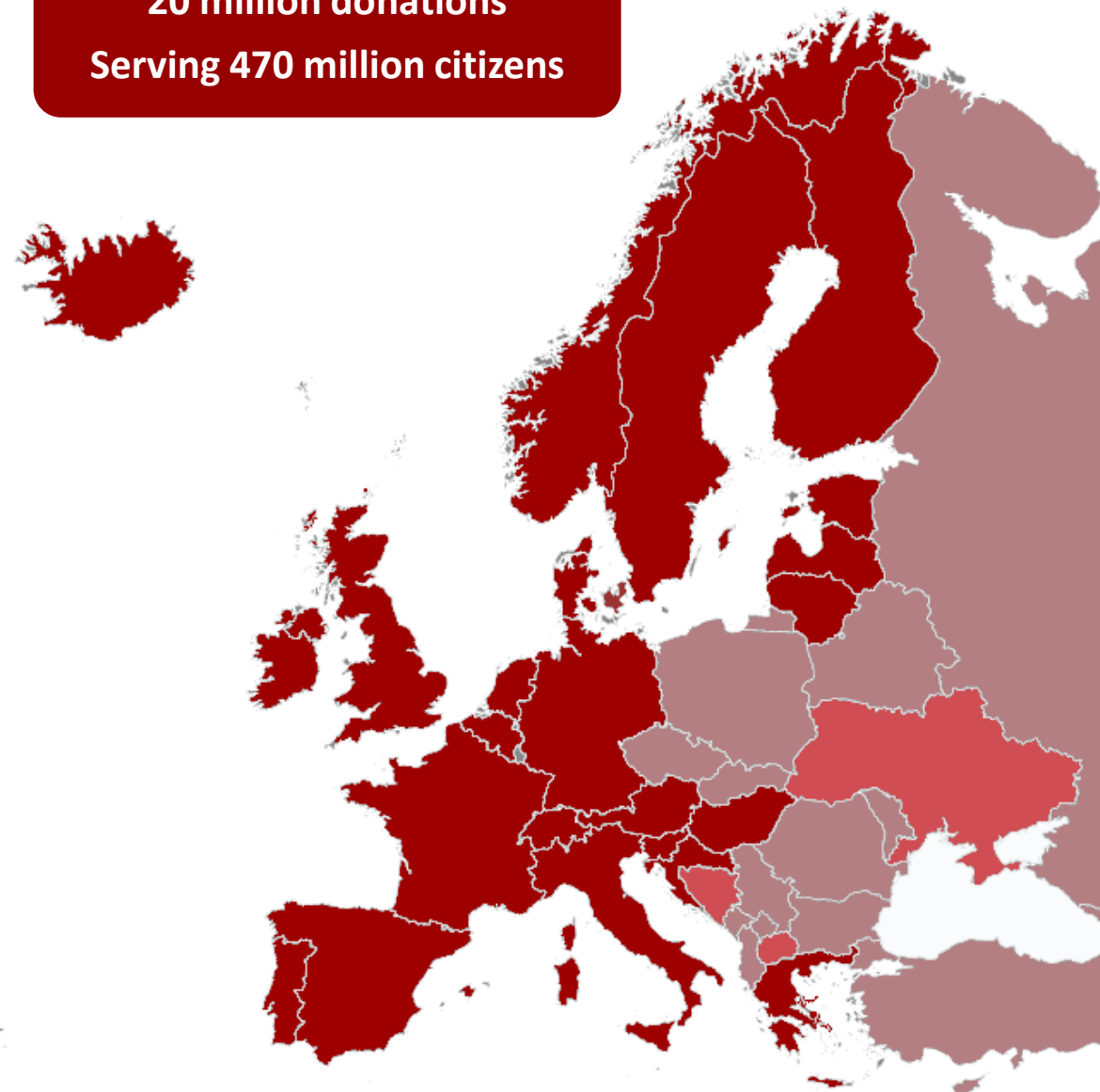
25 member countries, 4 observers

|   |         |   |             |  |                      |
|---|---------|---|-------------|--|----------------------|
|    | Austria |    | Iceland     |     | Portugal             |
|    | Belgium |    | Ireland     |     | Spain                |
|    | Croatia |    | Italy       |     | Sweden               |
|    | Denmark |    | Latvia      |     | Switzerland          |
|    | Estonia |    | Lithuania   |     | United Kingdom       |
|    | Finland |    | Luxembourg  |     | Bosnia & Herzegovina |
|    | France  |    | Malta       |     | North Macedonia      |
|   | Germany |   | Netherlands |    | Ukraine              |
|  | Greece  |  | Norway      |  |                      |
|  | Hungary |  | Slovenia    |  |                      |

**One vision:**

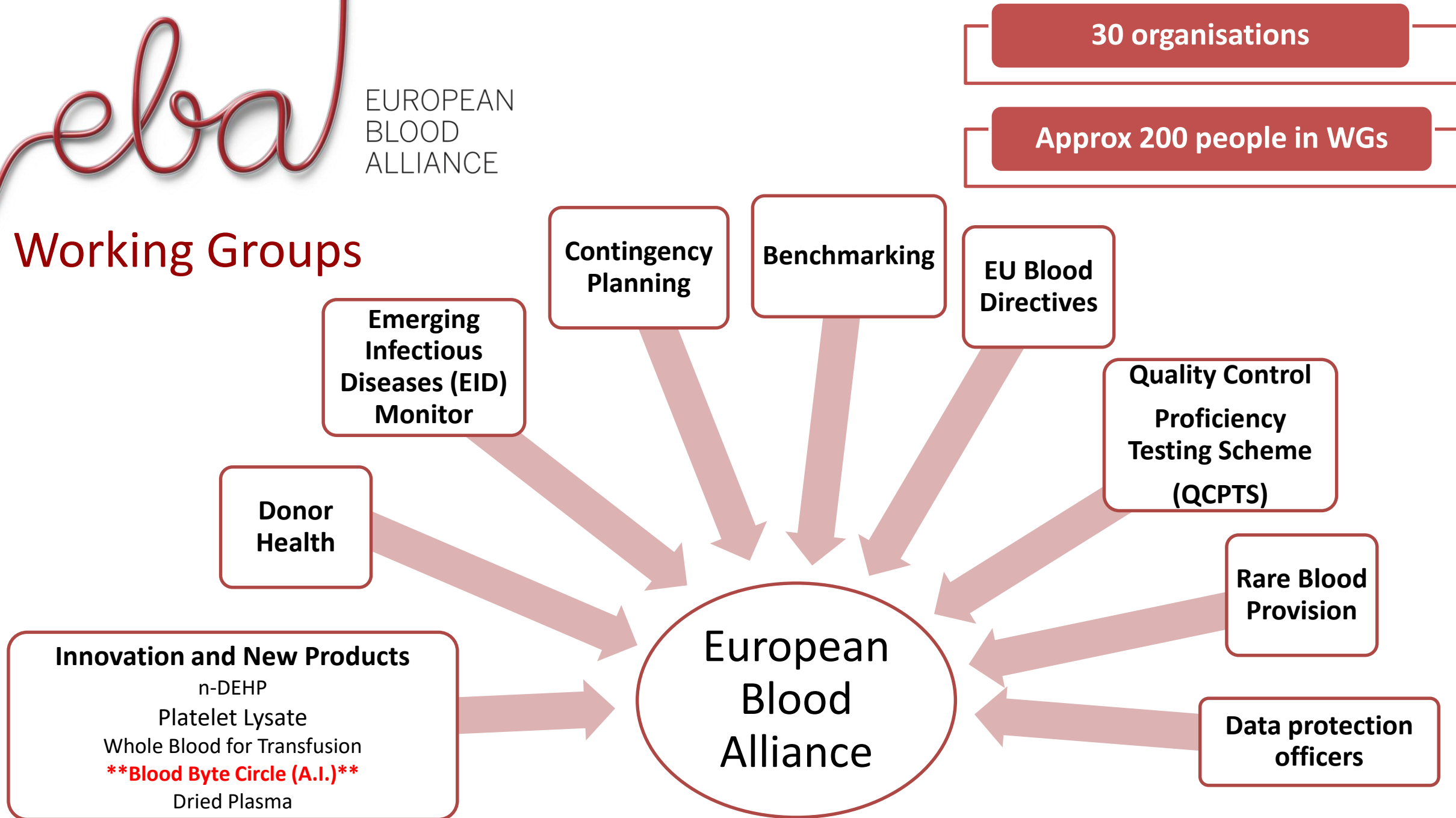
**A Safe and Sustainable Blood Supply for Europe**

**20 million donations**  
**Serving 470 million citizens**





## Working Groups



## AI Mapping Survey



Introduction & Methodology

Distribution of AI Initiates

Areas of application

Implementation phases

Case studies

Support needed

Conclusions and recommendation



## Introduction & methodology

### AI Mapping Survey

#### **Aim:**

- ✓ Assess current AI-utilisation within EBA
- ✓ Discover challenges and innovations
- ✓ Identify opportunities for collaboration

#### **Methodology:**

The survey conducted in April 2024 among 28 member organizations from 24 countries

Response rate: 75% (21 organisation from 19 countries:

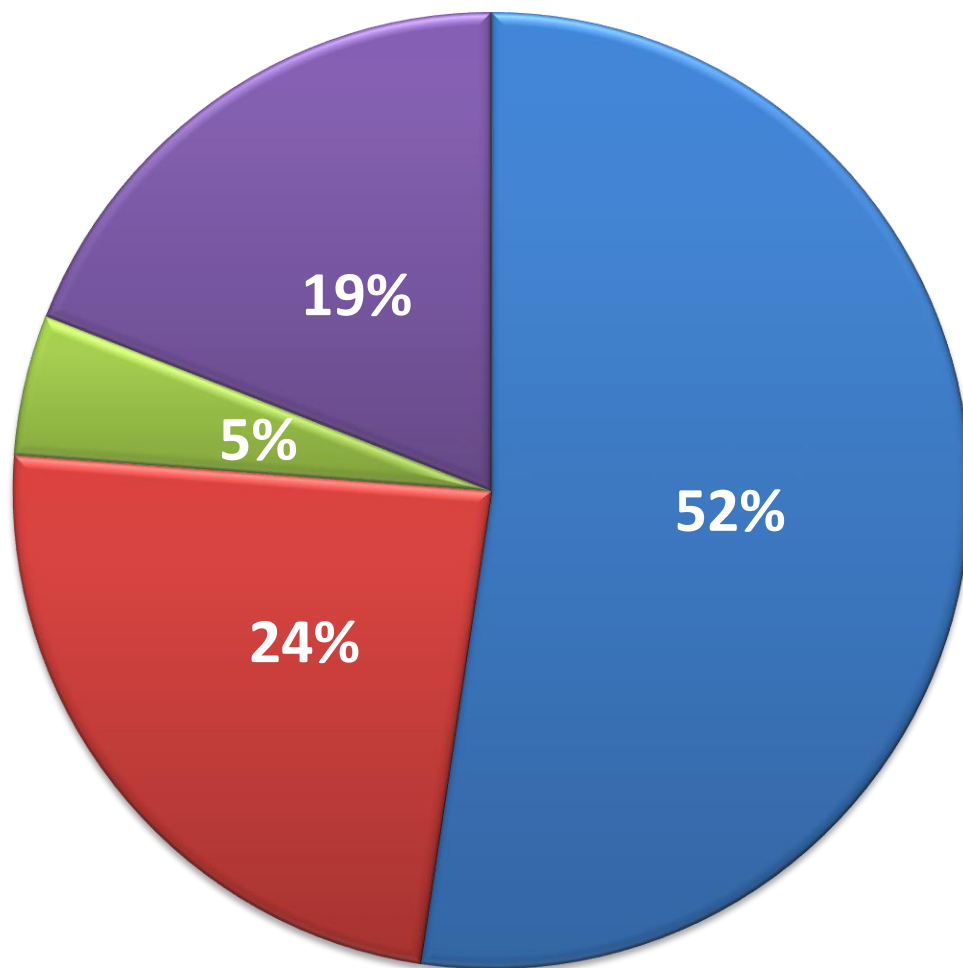
Austria, Belgium, Croatia, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Scotland, Slovenia, Spain, Switzerland, The Netherlands, United Kingdom)



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BLOOD  
ALLIANCE

## AI Status

Does your organization currently have any Artificial Intelligence (AI) initiatives?

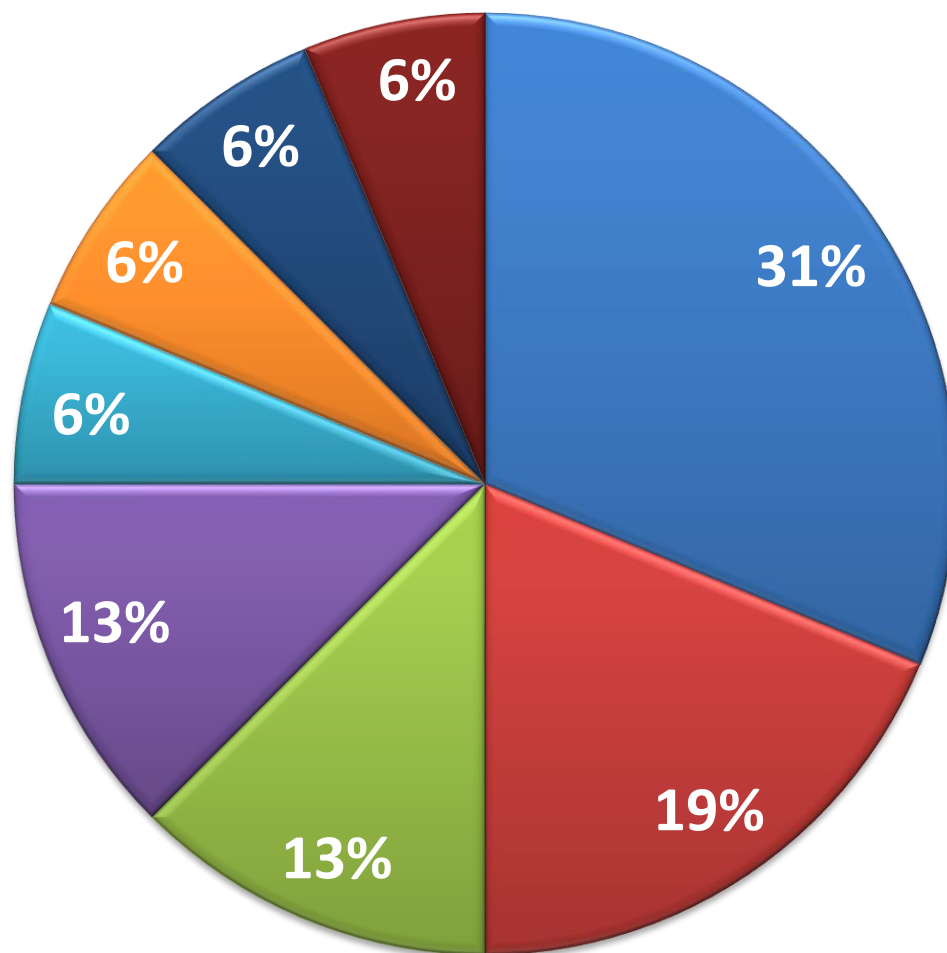


- No, but we are considering
- No and are not considering
- Yes, in the planning stages



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## Areas of Application



■ Donor Recruitment and Engagement

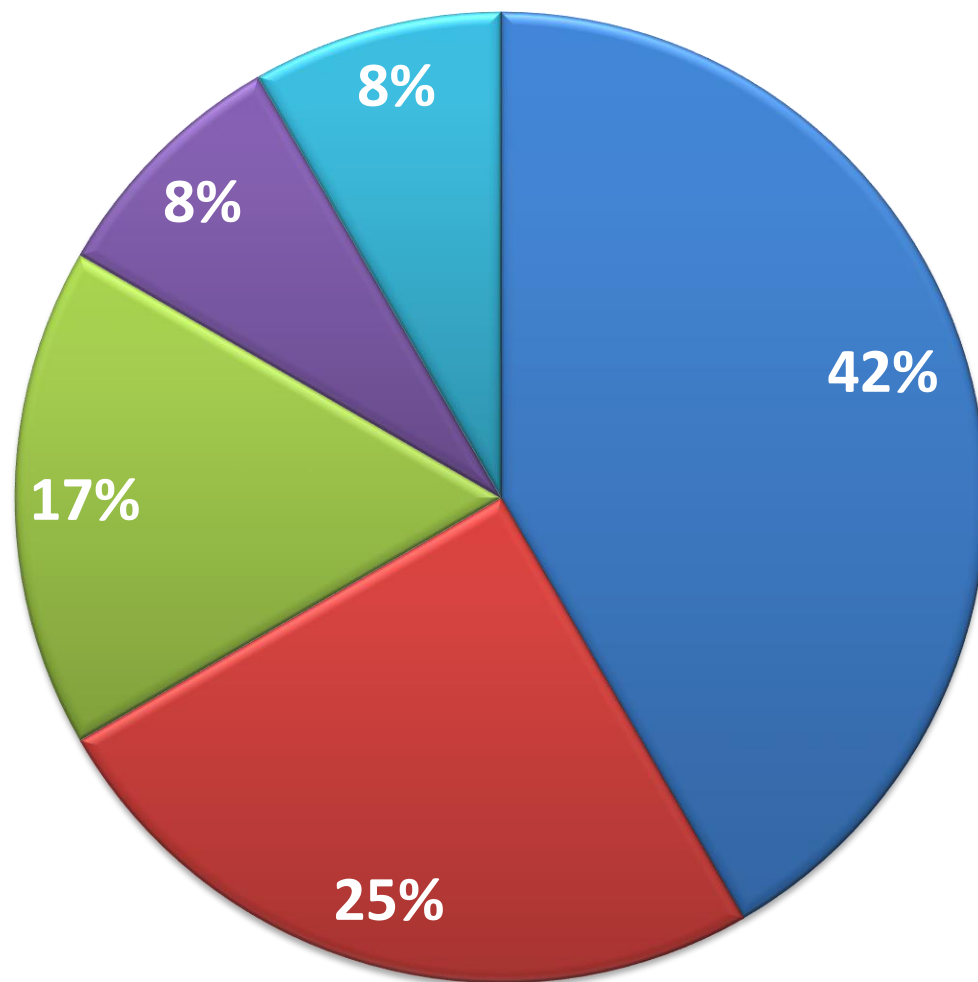
■ Demand Forecasting

■ Data Management and Analytics



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## Implementation Phases



- Scientific Research
- Exploration / Trial



Supply chain management: managing stock levels (ordering strategies) and issuing strategies of blood products to optimize stock rotation and reduce waste and product shortages. (Scientific Research)



Development of machine learning models for prediction of blood groups from genotyping data. The work has been published



## Case studies: Initiatives in action

Streamlining the Donation Process: "How can we redesign the blood donation process to make it more convenient and less time-consuming, thereby encouraging repeat donations?" (Exploration)



**Blood and Transplant**

Engaging in a range of predictive analytics activity using Data Science methods and technologies



**Gwasanaeth Gwaed Cymru  
Welsh Blood Service**

## Challenges Encountered

### Expertise and Skill Shortages

- Difficulties in attracting the necessary expertise to develop and implement AI systems.

### Regulatory and Compliance Issues

- Concerns about compliance with privacy laws, including GDPR, and the European AI Act.

### Technological and Data Challenges

- Validation of data and ensuring accuracy
- Difficulties accessing raw data across various IT systems to enable full inventory transparency

### Resource and Infrastructure Needs

- Need for more substantial support in terms of technology partners and collaborations to address skill and technology shortages

### Strategic and Decision-Making Barriers

- Despite understanding the potential of AI, no formal decisions had been made to implement such technologies.



## Benefits Observed/Predicted

### Enhanced operational efficiency

- Demand Forecasting, Data Management
- AI algorithms are utilised to predict future blood demand, handle large datasets, and automate routine tasks
- By automating and optimizing these processes, organizations can streamline operations, reduce manual labour, and ensure timely availability of blood products.

### Improved diagnostic accuracy

- Predictive Analytics, Machine Learning Models
- AI-driven predictive models and machine learning algorithms are used to analyze complex data patterns for better diagnosis.
- These tools can enhance the accuracy of diagnostics, leading to better patient outcomes and more effective treatment plans.

### Optimised resource utilisation

- Inventory Management, Predictive Analytics
- AI applications in inventory management help in optimizing the use of blood products and reducing wastage.
- Effective inventory management ensures that blood products are used efficiently, minimizing waste and reducing costs.

### Cost reduction

- Operational Automation, Data Management
- Implementing AI for routine operational tasks and data management can significantly cut down on manual labor and operational costs.
- Lower operational costs and improved efficiency in handling large volumes of data.

## Support Needed by Blood Establishments

### Knowledge Sharing and Best Practices

- Understanding what has been successful elsewhere to guide their own initiatives

### Expertise and Technical Assistance

- Direct technical assistance and expertise, especially from those who have advanced further in similar technologies

### Regulatory Guidance and Advocacy

- Guidance on navigating complex laws such as GDPR and the European AI Act.
- "regulation guidelines,"
- EBA could advocate for a harmonized regulatory approach across the EU, which would provide a necessary "regulatory toolbox before starting with AI."




AI-assisted laboratory result interpretation



Automating donor selection and health screening



Inventory optimization for platelets



AI applied in IT systems (cybersecurity, chatbots, coding ...)



Legal services: Drafting of contracts, contract analysis, jurisprudence



Short-term goals and ongoing reassessment

## Correlation Insights

### Demand Forecasting

#### Challenges:

- Data quality and integration issues
- Difficulty in attracting expertise for developing predictive models

#### Benefits

- Improved inventory management
- Reduced wastage of blood products
- Better alignment with patient needs

### Data Management and Analytics

#### Challenges:

- Data validation and accuracy
- Accessing comprehensive datasets
- Regulatory compliance

#### Benefits

- Enhanced data-driven decision-making
- Improved operational efficiency
- Insights from large datasets

### Integration with Operations

#### Challenges:

- Resistance from staff and management
- Compliance issues with national regulations, particularly for cloud-based AI solutions

#### Benefits

- Streamlined workflows
- Increased efficiency in routine tasks
- Improved operational effectiveness



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BLOOD  
ALLIANCE

## Recommendations for EBA

**Address Data Quality and  
Integration Issues**

Develop strategies/tools to improve data quality  
and facilitate integration into existing systems

**Develop Training Programs**

Invest in training programs to build AI expertise  
within the EBA community

**Provide Targeted Support**

Tailor support initiatives to the specific needs of  
organizations at different implementation phases

**Promote Success Stories**

Share case studies and success stories to  
demonstrate the benefits of AI-applications

**Foster Collaboration**

Encourage partnerships and collaborations  
within the EBA community

## Key Takeaways

### 1. Acknowledging the Challenges:

- Skill Gaps: Building AI expertise within blood establishments.
- Technical Complexity: Data integration, validation, and AI adoption hurdles.
- Regulatory Barriers: Adapting to evolving frameworks like the European AI Act.

### 2. Opportunities Ahead:

- AI can structurally improve existing processes.
- Broad range of applications possible.
- Collaboration across organizations may accelerate innovation, problem-solving and acceptance.

### 3. EBA's Role:

- Sharing success stories and fostering partnerships to tackle shared obstacles – **Blood Byte Circle**
- Providing guidance on navigating regulatory complexities.



- Quarterly online meetings, open to anyone interested
- Invited speaker to discuss experiences with AI-application development or implementation within the blood supply

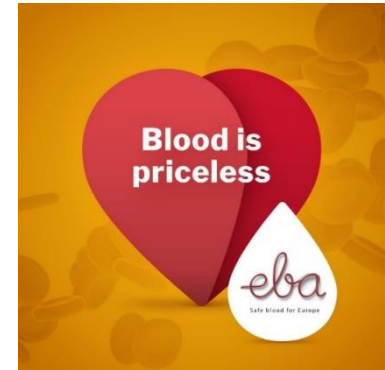
### Topics of the meetings in 2024:

- 25/07/2024: Iris Garcia Martínez from Banc de Sang i Teixits: Artificial Intelligence in Blood Donation: Implementation of an Automated and Efficient System to Optimize the Call for Donors in Three Hospitals of Catalonia
- 20/09/2024: Iris Garcia Martínez from Banc de Sang i Teixits: A more elaborate elucidation and discussion of the work presented in the July meeting
- 13/12/2024: Judita Rudokaite from Sanquin/Tilburg University: Predicting vasovagal reactions using video analysis with AINAR Artificial Intelligence for Needle Anxiety Reduction



Thank you

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[www.europeanbloodalliance.eu](http://www.europeanbloodalliance.eu)

If you want to join the Blood Byte Circle, you can do so by completing this online form:

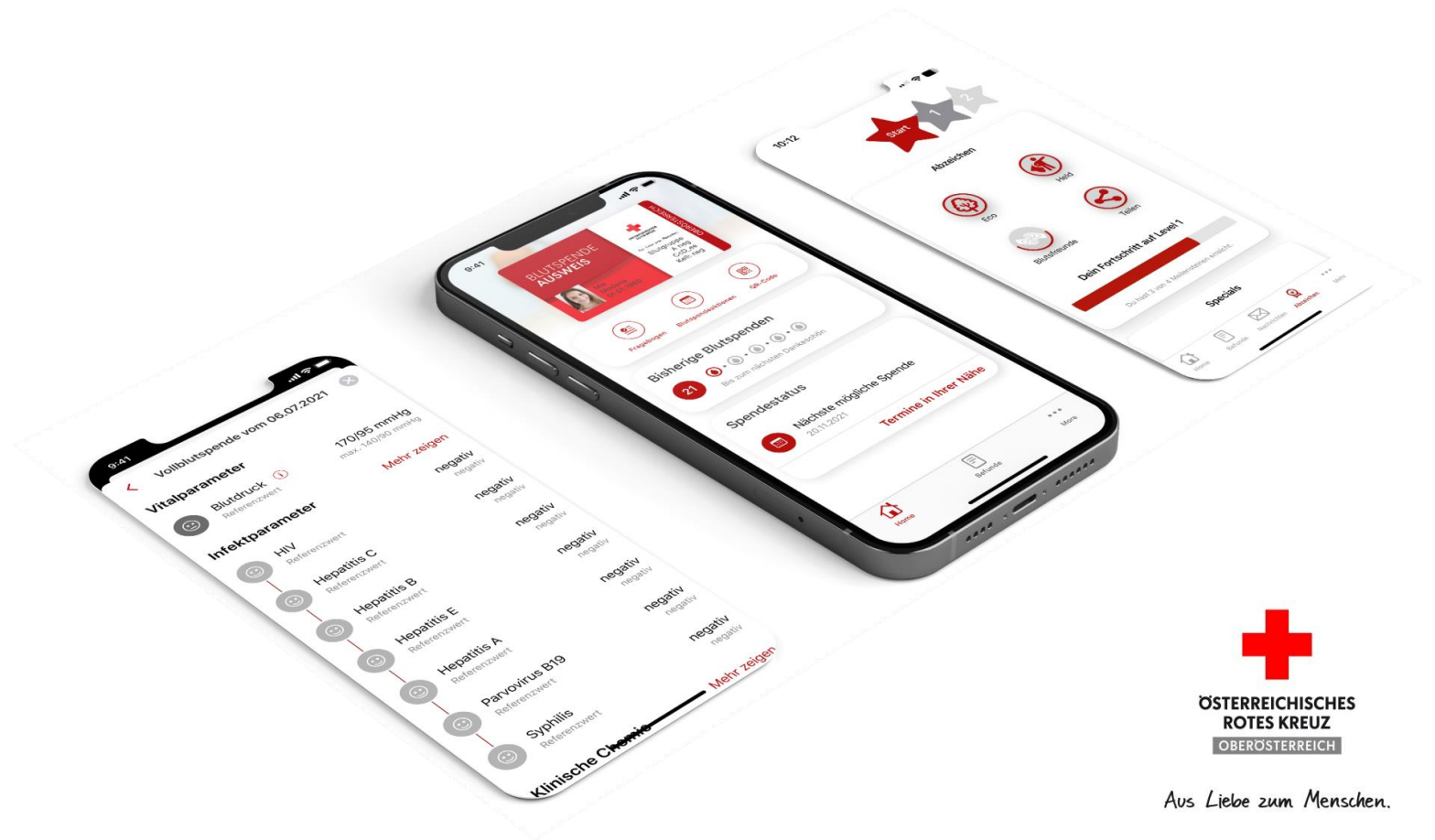
<https://forms.office.com/e/6JScdp0cuS>

\*register using your organizational email

# Adding virtual badges to the incentive strategy of blood donation

Dr. Norbert Niklas

Red Cross Transfusion Service  
for Upper Austria



Aus Liebe zum Menschen.

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All authors declare no conflicts of interest.



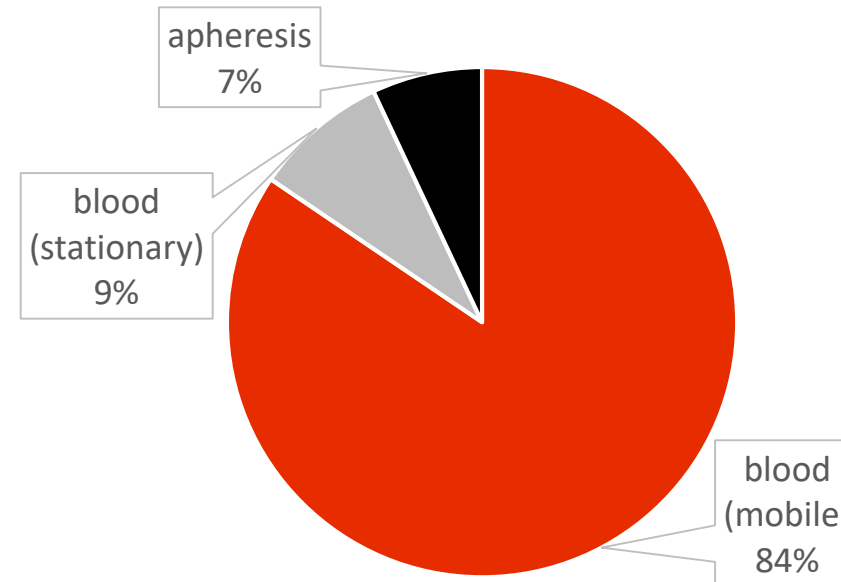
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# Institute

- Blood donation service and blood bank
- Blood depot and transportation of blood products

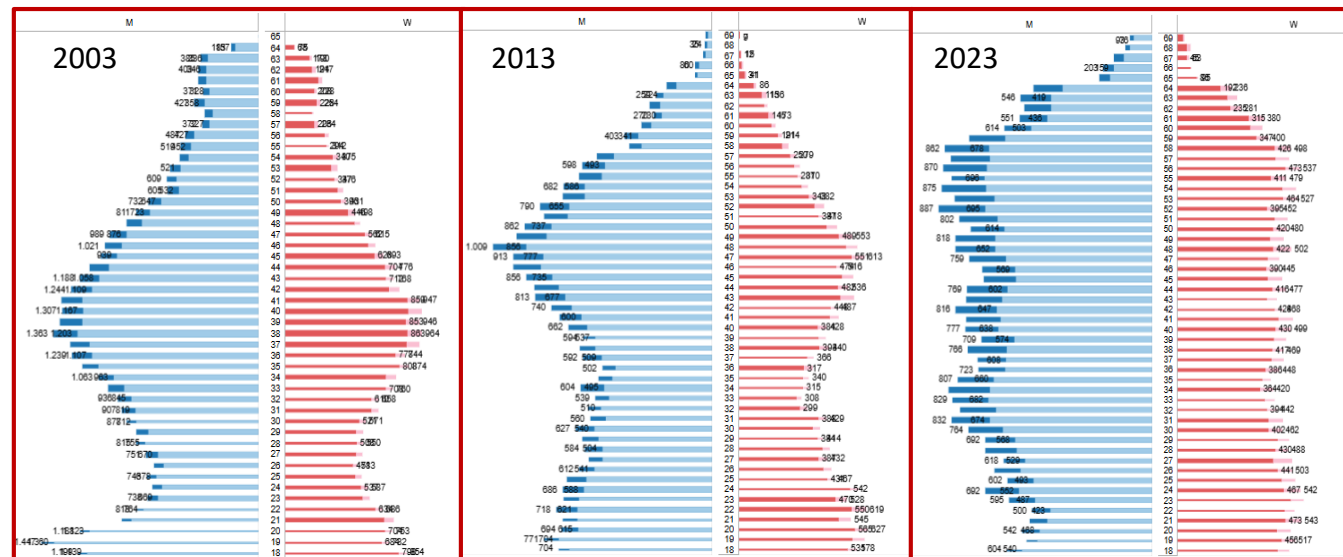


|                       |       |
|-----------------------|-------|
| Red cell concentrates | 52678 |
| Platelets, pooled     | 2283  |
| Platelets, apheresis  | 4276  |
| Plasma (liter)        | 14273 |



# Maintaining a blood donor pool

- voluntary and unpaid blood donation ( § 8 (4) blood safety law, BSG)
- How to keep donors motivated?
  - intrinsic (altruism, appreciation, emotions, personal concern)
  - extrinsic (incentives)

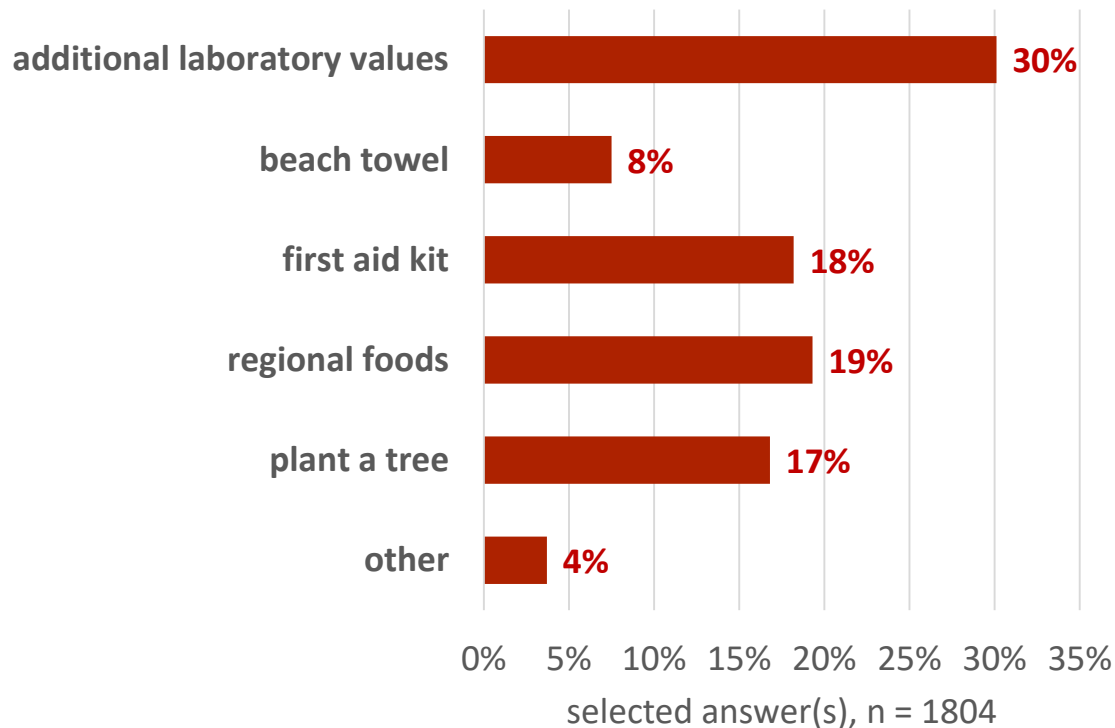


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# Donor opinions

What of the following recognitions would interest you the most?

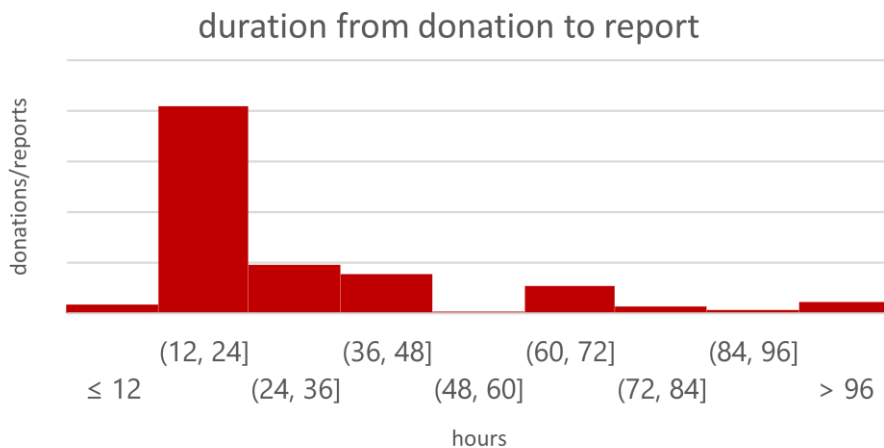


# Incentives

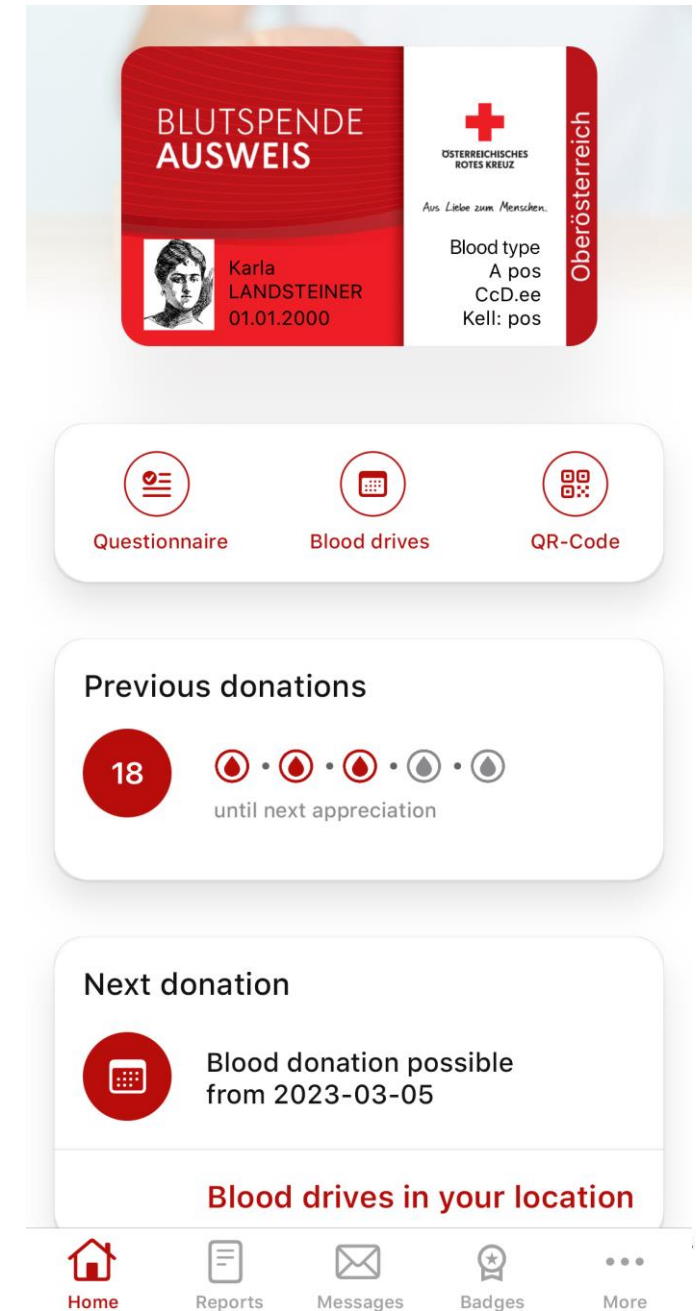
- thank-you gifts
- awards (25x, 50x, ...)
- blood analysis (medical report)
- extended analyses (HDL, LDL, TSH, VitD - every 5th donation)
- notification when blood has been used
  
- blood donation app
- **virtual badges (gamification)**
  
- not established: cash-payment, vouchers

# Digitalization & blood donor app

- used by 67 % of all donors
- estimation of eligibility after completion of the digital questionnaire
- access to all personal laboratory reports (even historical)

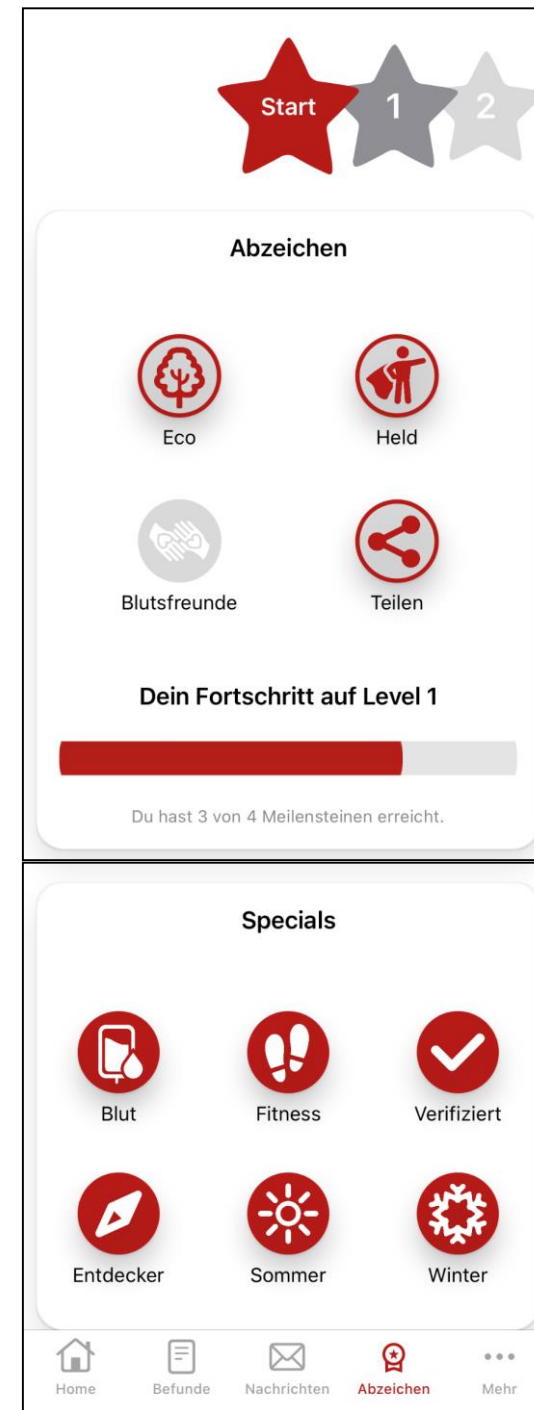


paper report:  
3 to 6 weeks



# Gamification concept

- blood donation related activities
  - stay connected between blood donations (8w)
  - motivate donor to beneficial behaviour
- 
- integrated in blood donation app
  - automatic granted, no staff interaction required
  - digital-only (cannot be redeemed)



# Regular badges

- can be achieved multiple times
- next level is reached when all conditions are met



exclusive switch to digital report



donate (at least) twice a year



connect with other donors



share appointments

# Special badges

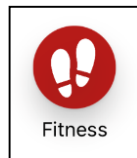
- can be achieved once
- flexible to add other badge types



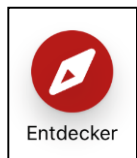
initial badge



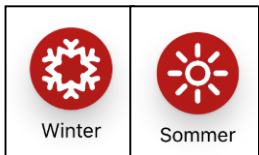
for the first donation with the app



motivation for a healthy lifestyle (10000 steps per day)



awarded for special/hidden blood drive



awarded for donation during winter/summer



# Study design

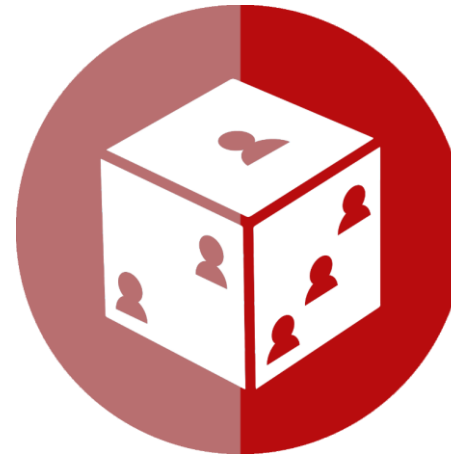
- 18 months after introduction of badges
- only including whole blood donations

58,826 donors

85,432 donations

9,880 deferrals

156,463 badges



# Study design

no app users

„offline“ donors without badges

gamers

active involvement  
(meet & greet, share, fitness)

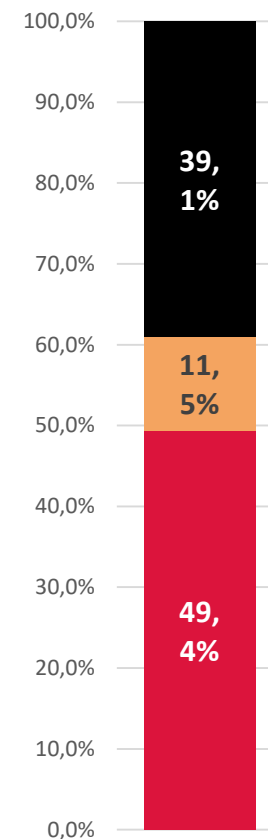
app users

passive usage



**93,610 registered**  
**51,276 verified**

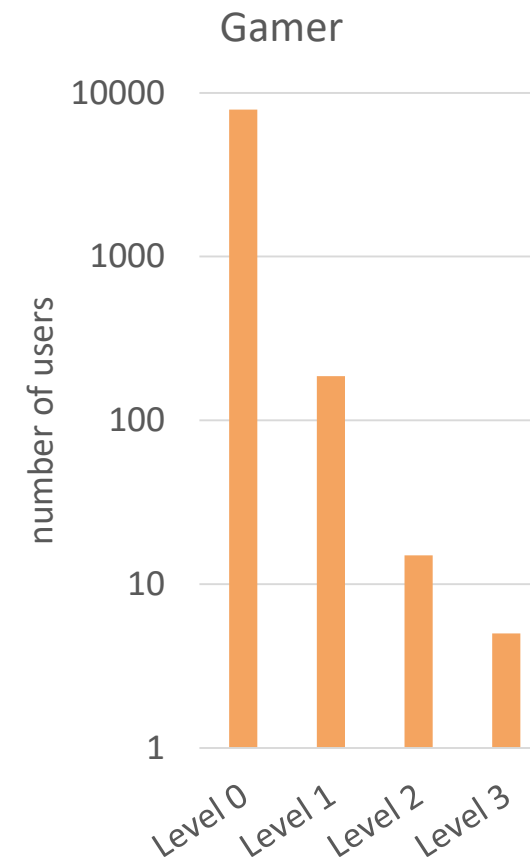
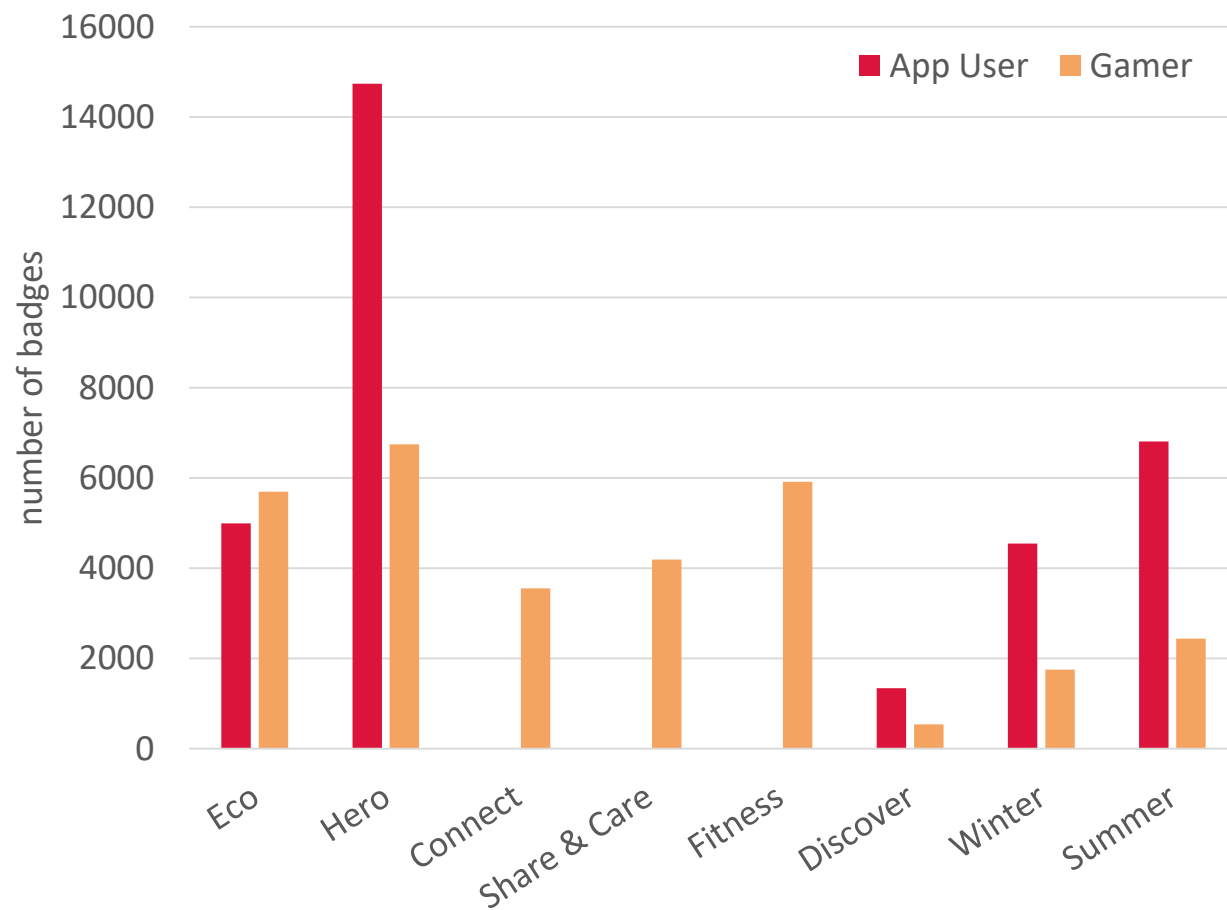
(2024-12-06)



ÖSTERREICHISCHES  
ROTES KREUZ  
OBERÖSTERREICH

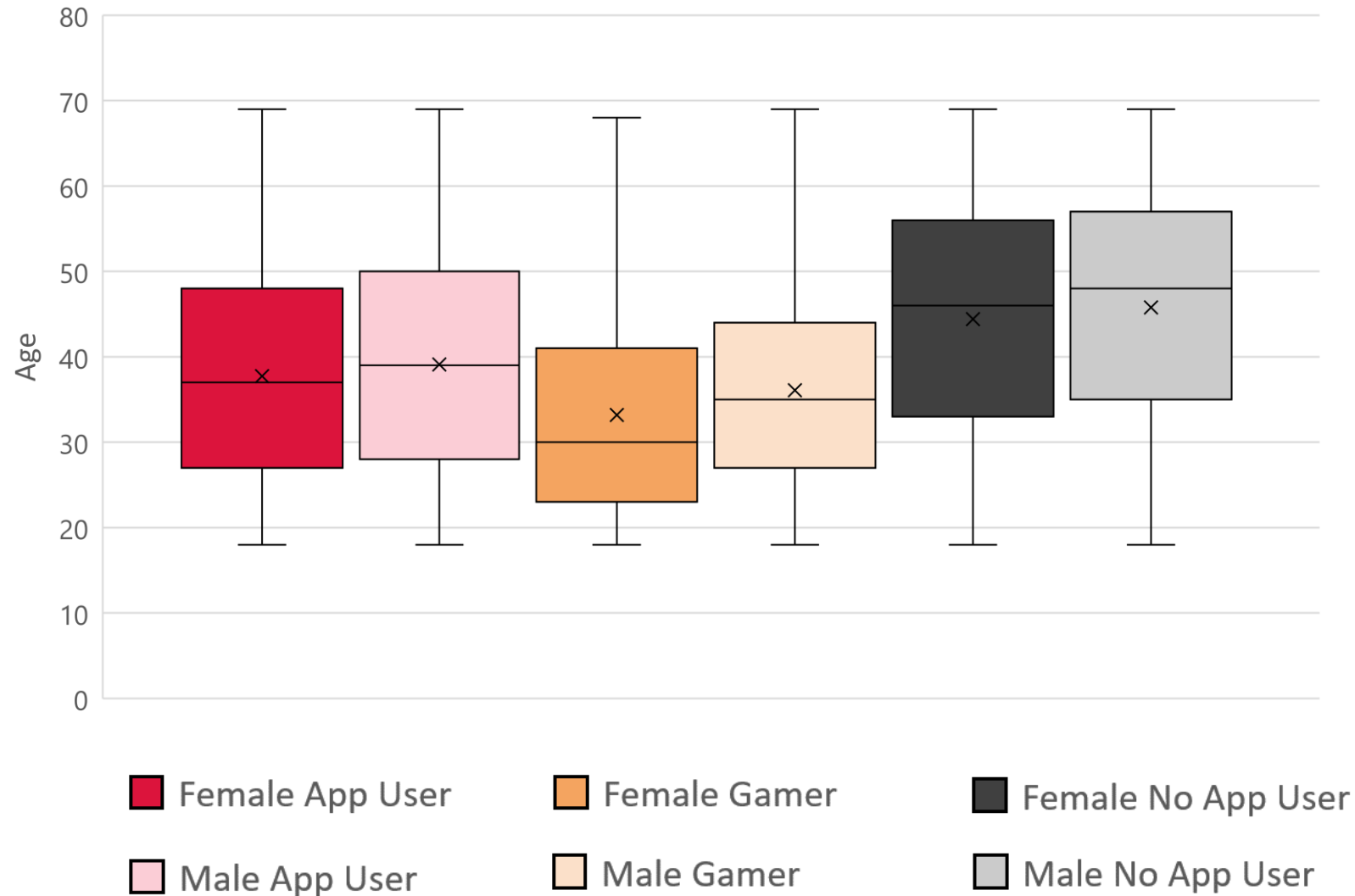
*Aus Liebe zum Menschen.*

# Earned badges



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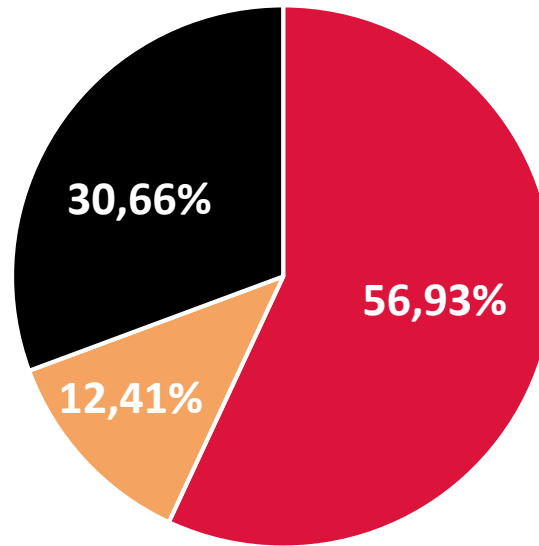
# Demographic



ÖSTERREICHISCHES  
ROTES KREUZ  
OBERÖSTERREICH

Aus Liebe zum Menschen.

# First time donors



■ App User ■ Gamer ■ No App

Average age

**27.51**

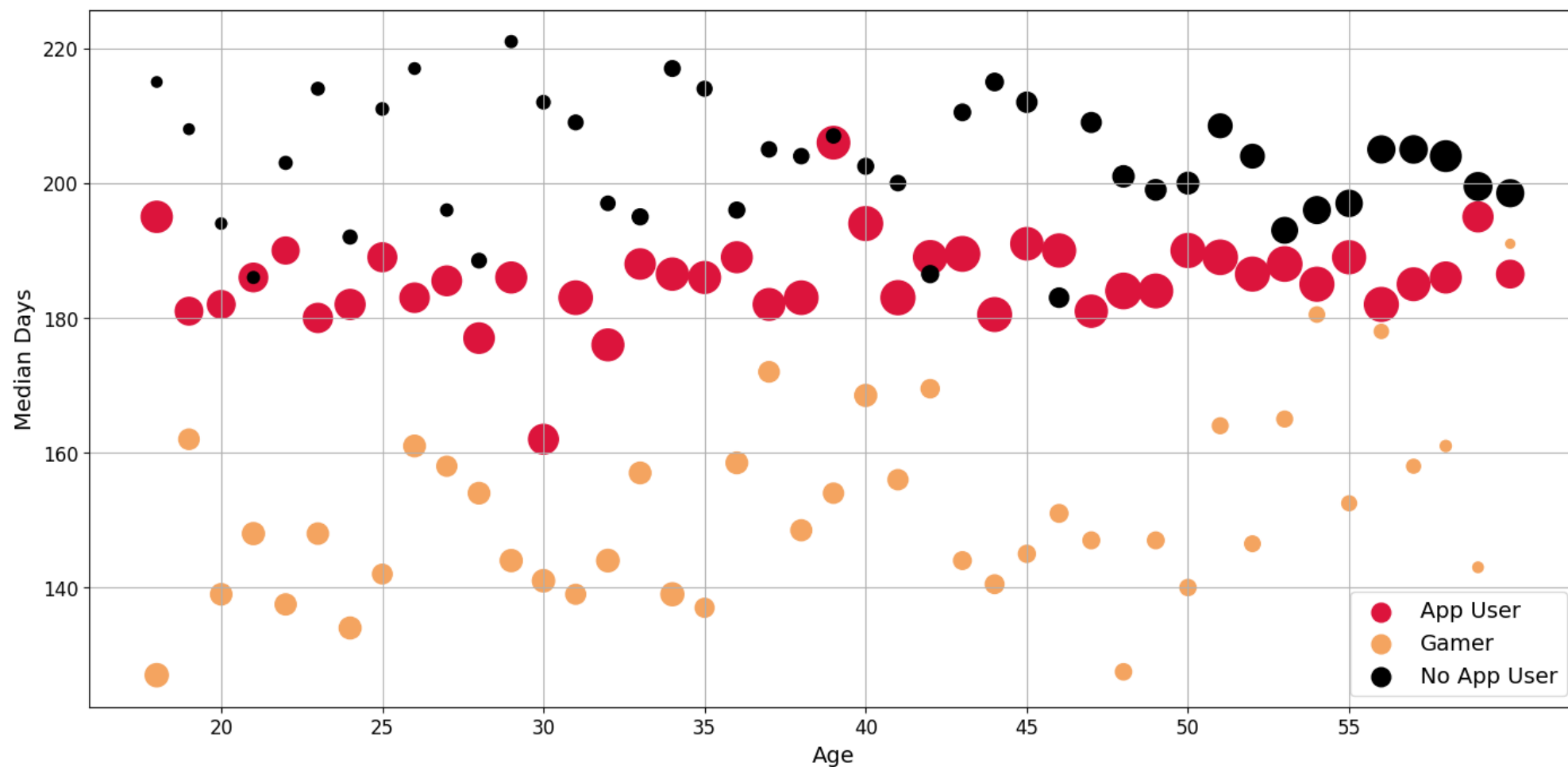
**25.68**

**32.86**



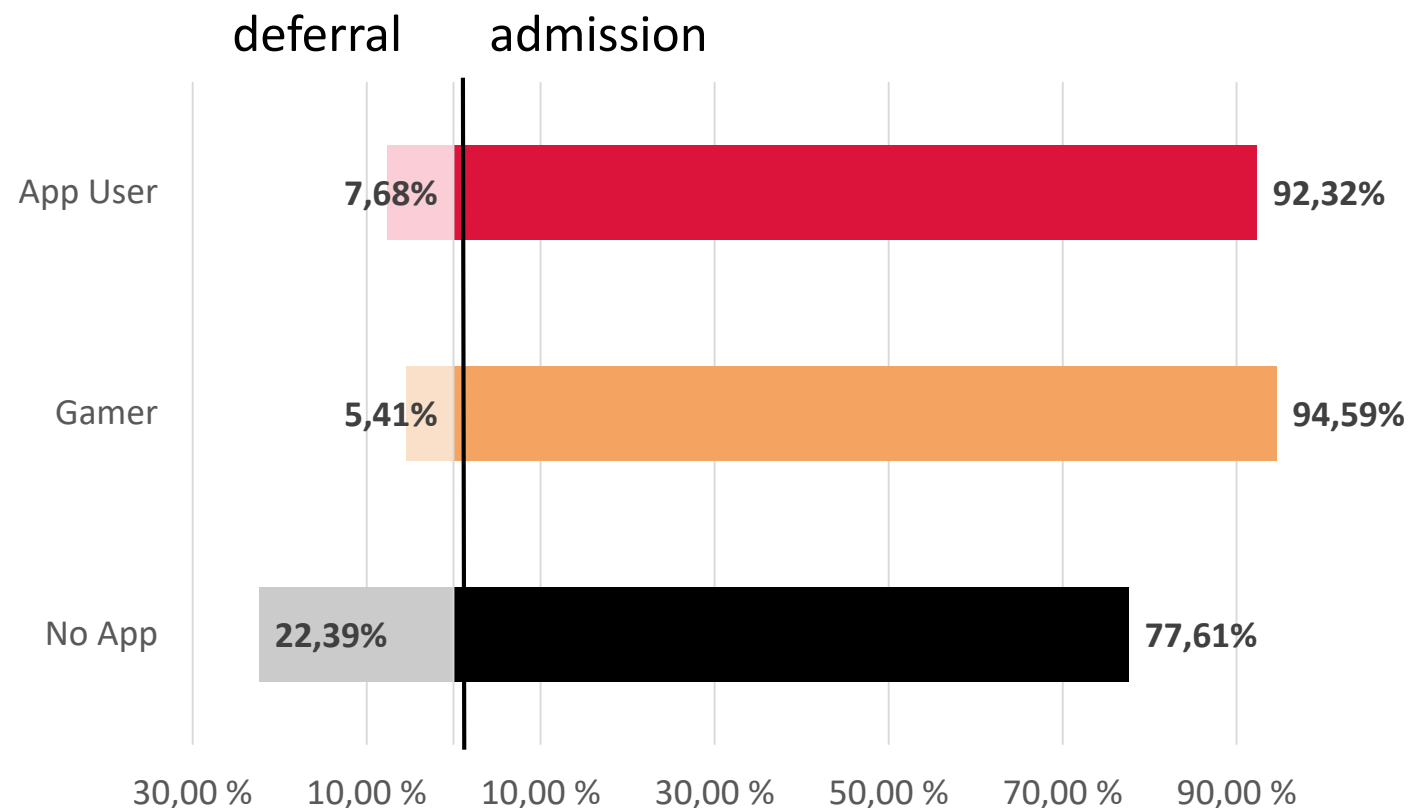
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# Regular donations





# Deferral vs. admission



Donor health questionnaire

**Questionnaire completed**

One or more answers need to be clarified with the medical blood donation staff on-site. This will determine eligibility for blood donation.

valid until: 02.02.2024 12:22

[Blood donation campaigns nearby](#)

[Back to dashboard](#)

# Benefits

- digitalization is a key aspect for modern blood banking
- virtual badges are cost-effective
- good addition to other incentives
- attraction of especially young donors
- donors return more often

# Further ideas

- (anonymous) ranking feature
- group challenges
- donor-centric integration of new features
- feedback of yearly survey and app stores

Current development:

download ISO 15189 conform medical report  
appointment reservation



4.705 ★

Standardbewertung bei Google Play ?

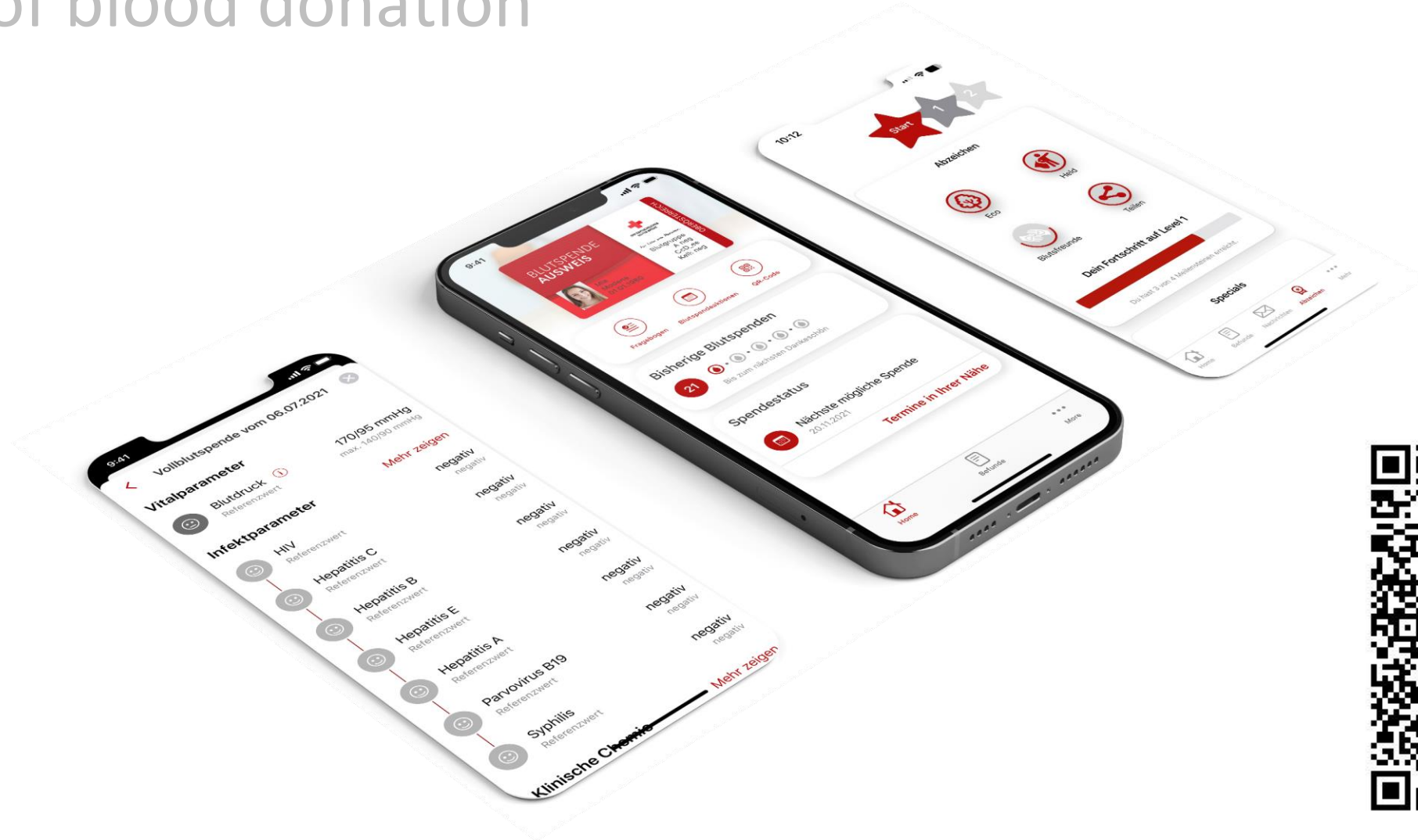


Aus Liebe zum Menschen.

# Conclusion

- donor (user) behaviour and motivation is changing
- target group exists and responds well
- donors engage in blood donation-related activities between donations
- stay in contact with donors
- incentives in general are currently not actively promoted
- moderate communication might yield additional benefits

# Adding virtual badges to the incentive strategy of blood donation



vCard



