EDQM Blood Conference
Innovation in Blood Establishment Processes

14-15 January 2025
Strasbourg, France

Session A2:
Blood collection & apheresis
(13:30 – 15:00)

Moderators: **Hans Vrielink**, Sanquin Blood Supply Foundation, the Netherlands
Vanja Nikolac-Markić, Head of SoHO Quality Section, EDQM

Speakers: **Johanna Castrén**, Finnish Red Cross Blood Service, Finland
Jan Hartmann, Haemonetics Corporation, USA
Torunn Oveland Apelseth, Department of Immunology and Transfusion Medicine, Haukeland University Hospital & Faculty of Medicine, University of Bergen, Norway

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*

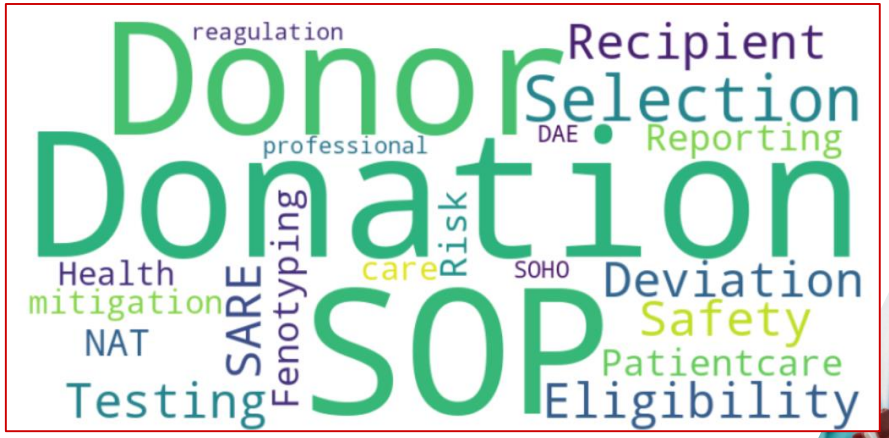
Blood Collection & Apheresis

Johanna Castrén MD, PhD
Chair, CD-P-TS
Director, Blood Donation, Finnish Red Cross Blood Service

EDQM Blood Conference 2025

- no conflicts of interest -

1. Introduction
2. Data – Trends 2013, 2020 and 2023
3. Thoughts about Challenges and Future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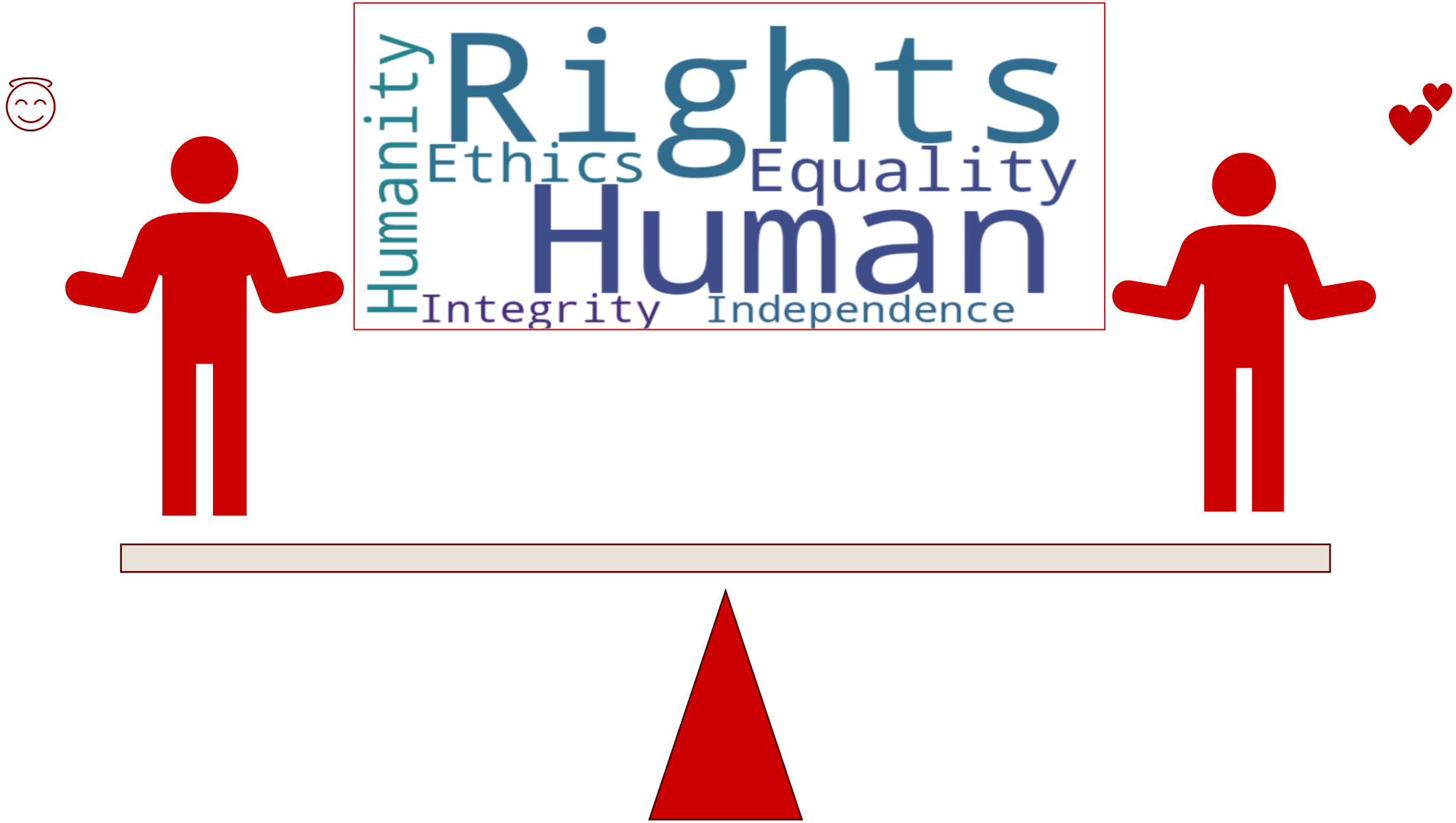

Rights
Humanity
Ethics
Equality
Human
Integrity
Independence

Donors and Donations in Europe – Overview 2013 and 2020&2023

Ref:
L.R. van Hoeven, M.P. Janssen and G. Rautmann: The collection, testing and use of blood and blood components in Europe 2013 report. Published by European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM).

M. Janssen, R. Forde: Draft: The collection, testing and use of blood components in Europe 2020-2023 report (not yet published)

https://www.worldometers.info/world-population

Number of Donors 2023 vs. 2020

12 out of 23 reporting increase

Country	Change in number of donors 2023 vs 2020
Bulgaria	50 %
Republic of Moldova	21 %
Montenegro	17 %
Iceland	14 %
Poland	12 %
Slovak Republic	11 %
Latvia	10 %
Hungary	8 %
Croatia	6 %
Italy	3 %
United Kingdom	3 %
Sweden	1 %
France	-1 %
Switzerland	-2 %
Norway	-2 %
Finland	-3 %
Germany	-4 %
Czech Republic	-4 %
Belgium	-5 %
Estonia	-5 %
The Netherlands	-6 %
Portugal	-6 %
Denmark	-30 %

Number of Donors 2023 vs. 2013

Only 5 out of 23 reporting increase

Total: 17% less donors in 2023

Country	Change in total number of donors	
	2023 vs 2013	2023 vs 2020
Montenegro	23 %	17 %
Bulgaria	8 %	50 %
Poland	3 %	12 %
Latvia	3 %	10 %
Slovak Republic	1 %	11 %
Belgium	-1 %	-5 %
Switzerland	-3 %	-2 %
Croatia	-6 %	6 %
France	-6 %	-1 %
Italy	-8 %	3 %
Norway	-8 %	-2 %
Republic of Moldova	-14 %	21 %
Hungary	-17 %	8 %
Czech Republic	-18 %	-4 %
United Kingdom	-20 %	3 %
Estonia	-24 %	-5 %
Finland	-26 %	-3 %
Sweden	-28 %	1 %
The Netherlands	-28 %	-6 %
Portugal	-28 %	-6 %
Germany	-30 %	-4 %
Iceland	-38 %	14 %
Denmark	-60 %	-30 %

Proportion of Blood Donors in the age-appropriate Population

Only 7 out 23 reporting increase
In 10 years – from 4.0% to 3.4%

Country	Donors (%) of the age-approriate population	
	2013	2023
Italy	4,7 %	4,4 %
Montenegro	3,5 %	4,3 %
Bulgaria	3,4 %	4,0 %
Slovak Republic	3,8 %	3,8 %
Switzerland	4,3 %	3,8 %
Croatia	3,7 %	3,8 %
Belgium	4,0 %	3,8 %
Germany	5,5 %	3,8 %
Hungary	4,4 %	3,7 %
France	4,0 %	3,5 %
Republic of Moldova	2,8 %	3,4 %
Estonia	4,4 %	3,4 %
Czech Republic	4,0 %	3,2 %
Portugal	4,2 %	3,1 %
Finland	4,2 %	3,0 %
Latvia	2,6 %	2,9 %
Sweden	4,4 %	2,9 %
Poland	2,5 %	2,7 %
Norway	3,0 %	2,5 %
Iceland	4,6 %	2,5 %
Denmark	6,3 %	2,4 %
United Kingdom	2,9 %	2,2 %
The Netherlands	2,9 %	2,0 %
Median	4,0 %	3,4 %

Number of Collected WB Units

23 vs. 20: 13 out of 23 reporting increase

23 vs. 13: 7 out of 23 reporting increase
Total 23 vs 13: 12% less donated WB units

Country	Change in number of donated WB units	
	2023 vs 2020	2023 vs 2013
Republic of Moldova	24 %	-17 %
Poland	22 %	16 %
Montenegro	21 %	23 %
Latvia	17 %	15 %
Bulgaria	16 %	3 %
Slovak Republic	14 %	8 %
Croatia	11 %	5 %
Iceland	10 %	-7 %
Hungary	9 %	-14 %
Czech Republic	8 %	8 %
Portugal	6 %	-16 %
Italy	5 %	-3 %
United Kingdom	3 %	-20 %
Germany	0 %	-21 %
Sweden	0 %	-18 %
Norway	-1 %	-10 %
Switzerland	-1 %	-24 %
Estonia	-4 %	-20 %
Belgium	-4 %	-18 %
Finland	-6 %	-20 %
France	-6 %	-13 %
The Netherlands	-6 %	-16 %
Denmark	-8 %	-36 %

Number of Collected Apheresis Platelet Units

23 vs. 20: 9 out of 19 reporting increase

23 vs. 13: 15 (?) out of 19 reporting increase – but long-term trend analysis difficult…

Country	Change of donated Platelet units	
	2023 vs 2020	2023 vs 2013
Germany	191 %	64 %
Slovak Republic	93 %	128 %
Iceland	34 %	27 %
Bulgaria	26 %	138 %
Portugal	13 %	43 %
Croatia	7 %	61 %
Poland	6 %	41 %
Latvia	4 %	43 %
United Kingdom	2 %	17 %
Norway	-2 %	77 %
Finland	-10 %	312 %
Hungary	-10 %	368 %
Belgium	-11 %	-20 %
The Netherlands	-14 %	35 %
Estonia	-15 %	1323 %
Switzerland	-15 %	-25 %
France	-17 %	1502 %
Denmark	-29 %	-48 %
Italy	-35 %	-50 %

Amount of Collected Apheresis Plasma

With plasma it will become even more difficult…

Data from plasma vs. other types of donations

			WB Donations			Platelets			Plasma-units		
		ll	2020	2023	trend 23vs	2020	2023	trend 23 v	2020	2023	trend 23 vs 20
1	A	%	348778	385934	11 %	23933	28764	20 %			
2	B	%	425982	407598	-4 %	11379	10087	-11 %	187284	185083	-1 %
3	B	%			na	547	731	34 %			na
4	B	%	148483	171673	16 %	2496	3152	26 %	2441	708	-71 %
5	C	%	171734	189976	11 %	4941	5290	7 %	4697	5042	7 %
6	C	%	411200	444429	8 %			na	671500	963000	43 %
7	D		200724	184584	-8 %	1465	1036	-29 %			na
8	E	%	49048	47170	-4 %	1750	1494	-15 %			na
9	F	%	188294	177550	-6 %	4303	3873	-10 %			na
10	F	%	2421930	2268672	-6 %	96215	79927	-17 %			na
11	G	%	3672795	3672317	0 %	110506	321315	191 %	2090298	2482918	19 %
12	H	%	326310	354984	9 %	17760	15910	-10 %			na
13	I	%	9862	10830	10 %	654	876	34 %	54	128	137 %
14	I	%	2438349	2563717	5 %	8194	5349	-35 %	382927	393907	3 %
15	I	%	51100	59649	17 %	2582	2692	4 %	3609	1401	-61 %
16	L	%	89825	108375	21 %	1809	2692	49 %	380	150	-61 %
17	M	%	15306	15538	2 %	297	291	-2 %			
18	P	%	48198	59821	24 %	2353	2189	-7 %	32974	33349	1 %
19	M	%	16747	20344	21 %	0	78	na			na
20	M		44337	56431	27 %	300	9855	na			na
21	M	%	165765	164901	-1 %	10173	9946	-2 %	14890	13349	-10 %
22	P	%	1115944	1357952	22 %	43988	46608	6 %	208895	291207	39 %
23	P	%	282406	299713	6 %	6054	6865	13 %	789	1068	35 %
24	P	%	313843	416549	33 %	6352	6480	2 %			na
25	S	%	58327	75644	30 %	2623	3454	32 %			na
26	S	%	199961	228081	14 %	6449	12478	93 %	40	18415	45938 %
27	S	%	75638	81976	8 %	931	1261	35 %	1861	2341	26 %
28	S	%	1549867	1564886	1 %	1118	33691	2914 %	50510	109311	116 %
29	S	%	370971	369535	0 %			na			na
30	S	%	249385	246034	-1 %	15296	12928	-15 %			na
31	T	%	411518	384998	-6 %	6129	5251	-14 %	325075	366503	13 %
32	U	%	1649057	1696308	3 %	151422	154620	2 %			na

Amount of Collected Apheresis Plasma

Very limited data
23 vs. 20: Increased collection volumes?

23 vs 13: Increased collection volumes?

Country	Apheresis Plasma 23 vs 20
Iceland	137 %
Czech Republic	43 %
Poland	39 %
Portugal	35 %
Germany	19 %
Croatia	7 %
Italy	3 %
Republic of Moldova	1 %
Belgium	-1 %
Norway	-10 %
Lithuania	-61 %
Latvia	-61 %
Bulgaria	-71 %

Country	Plasma apheresis (L) 23 vs 13
United Kingdom	10810 %
Denmark	2559 %
Spain	104 %
Czech Republic	81 %
Estonia	79 %
Germany	27 %
Sweden	-47 %

Other types of Apheresis Donations

2023
Granulocyte Apheresis: 9 out of 37 reporting collections

Red Cell Apheresis: 11 out of 37 reporting collections

Summary of the Statistics – Long Term

- Less WB collections
- Even more less donors (per population)
- But lot of variation between countries
- Limited data for plasma collections (need for more)

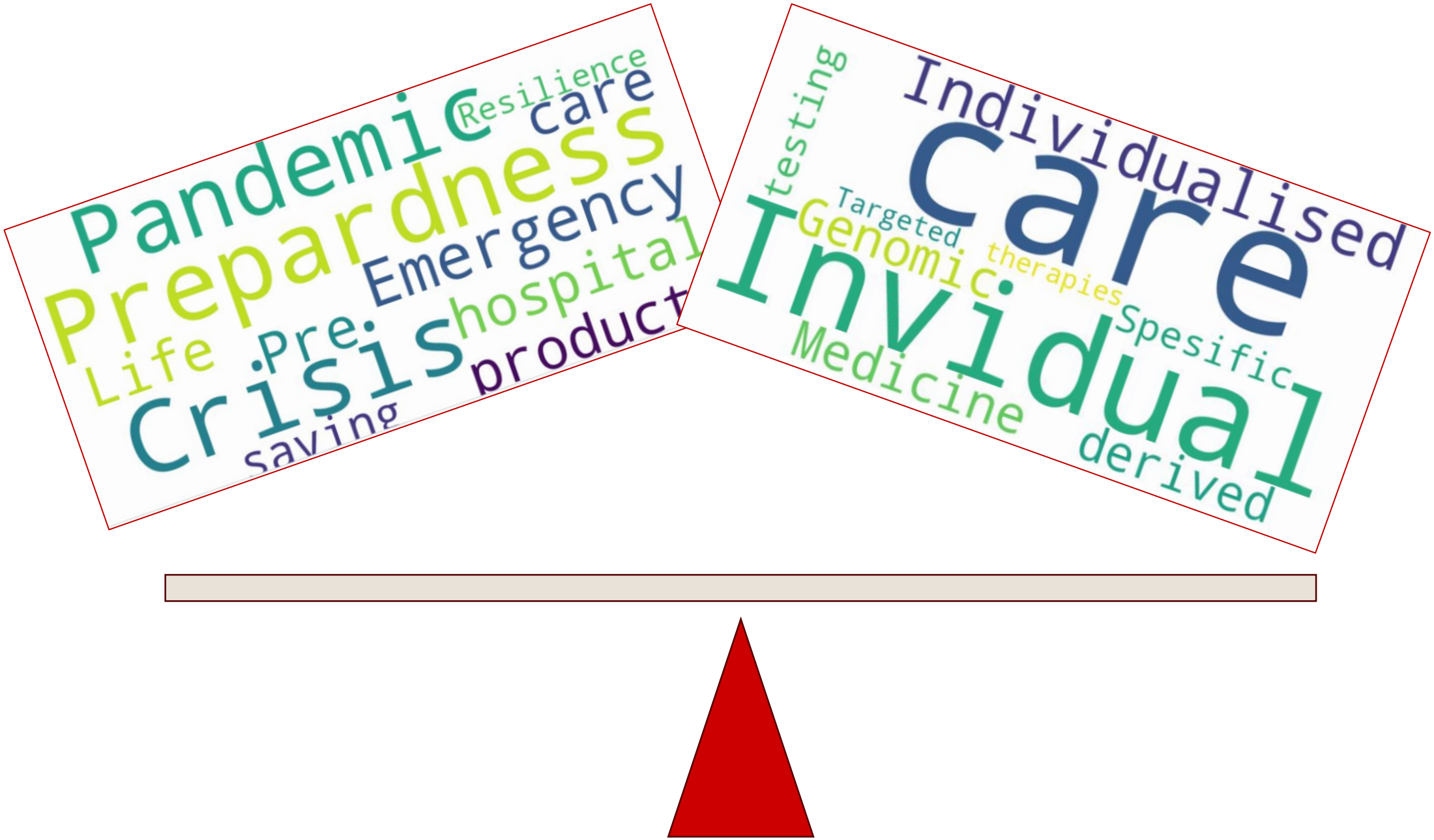
Challenges and Future

1. More Donors Needed

- Resilience (more blood needed or less donors availabe)
- Less donations per year per donor – donor health protection
- Critical and evidence based re-evaluation of donor eligibility criteria
- We ”only need” to reach the proportion of population we had in 10 years ago

2. Plasma Apheresis

- Topic nr 1 in Europe in many years
- Data?
- Concrete achievements?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Spesific
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Crises Specific Products
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Genotyped Products
Individualised Donor Care
More sensitive Virus Testing
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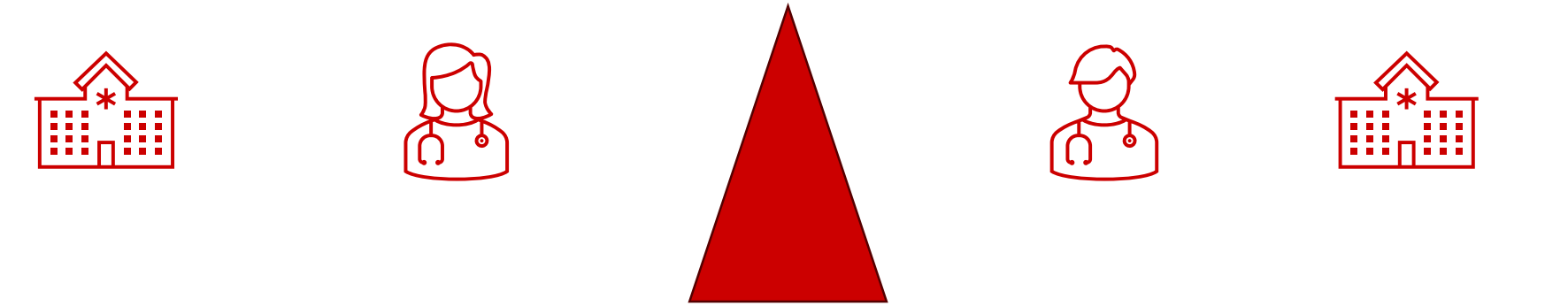


Mart Janssen

Richard Forde

Colleagues in the CD-P-TS

Marketing Team in the FRCBS

Thank You

EDQM Blood Conference 2025

Personalised Source Plasma Donations: Could U.S. Learnings Benefit Europe?

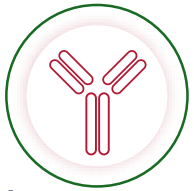
Dr. Jan Hartmann

Haemonetics Corporation

Disclosures

- Dr. Hartmann is the Senior Vice President and Chief Medical Officer at Haemonetics Corporation

Plasma donations underpin the manufacture of life-saving/sustaining plasma-derived products


Immuno-deficiencies


Auto-immune diseases

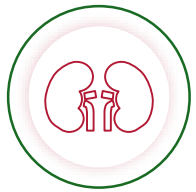

Burns


Cardiopulmonary issues

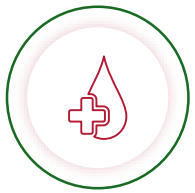

Hepatitis

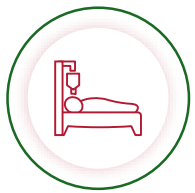

Liver conditions


Major surgery


Organ transplants


Animal bites


Haemophilia


Shock


Trauma

- Plasma for transfusion
- Immunoglobulin (e.g., IVIG)
- Albumin
- Factor VIII
- Factor IX
- Fibrinogen
- Anti-Tetanus IG

IG, immunoglobulin; IVIG, intravenous immunoglobulin

Plasma donation volumes are typically governed by nomograms

- Germany is one of four European countries that together currently provide the majority of Europe's own source plasma[1]
- A three-tiered weight-based approach sets donation volume limits in Germany[2], and the U.S. has historically implemented a similar method

Volume Limits - Automated Collection of Source Plasma in the U.S. (11/4/1992)[3]

Donor weight	Plasma volume or weight	Collection volume
50 – <68 kg	625 mL (640 g)	690 mL (705 g)
68 – <79 kg	750 mL (770 g)	825 mL (845 g)
≥79 kg	800 mL (820 g)	880 mL (900 g)

U.S., United States

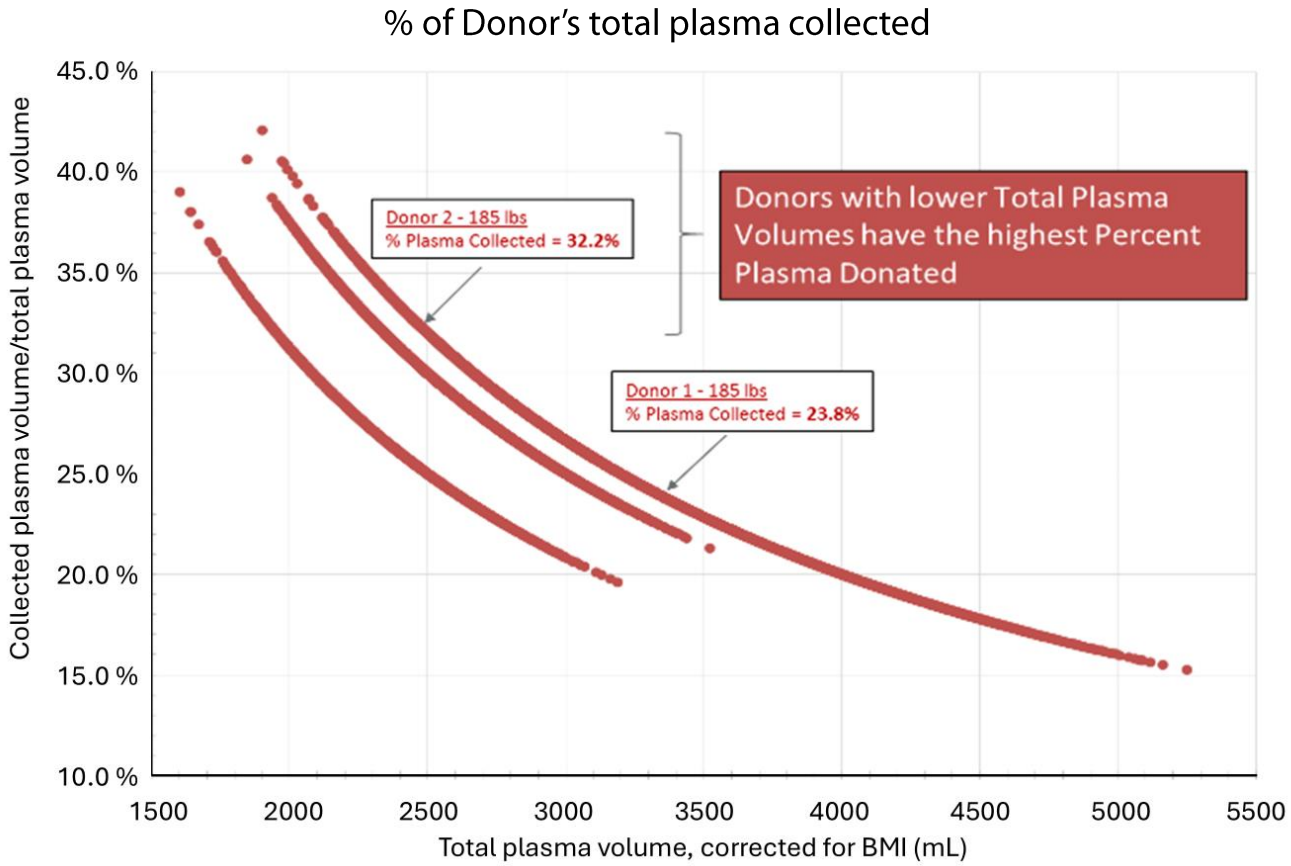
1. https://health.ec.europa.eu/system/files/2016-11/20150408_cc_report_en_0.pdf (accessed December 2024);
2. https://www.bundesaerztekammer.de/fileadmin/user_upload/BAEK/Themen/Medizin_und_Ethik/Richtlinie-Haemotherapie-2023_neu2.pdf (accessed December 2024)
3. https://www.fda.gov/media/70951/download (accessed December 2024)

Implications of the U.S. weight-based nomogram[1]

Three curves (weight categories)

Donors with least total plasma volume donate highest percentage

Large inter-donor variability (% of plasma donated)



1. Hartmann et al, Transfusion 2021;61(6):1789-1798

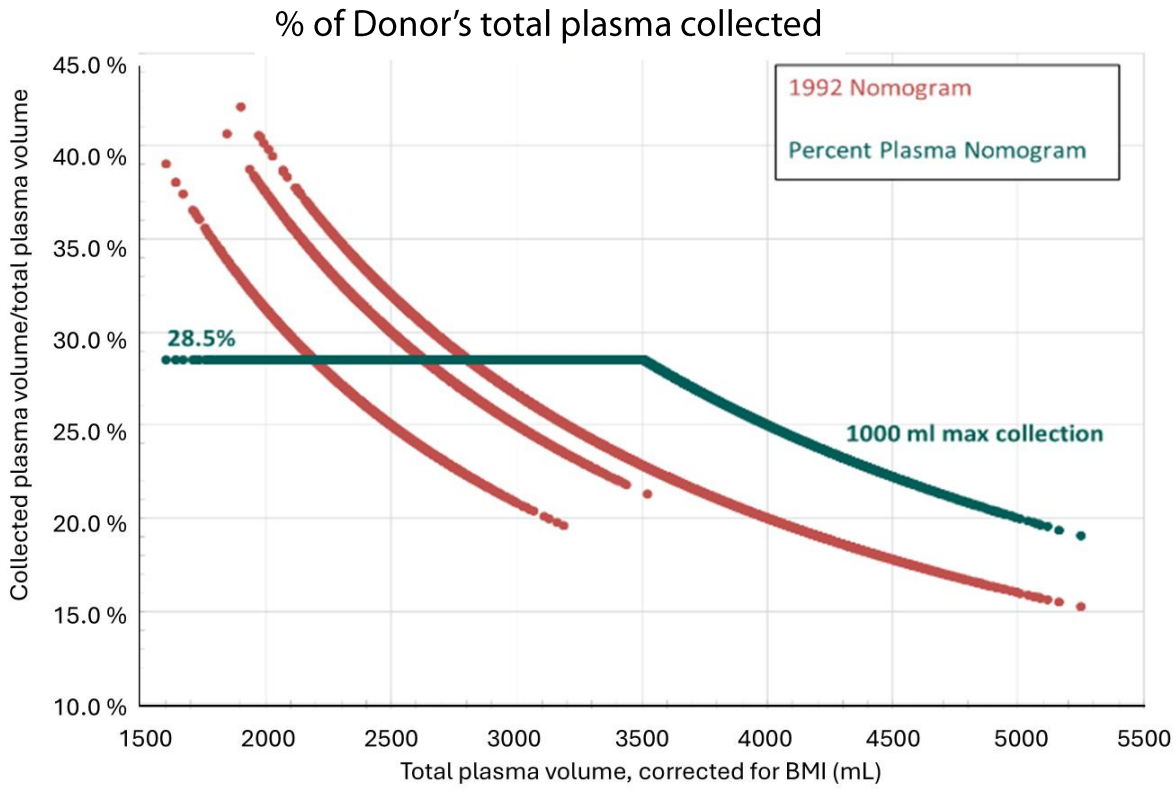
A nomogram personalised to the donor's total plasma volume has been cleared by the U.S. FDA

Personalised nomogram* calculates donor's Total Plasma Volume (TPV) based on BMI and haematocrit[1]

Plasma collection target is set at 28.5% of donor's TPV, capped at 1,000 mL[1]

Target is tailored to each individual donor

Enabled by current technology to automate calculations and set targets, minimizing the risk of human error



*Personalised nomogram refers to the Persona® nomogram
BMI, body mass index; FDA, U.S. Food and Drug Administration; TPV, total plasma volume; US, United States
1. Hartmann et al, Transfusion 2021;61(6):1789-1798

Testing the Persona® nomogram in a U.S. population: The IMPACT clinical trial[1]

- Prospective, blinded, multicentre RCT (NCT04320823) with two arms
  - Control: existing nomogram (FDA 1992)
  - Experimental: the Persona nomogram
- Primary endpoint: non-inferiority of safety (significant hypotensive/ vasovagal AEs, based on IQPP standards [signs & symptoms])
- Secondary endpoint(s): plasma volume collected, among others
- Three representative plasma collection centres across the U.S.
- 23,137 collections from 3,443 subjects

IQPP DAE classifications[2]

Category	Recording requirement (* = record)	Sub-category
Hypotensive Event (vasovagal/ Hypovolemia)		Prefaint, no LOC (minor)
	*	Prefaint, no LOC (moderate)
	*	LOC approximately less than 60 Seconds
	*	LOC approximately 60 seconds or longer
	*	Severe (with or without LOC)
	*	Injury

AEs, adverse events; DAE, donor adverse event; FDA, U.S. Food and Drug Administration; IMPACT, IMproving PlasmA CollecTion; IQPP, International Quality Plasma Program; LOC, loss of consciousness; RCT, randomised control trial; SD, standard deviation; US, United States

1. Hartmann et al, Transfusion 2021;61(6):1789-1798; 2. https://www.donatingplasma.org/images/IQPP_Standards/IQPP_Donor_Adverse_Events_Standard_V2.pdf

The IMPACT clinical trial: donor characteristics[1]

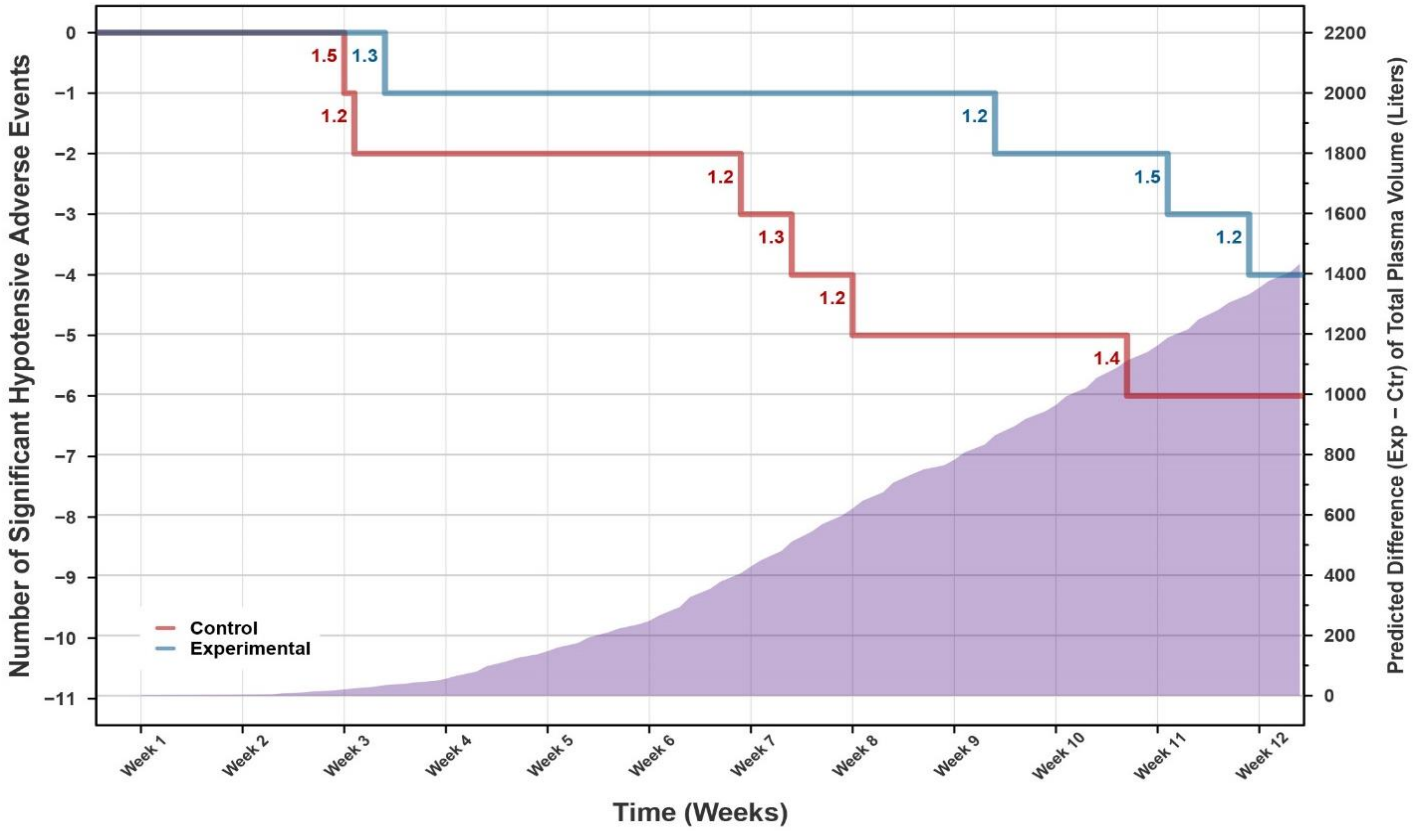
Donor characteristics at baseline (ITT population)

Parameter	Control	Experimental	Overall
Age, mean (SD), years	35.4 (11.10)	35.5 (11.69)	35.4 (11.40)
Female, n (%)	601 (34.8)	605 (35.2)	1206 (35.0)
Male, n (%)	1125 (65.2)	1112 (64.8)	2237 (65.0)
Weight, mean (SD), kg	93.4 (23.3)	94.1 (23.1)	93.8 (23.4)
BMI, mean (SD), kg/m^2	31.8 (7.75)	32.1 (7.74)	32.0 (7.74)
Repeat donor, n (%)	1618 (93.7)	1608 (93.7)	3226 (93.7)
First-time donor, n (%)	108 (6.3)	109 (6.3)	217 (6.3)
Haematocrit, mean (SD), %	45.4 (3.77)	45.5 (3.81)	45.5 (3.79)

BMI, body mass index; IMPACT, IMproving PlasmA CollecTion; ITT, intention to treat; SD, standard deviation; US, United States

1. Hartmann et al, Transfusion 2021;61(6):1789-1798.

Persona® nomogram: IMPACT clinical trial data suggests acceptable safety profile and improved plasma yield[1]



Results from the IMPACT trial show the safety profile of Persona® nomogram is non-inferior compared to current standard practice

Average increase of ~64 mL or ~8.2% plasma per collection (p<0.0001)

Ctr, control; Exp, experimental; IMPACT, IMproving PlasmA CollecTion; US, United States

1. Hartmann et al, Transfusion 2021;61(6):1789-1798.

Challenges facing European plasma donation: could a personalised approach help increase yields?

Fractionation of human plasma provides a range of more than two dozen therapeutic proteins used worldwide[1,2]

The U.S. is the largest contributor to the global source plasma supply with close to 40 million litres collected in over 50 million donations in 2019[3]

Collection of plasma in Europe for fractionation into medicinal products or for transfusion is plateauing/decreasing[4]

There is an estimated 38% deficit of plasma in Europe[5]

Plasma donations in Europe 2017-2019[4]

Year	Total plasma collected for transfusion (L)	Total plasma collected for fractionation (L)
2017	4.2 million	3.1 million
2018	3.6 million	3.4 million
2019	3.8 million	2.8 million

US, United States

1. Burnouf T. Ann Blood. 2018;1; 2. Strengers PFW. Ann Blood. 2017;2(9); 3. Hartmann & Klein. Transfusion 2020;60:2748-2752; 4. European Committee on Blood Transfusion EDQM 2017, 2018 & 2019 Report. https://www.avis.it/application/files/3316/7336/4731/the-collection-testing-and-use-of-blood-and-blood-components-in-europe-2017-2018-and-2019-report.PDF; (accessed December 2024); 5. Simonetti & Smith. International Journal of Transfusion Medicine;2023:https://doi.org/10.1111/vox.13540

How would a personalised percentage total plasma nomogram translate to Europe?

- Germany is one of the largest plasma donation markets in Europe[1]
- The maximum total collection volumes and donation frequencies differ in the US and Germany

	USA[2]		GERMANY[3]	
Collection volume*	Max 880 mL		Max 850 mL	
Frequency	• Maximum of two donations per week and 104 donations per year per individual • There must be at least one donation-free day between donations		• Maximum 60 donations per year per individual • Requires two-donation free days between donations	
Donation weight groups	50 – <68 kg	690 mL	≥ 50 kg ≤ 60 kg	650 mL
	68 – <79 kg	825 mL	≥ 60 kg ≤ 70 kg	750 mL
	≥79 kg	880 mL	≥ 70 kg	850 mL

* includes plasma + anticoagulant & test samples

How would Persona® perform using the German plasma donation schedule?

Max, maximum; U.S., United States

1. https://health.ec.europa.eu/system/files/2016-11/20150408_cc_report_en_0.pdf (accessed December 2024); 2. https://www.fda.gov/media/70951/download (accessed December 2024);
3. https://www.bundesaerztekammer.de/fileadmin/user_upload/BAEK/Themen/Medizin_und_Ethik/Richtlinie-Haemotherapie-2023_neu2.pdf (accessed December 2024)

Study design: Using IMPACT data to assess patients on a European-style donation schedule

Real-world plasmapheresis data for active donors using the personalised nomogram at U.S. centres from May 2021–2022 were analysed

- Active donors defined as donating at least once per quarter

Two populations assessed based on U.S. or German donation schedules

U.S. active population *(N= 8,510 donors, 455,100 collections)*	Maximum two donations/week or 104 donations/year with at least one donation-free day between donations
German-modelled active population *(N= 4,649 donors, 208,353 collections)*	A subpopulation of donors with a 60-donation maximum and at least two donation-free days between a majority (defined as ≥75%) of donations

Study Objectives

- Calculate the real-world significant hypotensive AE rate (1.2+ according to the IQPP Standard for Recording Donor AEs, as defined in the IMPACT trial)
- Calculate target volumes and percent change for the standard German nomogram compared to the personalised nomogram

AE, adverse event; IMPACT, IMproving PlasmA CollecTion; IQPP, International Quality Plasma Program; US, United States

Participant demographics

		U.S. active population (N=455,100)	German-modelled active population (N=208,353)
Age, years	Mean (SD)	42.2 (12.3)	41.2 (12.4)
Sex, n (%)	Male	313,351 (68.9%)	138,011 (66.2%)
	Female	141,699 (31.1%)	70,320 (33.8%)
BMI, kg/m^2	Mean (SD)	32.6 (7.85)	32.0 (7.83)
Weight, kg	Mean (SD)	96.6 (23.6)	94.3 (23.2)
Height, cm	Mean (SD)	172.5 (9.2)	172.0 (9.2)
Haematocrit	Mean (SD)	0.449 (0.0377)	0.448 (0.0381)

BMI, body mass index; SD, standard deviation; US, United States

Study results

		U.S. active population	German-modelled active population
Number of donations		455,100	208,353
Number of donors		8,510	4,649
Nomogram target plasma volume (mL)	**German nomogram, mean (SD)**	759 +/- 38	756 +/- 41
	U.S. personalised nomogram (Persona®), mean (SD)	855 +/- 109	845 +/- 109
	% Change	12.6%	11.8%
1.2 + AE Rate		0.00026	0.00031

The target yield change for the German-modelled active population was **+11.8%**

A personalised nomogram could have **a low 1.2+ hypotensive AE rate** and an **average increase in target plasma volume** for active donors when applied to European plasma donation schedules (example Germany)

AE, adverse event; SD, standard deviation; US, United States

Summary

Global source plasma supply is donor dependent, and shortages have occurred in the past, most recently during the COVID-19 pandemic

This study suggests a personalised nomogram could have an acceptable safety profile and increase total volume of plasma collected per donation in Europe

This could provide a method of increasing plasma collection volumes whilst maintaining existing donation schedules, improving self-sufficiency of European plasma sources

As this research was limited to U.S. donations, additional research is required to fully assess the impacts of a personalised nomogram on German and other European donor populations

COVID-19, coronavirus disease 2019; US, United States

Appendix

GERMAN Haematotherapy Guidelines 2023:

- For plasmapheresis
  - For a body weight of 50 kg to ≤ 60 kg, a maximum of 650 mL can be taken
  - For a body weight of more than 60 kg up ≤ 70 kg, a maximum of 750 mL can be taken
  - For a body weight of more than 70 kg, a maximum of 850 mL can be taken

  (in each case including anticoagulant, plus examination samples)
- Alternating types of donation are permissible in compliance with the annual permitted loss of erythrocytes:
  - After the collection of an erythrocyte concentrate, there should be a break of 12 weeks, but at least 8 weeks (day of blood collection plus 55 days) until the next collection of a whole blood donation
  - After the simultaneous collection of two erythrocyte concentrates, a 16-week break (day of blood collection plus 111 days) is required until the next collection of a whole blood donation or erythrocytapheresis donation
  - There must be at least 2 donation-free calendar days between two plasmapheresis sessions and another preparative haemapheresis session or collection of a whole blood donation

https://www.bundesaerztekammer.de/fileadmin/user_upload/BAEK/Themen/Medizin_und_Ethik/Richtlinie-Haemotherapie-2023_neu2.pdf

CZECH Haematotherapy Guidelines 2018:

For plasma sampling

- The amount of plasma collected in one collection is not more than 650 mL, unless a replacement solution is administered intravenously
  - The quantity of plasma collected in one week shall not exceed 1.5 L
  - The total volume of plasma without counter-clotting solution collected over a 12-month period shall not exceed 25 L
- The minimum interval between plasma collection and subsequent standard whole blood or platelet collection is 48 hours
  - The minimum interval between standard whole blood collection and plasma collection is 4 weeks, with failure of erythrocyte return during plasma collection treated as a standard whole blood collection
  - The minimum interval between two instrumental plasma collections is 14 days

ASPI system - status as of 1.7.2018 until the amount of 69/2018 Coll. and 22/2018 Coll. 143/2008 Coll. - Decree on human blood - the latest text will not come into force until 13 July 2018 143/2008 Coll (DeepL translated).

AUSTRIAN Haematotherapy Guidelines 2024:

If plasma is taken from a donor:

1. The maximum withdrawal volume is one hundredth of the donor's body weight, but in no case more than 700 mL without anticoagulant, a donor may not exceed the maximum withdrawal volume according to Z1 of the Blood Safety Act
2. Taken once within 72 hours
3. Taken twice within 7 days
4. Taken three times within 14 days
5. Taken fifty times within one year
6. If the corpuscular blood components are not purified, the minimum interval until another plasma donation is obtained is 14 days

Austrian, Entire legal regulation for blood donor ordinance, version dated 06.02.2024 (DeepL translated)

Emergency collection of Whole Blood in preparedness – an implementation guide and report from the Norwegian Civilian Walking Blood Bank Project

Torunn Oveland Apelseth, MD PhD

Norwegian Centre for Blood Preparedness, Department for Immunology and Transfusion Medicine, Haukeland University Hospital, Bergen, Norway; Faculty of Medicine, University of Bergen

Disclosures

I have no conflict of interest in relation to this congress or this presentation

Nokblod

The Norwegian Center for Blood Preparedness

Government funded center for national coordination of Civilian-Military blood preparedness in Norway
Established June 2022

Stakeholders represented:

- Civilian blood services
- Clinical hospital services
- Prehospital and community health services
- Military medical services

Work tasks:

- Coordination of civilian and military blood supply in crisis and war
- Training
- Counselling
- Logistics
- Research and innovation

Our team

The Norwegian Center for Blood Preparedness have been working together with the Northern Norway Regional Health Authority to develop a program for emergency collection of whole blood in smaller rural communities and local hospitals in the Northern part of Norway.

Authors: Torunn Oveland Apelseth[1,2], Geir Strandenes[1], Bent-Ove Jamtli[3], Mirjana Arsenovic[4]

Affiliations:

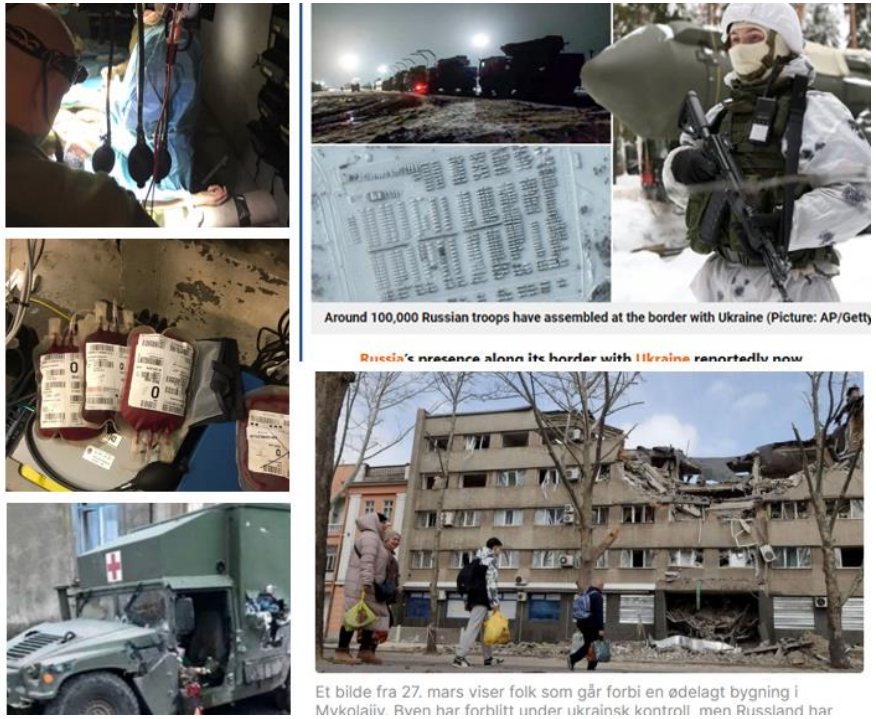
1. Norwegian Center for Blood Preparedness, Department of Immunology and Transfusion Medicine, Haukeland University Hospital, Bergen, Norway
2. Institute of Clinical Science, Faculty of Medicine, University of Bergen, Bergen, Norway
3. Northern Norway Regional Health Authority
4. Department of Laboratory Medicine, University Hospital of North Norway, Tromso, Norway

Emergency collection of whole blood from a civilian walking blood bank

<u>Overview of presentation:</u>

- Background
- Definitions
- Regulatory aspects
- Lessons learnt from the civilian walking blood bank project in Northern Norway
- Conclusion

Background: We need to build systems to ensure blood preparedness for all types of bleeding patients both for peacetime, crisis and war



Nokblod

Illustration: Lene Tordal

«… when banked blood is unavailable»

Scenarios:

<u>Long transport times or delayed transport</u>

- Remote areas
- Military operations and war
- Oil industry

<u>Large scale events</u>

- Natural and man-made disasters

<u>Reduced availablity</u>

- Pandemic
- No/delayed resupply
- No platelet-containing blood product

Definitions

Emergency blood collection (EBC): describes the donation of blood or blood components with the intent to be transfused immediately to a known casualty.

Walking blood bank (WBB) is a structured system for emergency collection of whole blood from a preselected donor pool used in military and civilian settings for treatment of patients with life-threatening bleeding when banked blood is unavailable.

- Collection is performed "on site", i.e. most often outside hospitals, but the system can also be used for emergency whole blood collections in hospital.
- Synonyms: Emergency collection of whole blood, fresh whole blood transfusion etc.

An Emergency Donor is a voluntary, unpaid prescreened blood donor assessed as fit to donate. A group of preselected Emergency Donors are described as an **Emergency Donor Pool (EDP)**.

Regulatory considerations: The EDQM B-SCEP recommendations and walking blood banks

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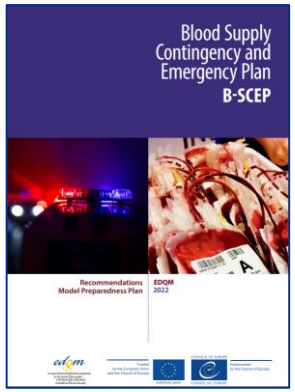

https://www.edqm.eu/en/blood-supply-contingency-and-emergency-plan-b-scep-

Specific recommendations to regulatory oversight bodies

- Regulatory oversight bodies should ensure there are appropriate control measures in place to support the blood system and the development, implementation and maintenance of a B-SCEP. Control measures may include: inspection, authorisation, haemovigilance, monitoring and reporting, as appropriate.
- Regulatory oversight bodies should ensure that B-SCEP are subject to review as part of regulatory oversight inspections. In particular, inspections should cover:
  - the procedures in place to ensure a B-SCEP is regularly updated, tested and fit for purpose, and the consequences of any significant changes made;
  - the management of strategies and arrangements in place for backup donation, processing, storage, distribution and testing of blood and blood components.
- Regulatory oversight bodies should ensure that their authorisation processes allow for flexibility or specific derogations, where required, in response to defined key risk scenarios or other crisis or emergency situations. This could include, for example: processing of new blood components, co-ordination of new donation sites, walking blood banks, changes in donor deferral criteria, blood cold chain and transport logistics.

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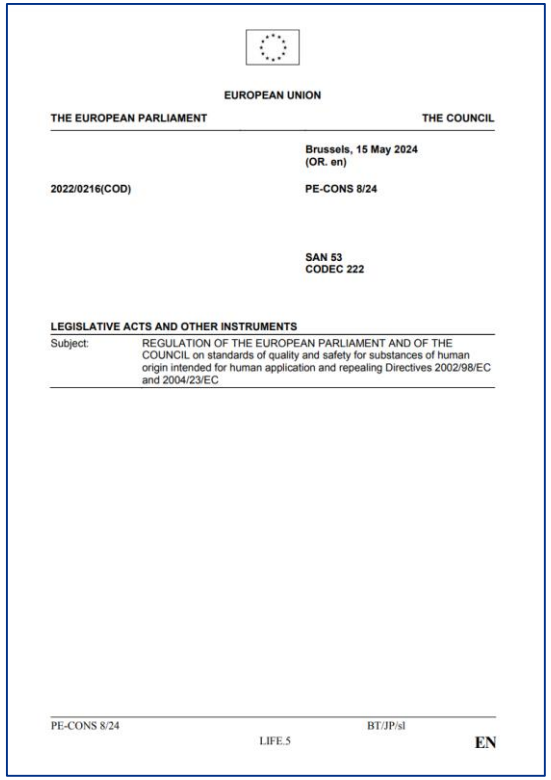
The new EU SoHO



EUROPEAN UNION

THE EUROPEAN PARLIAMENT — THE COUNCIL

Brussels, 15 May 2024
(OR. en)

2022/0216(COD) — PE-CONS 8/24

SAN 53
CODEC 222

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: 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

PE-CONS 8/24 — BT/JP/sl
LIFE.5 — EN

Article 65

Derogation from the obligations to authorise SoHO preparations in health emergency situations

1. By way of derogation from Article 19, SoHO competent authorities may permit, at the request of a SoHO entity as referred to in Article 38(3) and duly justified by a health emergency situation, the distribution, or preparation for immediate human application, of SoHO preparations within their territory even if the procedures referred to in Article 19 have not been carried out, provided that:

(a) the human application of those SoHO preparations is in the interest of public health;

(b) the SoHO preparations have a level of quality and safety that is acceptable considering the requirements of this Regulation or the available data indicate a positive benefit-risk assessment; and

(c) the SoHO preparation is for immediate human application to a defined group of SoHO recipients, who have no therapeutic alternative, the treatment cannot be postponed, the prognosis is life-threatening and the expected benefit outweighs the risks.

Ref.: https://data.consilium.europa.eu/doc/document/PE-8-2024-INIT/en/pdf

Nokblod

Article 66

Emergency derogations in man-made or natural disasters

1. Insofar as necessary to ensure supply of critical SoHO, Member States may allow for derogations from certain standards and obligations set out in this Regulation when large scale life-threatening situations in the context of man-made or natural disasters, in particular in the context of armed conflicts, pose a risk to human life, and such derogations are the only measure available to mitigate the risk. Derogations shall not be granted from the provisions of this Regulation that concern voluntary and unpaid donation and SoHO donor consent. The derogations shall be applied in a manner that ensures the protection of SoHO donors and SoHO recipients to the maximum extent possible in the circumstances of the crisis.

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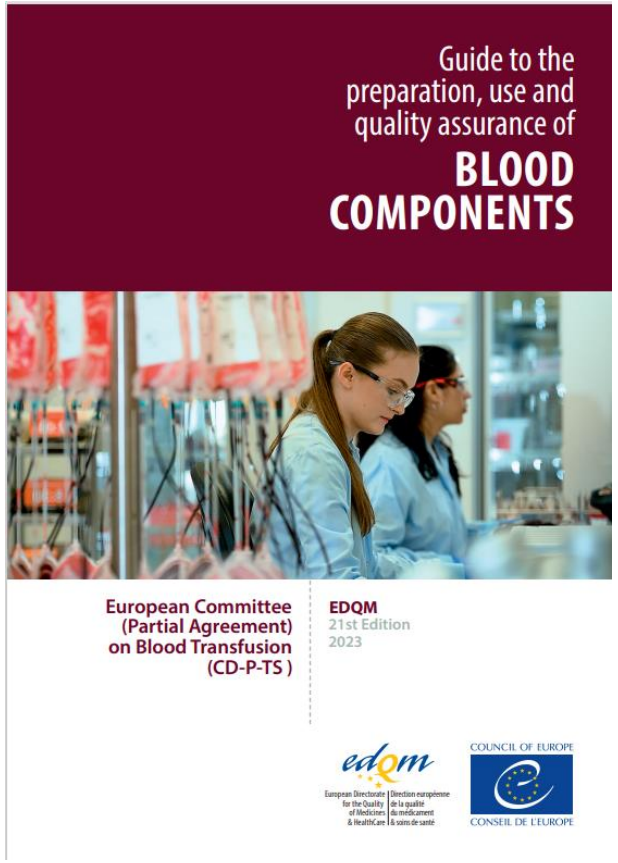
EDQM Blood Guide 21st ed: Whole blood monograph



Component monographs

Part A. **Whole Blood components**

A-1. WHOLE BLOOD

Definition and properties

Whole Blood is blood taken from a suitable donor using a sterile and pyrogen-free anticoagulant and container. *Whole Blood* is a source material for *Whole Blood, Leucocyte-Depleted* and component preparation, which is its major use. *Whole Blood* for transfusion is used without further processing.

Whole Blood for transfusion should not contain irregular antibodies of clinical significance.

Table 5A-1

Parameter to be checked	Requirements	Frequency of control
ABO, RhD	Grouping	All units
Anti-HIV 1 & 2	Negative by approved screening test	All units
HBsAg	Negative by approved screening test	All units
Anti-HCV	Negative by approved screening test	All units
Volume [a]	450 mL ± 50 mL volume (excluding anticoagulant) A non-standard donation should be labelled accordingly	as determined by SPC
Haemoglobin per final unit [a]	Minimum 45 g	as determined by SPC
Haemolysis at the end of storage [a]	< 0.8 % of red cell mass	as determined by SPC

[a] A minimum of 90 % of units tested should meet the required value.

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Aim:

To evaluate our program for emergency collection of whole blood for treatment of patients with life-threatening bleeding in smaller rural communities and local hospitals towards to the new European regulation for substances of human origin (EU SoHO).

Blood Preparedness systems for all treatment levels

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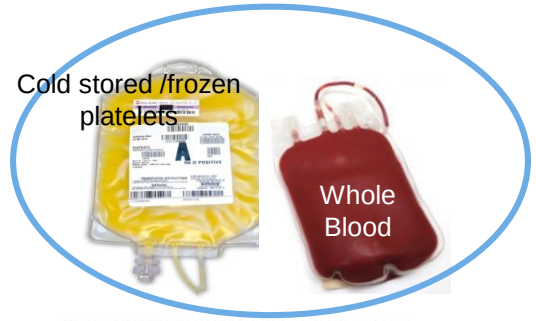
International and national guidelines recommend early balanced blood transfusion for patients with severe bleeding.

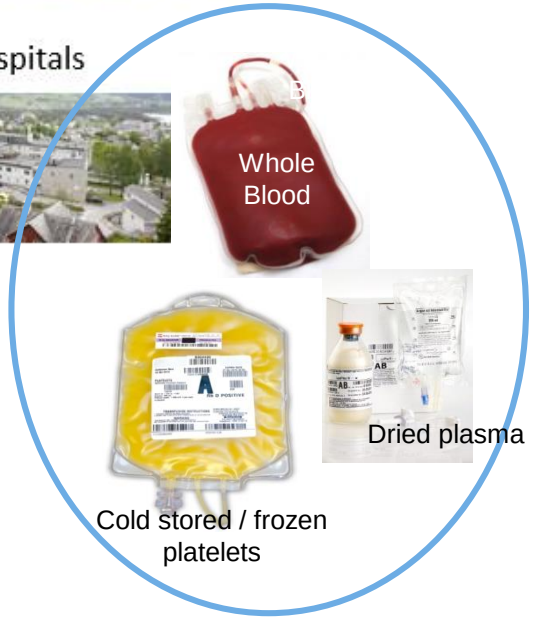
- Emergency Blood Products for all levels of health care



Level 1 Trauma Centers

Ambulance Services

Small rural hospitals



Municipal Health Care Services

Military services
Oil industry

Emergency whole blood collection: The Norwegian experience

Nokblod

SUPPLEMENT ARTICLE

How do I get an emergency civilian walking blood bank running?

Silje Helland Kaada,[1] Torunn Oveland Apelseth,[1,2] Kristin Gjerde Hagen,[1] Einar Klæboe Kristoffersen,[1,3] Stig Gjerde,[4] Kristian Sønstabø,[4] Henrik Halvorsen,[5] Tor Hervig,[1,3] Geir Arne Sunde,[4] Geir Olav Dahle,[4] Mari Christine Johnsen,[4] and Geir Strandenes[1,6]

DOI: 10.1111/trf.16057

HOW DO I?

TRANSFUSION

How do I implement a whole blood–based blood preparedness program in a small rural hospital?

Torunn O. Apelseth[1,2] | Geir Strandenes[1,2] | Einar K. Kristoffersen[1,3] | Kristin G. Hagen[1] | Hanne Braathen[1,3] | Tor Hervig[1,3,4]

Received: 15 February 2022 | Revised: 2 May 2022 | Accepted: 2 May 2022

DOI: 10.1111/trf.16968

DISASTER PREPAREDNESS

TRANSFUSION

The Norwegian blood preparedness project: A whole blood program including civilian walking blood banks for early treatment of patients with life-threatening bleeding in municipal health care services, ambulance services, and rural hospitals

Torunn Oveland Apelseth[1,2,3] | Mirjana Arsenovic[4] | Geir Strandenes[1]

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The Civilian Walking Blood Bank project – Northern Norway

Commissioned by the Ministry of Health to The Northen Norway Regional Health Authority

Aim of project: Develop systems to ensure adequate access to blood and blood products

The self-sufficiency principle: Decentralized system for the provision of blood and blood components

Project participants:

Local hospitals

- Longyearbyen
- Hammerfest
- Kirkenes

Air Ambulances (HEMS and SAR)

- Banak
- Kirkenes
- (Tromsø and Harstad)

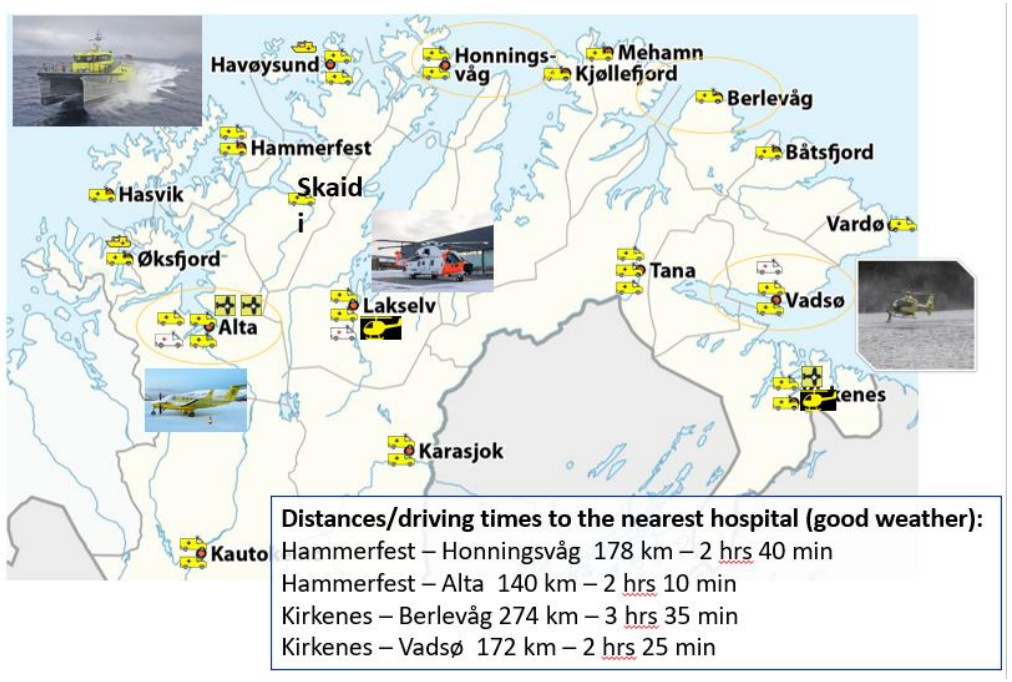
Municipalities (primary health care services)

- Alta (20600 inhabitants)
- Nordkapp (3000 inhabitants)
- Berlevåg (970 inhabitants)
- Vadsø (5600 inhabitants)

Norwegian Center for Blood Preparedness (Nokblod)

University Hospital of North Norway Blood Service

Norwegian Armed Forces



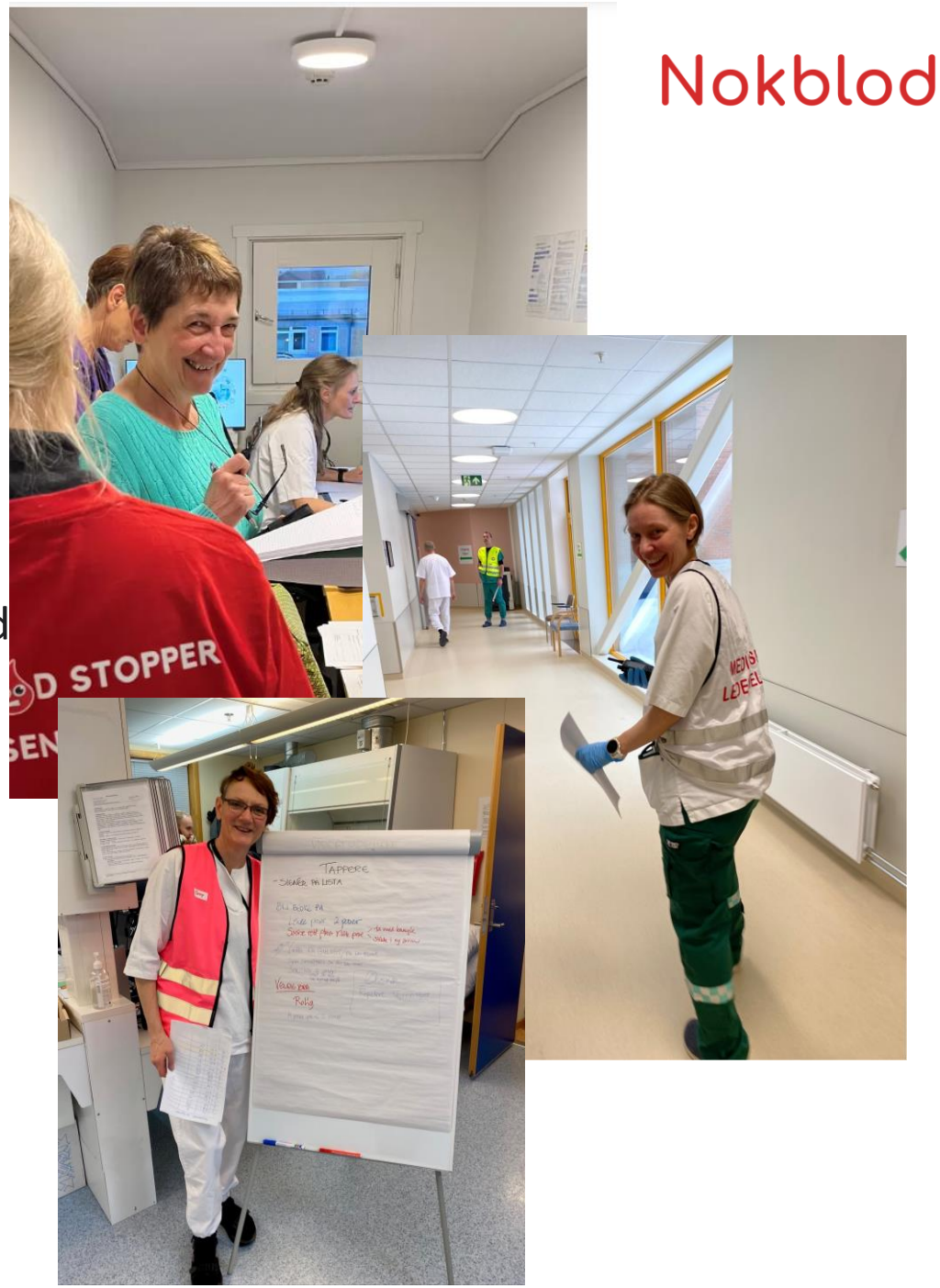
What do you need to do to establish walking blood bank program?

1. Recruit emergency whole blood donors and maintain the emergency donor pool
2. SOPs
3. Train personnel and maintain knowledge by regular exercises and rehearsals
4. Obtain regulatory approval
5. Supervision from a local blood service

Roles and responsibilities

Key personnel:

- **Medical director for the local blood service** (mother blood bank) responsible for emergency donor panel and collection procedures
- **Senior municipal physician** responsible for the clinical use of the emergency collected whole blood in primary care
- **WBB coordinator** perform training of personnel collecting blood and maintenance of emergency donor pool



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Establishing the Emergency Donor Pool (EDP)

Unpaid volunteer donors

- Approved by the same criteria as ordinary Blood Donors in Norway

Donor interviews and testing:

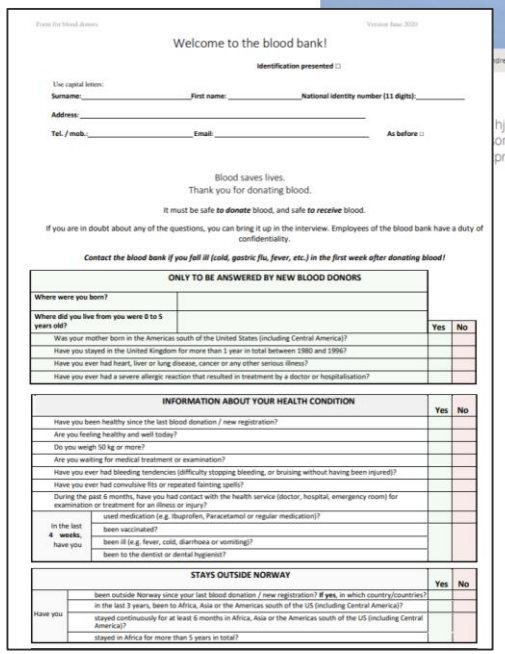
- Low titer group O blood donor
- National donor questionnaire

Recruitment

- Personal communication
- Local newspapers
- Social media
- Promotion videos


PILOTKOMMUNE BLODBANKEN HELSE NORD

Ordføreren er nødblodgiver i nytt pilotprosjekt: - Det er en god følelse å kunne hjelp


Welcome to the blood bank!

Identification presented ☐

Use capital letters:

Surname:_____ First name:_____ National identity number (11 digits):_____

Address:_____

Tel. / mob.:_____ Email:_____ As before ☐

Blood saves lives.
Thank you for donating blood.

It must be safe **to donate** blood, and safe **to receive** blood.

If you are in doubt about any of the questions, you can bring it up in the interview. Employees of the blood bank have a duty of confidentiality.

Contact the blood bank if you fall ill (cold, gastric flu, fever, etc.) in the first week after donating blood!

ONLY TO BE ANSWERED BY NEW BLOOD DONORS			
Where were you born?			
Where did you live from you were 0 to 5 years old?			
		Yes	No
Was your mother born in the Americas south of the United States (including Central America)?			
Have you stayed in the United Kingdom for more than 1 year in total between 1980 and 1996?			
Have you ever had heart, liver or lung disease, cancer or any other serious illness?			
Have you ever had a severe allergic reaction that resulted in treatment by a doctor or hospitalisation?			

INFORMATION ABOUT YOUR HEALTH CONDITION		Yes	No
Have you been healthy since the last blood donation / new registration?			
Are you feeling healthy and well today?			
Do you weigh 50 kg or more?			
Are you waiting for medical treatment or examination?			
Have you ever had bleeding tendencies (difficulty stopping bleeding, or bruising without having been injured)?			
Have you ever had convulsive fits or repeated fainting spells?			
During the past 6 months, have you had contact with the health service (doctor, hospital, emergency room) for examination or treatment for an illness or injury?			
In the last 4 weeks, have you	used medication (e.g. Ibuprofen, Paracetamol or regular medication)?		
	been vaccinated?		
	been ill (e.g. fever, cold, diarrhoea or vomiting)?		
	been to the dentist or dental hygienist?		

STAYS OUTSIDE NORWAY		Yes	No
Have you	been outside Norway since your last blood donation / new registration? **If yes**, in which country/countries?		
	in the last 3 years, been to Africa, Asia or the Americas south of the US (including Central America)?		
	stayed continuously for at least 6 months in Africa, Asia or the Americas south of the US (including Central America)?		
	stayed in Africa for more than 5 years in total?		


Altaposten

din lokale mediekanal

Akutt hjelp fra vandrende blodbanker

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Emergency donor recruitment: Example: Promotion video

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Donor care (1):

Maintain the Emergency Donor Pool

- Regular interviews and TTID testing every 6th month
- Information and social events

Updated list over emergency donors

Example:

Blood type	Name	National ID number	Phone	Place of work	Date of last negative virus screening	Other info
0+	Navn Navnesen	121292-12121	+47 411 11 111	School	30/12-23	
0-	Line Danser	010190-11111	+47 900 00 000	Town Hall	30/12-23	
0-	Gry Telokk	020285-21212	+47 455 55 555	Hospital	14/11-23	

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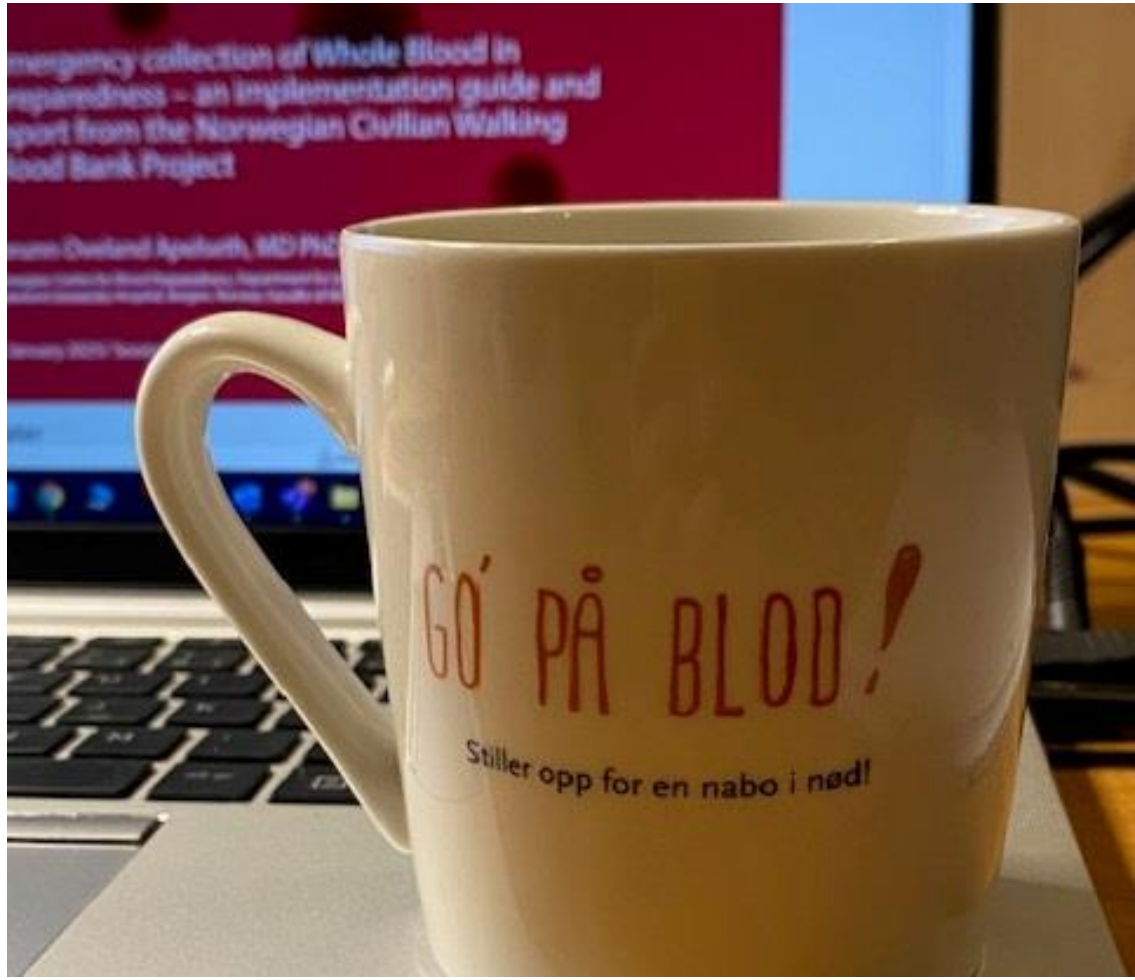
Donor care (2):

Taking care of the donors in relation to donation:

- Interview to evaluate eligibility
- Donor questionnaire and blood sampling
- Food and drink
- Resting period after donation
- Follow up if complications:
  - Close monitoring during donation
  - Contact information provided if complications occur after donation or donors get sick after the donation
- Follow up of donors by Mother Blood Bank:
  - Interview and analysis of blood samples
  - Documentation
  - Hemovigilance and traceability
- 3 months quarantine after donation



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Standard Operating Procedures (SOPs)

DS18497 Utgitt

VB - Koordinator i vandrende blodbank - oppgaver

Dokumentsamling

Dokumentnummer	Tittel	Gyldig fra
PR62390	VB - Mottak og oppdatering av nødblodgiverlister - Vandrende blodbank sine oppgaver	06.06.2024
PR62793	VB- Innkallingssystem i vandrende blodbank	12.06.2024
PR62466	VB- Verving av nye nødblodgivere - Vandrende blodbank sine oppgaver	06.06.2024
PR62290	VB - Mottak av nye nødblodgivere - Vandrende blodbank sine oppgaver	11.06.2024
PR62791	VB - Informasjonsmøte med nødblodgivere i vandrende blodbank	12.06.2024
OL3724	VB- Rekvisisjon ny Nødblodgiver i Vandrende blodbank	11.06.2024
PR62287	VB - Prøvetaking for regodkjenning av nødblodgivere - Vandrende blodbank sine oppgaver	11.06.2024
PR62776	VB - Bruk av Biomixer BM 323-1 i vandrende blodbank	11.06.2024
SJ18131	VB-Kontroll av BioMixer 323 -1 i vandrende blodbank	11.06.2024
SJ18134	VB - Kontroll av kjøkkenvekter i bruk ved nødtapping vandrende blodbank sine oppgaver	11.06.2024
SJ18071	VB- Opplæringsskjema - vandrende blodbank	03.05.2024

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Equipment and disposables

8. Equipment and walking blood bank equipment container

Equipment	Check if precent	Expiry date
Flow chart: "5-A. Preparation before blood collection" "5-B. Blood collection"		
Procedure: "4-B. Interview interpretation guide for the interviewer"		
Forms: "4-A. Emergency blood donor interview form" "4-C. Blood collection form "4-D. National "Form for blood donors" "7. Transfusion journal"		
1 x 3.5ml serum blood sample tube (yellow cap)		
2 x 4ml K2EDTA blood sample tube (purple cap)		
1 x plasma preparation blood sample tube (white cap)		
Disinfection wipes "70 % isopropanol"		
Cotton balls		
Tape		
Torniquet strap		
Donation blood bag		
Scissors		
New donation identification label		
Rubber band		
Transfusion set		
Freeze dried plasma		

Find elsewhere:

Weight scale/blood mixer	On shelf/in drawer _____
Stopwatch (alternatively your own phone)	On shelf/in drawer _____
Transport tubes for blood sample tubes	On shelf/in drawer _____
Envelope for samples and documents	On shelf/in drawer _____
Sharps container	On shelf/in drawer _____

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Training and rehearsals

Training program:

- Education sessions and regular exercises
- Training material
  - Lectures (in person and e-learning)
  - Instruction videos

➢ Documentation of activity, all attendees must be named

➢ System for maintenance of skills described and documented

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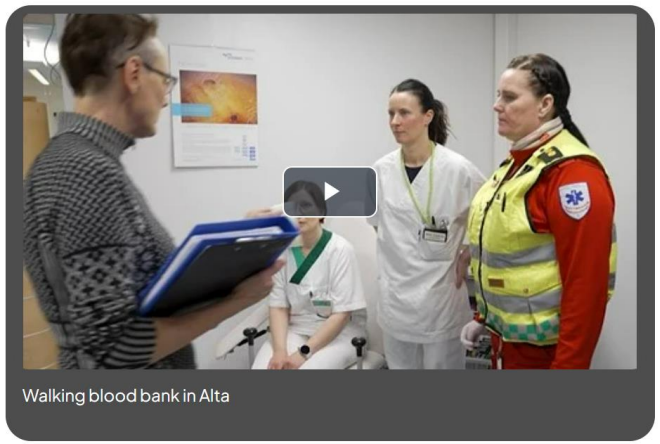
Instruction videos and e-learning

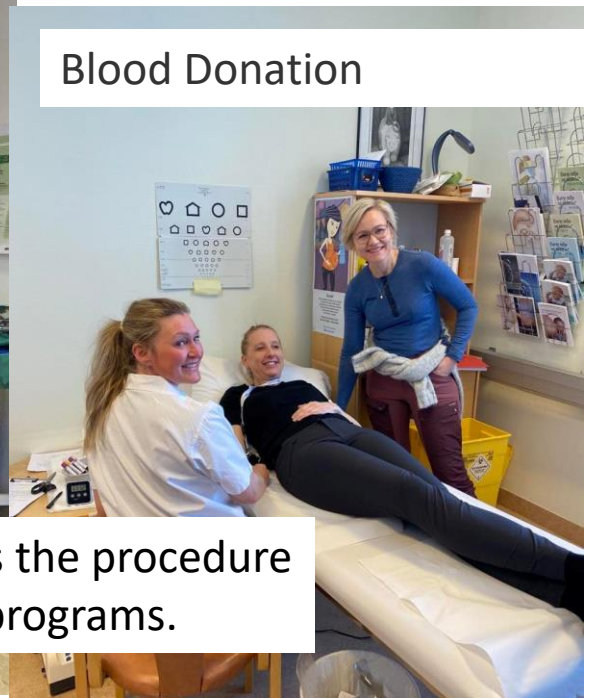


Supervision and regulatory approval

- The Walking Blood Bank is approved by civilian regulatory authorities, belongs to a local “Mother Blood Bank” and is inspected by the same regular authority as ordinary blood banks.
- All WBBs have to complete training and certification drill before approval.

Longyearbyen: Pictures form our certification drill the 25th of April 2023.

The Norwegian Minister of Health observes the procedure to learn about civilian walking blood bank programs.



External evaluators follow the certification drill.

Emergency donor fills out the donor questionnaire

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Evaluation of risk

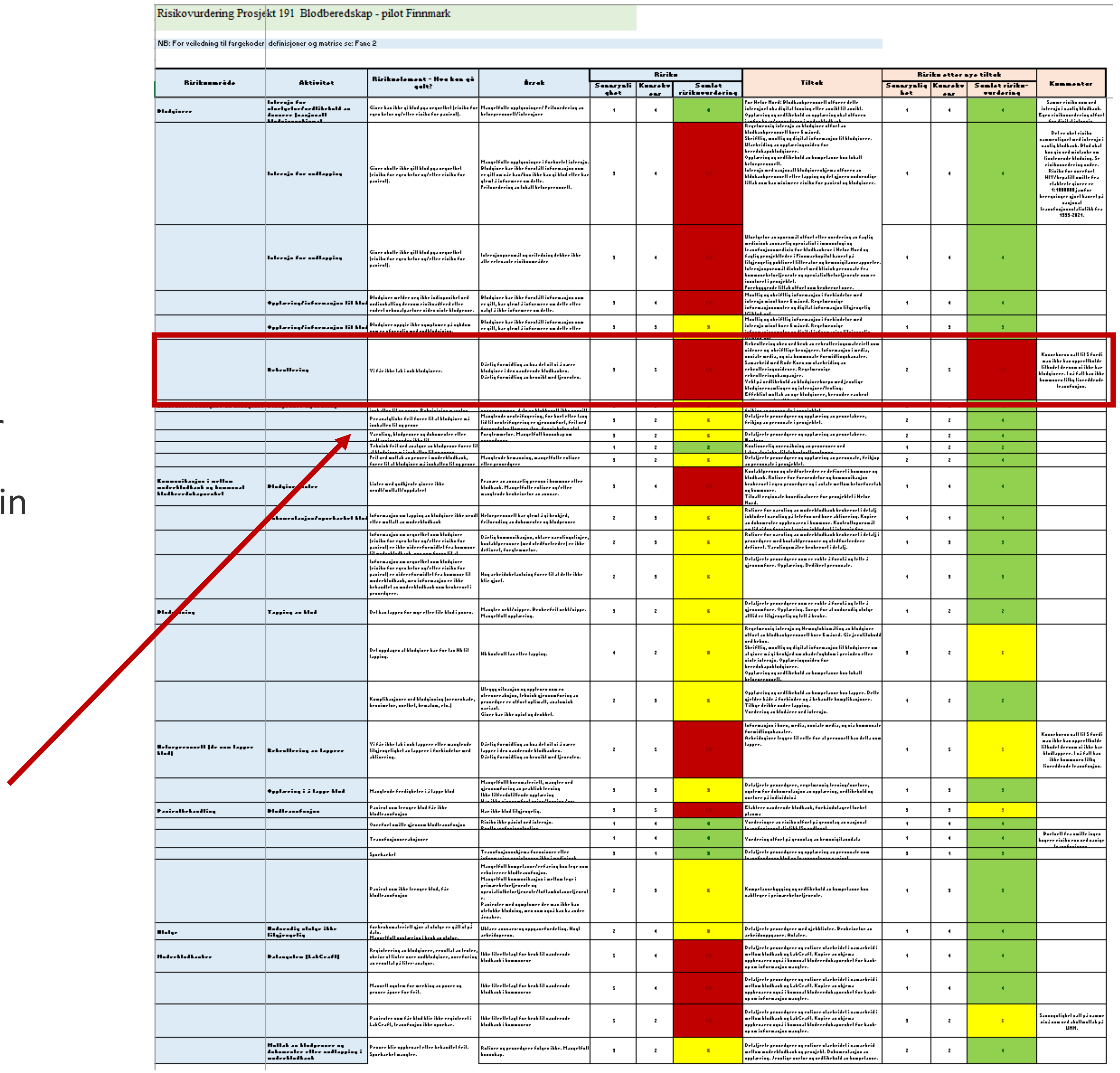
Potential risks:

1. Posttransfusion TTID testing
   - ➢ The donors are included based on our national blood donor questionnaire and criteria
   - ➢ Regular testing and interviews (6 months)
   - ➢ Information to the donors on risk behavior and exclusion criteria
   - ➢ Very low prevalence of positive TTID tests in regular donors in Norway (1: 1 000 000)
2. Non-leukoreduced blood

Benefit:

Emergency collected whole blood is only be used for treatment of patients with life-threatening bleeding when banked blood is unavailable.

➢ Benefit outweights the risk.



Public information

HELSE NORD

Forside > Nyheter > Statsråden traff blink på Arendalsuka

Statsråden traff blink på Arendalsuka

Helse- og omsorgsminister Ingvild Kjerkol (Ap) leverte til tjue i stil da hun tappet blod av prosjektleder Bent-Ove Jamtli i Prosjekt blodberedskap under Arendalsuka.

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HELSE NORD

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Stor totalforsvarsøvelse under Nordic Response

Som en del av øvelse Nordic Resonse ble det det øvd på massetilstrømming og sivil-militære masseskadescenarier i Tromsø og Alta.

Publisert 25.03.2024

Sivil- militær samhandling mellom legevaktstjenesten i Alta, spesialisthelsetjenesten og sanitetet i Brigade Nord

Totalforsvaret og det sivil-militære samarbeidet i en krisesituasjon er noe man sjeldent har fått trent på i større skala. Men under den store NATO-øvelsen Nordic Response var totalforsvaret integrert.

UNN Tromsø gjennomførte en massetilstrømningsøvelse med 80 markører onsdag 6 mars. Scenarioet var et terroranslag mot et flyktningmottak i Tromsøhallen, og UNN Tromsø. Heimevernet, US marines, politi, brann og tivilforsvaret deltok på øvelsen.

Aktiverte vandrende blodbank

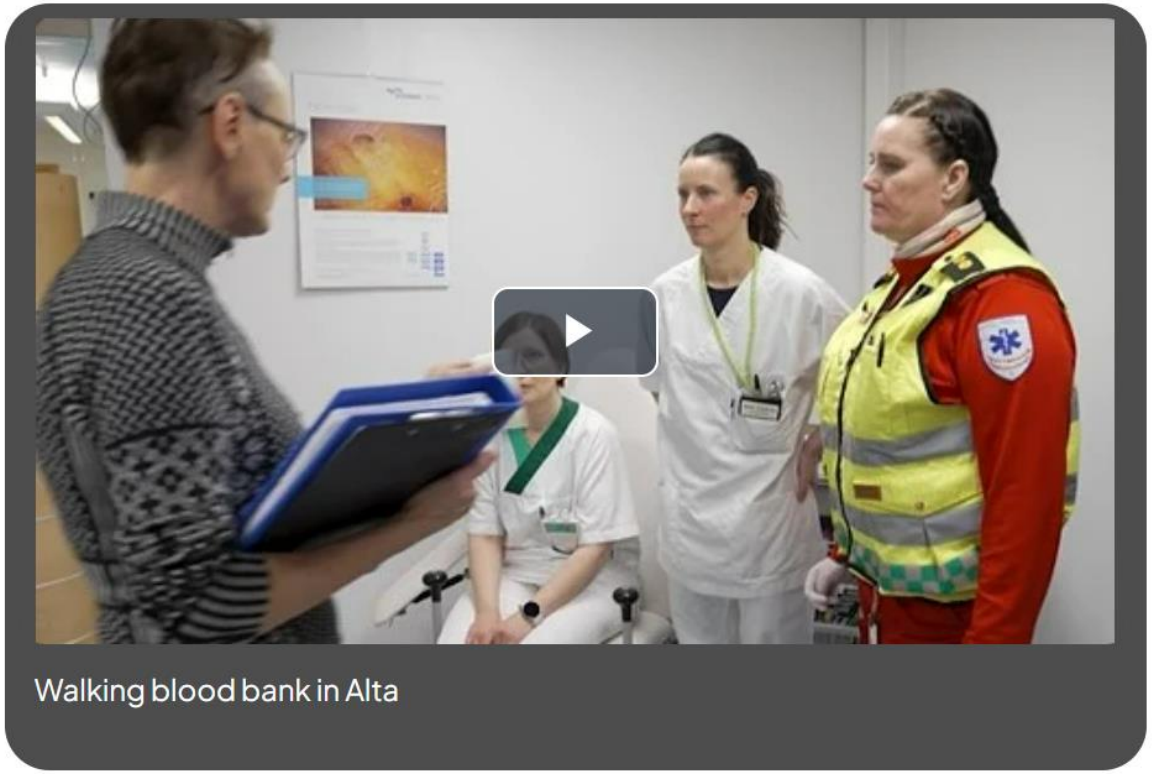
Tirsdag 12 mars ble det som en del av øvelse Nordic Response gjennomført en sivil-militær masseskadeøvelse i Alta. 24 skadde soldater ble fraktet med militære og sivile ambulanser til legevakten i Alta for behandling.

Legevaktstjenesten i Alta aktiverte vandrende blodbank og ba om støtte fra vandrende blodbank i Vadsø og Berlevåg. Pasienter med behov for kirurgisk behandling ble tatt videre til et fremskutt kirurgisk team fra Helse Vest som utførte skadebegrensende kirurgi på klinikk Alta, veggi veggmed legevakten.

Blodet fra de vandrende blodbankene i Vadsø og Berlevåg ble hentet med et helikopter fra Forsvaret, og var på plass i Alta tre timer etter aktiveringen. Fullblod fra vandrende blodbank i Alta var tilgjengelig 26 minutter etter aktiveringen.

Nokblod

Information video:
The Civilian Walking Blood Bank in Alta



Nokblod

Results

Key numbers:

- Number of Civilian Walking Blood Banks established: **4**
- Number of activations per December 2024: **15**
- Number of whole blood bags collected: **31**
- Mean time from activation to blood bag ready for transfusion: **30 minutes**

Indication for transfusion:

- Trauma
- Gastrointenstinal (GI) Bleeding
- Re-bleeding after surgical interventions
- Others (suspected aortic aneurism, etc.)

Number of personnell trained: **60 (+)**
Number of emergency blood donors: **100 (+)**

Next step: Nordic joint Blood Preparedness project

Nokblod

"Blood supply continency and emergency preparedness for patients with life-threatening bleeding in the Barents region"

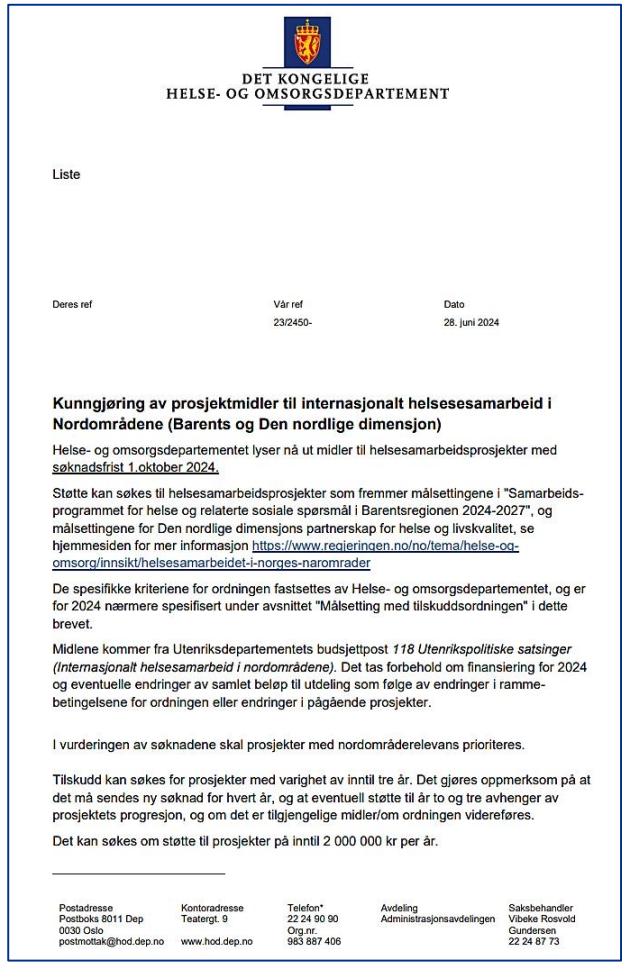
Aim:
To develop and pilot a cross-country blood preparedness program which ensures blood supply on all health care levels and access to treatment for bleeding patients in the Barents region.

- Facilitate co-operation and interoperability in the Nordic countries
- Build a platform for future collaborations
- Cross-border interoperable blood preparedness system
- Emergency Whole Blood collection in hospitals and primary health care services

Project participants:

Blood Services, local hospitals, prehospital and primary health care services in the Northern areas of Norway, Sweden and Finland.

Timeline: January 2025-December 2027



DET KONGELIGE
HELSE- OG OMSORGSDEPARTEMENT

Liste

Deres ref	Vår ref	Dato
	23/2450-	28. juni 2024

Kunngjøring av prosjektmidler til internasjonalt helsesamarbeid i Nordområdene (Barents og Den nordlige dimensjon)

Helse- og omsorgsdepartementet lyser nå ut midler til helsesamarbeidsprosjekter med søknadsfrist 1.oktober 2024.

Støtte kan søkes til helsesamarbeidsprosjekter som fremmer målsettingene i "Samarbeids-programmet for helse og relaterte sosiale spørsmål i Barentsregionen 2024-2027", og målsettingene for Den nordlige dimensjons partnerskap for helse og livskvalitet, se hjemmesiden for mer informasjon https://www.regjeringen.no/no/tema/helse-og-omsorg/innsikt/helsesamarbeidet-i-norges-naromrader

De spesifikke kriteriene for ordningen fastsettes av Helse- og omsorgsdepartementet, og er for 2024 nærmere spesifisert under avsnittet "Målsetting med tilskuddsordningen" i dette brevet.

Midlene kommer fra Utenriksdepartementets budsjettpost *118 Utenrikspolitiske satsinger (Internasjonalt helsesamarbeid i nordområdene)*. Det tas forbehold om finansiering for 2024 og eventuelle endringer av samlet beløp til utdeling som følge av endringer i ramme-betingelsene for ordningen eller endringer i pågående prosjekter.

I vurderingen av søknadene skal prosjekter med nordområderelevans prioriteres.

Tilskudd kan søkes for prosjekter med varighet av inntil tre år. Det gjøres oppmerksom på at det må sendes ny søknad for hvert år, og at eventuell støtte til år to og tre avhenger av prosjektets progresjon, og om det er tilgjengelige midler/om ordningen videreføres.

Det kan søkes om støtte til prosjekter på inntil 2 000 000 kr per år.

Postadresse	Kontoradresse	Telefon*	Avdeling	Saksbehandler
Postboks 8011 Dep 0030 Oslo postmottak@hod.dep.no	Teatergt. 9 www.hod.dep.no	22 24 90 90 Org.nr. 983 887 406	Administrasjonsavdelingen	Vibeke Rosvold Gundersen 22 24 87 73

Nokblod

Conclusions

We conclude that establishing a civilian walking blood program for emergency collection of whole blood is feasible and may improve resilience and increase emergency preparedness in areas and situations where banked blood is unavailable or unsufficient.

Emergency collection of whole blood is in accordance with the requirements of the new EU SoHO article 65 and 66:

- It is in interest of public health
- It can be established in a structured way that ensures that the level of quality and safety is acceptable
- The whole blood collected is for immediate use for a defined patient population with severe bleeding
  - who have no other therapeutic alternative,
  - the treatment cannot be postponed,
  - the prognosis is life-threatening,
  - and the expected benefit outweighs the risk.

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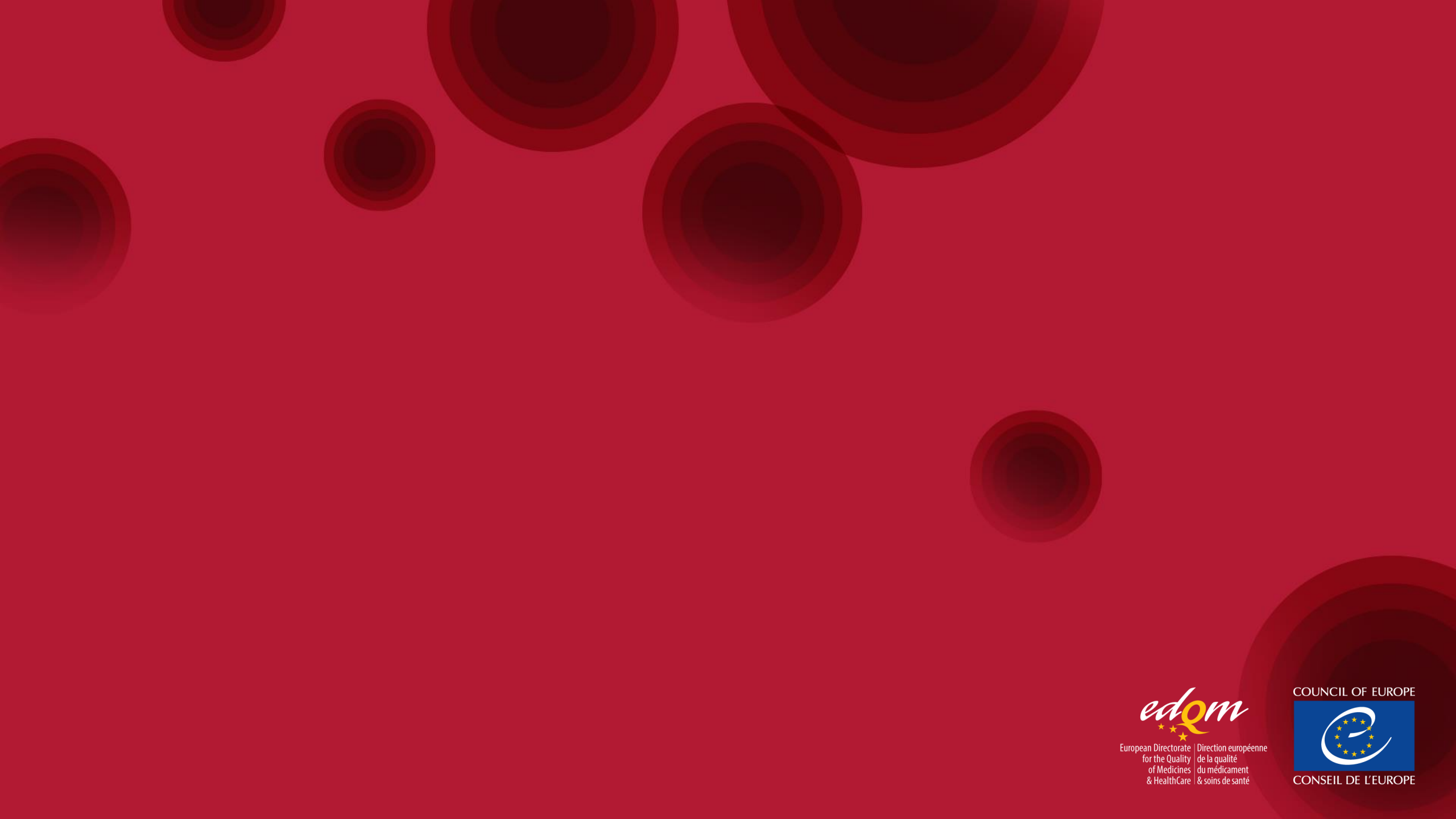
Web-page: Norwegian Center for Blood Preparedness (Nokblod)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