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MILITARY UNIVERSITY HOSPITAL
PRAGUE



Implementation of LTWB in Czech Republic

COL(GS).Miloš Bohoněk, MD, PhD

Implementation of whole blood transfusion -
webinar EBA

December 09th, 2022



2018

WB in CZ - discussion starts there:

November 15th 2018

Orea Hotel Pyramida

Bělohorská 24, Prague

Czech Republic



12th



**Střešovice Blood
Transfusion Day**

**Whole Blood
is Coming Back !**

www.uvn.cz/transfuzniden

LTWB as licenced product with a fixed maximum price

Tabulka 1: Výše úhrad

Kód	NAZ	DOP	CES	TYP	MJD	UHR1	UHR2	LEG_UHR	LIM	OME	IND	ATC
0007901	Plná krev		INF	12	T.U.	1 521,24		S	B			B05AX01
0007905	Erytrocyty z odběru plné krve		INF	12	T.U.	1 521,24		S	B			B05AX01
0007917	Erytrocyty bez buffy coatu	resuspendované	INF	12	T.U.	2 312,12		S	B			B05AX01
0007955	Erytrocyty deleukotizované		INF	12	T.U.	2 813,21		S	B			B05AX01
0007956	Erytrocyty deleukotizované	u lůžka (bed side)	INF	12	T.U.	2 312,12		S	B			B05AX01
0007957	Erytrocyty deleukotizované	pediatrické	INF	12	ks	1 845,00		S	B			B05AX01
0007961	Erytrocyty deleukotizované	pro výměnnou transfuzi	INF	12	ks	4 677,30		S	S		P	B05AX01
0007962	Erytrocyty deleukotizované	pro intrauterinní transfuzi	INF	12	ks	4 677,30		S	S		P	B05AX01
0007963	Erytrocyty z aferézy	resuspendované	INF	12	T.U.	2 312,12		S	B			B05AX01
0007964	Erytrocyty z aferézy deleukotizované		INF	12	T.U.	2 813,21		S	B			B05AX01
0007965	Erytrocyty deleukotizované kryokonzervované		INF	12	T.U.	13 983,73		S	B		P	B05AX01
0007966	Erytrocyty z aferézy deleukotizované kryokonzervované		INF	12	T.U.	13 983,73		S	B		P	B05AX01
0007967	Plná krev deleukotizovaná pro univerzální podání	krevní skupiny 0 s nízkým titrem anti-A a anti-B	INF	12	T.U.	8 296,52		S	B		P	B05AX01
0107930	Trombocyty z odběru plné krve		INF	12	T.U.	1 584,16		S	B			B05AX02
0107931	Trombocyty z aferézy	minim. 200 miliard TRC	INF	12	T.D.	8 990,33		S	B			B05AX02
0107935	Trombocyty z buffy coatu směsné	minim. 200 miliard TRC	INF	12	T.D.	8 128,05		S	B			B05AX02
0107936	Trombocyty z buffy coatu směsné, deleukotizované	minim. 200 miliard TRC	INF	12	T.D.	9 345,81		S	B			B05AX02
0107937	Trombocyty z buffy coatu směsné, deleukotizované	pediatrická jednotka	INF	12	ks	4 600,41		S	B			B05AX02
0107952	Trombocyty z aferézy deleukotizované	minim. 300 miliard TRC	INF	12	T.D.	15 335,92		S	B			B05AX02
0107958	Trombocyty z odběru plné krve - deleukotizované		INF	12	T.U.	2 469,08		S	B			B05AX02
0107959	Trombocyty z aferézy deleukotizované	minim. 200 miliard TRC	INF	12	T.D.	10 561,71		S	B			B05AX02
0107960	Trombocyty z aferézy deleukotizované	méně než 200 miliard TRC	INF	12	ks	4 929,79		S	B			B05AX02
0107961	Trombocyty patogen-inaktivované	minim. 200 miliard TRC	INF	12	T.D.	10 561,71	15 041,29	S	B		P	B05AX02
0107962	Trombocyty patogen-inaktivované	minim. 300 miliard TRC	INF	12	T.D.	15 335,92	18 718,94	S	B		P	B05AX02
0107963	Trombocyty z aferézy deleukotizované kryokonzervované		INF	12	T.D.	19 424,25		S	B		P	B05AX01
0107964	Trombocyty z buffy-coatu směsné deleukotizované kryokonzervované		INF	12	T.D.	13 374,24		S	B		P	B05AX01
0207921	Plazma čerstvá zmrazená	pro klinické použití	INF	12	T.U.	1 340,29		S	B		P	B05AX03
0207922	Plazma patogen-inaktivovaná	pro klinické použití	INF	12	T.U.	1 340,29	2 663,83	S	B		P	B05XA03
0207925	K-plazma	pro klinické použití	INF	12	T.U.	1 340,29		S	B		P	B05AX03
0207926	Kryoprotein		INF	12	T.U.	2 888,21		S	B			B05AX
0207927	Kryoprotein z 1 lt plazmy		INF	12	T.D.	7 036,06		S	B			B05AX
0207928	Plazma rekonvalescentní		INF	12	T.U.	2 549,56		S	B		P	B05AX03
0207929	Plazma rekonvalescentní patogen-inaktivovaná		INF	12	T.U.	3 562,24		S	B		P	B05XA03
0307934	Granulocyty z aferézy		INF	12	T.D.	15 433,58		S	S		P	B05AX

2020

WB in CZ

June 2020 introduced into production and clinical use:

- **University Hospital Hradec Králové,**
- **Military University Hospital Prague**
- **University hospital Ostrava**
- **University Hospital Motol Prague**
(from 2022, supplied form Military University Hospital Prague)

- **in traumacenters (massive transfusion, polytrauma)**
- **prehospital care – Air Ambulance Services:**
 - **Hradec Králové (from 06/2020)**
 - **Ostrava (from 08/2022)**
- **indications are gradually being refined based on experience**



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Germany

Poland

Liberec

Teplice

Ústí nad Labem

Karlovy Vary

Kladno



ÚVN FN MOTOL



Prague (Praha)



Hradec Králové

Pardubice

Krnov



Ostrava

Pilsen (Plzeň)

Rokycany
Příbram

Czech Republic

Tábor

Havlíčkův
Brod

Prostějov

Olomouc

Frydek-Místek

Brno

Uherské
Hradiste

Kroměříž

Zlín

Ceské
Budějovice

Austria

Slovakia

Vienna
(Wien)

Bratislava

14°

RABBIT2

RAPID ADMINISTRATION OF WHOLE BLOOD BY HEMS IN TRAUMA

Air Ambulance Service
Hradec Králové



Plnou krev dostanou pacienti už i ve vrtulníku v Moravskoslezském kraji

10. srpna 2022 10:20



Šance na přežití zraněných lidí, které převážejí moravskoslezští letečtí záchranáři, výrazně vzroste. Už od pátku totiž budou posádky podávat pacientům po velmi těžkých úrazech plnou krev přímo na palubě vrtulníku.



Ředitel Letecké záchranné služby Moravskoslezského kraje Roman Gřegoř ukazuje box s plnou krví, který budou mít záchranáři nově k dispozici přímo ve vrtulníku. | foto: Alexandr Satinský, MAFRA

„Plná krev dokáže změnit osud pacienta. Doposud jsme měli možnost v terénu pacienta ošetřit, omezit krvácení a převést ho do traumatologického centra. Teprve tam mu mohla být aplikována krev. Včasná náhrada krevní ztráty pomocí masivního transfuzního protokolu je ale často otázkou života a smrti,“ uvedl náměstek ředitele a primář zdravotnické záchranné služby kraje David Holeš.

„Průměrná doba od úrazu po předání pacienta do traumacentra je šedesát minut. Životně důležitých je ale prvních patnáct minut. Udělali jsme tedy

Reklama

**Těšte se z výhod
operativního
leasingu
bez starostí.**

TUCSON s navigací
v limitované nabídce.

Mám zájem



Již za **8 699 Kč**
měsíčně bez DPH

AUTO LAŠÁK RÝMAŘOV

HYUNDAI | OPERATIVNÍ LEASING

**Air Ambulance Service
Ostrava**



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WB is back... which one ?

1/ 0 RhD neg /(pos)

2/ **Low Titre / LTOWB:**

WB from donors with low anti-A / anti-B IgM, ($< 256 / 128$)

4/ Low risk TRALI

3/ Leucodepleted

(Platelets sparing filter)

TERUMOBCT
Unlocking the Potential of Blood

IMUFLEX Whole Blood Filter
Saving Platelets (WB-SP)



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Production and use of LTWB in CZ (6/2020 – 8/2022)

	FN Hradec Kralove	UVN Prague	FN Motol	FN Ostrava	Total (T.U.)
Made (T.U.)	1052	244	0	221	1517
Transfused (T.U./patients)	933 / 308	125 / 51	13 / 9	171/120	1242/488
EMERGENCY	526 / 229	109 / 45	11 / 7	138/88	784/369
INTENSIVE CARE UNIT - TRAUMA	21 / 8	x	1 / 1	11/8	33/17
INTENSIVE CARE UNIT - SURGERY	188 / 72	5 / 2	1 / 1	5/4	199/79
INTENSIVE CARE UNIT - INT. MED.	43 / 13	x	x	x	43 / 13
OTHERS - OPERATING THEATERS	7 / 4	11 / 4	x	20/9	38/17
AIR AMBULANCE	148 / 79	x	x	3/3	151/82



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WB for small country ?



E IN NORWAY



FREEZE DRIED PLASMA (FDP)

RED BLOOD CELLS + FDP

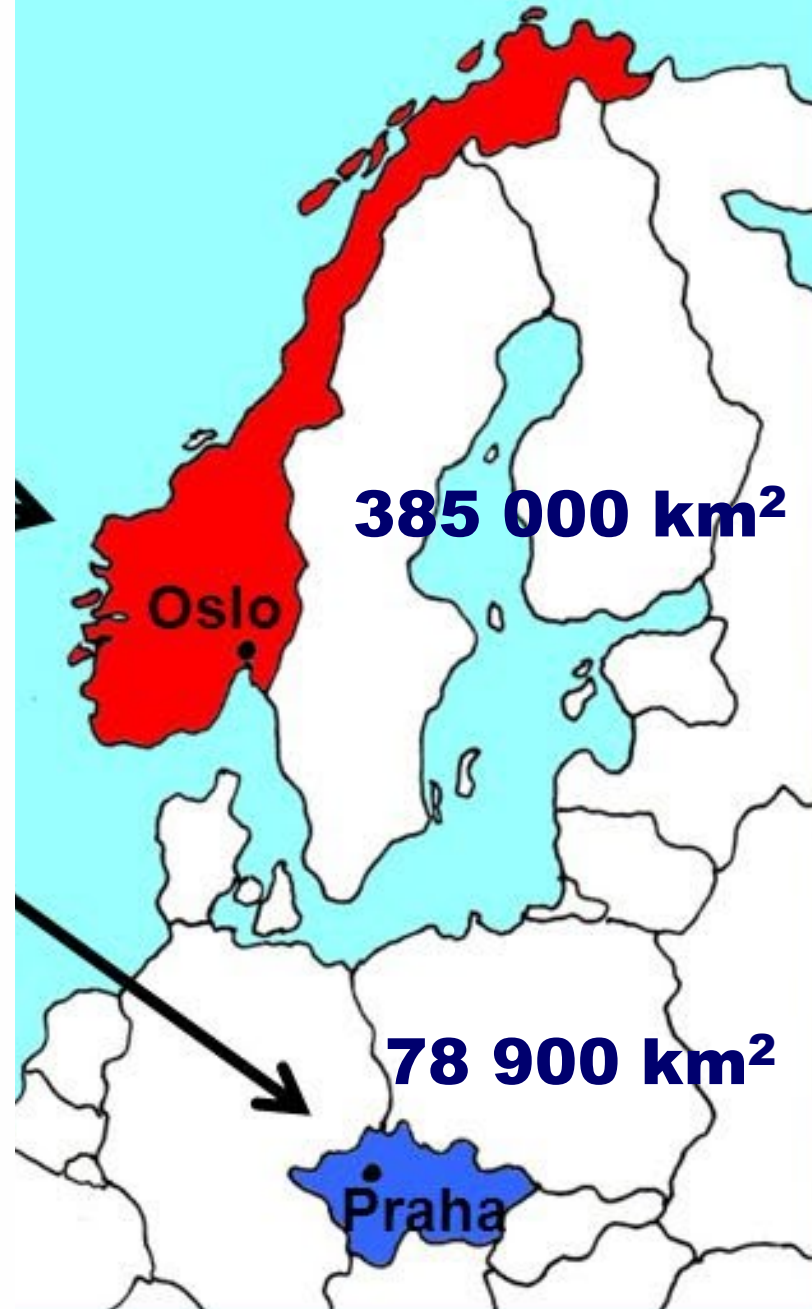
WHOLE BLOOD + FDP

CRYSTALLOIDS

AIR AMBULANCE

SEARCH & RESCUE

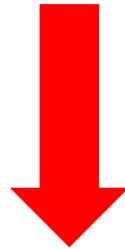
OFFSHORE OIL RIG



WB for small country ?

Despite the fact that the arrival time of the ambulance is guaranteed by law to be a maximum of 20 min:

- **difficult traffic or weather conditions may occur**
 - **in addition, the occurrence of an injury may be long before it is reported**
- **extrication and stabilization of the patient on site may take time**
- **the trauma center may be far from the scene of the injury**



YES !



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WB... WHERE ?

* Military Medicine



* Traumacenter (EMERY)



* Air Ambulance



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Blood Far Forward!



milos.bohonek@uvn.cz



Whole blood-prehospital and in-hospital in Sweden

Agneta Wikman
Senior Consultant, professor
Clinical Immunology and Transfusion Medicine



Karolinska
Institutet



Short version

- *Where and when is whole blood used in Sweden?*
Since 2019 on two ambulance helicopters in west-Sweden
Since October 2022 pre-hospital in one 24/7 emergency car with a physician and in-hospital at the trauma center at Karolinska in Stockholm
- *Production-logistics*
In West Sweden: 2 units one week on the ambulance-helicopter, then back to the blood bank and packed red cells are prepared. Plasma is discarded.
In Stockholm: one unit one week at the emergency car then up to the trauma fridge. Base production 3 units/week.
- *Material*
CPD, leukoreduced, platelet sparing filter (Terumo), 21 days storage. Blood group O RhD pos/neg, male, low-titer donors.
- *Experiences*
low wastage-0%
the clinicians are very positive; "easy, fast, everything in one bag"
Data from west Sweden after 3 years will be published
Stockholm started Oct-until now; prehospital 3 units, in-hospital 15 units are transfused
Other regions are planning to start- independant routines



Whole Blood



Pro:

- Time "every minute counts"
- balanced transfusion with platelets early
- high concentration of red cells, platelets, coagulation factors compared to blood components diluted in additive solutions

Con:

- logistic challenges for the Blood Bank
- blood groups (incompatible plasma)
- only one supplier of leukocyte reduction and platelet sparing filter



Whole Blood Product in Finland and Finnish Prehospital Whole Blood Study

Jouni Lauronen

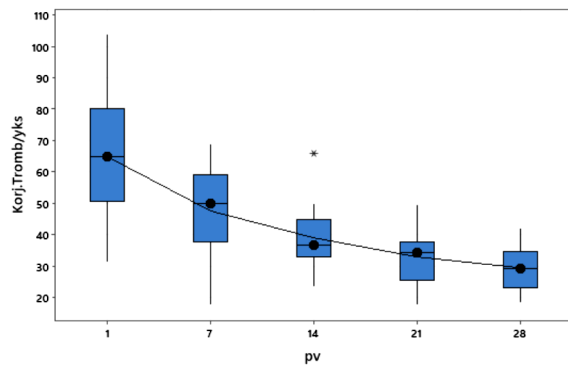
Implementation of Whole Blood for Transfusion
EBA Webinar 9.12.2022

FinnPHWB

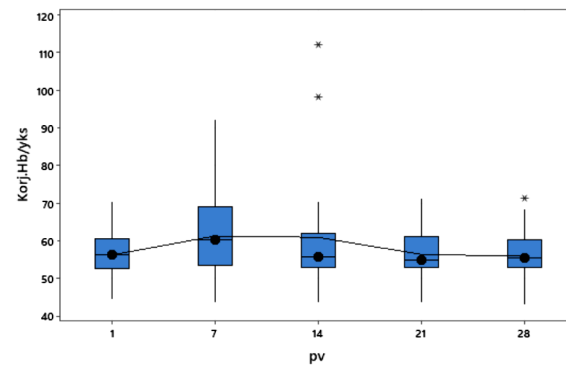
FRCBS whole blood (LTOWB)

- Leukoreduced
- Male donors only, no HLA antibody measurement
- O RhD pos
- Titer ≤ 128 , measured after every LTOWB donation
- 21 days shelf life, $+2 - +6^{\circ}\text{C}$
- Indication: emergency transfusion at prehospital emergency care
- Currently delivered only to the hospitals that participate for case group patient recruitment for Finnish Prehospital Whole Blood study (FinnPHWB)

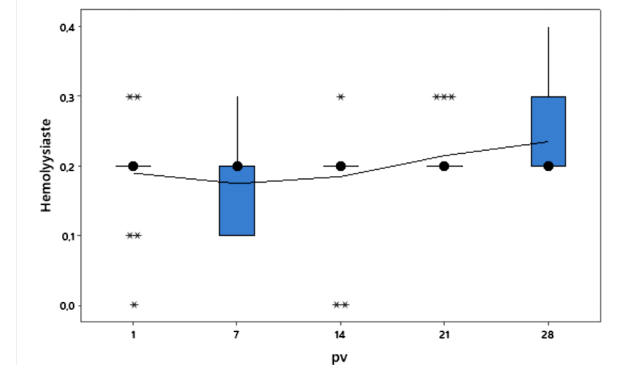
Platelets



Hb



Hemolysis



Finnish Prehospital Whole Blood Study



- Open, non-randomized, multicenter clinical study
 - LTOWB will be used in three centers while other centers will continue to use PRBC
- Hypotheses
 - Use of LTOWB is feasible, and it is **easier to use** than current transfusion therapy
 - LTOWB as prehospital transfusion therapy is clinically **non-inferior** compared to PRBC
 - **Coagulation properties of LTOWB are better** and LTOWB is associated with **less severe endothelial damage and inflammation** compared to PRBC
- Approved by the ethics committee for Helsinki and Uusimaa hospital district
- Funding from EBA, state subsidy for university hospitals, MATINE (Scientific Advisory Board for National Defence)
- 3 (-4) years recruitment, first control patients recruited, no LTOWB used yet

Concerns

- Only limited number of users and thus patients, lot of wastage
 - Is 21 days shelf life OK?
 - Should we allow in-hospital use?
 - What are the other options for old units?
- FRCBS LTOWB could be useful in limited crisis while blood service operates normally, but may not be useful in large and long-lasting crisis
 - Expensive, laborious, supply of consumables?
 - Donor pool might be too small; male donors only, O RhDpos
- One bag system without leukoreduction may be better in larger, long-lasting crisis
 - Emergency donor pool and walking blood bank option

Base code	Approximated number of patients per year
FH10	35
FH30	20
PH00	15

Whole Blood -England

Rebecca Cardigan PhD, FRCPath

Head of Component Development/PI, NHS Blood & Transplant, England


Affiliated Lecturer, Dept Haematology, University of Cambridge

Caring Expert Quality

Status of whole blood

- Currently not routinely provided
- Started a programme of activity to explore options for provision
- Assessed feasibility of supplying LD WB (without platelets) whilst validating LD WB containing platelets
 - Feasible
 - Wastage issues to overcome
 - Reduction in time to administer red cells and plasma
- Surveyed pre-hospital teams to ask what product they would want and what level of evidence prior to implementation
 - Would like product all in one bag, preferably with platelets
 - Would like to see clinical trial prior to routine use
- Secured funding and set up RCT of WB v standard of care
 - Started this week, 18-24 months to recruit

Lessons learned

- Blood collection considerations
 - Most practical to use standard collection systems & CPD anticoagulant
 - ‘sterile connect’ Terumo LD sets back in the blood centre
 - Not easy for us to identify donors with anti-platelet meds – easier way to exclude was to use BAT systems which are only used if donors fulfil requirements for platelets
 - Wastage
 - Not practical to ‘recycle’ blood once it has left our organisation
 - Consider extending use to non-trauma MH patients
 - Shelf-life
 - Needs to be pragmatic balance between what’s in the bag and ability to supply
- 
- A thick, solid blue wavy line that curves across the bottom of the slide, starting from the left edge, dipping down, and then rising towards the right edge.

Key considerations for implementation

- Benefits will depend on current standard of care and need to be understood
- Whether to make from D neg/pos donations
- How to make collection/manufacturing practical
- Minimising wastage
- Defining an acceptable shelf-life



EBA Webinar

12 / 09 / 2022

Christophe Martinaud (MD, PhD)
Centre de Transfusion Sanguine des Armées

Overview of whole blood program

➤ Launched in 2018

- CS-FWB was still on the list of authorized products in France
- However:
 - No medical device was authorized to process it
 - No guidelines described its indications

➤ Approval of the medical device

- Imuflex SP (Terumo BCT)
- In vitro studies assessing:
 - Conformity of the CS-FWB according to French regulation
 - Quality of RCCs derived from 7-day stored CS-FWB

➤ Guidelines and clinical trial

- Use in military settings according to French Military Medical Service Guidelines
- Use in civilian settings for patients included in the STORHM clinical trial

➤ First delivery and transfusion

- June 2021 in overseas operation
- November 2021 in the STORHM study





Lessons learned

- **Requires the involvement of all the actors from transfusion medicine**
 - Donors: call out for O RH1 with low titer
 - Blood collection – Preparation: selection criteria and coordination to filter within 12 hours
 - Blood donation screening: indicator for screening completed in less than 48h
 - Healthcare workers (nurses, physicians)
 - Regulatory authorities
 - Learned Societies
- **Providing the current best standard of care is a key success driver**
- **Daily management is highly feasible for (our) blood establishment**



Topic which needs special attention for the implementation of whole blood

- **Establish guidelines of utilisation and implement them in practices**
 - “first blood product to transfuse in emergency for massive hemorrhage patient”
 - Teaching and training
 - Provide evidences
 - From previous studies
 - By recording every transfusion in order to analyse properly the use
- **Mobilisation of the blood collect chain**
 - Promotional campaign
 - Training for medical interview:
 - Selection of supposed “low-titer”
 - Provide clear objectives, regularly re-assessed
- **Cost-effectiveness and clinical effectiveness**



Use of whole blood as an emergency preparedness product

- Highly desirable for the management of massive hemorrhage
- Will help to provide red cells – platelets and plasma in the right timeline in emergency situations
- Implementation of warm fresh whole blood from blood donor panel need to be considered

NORWEGIAN BLOOD BANK STRUCTURE

All hospitals in Norway have their own blood bank.
Inventory of blood components differ based on local policies.

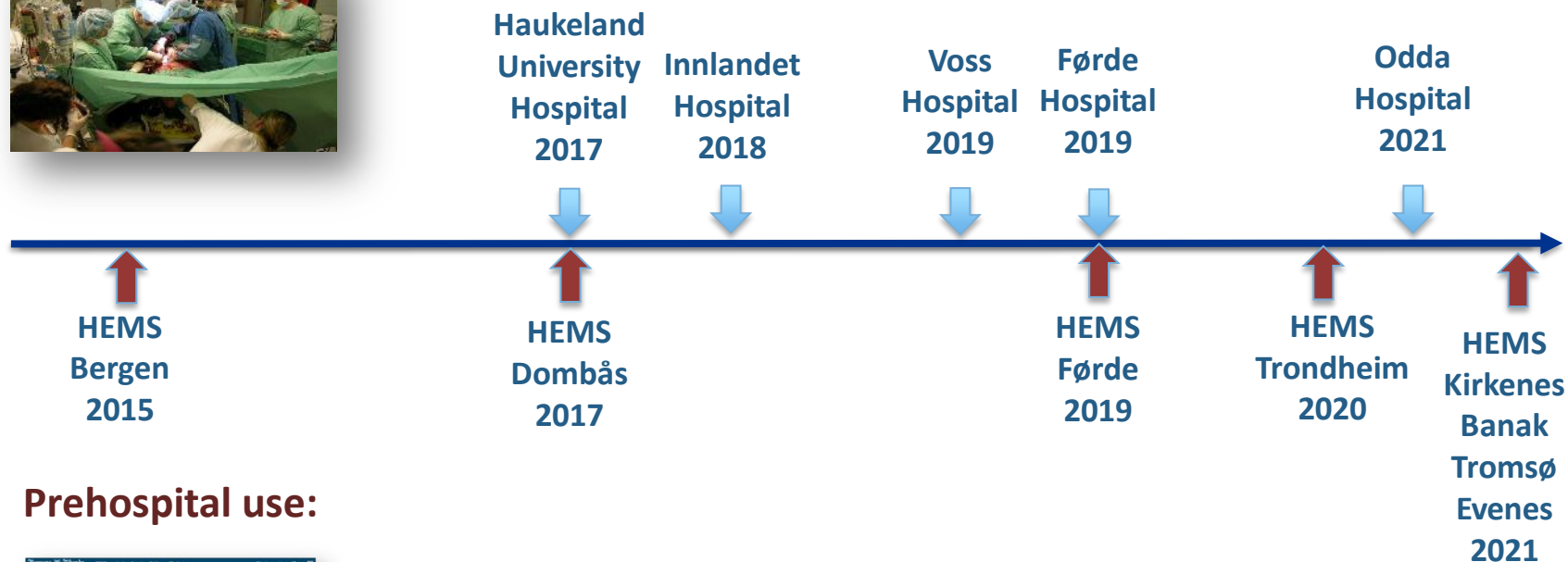
The Norwegian Blood Banks are:

- Hospital-based
- Activities include blood collection, component production and storage, in-hospital immunohematology and transfusion services



IMPLEMENTATION OF LTOWB IN NORWAY

In hospital use:



Prehospital use:






WHOLE BLOOD IN PREPAREDNESS PLANNING

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. Hagen¹ | Hanne Braathen^{1,3}  | Tor Hervig^{1,3,4}

Whole blood can be stored longer than platelet concentrates, which makes it an excellent solution in hospitals unable to maintain a sufficient inventory of platelet concentrates.

Ref. Apelseth et al. How Do I implement a whole blood based blood preparedness program in a small rural hospital. Transfusion 2020; 60:2793-2800

Emergency whole blood collection is also an important part of our contingency here in Bergen. Haukeland University Hospital is the Level 1 Trauma center for the Western part of Norway.



Example of activation of emergency whole blood collection:

Trauma patient

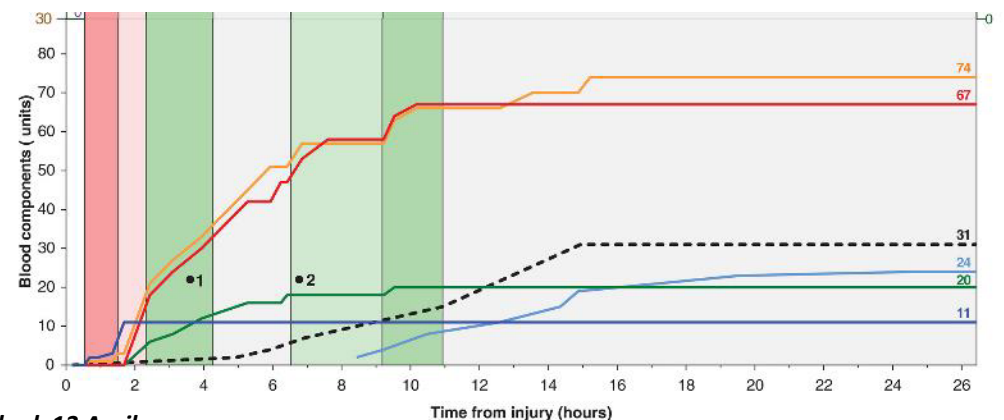
High demand for blood. Whole blood and platelet inventory depleted. Emergency collection of whole blood and apheresis platelet collections initiated with success.

Patient received 11 cold stored and 24 fresh whole blood units.

SUPPLEMENT ARTICLE

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

Silje Helland Kaada,¹ Torunn Oveland Apelseeth,^{1,2} Kristin Gjerde Hagen,¹ Einar Klæboe Kristoffersen,^{1,3} Stig Gjerde,⁴ Kristian Sønstabo,⁴ Henrik Halvorsen,⁵ Tor Hervig,^{1,3} Geir Arne Sunde,⁴ Geir Olav Dahle,⁴ Mari Christine Johnsen,¹ and Geir Strandenes^{1,6}



Transfusion, Volume: 59, Issue: S2, Pages: 1446-1452, First published: 13 April 2019, DOI: (10.1111/trf.15184)

WALKING BLOOD BANKS

Emergency collection of whole blood from prescreened and pretested low titer group O blood donors.

Whole Blood is collected on site or as part of a hospital-based blood preparedness plan and transfused immediately.

Used in military, oil industry, municipal health care (pilot)

