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Transfusion preparedness in today's world

Prof. Dr. Torunn Oveland Apelseth, MD, PhD:

Director, Norwegian Centre for Blood Preparedness, Bergen, Norway
Senior Consultant, Department for Immunology and Transfusion Medicine, Haukeland University Hospital, Bergen, Norway
Professor II, Faculty of Medicine, University of Bergen

Email: torunn.oveland.apelseth@helse-bergen.no

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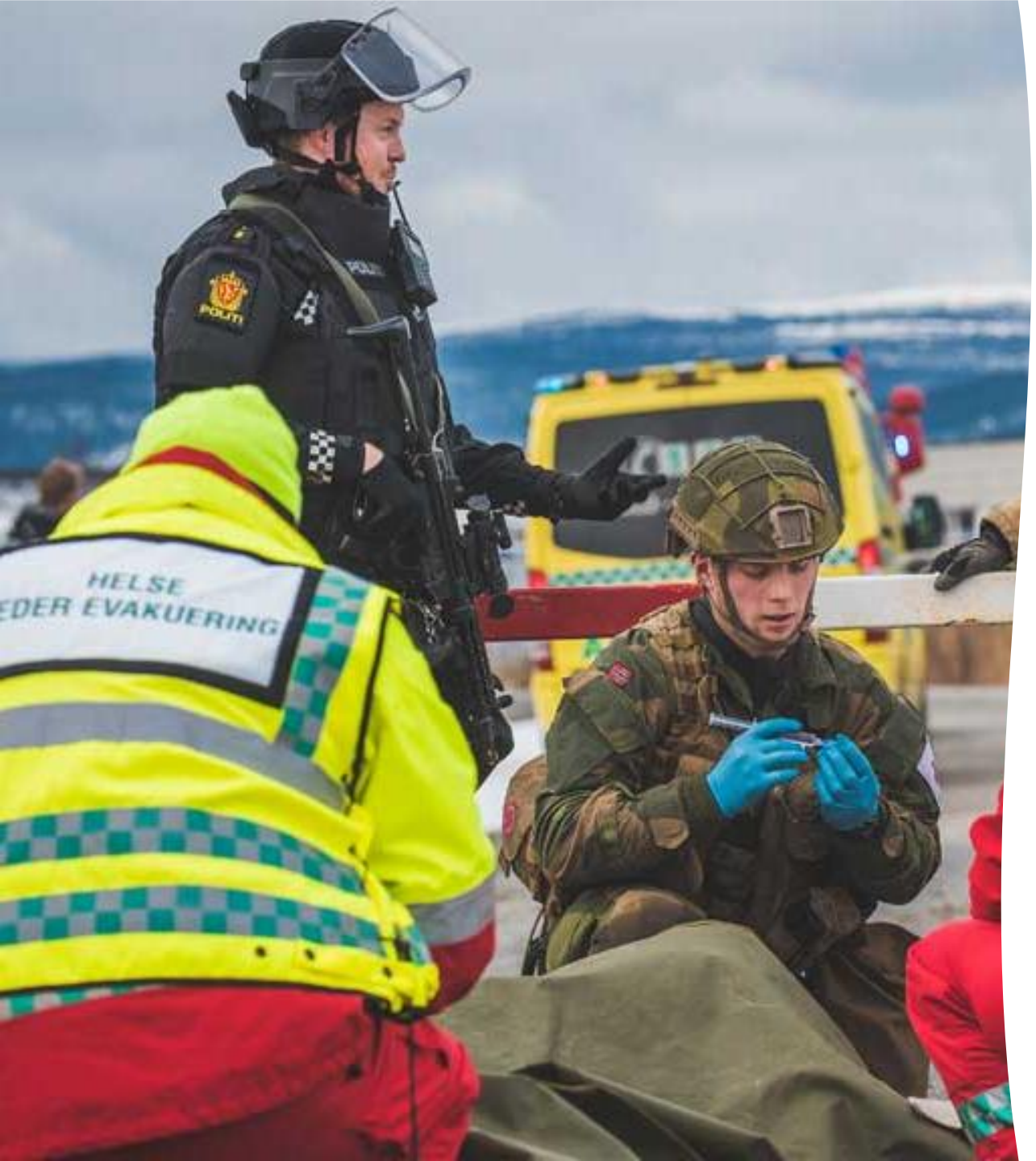
No disclosures

I have no conflict of interest in relation to this presentation.

The opinions expressed in this presentation are my personal views and not to be seen as the official view of the Norwegian Armed Forces or the Norwegian Ministry of Health.



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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

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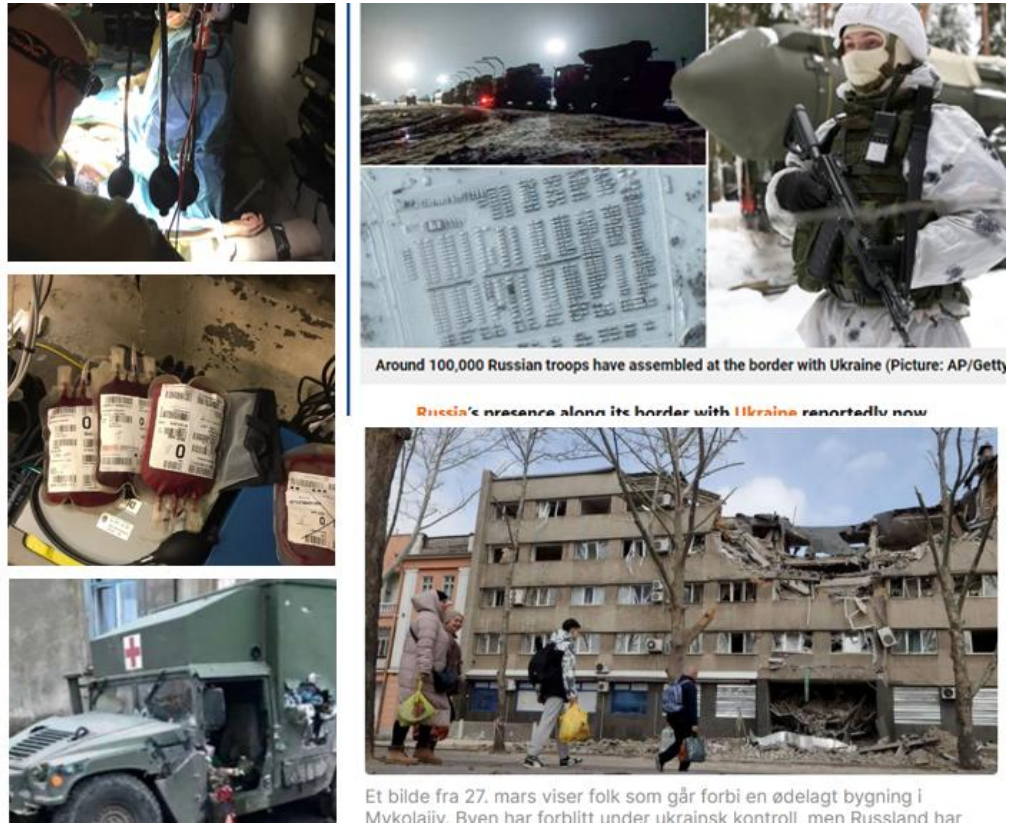
Blood supply continency and emergency preparedness = systems to ensure blood preparedness for all patients in peacetime, crisis and war



Delayed transfusion can result in death of the patient

Received: 14 February 2026 | Revised: 15 April 2026 | Accepted: 17 April 2026
DOI: 10.1111/vox.70279

SHORT REPORT

Vox Sanguinis ISBT International Society of Blood Transfusion

Life, death and rapid diagnostic tests in the world's blood deserts

Avery A. Thompson[1,2] | Samir C. Seshadri[1,3] | Cindy Makanga[4] | Riya Sawhney[1] | Edward Mutebi[5] | Nick Mogaka[6] | Tecla Chelagat[4] | Linda S. Barnes[7] | Nakul Raykar[1,2]

[1]Department of Global Health and Social Medicine, Harvard Medical School Program in Global Surgery and Social Change, Boston, Massachusetts, USA
[2]Brigham and Women's Hospital Department of Surgery, Boston, Massachusetts, USA
[3]Boston Children's Hospital Department of Anesthesiology, Critical Care and Pain Medicine, Boston, Massachusetts, USA
[4]Strathmore University, Institute of Healthcare Management, Nairobi, Kenya
[5]Lodwar County Referral Hospital, Blood Transfusion Services, Lodwar, Kenya
[6]Lodwar County Referral Hospital, Lodwar, Kenya
[7]Linda S Barnes Consulting, Seattle, Washington, USA

Correspondence
Avery A. Thompson, 641 Huntington Ave, Boston, MA 02115, USA.
Email: athompson24@mgb.org

Present addresses
Avery A. Thompson, Riya Sawhney, and Nakul Raykar, 641 Huntington Avenue, Boston, Massachusetts 02115, USA; Cindy Makanga and Tecla Chelagat, Ole Sangale Road, P.O. Box 59857-00200, Nairobi, Kenya; and Linda S. Barnes, 2247 Prescott Avenue, Seattle, Washington 98126, USA.

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Abstract

Background and Objectives: Millions of people globally reside in 'blood deserts', where systemic barriers prevent timely access to safe blood components. Lodwar County Referral Hospital (LCRH) in Turkana County, Kenya, is a district hospital lacking on-site testing capacity for transfusion-transmissible infection (TTI) screening, resulting in critical transfusion delays. We present three cases in which validated rapid diagnostic tests (RDTs) could have facilitated point-of-care donor screening and transfusion in life-threatening situations.

Patients and Methods: We present three cases of critically ill patients—two teenagers and an elderly woman—who presented to LCRH over the course of a single week.

Results: Each patient required emergent transfusions but experienced fatal delays along various points in the transfusion continuum due to the inability to rapidly screen available donor or banked blood for TTIs.

Conclusion: These cases illustrate how delays in TTI screening can directly contribute to preventable mortality, even when blood is otherwise available. They highlight the urgent need for standardized, contextually appropriate emergency transfusion protocols that formally incorporate RDT use. Our experience suggests that such protocols may reduce transfusion delays, improve access to lifesaving blood and serve as a scalable model for improving blood access in rural and remote 'blood deserts' around the world.

Keywords
blood transfusion, global health, Kenya, rapid diagnostic tests, sub-Saharan Africa, transfusion-transmissible infections

11 Delayed Transfusions n=312

Authors: Josephine McCullagh, Paula Bolton-Maggs and Vera Rosa

Headline data 2024

Number of reports n=312
Deaths n=18
Major morbidity n=12

Delayed transfusion reports by year

Demographic data

Male n=132
Female n=179
Adults n=282
Paediatric n=30
Unknown n=1

Blood component data

Red cells n=214
Platelets n=47
Fresh frozen plasma (FFP) n=9
Cryoprecipitate n=2
Solvent-detergent FFP n=1
Granulocytes n=1
Multiple components n=38

Key findings:

- There was a striking increase in the number of delays particularly in the laboratory
- There was an increase in the number of serious adverse patient outcomes
- Transfusion delays in major haemorrhage (MH) continue to rise

Gaps identified:

- Communication failures were the most frequently cited issue, affecting decision-making, blood component requests, and sample processing
- Lack of training, understaffing, and unfamiliarity with emergency protocols significantly impacted transfusion response times in both clinical and laboratory areas
- Failure to effectively implement major haemorrhage protocols (MHP)
- Many delays resulted from failure to identify and escalate cases early, leading to late transfusion initiation

Good practice:

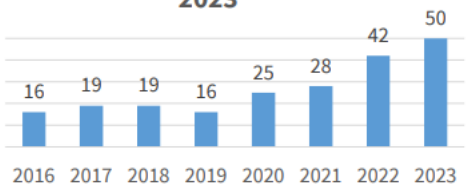
- Increased levels of recognition of delays and reporting of such events
- Improved staff awareness
- Increasing recognition of causal and contributory factors that can help improve safety

SHOT Bite No. 8
Massive haemorrhage – delayed transfusion

SHOT Serious Hazards of Transfusion
February 2025

The number of reports of transfusion delays with patient harm, including in major haemorrhage (MH), are increasing every year (Figure 1). Common themes include poor communication, gaps in knowledge and failure to activate or follow the major haemorrhage protocol (MHP) correctly.

Figure 1:MHP Delays 2016-2023



215 MHP related delays reported from 2016-2023. Of these, 22 resulted in patient death and 20 in major morbidity

Between 2016-2023, delays were reported in 52 obstetric and 12 paediatric cases

Poor communication is a leading cause of transfusion delays

Contributing factors

Recognition and unfamiliarity
Difficulty in detecting MH, particularly in gastrointestinal bleeding or leaking abdominal aortic aneurysms. Staff experience in managing MH may be limited where it occurs only rarely. Anticoagulants exacerbate the severity of bleeding. Obstetric haemorrhage can be rapid and massive

MHP activation
Delays in activation, incorrect activation and lack of knowledge of MHP activation are all contributing factors to delays

Patient movement and location
Patients transferring between clinical areas can result in delays when there is poor communication between staff about the patient's location. This impacts on delivery of samples to and components from the laboratory

Laboratory delays
Correctly labelled samples ensure that laboratory staff can release group-specific or crossmatched components for delivery to the clinical area - mislabelled samples will slow this process

Venous access
Blood transfusion can be delayed by poor or inadequate venous access

Stand down
Poor communication between clinical area and laboratory teams during stand down can delay other laboratory work which might have been put on hold

https://www.shotuk.org/wp-content/uploads/2025/07/11.-Delayed-Transfusions-2024.pdf
https://www.shotuk.org/wp-content/uploads/2025/10/SHOT-Bite-No.-08-Massive-haemorrhage-delayed-transfusion-February-2025.pdf

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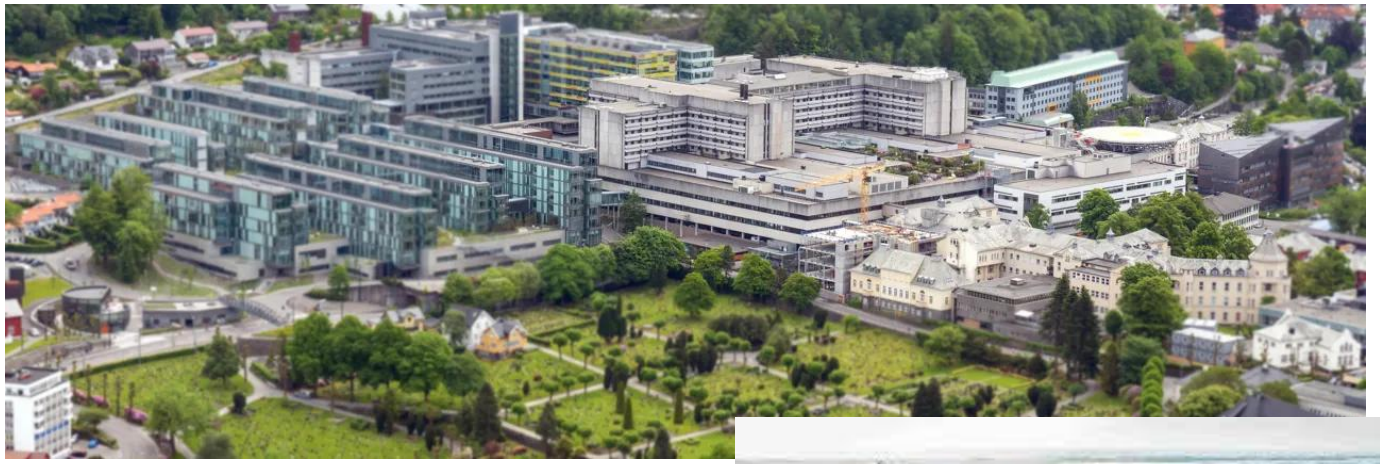
What is perceived as a crisis depends on where you are and the resources you have at your disposal



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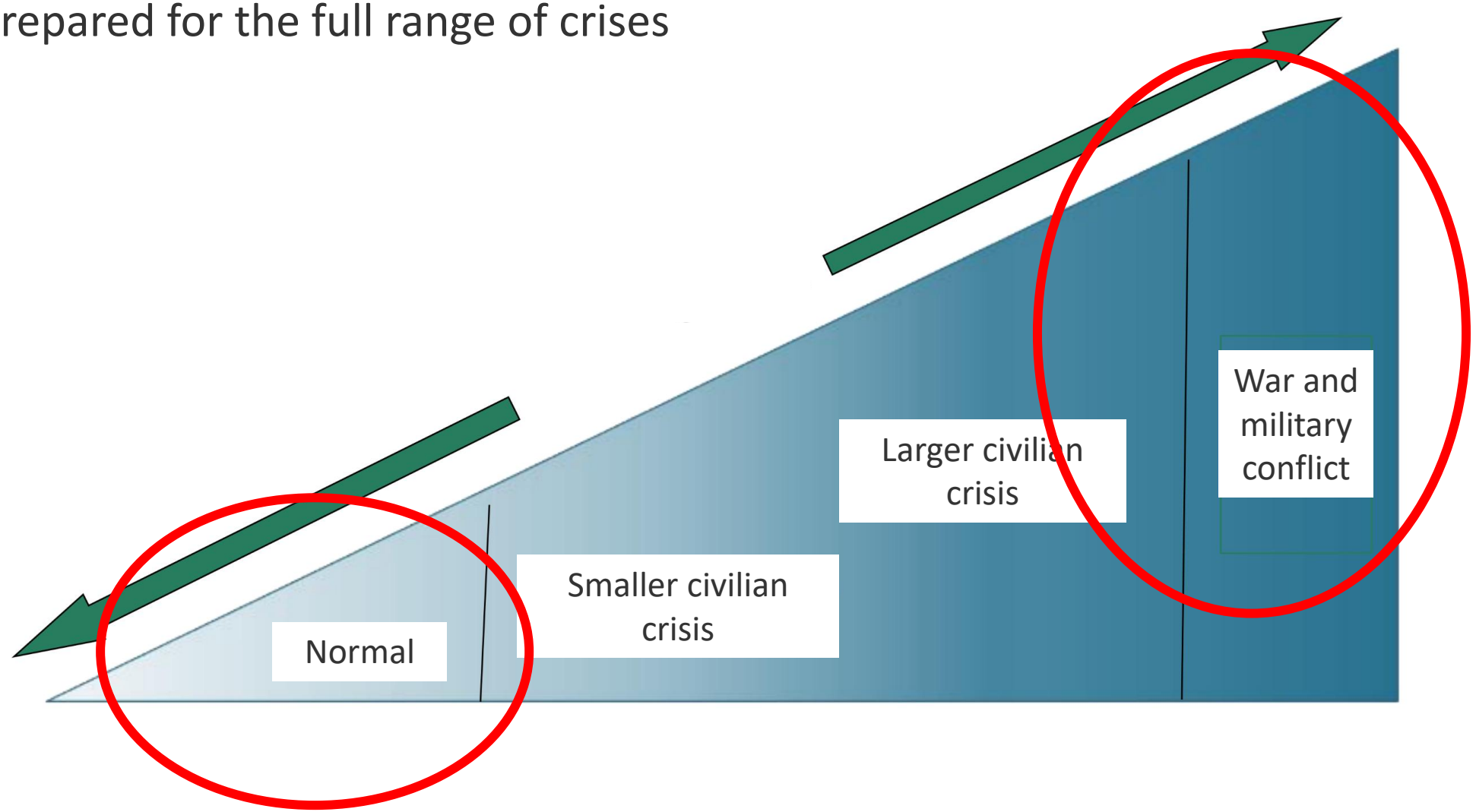
Prepared for the full range of crises



BLOOD D.E.S.E.R.T COALITION

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The Coalition define blood deserts as a “geographical region where essential clinical demand for blood components cannot be met at the point of care in a timely and affordable manner, in at least 75% of cases.”

Blood deserts exist all over the world, largely in rural areas that are distant from healthcare facilities. Every single country in sub–Saharan Africa and South Asia has blood deserts.

https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(23)00564-8/fulltext


ALPHA

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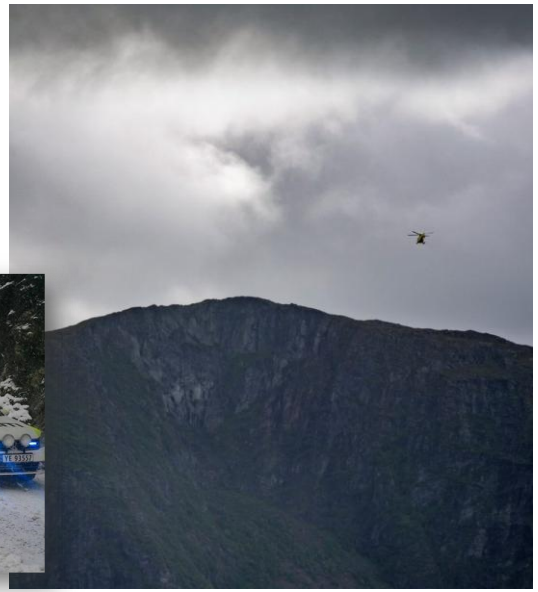
Norway

- Population: 5.4 million
- Size: 385, 000 km^2
- Fjords, mountains and scattered populations.
- Larger cities mainly in the southern part
- Long distances between Level 1 trauma centers. Many small rural hospitals with limited recourses



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Blood services in Norway

Decentralized system

- Individual hospital-based blood services (N=30)
- Blood collections, blood component production and issue of blood performed in all hospitals
- Viral testing performed in large hospitals

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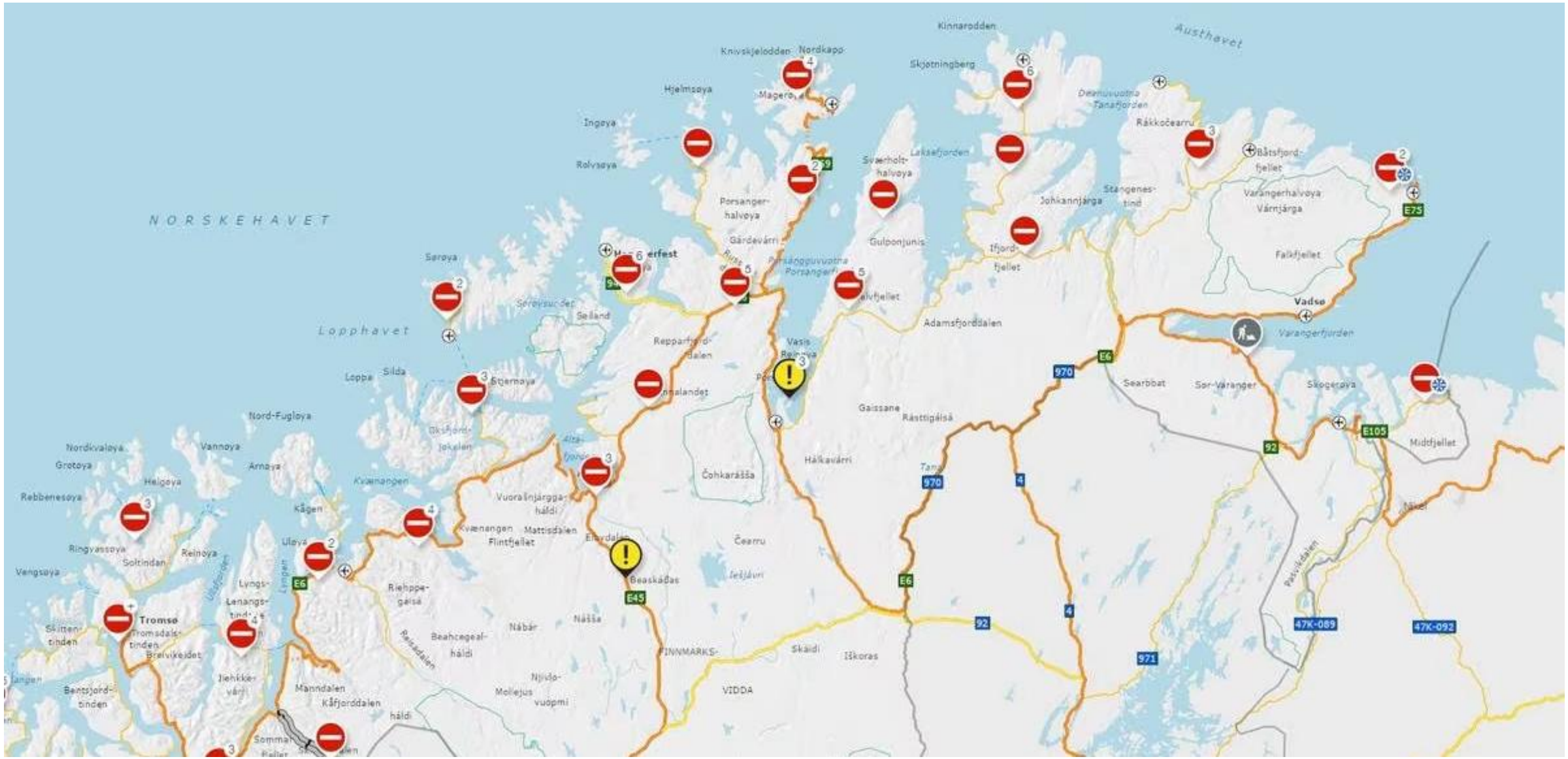
https://www.vegvesen.no/trafikk



How large-scale crisis and war affect the supply and demand of blood

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1. Pasient population and blood usage
   - More patients with severe bleeding due to traumas. Special needs (burn injuries and nuclear events) adds upon non-war related blood needs
   - Increased need for all types of blood products, but especially balanced transfusion
2. Limited access to equipment
   - Blood bags and infusion sets
   - Reagents for testing
3. Location
   - Prehospital transfusions increased
   - Challenging logistics
     - Equipment for transport and prehospital storage of blood
4. Infrastructure
   - Hospitals and Blood Services under attack: need for alternative production facilities
   - Plan for collection, testing and production with no electricity, IT, or water
5. Access to donors and personell
   - Alternativ collection sites, mobile blood drives
   - Civilian population on the move/evacuated
   - Communication hampered/unsafe

Scenarios where banked blood may be or become unavailable…

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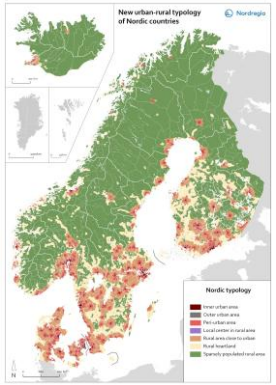
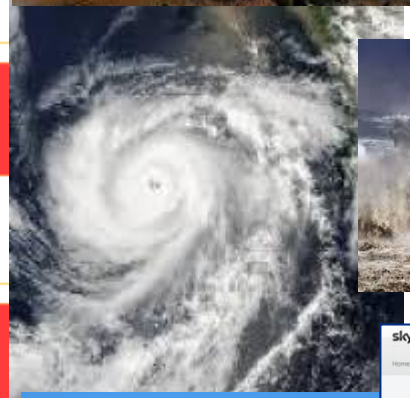
Delayed patient transport

- Remote areas
- Military operations and war
- Industry



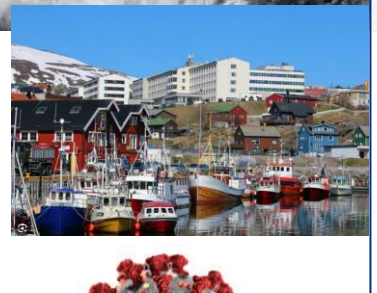
Large scale events

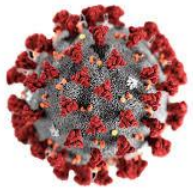
- Natural or man-made disasters

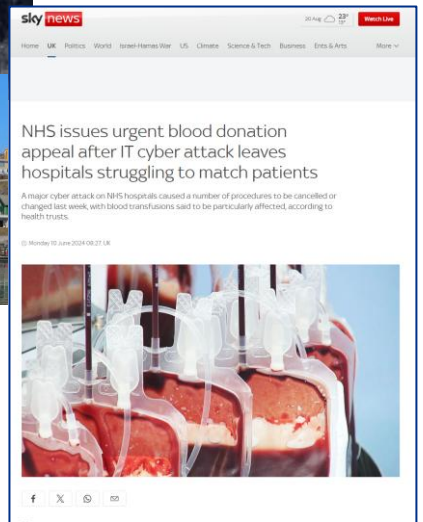


Reduced availability

- Rural hospitals with limited inventory of blood
- Pandemics
- Cyberattacks
- Military attacks on blood services







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«Sorry, we’re sold out»

So, what do we do?

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DOI: 10.1111/vox.70242

Vox Sanguinis ISBT International Society of Blood Transfusion

REVIEW

Blood supply continuity and emergency preparedness in natural and man-made disasters and in armed conflicts—The Nordic perspectives

Agneta Wikman[1,2,3] | Christian Medby[4,5] | Denise Bäckström[6,7] | Jarkko Ihalainen[8] | Markus Lyyra[9] | Patrik Nimberger-Hansson[3,10] | Geir Strandenes[11] | Jouni Lauronen[8] | Torunn Apelseth[11,12,13]

[1]Department of Clinical Immunology and Transfusion Medicine, Karolinska University Hospital, Stockholm, Sweden
[2]Department of Medicine Huddinge, Karolinska Institutet, Stockholm, Sweden
[3]Swedish Armed Forces, Stockholm, Sweden
[4]Norwegian Armed Forces Joint Medical Services, Sessvollmoen, Norway
[5]Department of Trauma, St. Olavs University Hospital, Trondheim, Norway
[6]Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden
[7]Department of Leadership and Command & Control, Swedish Defence University, Karlstad, Sweden
[8]Finnish Red Cross Blood Service, Vantaa, Finland
[9]Centre for Military Medicine, Finnish Defense Forces, Helsinki, Finland
[10]Department of Anaesthesiology and Intensive Care, Linköping University Hospital, Linköping, Sweden
[11]Norwegian Centre for Blood Preparedness, Bergen, Norway
[12]Department of Immunology and Transfusion Medicine, Haukeland University Hospital, Bergen, Norway
[13]Department of Clinical Science, Faculty of Medicine, University of Bergen, Bergen, Norway

Correspondence
Agneta Wikman, Clinical Immunology and Transfusion Medicine, Karolinska University Hospital, 143 46 Stockholm, Sweden.
Email: agneta.wikman@ki.se

Abstract

Recent events have highlighted the urgent need for comprehensive blood preparedness plans at local, regional, national and cross-border levels within the Nordic countries. This article outlines the perspectives and strategies related to blood preparedness in Norway, Sweden and Finland, in the context of emergencies, disasters and armed conflicts. Norway, Sweden and Finland share long borders and similar geography, including vast rural areas with limited health care resources. Finland operates a centralized blood service, whereas Norway and Sweden maintain decentralized systems, with regional authorities responsible for their own blood supply. All three countries adhere to a total defence concept, wherein military forces depend on civilian transfusion services. In mass casualty events, the demand for transfusion services to provide urgent blood and blood components is expected to be high. Haemorrhage remains the leading cause of preventable prehospital death in trauma cases, and the availability of blood products in prehospital settings is critical in both civilian and military environments. Key priorities identified include: establishing stockpiles of shelf-stable blood products, developing surge capacity plans for rapid upscaling of blood collection and whole blood and component production, conducting joint training and exercises involving blood establishments, transfusion services, hospitals and military units, and collaboration in a pilot cross-border initiative—the *Nordic Blood Preparedness Project*—in northern Norway, Sweden and Finland, aimed at harmonizing regulations and procedures during emergencies. To effectively save lives during disasters and armed conflicts, it is essential to have well-documented and operational blood preparedness plans in place.

Keywords
blood preparedness, blood supply, disasters, emergencies, war

TABLE 1 Needs and activities of blood preparedness (Substances of Human Origin Regulation European Union [EU] 2024/1689, articles 63-67).

Needs	Activities	Responsible
Timely available blood products in bleeding situations	• Implement guidelines of required blood inventory, including dried and thawed plasma and platelets (room temperature, cold-stored, cryopreserved).	Authorities, regions, hospital boards, blood bank boards
Surge plans	• Implement surge plan guidelines in blood banks and hospitals. • Establish emergency whole blood collection in hospitals, remote locations and in military environment. • Implement guidelines of required stock of material and reagents.	Authorities, regions, hospital boards, blood bank boards, military commanders
Harmonized procedures nationally and across Nordic countries	• Implement harmonized procedures of emergency blood collection and testing. • Implement guidelines of emergency blood transfusions, including prehospital blood transfusions.	Authorities, regions, hospital boards, blood bank boards
Formal agreements	• Establish formal agreements for emergency blood support between regions and nations.	Authorities, regions, hospital boards, blood bank boards
Labelling/bar codes	• Implement procedures for importing blood products in emergencies with new or unknown product codes.	Blood bank boards
Exemptions in emergencies	• Harmonize and document permissible exemptions under SoHO art. 62-67 (e.g., virus testing, non-leucocyte depleted blood, transfusion of RhD positive red blood cells to females of childbearing age).	Authorities
Training and exercises	• Conduct regular training on emergency routines in blood banks. • Ensure annual participation of the blood banks in hospital emergency exercises. • Include blood supply planning and military-civilian cooperation in military exercises.	Blood bank boards Hospital boards Authorities and military commanders

Abbreviation: SoHO, Substances of Human Origin.

https://onlinelibrary.wiley.com/doi/epdf/10.1111/vox.70242

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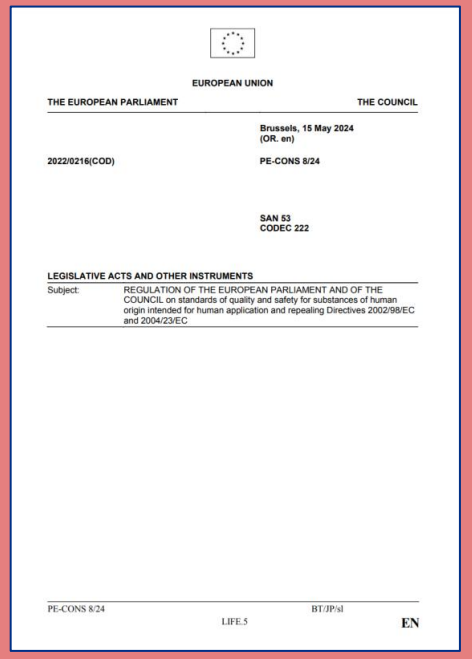
Regulatory requirements

"European Regulation on standards of quality and safety for substances of human origin intended for human application (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

CHAPTER VIII

SUPPLY CONTINUITY

European Commission

Article 62

Establishment of national SoHO emergency plans

1. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO emergency plans setting out measures to be applied without undue delay when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health.

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.

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

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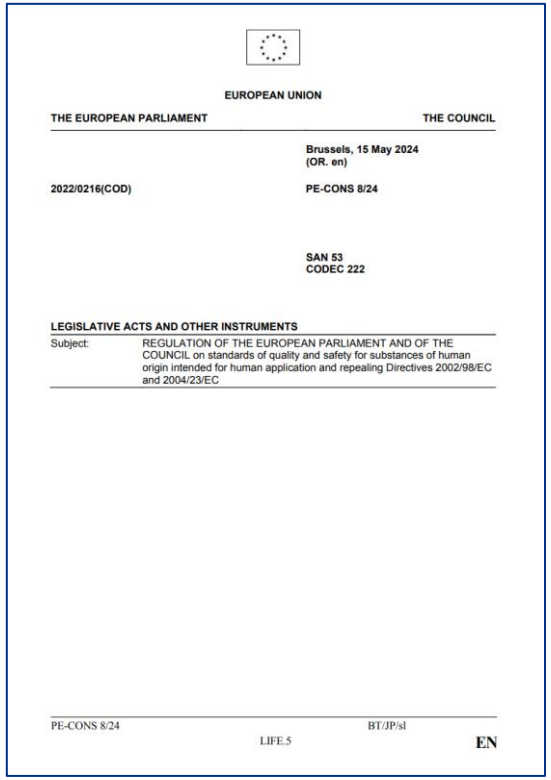
Derogations in health emergencies



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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

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And war

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.

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

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To be able to supply blood when banked blood are unavailable, we must balance:

- Rapid upscaling of high-volume production of blood
- Collection of blood outside hospitals and/or blood services (i.e. no lab)
- Product must have a level of quality and safety that is acceptable
- Used for immediate transfusion

Avoid doing harm!

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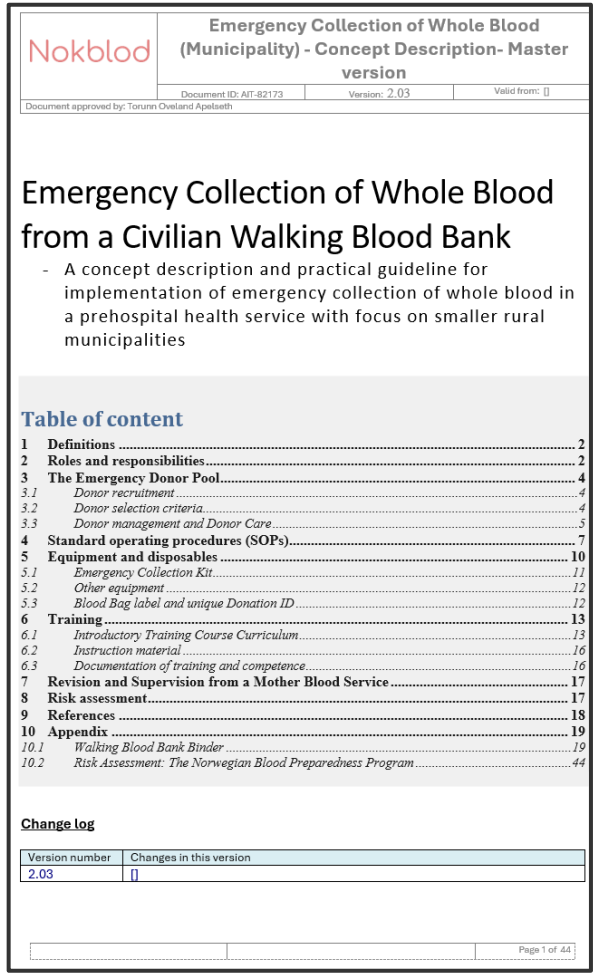
What is the best way to save most?
What is good enough?
How does one measure “good enough”?
What is the best I can do in this scenario?
How do I prepare for not having the resources that I have made myself dependent on?

Emergency collection of whole blood



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Emergency Collection of Whole Blood (Municipality) - Concept Description- Master version

Document ID: AIT-82173 | Version: 2.03 | Valid from: []

Document approved by: Torunn Oveland Apelseth

Emergency Collection of Whole Blood from a Civilian Walking Blood Bank

- A concept description and practical guideline for implementation of emergency collection of whole blood in a prehospital health service with focus on smaller rural municipalities

Table of content

Change log

Version number	Changes in this version
2.03	[]

Page 1 of 44

Emergency Donors

Trained phlebotomists

Procedures and routines

Training and exercises

Equipment

Regulatory approval

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Preselected Emergency Donor Pool (EDP)

Unpaid volunteer donors

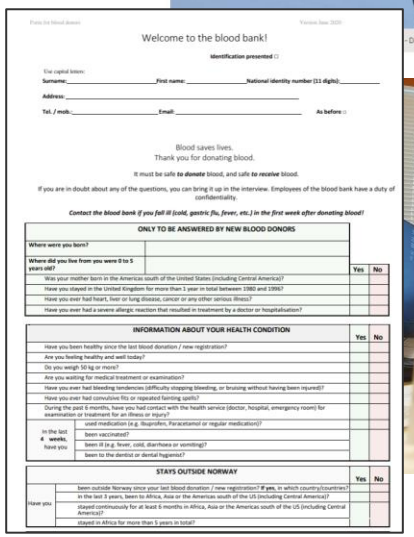
- Approved by the same criteria as ordinary Blood Donors in Norway
- Low titer group O blood donor
- National donor questionnaire

Emergency Donor Pool Donor care

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


PILOTKOMMUNE BLODBANKEN HELSE NORD

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


Welcome to the blood bank!

Identification presented

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

INFORMATION ABOUT YOUR HEALTH CONDITION

STAYS OUTSIDE NORWAY


Altaposten

ONSDAG

din lokale mediekanal

Akutt hjelp fra vandrende blodbanker

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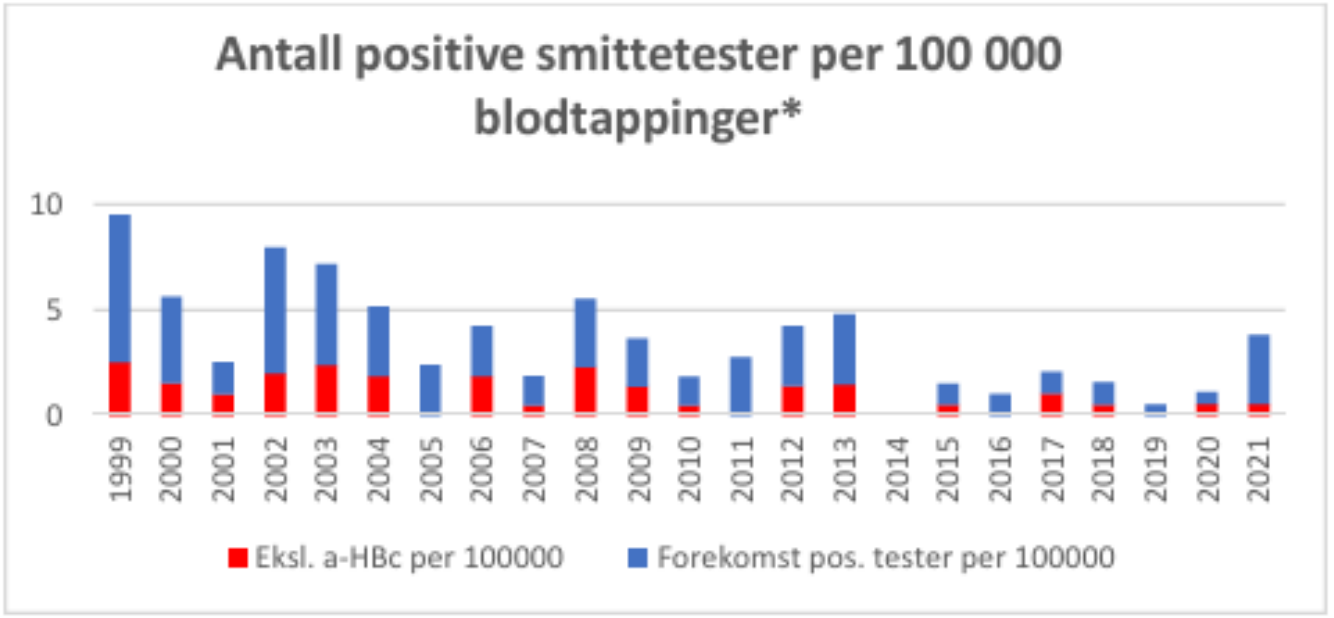
Risk reduction strategies

- Preselected donor pool interviewed and tested within 6 months prior to donation
- Donor questionnaire and interview in relation to donation
- Donor self exclusion
- Transparency: public information and end user training
- Hemovigilance
- Regulatory approval and supervision



Forekomst av positive smittetester per 1 000 000 blodtappinger fra 2014-2021:

Totalt	11,00
Totalt uten a-HBc	4,52
HBV*	2,71
HCV	1,56
HIV	1,94
Syfilis**	1,29

**Forekomst av mulig HBV-smitteførende enheter ved positive anti-HBc beregnet ut av estimering at antall tester utført er lik totalt antall tester delt med 2.1 (gjennomsnittlig frekvens for tapping per år). Tilgjengelige litteratur 20% av disse kan være smitteførende (se referanser)*

***Forekomst av mulig smitteførende blodenheter for syfilis beregnet ut av estimering at antall tester utført er lik totalt antall tester delt med 2.1 (gjennomsnittlig frekvens for tapping per år)*

Rapid testing

Transfusion Medicine Reviews 29 (2015) 35–44

Contents lists available at ScienceDirect

Transfusion Medicine Reviews

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The Use of Rapid Diagnostic Tests for Transfusion Infectious Screening in Africa: A Literature Review

Cristina R. Pruett [a,*], Marion Vermeulen [b], Pete Zacharias [c], Charlotte Ingram [b], Claude Tayou Tagny [c], Evan M. Bloch [d,a]

[a] University of California San Francisco, San Francisco, CA
[b] South African National Blood Service, Johannesburg, South Africa
[c] Safe Blood for Africa Foundation, Washington, DC
[d] Blood Systems Research Institute, San Francisco, CA

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ABSTRACT

Infectious risk associated with blood transfusion remains a major public health challenge in Africa, where prevalence rates of the major transfusion-transmissible infections (ie, hepatitis B, hepatitis C, human immunodeficiency virus, and syphilis) are among the highest in the world. Resource-limited blood services often operate with minimal predonation screening safeguards, prompting exclusive reliance on laboratory testing to mitigate infectious risk. Transfusion screening with rapid diagnostic tests (RDTs) has been adopted in areas that lack the capacity to support the routine use of more sophisticated technologies. However, uncertainty surrounding the performance of some RDTs in the field has spurred debate regarding their application to blood donation screening. Our review of the literature identified 17 studies that evaluated RDTs for the infectious screening of blood donors in Africa. The review highlights the variable performance of available RDTs and the importance of their use in a quality-assured manner. Deficiencies in performance observed with some RDTs underscore the need to validate test kits prior to use under field conditions with locally acquired samples. Suboptimal sensitivities of some available tests, specifically hepatitis B virus rapid assays, question their suitability in single-test algorithms, particularly in high-prevalence regions. Although RDTs have limitations, many of which can be addressed through improved training and quality systems, they are frequently the only viable option for infectious screening in resource-poor African countries. Therefore, additional studies and specific guidelines regarding the use of RDTs in the context of blood safety are needed.

Contents

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* Corresponding author at: Cristina R. Pruett, MS, Department of Global Health Sciences, University of California, San Francisco, Mission Hall: Global Health & Clinical Sciences Building, 550 16th St, San Francisco, CA 94143-1224.
E-mail address: cristina.pruett@ucsf.edu (C.R. Pruett).

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Conclusion

The risks and benefits of RDTs in transfusion screening in Africa seem similarly weighted leaving uncertainty as to their role. However, in some settings, RDTs may well be the only realistic option for testing with use borne by necessity rather than choice. Rapid diagnostic tests have a number of advantages, presenting an affordable option for blood safety where conventional laboratory testing remains unfeasible. However, the effectiveness of RDTs in the field is dependent on test quality and conditions of use. Studies evaluating their use in transfusion screening in Africa highlight the variability in performance, specifically those for HBV and HCV. Nevertheless, until more advanced screening or inactivation technologies are achievable, RDTs should be used in an informed and quality-assured manner to improve the safety of the regions blood supply. Ultimately, resource-constrained countries should continue to strive for the development of national transfusion services and low-risk donor recruitment networks to support safe and reliable blood systems.

Table 2
Characteristics of studies included in the review

Reference	Country	Product name	Target agent	Comparison assay(s)	Reference/ Confirmation assay(s)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Cost (USdollars)
[88]	Tanzania	Determine HIV 1/2 (Inverness Medical Japan Co. Ltd., Tokyo, Japan)	HIV-1/HIV-2		Immunoblot	100.0	99.6			0.80
		SD Bioline (Standard Diagnostics Inc., Kyonggi-do, Korea)	HIV-1/HIV-2		WB	100.0	99.2			0.47
		Uni-Gold (Trinity Biotech, Wicklow, Ireland)	HIV-1/HIV-2		WB	100.0	100.0			1.80
		First Response (PMC Medical India Pvt. Ltd., Daman, India)	HIV-1/HIV-2		WB	91.7	99.6			0.65
		Stat-Pak Dipstick (Chembio Diagnostic System, Inc., Medford, NY)	HIV-1/HIV-2		WB	100.0	100.0			0.80-0.95
[67]	Cameroon	Camstix–HIV 1 + 2 (Camdiagnostix, Yaounde, Cameroon)	HIV-1/HIV-2 Ab	EIA	WB, NAT	100.0	98.3	(94.4, 91.5)[a]	(100, 100)[a]	1.50
		Determine HIV 1 + 2 + 0 (Abbott Laboratories, Tokyo, Japan)	HIV-1/HIV-2 Ab	EIA	WB, NAT	100.0	98.3	(94.4, 91.5)[a]	(100, 100)[a]	2.50
		Genie II HIV-1/HIV-2 (Bio-Rad, Marnes la Coquette, France)	HIV-1/HIV-2 Ab	EIA	WB, NAT	98.9	100.0	(100, 100)[a]	(99.3, 99.3)[a]	4.00
		ImmunoComb II HIV 1/2 BiSpot (Orgenics, Yavne, Israel)	HIV-1/HIV-2 Ab	EIA	WB, NAT	99.3	99.5	(98.1, 97.5)[a]	(99.6, 99.6)[a]	3.70
[90]	Ethiopia	Determine HIV 1/2 (Abbott, Tokyo, Japan)	HIV-1/HIV-2 Ab	EIA	WB	60.5	98.9	88.5	94.9	
[66]	Cameroon	Determine HIV 1/2 (Determine HIV-1/-2, Inverness Medical France, Courbevoie, France)	HIV-1/HIV-2 Ab	EIA, HIV Ag/Ab	WB, NAT	79.2	99.1	71.2	99.4	
[86]	Uganda									
		Uni-Gold Recombigen HIV (Trinity Biotech, Wicklow, Ireland)	HIV-1 Ab	EIA	N/A	100.0	99.1	55.6	100	
		HIV 1/2 STAT-PAK (Chembio, Medford, NY)	HIV-1/HIV-2 Ab	EIA	N/A	100.0	99.6	76.9	100	
		Determine HIV 1/2 (Abbott, Tokyo, Japan)	HIV-1/HIV-2 Ab	EIA	N/A	100.0	96.2	22.2	100	
		OraQuick HIV-1 (Orasure, Bethlehem, PA; assembled in Thailand)	HIV-1 Ab	EIA	N/A	100.0	99.8	83.3	100	
[109]	Zambia	HIV-spot (non-expired)[b] (Diagnostic Biotechnology Ltd., Singapore, Singapore)	HIV-1/HIV-2 Ab		EIA/ Immunoblot	91.7	98.8	90.9	98.9	
[93]	Egypt[c]	ADVANCED QUALITY ONE STEP TEST (Intec Products, Fujian, China)	Anti-HBs		EIA	64.2	95.1	71.23	93.33	
		ADVANCED QUALITY ONE STEP TEST (Intec Products, Fujian, China)	Anti-HBc		EIA	85.5	98.4	94.64	95.45	
		ADVANCED QUALITY ONE STEP TEST (Intec Products, Fujian, China)	Anti-HBe		EIA	82.8	100.0	100	98.97	
[92]	Ghana	Latex agglutination (VEDAlab) (VEDAlab, Alençon, France)	HBsAg		EIA, NAT	53.8	97.0			
		Dipstick assay (VEDAlab) (VEDAlab, Alençon, France)	HBsAg		EIA, NAT	71.0	99.4			
[95]	Egypt	ImmunoComb II HCV (Inverness Medical Innovations, Waltham, MA)	Anti-HCV	EIA	NAT	97.0	78.5	70.8	98.1	
		HCV one-step (ACON Laboratories, San Diego, CA)	Anti-HCV	EIA	NAT	97.0	77.0	69.4	98.0	
		HCV TRI-DOT (J. Mitra, New Delhi, India)	Anti-HCV	EIA	NAT	97.0	77.0	69.4	98.0	
[96]	Cameroon	HCV rapid test (Human Diagnostics, Berlin, Germany)	Anti-HCV	Ag/Ab assay	Immunoblot, NAT	70.3	99.4			
[85]	Zimbabwe	HCV-SPOT (Genelabs Diagnostics, Singapore, Singapore)	anti-HCV	EIA	EIA	N/A	97.0			4.00
		SimpliRED HBsAg (AGEN, Brisbane, Australia)	HBsAg	EIA	N/A	93.3	100.0			1.50
		Dipstick-HBsAg (PATH, Seattle, WA/ Immuno-Chemical Laboratories, Bangkok-RIA)	HBsAg	EIA	N/A	93.3	100.0			0.64
[89]	Ghana									
		HBsAg Rapid test (Vedalab, Alençon, France)	HbsAg		EIA, NAT	93.0	99.0			0.80
		Anti-HCV (Intec, Hong Kong, PRC)	Anti-HCV		EIA, NAT	N/A	N/A			0.90
		Determine HIV-1/HIV-2 (Determine, Abbott Laboratories, Delkenheim, Germany)	HIV-1/HIV-2 Ab		EIA, NAT	N/A	N/A			
[91]	Mozambique	Determine HIV 1/2 (Abbott Laboratories, Chicago, IL)	HIV-1/HIV-2 Ab		RDT					
		Healtheasde HBsAg (Neomedic Ltd., Sea Cow Lake, South Africa)	HBsAg		EIA	98.6	80.4			
		AraGen RPR test (AraGen Biotech, Amman, Jordan)	Nontreponemal Ab		TPPA	100.0	98.8			
		SD Bioline HCV (Standard Diagnostics, Kyonggi-do, Korea)	Anti-HCV		EIA	100.0	99.1			

(continued on next page)

Table 2 (continued)

[87]	6 sub-Saharan African blood centers	Determine HIV-1/HIV-2 (Abbot)	HIV-1/HIV-2 Ab	EIA	100.0	94.0
		ImmunoComb II Trispot (Orgenics, in association with Genedia)	HIV-1/HIV-2 Ab	EIA	86.0	100.0
		SD Bioline HBsAg (Standard Diagnostics, Suwon, Korea)	HBsAg	EIA	43.0	100.0
		Core HBsAg (Core Diagnostics, Birmingham, UK)	HBsAg	EIA	43.0	100.0
		SD HCV Multi (Bioline, Standard Diagnostics)	anti-HCV	EIA	100.0	74.0
		Hexagon HCV	anti-HCV	EIA	50.0	100.0
[8]	17 Francophone African countries	5 rapid HIV tests[d]	HIV-1/HIV-2 Ab	EIA	72.4[e]	99.5[e]
		10 rapid HbsAg tests[f]	HbsAg	EIA	47.4[e]	99.1[e]
		8 rapid HCV tests[g]	Anti-HCV	EIA	63.7[e]	97.4[e]
[100]	8 laboratory sites	Determine Syphilis TP (Abbot, Chicago, IL)	Anti-TP	TPPA, TPHA	97.2	94.1
		Syphilis Fast (DIESSE Diagnostica, Senese SpA, Milan, Italy)	Anti-TP	TPPA, TPHA	86.0	92.8
		Espline TP (Fujirebio Inc, Tokyo, Japan)	Anti-TP	TPPA, TPHA	97.7	93.4
		Syphicheck-WB (Qualpro Diagnostics, Goa, India)	Anti-TP	TPPA, TPHA	84.5	97.7
		SD Bioline Syphilis 3.0 (Standard Diagnostics, Inc, Kyunggi-do, Korea)	Anti-TP	TPPA, TPHA	95.0	94.9
		Visitext Syphilis (Omega Diagnostics Ltd, Scotland, UK)	Anti-TP	TPPA, TPHA	85.0	98.0
		Syphicheck-WB (new version) (Qualpro Diagnostics, Goa, India)	Anti-TP	TPPA, TPHA	95.3	93.7
		Bioline Syphilis 3.0 (Pacific Biotech Co, Ltd, Petchaboon, Thailand)	anti-TP	TPPA, TPHA	92.2	97.0
		Syphilisonsite[mmite] Rapid Screening Test (CTK Biotech, Inc., San Diego, CA)	Anti-TP	TPPA, TPHA	96.3	94.6
[104]	Sudan	Qurum ICT	*Plasmodium falciparum* Microscopy	PCR	66.7	94.9

Abbreviations: N/A or blank, not available or unknown; WB, Western blot; TP, *T pallidum*; TPPA, *T pallidum* particle agglutination assay; TPHA, *T pallidum* hemagglutination; PCR, polymerase chain reaction.

[a] First value based on the highest HIV prevalence reported in Cameroon, second value based on the lowest reported prevalence.
[b] Reagents and kits were stored outside the refrigerator at room temperature, varying from 18°C to 35°C.
[c] All donors were HBsAg negative.
[d] Determine HIV-1/HIV-2 (Abbot), ImmunoComb II HIV 1/2 Bispot (Orgenics), GENIE II HIV1/2 (Bio-Rad), SD Bioline HIV 1/2 Version 3.0 (SD Standard Diagnostics), Rapid 1-2-3 HEMA Express HIV (Hema Diagnostic Systems).
[e] Overall performance of rapid assays.
[f] One-step HBsAg test (AccuBio Tech), HEXAGON HBsAg(Human), Immunocomb II HBsAg (Orgenics), Determine HBsAg (Abbot), SD Bioline HBsAg (SD Standard Diagnostics), Rapid Signal HBsAg Dipstrip (Orgenics), HEP-CHECK-1 (Vedalab), One-step HBsAg test (Pistis), AgHBs STRIPS test (Taytec), One-step HBsAg test strip (Plamatec).
[g] Rapid anti-HCV test (AccuBio Tech), HCV TRI-DOT (J. Mitra & Co.), Hexagon HCV (Human), ImmunoComb II HCV (Orgenics), Rapid signal HCV Dipstrip (Orgenics), SD Bioline HCV(SD Standard Diagnostics), One-step HCV test (Pistis), CYPRESS anti-HCV (Cypress Diagnostics).

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- Variable performance
- Training and quality systems essential
- Additional studies and specific guidelines needed

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ORIGINAL RESEARCH

TRANSFUSION

The risk of transfusion transmissible infection in a civilian walking blood bank using rapid diagnostic tests: A modeling study

Neil Thivalapill[1,2] | Zhaohui Geng[3] | Nikathan Kumar[2,4,5] | Elizabeth Stoeger[6] | Nobhojit Roy[5,7] | Bopaya Bidanda[8] | Nakul Raykar[2,5,6]

[1]Department of Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
[2]Program in Global Surgery and Social Change, Harvard Medical School, Boston, Massachusetts, USA
[3]Department of Industrial and Systems Engineering, Ohio University, Athens, Ohio, USA
[4]Department of Surgery, University of California San Francisco, Oakland, California, USA
[5]The Blood D.E.S.E.R.T. Coalition, Boston, Massachusetts, USA
[6]Brigham and Women's Hospital, Division of Trauma & Emergency Surgery, Center for Surgery and Public Health, Boston, Massachusetts, USA
[7]The George Institute New Delhi World Health Organization Collaborating Centre for Emergency, Critical, and Operative Care, New Delhi, India
[8]Department of Industrial Engineering, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

Correspondence
Nakul Raykar, 75 Francis St., Boston, MA 02115, USA.
Email: nraykar@bwh.harvard.edu

Abstract

Background: Civilian walking blood banks (WBBs) can transfuse fresh whole blood from mobilized donors who are screened using rapid diagnostic testing (RDT) for transfusion transmissible infections (TTIs) to preserve life when banked blood is unavailable. However, concerns regarding TTI risk using an RDT process instead of laboratory-based testing methods persist. We aimed to understand the additional risk of TTI using an RDT-based strategy compared to a laboratory-based strategy with a simulation model and accompanying online tool.

Study Design and Methods: We modeled expected TTIs per 100,000 donations from initial collection to transfusion and infection. Parameters included TTI prevalence, donor risk stratification, efficacy of stratification tools, TTI testing rates, platform test performance, and probability of infection.

Results: A baseline TTI prevalence of 1% (95% confidence interval [CI]: 0.25%, 1.75%) resulted in 56 TTIs (95% CI: 23, 91) when the RDT sensitivity was 90% (95% CI: 88%, 92%), 30 TTIs (95% CI: 12, 52) when the RDT sensitivity was 95% (95% CI: 93%, 97%), and 12 TTIs (95% CI: 4, 23) when the RDT sensitivity was 99% (95% CI: 97, 100%) per 100,000 donations. Compared to lab-based testing, 15,351 donations would need to be made under a high-sensitivity RDT testing strategy in order to incur one additional TTI.

Abbreviations: CD4, cluster of differentiation 4; CI, confidence interval; CMV, Cytomegalovirus; EBV, Epstein–Barr virus; EIA, enzyme immunoassay; HBV, hepatitis B virus; HIV, human immunodeficiency virus; HTLV, human T-lymphotropic virus; LB, lower bound; NAAT, nucleic acid amplification testing; NNH, number needed to harm; RDT, rapid diagnostic tests; TTI, transfusion transmissible infections; UB, upper bound; WBB, walking blood bank.

In conclusion, we emphasize that comparing RDT performance against an alternative of best-case scenario (EIA or NAAT) is ultimately a false comparison as risks for TTI transmission through an emergency WBB using RDTs should be compared against the actual alternative in that situation—no transfusion. The risk of TTI transmission through an RDT process, then, should be weighed against the risk of death from lack of transfusion as traditionally banked blood is *unavailable*.

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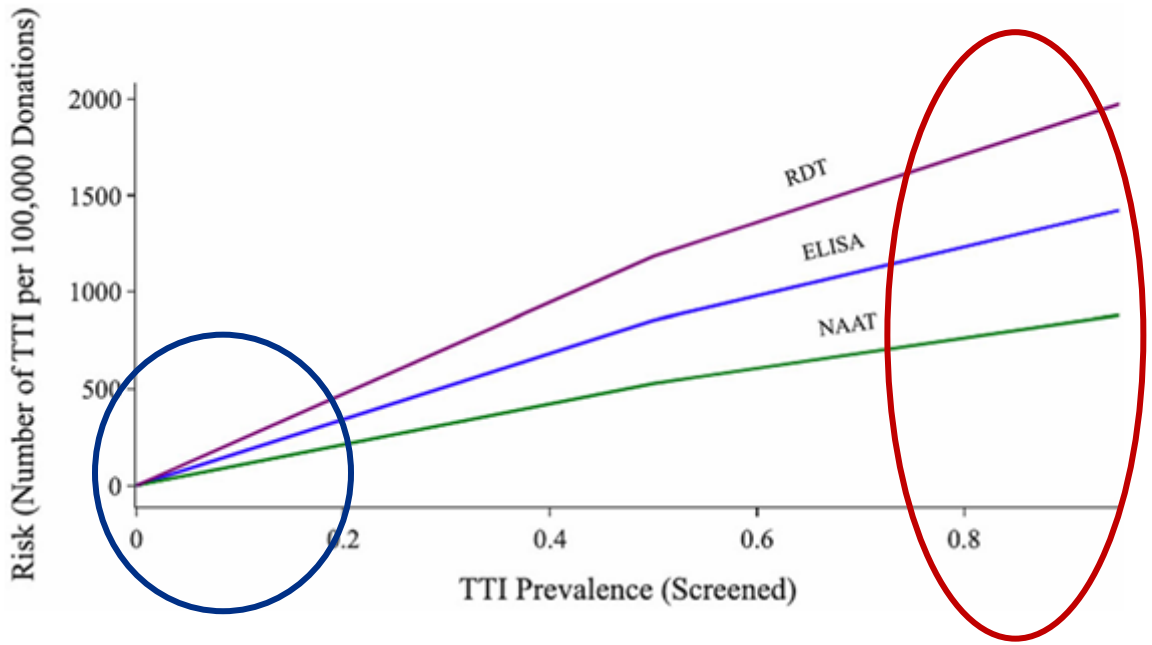

FIGURE 2 Transfusion transmissible infections (TTI) prevalence (among screened) versus TTI risk under a high rapid diagnostic testing (RDT) sensitivity strategy. ELISA, enzyme-linked immunoassay; NAAT, nucleic acid amplification test.

Discussion: In a simulated WBB model, modern RDT platforms demonstrated favorable test characteristics, with low absolute rates of TTI, particularly when low-risk donors are selected. These findings support WBB implementation as an emergency transfusion strategy in settings lacking banked blood.

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Conclusions:

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Transfusion preparedness is needed for the full range of crisis

Think «when» not «if»

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Russia-Ukraine war

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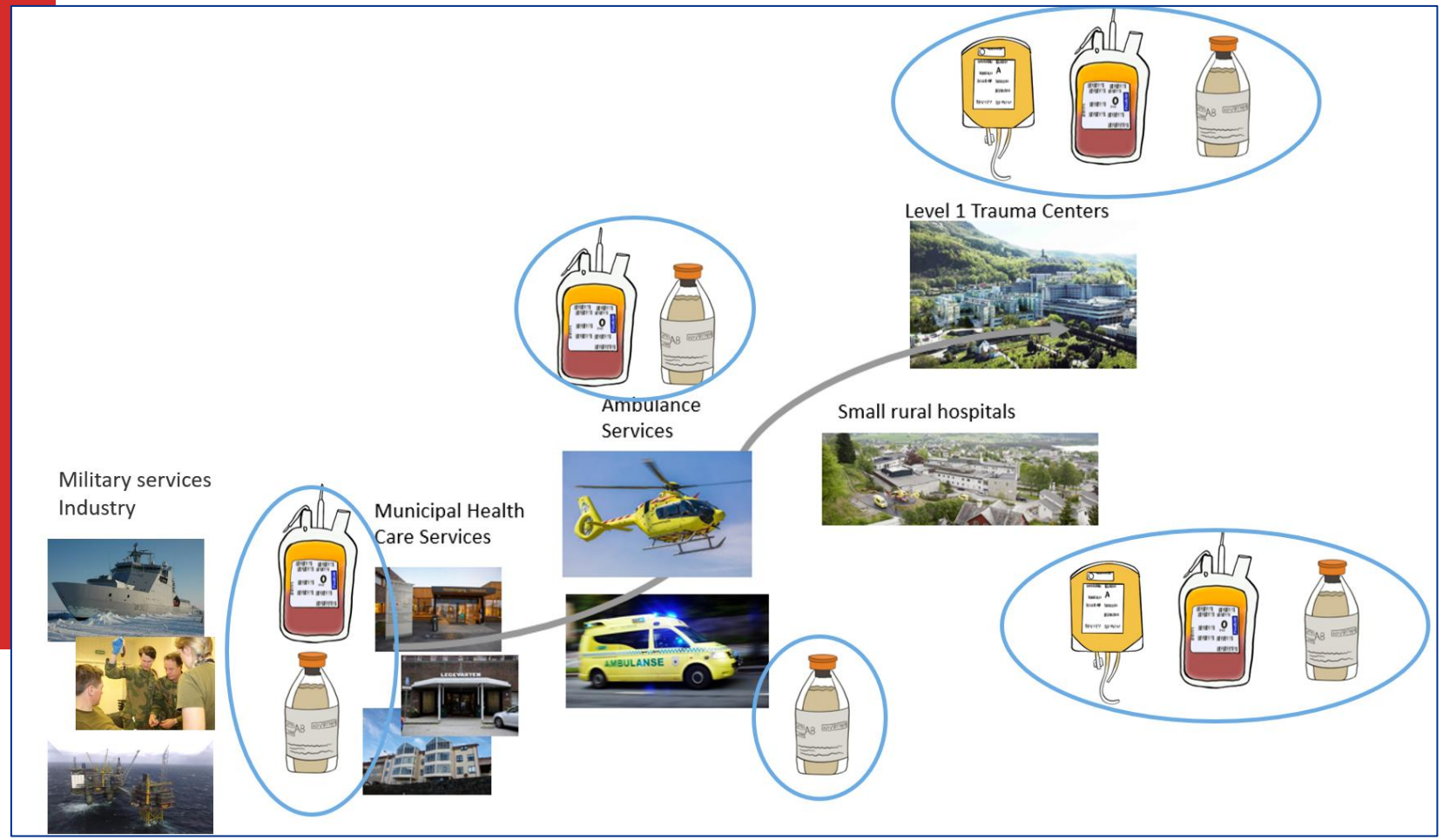

What do we do when banked blood is not available?

What is good enough?

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Thank you

E-mail: *torunn.oveland.apelseth@helse-bergen.no*

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