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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

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Abstract

Background: Civilian and military guidelines recommend early balanced transfusion to patients with life-threatening bleeding to improve survival. To provide the best care to patients with hemorrhagic shock in regions with reduced access to evacuation, blood preparedness must be ensured also on a municipal health care level. The primary aim of the Norwegian Blood Preparedness project is to enable rural hospitals, prehospital ambulance services, and municipal health care services to start early balanced blood transfusions for patients with life-threatening bleeding regardless of etiology.

Study Design and Methods: The project is designed based on three principles: (1) Early balanced transfusion should be provided for patients with life-threatening bleeding, (2) Management of an emergency requires a planned and rehearsed day-to-day system for blood preparedness, and (3) A decentralized system is needed to ensure local self-sufficiency in an emergency. We developed a system for education and training in blood-based resuscitation with a focus on the municipal health care service.

Results: In this publication, we describe the implementation of emergency whole blood collections from a preplanned civilian walking blood bank in the municipal health care service. This includes donor selection, whole blood collection, emergency transfusion and quality assessment of practice.

Conclusion: We conclude that implementation of a Whole Blood based emergency transfusion program is feasible on all health care levels and that a preplanned civilian walking blood bank should be considered in locations were prolonged transport-times may reduce access to blood transfusion for patients with life threatening bleeding.

KEYWORDS
arctic region, bleeding, blood preparedness, emergency blood transfusion, health care, prehospital transfusion, rural hospitals, transfusion management, walking blood bank, whole blood

1 | INTRODUCTION

Transfusion preparedness is an integrated part of the emergency health care planning and poses significant challenges to both isolated health care facilities and sophisticated modern health care systems.[1,2] In the process of establishing local, regional and national blood preparedness plans, one has to consider the magnitude of scenarios that might influence the ability to deliver optimal care to patients in need of life saving blood transfusion. Depending on the localization of the event, scenarios that may potentially challenge the availability of blood range from a single patient in hemorrhagic shock due to gastrointestinal (GI) bleed to mass casualty events and/or reduced access to blood as in the event of a pandemic.

International civilian and military guidelines recommend early balanced transfusion to patients with life-threatening bleeding.[1,3] The timing of transfusion is important. Hemorrhagic shock is a medical condition that needs to be addressed early based on the pathophysiology of the condition. Regardless of the etiology of bleeding (trauma, GI-bleed, obstetric bleeding or other nontraumatic causes of bleeding), if oxygen delivery (D02) falls below critical oxygen delivery (D02crit), initiating transfusion is crucial for survival and prevention of end organ damage.[4–8] The time taken to develop hemorrhagic shock may differ based on etiology and the patient's compensatory reserve. It is important to recognize that patients in hemorrhagic shock of other etiologies than trauma have an equal benefit of transfusion and that systems should be in place for management of all.

Low titer group O whole blood (LTOWB) are used for treatment of bleeding patients because it offers plasma, red cells and platelets in a balanced ratio in a logistical advantageous way.[9–14] Today, LTOWB is implemented in routine use for civilian and military prehospital air ambulance services, in a large trauma center, and in four local hospitals in Norway.[13,15,16–18] We have previously described our experience with whole blood based blood preparedness programs for a level 1 trauma hospital and for small rural hospitals with limited blood inventories.[16,18] However, bad weather conditions and long transport distances, especially in the Northern part of Norway, may limit access to emergency health care support and delay medical evacuation. Therefore, systems ensuring availability of blood transfusion for bleeding patients must also be considered on a municipal health care level to mitigate the negative effect of postponed medical interventions.

The term Walking Blood Bank (WBB) describes collection of whole blood for emergency use at the site of need.[19] The use of walking blood banks is not restricted to patients with bleeding due to trauma, but can be used for all causes of bleeding that require a balanced transfusion. Walking blood banks have been used with success in military medical services, for cruise liners, and in civilian hospital emergency preparedness plans in case of depletion of inventories.[5,13,16–18,20–24] In Norway, preplanned civilian walking blood banks have been established for the oil industry to be used in operations with long evacuation time. In case of bleeding, health care personnel on site are trained to collect and transfuse WB from prescreened fellow workers.

The Norwegian Blood Preparedness Project is a civilian military collaborative program aiming to develop and implement a system that enables blood transfusion for bleeding patients in all health care levels. It is based on the following three principles: (1) Early balanced transfusion should be provided for patients with life-threatening bleeding, (2) Management of an emergency requires a planned and rehearsed day-to-day system for blood preparedness, and (3) A decentralized system for obtaining blood and blood components is needed to ensure local self-sufficiency in an emergency.

In this manuscript, we present the results of the development phase of the program with a special emphasis on the municipal health care service. We present our experience from the implementation of emergency whole blood collections from a preplanned municipal based civilian WBB and discuss strategies and routines for ensuring a safe and effective transfusion for patients with life threatening bleeding in rural health care service.

2 | MATERIALS AND METHODS

2.1 | Study design and objectives

In 2020, the Norwegian Ministry of Health and Care Services commissioned the Northern Norway Regional

Health Authority, Helse Nord RF, to pilot a Blood Preparedness Project aiming to ensure adequate Blood Preparedness in the health care service, including rural hospitals, prehospital ambulance service and municipal health care services. The project is a civilian-military collaboration carried out in two stages, where the first part is a pilot project performed in the Northern part of Norway. The pilot will be followed by a step-by-step implementation throughout Norway if successful. The project follow the principals for a prospective intervention study, where the intervention is development and implementation of a decentralized system for blood preparedness which includes preplanned municipal based civilian walking blood banks. The study includes three work packages with blood bank, clinical, and supply/logistics related work tasks. The project is organized with a steering committee and a reference group. The project was evaluated by the Regional Ethics Committee, which defined it as health service research.

The primary aim of the project is to enable rural hospitals, prehospital ambulance services, and municipal health care services to start early balanced blood transfusions to patients with life-threatening bleeding. This includes development and evaluation of the use of preplanned civilian Walking Blood Banks.

The secondary aims are to establish: (1) systems for education and training in blood-based resuscitation in the municipal health care service, (2) routines for obtaining, storing and maintaining the cold chain for transport of blood, (3) a collaborative system for acquiring and storing consumables, and (4) a system for quality assessment and revision of practice.

2.2 | Regulatory considerations for community based civilian walking blood banks

The blood transfusion service in Norway is regulated by a national directive, the "Blodforskriften",[25] and relevant European regulations. Blood and blood components are provided by Governmental funded hospital-based blood banks which activities include blood collection, component production and storage as well as immunohematology and transfusion services. The inventory of blood in the individual blood banks differ based on local policies. A civilian WBB is regulated by the same regulations as the civilian Blood Banks. The WBBs are defined as blood collection units subject to the supervision and administration of their local hospital-based blood bank, the "Mother Blood Bank." Specific approval as such must be given by the National Health Directorate before implementation of a walking blood bank.

2.3 | Pilot study sites and timeline

Three rural hospitals, two air ambulance bases, and four municipal health care services are included as study sites in the pilot. The study timeline is 2 years, from January 2021 to December 2022. The first training courses in whole blood collection were given for blood bank personnel in September 2021, and for the municipal health care services in October 2021. Meetings, training courses and exercises are performed for the working groups and study sites on a regular basis throughout the study period. An evaluation of the project will be performed late 2022/early 2023.

2.4 | Development of a preplanned walking blood bank for municipal health care services

The selection criteria of blood donors in Norway are regulated on a national level, and only minor local differences apply. Emergency donors included in the preplanned municipal WBB donor pool are selected based on the same criteria as regular blood donors, which includes donor interview, physical examination, and laboratory investigations. Interviews are performed by trained blood bank staff.

Donor phlebotomy must be performed in accordance with procedures approved by authorized personnel and the responsible Mother Blood Bank. Only trained and certified personnel can perform blood collection. Detailed procedures for donor inclusion and maintenance, whole blood donation, and emergency transfusion were developed for the walking blood banks. This was performed in collaboration between the project leaders, the medical director of the transfusion services in the Northern Norway Health Region, the Mother Blood Banks and the local project coordinators in the municipal health care services. Similar, an education and training program was developed which included onsite training and exercises, written documents, web-based educational sessions and a web-based training course. The training is multidisciplinary and adapted to local needs for the different study sites.

3 | RESULTS

In this section, we present the results of our development process and discuss challenges with implementation of a preplanned civilian WBB in the municipal health care service. An overview of the Norwegian Blood Preparedness project is presented in Table 1.

TABLE 1 An overview of the Norwegian blood preparedness project

	Rural hospital with hospital-based blood bank	Prehospital health care services	Municipal health care
Emergency blood transfusion program	Stored blood. Emergency collection of fresh whole blood from regular blood donors if needed.	Stored LTOWB provided by civilian blood bank. Dried plasma.	Fresh LTOWB collected from preplanned walking blood bank. Dried plasma.

Abbreviation: LTOWB, low titer group O whole blood.

Establishing a system for the use of a preplanned WBB requires several processes. These include recruitment of emergency donors, training of personnel, establishing a supply chain for disposables, establishing a local system for management of the WBB and finally, establishing a system for revision and monitoring of the program.

3.1 | Establishing an emergency donor pool

A local recruitment campaign is performed for each study site. Information about the project and invitation to become emergency donors are given through newspapers, local TV and radio, advertising videos directed towards the specific community, posters, personal communication, information in social media and information on the municipality's website. During study visits, we also hold information booths for additional recruitment of blood donors. Potential emergency donors contact the local project coordinator either in person or by responding in to a local project email address. These initiatives are met with interest from the local inhabitants, and have served well in the recruitment of donors. Recruitment of emergency WBB donors among health care workers and participants in our training program (ambulance workers, nurses, physicians and others) has been successful. Similar, recruitment efforts directed towards firefighters and/or police are recommended. The number of donors needed in the emergency donor pool depends upon the population size and the frequency of events. In the pilot project, we aim to include as many donors as possible and use this information to predict potential numbers of WBB donors and identify factors with impact on the number of inclusions.

In our advertising campaign, we ask for healthy volunteer donors that are willing to give blood on short notice. We specifically ask for donors with ABO-type O, and the local project coordinator perform ABO-type quick test for potential blood donors that do not know their blood type. For potential donors with ABO-type O, blood samples are preferably taken and sent to the Mother Blood Bank for analyses before study team visits. During visits, the study team interview and perform follow up testing of the blood donors that have been recruited by the local project coordinator. Based on our current inclusion criteria, we have a low percentage of low titer donors. An evaluation and comparison of titer methods with other Norwegian Blood Banks are currently performed.

Since rural communities in need of emergency WBBs are located long distances from hospitals, mainly donors with no previous experience of blood donation join our program. We educate the emergency donors in donation routines and donor selection criteria, so that the safety of donors and patients are maintained. Information is given during interviews and as written information material. Every 6 months follow up Transfusion transmittable disease (TTD) (HIV, hepatitis B and hepatitis C) testing and a face-to-face interview with trained blood bank personnel are performed. Only donors with negative tests and approved interview within the past 6 months are accepted as emergency donors. The emergency blood donors recruited understand and comply with the routine. However, since the interviews are performed by project co-workers or blood bank staff from the Mother Blood Bank, challenges have been identified related to organizing the face-to-face interviews. To avoid resource-demanding travels for blood bank staff, a system for digital blood donor interviews are under development. A comparison between the WBB and the hospital based whole blood program is presented in Table 2.

3.2 | Walking blood Bank whole blood donation procedures

A detailed step-by-step description of the WBB donation process with pictures are included in the Appendix S1.

The WB collection/storage bag contain integral access ports for connection of infusion sets to enable immediate transfusion. Prepacked donation and transfusion kits should be provided and maintained regularly to ensure that all equipment are at hand and are easily accessed. Blood bags are labeled to ensure traceability and given a unique donation identification number that can be traced back to the donor. For quality control of whole blood

TABLE 2 Comparison between the walking blood bank and the hospital based whole blood program in the Norwegian blood preparedness pilot project

	Preplanned walking blood Bank	Hospital based blood Bank
Blood donor		
Donor status	Emergency whole blood donor	Regular whole blood donor
Blood type[a]	Low titer O High titer O considered if needed.	Low titer O ABO-type like considered if needed.
Donor gender[b]	Both male and female	Both male and female
Transfusion transmittable disease testing[c]	At inclusion, every 6 months, and at donation (sample taken at donation but results not available before emergency transfusion of whole blood, posttransfusion testing)	At inclusion and at donation.
Interview	At inclusion, every 6 months, and at donation. Before an emergency donation a screening interview are performed.	At inclusion and at donation.
Documentation of donation	Screening interview form and standard interview form filled out and signed by donor and interviewer. Donation documented by use of donation form at WBB collection site. Postdonation registration performed electronically by Mother Blood Bank.	Interview form filled out by donor and signed by donor and interviewer. Interview and donation documented electronically at donation.
Whole blood unit		
Volume	450 ml	450 mL
Anti-coagulant[d]	CPDA-1	CPD
Processing of whole blood unit after collection	No further processing	Leukoreduced with a platelet-sparing filter
Storage	No storage	21 days without agitation
Storage temperature	Not applicable	2–6 °C
Transfusion transmittable disease (TTD) testing[c]	Posttransfusion (Only donors with negative TTD tests within the past 6 months are accepted for donation)	Before transfusion

[a]Low titer defined as <256 for IgM and IgG anti-A and anti-B.
[b]Additional testing of female donors: anti-HLA, anti-HNA and anti-HPA.
[c]HIV, hepatitis B and hepatitis C.
[d]CPDA-1, citrate–phosphate-dextrose-adenine-1; CPD, citrate–phosphate-dextrose.

units collected in the walking blood bank, the hemoglobin values of the donor and the weight of the whole blood units are recorded. Validation of whole blood units was performed before start of project by the hospital blood banks. Airtight blood containers and temperature monitors are provided if needed for transport of blood.

The blood donors are monitored for adverse donor reactions during and for a minimum of 15 min after donation. The blood donors are reminded to make contact if donation reactions occur or they should get sick the days following donation. The blood samples taken are sent to the Mother Blood Bank for analysis together with copies of interview and donation forms. The Mother Blood Bank will follow up the results of blood samples taken and document the donation electronically in the Blood Bank Donor Registry. Any adverse reaction will be documented and reported to the Mother Blood Bank which follow up with relevant investigations and report the event to the national Hemovigilance system.

3.3 | Considerations on activation of the walking blood bank and follow up of emergency transfusions

Medical history or mechanism of injury that indicates ongoing bleeding should be the main trigger for activation of the WBB as bleeding is a time critical medical situation requiring early intervention. The time it takes for the donors to get to the collection site is the main factor

determining how fast blood can be provided for emergency transfusion. Early activation of the WBB is therefore recommended.

Early medical evacuation should be the main priority. Transfusion is started based on medical history or mechanism of injury indicative of ongoing bleeding and clinical criteria indicative of hypoperfusion. While waiting for whole blood to be collected, administration of reconstituted dried plasma are recommended. If this is not available, a combination of albumin and fibrinogen can be considered.

Emergency donation and transfusion must be documented and communicated. The unique donation identification numbers of the transfused whole blood units are registered in the transfusion form and in medical journals which follow the patient during transport to the hospital. Transfusion form and left-overs from whole blood bags are delivered to the Blood Bank in the receiving hospital.

A standardized set of laboratory analysis including ABO-type, anti-A and anti-B, screening for erythrocyte antibodies, hemolysis markers (direct antiglobulin test [DAT], haptoglobin, lactate dehydrogenase, and bilirubin) and creatinine are taken upon arrival at hospital.

3.4 | Training

The Norwegian Blood Preparedness Project develop a system for education and training in WBB whole blood collection and emergency transfusions in the municipal health care service because we aim to achieve early balance transfusion to patients with hemorrhagic shock. Our main focus are to ensure a safe and effective system of blood preparedness, however a decentralized system poses certain challenges when it comes to education and training. The implementation of a WBB requires two sets of education programs, one for implementation and one for maintenance of the program.

An emergency is better managed if the procedures involved are planned and rehearsed, and since these are not frequent events, a system for regular rehearsals are essential for the success of the program.

In emergency transfusion events, the personnel directly involved in treatment of the patients will most likely not have time to perform emergency whole blood collection as they are occupied with the management of the patient. Other personnel must therefore be trained to assist in emergency whole blood collection. The training and education of personnel must be adjusted to local needs and continuous communication between local coordinator and medical responsible personnel and the mother blood bank is essential. Detailed algorithms for activation of emergency collection must be described and trained regularly as must also all practical procedures involved.

During development and implementation of the preplanned WBB program, we have used the following set up: on-site start up training course with study team, on-site follow training course with study team and site rehearsals administered by local project coordinator. Written procedures and case stories for rehearsals are provided. A final certification exercise must be performed. This exercise includes an evaluation by external evaluators.

These criteria must be fulfilled before the preplanned walking blood program is ready for start-up: (1) An emergency donor pool must be established, (2) the local program must be tested and approved through the certification exercise, and (3) the WBB must have received approval from the regulators.

3.5 | Evaluation of the program

When establishing a community based walking blood bank, careful supervision and auditing of the procedures are needed. Continuous recruitment of emergency whole blood donors must be performed to maintain an adequately sized donor pool. All personnel must receive relevant training and supervision, and regular rehearsal of the system should be performed. Education and certification of new personnel must be done on a regular basis. The WBBs are defined as blood collection units subject to the supervision and administration of their local hospital-based blood bank, the "Mother Blood Bank", and regular supervision are performed and administered by them.

All emergency blood donors and all patients receiving blood transfusion should be monitored for adverse events according to regulatory requirements. As part of the program we carefully monitor all treated patients and evaluate the appropriateness, effect and safety of the transfusion. This is done by the Mother Blood Banks in collaboration with the Medical Director for the Blood Banks in the Northern Health Region. Also a patient quality registry is under development. In case of a WBB activation, an evaluation of the event will be performed. This includes measures of the processes performed from emergency collection to transfusion of whole blood with a focus on timing, adherence to procedures and appropriateness of responses.

4 | DISCUSSION

There are many aspects that must discussed and decided upon in the process of developing and whole blood based

blood preparedness program. In this manuscript, we have described the processes involved and challenges we have met during the development of our preplanned WBB program for the municipal health services.

The newly published European Directorate for the Quality of Medicines and Health Care (EDQM) Recommendations for a Blood Supply Contingency and Emergency Plan,[26] specifically recommend regulatory oversight bodies to ensure that their authorization process allow for flexibility and specific derogations where required in response to defined key risk scenarios or other crisis or emergency situations. Walking blood banks are given as an example on this. Local policies must be developed in collaboration with regulatory authorities. In smaller communities, an emergency donor selection plan may need to consider potential relaxations of donor selection requirements that do not compromise donor or patient safety.[20] Factors influencing on the potential number of eligible donors in the emergency donor pool are: (1) Definition of low titer cut off for anti-A and anti-B antibodies,[27] (2) TRALI mitigation strategies, (3) Whether RhD positive whole blood donors are included.[28,29]

It is important to carefully consider the risk versus the benefit of a transfusion. In seldom cases, like for patients with erythrocyte antibodies or paroxysmal nocturnal hemoglobinuria (PNH), compatible whole blood are advised. However, if no patient transport is available and the patient has a life-threatening bleeding, the benefit of transfusion might potentially outweight the risk.

Validation of the WB product should be performed before implementation, as for other blood components. Similarly, continuous monitoring of WB quality are recommended as descried in relevant regulatory documents like the European Directorate for the Quality of Medicines and Health Care (EDQM) Guide to the preparation, use and quality assurance of blood components.[30] Extensive whole blood validation studies were performed at Haukeland University Hospital and the air ambulance base in Bergen before the Norwegian Blood Preparedness Project started.[31–33] The studies included investigations of the quality of WB at collection and during storage both in hospital and in air-tight containers as are used for transport and remote storage.

We conclude that implementation of a preplanned walking blood bank program can be done also in municipal health care service. We encourage rural health care services to consider establishing a blood preparedness program to enable early balanced blood transfusion for patients with life-threatening bleeding.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Norwegian Armed Forces Medical Services.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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