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MAJOR HEMORRHAGE

TRANSFUSION

Current transfusion practice and need for new blood products to ensure blood supply for patients with major hemorrhage in Europe

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Abstract

Background: New blood products are considered for treatment of patients with major hemorrhage. The aim of this report is to describe the current transfusion practices in Europe for patients with major hemorrhage and explore the need for new or modified blood products to ensure prehospital and in-hospital blood supply.

Study Design and Method: The European Blood Alliance (EBA) Working Group on Innovation and New Blood Products' subgroup on major hemorrhage performed a survey among the EBA member states.

Results: The response rate was 58% (17 responses from 15 of the 26 EBA member states). Of these, sixteen (94%) provide massive transfusion packages (MTPs) with balanced ratio of red blood cells and plasma. Seven of the respondents included platelets from the start of treatment. Eleven (65%) provide prehospital blood products, mainly red cell concentrates or dried and/or thawed plasma with 5 days of extended storage. Two countries provide prehospital whole blood. Twelve respondents (71%) saw a need for implementation of new or modified blood components in their institution. The top three priorities were whole blood (12 of 12, 100%), dried plasma (8 of 12, 67%), and cold-stored platelets (7 of 12, 58%).

Discussion: Current national guidelines for use of blood products in patients with major hemorrhage in Europe agree on the use of balanced transfusion, however the timing and source of platelets differ. Blood products for prehospital transfusion are available in several European countries. An interest in new or modified blood products for patients with major hemorrhage was observed, especially for whole blood.

KEYWORDS

blood components, blood transfusion, cold-stored platelets, dried plasma, massive hemorrhage, whole blood

The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the Norwegian Armed Forces Joint Medical Services.

1 | INTRODUCTION

Civilian and military guidelines recommend early balanced blood transfusion to patients with major hemorrhage to improve patient survival.[1,2] Accordingly, the blood transfusion services consider blood products specifically targeted for the use in early stabilization and/or damage control resuscitation of patients with critical bleeding. Providing blood to patients in austere conditions differs from issuing balanced resuscitation to patients in larger hospitals. However, recent mass casualty events have illustrated the need for emergency preparedness planning also in larger blood establishments. Systems ensuring availability of blood must be established to enable early access to balanced transfusion in all levels of health care, from level 1 trauma centers to smaller rural hospitals with limited resources.[2–5] Also, in regions and/or situations with prolonged medical evacuation times, plans and routines ensuring an adequate supply of blood for prehospital transfusion are needed.[6–8]

In planning of sustainable systems for provision of blood in all levels of health care, a renewed interest has been given to blood products like whole blood, frozen platelets, and dried plasma.[9–11] Investigations are also performed to evaluate the effects of modifications of storage of blood components, like refrigerated platelets and thawed and/or liquid plasma.[1,2,12]

The European Blood Alliance (EBA) is an association of nonprofit blood establishments, with 26 member states throughout the European Union and EFTA States. The EBA working group on new blood products for major hemorrhage is a subgroup of the EBA Working Group on Innovation and New Blood Products. The aim of the subgroup is to investigate the need for implementation of new blood products and innovations that may improve treatment of patients with major hemorrhage. In order to do so, current practice must first be mapped and the need for new blood products and innovations for treatment of patients with major hemorrhage explored.

In this report, the subgroup describes the current transfusion practices in Europe for patients with major hemorrhage and explore the perception of the need for new or modified blood products to ensure prehospital and in-hospital blood supply for these patients.

2 | MATERIALS AND METHODS

The EBA subgroup on new blood products for major hemorrhage consists of volunteer members from nine EBA member states recruited through invitations sent to all EBA member representatives. The members of the subgroup and subgroup leader were appointed by EBA based on suggestions received from national EBA representatives.

A survey was created in English and piloted by the group before distribution. The survey questions are included as supplementary material to this report (Data S1). The survey asked for descriptive information about organization of blood transfusion service and practice guidelines and the use of massive transfusion packages (MTPs). The respondents were also asked about prehospital transfusions and whether the COVID-19 pandemic lead to implementation of new or modified blood products. Finally, the survey asked for the personal opinion of the respondents about the need for implementation of new or modified blood products in their institution.

The survey was distributed electronically to the national representative of all EBA member states ($N = 26$). In addition, the survey was sent to the members of the EBA subgroup on new blood products for major hemorrhage ($N = 10$) for supplementation and support of their national EBA representatives. The invitation to participate in the survey was sent in July 2021, and two reminders were sent electronically (by email) if no response was received. The survey closed in October 2021. All participants in the survey consented to the reported data being published in a peer-reviewed medical journal.

3 | RESULTS

We received 17 responses from the following 15 of the 26 (58%) EBA member states represented by their national EBA representative or a subgroup member appointed from the respective country/region: Germany, Denmark, Sweden, The Netherlands, Portugal, Belgium, Norway, Slovenia, Estonia, Iceland, Ireland, England, Wales, Scotland, Italy, France, and Switzerland. From United Kingdom, we received separated responses for England, Scotland, and Wales. For two countries (France and Norway) responses were received from both EBA representatives and subgroup members. The respective representatives combined the results into one unified response. We did not receive response from the following EBA member states: Austria, Croatia, Finland, Greece, Hungary, Latvia, Lithuania, Luxembourg, Malta, Serbia, and Spain.

Ten (59%) of the 17 participating blood services are organized as national and/or regional blood establishments, whereas the rest of the respondents reported that their blood service are organized as individual institutions and/or hospital based blood banks. Ten (59%) services report that they have a national standardized

TABLE 1 Massive transfusion packages (MTPs).

Country/region	Do you provide MTPs	RhD type of RBCs in MTPs
Switzerland	RBC and plasma 1:1 Addition of one platelet concentrate after 5 RBCs.	Not reported
Wales	May differ between institutions. Managed by the individual Health Boards based on British Society for Hematology guideline.	RhD positive for RhD positive and for unknown adult males and women >50 years. All other patient groups RhD-negative blood.
Germany	Do not provide MTPs. However in patients who (will) require massive transfusions or have bleeding-related life-threatening shock and coagulation therapy for massive transfusions is provided by the administration of FFP, a ratio of FFP:RBC:PLT in the range of 4:4:1	RhD-negative RBCs are used.
Denmark	The principle is transfusion packages of RBC, FFP, and PLT that corresponds to whole blood equivalents. For example, RBC:FFP:PLT in the range of 4:4:1	RhD negative for females <50 years. For other groups it is an individual judgment taking into account the available stocks
Sweden	RBC:FFP:PLT in the range of 4:4:1	At Karolinska University Hospital RhD neg, but can differ in other hospitals in Sweden.
The Netherlands	Fixed proportion, but actual proportions may vary between hospitals.	Not reported
Portugal	Initial MTP: 4 RBC + 4 FFP + 1 pool platelets Fibrinogen concentrate 30–50 mg/kg	Whenever possible, use isogroup cross-matched RBC. In extreme emergency RhD negative is used.
Belgium	RBC, plasma and platelets in a ratio of 1:1:1.	Start with RhD neg and switch to isogroup as soon as possible
Norway	If platelets available: RBC, plasma and platelets in a 1:1:1 ratio. If platelets not available: RBC and plasma in a 1:1 ratio. Whole blood can be used as an alternative to fixed ratio of blood components. Actual number of units may vary between hospitals.	RhD pos WB/RBC for male patients and for female patients >50 years Female patient <50 years with unknown blood type; RhD neg WB/RBC
Slovenia	RBC: FFP: platelets in a ratio of 6:6:1	We issue RhD neg and as soon as possible, we switch to patient blood type.
Estonia	I pack 3 units O RhD pos/neg RBC II pack 3 units O RhD pos/neg RBC + 3 units AB RhD neg FFP III pack 3 units ABO-mached RBC + 3 units AB RhD neg FFP + 1 unit PLT + 1 unit Cryo (pooled) IV pack 3 units RBC + 3 units FFP + 1 unit PLT + unit Cryo	RhD negative to women <50 years and children. Others RhD positive
Scotland	Content of MTPs vary by site. Initially, give FFP and red cells in at least 1:2 ratio. If bleeding continues, if no blood results to guide, give FFP and red cells in 1:1 ratio and consider 2 pools cryo. Code Red protocol for trauma patients (major trauma centers): 8 red cells, 4 FFP and 1 pool platelets. Promotion of ROTEM use in Emergency Department to guide replacement is being carried out. For in-patient major hemorrhages there are Pack 1 and Pack 2 available - again, contents vary but many have no platelets in pack 1.	Varies. Most sites issue RhD neg for all. Some policies support use of RhD pos for adult males and females over 50 without immune anti-D.
Iceland	Adults: RBC: FFP:PLT in the range of 4:4:1	Female: RhD neg, Male RhD Pos
Ireland	Major hemorrhage pack will contains 4 units of red cells and 4 units of plasma (SD plasma). Fibrinogen and Platelet supplement by Blood Volume (BV) loss or laboratory testing.	RhD type by known patient group. RhD neg for women of childbearing potential and children (+ Male <18 years/1BV unless blood supply shortage)

(Continues)

TABLE 1 (Continued)

Country/region	Do you provide MTPs	RhD type of RBCs in MTPs
	(Fibrinogen 4 g for every BV bleed - target >1.5 g/L. Platelets—1 adult dose for every 1.5 BV bleed and target >50 × 10^9/L, order early to bring on-site and transfuse <100^9/L.)	
England	Yes some variation between sites. As an example, in CRYOSTAT trial pack 1 contained 6 units RBC and 4 units FFP. If hemorrhage continued, pack 2 was transfused (6 units RBC, 4 units FFP, 2 pools cryoprecipitate and 1 adult pool of platelets (=4 pooled buffy coat platelets or 1 single apheresis unit)).	RhD negative
Italy	MTPs include the use of fixed ratio of RBCs and FFP as first approach, adding platelet concentrates and fibrinogen supplementation (concentrate or cryoprecipitate). Where viscoelastic testing (ROTEM or TEG) is adopted a goal directed coagulation support is applied.	RhD-negative RBCs are used upfront. RhD-positive RBCs in case of shortage and in males and females >50 years; group specific RBCs as soon as possible.
France	The composition of the MTP may differ from one hospital to another General composition: Pack 1: 3–4 RBC + 2–4 FFP Pack 2: 3–4 RBC + 2–4 FFP + platelet concentrate	Main idea: Young female RhD neg, Male and aged female: RhD pos

Abbreviation: FFP, fresh frozen plasma; PLT, platelets; RBCs, red blood cells; ROTEM, rotational thromboelastometry; TEG, thromboelastography.

approach to managing major hemorrhage, three (18%) report that they have a standardized approach for each institution, and four (24%) report that they have no standardized approach to managing major hemorrhage. Eight (47%) blood services reported that their recommendations included different approaches for treatment of patients with bleeding based on the reason for bleeding (Data S1).

Sixteen (94%) of the responders provide MTPs as a service from the blood centers or from the hospital transfusion service. The content of the MTPs varies between countries and between institutions within countries (Table 1). All aim to provide a balanced transfusion; however, there are differences when it comes to the ratio and timing of the platelet products given. Seven (44%) of the respondents report that they include platelets from the start of treatment of patients with massive bleeding. Seven (44%) respondents describe that current practice is to start with red cells and plasma first, and consider the addition of platelets and fibrinogen during treatment. One country reported the use of whole blood in MTPs for some hospitals. Most respondents provide both RhD-positive and RhD-negative red blood cells (RBCs) in their MTPs, but use RhD-negative RBCs for females in childbearing age (<50 years) (Table 1). An emphasis is placed on switching to patient RhD type-like transfusion as soon as possible. Some countries report the use of point-of-care viscoelastic tests for guidance on treatment, but as we did not ask specifically about whether this was used, no accurate number on this practice can be provided. Details on content and use of MTPs are given in Table 1.

3.1 | Prehospital transfusion

Eleven (65%) of the 17 respondents report that they provide blood products for prehospital use (Table 2). Of the 11 that report that they have implemented prehospital blood transfusion, most use red cell concentrates, or dried and/or thawed plasma stored for up to 5 days. There were variations between the types of blood products available for the prehospital services within the countries. Two countries reported the use of whole blood in prehospital air ambulance services and one site reported an ongoing clinical study on the use of red cells in plasma (platelet-depleted whole blood) (England). Two countries reported on plans for clinical study on whole blood (England and France).

Hemostatic agents included in the protocol for treatment of patients with major hemorrhage were tranexamic acid (TXA), calcium supplementation, prothrombin complex concentrates (PCCs), factor concentrates, and fibrinogen concentrates. Depending on the organization of the health service, the clinical service, pharmacies, and/or the blood service provided these agents.

3.2 | COVID-19 pandemic blood supply

For the time period covered by this survey, only three respondents reported minor temporary difficulties in providing blood supply. This did not influence on the availability of blood for bleeding patients. Three sites implemented, or prepared for implementation, extended storage time for RBCs and/or two sites extended storage time for platelets. Laboratory studies on the effects of reduced platelet dose were performed in two sites. In one country, cold-stored platelets were implemented.

3.3 | Need for implementation of new or modified blood components

When asked about their personal opinion on whether there is a need for implementation of new or modified blood products for treatment of patients with major hemorrhage in their institution, 12 respondents (71%) answered that they saw a need for implementation of new or modified blood products, whereas 4 (24%) reported that they saw no need. One respondent did not answer the question. Of the EBA national representatives, the following countries reported that they considered that there is a need: Sweden, Portugal, Estonia, Italy, and Norway. The following national EBA representatives reported that they see no need: Switzerland, Germany, Denmark, and Slovenia. For the subgroup members, the following respondents reported that there is a need: The Netherlands, Belgium, Scotland, Iceland, Ireland, England, and France.

When asked to mark their three top priorities of blood products, all 12 respondents wished to implement whole blood (12 of 12, 100%), whereas dried plasma (8 of 12, 67%) and cold-stored platelets (7 of 12, 58%) were the second and third highest ranked products (Figure 1).

TABLE 2 Blood products for prehospital transfusion.

Country/region	Do you provide blood products for prehospital transfusion	Type of blood products
Switzerland	No	
Wales	Yes	Dried plasma, RBCs
Germany	No	
Denmark	Yes	Dried plasma
Sweden	Yes	Whole blood, dried plasma, RBCs, extended shelf life thawed plasma
The Netherlands	Yes	Extended shelf life thawed plasma, RBCs
Portugal	No	
Belgium	No	
Norway	Yes	Whole blood, dried plasma, RBCs
Slovenia	No	
Estonia	Yes	RBCs
Scotland	Yes	RBCs
Iceland	No	
Ireland	Yes	Extended shelf life thawed plasma, RBCs
England	Yes	Extended shelf life thawed plasma, RBCs, dried plasma, red cells in plasma (trial)
Italy	Yes	RBCs
France	Yes	RBC, dried plasma (military)

Abbreviation: RBCs, red blood cells.

4 | DISCUSSION

In a recent international forum on management of major hemorrhage that describes practices in 13 countries from around the world, the authors conclude that there is a wide variation on definitions of massive hemorrhage and massive transfusion as well as management of acquired massive hemorrhage. Of the participants in this publication, only three were from Europe.[13] In our survey, we observe an organizational diversity among European countries and regions; however, when it comes to the use of blood products in patients with major hemorrhage, there is a consensus on the need to provide balanced, or fixed, ratios of red cells and plasma for patients with major hemorrhage. Our respondents mainly differ when it comes to the timing of platelet transfusion and the use of prehospital transfusion.

A publication describing prehospital transfusion practices in 11 different European countries found large dissimilarities in practice between the different European countries.[13] There were not an absolute consensus among providers on the benefit of prehospital transfusion; however, the majority felt that they were beneficial.[14] Compared with our findings, a lower availability of prehospital transfusion was reported. In the previous study, 48% of providers reported prehospital access to packed red cells, 22% to fresh plasma, and 14% used lyophilized plasma. In our survey of blood transfusion services in 17 European countries/regions, we found that blood services in 65% of the responders provide blood products for prehospital transfusion and that whole blood

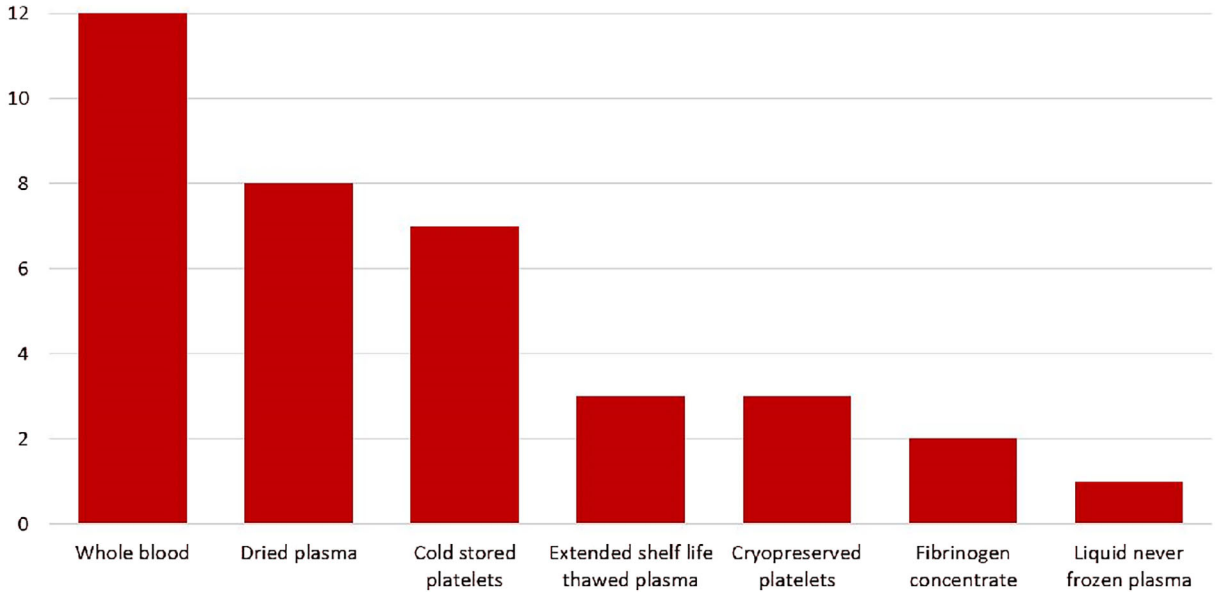

FIGURE 1 New or modified blood products for treatment of major hemorrhage. Twelve respondents (71%) answered that there was a need for implementation of new or modified blood components, whereas four (24%) reported that they saw no need. One respondent did not answer the question. When asked to mark their three top priorities of blood products, all 12 wished to implement whole blood (100%), whereas dried plasma (67%) and cold-stored platelets (58%) were the second and third highest ranked products.

is used in addition to RBCs and plasma. The increasing use of prehospital transfusion is in accordance with the recommendation of early transfusion to patients with major hemorrhage. Differences in use of prehospital transfusions may reflect differences in geography and transport distances within the countries and regions in addition to differences in transfusion policies.

In our survey, we observed an interest among respondents for implementation of new or modified blood components and products to improve availability of blood transfusion for patients with major hemorrhage. In our survey, we asked for the respondent's personal view on this topic, as it is difficult for the representatives to answer such a question on behalf of a whole country or region. The results should be interpreted accordingly. It is a limitation of our survey that we were not able to present consensus information from each country and/or region. However, our findings are in line with the general increasing interest in, and focus on, new blood products for emergency blood preparedness and contingency planning. Another limitation of this survey is that we were not able to engage all EBA member states in responding to our survey. We received responses from 15 EBA member states, but potentially there could be a selection bias in who answers this type of survey, as people interested in the topic or finding supply of blood for bleeding patients as a challenge may want to answer. In the light of the recent events forcing a renewed focus on emergency blood preparedness and blood supply contingency planning in Europe, a follow-up survey should be considered focusing on the use and need for new or modified blood products in preparedness planning for patients with major hemorrhage.

There is a growing interest in the use of whole blood in treatment of patients with major hemorrhage and in emergency preparedness.[5,10,15–21] Recent publications describe improvement in patient survival and reduction of total blood usage in patients receiving whole-blood-based compared with blood-component-based resuscitation.[22,23] The group will follow up its findings with further discussion on how to implement whole blood in treatment of patients suffering major hemorrhage.

We conclude that the current guidelines for use of blood products in patients with major hemorrhage in Europe agree on the use of balanced transfusion. A high proportion of our respondents provide blood products for prehospital transfusion. There is a growing interest in implementation of new blood products specifically targeted toward the treatment of patients with major hemorrhage, and whole blood is the product with most interest. We recommend development of systems that make blood transfusion available on all level of care for patients with major hemorrhage so that early balanced transfusion can be provided.

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CONFLICT OF INTEREST STATEMENT

The authors have disclosed no conflicts of interest.

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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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