

Supplementary document

Additional guidance for Laboratory and Organisational Aspects of the Haematological Management of Major Haemorrhage – A British Society for Haematology Guideline

Introduction

The aim of this supplement is to provide additional practical guidance on laboratory and organisational support to improve outcomes in major haemorrhage in adults.

This supplement should be read alongside the main document on the 'Haematological Management of Major Haemorrhage: A British Society for Haematology Guideline.' Delays in diagnosis, communication and laboratory related issues are risk factors for adverse outcomes of major haemorrhage. A recent SHOT report described 133 cases of delays to transfusion which may have contributed to mortality, 26 in the context of major haemorrhage.¹ Addressing these issues requires multiple strategies, from education to training, aiming at both laboratory and clinical practices, and the interfaces between laboratory and clinical practices (Tables 1 and 2).

MHP Activation Practical Advice

Roles and responsibilities – Clinical

A suitably trained individual at the scene should assume the role of the 'Team Leader' to co-ordinate patient care, including the activation and deactivation of MHP. The 'Team Leader' should nominate a 'Transfusion Communication Lead' to act as a liaison role between the clinical team and the laboratory staff to ensure unambiguous communications. This role should include ensuring suitable samples are collected and transferred and management of blood components (ordering, ensuring cold chain compliance, traceability). A designated porter or 'Runner' should be found to transport emergency blood samples to the laboratory and collect blood components.

Roles and responsibilities – laboratory

Communication through a lead/designated Laboratory Scientist should reduce delays in handling calls/requests and avoid repetition of details and will address oversight of the complex issues of laboratory support, especially if there are multiple bleeding casualties. The laboratory should ensure that there is a method to record the requests for component support. A structured response to messaging including requests for blood components is recommended together with readback² (closed loop communication). Where available, other staff should be involved including transfusion practitioners to support communication between laboratory and clinical areas or haematology clinicians to provide additional advice. The Laboratory should also take responsibility for communicating abnormal results which will impact transfusion support (e.g., Hb, coagulation screen, fibrinogen).

Viscoelastic tests in major haemorrhage

Practical guidance on the selection of parameters to use for viscoelastic tests in major haemorrhage is beyond the scope of this guideline, and the reader is referred to BSH guidelines on the use of viscoelastic haemostatic assays.³ An example of a transfusion algorithm for trauma is provided in Table 3, based on a process for developing, validation and testing in a clinical trial.⁴

Patient identification and group and screen sample

Patient identification.

Hospitals must have clear guidelines for positive patient identification for both known and unknown patients (see Table 4). During mass casualties or other emergency situations, where the patient's identity may be unknown, a system must be in place for the identification of unknown patients. At least one unique identifier must be used (e.g., a randomly generated 7 digit number with a prefix), a naming convention

(suggest randomly generated from an edited phonetic alphabet), a date-of-birth system and the patient's sex.^{5,6,7} When changing from 'Emergency' or 'Major Incident' identifiers' to 'Routine' identifiers, it may be safer to defer ID changes until after emergency surgery.

The group and screen sample. Samples must be hand-written or electronically labelled at the patient's side (Table 4); the patient's details on the blood sample tube must match the patient's ID band and the request form.^{5,6,7,8} Electronic systems for patient identification should help minimise wrong blood in tube errors.⁹ A secure electronic patient identification system includes systems which identify the patient from the ID band and ensure the sample is labelled at the bedside by re-scanning of the ID band within a set time span. There should be zero tolerance of incorrect patient identifiers even in the emergency situation. Therefore, the laboratory must have a protocol in place to avoid delays to component provision in a major haemorrhage scenario caused by incorrect sample labelling (e.g., release of universal components).

A written, or electronic request must be sent to the laboratory with a sample. If a valid sample is already in the laboratory (e.g., previous group and screen), then in an emergency, the request may be telephoned, but there should be clear methods of documentation to reduce the risk of transcription error.

In the case of patients with an unknown identity, then the patient should continue to be transfused on the emergency identification, until the record is merged and updated, and a new, fully labelled sample is collected and fully tested in preparation for release of components labelled with the updated identity. In all cases the details on the blood component identity tag must match the details on the patient ID band or be labelled as emergency blood.

There must be an agreed policy for confirmation of the blood group for patients without a blood group on the LIMS and for the prioritisation of testing samples for major haemorrhage cases. Unless a secure electronic patient identification system is in place, a second sample should be obtained to confirm the ABO group of patients with no historic blood group on record before group compatible transfusion of blood components. However, processes should be in place to ensure this does not impede delivery of urgent components, and group O RBCs or group A or AB plasma can be given until the group is confirmed.

Early determination and confidence in the ABO group and RhD type is paramount if patients are to be safely moved to policies for group specific RBC transfusion; however, there is increasing evidence that transfusion of un-crossmatched blood does not interfere with most ABO typing.¹⁰ It may be acceptable to issue group-specific RBC without completion of an antibody screen in an emergency. However, a retrospective antibody screen should be undertaken as well as routine compatibility procedures.

If an antibody screen is subsequently found to be positive, this must be communicated to the clinical team urgently and, a recall and reporting procedure should be in place, so that the patient can be assessed for the risk of haemolysis.

Where there is insufficient time to complete antibody identification in a haemorrhage situation, laboratories must have a policy in place detailing appropriate RBC to issue with concessionary release to avoid harmful delays.⁸

Selection and issue of blood components

Table 5 provides an overview of blood components currently available in the UK for adults and children >1 year old. For doses of plasma and platelets, please refer to main guideline document.

Laboratory staff should be familiar with the use of safe substitutes of blood group to support the speed and safety of transfusion support in an emergency especially when universal components are required. Hospitals should have a policy for the urgent supply of blood components to patients with special requirements for blood transfusion. This should include a risk/benefit analysis and escalation to a clinical Haematologist when appropriate (without causing delay to component support).

Red cells. Group O RBC should be used in emergency until the patient has a valid blood group. Until the patient's blood group is confirmed, group O RhD negative and K-negative RBC should be prioritised for people of childbearing potential (<50 years), children and where the patient's sex is unknown. Adults who do not have childbearing potential should receive group O RhD positive RBC. Labels applied to Group O red cells for emergency use should highlight which patient groups they are suitable for (e.g., sex and adult or neonatal specification), however the age of red cells does not need to be specified. Current evidence from randomised trials indicates no difference in multiorgan system dysfunction or mortality in patients receiving RBC at different storage ages,^{11,12} and at the time of writing this guideline, we recommend standard stock storage management for red cells.

Components including plasma and cryoprecipitate. If fresh frozen plasma (FFP) is required urgently in a bleeding patient before the ABO group is known, group A (high-titre negative) can be issued as an alternative to group AB¹³ (for Octaplas and LyoPlas-N and other commercial products please refer to manufacturer's guidance).

Platelets. Platelets are less commonly required but may be needed where there are pre-existing conditions or medications that interfere with platelet function; Group A high titre-negative platelets may be used (if Group A unavailable refer to the guidance for selection of ABO group for platelet transfusions). RhD negative platelets

should be used for females <50 years with unknown group. If only RhD positive platelets are available for females <50 years, anti-D should be administered as per advice provided in BSH platelet guidelines.¹⁴

Availability of blood components for transfusion

A major risk in an emergency is delay in transfusion for example due to required thawing of plasma and its delivery. In hospitals that manage frequent cases of major haemorrhage, consideration should be given to having pre-thawed plasma on standby, which can be stored post-thawing for up to 5 days at 4°C ±2°C, and this can be used in unexpected major haemorrhage cases.¹³ A pre-thawed plasma protocol will be associated with wastage and hospitals should assess the level of wastage acceptable against the frequency of massive haemorrhage cases. Hospitals should be aware that the time to thaw FFP and cryoprecipitate will differ depending on the thawers and methods used.¹⁵ Hospitals should consider the implications for inventory management of holding platelets for rapid use in emergencies.

Inventory management of stock

Stock management. There needs to be a robust system in place to monitor blood stocks continuously during major bleeding so that stocks can be replaced as quickly as possible. Laboratories should have a stock algorithm listing stock levels held and cut-off levels for ordering further blood components, and by which delivery mechanism (e.g., *ad hoc* or emergency deliveries).

Remote fridges. Emergency group O RBC should be clearly marked as such in remote fridges and separated from other stock. When components are removed from a remote blood fridge there must be a mechanism to inform the blood bank (electronic or verbal communication).

Releasing emergency components from the blood bank: To prevent delay, consider releasing blood components when they are ready rather than waiting for all the components to be prepared before issuing them in packs. This is particularly important for hospitals that do not hold pre-thawed plasma

Return of blood components to stock. If blood components are not needed once received in the clinical area, there should be a clear record of the identity of the person returning the units, and the date/time when units were placed in storage or returned to the laboratory. Unused RBC and FFP removed from cold storage within 30 minutes can be returned to temperature control storage by clinical or laboratory staff. If RBC and FFP have been out of their permitted temperature range beyond 30 minutes clinical staff should return the units to the laboratory immediately. The laboratory must have clear policies for recording the fate of units out of temperature-controlled storage for greater than 30 minutes. Laboratories should have a policy to apply the 60-minute rule, where relevant, aiming to reduce red cell wastage.¹⁶ Platelets and cryoprecipitate should be returned to the laboratory as soon as possible and never stored in a refrigerator.

Transfusion traceability

The fate of all blood components issued must be recorded in the hospital transfusion laboratory records and documented in the clinical notes, with all records being kept for 30 years in line with the Blood Safety and Quality Regulations (2005).¹⁷ A vein-to-vein electronic blood tracking system can improve efficiency and safety of all blood transfusion processes.¹⁸ These systems can aid with rapid availability of blood, improve patient safety at administration, reduce sampling errors and improve blood component traceability. Electronic tracking systems may be able to alert laboratory staff of removal of emergency blood from remote fridges. Any removal must be

followed up to determine if components have been transfused; if the cold chain has been broken and if re-stocking is needed. Where electronic blood tracking systems are in use, clinical staff must be aware of the procedures, and be trained in obtaining emergency blood components from blood fridges via electronic tracking.

Pre-hospital transfusion and transfers.

Blood group selection. At the time of writing, the majority of UK pre-hospital services are using group O RhD negative RBC, although in other countries group O RhD positive RBC units may be used as the universal component to support the pre-hospital services, due to the low prevalence of group O RhD negative donors.^{19,20,21} An increase in the use of pre-hospital blood transfusion in the UK is likely to further impact the limited supply of group O RhD negative RBC, and the UK blood services and some hospitals are risk-assessing this practice and considering the use of O RhD positive blood. We recommend that pre-transfusion group and screen samples are collected pre-hospital prior to transfusion, although this may often be challenging. When a pre-transfusion sample cannot be obtained the hospital should have a clear policy to cover subsequent blood grouping anomalies (mixed field reaction).

Governance. Pre-hospital services require a robust governance framework in place to ensure full traceability of and confirmation of the cold chain and monitoring of either individual components or their container.¹⁵ Most modern thermal solutions are based on Phase Change Material for specific temperature ranges that ensure consistent temperature performance for up to a specified period. These should be validated for initial use and periodically re-validated for ongoing performance verification as per best practice and manufacturer's recommendations. Temperature logging devices enable cold chain confidence and reduce potential wastage of

components. Pre-hospital services may also require rapid dispatch of blood products such as prothrombin complex concentrate, as part of their pre-agreed care bundle.

Hospital transfers. Blood components may be transferred with patients at high risk of requiring transfusion en-route during transfer from one hospital to another for immediate specialist care. There is limited published experience of transfer practices for blood,²² but wastage of blood appears significant. Clinical teams must communicate effectively with the transfusion laboratory when the decision to transfer a patient with blood is confirmed. The transfusion laboratory from the referring hospital should coordinate the transfer and traceability of blood and ensure effective communication between laboratories. Blood should never be transferred without the knowledge of the transfusion laboratory. The transfusion laboratory must have a protocol in place to ensure the cold chain is maintained and evidenced during transport.

Mass Casualty Events

Hospital transfusion teams should engage with their Emergency Planning teams and be included in emergency communication cascades. This cascade should be tested periodically in an exercise format.²³ Transfusion teams should be aware of their Trust's pre-determined casualty load and their regional incident response plan. This information should be used to guide stock holding, redistribution, and re-stocking during an incident. Systems should be in place to maintain cold chain and traceability during an MCE. Blood components may be moved within the hospital and potentially between hospitals. Consideration should be given to the use of a member of staff as a transfusion coordinator to co-ordinate activity including blood sample collection and labelling, maintaining cold chain and traceability evidence.^{24,25} All mass casualty

events in UK and internationally provide important learning points for enabling timely and safe transfusion support in emergencies.^{25,26,27}

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Table 1

Checklist and prompts for the clinical team calling the laboratory

| Clinical SBAR checklist for Massive Haemorrhage phone call | |
|---|--|
| Situation | Introduction – your name, role, contact number, department Patient location Purpose of call e.g., activate MHP How many patients Expected time of arrival |
| Background | Patient identification - full name, date of birth and unique patient identifier (emergency or hospital number) Is the patient on anticoagulants or anti-platelet medications? Is prothrombin complex concentrate needed? |
| Assessment | Has the patient received emergency blood pre-hospital or in the clinical area? |
| Recommendation | Timescale – degree of urgency – when are component needed If not using standard MHP provide clear instructions on components needed and why non-standard MHP Confirm clinical staff member in charge of communication (code red nurse) |

MHP, major haemorrhage protocol.

Table 2

Checklist and prompts for the laboratory team in discussion with the clinical team

| Laboratory SBAR checklist for Massive Haemorrhage phone call | |
|---|--|
| Situation | Introduction – your name as laboratory lead for the MHP Communicate relevant information from the blood bank that may impact the MHP e.g., 3 concurrent MHP activations, in contingency mode |
| Background | Confirm patient identification and location plus likelihood of moving (e.g., to theatre) Confirm clinical team know where emergency group O red cells are available |
| Assessment | Has the patient had emergency group O RBC? From which fridge? Check patient history – is there a group and screen available – is there any transfusion history |
| Recommendation | Confirm MH pack content or components agreed if non-standard MHP Agree timescale for component provision (15 mins, 30 mins, 1 hr) Emergency blood in the fridge will be replaced – agree timescale Confirm contact details of clinical lead Offer contact information for consultant haematologist |

MH, major haemorrhage; MHP, major haemorrhage protocol.

Table 3. An example of visco-elastic thresholds used as a transfusion algorithm in trauma, as developed, validated, and tested in the iTACTIC trial

| Treatment | Suggested thresholds for therapy | |
|--|---|--|
| | TEG | ROTEM |
| 2 pools cryoprecipitate (equivalent to 4g fibrinogen replacement) | FF TEG MA < 20 mm | FIBTEM CA5 < 10 mm |
| 1 pool platelets | rTEG MA – FF TEG MA < 45 mm | EXTEM CA5 – FIBTEM CA5 < 30 mm |
| 4 pools fresh frozen plasma | rTEG MA > 65 mm AND rTEG ACT > 120 sec | EXTEM CA5 > 40 mm AND EXTEM CT > 80 sec |
| Additional 1g tranexamic acid | rTEG LY30 > 10% | EXTEM LI30 < 85% |

These algorithms are suggestions and augment empiric MHP therapy. This table follows data published from the iTACTIC RCT⁴. It is recommended that if similar algorithms are to be used, the algorithm is optimised for the hospital in which it is to be used. Please note do not withhold TXA therapy whilst waiting for VHA results.

Table 4 Details required on blood samples for the transfusion laboratory

| Known Patient | Unknown Patient |
|---|---|
| <p>Surname (in full)</p> <p>Forename (in full)</p> <p>Date of birth</p> <p>Patient Identification Number</p> <p>Sex (child-bearing potential)</p> <p>Date and time of sample</p> <p>Signature of the person taking the sample (may be electronic)</p> | <p>If the patient is unknown the following data must be included⁷</p> <p>Unique patient number</p> <p>Randomly generated forename/surname</p> <p>DOB as per local policy</p> <p>Date and time of sample</p> <p>Signature of the person taking the sample</p> <p>On confirmation of patient details and once the patient is clinically stable inform the transfusion laboratory, ensure the patient is wearing an updated identification band and re-bleed the patient labelling the bottles with:</p> <p>Surname (in full)</p> <p>Forename (in full)</p> <p>Date of birth</p> <p>Patient Identification Number</p> <p>Gender</p> <p>Date and time of sample</p> <p>Signature of the person taking the sample</p> |

DOB, date of birth; NHSI, National Health Service Improvement

Table 5 A rapid guide to blood components used in major haemorrhage in adults.

| Blood component | Storage conditions & shelf life | Volume per pack | Dosing regimes | Additional points |
|--|---|---|---|--|
| Red cells in additive solution | Up to 35 days at 2-6°C | Mean pack volume: 282 ml +/- 32 ml | Order 4–6 units initially, see text for choice of group | Rate of administration guided by rate of blood loss & haemodynamic compromise, aiming to maintain oxygen delivery to tissues. Blood should be given through a warming device. |
| Fresh frozen plasma (from one donor) (FFP) OR Solvent-detergent FFP (SDFFP) (pooled) | FFP: 36 months when frozen. Once thawed, 4 hours at 22°C & 5 days at 4°C for bleeding patients SDFFP: once thawed 8 hours at 22°C or 5 days at 4°C | FFP: mean pack volume is 273 ml +/- 17 ml SDFFP 200 ml | FFP: order 15-20 ml/kg in first instance. | Allow time for thawing – order in anticipation. Familiarise yourself with whether the hospital has a pre-thawed plasma policy |
| Platelets - apheresis from a single donor or pooled from 4 whole blood donations | Up to 7 days at 22 +/- 2°C on an agitator rack | Apheresis mean pack volume: 215 ml +/- 53 ml. Pooled: 310 ml +/- 33 ml | Order 1 adult therapeutic dose, monitor platelet count and aim to maintain platelet count > 50 x 10 ⁹ /l | Use a blood or platelet giving set with integral filter (170-200 micron). There should be close communication between the blood service and the transfusion laboratory to enable timely platelet transfusion. Anticipate need for platelet transfusions in on-going bleeding as platelet count falls to near/below 50 x 10 ⁹ /l. If no platelets are available on site, the clinical team must be informed with an approximate ETA |
| Cryoprecipitate (pooled from 5 donations) | 36 months when frozen. Cryoprecipitate can be stored for up to 4 hours at ambient temperature. Do not refrigerate post-thaw. | Mean pack volume is 152 ml +/-12 ml | Order 2 packs (2 x 5-unit pools) and aim to keep fibrinogen > 1.5 g/l. 2 packs contain 3-6 g fibrinogen in a volume of 300-500 ml | Allow time for thawing – order in anticipation. |

Details about neonatal / paediatric specifications for major bleeding and locally agreed concessionary release policy for acceptable alternatives for emergency use can be found in BSH guidelines on paediatric and neonatal transfusion.²⁸ ETA, expected time of arrival.

