GUIDANCE AND TRIAGE TOOL FOR THE RATIONING OF BLOOD FOR MASSIVELY BLEEDING PATIENTS DURING A SEVERE NATIONAL BLOOD SHORTAGE

Executive summary
The purpose of this document is to guide healthcare professionals in triaging patients in need of massive transfusion during a severe blood shortage. It will become operational where demand for blood greatly exceeds supply, and where all measures to manage supply and demand have been exhausted.

The document provides an emergency framework and triage tool to guide the allocation of blood for patients with massive haemorrhage during significant shortage of blood stocks. It is based on the evidence- and ethics-based Canadian framework.1 https://nacblood.ca/resources/shortages-plan/emergency-framework-final.pdf

The guidance complements existing national shortage plans for red cells2 and platelets3. Its aim is to support clinical decision-making by detailing a procedure for rationing resources that protects the community by maximizing benefits and sharing resources fairly.

Further general information about the management of major trauma patients can be found in the recent NHS England ‘Clinical guide for the management of major trauma patients during the coronavirus pandemic’.4

Background
Major haemorrhage is a clinical emergency associated with most specialities, but particularly cardiothoracic and vascular surgery, obstetrics, trauma and gastroenterology.5 Early haemostatic resuscitation with blood transfusion support saves lives but is resource intensive.

In the event of significant blood shortage, the use of blood may need to be rationed including for patients with major haemorrhage. During this period, there should be fair, equitable and transparent distribution of blood components to individual patients.

The National Blood Transfusion Committee (NBTC) has provided organisational guidance to address blood shortages. National plans for red cell and platelet shortages describe three phases: green (supply generally meets demand), amber (blood inventory is insufficient to continue usual transfusion practice) and red (severe, prolonged shortage).2,3

The national guidance recognises that clinical judgement and the specific context of the blood shortage are both essential to inform blood allocation. This emergency framework for clinical transfusion triage for massively bleeding patients is based on an evidence-based Canadian framework.1 The focus of the plan is red cell shortage, although it recognises that some patients with massive haemorrhage may require additional components.

Traditional definitions of massive haemorrhage may be inappropriate in acute clinical situations. Individual hospitals may wish to develop more dynamic definitions. Examples include an expected blood loss of one blood volume in less than 24 hours: 0.5 x blood volume loss in 3 hours, or transfusion of four or more units of red blood cells in one hour.
Methods
This guidance was prepared by a working group on behalf of the NBTC in England whose overall objective is to promote good transfusion practice by providing a framework to channel information and advice to hospitals and Blood Services in England on best practice; the NBTC is accountable to NHS England. Its content is based on existing guidelines for the management of blood shortages\textsuperscript{2,3}, and the Canadian emergency framework for clinical transfusion triage for massively bleeding patients.\textsuperscript{1} It was reviewed by members of the NBTC, which is accountable to the National Medical Director of NHS England through the Chief Scientific Officer. Its membership includes representatives of the medical Royal Colleges, specialist societies and other professional organisations with an interest in blood transfusion, the Chairs of the Regional Transfusion Committees in England, and patient representatives. Comments and suggestions were sought and received both verbally and in writing from the members of the NBTC at and after its March 30\textsuperscript{th}, 2020 meeting.

Operation of the plan
Should a national red cell shortage occur, NHS Blood & Transplant (NHSBT) will activate its emergency plan with the support of NHS England if necessary. It will notify Transfusion Laboratory Managers to implement their Emergency Blood Management Arrangements (EBMA). Those arrangements include establishing an Emergency Blood Management Group (EBMG) or equivalent.\textsuperscript{2,3}

A ‘Red Phase’ shortage will be declared if there is a severe shortage of red cells, or if there is an imminent severe threat to the supply of red cells. It is essential that senior hospital managers (i.e. Chief Executive and Medical Director) and clinicians support the EBMA and the arrangements for transfusion triage.

Hospitals may already have established an independent clinical triage team for resource allocation in the event of shortages. Transfusion could be included in these local arrangements during a ‘Red phase’ of blood shortage. If not, we recommend that senior managers and experienced physicians in roles outside the direct patient care of potentially affected patients are employed to assist with rationing decisions related to transfusion, so that front-line clinicians are relieved of this burden.

The emergency framework for rationing blood for patients predicted to need massive transfusion
Goal: To provide blood transfusions in an ethical, fair, and transparent way. All efforts should be made to minimize suffering and maximize the use of blood alternatives, as appropriate, for those who are triaged to ‘no transfusion’ due to insufficient resources.

Inclusion Criteria: All patients needing, or predicted to need, massive transfusion due to massive haemorrhage (as defined above) during a ‘Red Phase’ blood shortage.

All such patients should have access to all available blood conservation strategies. These include (but are not limited to) intravenous/oral iron, haemostatic agents, anti-fibrinolytics, erythropoiesis-stimulating agents, intraoperative cell salvage, interventional radiological procedures, rapid access to endoscopy, and non-invasive surgery. Early surgical intervention, attention to the management of coagulopathy and intra-operative cell salvage may be of value in patients with massive haemorrhage.

The initial aim should be the early identification of those patients who might need massive transfusion, and to triage them for transfusion support. Guidance and tools such as
those developed by NICE and the Royal College of Physicians may be helpful for triaging patients.\textsuperscript{6,7} Triage is a dynamic process and patients should be actively re-assessed based on the following general and condition specific exclusion criteria.

Any decisions made to begin, withdraw or withhold care must also comply with the shared decision-making policies of the NHS. This means that these decisions should include the patient and their wishes (as much as is feasible for the given situation) and, if appropriate, the patient’s carers.

**General Exclusion Criteria**

*Note: These general exclusion criteria should be considered in patients needing massive transfusion support. An algorithm for triage is shown in Appendix A. Additional guidance for specific conditions is shown in Appendix B.*

A. Severe burns of patient with any 2 of the following:
   i) Age > 60 years.
   ii) 60\% of total body surface area affected
   iii) Inhalation injury requiring mechanical ventilation

B. Cardiac arrest where the cause is not considered reversible

C. Advanced, progressive baseline cognitive impairment

D. Advanced, progressive untreatable neuromuscular disease

E. Metastatic malignant disease with expected survival less than 6 months

F. Advanced and irreversible immunocompromise

G. Severe and irreversible acute neurologic event or condition

H. End-stage organ failure meeting the following criteria:
   i) *Heart*: NYHA class III or IV heart failure
   ii) *Lungs*:
      - COPD with FEV1 < 25\% predicted, baseline PaO\textsubscript{2} < 7 KPa or secondary pulmonary hypertension
      - Cystic fibrosis with post-bronchodilator FEV1 < 30\% or baseline PaO\textsubscript{2} <7 KPa.
      - Pulmonary fibrosis with VC or TLC < 60\% predicted, baseline PaO\textsubscript{2} < 7 KPa or secondary pulmonary hypertension.
      - Primary pulmonary hypertension with NYHA class III or IV heart failure, right atrial pressure > 10 mm Hg, or mean pulmonary arterial pressure > 50 mm Hg

I. Refusal of blood. Note that patients may vary in their acceptance of different blood components.

Abbreviations: SpO\textsubscript{2} = oxygen saturation measured by pulse oximetry, FIO\textsubscript{2} = fraction of inspired oxygen, NYHA = New York Heart Association, COPD = chronic obstructive pulmonary disease, FEV1 = forced expiratory volume in 1 second, PaO\textsubscript{2} = partial pressure.

**Reassessment for Triaged Patients**

1) **Patients triaged to no blood components:**
   Patients triaged to no transfusion care should be re-assessed at a minimum of every 24 hours. A system should be in place to support physicians caring for the patient if an improvement in a patient's status would now qualify them to be re-triaged to active transfusion management.

2) **Patients triaged to blood components:**
   Patients triaged to active transfusion care should be assessed at start of massive haemorrhage resuscitation, and after a minimum of every 8 units of red blood cells (adjusted for patient size, for example for children) or every 24 hours for patients receiving less than 8 units of blood or until cessation of haemorrhage (or more frequently – e.g.
every 4 units if deemed necessary). If there is persistent bleeding following surgical intervention, there should be close attention to the correction of coagulopathy and consideration of return to theatre.

At each assessment, the triage team should assess and document the patient’s status and overall futility for continuation of active treatment, utilizing the following variables to guide their decisions regarding the value of continued transfusions:

i) sequential organ failure assessment (SOFA) score;
ii) total blood components used;
iii) need for ongoing transfusion support;
iv) ability to control bleeding with either surgery or other procedure (e.g. interventional radiology, endoscopy).

Patients with a SOFA score >11, who have a continued need for large amounts of blood components, and where there is no foreseeable ability to control blood loss should be triaged to palliative care.

Ethical framework for triaging patients to active transfusion care
There is existing guidance to assist decision making where two or more patients, who equally qualify for active transfusion management, require blood components at the same time. The British Medical Association has drawn attention to a Government ethical framework designed to support thinking through strategic aspects of decision-making during a pandemic. It provides several guiding principles:

Equal respect: everyone matters and everyone matters equally, but this does not mean that everyone will be treated the same;
Respect: keep people as informed as possible; give people the chance to express their views on matters that affect them; respect people’s personal choices about care and treatment;
Minimise the harm of the pandemic: reduce spread, minimise disruption, learn what works;
Fairness: everyone matters equally. People with an equal chance of benefiting from a resource should have an equal chance of receiving it – although it is not unfair to ask people to wait if they could get the same benefit later;
Working together: we need to support each other, take responsibility for our own behaviour and share information appropriately;
Reciprocity: those who take on increased burdens should be supported in doing so
Keeping things in proportion: information communicated must be proportionate to the risks; restrictions on rights must be proportionate to the goals;
Flexibility: plans must be adaptable to changing circumstances;
Open and transparent decision-making: good decisions will be as inclusive, transparent and reasonable as possible. They should be rational, evidence-based, the result of a reasonable process and practical in the circumstances.

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29th April 2020
References


Appendix A

Emergency Framework for Blood Rationing - Algorithm for Triage Team (Part 1)

Patient needing or predicted to need massive transfusion

NO

Follow guidance from Emergency Blood Management Group and the Contingency Blood Shortage Plan

YES

General Exclusion Criteria

A. Severe burns of patient with any 2 of the following:
   i) Age >60yrs
   ii) >60% of total body surface area affected
   iii) Inhalation injury requiring mechanical ventilation

B. Cardiac arrest where the cause is not considered reversible

C. Advanced, progressive baseline cognitive impairment

D. Advanced, progressive untreatable neuromuscular disease

E. Metastatic malignant disease with expected survival less than 6 months

F. Advanced and irreversible immunocompromise

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H. End-stage organ failure meeting the following criteria:
   i) Heart – NYHA class III or IV heart failure
   ii) Lungs – COPD with FEV1 <25% predicted, baseline PaO₂ <7 KPa, or secondary pulmonary hypertension; Cystic fibrosis with post-bronchodilator FEV1 <30% or baseline PaO₂ <55mmHg; Pulmonary fibrosis with VC or TLC <60% predicted, baseline PaO₂ <7 KPa, or secondary pulmonary hypertension; primary pulmonary hypertension with NYHA class III or IV hear failure, right atrial pressure >10mmHg, or mean pulmonary arterial pressure > 50mmHg.

Does patient meet one of the above general exclusions?

YES

Do not transfuse.
Re-assess as per guidelines

NO

Specific Exclusion Criteria based on clinical factors specific to patient populations (see Appendix B for specific details for each)

- Trauma with significant or non-survivable brain injury
- Ruptured Abdominal Aortic Aneurysm with cardiac arrest, or unresponsive to fluid resuscitation or not eligible for surgery
- Extracorporeal Membrane Oxygenation/Ventricular Assisted Device with multi-organ failure
- Organ transplant
- Other: mortality likely >80%

Go to page 2 of algorithm
Emergency Framework for Blood Rationing - Algorithm for Triage Team (Part 2)

Does patient meet one of the above specific exclusions?

YES

Do not transfuse.
Re-assess as per guidelines

NO

Is there enough inventory to meet current demand at hospital level?

NO

Is inventory concern related to competing patients eligible for transfusion?

NO

Do not transfuse.
Re-assess as per guidelines

YES

Principles for prioritisation
1. Maximisation of benefits
2. Fair allocation of resources

Re-evaluate at specified intervals for eligibility for ongoing transfusion:
1. Every 24 hours
2. Every 8 units of RBC (to be adjusted by the EBMG as determined by blood availability)
3. Re-assess according to the reassessment criteria for triaged patients.

YES

Proceed with transfusion

NO

Is a patient meeting these criteria?

NO

Do not transfuse.
Re-assess as per guidelines

YES

Figures for Appendix A have been adapted from Emergency framework for rationing of blood for massively bleeding patients during a red phase of a blood shortage.¹
Appendix B

Senior clinical assessment is recommended for the following scenarios where the patients also have massive bleeding. We recognise that Royal Colleges and specialist societies have developed more tailored advice on ethical issues for their members.

**Trauma**

1) Children or adults considered to have significant or non-survivable brain injury.

   *Clinical Consideration: CT/MRI scanning should be done as soon as possible to confirm the diagnosis of a non-survivable brain injury.*

**Ruptured Abdominal Aortic Aneurysm (RAAA)**

1) Patients with pre-operative cardiac arrest

2) Patients with a systolic blood pressure less than 70mmHg who are unresponsive to fluid resuscitation and have lost consciousness.

3) Patients with RAAA that do not meet criteria for emergent vascular repair.

**ECMO/VAD**

1) Patients who require ECMO/VAD and who have multi-organ failure.

**Gastroenterology**

1) *Clinical Consideration: Triage patients with gastrointestinal bleeding to centres with endoscopy to minimise the use of blood products.*

**Organ transplantation**

1) Patients after the declaration of brain death who are awaiting deceased organ donation.

2) Patients undergoing deceased donor organ retrieval.

3) Deceased donor solid organ transplantation - patients and clinicians must be aware prior to the start of transplantation that blood may not be available for transfusion for massive bleeding during a ‘red phase’. This needs to be included in informed consent discussions.

4) Living donation – during a ‘red phase’ it is expected that these would be deferred due to the risk that blood may not be available for transfusion if massive bleeding occurred.

**Other Massively Bleeding Situations not listed above**

1) In a red phase, for patients with massive bleeding for reasons not listed above, do not transfuse patients for whom the triage team believes the mortality rate exceeds 80%.

Adapted from Emergency framework for rationing of blood for massively bleeding patients during a red phase of a blood shortage.1