Guidelines for the Blood Transfusion Services

Annexe 5: Blood Components for Contingency Use

http://www.transfusionguidelines.org/red-book/annexe-5

Annexe 5:

Blood Components for Contingency Use

This section contains specifications for blood components used for contingency for a limited time, which will be posted here for the applicable period. Use will be at the discretion of each UK Blood Service.

Guidance notes for use when implementing components for contingency use

This guidance has been produced in order to provide Blood Establishments with a checklist of items to be considered before implementing components for contingency use, or reactivation of components after they have been archived.

The findings may then inform any further validation work that is required prior to activation of a component.

Guidance

Before implementing or reactivating a component, the following should be considered:

- Any changes that individual Blood Establishments have since made to the way blood or blood components have been collected, including by whole blood or component donation. This must include blood bag material/plasticiser and anticoagulant etc.
- Any changes that individual Blood Establishments have since made to their manufacturing processes, as these may impact on component quality
- A review of any new scientific or clinical data in the context of the specification
- A review of the original validation data and output report, including any caveats or stipulations around use or application
- A review of the specification to ensure that the content remains current and accurate (this might also include a comparison with a similar or relevant component in Chapter 7)
- A review of any other, or new, specific clinical indications for use
- Approval from JPAC for use of the component in the context of the relevant situation (i.e. subject to a case by case review).

Blood Components for Contingency Use

A5.1: Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life

A red cell component containing less than 1×10^6 leucocytes and suspended in an approved additive solution.

A5.1.1: Technical information

- A red cell component prepared by removing a proportion of the plasma from leucocyte-depleted whole blood and suspending in an approved additive solution. Leucodepletion may be carried out on either the whole blood starting material or on the final component.
- Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life should be administered through a CE/UKCA/UKNI marked transfusion set.
- May be produced by remanufacture of Red Cells for Exchange Transfusion, Leucocyte Depleted (section 7.7.3) up to 6 days after donation.

A5.1.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Red Cells in Additive Solution, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the name, composition and volume of the additive solution
- the date of collection
- the expiry date*
- the temperature of storage
- the blood pack lot number.*

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

A5.1.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 42 days at a core temperature of 4 ±2°C.

- Variation from the core temperature of 4 ±2°C of the finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.

- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C, components may be released for transfusion provided that:
    - the component has been exposed to such a temperature change on one occasion only
    - the duration of the temperature excursion has not exceeded 5 hours
    - a documented system is available in each Blood Centre or hospital to cover such eventualities
    - adequate records of the incident are compiled and retained.

A5.1.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table A5.1 shall meet the specified values.

Table A5.1 Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	280 ±60 mL
Haemoglobin content [2]		>=40 g/unit
Haemolysis	As per section 7.1.3	<0.8% of red cell mass
Leucocyte count [3]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units measured and found to be >375 mL should not be issued for transfusion		
[2] Units measured and found to have <30 g/unit should not be issued for transfusion		
[3] Methods validated for counting low numbers of leucocytes must be used		

A5.1.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically

- if melting ice is used, it should not come into direct contact with the components

- dead air space in packaging containers should be minimised

- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours

In some instances, it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

A5.1.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.

Blood Components for Contingency Use

A5.2: Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency

A single-donor platelet component containing less than 1×10^6 leucocytes.

A5.2.1: Technical information

- Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency may be collected by a variety of apheresis systems using different protocols. Since platelet yields may vary, each procedural protocol must be fully validated, documented and specifications set accordingly.
- If a double or triple dose is collected the platelet concentrate must be temporarily split, as a continuous part of the collection process, into the storage packs integral to the collection set so that the capacity of an individual pack is not exceeded.
- If filtration is used the recommended capacity of the filter should not be exceeded.

- The volume of suspension medium must be sufficient to maintain the pH at >=6.4 at the end of the shelf life of the component.

- If the leucodepletion process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure the correct identification number is put on the final component pack.

- The plasma from group O donors should be tested for high-titre anti-A and anti-B, and 'high-titre negative' units labelled. The testing method and acceptable limits should be defined (see also Chapter 9). Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy.

- Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency should be administered through a CE/UKCA/UKNI marked transfusion set.

A5.2.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Platelets, Apheresis, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number and, if divided, sub-batch number*
- the ABO group*
- the RhD group stated as positive or negative*
- the expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*
- the name, composition and volume of the anticoagulant or additive solution.

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

A5.2.3: Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets and whether an open or closed system is used.

- Packs currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days, but due to concerns over bacterial contamination requires either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen inactivation procedure.

- Where any manufacturing step involves an open system the platelets should be used as soon as possible after collection. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours.

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided that no single interruption lasts for more than eight hours, and the total length of all interruptions is no longer than 24 hours.

A5.2.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.7.1), a minimum of 75% of those components tested for the parameters shown in Table A5.2 shall meet the specified values.

Table A5.2 Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count [2]		>=150 × 10^9/unit
pH at end of shelf life [3]		>=6.4
Leucocyte count [4]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units measured and found to be outside of the range 100 to 380 mL should not be issued for transfusion		
[2] Units measured and found to have <120 × 10^9/unit or more than the maximum recommended by the manufacturer of the storage pack, where stated, should not be issued for transfusion		
[3] A minimum of 95% of components tested shall meet the specified value		
[4] Methods validated for counting low numbers of leucocytes must be used		

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

A5.2.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.