Guidelines for the Blood Transfusion Services

A3.6 Whole Blood, Leucocyte Depleted, for Clinical Studies

http://www.transfusionguidelines.org/red-book/annexe-3/a3-6

Provisional Component

A3.6: Whole Blood, Leucocyte Depleted, for Clinical Studies

A unit of blood collected into CPD anticoagulant, containing red cells, plasma and platelets as well as less than 1×10^6 leucocytes.

A3.6.1: Technical information

- Whole Blood, Leucocyte Depleted (LD), for Clinical Studies is intended for the treatment of major haemorrhage only, and currently only as part of clinical studies, initially in the pre-hospital situation, with transfusion of a maximum of 4 units (or weight-related equivalent for children) prior to switching to standard component therapy.
- A unit of whole blood collected in the UK currently consists of 470 mL ±10% of blood from a suitable donor (see Chapter 3), plus 63 mL of CPD anticoagulant, which is then LD, and stored in an approved container. The Eurobloodpack contains 66.5 mL of anticoagulant and is suitable for the collection of 475 mL ±10%, although in the UK a volume of 495 mL will not be exceeded.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for direct clinical use.
- Donations should be selected from male donors as a TRALI risk reduction measure.
- The component should be produced from group O RhD negative, Kell negative donations
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B
- Whole Blood, Leucocyte Depleted, for Clinical Studies should be administered through a CE/UKCA /UKNI marked transfusion set.

A3.6.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Whole Blood, Leucocyte Depleted, for Clinical Studies* 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 anticoagulant 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

A3.6.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 21 days at a core temperature of 4 ±2°C.

- Variation from the core temperature of 4 ±2°C must be kept to a minimum during storage 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, red cell components which have been exposed to a core temperature not exceeding 10°C and not less than 1°C 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 to cover such eventualities
    - adequate records of the incident are compiled and retained.

A3.6.4: 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 A3.6 shall meet the specified values. Table A3.6 does not include plasma quality monitoring parameters as the component will not be within the Blood Service at the end of shelf-life. This should be revalidated annually.

Table A3.6 Whole Blood, Leucocyte Depleted, for Clinical Studies – 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 range
Platelet count		
Haemoglobin content		>=40 g/unit
Haemolysis	As per section 7.1.3	<0.8% of red cell mass
Leucocyte count [2]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] After volume losses resulting from leucodepletion		
[2] Methods validated for counting low numbers of leucocytes must be used. 100% of units must be monitored for residual leucocytes and any units measured and found to be $>5 \times 10^6$/Unit must not be issued for clinical use.		

A3.6.5: 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
- transport time normally should not exceed 12 hours.

In some instances, it is necessary to issue red cell components 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.

A3.6.6: Removal from and return to 2-6°C controlled storage within hospitals / pre-hospital clinical environment

For occasions when units of Whole Blood, Leucocyte Depleted, for Clinical Studies are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- the time out of a controlled temperature environment should be restricted to under 30 minutes and on one occasion only.

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