Change Notification for the UK Blood Transfusion Services

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No. 22 – 2023

Guidelines for the Blood Transfusion Services in the UK

Revised annexe

For this CN only, changes to the text are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

The following changes apply to:

Annexe 3 Provisional Components

A3.5 Red Cells and Plasma, Leucocyte Depleted

A unit of blood collected into CPD anticoagulant, containing less than 1×10^6 leucocytes.

A3.5.1: Technical information

- Red Cells and Plasma, Leucocyte Depleted (LD) is intended for the treatment of major traumatic haemorrhage ~~only, and currently only as part of clinical studies 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. ~~During the study period it may also be used for the treatment of non-traumatic major haemorrhage in patients who are blood group O and who require both red cells and plasma for treatment of bleeding, using the above dose.~~
- 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 made 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
- Red Cells and Plasma, LD, should be administered through a CE«/UKCA/UKNI» marked transfusion set.

A3.5.2: Labelling

For general guidelines, see section 6.6 of the Red Book.

The following shall be included on the label:

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

- Red Cells and Plasma, 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 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

A3.5.3: Storage

For general guidelines, see section 6.7 of the Red Book

- The component may be stored for a maximum of 14 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.

A3.5.4: 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 of the Red Book), a minimum of 75% of those components tested for the parameters shown in Table A3.5 shall meet the specified values. Table A3.5 does not include plasma quality monitoring parameters as the Red Cells and Plasma, Leucocyte Depleted component will not be within the Blood Service at the end of shelf-life and as plasma quality at the point of production is already monitored as part of the process of manufacturing Fresh Frozen Plasma, Leucocyte Depleted from whole blood, using the same filtration process.

Table A3.5 Red Cells and Plasma, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume*	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)	470 ±50 mL
Haemoglobin content	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)	≥40 g/unit
Haemolysis	As per section 7.2	<0.8%
Leucocyte count**	As per sections 6.3 and 7.1	<1 × 10^6/unit
* After volume losses resulting from leucodepletion		
** Methods validated for counting low numbers of leucocytes must be used		

A3.5.5: Transportation

For general guidelines, see section 6.11 of the Red Book.

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.

A3.5.6: Removal from and return to 2-6°C controlled storage within hospitals/pre-hospital clinical environment

For occasions when Red Cells and Plasma, Leucocyte Depleted 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.

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