Guidelines for the Blood Transfusion Services

7.7.1: Red Cells for Intrauterine Transfusion, Leucocyte Depleted

http://transfusionguidelines.org/red-book/chapter-7/7-7/7-7-1

7.7.1: Red Cells for Intrauterine Transfusion, Leucocyte Depleted

A component for intrauterine transfusion (IUT), prepared by removing a proportion of the plasma from fresh whole blood. The component should be leucocyte depleted to less than 1×10^6 leucocytes per unit.

7.7.1.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for intrauterine transfusion and use in neonates and infants under 1 year.
- The component must be prepared and used for IUT by the end of Day 5, should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B (see Chapter 12), and should be negative for antibodies to CMV.
- Whenever possible the component should be selected from male donors as a TRALI risk reduction measure.
- The component must be irradiated and should be transfused within 24 hours of irradiation. See the British Society for Haematology (BSH) 'Guidelines on transfusion for fetuses, neonates and older children'.[6]
- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.
- Red Cells for Intrauterine Transfusion, Leucocyte Depleted should be administered through a CE /UKCA/UKNI marked transfusion set.

7.7.1.2: 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 for Intrauterine Transfusion, 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

7.7.1.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 5 days at a core temperature of 4 ±2°C.
- The component must be used within 24 hours of irradiation and within the overall maximum 5-day shelf life.
- 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.

7.7.1.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.1 shall meet the specified values.

Table 7.7.1 Red Cells for Intrauterine Transfusion, Leucocyte Depleted – 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
Haematocrit [2]		0.70 – 0.85
Haemoglobin content [3]		Locally defined
Leucocyte count [4]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units measured and found to be <150 mL or >350 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to be <0.70 or >0.85 should only be issued for transfusion under concessionary release		
[3] Units measured and found to have <40 g/unit should only be issued for transfusion under concessionary release		
[4] Methods validated for counting low numbers of leucocytes must be used		

7.7.1.5: 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.

7.7.1.6: 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.