Guidelines for the Blood Transfusion Services

7.1.1: Leucocyte depletion

http://aws-lon-jpac.targetservers.uk/red-book/chapter-7/7-1/7-1-1

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With very few stated exceptions (e.g. granulocytes), from November 1999 all allogeneic blood components produced in the UK have been subjected to a leucocyte depletion process. The term ‘LD’ may be used where necessary instead of ‘leucocyte depleted’ or ‘leucocyte depletion’ although component names will state ‘Leucocyte Depleted’ where appropriate. The UK specification for leucodepletion is that more than 90% of leucocyte-depleted components from relevant processes should have less than 1×10^6 leucocytes and more than 99% of components should contain less than 5×10^6 leucocytes, both with 95% confidence. Process performance should be assessed against the 1×10^6 limit when using statistical process control (statistical process monitoring) measurements.

Leucocyte depletion can be achieved by a number of methods, which must be validated before use. If filtration is used the recommended capacity of the filter must not be exceeded.

Currently, it is not feasible to assess all components for the effectiveness of the leucodepletion process. Therefore, the UK Blood Transfusion Services (UKBTS) should apply recognised statistical process monitoring methodologies such as those proposed by the International Society of Blood Transfusion Biomedical Excellence for Safer Transfusion (ISBT) BEST Expert Working Party, published in Transfusion[1], to ensure the following:

- conformance of the process to the LD process specification
- identification of LD component specified limit failures
- stability of the process over time.

The residual leucocyte testing schedule should be defined in process monitoring and conformance checking procedures.

It is advisable to identify results to a production run or ‘batch’ and to ensure conformance of components to relevant specifications before release of components to stock or to ensure that a monitored filter batch is producing components that conform to specification.

A leucocyte depletion process is controlled if a control chart or equivalent is in use and does not currently display control limit or trend warnings.

A leucocyte depletion process is uncontrolled if a control chart or equivalent is not in operation for the process or if a current control chart or equivalent displays control limit or trend warnings.

Where statistical process monitoring methodology is not judged appropriate due to an inability to control the process or the production of small numbers of components, all components routinely issued to stock must have been shown to contain less than 5×10^6 leucocytes.

Issue (to stock) of components, which do not meet the leucocyte depletion specified limit of less than 5×10^6/unit, must follow a concessionary release procedure (see Section 6.10).

Patient-designated components should not be discarded before referral to a clinician.

Secondary components or split components produced from primary components do not require a leucocyte count provided the primary process is controlled or the individual primary component is tested and found to be acceptable.

Plasma components derived from whole blood filtration do not require residual leucocytes to be monitored provided the associated red cell process is controlled.

Leucocyte or platelet counts on components produced from frozen and thawed material should be made, where necessary, prior to the initial freezing process unless otherwise validated.

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.

Leucocyte depletion of components should take place before the end of Day 2 (Day 0 is the day of collection).

Once a red cell component has been cooled to its storage temperature (i.e. 4 ±2°C) prior to leucodepletion, and when leucodepletion by filtration is to take place at ambient temperature, the ambient temperature of the room in which filtration takes place should not exceed 26°C (see also section 6.4).

If components are removed from their designated storage temperature to undergo a leucodepletion process, they must be returned to their storage temperature as soon as possible and in any event within 3 hours (see also section 6.4).