II. Universal leucodepletion: Cost/Benefit Analysis

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Further to a Consensus Conference in Edinburgh, the UK published guidelines with indications for leucodepletion (LD) in 1998. These were:

- For intrauterine transfusions and for neonates and infants up to one year of age.
- Severe aplastic anaemia, to reduce allograft failure.
- When CMV-safe components are indicated.
- To manage/prevent febrile non-haemolytic transfusion reactions (FNHTR) for long-term red cell transfusion-dependent patients (e.g. thalassaemics) or where the use of buffy code depleted components does not work.

These guidelines would require 5-10% of red cells and 50% of platelet donations in the UK to be leucodepleted. Red cells are ID by filtration and platelets can be leucodepleted by filtration (usually as pools of concentrates separated from whole blood donations) or by modern apheresis technology. In the UK, a blood component is considered leucodepleted if it contains fewer than 5 million leucocytes in 99% or more of components tested, with 95% confidence. In France, LD components should contain fewer than one million leucocytes in 99% or more of components tested with 95% confidence. The Council of Europe's definition of LD is less than one million leucocytes in 90% of units and the level of confidence is not stated. In essence, these definitions of LD are very similar. Leucodepletion must be carried out within 24 hours and no longer than 48h of collecting the blood. Bedside LD is not considered appropriate or equivalent to pre-storage LD since it cannot be appropriately quality-controlled, and often, the blood component is older than 48 hours.

When universal LD is introduced, intensive monitoring of results and analysis of failures are essential. However, quality monitoring of LD is expensive and difficult since we cannot count white cells in every component tested even though automated methods are essential. Flow cytometry seems to give the most reliable results and the UK follows the strategy designed by the BEST group of ISBT. Process validation should be carried out by statistical process control and both internal and external quality assurance schemes for white cell counting should be in place.

In recent years, blood component therapy has witnessed opposing trends in the area of LD. On the one hand there has been widespread forced implementation of universal LD by several national blood services including the UK National Blood Services and the American Red Cross. The reasons in the UK were to prevent the hypothetical risk of transmission of vCJD by transfusion, since it was known that the vCJD prion has a particular lymphoreticular association. The USA and most Western European countries introduced leucodepletion in order to reduce the already very low risks of transfusion and approach "zero risk", as demanded by the public, the media and courts of law (precautionary principle). The forced implementation came at a high cost to blood services and hospitals and with the strong endorsement of the UK Departments of Health, the French Blood Agency and the US Food and Drug Administration (FDA). Buildings needed to be expanded, equipment needed to be purchased and more staff had to be recruited and trained.

Also, in recent years, several pivotal clinical trials have been published failing to demonstrate significant patient benefit from the use of LD-blood components. The emerging scientific and clinical evidence demonstrates that LD technology is an effective means to reduce the risk of 3 complications of blood transfusion: HLA alloimmunisation and immunological refractoriness to platelet transfusions; cytometalobirus (CMV) transmission and recurrent FNHTRs. The universal applications of LD technology to all blood components for all patients does not appear to be warranted in these times of ever-increasing demands for healthcare resources.

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