

Joint UKBTS / NIBSC Professional Advisory Committee (1)

UKBTS General Information 02

Evaluation of novel platelet components

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Background

Specific criteria for evaluation of new platelet components have not so far been defined in the Guidelines for the Blood Transfusion Services in the UK. Examples of new components, rather than minor amendments to existing components, are extended shelf life platelets and platelets in Platelet Suspension Medium. The criteria for approving, e.g. extended storage, have been discussed at FDA. Certain storage bags for apheresis and pooled platelets are already licensed for 7 days' storage, based on pH at outdate. FDA are also considering an additional requirement, based on results of recovery and survival studies in normal volunteers, whereby recovery at outdate has to be 66% of that of fresh platelets, and survival 58% of fresh. FDA has not mandated any requirement to perform a clinical trial.

SACBC have considered what criteria should be satisfied for approval of novel platelet components. (The definition of novel is "significant difference from current processing systems, as assessed by SACBC").

The options for assessing novel platelet components are as follows:

1. Licensed (CE marked) pack.
2. In vitro data comparable to currently used systems.
3. Volunteer (recovery and survival) studies to meet FDA requirements.
4. Platelet increment data from a clinical study.

Recommendation

Preferably data should be evaluable to satisfy assessment criteria 1, 2 and 3 above. For some systems, however, volunteer recovery and survival data is hard to obtain e.g. for pooled buffy coat derived components. In such circumstances, therefore, so long as in vitro data is satisfactory, an acceptable alternative would be platelet increment data from a clinical study.

Data will then be collated and further work sourced as appropriate to assess, in the first instance, extension of platelet shelf life to 7 days and platelets in Platelet Suspension Medium, according to these criteria.

(1) **Joint United Kingdom Blood Transfusion Services and National Institute for Biological Standards and Control Professional Advisory Committee**