

SaBTO

Advisory Committee on the Safety of
Blood, Tissues and Organs

Summary of the Seventh Meeting, 14/15 July 2009

1. Risk-reduction strategies for bacterial contamination of platelets

There are a number of measures already in place to reduce risk from platelet transfusion, such as diversion of the first 10-20 ml of the donation, and enhanced arm-cleansing. A working group consisting of SaBTO members and other experts has discussed possible further options, such as screening platelet donations for bacterial contamination, pathogen inactivation of platelets or reducing platelet shelf-life. Screening is already in place in Scotland, Northern Ireland and Wales but SaBTO did not recommend that it be implemented in England as there is uncertainty about its effectiveness in mitigating risk. SaBTO agreed with the expert working group and will not make a final recommendation concerning pathogen inactivation before results were available from a clinical trial being undertaken in the Netherlands. This should report in Autumn 2009. In the meantime, SaBTO asked that further work be done by the UK Blood Services on the ancillary benefits of pathogen inactivation.

2. Percentage of platelets collected by apheresis as a vCJD risk-reduction measure

Collecting platelets by apheresis reduces the donor exposure of the recipient and thus reduces risk from vCJD. The percentage of platelets collected by apheresis differs across the 4 UK Blood Services. SaBTO recommended that at least 80% of platelets should be collected by apheresis by all the UK Blood Services.

3. Evidence base for exclusion of high-risk blood donors

SaBTO were presented with an analysis of the most recent data in relation to risk of infections amongst certain groups currently excluded or deferred from donating blood. The committee will take into account information/views from the public meeting planned on this topic in October 2009. Members noted that the data are incomplete, but are the best available at this time. Members would like to see further analysis prior to the public meeting in October.

Members agree that donor deferral criteria must be based on estimates of risk, and any lifetime deferral must be justified by robust evidence. Members did not wish to recommend a change in policy at this stage but will further review this subject following the public meeting on this topic in October 2009. In addition, a report is expected in 2010 of a research study into donor compliance with deferral criteria.

A document will be produced for the October public meeting which clearly explains the evidence for current donor deferral and exclusion.

4. vCJD risk-reduction strategies for blood components

i. Update on blood tests for vCJD and prion filtration of blood

There are no licensed tests to screen blood for vCJD. Several tests are in development and at various stages of assessment, and SaBTO will be kept updated on progress.

The committee were updated orally on studies carried out on behalf of the Blood Services to assess the safety and efficacy of the prion filters. Some data had become available in the few days leading up to the SaBTO meeting from independent assessment of the removal capacity of the CE-marked prion filter for red cells. A further paper will be provided to SaBTO for its October meeting.

ii. Plasma

Members were appraised of a large body of work carried out by an expert working group looking at the available options for further reducing the risk of vCJD transmission to adult patients who require transfusion of fresh frozen plasma (FFP). UK-derived FFP is not used for children or for high usage adult patients (those with thrombotic thrombocytopenic purpura, TTP). The alternatives to UK-derived FFP presented to the committee were importation of single-unit FFP (which would need to be pathogen inactivated by the Blood Services or a commercial supplier) and use of commercially available pooled FFP that is pathogen inactivated. In-house pathogen inactivation of imported single unit FFP is thought to be less feasible than a commercial supply of pathogen inactivated pooled or single unit FFP. SaBTO made the following recommendations:

- Use of UK-derived FFP should be ceased, and replaced by imported FFP for all recipients;
- Source countries of plasma should show an estimated subclinical vCJD prevalence of at least 3 log below that of the UK (but in principle the lower the better);
- Use of pooled FFP is acceptable where a combination of sourcing and processing results in a 4-5 log decrease in relative risk compared with UK-derived FFP.

iii. Cryoprecipitate

SaBTO have previously expressed concern at the amount of cryoprecipitate used in the UK compared with other European countries. There is also concern that cryoprecipitate may be being used inappropriately. There is a commercially available fibrinogen concentrate available which could replace cryoprecipitate for use in hypo-fibrinogenaemias, but this product is not yet licensed in the UK. Another alternative to use of UK-derived cryoprecipitate would be to produce it from imported plasma, but this would be operationally challenging. A full paper with full cost-benefit analysis of the alternatives will be brought to a future meeting of the committee; in the meantime the licensing situation will be explored with the manufacturers of the concentrate.

5. Production of safety information leaflet for clinicians

During the course of the discussions at this meeting, members suggested that many clinicians are not aware of the potential microbiological hazards of prescribing platelets and cryoprecipitate. SaBTO will work with other professional groups to produce a document outlining these hazards to better inform clinicians, which may in turn lead to a decrease in inappropriate use of these components.

6. Pandemic flu

SaBTO were updated on the pandemic flu plans being put in place by the UK Blood Services.