

SaBTO

Advisory Committee on the Safety of
Blood, Tissues and Organs

Summary of the Eighth Meeting, 27 October 2009

1. Consent for blood transfusion

Members were reminded that questionnaires regarding informed consent for blood transfusion had been finalised by a working group consisting of SaBTO members and other experts. Two questionnaires have been developed which are specifically for either Healthcare Professionals or Patient groups. The working group had agreed the management of the consultation process with the Department of Health. The consultation process will be UK wide. Participants will be given 12 weeks to respond, after which time the consultation will close and the responses will be analysed.

2. MSBTO Guidance update

Members noted the urgent need for this update, which was expected to be forthcoming shortly.

3. Prion Filtration

Members had discussed prion filtration at previous meetings, and had asked to be kept updated on progress of both efficacy and safety assessments. This was provided via a presentation from the vCJD working group, with new data from both the ongoing clinical trial to assess safety of prion filtered red blood cells (the PRISM trial) and independent efficacy assessments of the performance of the same product. Early results from the clinical trial are encouraging, but members noted that the trial is still some way from completion. Members were appraised of data from the Health Protection Agency's independent evaluation of efficacy, in addition to information from the manufacturer and another independent study. The committee noted that independent data from animal based, endogenous studies of efficacy will not be available until 2014.

Having considered the information and analysis provided, the committee:

- is satisfied that there is now sufficient evidence that this particular filter reduces infectivity;
- recommends that filtered red cells be provided to those born since 1 January 1996, subject to satisfactory completion of the PRISM clinical trial.

The committee also noted that, if implemented, the continuing requirement for prion filtration should be reviewed in the event that either further data on prevalence or efficacy of the filters becomes available.

The committee had previously recommended the introduction of double dose red cells (DDRC) as a vCJD risk-reduction measure for under 16s and patients with haemoglobinopathies. SaBTO recommended that DDRC be rescinded for those groups receiving prion filtered blood.