SaBTO: Advisory Committee on the Safety of Blood, Tissues and Organs

Annual Report 2016-17

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Topics considered in 2016-17

Blood

Hepatitis E Virus (HEV)

Selective testing of a proportion of blood donations by UK Blood Services began in Spring 2016. SaBTO was notified that demand was considerably higher and that prevalence was around twice that predicted. Feedback from many stakeholders on a number of issues led to the formation of a working group, chaired by Professor Richard Tedder to review the measures taken to protect vulnerable groups from persistent HEV infection.

Review the epidemiology of hepatitis E in the UK together with evidence on clinical impact of hepatitis E infection, and in particular, review and define diverse groups of patients at risk of persistent hepatitis E infection, taking cognisance of current data. The review covered blood, tissues and cells, and organs.

A review of the evidence led to the recommendations below on which patients should be protected from HEV transfusion transmitted infection. Cost effectiveness analysis and estimation of the hidden costs to hospitals and blood services of running a dual inventory led the working group to recommend universal screening of blood donations for HEV and this was agreed by SaBTO in November 2016.

SaBTO considers the following patient groups at risk of harm from persistent HEV infection.

1. Patients with evidence of severe primary immunodeficiency

2. Patients currently being treated for malignant disease with immunosuppressive chemotherapy or radiotherapy, or who have terminated such treatment within at least the last six months.

3. Patients who have received a solid organ transplant and are currently on immunosuppressive treatment.

4. Patients who have received a haematopoietic stem and progenitor cell transplant for at least 12 months after finishing all immunosuppressive treatment or longer where the patient has developed graft versus host disease.

5. Patients receiving systemic high dose steroids until at least three months after treatment has stopped.

6. Patients receiving other types of immunosuppressive drugs, either alone or in combination with lower doses of steroids, until at least six months after terminating such treatment.

7. Patients who are immunocompromised due to Human Immunodeficiency Virus (HIV) infection with a CD4 count of <200/mm3.

8. Foetuses and neonates.

9. Patients who are within three months of a planned elective organ transplant and patients who may otherwise receive a solid organ transplant within three months due to being on the UK national transplant waiting list or are within three months of being placed on the waiting list.

aThe Green Book has the latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147824/Green-Book-Chapter-6-v2_0.pdf

Zika Virus

The April 2016 SaBTO had a presentation on Zika which included the Science Advisory Committee on Transfusion Transmitted Infections risk assessment and the policy measures put in place to mitigate this risk. SaBTO discussed the measures put in to place to protect the safety of blood, tissues and cells response to the risk of Zika and other tropical viruses

Donors (blood, tissues, cells) visiting affected areas (as defined in the Geographical Disease Risk Index, GDRI) are deferred from donation

For 28 days if asymptomatic

For 6 months if diagnosed with Chikungunya, dengue or Zika or have had symptoms suggestive of these illnesses

Cord blood donors deferred from donation

If less than 28 days from a mother's return from a risk area

If a mother has been diagnosed with Chikungunya, dengue or Zika or has had symptoms suggestive of these illnesses during the pregnancy

SaBTO was content with the measures in place but thought it necessary to keep a watching brief as further evidence emerges on the risk of Zika virus to the safety of blood tissues and cells.

vCJD risk and Appendix III Study

The Committee discussed whether the current recommendations concerning transmission of vCJD should be modified following the publication of the report of the Appendix III study. The Committee concluded that these findings did not indicate any need to revise the current guidelines. However, there was a consensus that the growing number of individuals born after 1995 may lead to challenges in retaining all the risk reduction measures. The transition of individuals from paediatric and children's services to adult services was identified as a potential problem. As the number of reported vCJD cases was very small it was becoming difficult to reconcile the prevalence data from the appendix II and III studies. It was noted there had been no proven cases of transfusion related vCJD since the introduction of leucodepletion.

Attention was drawn to the recent High Court judgement Wilkes versus DePuy. This may have a significant effect on the legal framework around product liability. It was noted that the Judge emphasised the need for recipients to have full information about the risks involved.

The Wilkes case may be appealed and the judgement was given in the English courts so the relevance to the other UK nations was raised. The Chair agreed to circulate the judgement when it became available. The Committee would review the risk reduction measures when the legal position became clearer.

Organs, Tissues and Cells

Hepatitis E Virus (HEV)

The evidence of transmission through transplantation of solid organs, tissues and haematopoietic stem cells is minimal; however case reports do exist in the literature. There is a balance between the risk of infection and the consequence of transmission occurring. The consequence of a transmission could justify screening donors. Screening of donors may be beneficial as there could be an opportunity to intervene prior to transplant in living donors and knowledge of the potential transmission would enable timely testing and appropriate follow up of the recipient.

Given the small, but identifiable, clinical benefit SaBTO decided that screening of donors of organs, tissues and stem cell donors would maintain consistency of approach in protecting highly vulnerable patients from HEV infection.

SaBTO Working Groups

Donor Selection Criteria Working Group Update

Donor Organ Risk Assessment (DORA) Working Group

Microbiological Safety of Human Organs, Tissues and Cells Guideline Review Working Group update

The review group has produced a near final draft which has been widely circulated and will be presented for final sign off at the June 2017 meeting.

Membership 2016-17

Updated Induction Pack for New Members

An updated Induction Pack for new members of SaBTO has been produced and endorsed by members.

Members:

Lorna Williamson

Richard Seton Tedder

Alison Murdoch

Paul Alexandre De Sousa

Frances Gould
Gill Hollis
Catherine Howell
Richard Knight
James Powell
John Cairns
Stephen Thomas
Susan Brailsford
Lynn Manson
Rachel Hilton
Charles Newstead
Akila Chandrasekar
Will Irving