Recommendations from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on measures to protect patients from acquiring hepatitis E virus via transfusion or transplantation

These recommendations were approved by SaBTO on 1 Nov 2016.

1. While hepatitis E virus (HEV) infection is mild and self-limiting in the majority of people, it can cause serious harm in those with an impaired immune system, and proportionate measures should continue to protect patients in these groups from exposure to infection. Evidence of harm from HEV infection to patients undergoing transplant had led to the original SaBTO recommendation to provide HEV screened products. There is a lack of evidence of harm in non-transplant immunocompromised patients, however, SaBTO has now concluded that it is reasonable to assume that patients who are significantly immunocompromised but do not fall into the solid organ or haematopoietic stem cell transplant recipient groups will also be at similar risk from HEV infection. SaBTO accepted that this was clinically credible and agreed with the definition of the "at risk" patients in this document (see 12). These updated recommendations from SaBTO replace those issued in 2015.

Blood components

1. Continued provision of HEV-screened blood components to patients who are immunosuppressed (whether resulting from disease or treatment) will reduce the risk of transmission of HEV via transfused components, and the consequent harm that may arise from chronic or, more rarely, acute infection. SaBTO has extended its July 2015 recommendation (that HEV-screened components be provided for solid organ and allogeneic stem cell transplant patients) to recommend that all immunocompromised patients (as categorised by the Green Book[a] as needing to avoid live vaccines) should receive HEV-screened blood components, together with neonates.

2. The screening approach, using pools of 24 donations, that is currently in operation to detect hepatitis E viraemia in donated blood is likely to detect the majority of viraemic donors. Those with viral loads below the level of detection remain a potential risk, though the likelihood of transmission from components containing very low levels of HEV RNA appears small. The cost-effectiveness analysis that has been undertaken was based on the assumption that this screening approach will continue.

3. Based on the best estimates of costs and workload across the healthcare system, universal screening of donated blood for HEV would deliver the same benefits for patients as does provision of screened components to selected patients, but at a lower overall cost and with a lower risk of errors occurring in blood provision and patient management.

4. Therefore, in recognition of the complexity, risks and costs to both the blood services and hospitals in maintaining and managing a dual inventory of screened and unscreened blood components, the Committee recommends that universal screening of blood donations for HEV should be introduced by the UK Blood Services as soon as it is practical to do so.

5. SaBTO acknowledges that there will continue to be supplies of unscreened longlife frozen plasma components available for some time after the move to universal screening. Advice to hospitals on clinical use of such components will be an operational matter for the Blood Services.

Organs and Haematopoietic Stem and Progenitor Cells

6. Although the risk of transmission via donated organs and haematopoietic stem and progenitor cells (HSPC) is very low, the Committee recommends that all organ and allogeneic

HSPC donors be individually screened for hepatitis E viraemia using HEV-NAT. The detection of viraemia is unlikely to be an absolute contra-indication to use of an organ or HSPC from a donor, but will inform clinical management decisions post-transplant. The Committee recognises that there are operational challenges in implementing such testing, particularly of deceased donors, and that these will need to be addressed.

Tissues

7. Most tissue recipients are not immunocompromised, so tissue donors would not generally need to be tested. However, recipients of allogeneic cellular therapies such as islet cells or hepatocytes or allogeneic advanced therapy medicinal products may require immunosuppression. Under a universal testing strategy, SaBTO recommends testing of all tissue donors regardless of nature of the tissue or cellular therapy

Gametes

8. The Committee identified no evidence that virus can be transmitted through ova or sperm. Therefore SaBTO does not recommend HEV screening for egg or sperm donors.

Annual reporting

9. SaBTO has requested a report on the impact of these recommendations from the UK blood services together with their public health bodies in November 2017, and annually thereafter.

Review of the recommendations

10. SaBTO will review these recommendations in three years (Autumn 2019) unless significant new information arises that would support an earlier review.

Other routes of infection

11. Immunocompromised patients are more at risk of HEV infection from diet than from transmission by blood, tissues, cells or organs. Whilst advising on control of exposure through diet is not within SaBTO's remit, the Committee would welcome steps by other agencies to control this source of infection.

Which patients need to be protected from HEV infection

12. The Green Book (UK Government Guidelines on Immunisation against Infectious Diseases) provides a list of clinical indications in which patients should avoid live vaccines. The British Committee on Standards in Haematology provides a similar but shorter list of clinical indications in which patients should receive irradiated blood components. One indication present in the BCSH Irradiation Guidelines but not the Green Book Guidelines is intrauterine transfusion (IUT) and exchange transfusion in foetuses and neonates; components for IUT and neonates are already supplied from HEV screened blood donations by UK Blood Services. Current SaBTO guidelines also indicate that patients who are within three months of a planned elective organ transplant and patients who may otherwise receive a solid organ transplant due to being on the UK national transplant waiting list should receive HEV screened blood components.

13. 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/mm^3.
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.

[a]The 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