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

Annual Report 2015-16

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Topics considered in 2015-16

Blood

Penrose Inquiry

SaBTO noted the background to the report and the statements made after publication in the Scottish and UK Parliaments. The committee noted the substantial changes that had occurred in the collection and provision of blood in the last 30 years. In particular SaBTO welcomed the better information provided to blood recipients and the better management of consent to transfusion to which SaBTO's own report had contributed.

The committee noted the reluctance to introduce early hepatitis C tests. These were based on an identification of a single peptide and unlike HIV tests at that time did not allow different assay processes for screening and confirmatory tests. It was noted that whilst Penrose was looking at a pre-devolution health landscape, now the four UK countries may take different stances and implement their own policies.

In the light of the Report SaBTO agreed to look at the current decision making framework document to ensure that it still fully meets the needs of the committee and is able to reflect all issues that need to be considered when deciding on new or revised actions.

Members agreed that action, in terms of a new risk reduction measures, was not always possible, but that the focus should always be on fully informing patients of both benefits and risks of any procedure.

Hepatitis E Virus

A report from the SaBTO Hepatitis E virus (HEV) working group was presented at the April 2015 meeting. The report noted the situation and knowledge of HEV was evolving rapidly and outlined current understanding of the situation. Noting that transfusion transmitted infections had occurred SaBTO agreed that further work was needed to formulate costed option plans to test donated blood (be it the whole supply or for a selected proportion), transplant material and/or transplant patients. It was agreed that this should be progressed before the next planned meeting in September.

An Extraordinary SaBTO meeting was held in July 2015 to further consider testing of blood donations for HEV. SaBTO then discussed whether to test blood donation and if so should this be performed universally or to provide blood components for selected patient groups. The following points were discussed:

a) the difficulties in producing accurate cost/benefit estimates

b) the relatively small amount of evidence of transmission but the clear potential for harm in certain cases

c) the impact of the Penrose inquiry which emphasised the need for a timely response to new infectious threats to the blood supply

d) the increasing incidence of HEV infection

e) the importance of recognising opportunity costs

f) the need to take account of the wider social, political and legal context

g) the patient groups to be provided with HEV tested blood components

h) the concern over dietary route of transmission which, compared with blood or transplant organ transmission is manifold more common.

SaBTO agreed that there was sufficient evidence of potential harm, together with the wider social, political and legal context, to introduce testing to provide blood components for patients undergoing solid organ or stem cell transplants. During the implementation of the recommendations a number of clinical, financial, legal and ethical issues were raised by stakeholders and it was agreed that a prompt review of the recommendations and their implementation should be undertaken. UK Blood Services introduced selective testing of blood donations for HEV in Spring 2016.

Human T-lymphotropic Virus (HTLV)

A paper was presented related to the testing of blood donations only, and not to donors of tissues, stem cells or organs. A change from universal HTLV screening of all donations to HTLV screening of new donors and non-LD donations only was permissible on the basis that:

a) universal screening is not cost-effective

b) all donors will be screened at least once at the time of first donation and the seroconversion rate has been shown to be very low

c) additional safety in the rare event that seroconversion has occurred in an established donor will be provided by:

- leucodepletion, which has been shown to be very effective in preventing transmission
- screening of non-leucodepleted components, which remain high risk.

The recommendation was accepted.

Donor Selection Criteria Review

The Department of Health and the Northern Ireland Minister for Health asked SaBTO to review evidence on donor deferral policy for men who have sex with men (MSM). In 2011, following a review of the evidence SaBTO recommended a change on blood donation deferrals for MSM from a permanent deferral to a 12 month deferral. SaBTO agreed that a review of donor deferral practice was timely. It was decided that the scope of the review would be to review donor deferral of infections that can be transmitted sexually but would also look at deferrals for these infections when potentially transmitted by other routes, tattooing, skin piercing or intravenous drug use for example.

UK Blood Services Donor Survey

The donor survey was designed to look at whether donors complied with donor selection criteria, it was done anonymously so that people could freely disclose information that they had not previously reported at the donation session. A methods paper has already been published and further publications are in preparation. The presentation to SaBTO concentrated on sexual behaviours and injecting drug use. SaBTO discussed the presentation and members expressed the opinion that data from the Donor Survey will feed into the Donor Selection Criteria Review.

Ebola survivors and donation deferral

SaBTO discussed recommendations of the Advisory Committee on Dangerous Pathogens (ACDP) on donor deferral and Ebola in response to questions from the Chief Medical Officer. SaBTO supported the ACDP recommendations which are detailed below.

1. Indefinite deferral for all Substances of Human Origin (SOHO) from those who have been infected with Ebola whether they have symptoms or not, with the exception of the collection of convalescent plasma.
2. Six month deferral for blood donors returning from areas where there is a risk of Ebola infection, those being monitored after exposure to Ebola infected persons and those being investigated for Ebola virus disease.

Tissues and Cells

Importation of Skin

A paper was presented giving the background to the current policy for importation of skin for the treatment of children born on or after 1 January 1996 as a vCJD risk reduction measure. The original guidance was provided by SaBTO in 2008, but was not mandated by the Department of Health. Skin is currently supplied by a Spanish tissue bank, being the only responders to the invitation to tender. However uptake is low, skin is a low risk tissue[1] and Spain is not a vCJD free country. SaBTO agreed with the recommendation not to import further skin

Organs

Hepatitis E Virus (HEV)

A paper giving a range of possible recommendations was presented. It was stressed that HEV in a potential organ donor was not a contraindication for transplantation

[1] Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Guidance; Annex 1

The incidence of HEV G3 is increasing in the UK population with dietary transmission being the major source of infection. HEV infection can also be transmitted by blood, blood components, stem cells and organs. Infection with HEV may cause hepatic decompensation in those with underlying chronic liver disease. To date, only one case of donor-derived transmission through solid organ transplant has been reported in the literature, other cases have occurred but it is not always clear whether the infection was acquired from the organ or blood/blood products.

HEV infection is a cause of chronic hepatitis, fibrosis and cirrhosis in immunosuppressed people. PHE has seen 49 instances of persisting HEV infection in the immunocompromised and is aware of death possibly related to chronic HEV in three patients. However, chronic HEV infection may be present with normal liver tests.

HEV hepatitis may be misdiagnosed and attributed to other causes. Many transplant clinicians do not believe HEV is a significant clinical issue although recognition of the problem is increasing. Ribavirin is effective in controlling viral replication in the majority of patients (unlicensed indication) and thus accurate diagnosis is important.

What is not yet known:

What is the sero-prevalence of HEV infection in transplant candidates in the UK?

What is the prevalence of chronic HEV infection in transplant candidates in the UK?

What is the sero-prevalence of HEV infection in organ donors in the UK?

What is the prevalence of incident HEV infection in organ donors in the UK?

What is the likelihood of organs from donors with current HEV infection causing infection in the recipients?

What is the consequence of blood or organ transmitted HEV in the immunosuppressed individual?

Will different organs from infected individuals transmit differently?

What is the impact of different classes of immunosuppression on likelihood of infection with HEV in exposed individuals or reactivation of infection?

What is the impact of HEV infection (however acquired) on those with pre-existing liver disease?

Discussion:

a) Delaying introduction of testing due to a lack of evidence goes against the precautionary principle established by the Penrose inquiry

b) Good clinical practice for the management of transplant recipients after transplantation other than in the setting of donor-derived transmitted infection is outside the remit of SaBTO but should be included in any recommendations

c) The commissioning of any additional testing would require funding streams to be clearly defined

d) A study of solid organ recipients, which will include some allogeneic stem cell recipients, in one centre is being planned to test the prevalence of HEV infection in these patient groups

e) The greatest risk for transplant patients is of dietary acquisition which is an ongoing risk after transplant

f) The frequency of testing of transplant recipients, by whom, where and management of results needs to be worked through to ensure clarity

g) Donor testing needs to differentiate between living and deceased. Living donors can be tested ahead of donation, but the timing would need to be defined. Results on deceased donors would be available only post-transplant but would inform management of recipient

h) Any new testing takes money away from others areas of the NHS.

All agreed that further research was required of donors and recipients to understand the probability of HEV infection in recipients becoming a chronic condition.

Recommendations:

Live donors should be tested pre-transplantation, the exact timing and frequency to be determined by further work.

The testing of samples obtained from deceased donors should be carried out as soon as possible to assist in the future management of recipients.

Any solid organ recipient with unexplained deranged liver function tests should be tested for the presence of HEV.

SaBTO Working Groups

Donor Organ Risk Assessment (DORA) Working Group update

Membership was refreshed to cover a wider range of specialist areas, with meetings being held every three months. A number of work streams are in progress including standards for microbiological testing of solid organ donors group, the effects of drugs, both medically prescribed and illicit, on donor organs. A greater understanding of how potential donors with a past history of neoplasia can be better utilised is also required.

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

Work by the review group continues with external expertise to inform the revision of the existing guidelines.

Guidance for SaBTO Working Groups Annex to the Code of Practice

A draft revised Code of Practice promoting the use of the SaBTO Safety Framework was presented and discussed. The addition of secretariat and Health Protection Analytical Team support was proposed by SaBTO to be added to the document to ensure that systematic assessments are made by working groups. SaBTO approved the additions to the Code of Practice and secretariat to circulated updated Code of Practice to members and updated the SaBTO website.

Membership 2015-16

John Forsythe

Lorna Williamson

Richard Seton Tedder

Alison Murdoch

Mallika Sekhar

Paul Alexandre De Sousa

Frances Gould

Gill Hollis

Catherine Howell

Tom Solomon

Richard Knight

James Powell

John Cairns

Stephen Thomas

Susan Brailsford

Lynn Manson

Rachel Hilton

Charles Newstead

Akila Chandrasekar