ADVISORY COMMITTEE ON THE SAFETY OF BLOOD, TISSUES AND ORGANS

FINAL MINUTES OF THE NINETEENTH MEETING, 24TH JUNE 2013

SKIPTON HOUSE, LONDON SE1 6LH

Present:			
Professor	John	Forsythe	Chair
Members			**Area of expertise**
Professor	John	Dark	Solid Organ Transplant Surgeon
Dr	Paul	De Sousa	Regenerative Medicine
Dr	George	Galea	Blood/Transplant Service Manager
Professor	Kate	Gould	Microbiologist/Bacteriologist/Virologist
Mrs	Gill	Hollis	Patient Representative
Mrs	Catherine	Howell	Nurse
Dr	Harpreet	Kohli	Epidemiology/Public Health
Dr	Eithne	MacMahon	Microbiologist/Bacteriologist/Virologist
Professor	Joanne	Martin	NHS Management
Professor	Alison	Murdoch	IVF/Fertility/Stem Cells
Dr	Mallika	Sekhar	Haematologist
Professor	Tom	Solomon	Microbiologist/Bacteriologist/Virologist
Professor	Richard	Tedder	Microbiologist/Bacteriologist/Virologist
Professor	Marc	Turner	Haematologist
Professor	Anthony	Warrens	Immunologist
Dr	Lorna	Williamson	Medical Director, Blood Services
Observers			
Ms	Victoria	Gauden	Human Tissue Authority (HTA)
Dr	Aileen	Keel	Scotland
Dr	Sheila	MacLennan	UK Forum
Dr	Elizabeth	Reaney	Northern Ireland
Dr	Andrew	Riley	Wales
Secretariat			
Mr	Andrew	Broderick	Department of Health (DH)/NHS Blood and Transplant (NHSBT)
Dr	Rowena	Jecock	DH
Mr	Mark	Noterman	DH
Mrs	Tina	Lee	DH
Others			
Mr	Ian	Beggs	Deputising for Ms Léonie Austin, NHSBT Communications
Mr	Andrew	Parker	DH Health Protection Analytical Team
Dr	Stephen	Thomas	NHSBT
Ms	Imogen	Swann	HTA

Item 1:Welcome, introductions and apologies

1.1 Apologies had been received from Professor John Cairns and Professor Richard Knight (SaBTO members); and Mr David Carter (Medicines and Healthcare products Regulatory Agency (MHRA)), Professor Adrian Newland (National Blood Transfusion Committee) and Ms Triona Norman (DH, Transplantation Policy Lead) (Observers).

1.2 The Chair welcomed Dr Mallika Sekhar, who was appointed to SaBTO on 1st December 2012 but was unable to attend the meeting on 10th December; Ms Imogen Swann of the HTA; Dr Andrew Riley, who had succeeded Mrs Jenny Thorne as Welsh Govt Observer; Dr Stephen Thomas, formerly of the Secretariat, who continued to work on the 'Tissues and Cells: MSM Donor Selection Review'; and Mr Andrew Broderick, who had succeeded Dr Thomas on the Secretariat. He noted Mr David Carter had succeeded Mr Nigel Goulding as Observer for the MHRA.

1.3 The Chair congratulated Professor Jo Martin on her appointment as National Clinical Director for Pathology for NHS England.

2 Item 2: Minutes of the meeting held on 10th December 2012

2.1 The Chair reminded members that, as was usual, the minutes of the meeting on 10th December had been approved by members via email, and had been published on the SaBTO website.

2.2 Members were asked to approve an amendment to the minutes, following a letter from Dr Patricia Hewitt, Chair of the NHSBT Transfusion Microbiology Clinical Group. Dr Hewitt commented that the initial wording of paragraph 5.3.7.3 could be misinterpreted as a recommendation by SaBTO on the notification of test results. SaBTO members agreed that the words '(eg. ideally face-to-face rather than by telephone), and appropriate counselling offered' added inessential detail and should be deleted, so the sentence should read: 'If such a donor tested positive for an infection, special care would need to be taken in feeding that back to such a young donor'.

2.3 A further amendment was agreed in paragraph 5.3.2, where 'components carrying a theoretical risk of vCJD' was changed to 'components carrying a very small risk of vCJD'.

2.4 The Chair reminded members that only the published version of the minutes should be shared: the full minutes remained confidential as they contained information that was commercially confidential, research not yet published and other sensitive details.

3 Item 3: Action points and matters arising from the meeting on 10th December 2012

3.1 Action point 18/01 was covered under Any Other Business.

3.2 Matters arising: there were no matters arising.

4 Item 4: Report and recommendations of the Tissues and Cells: MSM Donor Selection Review working group (MSM: men who have had sex with men)

4.1 The Chair thanked the working group members for the considerable work they had put into their extensive, scholarly report, and the difficult decisions involved.

4.2 SaBTO received a presentation on this subject from the Chair of the working group, Dr Lorna Williamson, and the draft report had been circulated. The group had reviewed the current donor selection criteria, with a view to achieving consistency with the criteria for blood donors, where appropriate. Fourteen different products had been identified, which were considered in four groups.

4.3 The group set out to review the infections of interest and epidemiology in relevant donors: however, the lack of data available meant they had to adopt a risk:benefit approach for individual tissues/cells instead. This involved complex and difficult judgements.

4.4 The criteria were noted which made infections particularly relevant to this review, such as whether there were case reports of transmission by tissue or cell transplantation, and any increased risk for any particular infection in MSM. HHV-8 was considered in detail, but the group concluded the risk of its transmission via tissues or cells was low. Overall, infection rates in tissue and cell donors were found to be comparable with those of first-time blood donors.

4.5 It was not possible to calculate residual viral risk for different deferral periods of MSM donors because of the small numbers of infections and the lack of repeat donations.

4.6 For the risk:benefit assessment for each product, the group considered a range of factors relating to the donor (the history available, testing, and whether there was an opportunity for patient/clinician discussion of that individual donation); and to the product (whether the transplant was life-saving, adequacy of supply, the importance of matching, impact of processing on the infection risk, and the number of recipients from each donation).

4.7 **SaBTO was asked** whether it agreed with each of the proposed recommendations.

4.8 Recommendation 1:

Group 1: Haematopoietic stem cells (HSC), whether from family and friends, or unrelated adult donors, or from cord blood:

For family and friend donors: no deferral. This would retain the current practice of assessing the risks and benefits in individual cases, with documentation of MSM risk but no specific restrictions.

For unrelated donors joining a registry: no deferral. This was current practice for Anthony Nolan but a change for the British Bone Marrow Registry (BBMR) which recruited via blood donation sessions, so used the blood donor deferral criteria. MSM behaviour would be recorded, and the information included in the assessment of risks and benefits in individual cases before donation. Maintaining the existing inconsistency with blood donor criteria was justified by the need to maximise life-saving, well-matched stem cell donations.

For cord blood donors: allow donation 12 months after last sexual contact by the donor with a man who has ever had MSM contact. The working group had found this decision finely balanced, and opted to retain a deferral period because of the small transmission risk.

4.9 Points raised in discussion about cord blood donation included the following:

4.9.1 Currently, there was a 12 month deferral from blood donation for women from last sexual contact with a man who had **ever** had sex with another man.

4.9.2 It was clarified, however, that if the male partner agreed to be tested and the donor was keen to donate, there would be 'medical discretion' to allow donation, although it would be operationally challenging.

4.9.3 There was support from some members for the proposal to retain deferral as for blood donors because:

4.9.3.1 The scientifically most logical option (deferral of a woman for 12 months following last sexual contact with a man who has had MSM contact within the previous 12 months) was felt to be operationally impracticable;

4.9.3.2 The male partner was not tested, so the female partner could be infected up to the time of donation, with a resulting small risk of a window period infection being transmitted;

4.9.3.3 Most cord blood from unrelated donors was stored long term, and only 4% of inventory was issued. Losing a small number of donors through this deferral would be unlikely to create a supply issue, especially as the documented MSM risk would be likely to mean such donations were not selected;

4.9.3.4 Cord blood donations were stored, in contrast to donations from family and friend donors and those joining a registry, where only information was stored.

4.9.4 There was disquiet, however, from other members about the proposed deferral because:

4.9.4.1 It was inconsistent with the lack of deferral for family and friend donors of HSC, and those joining a registry, as well as gamete donors;

4.9.4.2 As with other categories, considerations of the therapy being life-saving and the importance of HLA matching applied;

4.9.4.3 The EU Tissues and Cells Directive (EUTCD) required the donor to be tested at the time of donation or within 7 days after, and if NAT testing was not used, to be re-tested after 180 days, which significantly mitigated any viral risk;

4.9.4.4 There was an opportunity before use for patient/clinician discussion of any potential risk from that donor's cells;

4.9.4.5 The deferral could be perceived as discriminatory.

4.10 **SaBTO concluded**:
Family and friend donors: 'no deferral' was supported.
Unrelated donors joining a registry: 'no deferral' was supported.
Cord blood donors: in light of the points raised, and the fact that the working group had found it a very close decision, SaBTO recommended 'no deferral', with documentation of any potential MSM risk.

4.11 **Recommendation 2:**
Group 2: Pancreatic islets and hepatocytes: no deferral.

4.12 **SaBTO agreed** with this proposed recommendation.

4.13 **Recommendation 3:**

Banked tissues (corneas, heart valves, bone, skin, amnion, tendon): allow donation 12 months or more after last MSM sexual contact.

4.14 This was consistent with the criteria for blood donors, and considered to be proportionate to the risk.

4.15 **SaBTO agreed** with this proposed recommendation. However the working group agreed to provide further clarification on the deferral of female donors in a sexual relationship with an MSM, and whether it should be the same as for blood donors.

4.16 **Action 19/01: working group to provide clarification** of deferral criteria for female donors of banked tissues who are in a sexual relationship with an MSM.

4.17 Recommendation 4:

4.18 Sperm, eggs and embryos: no deferral.

4.19 This referred only to embryos for reproductive purposes.

4.20 Clinic procedures included in-depth history being taken on multiple occasions, and repeat testing. Also, there was no known case of transmission via sperm, eggs or embryos.

4.21 **SaBTO agreed** with this proposed recommendation.

4.22 The working group had made observations on a number of other points which they wished to bring to SaBTO's attention, with suggested actions in some cases.

4.23 **Collection of donor sexual history:** the working group had found the terminology used varied widely, and sometimes inappropriately referred to a donor's sexual orientation instead of sexual behaviour. The group suggested the use of standardised terminology by all tissue and cell providers should be encouraged, such as that in current use by the UK blood services ('men who have ever had oral or anal sex with another man with or without a condom or other protection').

4.24 **Donation testing:** it was noted the recommendations were not contingent on any change in practice. The working group had found variation in the use of NAT testing, which had been described as best practice in SaBTO's 2011 *Guidance on the microbiological safety of human organs, tissues and cells used in transplantation.* The group suggested that SaBTO might wish to clarify the position when that guidance is next reviewed, possibly recommending NAT testing for all banked tissues and cells and giving consideration to either the pool size to be used or to individual sample testing.

4.25 Manufacturing: for living MSM donors of banked bone tissue, the recommendation was to change the deferral from permanent to temporary. The working group recommended that on completion of the current study of a new processing method for living bone donations to remove residual cellular marrow, SaBTO should review the data on safety and clinical effectiveness with a view to considering whether or not this method should become the standard of care. **This recommendation was agreed by SaBTO:** the topic appears in SaBTO's 2013/14 workplan as one on which the Committee has a watching brief**.**

4.26 **Bio vigilance:** the working group observed that while notification systems existed for any viral transmission by tissue and cell products (which was now rare), and for

comprehensive documentation and national analysis of prevalence, incidence and risk factors for positive viral markers in blood donors, there was limited documentation and collation of data on the incidence and risk factors of virus positive donors of cells, tissues and gametes. The group's work had been hampered by the lack of such data, which in contrast was available for blood donors. Also, a bio-archive of samples such as the one for blood donors, which was valuable in investigating suspected transmissions and also in assessing emerging infections, was not available for tissues and cells: an opportunity to gather good epidemiological data was being missed. The group suggested that options for the collection and analysis of such data should be considered, to facilitate future policy decisions and the monitoring of emerging infections; and that any such bio vigilance should include the storage of archive samples from the donor and where possible from recipients.

4.27 The following points were raised in discussion:

4.27.1 An HTA representative noted the HTA collated data on serious and adverse events, and annual activity. The HTA would wish to contribute as much as possible to any initiative following up the working group's suggestion;

4.27.2 For gametes, a considerable amount of data on donors was collected. To mandate the collection of additional data on potential donors who did not donate would have no clinical value, and would be a burden;

4.27.3 It was noted that, as tissues such as unprocessed bone contain bone marrow cells, increased vigilance of the incidence of Kaposi sarcoma in recipients would be of merit.

4.27.4 The Royal College of Pathologists and the EC Directives both advised archive samples should be held. They were essential for a lookback exercise, in the event of a transmission; and might be valuable for the development of any new test which would need to be validated on banked material.

4.28 **Action 19/02: It was agreed that the Secretariat** would liaise with the working group and the regulators with the aim of setting up a meeting of interested parties to explore the possibilities for improved bio vigilance.

5 Item 5: Position Statement on West Nile Virus and solid organ transplantation

5.1 A draft had been circulated. West Nile Virus (WNV) was not currently endemic in the UK, and the maritime climate made it less likely to become so, but it was present in the EU and other areas of Eastern Europe, and in other areas including North America. Transmission through solid organ transplantation had been documented where it was endemic. SaBTO had considered what information should be provided to clinicians in case a UK donor whose organs had been transplanted should subsequently prove to be WNV positive.

5.2 WNV infections were usually asymptomatic in the immunocompetent, but could be more serious for the immunosuppressed. There was little good evidence in the literature on management of a recipient. Immunoglobulin would be unlikely to contain sufficient (if any) antibodies to WNV and therefore would not be effective in boosting the natural immune response; and removing the organ would not be beneficial, as the infection would already have been transmitted.

5.3 In the light of climate change, there was a need to remain vigilant. If the situation should change in the future, and the prevalence of WNV in the UK should rise, it might be advisable to review this advice.

5.4 The following points were raised in discussion:

5.4.1 The possibility was raised of quantifying the risk of transmitting WNV from a donor with undiagnosed encephalopathy, to inform the patient. It was noted that the risks resulting from a donor with undiagnosed encephalopathy from any cause, not just from WNV, would need to be assessed; rabies, for example, would also be a cause for concern. That risk would need to be balanced with the risk of the recipient remaining without a transplant;

5.4.2 Concern was raised that donors' travel history might not always be acted on appropriately. It was considered that if the donor was healthy, the travel record might just be filed, but if the donor was ill, advice would be sought;

5.4.3 It was noted that SaBTO's Donor Organ Risk Assessment working group would consider the question of using organs from donors with encephalopathy in due course.

5.5 **SaBTO agreed** that the proposed draft should be published as SaBTO's Position Statement.

6 Item 6: Use of 'Club 96' donations for intrauterine transfusions, neonates and infants

6.1 A paper had been provided by Professor Richard Tedder, Head of the Joint NHSBT/PHE Blood Borne Virus Unit. It was agreed at the SaBTO meeting on 10th December 2012 that blood donated by those born after 1st January 1996 ('Club 96') could be directed initially for use in intrauterine transfusions, then for neonates and infants as supply allowed. This could reduce the risk to those recipients from the potential of vCJD being transmitted through blood from older donors who may have been exposed through diet. A UK blood services working group had developed an operational plan to implement this.

6.2 SaBTO had also raised concerns, however, about the possible level of viral risk from the Club 96 donor cohort. Cytomegalovirus (CMV), Epstein Barr virus (EBV) and B19 parvovirus acquired in the late teenage years were the infections of particular interest, with the possibility of incident infections amongst young donors; by comparison, the residual risk of a donation being infected with HIV, hepatitis B (HBV) or hepatitis C (HCV) (which were routinely tested for by serology and by NAT) was extremely low. The impact of B19 and CMV infection in particular on very young recipients could be serious. Donations for neonates were not routinely tested for EBV or B19, nor for CMV DNA, only for anti-CMV antibody.

6.3 Data on the antibody prevalence and incidence of these viruses were lacking in very young donors, so a prospective study, funded in part by the UK Blood Services Forum, was to be undertaken by the Public Health England (PHE)/NHSBT Blood Borne Virus Unit, Colindale. This would follow current work on hepatitis E, beginning in late 2013/14 and taking 9 – 12 months to complete.

6.4 The study would use archived samples from blood donated in East and South East England by donors aged 17 years at the time of donation in calendar year 2011 (Note added after meeting: 17 year old donors and controls will be selected from those

whose samples were tested and archived at Bristol). The incidence of plasma viraemia and seroprevalence of antibody to EBV, CMV and B19 in blood from 17 year old donors (equal numbers of male/female) would be compared with that of a control group of donors aged 18 years or more at the time of donation selected to represent the normal donor profile. Subsequent donations from seronegative young donors would be tested to establish the attack rate of these infections.

6.5 **SaBTO was asked** whether the UK Blood Services should implement plans to direct donations from donors born after 1st January 1996 to neonates, including intrauterine transfusion, based on current information on virus risk; or should await the outcome of the planned study and a risk assessment based on the new information. This would delay provision of Club 96 blood for intrauterine transfusions by at least 12 months.

6.6 The following points were raised in discussion:

6.6.1 The possibility was raised of NAT testing on donation. There were, however, major operational issues because in-house assays could not be accommodated in the current NAT testing pathways. New tests were seldom introduced without background sensitivity and specificity data which were not available for these assays: the PHE/NHSBT study could provide these data;

6.6.2 Donors might self-defer if they are unwell, but there was often a period of plasma viraemia before symptoms might appear;

6.6.3 The fact that the risk of viral transmission was considered sufficient to justify funding the study suggested it was sufficient to justify awaiting the results;

6.6.4 The question was raised of how the results would be used. Antibody prevalence data will inform on the proportion of susceptible donors. If no viraemic donors were identified in 2,000 donations the upper 95% limit to the true incidence rate would be 0.234. If 2 or 3 cases of viraemia were identified, clinicians would need to consider whether 0.5% or 1% viraemia would be acceptable. An alternative would be to use blood from donors who had been seropositive for at least 6 or perhaps 12 months, who would have cleared the plasma viraemia. Such donations would also give recipients passive antibodies which could be beneficial;

6.6.5 The benefit of using seronegative donors was somewhat dependent on the turnover of that virus being low. It would be helpful to know the seroconversion rate in that population. It was thought possible that there would be a move to using seropositive donors in the future;

6.6.6 Given the potential viral risks, the study findings should be awaited, despite the presumed very low risk of vCJD transmission from this cohort.

6.7 **SaBTO concluded** that implementation of the plans to direct donations from donors born after 1st January 1996 to intrauterine transfusion and neonates should be delayed until the findings of the planned study, and a risk assessment based on the new information, became available and had been considered by SaBTO.

7 Item 7: Use of new donors' first donations

7.1 A paper had been provided by Dr Su Brailsford, Head of the Joint NHSBT/PHE Epidemiology Unit. Following advice in 1997 from the Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs for Transplantation (MSBTO), SaBTO's predecessor committee, blood components for intrauterine transfusion and

infants were manufactured from second or subsequent donations. This was because the risk of a window period infection being transmitted in a donation from a previously untested donor was higher than from a previously-tested donor.

7.2 NAT testing for HBV, HCV and HIV had been introduced since that advice was given, significantly reducing the window period. Leucodepletion had also been introduced, reducing the risk of leucocyte–borne infection. Modelling showed the risk of using donations from all donors to be higher than the risk of using only repeat donations, but only marginally.

7.3 Prevalent infections were more common in first time donors, often representing those acquired from the donor's mother. Acute infections overall were rare in all repeat donors and rarest in the young donor aged 20 and less.

7.4 Analysis of donations showed the age groups in which most infections were found in previously-tested donors. HBV was largely found in sexually mature and active adults rather than those in their late teens. Similarly, relatively few HCV infections were found in the younger age groups. In contrast HIV infections were seen in younger males.

7.5 It was accepted that compliance with the donor selection guidelines was one of the most important risk-reduction measures for window period infections.

7.6 **SaBTO was asked** if it agreed that the restriction on the use of first time donations for the manufacture of components for intrauterine transfusion and transfusion of infants under one year old should be removed.

7.7 The following points were raised in discussion:

7.7.1 It was clarified that the change was not intended to meet any particular supply need. The matter had arisen as part of the review of the use of blood donated by those born after 1st January 1996, given the use of NAT testing and the resulting decrease in the window period;

7.7.2 It was noted that if a donor ceased donating for more than two years, and then donated again, they would be categorised as a 'new' donor;

7.7.3 Large scale global HBV immunisation programmes were reducing the prevalence of this virus, which could be reflected in donors who had come to the UK from abroad, but HCV and HIV risk remained. HBV immunisation was not sterilising and could cause problems for transfusion practice as occult acute infections could arise, with viraemia but no symptoms. This was hard to detect as HBsAg was not found in the plasma.

7.8 **SaBTO agreed** that the restriction should not be lifted at that time given that (i) the benefit of removing the restriction was limited to bringing forward the time when donations from those born after 1st January 1996 could be used, leading to an earlier date of providing all products for each group, rather than meeting an urgent supply need; and (ii) the estimated risk of an HBV, HCV or HIV infectious donation entering the UK blood supply was anticipated to be very slightly but distinctly higher using all donations than using repeat donations only. SaBTO advised that, while there was no compelling reason to change the current practice at that time, the point should be included in the overall risk assessment of the use of blood donated by those born after 1st January 1996.

8 Item 8: Pathogen inactivation of platelets

8.1 A SaBTO working group had considered the introduction of pathogen inactivation (PI) of platelets in 2009, and found there was insufficient evidence of the clinical efficacy of treated platelets at the time. There was a concern about whether PI treated platelets were as effective in preventing or treating bleeding, or resulted in more side effects, given that many recipients were patients having chemotherapy treatment. The Blood Services had introduced bacterial screening rather than PI. Since that review, a second manufacturer's product had become available.

8.2 SaBTO had requested a systematic review of clinical trials of pathogen reduced / inactivated platelets, and this was published by the Cochrane Collaborative in March. It found no evidence of a difference in mortality, severe bleeding or adverse reactions between PI treated and standard platelets, but standard platelets showed some benefits for a range of laboratory outcomes.

8.3 A separate review was being undertaken, and would be reported to SaBTO by the Prion Sub group, of the vCJD risk reduction measure whereby 80% of platelets were collected by apheresis, to reduce the number of donors to whom recipients were exposed. Depending on the outcome of this review, it was possible the Blood Services would be able to source more platelets from whole blood. This would alter the cost effectiveness calculations for PI.

8.4 It was therefore proposed that SaBTO should set up a working group, chaired by Dr Lorna Williamson, to review the evidence on PI. As other countries were increasingly using PI, good data were becoming available.

8.5 **SaBTO agreed** that the working group should be established.

9 Item 9: Update: Donor Organ Risk Assessment working group

9.1 An update had been provided. The first phase of activity had been focused on the data. An automatic search programme developed by NHSBT had been validated using manual categorisation of risk factors and diagnoses, and would now be applied to donor data collected over ten years to correlate risk factors / diagnoses with organ utilisation and outcomes.

9.2 The work was a programme rather than a single project. The agreed topics for Position Papers included Virological test results at the time of organ donation; Drug abuse in a potential organ donor; Cancer in a potential organ donor, and Anatomical abnormalities. The Position Papers would have a common template.

9.3 The aim of the work was to increase organ utilisation by quantifying the risk factors for apparently 'high risk' donors. Although firm data were not yet available, the scope for increase was estimated at 5 – 10%.

10 Item 10: Update: Cell Based Advanced Therapies working group

10.1 An update had been provided. The group had agreed that its work fell into three sections, and had established sub groups to address these; Infectious risks in the donor which could result in problems for recipients of a resulting therapy; Genetic risks in the donor and when these might cause problems for therapy recipients, and issues arising from Consent and traceability, both for the donor and for recipients.

10.2 A number of organisations, including the MHRA, HTA, Human Fertilisation and Embryology Authority, Cell Therapy Catapult, Medical Research Council and BioIndustry Association, had been invited to join the group as Observers.

10.3 The group planned to complete its work and report to SaBTO in spring 2014.

11 Item 11: Revised SaBTO Code of Practice

11.1 SaBTO's Code of Practice needed to be reviewed in light of the Committee's change from an Advisory Non-Departmental Public Body to a Departmental Expert Committee on 1st December 2012, and to ensure consistency with the 2011 version of the Code of Practice for Scientific Advisory Committees published by the Government Office for Science.

11.2 **Members agreed** to accept the revised Code of Practice.

12 Item 12: SaBTO Annual Report 2012/13

12.1 It was observed that the Annual Report was useful in letting people know what SaBTO was engaged in, and especially in avoiding duplication with the work of other advisory bodies and committees.

12.2 A draft Annual Report had been submitted. With small amendments of wording, it was approved for publication.

13 Item 13: Council of Europe action on sexual behaviours and blood transfusion

13.1 An update was given on the adoption and implementation of the Council of Europe resolution on sexual behaviours of blood donors that have an impact on transfusion safety. A working group would develop a dataset of epidemiological data to be collected, and it was thought likely that this would be modelled largely on that in use in the UK.

13.2 It was noted that in Canada, lifetime deferral of MSM had been changed to deferral for five years following last MSM contact; and that in Australia, it was planned to reduce deferral from twelve months to six months.

14 Item 14: Strongyloidiasis and solid organ transplantation

14.1 A paper had been circulated for SaBTO members' interest and information.

15 Item 15: Any other business

15.1 NHSBT / PHE work on hepatitis E virus (HEV)

15.2 There was an Action point arising from the SaBTO meeting of 10th December 2012: **Action 18/01: The Chair and Professor Tedder** to consider the implications of hepatitis E, and report back to SaBTO on what action, if any, was needed.

15.3 A joint study by NHSBT / PHE was under way to define the frequency and clinical impact of the parenteral transmission of HEV, and a preliminary report on its findings had been provided.

15.4 The study was to run until September 2013, to gather one year's data, and analysis would follow.

Note: It is planned that this research will be published in due course. The information has been removed from these minutes meanwhile.

Dates of 2013 SaBTO meetings

Tuesday 17 September 2013
Tuesday 3 December 2013