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

Annual Report 2014-15

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Topics considered in 2014-15

Blood

Presentation on the Alliance of Blood Operators "Risk-based decision making from donor to recipient" project

The Alliance of Blood Operators (ABO) was seeking to develop a framework document which could be used in various jurisdictions, to improve services for blood recipients. Volunteers were being sought to participate in a consultation exercise regarding the draft framework, by means of a Choicebook. Individuals were needed, especially blood users, lay people and regulators.

Separately, groups were being sought who could test the feasibility of the draft framework, ideally in parallel with any 'live' issue under consideration. The review of HTLV testing being led by the Specialist Advisory Committee on Transfusion Transmitted Infections could be used for this purpose.

SaBTO was asked to agree that the working group which had been set up to consider Hepatitis E in the blood supply should use the ABO framework in parallel to its usual framework. The group would report back to SaBTO in the usual way, but would also report back to the ABO on the performance of the draft framework. SaBTO agreed this, with the proviso that if issues with the framework arose that could cause controversy; SaBTO would be informed at an early stage.

The following points were raised in discussion:

Feedback would be qualitative. The draft ABO framework was also being trialled by those who did not have an equivalent to SaBTO or SaBTO's current framework.

Apheresis and Additive Solution in the Production of Platelet Concentrates: Revision of the SaBTO Recommendation of September 2013

In September 2013 SaBTO recommended that 'SaBTO should remove the requirement to produce 80% of platelets by apheresis and platelet additive solution is used for the suspension of platelets'. This was in line with thein formation provided by manufacturers. The UK blood services subsequently found that platelets collected by apheresis and suspended in platelet additive solution were of suboptimal quality. Suboptimal platelets are discarded from stock and so increase wastage and an increased cost per unit. In addition measures to address these issues, in particular extending the collection time for collecting apheresis platelets into additive solution, reduced the cost-effectiveness of the measure below an acceptable level. In light of this new evidence the SaBTO Prion Sub Group proposed:

Maintenance of the 2013 recommendation that procuring 80% of platelets through apheresis is no longer a required vCJD risk reduction measure;

Maintenance of the 2013 recommendation that pooled platelets should be suspended in platelet additive solution; and

That apheresis platelets could continue to be suspended in single donor plasma.

SaBTO agreed with these recommendations on the basis that they did not adversely affect the level of protection against potential vCJD transmissions. SaBTO noted that it was now, although not mandated, usual practice to provide apheresis platelets for paediatric patients.

Club 96: Initial Results of the Study of Virological Risk

The interim results were presented from a study of blood donated by those born on or after 1st January 1996 who are presumed to carry a low risk of vCJD. The study was carried out to measure the prevalence of EBV, CMV and B19 infections in donors of the Club '96 cohort compared to the general population. These infections were thought to be of higher prevalence in young adults, are not routinely tested for and may pose a potential risk to vulnerable recipients if Club '96 blood is directed to intrauterine transfusions, neonates and infants, as agreed by SaBTO in June 2013. It was reported that the blood services have established a Club '96 working group to look at the operational issues and practicalities of using Club '96 donor blood when and if SaBTO approve its use. However decisions on use would await full consideration of the virological study results at the April 2015 meeting; be subject to continuity of supply as younger donors have lower return rates than older donors; and substantive actions will only be agreed after the results of the ongoing Appendix III vCJD prevalence study are known in 2016.

Hepatitis E Working Group

A final report of the group considering the effects of hepatitis E virus on susceptible recipients of blood components and blood products was due to be presented to SaBTO at the meeting in April 2015. Given the primary source of human hepatitis E infection in the UK is pig meat a representative of the Food Standards Agency was invited to attend the April meeting.

SaBTO Statement on Donor Deferral in the Context of Ebola Virus Outbreak

Urgent work was undertaken to prepare a SaBTO statement with reference to the safety of substances of human origin during the Ebola virus outbreak in West Africa.

Blood Service/PHE Protocol for the use of Convalescent Plasma – with Particular Reference to Ebola

A protocol had previously been developed for the use of convalescent plasma for MERS CoV infection; this protocol was activated to collect four units of Ebola virus convalescent plasma from a UK recovered patient by NHSBT. NHSBT agreed to coordinate the management and use of Ebola convalescent plasma across Europe.

Tissues and Cells

Cell Based Advanced Therapies

The Working Group was established to review the endogenous risks associated with cellular therapies, particularly with respect to donor selection, consenting and testing, and to make recommendations to SaBTO on how these could be optimised in order to support the development of cellular therapies in the UK while maximising donor and patient safety. Many aspects were covered by regulation, but open issues concerning donor screening for infectious agents or genetic abnormalities, and consent and traceability, fell within SaBTO's remit. As this was such a fast-developing field, the Working Group concluded that detailed and specific recommendations would quickly become out of date, and sought instead to draw out guiding principles.

The Working Group's recommendations were as follows:

Infectious risks: Risk Assessment

Follow existing SaBTO guidance on the selection and assessment of donors, and on risk assessment for infection, and apply it to tissues and cells; abide by legal requirements, and follow the best available professional guidance.

For live donors, risk assess to mitigate risk at the point of donation, and consider infections or agents that may not be cytopathic but could replicate in vitro or precipitate cell replication or transformation.

Maintain vigilance for new and emerging infections, and consider the potential for their transmission through a cell line.

Consider follow up of the donor.

When considering the safety of a product, take into account the effect of inactivation / decontamination strategies undertaken during processing, and their effect on the infection potential.

Consider assessment of the risk to the potential recipient, for example whether they are immunosuppressed or not.

Infectious risks: Testing

Follow existing SaBTO guidance on donor testing. Test the end product for bacteria and fungi using assays such as the existing 16S and 18S PCRs. Validate appropriately these and other tests required, including new tests, for use on each cell line or product.

Genetic risks:

The recommendation is that no genetic screening should be carried out on donors and that relevant genetic tests should be done on the stem cell lines / derived product.

Informed Consent and Traceability:

The subject of cell-based advanced therapies should be discussed openly and transparently, in order to build growing and informed public awareness. Consent should always be considered as a process, not an event.

SaBTO concluded that, with some amendments to the report, it agreed with the working group's recommendations. The final report would be published, and widely Promulgated.

Organs

Donor Organ Risk Assessment published their report on transplantation of organs from donors with cancer or a history of cancer

A paper in the transplantation of organs from donors with cancer of a history of cancer was published on the SaBTO website on 22 April 2014.

DORA Position Paper – Anatomical Abnormalities

It was noted that with the increase in the number of organs retrieved from Donation after Circulatory Death (DCD) donors there is often an increasing complexity of the retrieval process. DCD retrieval is on occasion a more difficult procedure than the subsequent transplant. Unexpected anatomical anomalies in otherwise healthy organs can delay the retrieval process and potentially lead to a higher risk of discard. It was estimated that some 20% of organs may be injured during retrieval, and that anatomical abnormalities contribute to this percentage. It was with such a background that the DORA group have produced their latest paper to help provide surgeons with guidance to help in their decision making, and so help increase the number of organs made available for transplant. Whilst this paper focussed on abdominal organs, a subsequent paper will focus on thoracic organs. SaBTO agreed to publish this document and include references on the need to retrieve donor vessels at the time of retrieval, on biliary anatomy and to highlight the increasing number of DCDs.

Report of Study on Testing Deceased Donors for Abnormal Prions Using Splenic / Ocular Tissue

This paper reported on a study which began in 2005/6 to test the feasibility of using splenic or ocular tissue as an analyte in testing tissue donors for abnormal prions. Initially the study considered the use of tonsils as an analyte, however they were very difficult practically to retrieve and only 25% of donors could be tested. The study moved in 2009 to using spleen and optic nerve as analytes. For spleens it was noted that the distribution of prion infectivity through the organ was patchy and the Western Blot testing process may not with certainty identify cases. For ocular tissue it was noted that the risks of transmission via cornea were vanishingly small with only a single presumed (though not well evidenced) transmission in over 40 years, with 100,000 new corneal transplants every year. SaBTO noted and agreed the conclusions of the study that: a) prion testing of spleen is not recommended because a negative result in the samples tested may not reflect the true donor status due to patchy distribution of prion in spleen in asymptomatic individuals; and b) prion testing of ocular tissue is not recommended because the risk of transmission is extremely

low and there is no known clinical transmission of prion disease through ocular tissue transplant in the UK.

SaBTO agreed that the testing of deceased donors for abnormal prions using splenic/ocular tissue should cease.

Revision of Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation

SaBTO agreed to establish as working group to review and propose amendments and additions to the current guidance. The aim was to improve the clarity and availability, as well as ensuring that the information was current and accurate.

General

Three members down from SaBTO when their terms of appointment ended on 30th November 2014: Dr Harpreet Kohli, Dr Eithne MacMahon and Professor Anthony Warrens.

Recruitment to SaBTO in 2014/15

Due to vacancies and other members standing down when their terms of appointment ended on 30th November it was necessary to undertake a recruitment exercise late in 2014 to fill the posts listed below.

The posts to fill were:

a) Blood Service Manager

b) Tissue Transplantation Specialist

c) Paediatrician, ideally involved in treatment with blood products or by organ transplantation

d) Solid Organ Transplant Surgeon

e) Organ Procurement Service Manager

f) Transplant clinician with an interest in immunology

g) NHS Management Specialist (Acute Trust or Board Director level post holder preferred)

h) Haematologist

i) Epidemiology / Public Health Specialist.

Details were sent to a wide range of relevant professional groups and organisations to bring to their members' attention.

SaBTO work plan 2014/15

Current / ongoing topics

Use of future donations from 'Club 96' – including results of risk assessment of vCJD vs. other risks, and use of first time donations.

Donor / Organ Risk Assessment Working Group (DORA) – developing Position Papers on a series of subjects as resources allow.

Hepatitis E Working Group – to consider the risk of hepatitis E transmission via blood and what action, if any, should be taken.

Work to begin in 2014/15

Review of Guidance on the microbiological safety of human organs, tissues and cells used in transplantation – due in 2014 (i.e. 3 years after publication in 2011).

Donor Deferral –SaBTO to review blood donor deferral and exclusion criteria related to sexual behaviour, other than MSM and CSW. Suggested next topic: those who have (had sex with a partner who has) been sexually active in areas where AIDS/HIV is common (especially sub-Saharan Africa).

Note: due to overlap in WG membership, the Review of guidance will need to follow the Hepatitis E work, with the Donor deferral work after that (possibly in 2015/16).

Topics on which SaBTO has a watching brief

Cryoprecipitate and alternatives – any alternatives that become licensed, and use of fibrinogen in place of cryoprecipitate.

Washing of femoral heads – the Bone and Tissue Working Group is to report back when data are available from clinical trials of the process developed by NHSBT and the SNBTS.

Testing deceased donors for abnormal prions using splenic / ocular tissue – testing the feasibility of an alternative approach to a blood test.

Topics for SaBTO to be aware of: no work currently planned

Use of murine fibroblasts (or other xeno elements) and how to test for / detect murine retroviruses, in humans.

Cell therapy for bone and cartilage - issues similar to other cell based therapies currently being planned.

Membership 2014-15

John Forsythe

Lorna Williamson

Anthony Warrens

Richard Seton Tedder

Eithne MacMahon
Harpreet Kohli
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