

SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

MSM TISSUES AND CELLS WORKING GROUP

The Remit and Terms of Reference

Background

1. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) recently reviewed the blood donor deferral and exclusion criteria in relation to specific sexual behaviours. Following the review, SaBTO recommended that the blood donor deferral for men who have ever had sex with men (MSM) should be changed from lifetime deferral to 12 months from the last at-risk behaviour. This recommendation was accepted by Ministers and implemented in England, Wales and Scotland on 7 November 2011.
2. The UK Blood Services have generally tried to adopt common donor selection procedures for blood, tissue, and stem cell donors. The previous MSM review was limited to blood donors, but this has resulted in an inconsistency in donor selection for the UK Blood Services. For example, a man who has had MSM contact more than 12 months prior to donation can be acceptable as a platelet donor, but currently not as a stem cell or tissue donor with the UK blood services. The same individual could be deemed acceptable as a non-blood services stem cell donor. Therefore, all tissue and stem cell establishments need definitive advice regarding MSM eligibility.

Remit

3. The working group will review the evidence base for selection of living and deceased donors of cells and banked tissues in the UK in relation to MSM behaviour and make recommendations to SaBTO on the most appropriate ways to ensure the safety of the supply.
4. Its remit includes:
 - Evaluating the evidence base for deferral and exclusion policies;
 - Defining the infections of interest, whether currently screened for or not ;
 - Reviewing the UK epidemiology of relevant infections;
 - Assessing the performance of current testing procedures;
 - Determining the residual risks for specific infections;
 - Reviewing relevant policies in other countries;
 - Evaluating the operational impact of any recommendations;
 - Evaluating the cost/benefit ratio of any recommendations;
 - Evaluating the impact of any recommendations on overall availability of supply;
 - Recommendations for disseminating the outcome of the review.

5. It is recognised that both organs and bankable tissue may be taken from the same deceased donor. Therefore the scope is described in terms of the material for which the recommendations will apply, rather than the donor.

6. In scope

From donors who are alive at the time of donation:

- Banked tissues;
- Haematopoietic and non-haematopoietic stem cells and immunotherapies, to include cord blood, 'family and friend' donors and unrelated donors from registries;
- Gametes and embryos for reproductive use.

From donors who are deceased at the time of donation:

- Banked tissues, including eyes;
- Gametes and embryos for reproductive use;
- Cells eg pancreatic islet cells.

7. Out of scope

- Solid organs, which cannot be banked, from living or deceased donors.
- Commercial sex workers and their sexual partners.

Terms of Reference

8. In formulating and communicating its advice, the working group will:

- take account of the scientific evidence available, including the nature of uncertainties and assumptions used to reach conclusions;
- take account of the infectivity risk of different tissues including the effects of processing;
- take account of the differences in risk/benefit for different types of tissue and cellular products;
- identify specific areas of research where further work is required to reduce uncertainty;
- take account of the risk of policies being perceived as unfairly discriminatory;
- consider the impact of its advice on all stakeholders in the supply chain, including but not exclusively donors, patients, the UK blood services and the wider NHS;
- take account of the need to maintain the safety of cells and tissues under the remit of the Precautionary Principle;
- take account of any legal requirements;
- take account of any other SaBTO recommendations;
- be ultimately accountable to SaBTO.

Membership

9. Membership of the group will be as follows:

Name	Position	Role on Working Group
Dr Lorna Williamson (Chair)	SaBTO member (Medical Director of Blood Service) Medical and Research Director, NHSBT	Chair on behalf of SaBTO
Dr George Galea	SaBTO member (Blood/Transplant)	Tissues expert

	Service Manager)	
	Head of Tissue Services, SNBTS	
Dr Eithne MacMahon	SaBTO member (Microbiologist/Bacteriologist/Virologist) Consultant Virologist, Guy's and St Thomas' NHS Foundation Trust	Infection expert
Prof Marc Turner	SaBTO member (Haematologist) Medical Director, SNBTS	Stem cell expert
Mr Elwyn Nicol	SaBTO member (Patient Representative)	Layperson
Dr Phil Yates	Chair of Standing Advisory Committee on Tissues and Cellular Therapy Products Consultant, SNBTS	Tissues expert
Dr Su Brailsford	Consultant in Epidemiology and Health Protection NHSBT and HPA	Epidemiology expert
Dr Stephen Thomas	SaBTO Secretariat Safety Programme Coordinator, NHSBT	Secretariat support
Dr Allan Pacey	Senior Lecturer Academic Unit of Reproductive & Developmental Medicine, Sheffield University	Representing British Fertility Society
Dr Liezl Gaum	Royal Liverpool and Broadgreen University Hospitals NHS Trust	Representing NHSBT Ocular Tissue Advisory Group
Prof Francisco Figueiredo (or nominee)	Professor of Ophthalmology & Ocular Surface Disease Royal Victoria Infirmary & Newcastle University	Representing RCOphth Ocular Tissue Transplant Standards Group
Dr Mickey Koh	Consultant Haematologist St George's Hospital, London	Representing British Society for Blood and Marrow Transplantation
Dr Joan Power	President BATB	Representing British Association of Tissue Banks
Mr John Casey	Consultant Transplant Surgeon The Royal Infirmary of Edinburgh and St. John's Hospital, Livingston	Representing British Transplantation Society
Dr Robert Lown	Medical Officer of ANT and Registrar at The Royal Marsden	Representing Anthony Nolan Trust
Dr Yusef Azad	Director of Policy and Campaigns National AIDS Trust	Representing National AIDS Trust

Mr Carl Burnell	Chief Executive Officer GMFA	Representing GMFA and LGBT Partnership
Mr James Taylor	Senior Health Officer Stonewall	Representing Stonewall
Ms Clare Lewis-Jones	Chief Executive Infertility Network UK	Representing Infertility Network UK
Mrs Laura Witjens	Chief Executive National Gamete Donation Trust	Representing National Gamete Donation Trust
Ms Catherine Davies	External Affairs Manager NHS Blood and Transplant	Communications lead
Ms Triona Norman	Head of Policy, Organ and Tissue Transplantation Department of Health	Observer
Mr Emyr Harries	Senior Policy Manager - Cell Therapy and Regenerative Medicine Department of Health	Observer
Ms Kim Hayes	Policy Manager, Assisted Reproduction & Embryology Policy Department of Health	Observer

Work programme

10. The work of the group is expected to be completed by December 2012, according to the following schedule:

Subgroup meeting	Milestone	SaBTO meeting
April 2012 (Telecon)	Agreement of Terms of Reference. Review of JPAC paper. Identification of any further work needed.	Document briefing in place of 29 May 2012 meeting
16 July 2012 (Face to face)	First face to face meeting of full group. Discussion of remit and membership. Identification of areas where additional information needs to be gathered.	11 September 2012
24 September 2012 (Face to face)	Review of additional information and preliminary outline of report.	-
26 November 2012 (Face to face)	Formulation of recommendations, and drafting of report.	10 December 2012
29 January 2013 (Face to face)	Approval of final report.	5 March 2013

11. The working group may meet in person or by telecon.

12. Administrative issues will pass to the SaBTO Secretariat who will also maintain a document library.

13. Members of the Working Group are asked to claim expenses from their employing organisation. Where this is not possible, they can be claimed from DH. Expenses in relation to travel and subsistence necessarily incurred in carrying out the work of the Group are payable in line with DH rates for individuals who serve on committees. This is standard class for rail travel and economy class for air travel. Members of the Working Group are asked to make every effort to use public transport where possible, rather than taxis, although these may be used for local journeys (under 5 miles). Receipts must be submitted with claims.
14. Papers will be circulated no later than 7 days prior to any ordinary meeting.

Communications

15. The establishment of the working group was recorded in the minutes of the SaBTO meeting of 9 March 2012.
16. The Working Group will include stakeholders as detailed in section 9, and will consult those stakeholders listed at item 19. It will consider whether it is appropriate to conduct any other consultations when formulating its recommendations, although it is expected that sufficient expertise is included within the group. Unless specifically stated, members of the working group are not considered to be representatives of the organisations listed in section 9.
17. The recommendations of the Working Group will be published in a report and recommendation to SaBTO, with discussions and outcomes recorded in the public minutes of the meeting. A communications plan will be formulated.
18. This document will be appended to the report, so that the membership of the group is made public.
19. The Working Group will draw up a list of stakeholders that should be informed of SaBTO's recommendations and/or any decision by ministers. This will include:
 - UK Departments of Health
 - Human Tissue Authority
 - The HTA is the UK regulator for tissues and cells, and has agreed to assist with communication of any SaBTO recommendations to licensed establishments
 - HTA has also confirmed that Annex 1 of Directive 2006/17/EC does not require amendment to reflect any changes based on these recommendations.
 - Medicines and Healthcare products Regulatory Agency
 - Human Fertilisation and Embryology Authority
 - UK Blood Services
 - Health Professional organisations (in addition to those represented on the working group)
 - Royal Colleges
 - Patient groups
 - Groups representing MSM (in addition to those represented on the working group)
 - Fertility groups (in addition to those represented on the working group).

SaBTO Secretariat