

SaBTO Working Group on MSM donors of tissues and cells**Update for SaBTO, 10 December 2012****1. Background**

SaBTO had previously conducted a review of the blood donor selection criteria which had led to a recommendation to change the deferral period of men who have had sex with men (MSM) from lifetime to 12 months. This recommendation was accepted by three of the UK health ministers and is now operational in England, Wales and Scotland. The previous review had not covered tissue or cell donation, and the current working group is tasked with reviewing the evidence for donor selection, which currently differs in relation to MSM behaviour between providers of different tissue, stem cell and gamete products and services. Organ donation is not within the scope of this review, as there is no current MSM deferral due to the shortage of organs and the risk:benefit balance.

2. Terms of reference

The group's terms of reference are attached as an appendix to this update. The scope covers banked tissue (skin, bone, heart valves, tendons and ocular tissue have been considered individually), stem cells, gametes and embryos (for reproductive purposes), and pancreatic islets. Advanced Therapy Medicinal Products derived from either embryonic stem cells or induced pluripotent stem cells have been removed from the scope, as these will now be covered by the Cell Based Advanced Therapies working group.

3. Current legislation and practice

A review of the legislation and guidance for the selection of donors of tissues, stem cells and gametes has been undertaken, and in order to understand how these are applied, a survey of providers was conducted. It is clear that advice or standardisation of the wording used in donor selection and testing documentation is one of the areas where the working group can contribute.

4. Infections and epidemiology

Papers that set out the infections of relevance to cells and tissues, and their UK epidemiology have been prepared, and will form a key section of the final report. It has been noted that, unlike blood donation, few data are available for analysis and the group's report will reflect this.

5. Tissue specific risks and potential interventions

Information on each type of tissue and cell has been collated into a standardised template and reviewed by the working group. This includes assessment of the life-saving or life-enhancing properties of the therapy, supply issues, evidence of any previous viral transmissions (in the UK or globally), current donor history taking and testing procedures, and whether processing of the donation may reduce viral load. It also considers whether there is an opportunity to discuss the potential risks of an individual donor with the recipient (eg in stem cell transplantation), and whether one donation may potentially be used for many recipients (eg in deceased bone donation).

Following an initial review of these completed templates, we have created four main categories: banked tissues, haemopoietic stem cells, gametes, and pancreatic islets. Preliminary recommendations have been reached for each group in relation to donor selection. Some observations regarding virus screening will also be made. Further work will be undertaken to validate these for each group of products.

6. Schedule

An outline of the report and authors for each section have been agreed. The group will next meet on 29 January 2013 to review a draft of the report, and aims to provide a final version to SaBTO at the 5 March 2013 meeting. The working group has a communications lead, and a communications plan will be developed and appended to the final report.

SaBTO Secretariat