SaBTO Working Group on MSM tissues and cells

Update for SaBTO, September 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 was 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 between providers of different tissue, stem cell and gamete 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 different balance of risk.

2. Terms of reference

At the 2nd Meeting of the group (first face-to-face meeting of the full group) held on 16 July 2012, the terms of reference and scope of the group's work were agreed. The review would cover banked tissue (including ocular tissue), stem cells and other cellular therapies, and gametes. Given the thoroughness of the review of blood donation selection criteria, it was considered unnecessary to repeat the viral risk work in detail, but rather to remain focussed on issues specific to tissue and cell donation ie the use of deceased donors, donors related to the patient, 'unique' HLA matched donors of stem cells, and the potential for one donor's tissues to infect many recipients. Commercial Sex Workers (CSW) were agreed to be out of scope of the review, as insufficient evidence had been available to make a recommendation regarding blood donation, and it was considered highly unlikely that there would be sufficient evidence for tissue and cell donation.

The membership of the group includes representatives of blood service and non-blood service providers of tissues, cellular therapies and gametes, professional organisations and MSM stakeholder groups. A communications lead will be included in due course.

3. Current practice and legislation

In view of the many providers in the areas to be covered, it was agreed that a survey would be undertaken to collate current practice in donor selection, consent, testing, to cover:

- what questions are asked
- what deferral policy is followed currently re MSM
- what testing is used (which pathogens)
- who does the testing (which lab)
- what test protocol is used (NAT, pooling etc)
- are results transferred electronically
- is there a quarantine period between test and issue
- the interval between test and donation.

The legal requirements for tissue and stem cell donation had been reviewed but the legal requirements for gamete donation needed to be considered. Additional information would be required on the risk/benefit ratio with respect to matched stem cell donors.

4. Infections and epidemiology

The first draft of two papers that set out the infections of interest and their epidemiology had

been prepared and were discussed. The blood-borne infections of interest were HIV-1, HIV-2, HBV, HCV, HHV-8 and HSV. Of less significance in this context were HTLV-1, HTLV-2, Hepatitis A, Hepatitis E, CMV, EBV, and VZV. However, genital infections such as syphilis, Chlamydia and gonorrhoea are a concern for MSM and for gamete donation in particular, and need to be considered further.

It was noted that if sufficient data were not available for analysis to the degree performed for the blood donor review, the group's report would need to include a clear explanation of this.

5. Tissue specific risks and potential interventions

Work is in progress to collate data on different types of tissue, their current preparation methods, the transmission of specific agents, processes that may be used to reduce the risk of transmission, what testing could be done and what deferral period may be advisable.

6. Schedule

The group will next meet on 24 September, and then in November 2012 and January 2013. The report will be provided to SaBTO at the 5 March 2013 meeting.

SaBTO Secretariat