

MSM Tissues and Cells: Donor Selection Criteria review

The group sought to make recommendations on the selection criteria for donation of tissues and cells by men who have had sex with men (MSM), following the recent change for blood donors from a lifetime to a 12 month deferral from last MSM contact. The scope included haematopoietic stem cells; pancreatic islets and hepatocytes; banked tissues, and gametes and embryos for reproductive purposes.

The working group reviewed

- the evidence base for selection of living and deceased donors of cells and banked tissues in the UK in relation to MSM behaviour
- updated data on generic virus risks, and considered in depth any tissue-specific infection risks, notably HHV-8.

A risk-based approach was adopted and factors that would determine the overall risk/benefit balance were identified.

Recommendations on donor deferral

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

For ‘family and friend’ donors: NO DEFERRAL

For unrelated donors joining a registry: NO DEFERRAL

For cord blood donors: ALLOW DONATION 12 MONTHS AFTER LAST SEXUAL CONTACT BY THE DONOR WITH A MAN WHO HAS EVER HAD MSM CONTACT.

Group 2: Pancreatic islets and Hepatocytes

NO DEFERRAL.

Group 3: Banked tissues (corneas, heart valves, bone, skin, and tendon)

ALLOW DONATION 12 MONTHS OR MORE AFTER LAST MSM SEXUAL CONTACT.

Group 4: Sperm, eggs and embryos

NO DEFERRAL.

Other Observations**Observation on collection of donor information**

It is desirable that standardised terminology should be used by all tissue and cell providers. The wording currently used by UK blood services was considered appropriate (eg “men who have ever had oral or anal sex with another man with or without a condom or other protection”).

Observation on donation testing

The group noted inconsistencies in the use of nucleic acid testing (NAT) between different tissue and cell products, and between different providers of the same product. SaBTO issued guidance in 2011 on the microbiological testing of organs, cells and tissues, and this document alluded to NAT as best practice, but stopped short of a firm recommendation for its use for all banked tissues. Therefore, when this guidance is next reviewed, SaBTO may wish to clarify the position with regard to the use of NAT eg recommending its use for all banked tissues and cells, and giving consideration to either the pool size to be used or individual sample testing.

Observations on manufacturing

Additional processes to reduce viral risk were identified only with regard to bone (eg a combination of peroxide and peracetic acid). There is an ongoing study of a new processing method for living bone donations to remove residual cellular marrow. This was previously considered by SaBTO in the context of vCJD risk reduction, and a study of efficacy recommended. It is recommended that when this study is complete, the data on safety and clinical effectiveness should be reviewed by SaBTO, with a view to considering whether or not this method should become the standard of care.

Observations on bio vigilance

Reporting systems exist for the notification of virus transmission by all tissue and cell products considered in this review, and are mandatory under the Human Tissue Act. Such reported, confirmed events are now rare.

However, and in contrast to blood, there is limited documentation and no central collation of incidence and risk factors of virus positive donors of cells, tissues (except within Blood Services) and gametes. It is suggested that options are considered how best such data could be collected, analysed and published. This could include reporting of clinical manifestations of viral infections in recipients eg Kaposi's sarcoma.

The storage of archive samples from tissue and cell donors would assist in investigation of suspected infection transmissions and timely recalls.

Both data collation and archive samples have value in the identification and assessment of emerging infections.

SaBTO members are asked:

Do you agree with the proposed recommendations on donor deferral for each of the four groups?

NOTE

The report, Tissues and Cells: MSM Donor Selection Review is now published at <https://www.gov.uk/government/publications/donor-selection-criteria-for-men-who-have-had-sex-with-men>