



British Fertility Society

response to the

Advisory Committee on the Safety of Blood, Tissues and Organs

consultation draft document on

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

July 2010

This document represents the British Fertility Society (BFS) response to the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) consultation draft document on Guidance on the Microbiological Safety of Humans Organs, Tissues and Cells used in Transplantation.

The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

The use of donated sperm, eggs and embryos during assisted conception treatments is an important part of the workload of BFS members and as such the society has an interest in these draft guidelines.

This response was written by Dr. Allan Pacey, Senior Lecturer in Andrology at the University of Sheffield, on behalf of the BFS Executive Committee.

This document is submitted by the Honorary Secretary whose contact details are:

Mrs Alison McTavish
c/o British Fertility Society Secretariat
22 Apex Court
Woodlands
Bradley Stoke
BS32 4JT

bfs@bioscientifica.com

Specific Comments for the SaBTO committee

1. The BFS recognises that the draft SaBTO guidelines cover a wide clinical scope intended to cover donation and transplantation in all clinical contexts.
2. During their daily work, BFS members would typically be involved in the activities listed in paragraph 26a-c. Namely, (a) partner donation with direct use; (b) partner donation with in vitro manipulation; and (c) donation of gametes and embryos for use by a third party.
3. A minority of BFS members will have research interests with regard to the activities listed in paragraph 26d&e. Namely, (d) embryonic stem cells created from fresh gametes and embryos; and (e) embryonic stem cells created from stored embryos.
4. With regard to the activities listed in paragraph 26c (donation of gametes and embryos for use by a third party) SaBTO should be aware that in 2008 the BFS published guidance along with the Association of Biomedical Andrologists (ABA), Association of Clinical Embryologists (ACE), British Andrology Society (BAS) and the Royal College of Obstetricians and Gynaecologists (RCOG) concerning the medical and laboratory screening of sperm, egg and embryo donors.
5. The ABA, ACE, BAS, BFS and RCOG guidance was published in *Human Fertility* volume 11 pages 201-210 and the BFS suggests that this be included as a reference in the SaBTO guidance.
6. In the same matter that SaBTO note in paragraph 2 of their consultation document that they have “endeavoured to make [their] guidance congruent with the very extensive regulatory framework” the BFS suggests that to avoid confusion within the sector that a similar view is taken with regard to the above professional bodies guidance.
7. There are some areas of the SaBTO guidance that as currently worded may cause confusion as outlined below.
8. There are few (almost no) situations in reproductive medicine where time pressures mean that a donor cannot be adequately screened. Therefore the suggestion in paragraph 10 of the SaBTO guidance does not apply to reproductive medicine.
9. It is the BFS view that for reproductive tissues where cryopreservation is possible (e.g. sperm and embryos) that this continue to be carried out with a 180 day quarantine period followed by repeat testing. The proposed use of NAT testing to shorten this window in sperm and embryo donation is not currently supported (see 4).

10. In the case of egg donation, the BFS agrees that NAT testing gives additional reassurance, since the majority of egg donation cycles are performed without cryopreservation. However, as currently worded paragraph 26c might be read to imply that NAT testing removes the need for cryopreservation in all reproductive tissues and this is not the view of the BFS (see 9).
11. Table 3 of the SaBTO guidance is a helpful summary of the screening of candidate organ, tissue and cell donors. However, in the case of reproductive tissues it fails to mention screening for *Neisseria gonorrhoea* and *Chlamydia trachomatis*, although these are mentioned in paragraph 26c. This has the potential to cause confusion and in the BFS view they should be included in this table.
12. The interpretation of Cytomegalovirus (CMV) test results in Table 4 (page 27) is contrary to the ABA, ACE, BAS, BFS and RCOG guidance for reproductive tissues (see 4) where it was concluded that “The decision to treat a patient with a seropositive donor should be a matter of clinical judgement”.