

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

SCIENTIFIC AND CLINICAL ADVANCES GROUP

**HFEA SCREENING AND STORAGE POLICY FOR THE SAFE
CRYOPRESERVATION OF GAMETES, EMBRYOS AND
OVARIAN/TESTICULAR TISSUE**

Introduction

1. The aim of this paper is to
 - Set out the background on the development of the HFEA screening and storage policy for the safe cryopreservation of gametes, embryos and ovarian / testicular tissue;
 - Highlight other relevant work currently been undertaken by the Authority; and
 - To draft guidelines, to be sent to all licensed centres, on the requirements needed to implement this policy.

Background

2. The recommendations of the HFEA Cryopreservation Working Group were formulated into a policy position on the screening of patients by the Code of Practice Committee in April 2001. Chairman's letter CH(01)09, which detailed this position, was sent to centres in June 2001. This letter is attached at Annex A.
3. At the meeting on 31st March 2003 to launch the Sixth Edition of the Code, the Chair and Chief Executive stated that detailed guidance on screening issues would be available in the form of a letter in Autumn 2003. Following recent incidents (see Alert 3 attached at Annex B), work is to be done on guidance on the safety of storage dewars (low nitrogen level alarms etc). This work will not be completed until April 2004. It might be sensible to issue all guidance relating to dewars as one document, however this would delay the issuing of further guidance on screening and storage. It should be noted, however, that these two initiatives taken together have additive financial implications for clinics if, for example, all dewars including small dewars for infected samples must be alarmed.

Current Practice in Centres

4. Letter CH(01)09 requested that licensed treatment centres forward to their Inspector Co-ordinator, by the 30 August 2001, a timetable for the implementation of a policy for the routine screening of **all** patients for Hepatitis B, Hepatitis C and HIV. It was decided that implementation of this policy will be a requirement for all centres by 31 December 2004.

5. By April 2002, only 17 centres had complied with the request for a timetable to be forwarded to the HFEA. An analysis of these responses is attached at Annex C. Of these, one centre has now closed, and the implementation plan of another could not be located. The plans from just 6 centres fulfilled all the requirements of the policy. Of these, 4 will offer treatment and storage to infected patients and 2 will not. The actual implementation details, particularly with regard to the number and designation of dewars, should be followed up on inspection. For the remaining centres, more detail on all aspects is required.
6. Additionally, Regulation have been asked to provide recent inspection evidence on current practice. This is appended at Annex D. Regulation report that this policy, and problems centres are having with implementing it, particularly obtaining funding to purchase additional dewars, is regularly raised on inspection.

Previous Work

7. In April 2002, the HFEA Code of Practice Committee (COPC) considered this policy further, including queries raised by clinics. The paper considered at this time is attached at Annex E. The minute of this discussion is attached at Annex F.
8. From the responses that had been received from clinics, it was noted that a number of centres were having difficulty implementing the policy due to cost implications. The COPC discussed the cost implications but agreed that the HFEA is ultimately in existence to protect patients and therefore it agreed that all centres should be required to carry out screening.
9. In addition to agreeing relevant provisions for the Sixth Edition of the Code of Practice, the COPC agreed answers to certain queries raised by centres, however felt that further information was needed on certain issues. This is detailed at Annex G.
10. The COPC asked that a follow-up letter should be sent and include the following points:
 - a. The Authority's awareness of problems relating to implementing the policy
 - b. Why the Authority is implementing the policy
 - c. Summary report of evidence and potential risks in support of implementing the policy;
 - d. Reinforce the original timetable for implementation of the policy; and
 - e. Inform the centres that the Regulation team will follow-up implementation plans during the inspection process.
 - f. Clarify the position on the queries raised and note that further advice on re-screening is being sought.

11. It was also agreed that the Authority should update the professional bodies and inform them of what actions the Authority is taking in relation to this issue. Due to the work on the complete revision of the Code for the Sixth Edition, this work has not yet been completed.

Sixth Edition of the HFEA Code of Practice

12. The following additional sections are currently included in the Sixth Edition of the Code. These may be subject to amendment.

Additional Information

- 5.5 It is expected that information will also be given to individuals seeking treatment about the following:

- (ix) The availability of embryo freezing facilities and:
- (a) the likelihood of success with embryo freezing, thawing and transfer
 - (b) the implications of storage (including the possible deterioration or loss of viability of gametes or embryos as a consequence of storage and the potential risk of cross contamination between samples)

Screening

9.2 All patients placing gametes, embryos and ovarian or testicular tissue in storage which falls under an HFEA licence are expected to be screened for Hepatitis B, Hepatitis C and HIV, as outlined in Section 9.4 of the Association for Clinical Embryologists' Guidelines.

9.3 Centres are expected to ensure that storage of tissue that does not require a licence from the HFEA fulfils the requirements of the Code of Practice for Tissue Banks (Department of Health, 2001). (See also Guidance on the Microbiological Safety of Human Organs, Tissues and Cells Used in Transplantation (Department of Health 2000))

9.4 It is expected that screened samples will be kept in a separate cryostore from unscreened samples. Unscreened samples include:

- i) Any samples stored before comprehensive screening of all patients was introduced, and
- ii) Any samples in temporary storage while the results of screening tests are obtained

EU Tissue Directive and DH Code of Practice for Tissue Banks

13. The EU Tissue Directive covers all aspects of the handling of human tissues and cells intended for transplantation, including all use of gametes and embryos in treatment. It is expected that the Directive will be adopted by April 2004 and become legally binding in the UK by April 2006.

14. It will be a requirement for all establishments undertaking activities within the scope of the Directive, whether NHS or private, to be inspected and accredited. The standards required for accreditation will not be fully developed within the Directive itself. In early 2004, an expert Committee will be set up to develop detailed Annexes on matters such as donor selection and testing, traceability, packaging etc. The Department of Health have advised that their *Code of Practice for Tissue Banks* gives a good indication as to the type of standards that will have to be met.

Additional Information

15. Following an incident at a licensed centre where an HIV positive sperm sample was inadvertently stored with other samples, a copy of the subsequent incident alert is attached at Annex H, the HFEA sought advice from the Department of Health on whether there was a need to inform the other patients with samples in the same cryostore of the risk of HIV transmission. A copy of this advice is attached at Annex I.

Further Guidance for Centres

16. Draft guidance for centres on the screening / storage policy has been drawn up. This is based on the HFEA Code of Practice, discussions of the COPC as discussed above, discussions of the HFEA (1999), and the standards contained in the Department of Health's *Code of Practice for Tissue Banks*, other guidelines as referenced and further advice obtained from the Department of Health, professional bodies and other experts. Certain issues require further consideration and SCAG is asked to consider these matters. The draft guidance is attached at Annex J.

Conclusion

17. Members are asked to:
 - Review the draft guidance for centres, and
 - To suggest further work that needs to be undertaken prior to this guidance been sent to all licensed centres.

HFEA Policy Team

November 2003

Annex ACH(01)09
6 June 2001

To: All Persons Responsible

Dear Colleague,

Screening of Patients

In 1998 a working group made up of HFEA members and representatives of relevant professional organisations, including ACE, BAS and the BFS, met to discuss the issues surrounding the safe cryopreservation of human gametes and embryos.

In June of that year the HFEA published a consultation on this subject to elicit a wider range of views. Responses to this document were received from a number of bodies including, licensed centres, patient groups and professional bodies, including those with an interest in fertility.

Following this consultation the working group on safe cryopreservation was reconvened for further discussions, which resulted in a series of recommendations to the HFEA on all aspects of cryopreservation. Many of these recommendations have been incorporated into the fifth edition of the Code of Practice.

One of the working group's recommendations, endorsed by the Authority but not yet enshrined in the Code, stated that all patients placing gametes or embryos in storage should be screened. A further recommendation suggested that screened samples should be kept in a separate cryostore from unscreened samples.

Full screening and separate storage reduces the risk of cross contamination between stored samples. A comprehensive screening protocol may also reduce the need for hazardous sanitisation or secondary containment of samples since the risk of introducing a contaminated sample would be greatly reduced.

The HFEA therefore requests that all centres submit to their Inspector Co-ordinator, by the 30 August 2001, a timetable for the implementation of a policy for the routine screening of **all** patients for Hepatitis B, Hepatitis C and HIV, as outlined in the ACE Guidelines at section 9.4. It is suggested that presently such screening might simply involve immediate, first round screening and not a quarantine period. Such a screening policy will reduce the risk of cross contamination between samples.

Centres should also detail their plans for the separate cryostorage of screened and unscreened samples. This might involve, for example, a separate holding vessel to hold samples for the short period of time necessary to carry out screening; a storage vessels for

clear samples; one for HIV positive samples; one for Hepatitis B infected samples; and one for Hepatitis C infected samples.

This screening policy should be in place as soon as possible and will be a requirement for all centres by 31 December 2004 unless exceptional circumstances for an extension of this period can be demonstrated. These circumstances should be detailed in a letter accompanying that centre's implementation timetable.

I look forward to receiving your centre's action plan, if you have any queries please get in touch with your HFEA inspector co-ordinator.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ruth Deech', written in a cursive style.

Ruth Deech
Chairman

Annex D**Feedback from Regulation on screening / storage issues raised on inspections during 2003****General Comments**

Many centres raise the cost issue of separating screened from non-screened or storing each patient's samples in separate dewars in case of dewar failure. They all ask for clear guidance from us on what exactly we are asking them to do – I think so they can use us as their argument to get the funds for the extra dewars and space that is required if we are asking for all these things definitively.

There have also been questions about how often patients should be re-screened.

They have asked if the use of heat sealed straws makes any difference (to which our answer has been no).

Some have asked if its ok to store HepB with Hep C providing they explain the risks to patients.

Some centres still believe that storing in vapour phase will mean that samples of a different status can be stored together. The vapour vs liquid question is another one that centres regularly ask about (again our answer is it makes no difference to the requirements).

Last week Paul Gemmill discussed this on inspection. The staff felt there were no practical benefits from screening, they are concerned about the cost and have been told by their Trust that they would have to fund it from within current budgets and therefore would have to provide fewer treatments. They want to know what the practical basis for the screening is as opposed to the theoretical.

Does the Authority intend to produce information for patients outlining why they need to be screened?

What level of counselling should be provided?

Under the Human Rights legislation can a centre refuse to treat a patient if they refuse to be tested?

Extracts from recent inspection reports**Small DI Centre**

The Inspection Team asked the Person Responsible about the impact of the forthcoming EU Tissue Directive on the centre, as recently communicated in a letter from the Department of Health. The Person Responsible stated that she was unaware of the Directive. The Inspection Team suggested that she looks this up on the Department of Health website and explained that the tissue banking requirements that need to be met by 2005 will have significant consequences for small centres.

Oncology Storage CentreClean room

This room is next to the storage room and has been designed and installed in line with EU directives concerning "clean room" standards. This room will be used for semen analysis and procedures involving stem cells. All equipment and facilities have been checked and installed by an approved company that specialise in this type of work.

The hospital has a dedicated Quality Assurance Manager to oversee the stem cell storage requirements. The Trust will formally open the clean room in the next few weeks.

The centre informed the inspection team that from December 2004 they will only store screened samples and will counsel all patients before screening. They also, will not mix samples that were stored before December 2004 and after it. They will, however, have to obtain more dewars to enable screened and unscreened samples to be stored separately. The centre stated that it was the role of the clinician to counsel the patient regarding the implications of screening, rather than the laboratory staff.

Other matters

The hospital received its CHAI inspection last year. The inspectors did not focus on this area during their interviews with staff.

The Nominal Licensee queried the ongoing licensing and jurisdiction of material. The inspection team advised that stored gametes will continue to be inspected under the HFE Act 1990. However, the long term inspection of stem cells is yet to be fully scoped.

Private IVF and Storage Centre

The inspection team enquired about the centre's policy for screening patients for HIV, Hepatitis B and C. The Person Responsible explained that it is the unit's policy to screen all patients receiving treatment. This policy came into effect as of May 2003. The centre does not have facilities to treat positive patients, however there is a local Gastroenterologist who is the Hepatitis C coordinator for the region. The centre would refer patients to a centre that has adequate facilities to treat positive patients. The centre would welcome further guidance from the HFEA on the screening requirements that come into effect in December 2004.

NHS IVF and Storage Centre

Patients are screened for HIV as well as hepatitis B and C before treatment. However patients are not re-screened after a six month period nor are screened samples stored in a separate dewar during any quarantine period. The inspection team advised that screening should not be confused with 'quarantining', as used for donor sperm for example. Patient information should be changed to clarify this ambiguity. If a patient proves positive HIV or hepatitis they are referred to an appropriate clinic. Donors are stored in a separate dewar.

NHS and Private IVF and Storage centre

Patients with viral infections

It was noted that the Centre implemented a full patient screening programme for Hepatitis B & C and HIV in October 2002. The Centre does not have the facilities to treat patients with either HIV or active Hepatitis B or C infections. Again, these patients would be referred to other clinics.

Current re-screening practice

NHS and Private IVF and Storage centre

On inspection, the centre stated that they re-screen annually because "the HFEA told us we have to". When asked where this came from (Licence Committee? Inspector?) ,as it is not a requirement of the HFEA, they could not remember.

Current temporary storage practice

Oncology Storage Centre

The centre has 2 small storage flasks that they can store semen samples in until the screening results come through. If found to be positive, the samples stay in that flask and another is bought to replace it. If negative the samples are moved to one of the main dewars.

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

CODE OF PRACTICE COMMITTEE

ISSUES ARISING FROM THE IMPLEMENTATION OF THE SCREENING POLICY FOR PATIENTS STORING GAMETES, EMBRYOS AND OVARIAN/TESTICULAR TISSUE**1. Introduction****1.1 General**

- 1.1.1 The recommendations of the Cryopreservation Working Group were formulated into a policy position on the screening of patients by the Code of Practice Committee in April 2001. The paper considered at this time is attached at Annex 1. The record of this discussion is attached at Annex 2. Chairman's letter CH(01)09, which detailed this position, was sent to centres in June 2001. This letter is attached at Annex 3.
- 1.1.2 Letter CH(01)09 requested that licensed treatment centres forward to their Inspector Co-ordinator, by the 30 August 2001, a timetable for the implementation of a policy for the routine screening of **all** patients for Hepatitis B, Hepatitis C and HIV. It was decided that implementation of this policy will be a requirement for all centres by 31 December 2004. Regulatory Managers report that, to date, only around a quarter of centres have complied with the request for a timetable to be forwarded to the HFEA.

1.2 Issues for consideration

- 1.2.1 This paper highlights queries and requests for guidance that have been received from centres since letter CH(01)09 was circulated. It is suggested that a follow-up letter clarifying the situation be sent to centres.
- 1.2.2. Additionally, the HFEA has received indications from patients that centres may not always be clearly explaining to patients the reasons for requiring that screening tests be done. It is suggested that the need for the patients' informed consent should also be included in the letter.
- 1.2.3 Many issues arising from the Cryopreservation Working Group have already been incorporated into the Fifth Edition of the Code of Practice, e.g. laboratory facilities and operating procedures. The patient screening policy and the requirement that screened samples should be kept in a separate cryostore from unscreened samples have not been incorporated into the Code and are addressed below.

2. Meeting with Professor Tedder

- 2.1.1 In response to an incident that had occurred at a licensed centre, a meeting with Professor Richard Tedder at The Windeyer Institute was arranged. Professor Tedder is Professor of Medical Virology at the Royal Free and University College Medical School. He is additionally an external consultant to the National Blood Service, involved with many aspects of transfusion microbiology and the safety of blood and blood components.
- 2.1.2 Issues discussed in this meeting are relevant to the safe cryopreservation and screening issue. A draft report is attached at Annex 4.

3. Issues from centres

3.1 *Critical incident*

- 3.1.1 A centre licensed by the HFEA has recently reported a case where a patient with embryos in storage was found to be HIV infected. The hospital concerned established a Risk Assessment Group to consider the incident in detail. The consideration of the risk associated with the particular circumstances of this situation and the conclusions reached by the Group may be informative to the Code of Practice Committee's considerations on this issue. An anonymised report of the meeting of this Group is attached at Annex 6. Please note that this report was submitted to the HFEA on a confidential basis, and should not be discussed outside of the HFEA. This report is provided for background information.
- 3.1.2 The Group consisted of the following personnel:
- Head of Microbiology and Lead Infection Control Doctor;
 - Consultant Medical Virologist, Public Health Laboratory Service;
 - Consultant Communicable Diseases Control;
 - Infection Control Nurse;
 - Scientific Director of the licensed unit;
 - Consultant Obstetrician and Gynaecologist from the licensed unit;
 - Senior Embryologist from the licensed unit.

3.2 *General queries*

- 3.2.1 Many centres have reported problems with the space and cost implications of implementing this policy. Some centres have responded by simply stopping storing samples for infected patients and others have requested clarification on certain aspects in order to aid their implementation planning.
- 3.2.2 Specific areas of uncertainty raised by centres are listed below followed by summaries of relevant discussions or guidelines, as appropriate. Members are

asked to agree responses or further action regarding these queries. It is suggested that a letter be sent to centres clarifying the implementation of the policy.

3.2.3 How often should patients who return for several cycles be re-screened?

Antibodies to HIV may not appear in the blood for up to 3 or even 6 months after infection. Annex C of the fifth edition of the HFEA Code of Practice (“*HIV screening for gamete donors*”) thus states that semen donors should have immediate and 180 day tests for HIV before their semen is used for treating others.

3.2.4 The re-screening of sperm donors is consistent with practice for other tissue donations. Tissue donors are re-tested for mandatory markers, including HIV-1 and -2, 180 days after the tissue donation is taken. (Guidelines for the Blood Transfusion Services in the UK, Fifth Edition)

3.2.5 The Blood Transfusion Service performs mandatory initial screening for HBsAg, anti-HIV 1 and 2, and anti-HCV of all blood donations received, having excluded high risk donors via a medical/lifestyle questionnaire. Positive samples are re-screened, and repeat positive samples are sent for confirmatory testing at a designated laboratory. If the sample is designated positive, counselling and further investigation of the patient is organised. If the specimen is considered to have been falsely reactive, reinstatement to the donor panel may be considered after a period of follow-up. The donor would need to be re-bled for consideration for reinstatement after not less than six months. (Guidelines for the Blood Transfusion Services in the UK, Fifth Edition)

3.2.6 The report of the Risk Assessment Group at the centre at which the critical incident occurred briefly addresses repeat screening of patients (Annex 6, final paragraph). It notes that individuals awaiting transplantation are usually re-tested annually. They propose that ART patients be re-screened only every three years or if a change in marital or social circumstances occurs within that period. What might constitute such a change is not detailed. The centre additionally asks for further guidance on this from the HFEA.

3.2.7 Should all positive samples be stored individually in separate dewars or can, for example, all Hepatitis B positive samples be stored together in a single dewar?

The policy has been implemented and communicated on the basis that all samples similarly infected can be stored in the same dewar (see CH(01)09 at Annex 3). It is suggested that this position be restated.

3.2.8 Is it acceptable to store screened/unscreened samples or, for example, Hepatitis B and C positive samples in the same dewar, if the risks are explained to patients?

Based on the recommendations of the Safe Cryopreservation Working Group, the Authority recommended in 1999 that screened samples should be kept in a

separate cryovessels from unsorted samples. This was not qualified and has been implemented as applying to all instances, no matter what information is given to patients. It is suggested that this position be restated.

3.2.9 If a brief quarantine period while test results are obtained is required e.g. if emergency referrals are received prior to orchidectomy, chemotherapy or radiotherapy, what action should be taken if with regards to other samples stored if a test should be returned with a positive result?

In November 2001, the Department of Health announced a new policy on informing patients when a health care worker is found to be infected with HIV. The press release is attached at Annex 5. Previously, patients were informed of the potential risk no matter what level of risk they were deemed to have been exposed to. The new policy links the extent of patient notification to the level of risk of exposure, to be considered on a case by case basis, suggesting that there may be no patient notification exercise in some cases. Further guidance on this is expected to be published by the Department in late May. The principle enshrined in the new policy might also be applicable to cases of potential exposure of embryos, gametes or tissue to viruses.

3.2.10 Professor Tedder (see Annex 4) was asked to consider whether, in his opinion, patients should be informed if they had embryos stored with other embryos that have been exposed to the HIV virus. He considered that this question was difficult to answer, however, if the centre had used best practice, routinely storing in vapour phase dewars with the sample/embryos being stored in primary and secondary containers, then there would be no need to contact the patients as it may cause more harm than good.

3.2.11 This would not currently be the case in most licensed clinics however. Professor Tedder considered that if liquid nitrogen is used and open tubes have been detected, then a careful risk assessment would need to be carried out to decide whether or not patients should be contacted. Even in this incidence there would probably be a very small risk.

3.2.12 In the recent case where embryos created from the eggs of an HIV infected patient were in storage with other embryos, the Risk Assessment Group set up by the clinic to consider the incident in detail concluded that in this particular case, *“the extent of HIV contamination would be close to zero and therefore posed no risk to other stored embryos.”* The Group therefore agreed that patients who had embryos stored in the same dewar should not be informed. A report of the Group’s consideration is attached at Annex 6.

3.2.13 The evidence suggests that the risk will differ depending on the exact conditions of storage, and also the particular virus concerned. It is suggested that centres should be advised to take all steps to minimise the risk, but should an incident arise, a risk assessment on their particular circumstances would be required before

any view on informing patients could be taken. This question feeds into a wider question of informing patients of critical incidents in general, which will be presented to the Committee for its consideration at a later date.

3.2.14 Would the use of vapour phase storage be an acceptable alternative to the use of separate dewars for samples of differing infection status?

Professor Tedder advised the HFEA Executive (see Annex 4) that use of vapour or air phase dewars would be best practice and minimise the risk of cross-contamination, although the risk of overfilling the tanks and consequent immersion of samples in liquid nitrogen meant a small risk of liquid phase cross-contamination remained.

- 3.2.15 Guidelines for the Blood Transfusion Services in the UK, Fifth Edition detail the requirements for the cryostorage of blood and marrow progenitor cells. The relevant section of the Guidelines is attached at Annex 7. This states the following regarding storage conditions:

*It is recommended that the vapour phase of liquid nitrogen is used to reduce the risk of cross-contamination. It is recognised however that this is associated with a greater temperature fluctuation and measures should be taken to ensure that the paragraph above applies. Some facilities may employ total or partial immersion in liquid phase to store HPC donations. Whatever method of storage is used it **must** always be assumed that liquid nitrogen is microbially contaminated and secondary enclosure **must** be employed and validated for each product stored.*

- 3.2.16 The risk of cross-contamination via liquid nitrogen therefore remains even if vapour phase storage is used. Samples of differing infection status should therefore be stored separately even if vapour phase storage is used.

3.2.17 Should current cryostores be tested for viral contamination?

The Safe Cryopreservation Working Group considered that liquid nitrogen storage vessels are invariably contaminated with microorganisms, although these may not be pathogens, and that it would be impossible to ensure that a contaminated vessel could be made completely clean. It recommended, therefore, that vessels should be sampled so that clinics might be aware of the presence of pathogens, but that a standard protocol for the sanitisation of vessels would not be helpful. In the event of a positive result, clinics could begin to use a new vessel. It is suggested that centres are advised that vessels should be sampled.

4. Information for patients – reasons for the implementation of the screening procedure

- 4.1.1 The supporting arguments for this at the Meeting for the Safe Cryopreservation of Gametes and Embryos (Annex 1D) were: the welfare of the child assessment; to reassure patients that all measures were being taken to reduce risk; to minimise risks to clinic staff; and for the protection of the clinic in the event of litigation. It

was also recognised that a comprehensive screening protocol might circumvent the necessity for hazardous sanitisation or secondary containment since the risk of introducing a contaminated sample would be much reduced.

- 4.1.2 It is suggested that clinics be reminded of the reasons for the introduction of the screening policy, and that patients should be aware of the reasons why they are asked to have such tests.

5. Additions to the Sixth Edition of the Code of Practice

- 5.1.1 The Committee is asked to consider the following outstanding issues (see recommendations of the Meeting on the Safe Cryopreservation of Gametes and Embryos, Annex 1D) for inclusion in the Sixth Edition of the Code of Practice:

- the screening of all samples to be placed in storage;
- keeping screened samples in a separate cryostore from unscreened samples;
- where CMV is screened for, these samples should be stored separately from unscreened samples;
- patients should be informed of the risk of cross-contamination and a statement should be included in the patient information.

- 5.1.2 Suggested amendments to the Code of Practice are attached at Annex 8. Members may wish to expand these amendments in the light of their consideration of queries raised by centres. For example, Members may wish to give consideration to the secondary containment ('double bagging') of samples stored (see extract from Guidelines for the Blood Transfusion Services in the UK, Fifth Edition, Annex 7) or how often patients should be re-screened.

5.2 Screening policy

- 5.2.1 The requirement for all patients requiring storage of gametes, embryos and ovarian/testicular tissue to be screened for Hepatitis B, Hepatitis C and HIV should be included in the Sixth Edition of the Code of Practice. The Meeting on the Safe Cryopreservation of Gametes and Embryos suggested that all samples placed in storage could be screened in accordance with blood and tissue screening protocols.
- 5.2.2 Chairman's letter CH(01)09 communicated this policy to centres, stating that: *The HFEA therefore requests that all centres submit to their Inspector Co-ordinator, by the 30 August 2001, a timetable for the implementation of a policy for the routine screening of **all** patients for Hepatitis B, Hepatitis C and HIV, as outlined in the ACE Guidelines at section 9.4. It is suggested that presently such screening might simply involve immediate, first round screening and not a quarantine period. Such a screening policy will reduce the risk of cross contamination between samples.*

5.2.3 Section 9.4 of the ACE Guidelines states:

For patients having embryos frozen, consideration should be given to screening for Hepatitis B and C, and HIV.

- *Where a patient is known to be a source of infection risk, or test results are unavailable, a system of separate storage must be devised.*

5.2.4 As noted above, the Blood Transfusion Service mandatory screening includes initial screening of all blood donations received for, amongst other markers, HBsAg, anti-HIV 1 and 2, and anti-HCV. Tissue donors are also screened for these mandatory markers, and are re-screened 180 days after the tissue donation is taken. Note that the Guidelines include screening for other infections such as syphilis that the HFEA does not require prior to storage (Guidelines for the Blood Transfusion Services in the UK, Fifth Edition). The screening requirements under A Code of Practice for Tissue Banks (Department of Health, 2001) are attached at Annex 9.

5.3 Screening of people considering donation

5.3.1 Additionally, regarding the 3 month period before antibodies can be detected in the blood, Members may wish to note that Annex C of the Code specifically states In order to avoid transplanting gametes collected during this “window” period of infection, donors of gametes which can be stored before use (semen) should be tested a second time for HIV antibody at least 180 days after the first test.

5.3.2 Members may also wish to consider whether this should be amended in view of the more recent innovation of freezing eggs for donation.

6. Conclusions

6.1.1 Members are asked to:

- consider the questions raised by centres for inclusion in a letter to follow-up the implementation of this policy;
- consider any other issues that should be included in this letter;
- consider the suggested amendments to the Code of Practice.

**HFEA Executive
April 2002**

Annex F

Extract from the minutes of the 54th meeting of the Code of Practice Committee**MINUTES OF THE FIFTY FOURTH CODE OF PRACTICE COMMITTEE HELD AT 11.00 ON 17 APRIL 2002 AT PAXTON HOUSE, 30 ARTILLERY LANE, LONDON E1 7LS****THOSE PRESENT:**

Jane Denton (Chair)
David Barlow
Sue Avery
Lis Woods

HFEA EXECUTIVE:

Jo Rippington
Rita O'Brien
Kerri Treston
Ann Furedi
Christina Panton

Item 5- Issues arising from the implementation of the screening policy for patients storing gametes, embryos and ovarian/testicular tissue COP(02)04

- 5.1 Jo Rippington presented this paper. She briefly informed the Committee of the history behind this issue. A policy position was agreed by the Code of Practice Committee in April 2001.
- 5.2 It was noted that the Regulation Managers had seen very few responses from centres informing the Authority of their implementation plan as requested by the Chairman in her letter CH(01)09 dated 6 June 2001.
- 5.3 Members discussed the lack of responses from the centres. The Committee enquired if centres should be sent written information on what they should be implementing and what to inform their patients so that centres are confident that they are passing on the correct information in order to protect their patients and themselves.
- 5.4 It was questioned whether there should be a patients' guide to screening, however, the Committee noted that this suggestion was not ideal as it was considered that centres may not pass on the information. It was suggested that the communication of information between the centre and its patients could be monitored through the inspection process.
- 5.5 Currently, Regulatory Managers follow-up any non-compliant centres during the inspection process, however, centres have not been chased for their implementation timetable. The Committee agreed that a strong letter be sent to all centres to remind them that they are required to have the screening policy in place as soon as possible and it will be a requirement by 31st December 2004. An analysis of implementation plans received so

- far was requested, including any discussions that had been held on inspection.
- 5.6 It was noted that the Regulation team had expressed that it would like to see this policy implemented before 2004 as it is currently difficult to recommend that all patients placing gametes or embryos in storage should be screened as it is not enshrined in the current Code.
- 5.7 From the responses that have been received from centres, it was noted that a number of centres having difficulty implementing the policy due to cost implications. The Committee discussed the cost implications but agreed that the HFEA is ultimately in existence to protect patients and therefore it agreed that all centres should be required to carry out screening.
- 5.8 The Committee further discussed issues raised by centres and in particular noted the query at 3.2.3: how often should patients who return for several cycles be re-screened? The Committee noted the following points:
- Ideally patients should be screened every time gametes are stored; however this is not always feasible but centres must take into account the welfare of the child, ante-natal screening and ensure best practice on handling materials that are affected or unaffected to reduce risks of cross contamination.
 - The procedures in place may be dependent on whether a centre treats HIV positive patients or not and the procedure of re-screening should be looked at more carefully at these centres.
- 5.9 The Committee agreed that the Authority should be aware of which centres treat HIV positive patients. These centres should have a policy in place in case a critical incident occurs and those who do not treat HIV positive patients should have a procedure on what would happen if the centre did have a HIV positive patient. It was also asked that Health and Safety requirements for handling known HIV positive samples should be checked.
- 5.10 The Committee found that it was difficult to know what to advise centres as it is difficult to detect if there has been a lifestyle change with patients who return for further treatment. The Committee noted that re-screening would be dependent on the time period between cycles, change in partner and change in lifestyle.
- 5.11 The Committee agreed that it would be best to ask various centres what their practice is regarding re-screening of patients and why.

- 5.12 The Committee noted query 3.2.7 – should all positive samples be stored individually in separate dewars or can, for example, all Hepatitis B positive samples be stored together in a single dewar? The Committee agreed that all Hepatitis B samples be kept together and that this position should be re-stated.
- 5.13 The Committee noted query 3.2.8 – is it acceptable to store screened/unscreened samples or, for example, Hepatitis B and C positive samples in the same dewar, if the risks are explained to patients? The Committee agreed that differently infected samples should be kept separate.
- 5.14 The Committee noted query 3.2.9 – if a brief quarantine period while test results are obtained is required e.g. if emergency referrals are received prior to orchidectomy, chemotherapy or radiotherapy, what action should be taken if with regards to other samples stored if a test should be returned with a positive result? The Committee noted that in principal there should be a separate dewar for unscreened samples. However, in this case the centre would need to carry out a risk assessment on an individual basis as cases arose. If the risk was minimal the centre would not necessarily have to worry the patients however if the risk was significant the centre would need to consider what action would be required. The Committee asked if a sample could be screened rather than the patients, however, it was noted that undertaking such a test could damage the sample. It was also noted that virologists would still not know absolutely what risk was involved. The Committee suggested that if centres anticipate cases similar to the above scenario, a possibility would be for that centre to have a clause in their patient information or on a consent form and inform their patients that it cannot absolutely protect the samples from risk.
- 5.15 The Committee noted query 3.2.14 – would the use of vapour phase storage be an acceptable alternative to the use of separate dewars for samples of differing infection status? The Committee noted that there is no evidence that vapour-phase storage removed the risk of cross contamination. Vapour phase is not completely risk free and it was noted there could be an additional risk to safety due to the temperature it must be kept at. The Committee also noted the following advice from Professor Tedder “the risk of cross-contamination via liquid nitrogen therefore remains even if vapour phase storage is used. Samples of differing infection status should therefore be stored separately even if vapour phase storage is used.”
- 5.16 The Committee noted query 3.2.17 – should current cryostores be tested for viral contamination? The Committee noted that the Code of Practice is quite clear and reasonable in its guidance under section 2.9-2.17,

Laboratory Facilities and Safe Cryopreservation. The Committee did agree that a formal response on the question of sampling should be sought from ACE.

- 5.17 The Committee asked that the follow-up letter should include the following points:
- The Authority's awareness of problems relating to implementing the policy;
 - Why the Authority is implementing the policy
 - Summary report of evidence and potential risks in support of implementing the policy;
 - Reinforce the original timetable for implementation of the policy; and
 - Inform the centres that the Regulation team will follow-up implementation plans during the inspection process.
 - Clarify the position on the queries raised and note that further advice on re-screening is being sought.
- 5.18 The draft letter should be passed to the Chairman of the Code of Practice Committee for comments before being sent to centres.
- 5.19 It was also agreed that the Authority should update the professional bodies and inform them of what actions the Authority is taking in relation to this issue.
- 5.20 The Committee also agreed that correspondence resulting from the follow-up letter should be analysed and the findings be presented to the Committee at the next meeting.
- 5.21 The Committee was asked to consider recommendations of the Meeting on the Safe Cryopreservation of Gametes and Embryos, for inclusion in the next edition of the Code of Practice. Suggested amendments were at annex 8 to this paper and the Committee agreed the following wording:

Part 10 Storage and Handling of Gametes and Embryos

- Screening

10.2 All patients placing gametes, embryos and ovarian or testicular tissue in storage *which falls under a HFEA licence* should be screened for HFSAg, anti-HIV 1 and 2, anti-HCV infection. This is a first round of screening and need not involve a quarantine period.

Centres should ensure that storage of tissue that does not require a licence from the HFEA fulfils the requirements of A Code of Practice for Tissue Banks (Department of Health, 2001).

10.3 Screened samples should be kept in a separate cryostore from

unscreened samples. Unscreened samples include i) any samples stored before comprehensive screening of all patients was introduced, and ii) any samples in temporary storage while the results of screening tests are obtained.

10.4 Samples from infected patients should be stored separately from samples from uninfected patients. This will necessitate having separate cryostores for HIV-infected samples, Hepatitis B-infected samples and Hepatitis C-infected samples. Where CMV is screened for, negative samples, positive samples and unscreened samples should be stored separately. If CMV positive samples are to be stored, Igm negative samples should be stored separately from Igm positive samples (see 4.14).

Part 6 Information

f. the availability of embryo freezing facilities, including the likelihood of success of embryo freezing, thawing, transfer and implications of storage; including (where relevant) the possible deterioration of gametes or embryos associated with storage and the potential risk of cross-contamination between samples;

Annex G

The following responses to queries raised by centres were agreed:

Should all positive samples be stored individually in separate dewars or can, for example, all Hepatitis B positive samples be stored together in a single dewar?

All similarly infected samples, for example all Hepatitis B infected samples, could be kept together.

Is it acceptable to store screened/unscreened samples or, for example, Hepatitis B and C positive samples in the same dewar, if the risks are explained to patients?

Differently infected samples should be kept separately.

Note:

Based on the recommendations of the Safe Cryopreservation Working Group, the Authority recommended in 1999 that screened samples should be kept in a separate cryovessels from unscreened samples.

A similar decision was not minuted in this case but could be inferred from the previous decision.

If a brief quarantine period while test results are obtained is required e.g. if emergency referrals are received prior to orchidectomy, chemotherapy or radiotherapy, what action should be taken with regards to other samples stored if a test should be returned with a positive result?

In principal there should be a separate dewar for unscreened samples.

However, in this case the centre would need to carry out a risk assessment on an individual basis as cases arose. If the risk was minimal the centre would not necessarily have to contact the patients, however if the risk was significant the centre would need to consider what action would be required.

Note:

The Committee suggested that if centres anticipate cases similar to the above scenario, a possibility would be for that centre to have a clause in their patient information or on a consent form and inform their patients that it cannot absolutely protect the samples from risk.

Would the use of vapour phase storage be an acceptable alternative to the use of separate dewars for samples of differing infection status?

There is no evidence that vapour-phase storage removes the risk of cross contamination. Vapour phase storage is not completely risk free and there could be an additional risk to safety due to the temperature of the dewar.

Note:

The Committee noted in agreeing its advice the advice from Professor Tedder of The Windeyer Institute that “the risk of cross-contamination via liquid nitrogen [...] remains even if vapour phase storage is used. Samples of differing infection status should therefore be stored separately even if vapour phase storage is used.”

This may need to be referenced in further guidance and should thus prior permission from Prof Tedder should be sought.

On the following queries, the Committee agreed that further guidance was required:

Should current cryostores be tested for viral contamination?

The Committee noted that the Code of Practice is quite clear in its guidance under section 2.9-2.17

Note:

The Committee agreed that a formal response on the question of sampling should be sought from ACE.

How often should patients who return for several cycles be re-screened?

Ideally patients should be screened every time gametes are stored; however this is not always feasible but centres must take into account the welfare of the child, ante-natal screening and ensure best practice on handling materials that are affected or unaffected to reduce risks of cross contamination.

Note:

The Committee found that it was difficult to know what to advise centres as it is difficult to detect if there has been a lifestyle change with patients who return for further treatment. The Committee noted that re-screening would be dependent on the time period between cycles, change in partner and change in lifestyle. *A brief survey of practice regarding re-screening to be undertaken for SCAG consideration.*

The Committee noted that the procedures in place may be dependent on whether a centre treats HIV positive patients or not and the procedure of re-screening should be looked at more carefully at these centres. These centres should have a policy in place in case a critical incident occurs and those who do not treat HIV positive patients should have a procedure on what would happen if a HIV positive patient presented for treatment.

Note:

Since then, Appendix F of the Sixth Edition of the HFEA Code of Practice referenced the following guidance that should be followed in treating infected individuals:

- Protection Against Blood-borne Viruses In The Workplace: HIV and Hepatitis, Advisory Committee on Dangerous Pathogens, 1995
- Guidance For Clinical Health Care Workers: Protection Against Blood-borne Viruses, Department of Health, 1998
- Revised Advice On Laboratory Containment Measures For Work With Tissue Samples In Clinical Cytogenetics Laboratories, Advisory Committee on Dangerous Pathogens, 2001

It was stated at ESHRE 2003 that the Chelsea and Westminster Hospital and the BFS are generating guidance for providing fertility treatment for HIV positive individuals. *Further information will be sought.*

Incident Alert 6

Date alert issued

12th September 2003

Description of the incident

Discovery that an unscreened cryopreserved TESE sperm sample about to be used had been stored in an “unscreened” dewar with a sample from a patient who had just been found to be HIV+ve.

Patient 1 had undergone egg retrieval and was awaiting ICSI using sperm from a cryopreserved TESE specimen when it was realised that the partner’s sample was stored in the same tank in which was also stored a sample from a patient who had just been found to be HIV+ve.

Discussions took place with Patient 1 about the possible risk of viral contamination and although the couple were happy to proceed they were advised that, until a full risk assessment had been undertaken, the actual risk of contamination was not certain. The couple were offered a further fresh PESA and decided to accept. The procedure was undertaken later the same day. The ICSI was completed and good fertilisation achieved. After completion of a full risk assessment of the potential risk of viral contamination, the centre then began a process of informing all other patients with material stored in the relevant dewar. No breaches of the HFE Act 1990 or the Code of Practice took place.

Recommendations for all centres

Patient information relating to storage of unscreened materials should advise of the very small, but theoretical possibility of viral infection. By doing this centres will have ensured that all patients have been informed so if a similar incident occurs elsewhere there will not be a need for calling in potentially large numbers of patients. This incident also reinforces the advice given in CH (01) 09.

Centres, where applicable, in the course of their normal invoicing of patients for annual storage should consider including their revised patient information and draw attention to the minor alteration.

The HFEA’s Policy department is undertaking additional work in the next two months relating to screening building on the Chair’s letter of June 2001.

Annex I



19 AUGUST 2003

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Request for advice from the Human Fertilisation and Embryology Authority

Issue:

An HIV positive sperm sample inadvertently stored with other samples at a fertility clinic. Is there a need to inform other patients with samples in the same cryostore of the risk of HIV transmission?

We understand that a similar issue arose a few years ago and the advice at that time was the risk of transmission of HIV to other samples was extremely small and there was no need to inform the other patients.

Without knowing the full circumstances of the current or past incident, the virology experts we consulted agreed the following advice.

Advice:

1) If the samples have been stored in proper screw-top cryo vials in the vapour phase of liquid nitrogen and there is no reason to suspect leakage, the risk of contamination of other samples is considered to be negligible. No need to inform other patients but review systems to prevent recurrence.

2) If the samples have been stored in chalk-sealed capillary tubes ('straws') or similar in the liquid phase, the risk of contamination of other samples will be greater. The need to inform patients should be guided by a detailed risk assessment including considerations such as:

- The precedent set by the previous incident if comparable
- The size of the cryostore and the number of individuals affected
- Whether the samples are irreplaceable
- Advice from ethicists

If there is considered to be a risk of transmission, albeit remote, regardless of whether other patients are informed, the HIV positive sperm sample should be retained for future reference (e.g. molecular epidemiological studies).

If situation 2 has occurred, further advice could be sought from experts in fertility treatment for HIV-infected individuals, for example, regarding whether sperm washing might be a risk reduction option for irreplaceable samples.

Prepared by Dr Linda Lazarus, Scientific Secretary to the Expert Advisory Group on AIDS

Reference:

Tedder RS *et al.* Hepatitis B transmission from contaminated cryopreservation tank. *Lancet* 1995; **346**: 137-140.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7603227&dopt=Abstract

Annex J**Guidance on the screening of patients and the safe cryostorage of gametes, embryos and ovarian/testicular tissue**

This guidance builds on that given in the HFEA Chairman's letter CH(01)09 sent in June 2001. It takes account of queries raised by licensed centres and is based on the *HFEA Code of Practice* (Sixth Edition, 2003), *A Code of Practice for Tissue Banks* (Department of Health, 2001), other guidelines as referenced below and further advice obtained from the Department of Health, professional bodies and other experts.

Staff of licensed centres should note that the EU Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells is relevant to this issue. The Directive covers all aspects of the handling of human tissues and cells intended for transplantation, including all use of gametes and embryos in treatment. It is expected that the Directive will be adopted by April 2004 and become legally binding in the UK by April 2006.

It will be a requirement for all establishments undertaking activities within the scope of the Directive, whether NHS or private, to be inspected and accredited. The standards required for accreditation will not be fully developed within the Directive itself. In 2004, an European Commission Expert Committee will be set up to develop detailed Annexes on matters such as donor selection and testing etc. The HFEA is involved in developing accreditation standards for Assisted Conception Units. It is expected that this work will be completed in early 2004.

HFEA Code of Practice, Sixth Edition

In addition to the guidance given below, centre staff should refer to the following sections of the Sixth Edition of the HFEA Code of Practice:

S. 2.9 – 2.17, S. 9.1 – 9.4, Appendix C etc

This guidance addresses the following issues:

PATIENT SCREENING AND INFORMATION PROVISION

- Screening procedures
- Information provision
- Provision of counselling
- Refusal of screening by patients
- Frequency of re-screening
- Informing patients of adverse incidents

STORAGE FACILITIES

- Facilities for handling infected samples
- Storing similarly infected samples in the same dewar
- Storing differently infected samples in different dewars

- Storing screened and unscreened samples in different dewars
- 'Emergency' storage prior to orchidectomy, chemotherapy etc
- Use of vapour phase storage
- Use of heat-sealed straws
- Sampling current storage dewars for viral contamination

PATIENT SCREENING

Screening procedures

All patients placing gametes, embryos and ovarian or testicular tissue in storage which falls under a HFEA licence are expected to be screened for Hepatitis B, Hepatitis C and HIV, as outlined in Section 9.4 of the Association of Clinical Embryologists' Guidelines.

(Code of Practice, Sixth Edition, s.9.2)

The *Guidance on the Microbiological Safety of Human Organs, Tissues, and Cells used in Transplantation* (Department of Health, 2000) also requires that screening of donors for HIV 1 and 2, Hepatitis B and Hepatitis C be undertaken.

In practice, this will therefore include all patients presenting for IVF treatment or storage, and all men whose sperm are to be used in the treatment of their partners or others.

Due to the potential reduction in viability associated with storage such screening need simply involve immediate, first round screening and not a quarantine period, unless the individual(s) concerned would be considered 'donors' under the HF&E Act 1990. In this case, the Guidelines at Appendix C of the HFEA Code of Practice (2003) should be followed.

Those who do not offer treatment to infected patients should have a procedure for referring on an infected patient who presents for treatment.

Provision of information and counselling

Arrangements for suitable information-giving and counselling must be in place as part of the screening protocols.

Should the HFEA produce standard information for patients on this issue?

Refusal of screening by patients

The requirement for HIV testing is capable (and probably does) amount to an interference with a patient's rights under Article 8 of the European Convention on Human Rights. However, this interference could be justified under Article 8(2) as being in pursuit of the legitimate aim of protecting the health of others.

The Executive is currently working with Morgan Cole to formulate precise wording for this section.

Frequency of re-screening

Ideally patients should be screened every time gametes are stored; however this is not always feasible but centres must take into account the welfare of the child, ante-natal screening and ensure best practice on handling materials that are affected or unaffected to reduce risks of cross contamination.

The COPC found that it was difficult to know what to advise centres as it is difficult to detect if there has been a lifestyle change with patients who return for further treatment. The Committee noted that re-screening would be dependent on the time period between cycles, change in partner and change in lifestyle. Members are asked to note the feedback from Regulation and decide whether further work needs to be undertaken on this issue.

Informing patients of adverse incidents

Members are asked to review the generic guidance from DH (attached at Annex I) and decide what further work needs to be undertaken prior to formulating advice on this issue.

STORAGE FACILITIES

Facilities and procedures for handling unscreened and infected samples

The facilities and procedures in place will be dependent on whether a centre treats infected patients or not. These centres should have a policy in place in case a critical incident occurs.

Appendix F of the Sixth Edition of the HFEA Code of Practice references the following guidance that should be followed in treating infected individuals:

- Protection Against Blood-borne Viruses In The Workplace: HIV and Hepatitis, Advisory Committee on Dangerous Pathogens, 1995
- Guidance For Clinical Health Care Workers: Protection Against Blood-borne Viruses, Department of Health, 1998
- Revised Advice On Laboratory Containment Measures For Work With Tissue Samples In Clinical Cytogenetics Laboratories, Advisory Committee on Dangerous Pathogens, 2001

It was stated at ESHRE 2003 that the Chelsea and Westminster Hospital and the BFS are generating guidance for providing fertility treatment for HIV positive individuals. Further information is being sought.

Storage of similarly infected samples

All similarly infected samples, for example all Hepatitis B infected samples, can be kept together in the same dewar.

Storage of differently infected samples

Differently infected samples should be stored in separate dewars.

Separate storage of screened and unscreened

Screened samples are expected to be kept in a separate cryostore from unscreened samples. Unscreened samples include:

- i) any samples stored before comprehensive screening of all patients was introduced, and
- ii) any samples in temporary storage while the results of screening tests are obtained.

(Code of Practice, Sixth Edition, s.9.4)

'Emergency' storage prior to orchidectomy, chemotherapy etc

There should be a separate dewar for unscreened samples that need to be held while screening results are obtained. If a sample placed in storage under these circumstances is subsequently found to be infected, the centre would need to carry out a case-specific risk assessment regarding any other samples that may be affected. *[If the risk is minimal the centre would not necessarily have to contact the patients, however if the risk is significant the centre would need to consider what action would be required. DoH guidance should be consulted on this point.]*

If centres anticipate the possibility of such cases, it would be good practice to include in patient information or on a consent form a clause to the effect that samples cannot absolutely be protected from risk.

Some centres that store semen samples prior to oncology treatment have found it effective practice to have a number of small storage flasks that can be used to store samples in until screening results are obtained. If screening results are positive, the samples could remain in that flask and another be bought to replace it. If negative, the samples could be moved to one of the main dewars.

This may need further consideration.

Use of vapour phase storage

Use of vapour phase storage would be good practice where possible, however the risk of cross-contamination via liquid nitrogen remains even if vapour phase storage is used. Samples of differing infection status should therefore be stored separately even if vapour phase storage is used. Vapour phase storage is not completely risk free and there could be an additional risk to safety due to the temperature of the dewar.

Use of heat sealed straws

A Code of Practice for Tissue Banks (DH, 2001) states at section 9.1 that procedures must be established and maintained to ensure that tissue is

presented in a container designed to maintain quality and prevent contamination. It also states at 4.2.4 that systems designed to prevent cross-contamination from tissues from different donors must be in place. Use of heat-sealed straws would be good practice towards meeting these standards, however it does not mean that other aspects of best practice, such as storing screened and unscreened samples separately, do not have to be applied, especially as there is always the risk, however small, of straws splitting.

Sampling current storage dewars for viral contamination

The COPC noted in April 2002 that the Code of Practice is quite clear in its guidance under section 2.9-2.17 (fifth edition). The Committee agreed that a formal response on whether and how dewars should be sampled should be sought from ACE.

References

A Code of Practice for Tissue Banks (Department of Health, 2001)

Accreditation Standards and Guidelines for IVF Laboratories (Association of Clinical Embryologists, 1999)

Guidance For Clinical Health Care Workers: Protection Against Blood-borne Viruses (Department of Health, 1998)

Guidance on the Microbiological Safety of Human Organs, Tissues, and Cells used in Transplantation (Department of Health, 2000).

HFEA Code of Practice (HFEA, 2003)

Protection Against Blood-borne Viruses In The Workplace: HIV and Hepatitis (Advisory Committee on Dangerous Pathogens, 1995)

Revised Advice On Laboratory Containment Measures For Work With Tissue Samples In Clinical Cytogenetics Laboratories (Advisory Committee on Dangerous Pathogens, 2001)

Tedder RS *et al.* Hepatitis B transmission from contaminated cryopreservation tank. *Lancet* 1995; **346**: 137-140.

And those contained in COP(02)04 eg blood guidelines etc