

Welcome to the January issue of HFEA Update.

January has been a busy start to 2004 for the HFEA. The sixth edition of the Code of Practice was launched at the beginning of the month including new guidance on the number of embryos to be transferred during treatment. In addition, proposed changes to the law surrounding donor anonymity and a review of the Human Fertilisation and Embryology Act were announced at the HFEA Annual Conference.

HFEA Update is also available online: www.hfea.gov.uk/HFEAPublications

INSIDE

Disclosure of donor codes

Transport of gametes and embryos

HFEA fees

Unannounced inspections

Dewar's consultation

Department of Health announces removal of donor anonymity

A change in the law is planned which means that children born as a result of sperm, eggs or embryos donated from 1 April 2005 will be able to access the identity of their donor when they reach the age of 18.

Why has donor anonymity been removed?

Many individuals and organisations, including the HFEA, believe that children born from donated sperm, eggs or embryos should be able to have access to information about their genetic origins.

How does this affect existing donors?

The new regulations surrounding information on donors will not be retrospective. This means that anybody who has registered as a donor before 1 April 2005 will remain anonymous.

How will this affect the future availability of donors?

It is acknowledged that ending donor anonymity does involve some risk to the future availability of donors. However, the HFEA does not feel that this practical consideration should outweigh the more fundamental principle that donor offspring should have knowledge about their genetic origins.

How will the change be implemented?

The HFEA is currently undertaking talks with the Department of Health to discuss how the new regulations will be put into practice and to raise some of the issues which have been highlighted by centres. The HFEA will inform centres of the implementation plans once these are known.

HFEA Code of Practice sixth edition

The sixth edition of the HFEA Code of Practice will come into force on 1 March 2004. Copies can be obtained by contacting the HFEA or can be downloaded from the HFEA website.

Human Fertilisation and Embryology Authority
Paxton House
30 Artillery Lane
London E1 7LS

T: 020 7377 5077
F: 020 7377 1871
E: admin@hfea.gov.uk

Disclosure of donor codes

It has been brought to the attention of the HFEA that donor codes are in some cases disclosed by centres to the recipients of donor treatment. The HFEA will be issuing a Chief Executive's letter in order to remove any ambiguity surrounding this issue.

Donor codes are unique and therefore potentially identifying and should not be disclosed due to the confidentiality provisions in the Human Fertilisation and Embryology Act 1990.

Transport of gametes and embryos

• Import and export

During 2003, the HFEA received its highest number of applications for Special Directions to authorise the import or export of gametes or embryos. The need to move gametes or embryos to and from the UK has become increasingly common as patients relocate to the UK or abroad or require access to a wider choice of donors.

Special Directions are subject to conditions and last year a number of centres had reported experiencing difficulties in satisfying those conditions once an import or export had been effected. As a result, centres have found themselves in breach of conditions of their treatment licences.

The HFEA is currently developing the process by which centres may apply for a Special Direction to import or export gametes and embryos. This is intended to eradicate the recurrent problems, particularly those associated with importing donor gametes or embryos created with donated gametes. A letter from the Chief Executive will be issued in due course detailing the new procedure.

The HFEA would like to remind centres that following the issue of a Special

Direction authorising the import or export of gametes or embryos, in accordance with section 12 (j) of the Human Fertilisation and Embryology Act 1990, the centre is required to inform the HFEA in writing **within two working days** of the import or export being effected. Written notice should also be given if for any reason it has not been possible to effect the import or export within the terms of the Special Direction, for example if the Direction has expired without the import or export having been completed.

If you have any questions relating to import or export please contact Kerri Treston, Policy Officer: 020 7539 3343.

• Transfer between licensed centres

Where donor gametes or embryos are transferred between licensed centres, **an anonymised copy of the consent and HFEA Register forms (or paperwork to that effect) must accompany the gametes or embryos** as per Directions D.2001/1.

Where patient gametes or embryos are transferred between centres for use in the patient's own treatment, the centre is required to send a copy of all relevant documentation, including consent forms, to the receiving centre. This documentation **does not need to be anonymised, however, the Person Responsible sending the information must ensure that all identifying information is sent in a secure manner**, that is either with the patient themselves or by registered / recorded post.

If you have any queries relating to transfer between licensed centres please contact Dr Chris O'Toole, Policy Manager: 0207 539 3324.

HFEA fees

In 2002 the HFEA consulted on the issue of fees and funding. Following this consultation the HFEA decided to revise its fees each year. There will therefore be a small fee increase, in line with inflation, to take effect from 1 May 2004.

As indicated at the HFEA Research Conference in November 2003, there is a large shortfall between the costs of regulating research and the fee income from research licences. The HFEA plans to carry out a consultation on this issue.

Egg giving guidance

Following a number of enquires and expressions of concern from patients and clinics, the HFEA conducted a review of egg giving in 2003. Of particular concern to the HFEA was the extra risk of ovarian hyperstimulation syndrome associated with unnecessarily undergoing two cycles of treatment.

The conclusion of the review was that the HFEA wrote to all licensed centres in December 2003 telling them not to practise egg giving.

Deceased Fathers Act

On 18 September 2003, Parliament changed the law to allow for a man to be registered as the father of a child born following assisted conception treatment undertaken after his death. This change took effect from 1 December 2003.

The HFEA has produced guidelines detailing the legal requirements and processes to follow to register the deceased man as the father. These guidelines are available on the HFEA website:
www.hfea.gov.uk/AboutHFEA/HFEAPolicy

Unannounced inspections

The unannounced inspection programme was launched in 2003 to ensure that high standards of treatment are maintained and that adverse incidents are swiftly inspected and managed.

Three unannounced inspections have taken place to date. The centres were selected for unannounced inspection using a random number-generating computer programme. Attitudes from all three centres to the inspection were generally very positive.

Feedback will be requested from all centres who have undergone an unannounced inspection in order to improve the process in future.

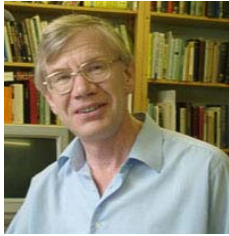
Consultation on dewars

The HFEA is proposing to give guidelines on the safety of equipment used to store cryopreserved gametes and embryos. The HFEA is issuing a consultation as part of this process. Responses to the consultation will inform the guidelines issued to licensed centres.

Paper copies of the consultation questionnaire have been sent to licensed centres plus professional organisations.

Centres may also respond to the consultation via the HFEA centres website: <https://centres.hfea.gov.uk>

Centres can obtain passwords for the website by contacting Daisy Thomas, Information Officer:
daisy.thomas@hfea.gov.uk

**Tom Baldwin**

Member Focus

Professor Tom Baldwin

Deputy Chair, HFEA

Professor of Philosophy, University of York

There's a dog-eared copy of the Warnock report on Tom Baldwin's desk. He's been discussing the ethics of assisted reproductive technology with his philosophy students since the 1980's. Joining the HFEA as a member of the authority was for him a logical extension of his work for the Nuffield Council on Bioethics on stem cells and the genetics of human behaviour. 'I've greatly enjoyed getting out of the ivory tower and taking part in the HFEA's debates on sex selection and HLA tissue typing. I used to worry that I would not be able to contribute much to the regulatory work of the HFEA, but in fact so much of this work takes place in a public arena where questions of value are at stake that I feel quite at home.'

One of the highlights has been a visit to the Roslin Institute 'I saw the place where Dolly the sheep had been cloned. The small scale of the place surprised me. Such a huge step for science from such modest premises. I got a real sense that a lot of the techniques now being used in embryo research had come out of their basic veterinary work.'

The biggest challenge for the coming year is going to be producing a thorough solid report on gamete donation. The first step is a consultation involving clinics and stakeholders. 'What we need to avoid is people being coerced into donation either through direct payment or offers of treatment for themselves or indeed pressure from friends or relatives. Its difficult to find donors, how do we put in place a workable system to make sure that people get the treatment they need?'

Staff news

The HFEA has recently recruited the following new members of staff

Trish Davies Director of Regulation

Sandra Mather Head of Inspection

Helena Hird Head of Public Relations

HFEA move planned for March 2004

At the end of March, the HFEA will be moving to a new office on Bloomsbury Street, London WC1. HFEA staff are currently split between two sites; the move to Bloomsbury Street will allow all staff to be housed in one office.

DIARY DATES

HFEA Open Authority Meetings during 2004

Wednesday 18 February 2004, New Connaught Rooms, London

Wednesday 12 May 2004, venue to be announced

Wednesday 20 October 2004, (will be outside London)

To reserve a place at an HFEA Open Authority Meeting please contact Stephen Sobey, Communications: stephen.sobey@hfea.gov.uk or 020 7539 3332.

The HFEA appreciates any comments on the content of the HFEA Update.

Please contact
Daisy Thomas,
HFEA Update Editor:
daisy.thomas@hfea.gov.uk