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

Tel: 0171 377 5077

Fax: 0171 377 4871

Website: www.hfea.gov.uk

HFEA Update

Introduction

This is the second issue of the *HFEA Update*. We hope that it will be distributed widely within clinics as well as with patient groups and other interested bodies. We hope that the issues raised are relevant, informative and interesting for everyone. We would appreciate any comments and suggestions on the content or format and these can be directed to Danielle Marx at Paxton House.

Ruth Deech
Chairman

New HFEA Members

The following Members have recently joined the HFEA:

Professor Brenda Almond
Professor of Moral and Social
Philosophy, University of Hull

Professor Henry Leese
Professor of Biology, University of
York

Dr Sadia Muhammed
General Practitioner, Priory Medical
Group, York

Ms Sara Nathan
Freelance Journalist, previously Editor
of Channel 4 News

Ms Sharmila Nebhrajani
Head of Corporate Planning, BBC

Retired HFEA Members: The following Members have left the HFEA since August 1998: Professor Ruth Chambers, Ms Liz Forgan, Mr David Greggains, Professor Martin Johnson, Mr Richard Jones and Professor the Reverend Canon Anthony Thiselton

Forthcoming events

An HFEA regional meeting took place in Cambridge on 24th May. The next meetings will be in London (October) and in York (Spring 2000). Those interested in attending should contact Kim Hayes at Paxton House.

Annual Conference

The HFEA Annual Conference was held in London in December 1998. A summary of the presentations and discussions can be obtained from Julie Jones. The 1999 Conference will be held on 3rd December at Hulme Hall, Manchester.

Videos

Patient videos on IVF and DI are available from the HFEA should clinics wish to purchase them. **The cost has been reduced to £2 each.** For further information, please contact Tony Burkett at Paxton House.

Policy Issues

This section provides an update on, or clarification of, a number of policy issues which have recently been raised by clinics. Material contained here does not supersede anything in the Code of Practice.

Frequently asked questions

Q. What is the statutory storage period of embryos created using donor sperm?

A. Regulations for the extension of the statutory storage period for embryos were introduced in 1996. Under those Regulations embryos may be kept in storage for ten (or, in exceptional circumstances, more than ten) years. Donors can, therefore, consent to embryos created using their sperm being stored for ten years. This avoids problems that may arise if a donor only consents to a five year storage period. (Donors may withdraw their consent for storage or use at any time.)

Clinics should note that the storage period for embryos begins from the time they are placed in storage. This is the case even if they have been created with donor sperm that has itself been in storage for any length of time. Thus, for example, an embryo created in 1999 using sperm donated in 1996 may itself be kept in storage until 2009 if the sperm donor has consented to a ten year storage period.

Q. What happens when consents become incompatible?

A. The storage of an embryo requires the consent of the providers of both gametes, and their consents must remain compatible for continued storage. In the event that one of the parties chooses to withdraw their consent, the embryo can no longer remain in

storage and must be allowed to perish.

Although the clinic is under no legal obligation to inform the other party of the withdrawal of consent, it is good practice to write to both parties explaining the position and informing them of the clinic's intention to remove the embryo from storage, on or after, a certain date.

Q. To whom should patient complaints be directed?

A. Patients should in the first instance follow the clinic's complaints procedures. Although the investigation of such complaints does not fall within the HFEA's remit, compliance with these procedures is a licence requirement and the annual HFEA inspection includes an assessment of the number, and nature of, such complaints. If the complaint concerns a doctor's clinical judgement then the patient can also contact the General Medical Council.

The HFEA has no jurisdiction over the funding of NHS treatment and any comments about that issue should be directed to the local health authority.

Q. Who should be named on a clinic's licence?

A. Any personnel associated with patient care or who have access to patient records must be named on their licence. Clinics should notify the HFEA if changes of staff occur. This applies both to the addition of new staff and to staff departures.

Clinics are reminded that it is a criminal offence for confidential information to be disclosed to anyone not covered by a licence.

HFEA website expansion

The HFEA has expanded its website to include the text of the 1998 Annual Report, the clinic tables of the 1998 Patients' Guide, and the 4th edition of the Code of Practice. In addition, there is a 'What's New' page with recent HFEA press releases and summary minutes of HFEA meetings. The site can be found at www.hfea.gov.uk.

Data presentation of live birth rates

Paragraph 4.1 of the Code of Practice states that information provided for prospective patients should include: *the centre's own live birth rate per treatment cycle and the national live birth rate per treatment cycle.*

Clinics are reminded that data should not be published in a potentially misleading manner. This means that no information should be issued unless reference is made to standard data for an annual period (ie. the most recent annual live birth rate per treatment cycle). The data presented should be actual live births not including ongoing pregnancies and the annual live birth rate should be shown. Data from the HFEA Patients' Guide should not be presented as a league table.

Computer security and access

A clinic's responsibility to maintain confidentiality must be reflected in the security of their computer systems. Each clinic must make its own assessment of the degree of risk entailed by access to the Internet or by a link to an external site. In doing this, clinics might find the following information helpful.

The advice from the Government Central Computer and Telecommunications Agency (CCTA) is that the 'Internet is inherently insecure and the security of any computer connected to the Internet is the responsibility of the computer's owner. A PC connected to the Internet should not normally run the sort of software that would allow access from elsewhere. However, it could possibly provide a route to other computers on a network, and these computers may be more vulnerable. Therefore the use of a stand-alone PC for individual Internet access is highly recommended.'

In considering the benefits and risks of a link from the clinic's systems to another site, clinics might wish to consider the following questions:

Does the information being passed need to contain, for example, patient information, donor or treatment details?

If it does, then can the link operate from a stand-alone PC?

If a stand-alone PC is not practicable, does the software that is being used provide the necessary level of security to ensure secrecy?

Taking into account the content of the information and whether a stand-alone PC is to be used, what types of modems, telephone lines etc. are most appropriate and will provide adequate levels of security?

What mechanisms exist for the detection of a breach of security?

Clinics should also consider who has access to the information at the other end of the telephone line. A software supplier, for example, may find it difficult to work on an existing system without having access to the data. Access to information can be made legal by adding named people to a licence. Such people are generally expected to work largely at the clinic's premises since it is difficult to monitor the security provisions of external organisations. Clinics are reminded that it is a criminal offence for confidential information to be disclosed to anyone not covered by a licence.

Each clinic must decide its own policy on the basis of an assessment of its needs and the risks involved. The HFEA is happy to discuss matters with individual clinics and will

endeavour to provide further advice as our expertise permits.

Development of new register

The March workshops to introduce the new HFEA data forms to centres were well attended. Further consideration will be given to the possibility of

Clarification of charging policy

The HFEA has received some confusion about charges. The present policy is as follows:

A fee of £40 is charged to clinics for each donor information treatment cycle completed.

A fee of £115 is charged for each occasion that eggs are mixed with sperm and when embryos are removed from storage. If a cycle is abandoned before either of these activities take place, ie in an IVF cycle does not reach egg collection, where no eggs are collected or a cycle is abandoned before embryos are thawed, then there is no charge.

For example:

An IVF cycle using donor gametes is charged at £40. The fact that donor gametes are used does not increase the cost to £50.

An ICSI cycle is charged at £40.

Department of Health Reviews

Cloning

In December 1998 the HFEA and the HGAC (Human Genetics Advisory Commission) produced a report to Ministers. The report recommended banning human reproductive cloning. It also recommended the introduction of regulations to specify two further purposes for which the HFEA might issue licenses for research: the development of methods of therapy for mitochondrial disease; and the

Use of blastocyst transfer in treatment

As the practice of embryo transfer at the blastocyst stage becomes more widespread, the HFEA would like to draw centres' attention to work on cattle and sheep which shows that prolonged embryo culture, followed by blastocyst transfer, can, in some cases, give rise to neonatal problems; notably, increased birthweight and fetal abnormalities (Young *et al.*, 1998; Leese *et al.*, 1998). There is no evidence so far of similar changes following the transfer of human blastocysts. However, centres may wish to pay particular attention to the outcome of this new form of treatment and add a cautionary statement in their patient information.

Young, L.E., Sinclair, K.D. and Wilmut, I (1998). Large offspring syndrome in cattle and sheep. *Reviews of Reproduction* 3, 155-163.

Leese, H.J., Donnay, I. and Thompson, J.G. (1998). Human assisted conception; a cautionary tale. Lessons from domestic animals. *Human Reproduction* 13, supplement 4, 184-202

development of therapeutic treatments for diseased or damaged tissues or organs. In June 1999 the Government announced that it would set up an expert advisory group to consider further the proposals for research.

Surrogacy Review

This review recommended the passage of a new Surrogacy Act to ban payments other than expenses, to require the registration of surrogacy agencies and to give statutory force to a Code of Practice. The HFEA supports these recommendations.

Use of diagnostic embryo culture

The HFEA wishes to remind clinics of its policy regarding the use of diagnostic embryo culture in treatment. The HFEA's position regarding such activities under a treatment license is, as previously outlined in a chairman's letter [CH(94)9], as follows:

- Embryos may not be kept in vitro and preserved for a number of days as a quality control check on the culturing systems.
- Embryos may not be kept in vitro if they are no longer to be used in the treatment of a woman, or if any information that may be obtained from keeping them will not be of specific use in the treatment or diagnosis of the individuals whose gametes were used to produce them.
- If a clinical judgement is made that there is some specific value for a couple in continuing to culture spare embryos from a particular treatment cycle, this should be done with the knowledge and agreement of the couples concerned.

HFEA committees

The following committees are currently licensed by HFEA committees

Code of Practice Committee

Currently considering the issue of home insemination, the impact of IVF and ICSI on embryos, expenses for donors including the formulation of guidelines for egg sharing procedures and the next revision of the Code of Practice

Working Group on New Developments in Reproductive Technology

Considering the use of spermatazoa in ICSI treatment, laser assisted hatching, pre-implantation genetic diagnosis and the use of stem cells in research

The Ethics Committee

Considering the role of ethics committees in treatment and information to be given to children born from donor insemination

The Information Committee

Consulting with clinics on additional information that should be collected by the HFEA once the system of electronic data transfer is in place