

Welcome to the April issue of HFEA Update.

This issue focuses on the responsibilities of the HFEA and developments and improvements made over the last 12 months. The aim is to provide information about our work for those staff who do not have regular contact with the HFEA. It also outlines our plans for the coming year.

**Please distribute copies of the Update to members of staff working at your clinic or organisation. Additional copies can be obtained from the HFEA. The Update is also available on the HFEA website: [www.hfea.gov.uk/HFEAPublications](http://www.hfea.gov.uk/HFEAPublications)**

## INSIDE

**How we regulate**

**Improvements to regulation**

**Developing relationships with patients**

**Openness, accountability and transparency**

### **The challenges of regulating infertility treatment**

Regulating infertility treatment or assisted reproductive technology (ART) is a challenge. The ethical issues are more sensitive and the moral ground more contested than in most other areas of medicine. There is also a lively scientific research base to respond to and there is clearly more market activity than in other areas of medicine where NHS provision dominates.

There are very high levels of public and media interest. It is vital that, regardless of what they may have read or heard from some sources, the public – especially patients and potential patients – have confidence in the regulation of ART in the UK. This means having reliable and relevant information and being assured that treatments are carried out safely by licensed and regulated clinics.

### **The regulatory responsibilities of the HFEA**

The HFEA has responsibility for regulating infertility treatment and human embryo research. Major achievements of the HFEA in this regulation include greater openness in our work, improvements in efficiency, development of key policies, the launch of a new Data Register, and the production of better information for patients.

The five principles of good regulation as defined by the Better Regulation Taskforce are: transparency, consistency, proportionality, targeting and accountability. The HFEA's challenging agenda for the coming year will ensure progress in each of these areas.

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HFEA UPDATE

## How we regulate

The HFEA's team of regulation staff work with approximately 80 inspectors, to inspect each of the 106 centres annually. In the last 12 months, we carried out 161 inspections.

## How we license a clinic

The HFEA issues three different types of licence: for treatment, for gamete and embryo storage, and for research. It is illegal for anyone to carry out activities governed under the HFE Act without a licence.

## How we inspect

The inspection team members have a range of expertise, both clinical and scientific, as well as those with nursing and counselling experience. Every clinic is inspected for renewal of its licence approximately six months before the expiry of the licence.

## Regulating research

The HFEA has responsibility for regulating research on the use of embryos. We currently license 28 research projects, nine of which relate to the derivation of embryonic stem cells.

## Code of Practice

The HFEA's Code of Practice gives guidelines to clinics about the proper conduct of licensed activities. Its object is more than just to secure the safety and efficacy of particular clinical or scientific practices, it is also concerned with areas of practice which raise fundamental ethical or social questions.

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## How we are improving our regulation

### Incident Alert System

The Incident Alert System was introduced to improve practice and to avoid harm, and is the first of its kind in the world. All clinics have to report all incidents to the HFEA within 12 hours of the incident occurring.

An 'incident' is defined as any event, circumstance, activity or action which has caused, or could cause, harm, loss or damage to patients, embryos and/or gametes, or to staff at a licensed clinic.

Clinics must keep a written policy and procedure for dealing with incidents, should they arise, and they must report all such incidents. We in turn alert all other clinics in the UK with the details of significant incidents and our recommendations, so that the whole sector can learn from actual and potential mistakes.

## Complaints

Most patient complaints are dealt with directly between patients and the clinics, with the HFEA monitoring this through the inspection process. Some patient complaints are sent directly to the HFEA. In the last 12 months, we received 76 such complaints, relating primarily to consultation issues. When appropriate the HFEA facilitates resolution between the clinic and patient.

## New inspectors

As part of our reforms to strengthen regulation, and in line with a strict separation of powers and responsibilities, the HFEA has changed some of its own corporate governance arrangements. We have recruited and trained new inspectors and expect existing inspectors to undergo updated training and accreditation.

## Checking clinics and inspection protocols

The system of double witnessing in clinics ensures that the identity of every embryo and gamete is checked twice before use in treatment. We also require clinics to carry out an annual 100% audit of gametes and embryos that they hold in storage. The inspections themselves are rigorous and based on good intelligence, including monitoring all patient complaints. Formal protocols are being adopted for all Licence Committees and each committee has the support of legal advice. We will also be introducing a

rigorous monitoring system to ensure compliance with licence committee recommendations.

### **Patient feedback**

We have started to seek patients' views in inspections to ensure their voices are heard. We have piloted a variety of methods of gathering patients' views, with questionnaires proving a particular success, enabling patients to share their perspectives with the HFEA directly. Patient complaints are also considered during inspections.

### **Random unannounced inspections**

We are now doing random and targeted unannounced inspections. These increase the robustness of the inspection process.

### **Improving standards**

We are working with the professional bodies here and in Europe to draw up laboratory standards and accreditation for laboratory professionals to comply with the forthcoming EU Tissue Directive, which comes into force in April 2006. We are also looking at options for training and support for the staff responsible for clinics.

### **Improving research regulation**

We are widening the range of expert input into the Authority. We have recruited more peer reviewers for research licence applications and we have co-opted experts onto our committees.

### **Working in partnership with other regulators**

We are working with other regulators such as the NPSA (National Patient Safety Agency), the Nursing and Midwifery Council (NMC), the General Medical Council (GMC) and the Commission for Healthcare Audit and Inspection (CHAI).

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## **Developing relationships with patients and patient groups**

The HFEA intends to develop a greater patient focus in the coming year as indicated in the HFEA Corporate Plan.

### **Patient strategy**

The HFEA has begun to consult patient and user groups on HFEA information, and run pilot projects for involving patients in the inspection process. One of the priorities for 2004 is to establish a clear patient strategy to ensure that patient experience is reflected in the work of the HFEA.

### **Patient information**

Working with patient groups, the HFEA produces an extensive range of patient information leaflets about all aspects of infertility treatment, egg and sperm donation, and relevant aspects of the law. In addition, we have produced a *Guide to Infertility*, a patient-focused guide to the different treatment options available and a comprehensive directory of licensed clinics and the services they provide.

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## **Openness, accountability and transparency**

The HFEA is committed to being an open and accountable regulator, with transparency in its decision-making. Several Authority meetings are open to the public each year, with papers, agendas and minutes available on the HFEA website. (The next open meeting will be held on 12 May - see page 4 for details). We also hold public launches on policy issues such as sex selection. Our Annual Conference is another opportunity for stakeholders and interested parties to join a forum for information and discussion, as is our Annual Research Conference, where the focus is specifically on progress in human embryo research.

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Emily Jackson

## Member Focus

### Emily Jackson

#### Senior Lecturer in Law, London School of Economics

Emily Jackson joined the HFEA in June 2003 and brings expertise in medical law to the Authority. She read law at Oxford University and after teaching law at Cambridge University and Birkbeck College, London, she joined the Law Department at the London School of Economics in 1999. Here she set up an undergraduate course in medical law and a postgraduate course in regulating new medical technologies.

Emily decided to apply for membership because she wanted to use her existing knowledge of medical law. She has always been interested in the regulation of reproductive issues, and her book *Regulating Reproduction* won the Society of Legal Scholars Annual Book Prize in 2002. Emily says the main challenge of being a member is time. "It is difficult to juggle my time between HFEA work and my other role. It can also be difficult for non-scientific members to get to grips with some of the technical questions that arise in the licensing process."

As an HFEA member, Emily takes part in Authority meetings and is a member of sub committees such as Ethics and Law, Audit and Licence committees. In this coming business year Emily will also be involved in various working groups on the review of the Human Fertilisation and Embryology Act, the review of the Welfare of the Child, and the Sperm, Egg and Embryo Donation review. Emily said "the main challenges of the review of the HFE Act are to ensure that the parts of the act that work well are retained, while other out of date aspects of the legislation are amended effectively".

"If I could change one thing in relation to infertility treatment, I would make it free."

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## Staff news

- The HFEA has recruited the following new members of staff: Charlotte Augst, Policy Manager and Claire Keates, Information Projects Manager.
  - The HFEA Business Plan 2004/2005 will be published in May.
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## DIARY DATES

### HFEA Open Authority Meetings

*Wednesday 12 May 2004 (London) and Wednesday 20 October 2004 (Edinburgh)*

### House of Commons Science and Technology Select Committee Inquiry into Human Reproductive Technologies

*Deadline for written submissions – Wednesday 26 May*  
[www.parliament.uk/parliamentary\\_committees/science\\_and\\_technology\\_committee/scitech300304.cfm](http://www.parliament.uk/parliamentary_committees/science_and_technology_committee/scitech300304.cfm)

### HFEA Research Conference 2004

*To be held in November (exact date to be confirmed)*

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

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