



Welcome to the July issue of HFEA Update.

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Minister approves HFEA priorities

Health Minister Caroline Flint MP has just officially approved the HFEA Business Plan which reduces the burden on clinics through more streamlined regulation.

We're currently piloting a risk based approach to inspections which focuses resources and inspections on those centres which are falling below standard or need support. We are also cutting down the amount of information we require from clinics during inspection and the data collected is used more effectively.

We will expect clinics to demonstrate that their internal quality control systems are effective and that they have standard operating procedures. We're helping to develop these together with the professional bodies.

We'll offer better support to PR's in meeting their responsibilities through training and information. We're also introducing a new assessment procedure for PR's.

On policy issues, we're starting to develop a policy on single embryo transfer.

Implementing the EU Tissue Directive is another top priority in the coming year. A programme of work, in conjunction with the professional bodies and other representatives from the sector, is under way on developing standards that meet the EU requirements.

An EU Consortium has been set up, bringing together regulators and sector representatives from across Europe, to help shape the implementation of the directive and make sure all clinics are ready for the directive.

We continue to modernise the HFEA data systems and register. The last phase of this project will move to see better use made of the information we collect.

There still needs to be greater attention to the need of patients. We aim to empower patients to play a more active role, building on their current involvement in inspections and the patient communication programme.

SEED review nearing completion

The HFEA's Sperm, Egg and Embryo Donation (SEED) review is nearly finished. It is anticipated that a report on the review, including the Authority's conclusions, will be available in the early autumn.

HFEA UPDATE

Single Embryo Transfer

We are currently starting work on a project to look at the issues around Single Embryo Transfer (SET) and assessing how to develop an appropriate model for clinical practice in the UK. We will work closely with centres and professional bodies to review the effectiveness of the two-embryo transfer policy and also the experiences of other countries in Europe who have moved towards single embryo transfer.

There is an increasing body of research about the benefits of single embryo transfer, particularly in reducing the risk to mothers and children of multiple births. Many research papers were presented at this year's ESHRE conference, particularly from northern European countries where there is substantial state funding of SET. The HFEA wishes to see any changes achieved through close working with RCOG, BFS and ACE. We also intend to establish a dialogue with Primary Care Trusts and commissioners of services.

Panel gives clinics a better say

The HFEA has launched a new panel that will allow clinics to give us their views on modernising the way we regulate. The Licensed Centres Panel has been created in order to gain feedback from centre staff on key issues such as developing policy and improving regulation.

One key project will be considering the details around the 'risk matrix' used to determine a proportionate level of inspection and regulatory attention for each centre.

Other topics for discussion will include the process for assessing PRs, incident reporting and alerts, patient feedback, proposed letters and Directions from the Chair and more direct feedback on HFEA consultations.

The panel represents the breadth of centre staff in terms of expertise and

experience, including counsellors, fertility nurses as well as embryologists, clinicians and persons responsible from all over the UK. We have recruited 25 members, who will meet two or three times a year face to face, with virtual meetings on occasion.

Keeping up with scientific developments

We have set up a horizon scanning function, as part of the work of the HFEA's policy team, to keep abreast of developing technologies and techniques. This work is supported by an international panel of experts from the fields of stem cell science, animal cloning and cryopreservation, as well as doctors and embryologists working in clinics.

The panel, established for more than a year, has helped to inform the HFEA of new developments, such as the technologies around artificial gametes and has informed our understanding of the impact the technologies may have and of possible timescales for introducing them.

Bringing together European partners

A new European forum, the European Assisted Conception Consortium (EACC), has been established in a partnership between HFEA and ESHRE. Set up in response to the EU Tissues and Cells Directive the EACC brings together national ART regulators and practitioners within the European Union to:

- Provide an organisational framework for developing and presenting joint positions to the European Commission and Parliament on matters concerning the regulation of assisted reproduction services in the EU
- Share learning during implementation of the EU Tissue & Cells Directive and to develop solutions to common problems where possible

- Improve consistency and share best practice approaches to promoting safety and quality through open communication between organisations across Europe
- Address the need for continual improvements in meeting and exceeding the requirements of the Directive, and to cooperate in the development of an evidence base to support new measures.

So far, the EACC comprises representatives from 17 of the EU Member States. The UK representatives are Alison Murdoch, Dave Morroll and Angela McNab. At its inaugural meeting in Copenhagen on 20 June, a five-person Executive Committee was established:

Chair: Angela McNab (UK regulator)

Executive members:

Bernard Loty (French regulator)

Anna Veiga (Spanish embryologist)

Josiane Van der Elst (Belgian embryologist)

Ioannis Messinis (Greek clinician)

The EACC is funded by ESHRE and its activities and documents will be published on the ESHRE website. More details to follow in your next Update.

Welfare of the child

We expect to publish the revised guidance in the autumn.

Review of consent forms

We have started a review of HFEA consent forms and guidance to address the variety of problems that are encountered with the use of statutory consent forms. The review will also consider other issues related to the consent process.

We plan to invite clinic and patient representatives for a consultative meeting in October and will also seek feedback from the Licensed Centres Panel.

We expect to have new consent forms and guidance by the spring of 2006.

If you have any suggestions on how the current forms could be improved, or if you would like further information on the review, please contact Dr Cathleen Schulte, Policy Manager on 020 7291 8231 or at cathleen.schulte@hfea.gov.uk

Fertility Views

Nearly 600 patients have signed up to take part in our new online patients consultative panel, *Fertility Views*.

The panel, set up to get an insight from patients on a range of topics, will help us improve our services. The results from the first questionnaire are due in September and include views on issues, such as:

- Guide to Infertility 2005/06
- Published success rates
- Interactive clinics search
- Information leaflets
- Clinic inspection reports
- HFEA role as a regulator

Panel members will get a newsletter after each questionnaire outlining the results and how we intend to use them.

Historic Audit Project update

HAP visits are planned with Centres up to August 2005, and we are about to organise further visits to December.

We have deliberately focused on the larger centres in the early stages of our project. We recognise identifying and removing anomalies within the HFEA register is a joint responsibility and will try to make the process as easy as possible.

We urge Centres to ensure that the locations of all the files which require verification are known. Starting this exercise immediately after the initial planning meeting will negate the need to re-visit your Centre at a later date to verify any missing files from the first audit.



**Dr Maybeth
Jamieson**

Member Focus: Dr Maybeth Jamieson

The pace of change in the fertility sector is clearly reflected in the experiences of Dr Maybeth Jamieson, HFEA Member and Consultant Embryologist at Glasgow Royal Infirmary. "As part of the team that set up the Assisted Conception Unit at GRI in 1984 we carried out nine cycles per year – it's now nearer 900."

Maybeth was a founder member of the Association of Clinical Embryologists, established in 1993, which now has around 400 members. In December 2002, she joined the HFEA and has enjoyed a great deal of the Authority's work after "having been on the receiving end of inspections for many years".

One of her responsibilities is Chair of the Safety and New Technologies Group which looks at ways to improve laboratory practices. She said: "This is an interesting part of my role and we're looking closely at new techniques like bar coding and RFID to encourage greater levels of safety".

There have been a number of developments in the field of stem cell research in recent years and, according to Maybeth: "This shows the benefits of embryologists working together. We are always willing to help each other even when you'd think there would be some rivalry between us".

The pace of change in the sector is highlighted by the changes at the Glasgow Royal Infirmary, where Maybeth is focusing on the Unit's new status as the only PGD referral clinic in Scotland following funding from the Scottish Executive. "Before now, patients had to travel to Guy's in London so this is good news for people in Scotland".

Improved assessment for Persons Responsible

The HFEA is launching a consultation to improve the process of assessing Persons Responsible (PRs), in line with the 2004 Toft Report recommendations.

We will work closely with professional bodies across the sector and hope that the proposals encourage improvements in management standards in clinics. Currently assessment is based on a HFEA Licence Committee's appraisal of a candidate's curriculum vitae.

Trish Davies, Deputy Chief Executive, explains: "We are looking forward to consulting with stakeholders on this important issue. We hope that this will improve the skills of PRs across the sector and will ensure that training and development opportunities are prioritised by clinics."

Information training

Public Partners, specialists in Freedom of Information (FOI) and other information access legislation, is offering a training course to clinicians on confidentiality and current legislation on 16 September. For more details <http://www.foi-uk.org/events.html#candc>

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

Please contact
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Diary dates

**Open
Authority
meeting**
11 October

**Research
conference**
1 December