

## Welcome...

to the last edition of HFEA Update for this year. Find out about our next steps following our Annual Conference, read about the SEED evaluation, who the new Authority members are and about the next multiple births rate target.

## Annual Conference – the way forward

Clinic staff came together on 1 October to discuss the new Human Fertilisation and Embryology (HFE) Act, 8th Code of Practice and new approaches to inspection and licensing. Delegates took part in interactive workshops and joined in plenary sessions.

### Actions taken

- A briefing paper on **Freedom of Information (FOI) legislation** has been sent to clinics.
- Last month, HFEA Interim Chief Executive, Alan Doran, wrote to clinics to explain the process and rationale behind **publishing incident reports** and highlighted new information covering transitional arrangements for the **disclosure of patient information for research**.

Read the briefing paper and Alan Doran's letter at [www.hfea.gov.uk/5607.html](http://www.hfea.gov.uk/5607.html)

### The next steps

Over the coming months we are reviewing:

- **Quality Improvement** and how to help share recognised good practice, including the feasibility of holding future HFEA workshops for clinic staff.
- The extent to which **ISO requirements** overlap with our new inspection processes to eliminate duplication.
- **Sharing HFEA standard operating procedures** with clinics, including inspection protocols, witnessing and audit templates. To help clinics get the most out of inspections, we're considering providing training / introductory materials for clinic staff.
- How **patient feedback** can be used in HFEA publications to support patient choice. In spring 2010 the HFEA will consider the next steps and clinics will continue to be consulted and informed.

### Couldn't take part?

Workshop feedback summaries, audio and transcriptions of the plenary sessions are available at [www.hfea.gov.uk/5565.html](http://www.hfea.gov.uk/5565.html)

Winter 2009

## Inside...

New HFEA members appointed	2
Horizon Scanning report – What's next for fertility treatment & embryo research?	2
Choose a Fertility Clinic- new service launched	3
SEED evaluation – impact of the policies	4
Next multiple births rate to be set	4, 5
Fertility treatment in 2006: a statistical analysis	5
Review of case by case decision making in embryo testing	6
Update on the risk tool and the self assessment questionnaire	7
Online applications coming in 2010	7
News in brief	8
Upcoming events	8

## News

# New HFEA members appointed

Three new members have recently been appointed to the HFEA.

Dr Andrew Greenfield and Dr Alan Thornhill joined the Authority on 9 November 2009. Reverend Ermal Kirby will begin his appointment on 1 January 2010. Each new member has been appointed for three years.



Four members will step down from the Authority this year when their appointments come to an end. Lord Richard Harries of Pentregarth will step down on 31 December 2009. Roger Neuberg, Chris Barratt and Jenny Hunt stepped down on 6 November 2009.

Professor Bill Ledger, Mrs Sally Cheshire and Ms Anna Carragher have been reappointed as Authority members for a further three years.

Professor Lisa Jardine, HFEA Chair, said:

“I look forward enormously to working with these new members. Their talent and experience will make a valuable contribution to the Authority, complementing those of our current and reappointed members.

“Richard, Roger, Chris and Jenny have each made a wonderful contribution to the work of the Authority and they leave with our warm good wishes for the future.”

## Horizon Scanning report What's next for fertility treatment & embryo research?

In vitro derived gametes, gene transfer into embryos and alternatives to embryonic stem cells are just three of the rapidly developing areas of science examined in the HFEA's latest Scientific Horizon Scanning annual report, published in September.

Horizon scanning is an early warning system which allows the HFEA to consider the implications of any techniques that researchers or clinicians may wish to use in the future in HFEA-licensed research or treatment.

Issues prioritised for consideration in 2009 include non-invasive assessment of embryo quality, in vitro derived gametes, induced pluripotent stem cells and autologous transplantation of ovarian tissue.

For more information about the HFEA's horizon scanning process and to view the report visit [www.hfea.gov.uk/1132.html](http://www.hfea.gov.uk/1132.html)



## News

# Choose a Fertility Clinic new service launched

The new HFEA 'Choose a fertility clinic' service was launched on 1 October. The service is designed to help patients make informed choices about their treatment. It is by far the most popular area on the HFEA website and on launch day received over four times its usual visitor traffic.

### What are the changes?

The service has a much wider range of information than previously available, including:

- the treatments and services clinics offer, including any specialist areas
- meaningful statistics on all types of fertility treatment including IVF, ICSI and DI on a national level and for each individual clinic
- details of the diagnosis, age and length of infertility of patients typically treated at each clinic

Information and data is presented at different levels of detail – from an overview page and headline success rates, down to more detailed data.

### New presentation of statistics

- Clinic statistics are compared to the national average
- More information on singleton and multiple births
- Live births per embryo transferred are shown as well as live birth per cycle started
- Live birth rates are no longer presented just as a percentage point (eg. 30%) but show the predicted chance of an average patient having a live birth as a range

Choose a fertility clinic was developed following a wide consultation on how we present clinic information and user testing with patients.



*The HFEA is striving to provide an objective and transparent range of measures to help people who are making decisions about IVF treatment navigate a complex set of choices. It is essential for patients that the HFEA continues this work.*

Dr Jenny Kurinczuk,  
Deputy Director,  
National Perinatal Epidemiology Unit



## News

# SEED evaluation impact of the policies

In recent months, the HFEA has been evaluating the practical impacts of the sperm, egg and embryo donation (SEED) policies that were developed as a result of a policy review in 2005/6.

The original SEED review aimed to develop policies which ensure an effective and safe service for those requiring treatment with donor sperm, eggs and embryos, while protecting the interests of donors, recipients and those who may be born as a result.

### Evaluation process

This evaluation has been planned in two phases:

**Phase 1** – to evaluate the impact of the SEED policies on practice in clinics and with others affected by donation.

**Phase 2** – focused policy development work. Scope and objectives of work to be set by the Authority in December 2009, in light of the evidence gathered during Phase 1, and other donation projects relevant to the Authority.

Phase 1 sought to unpick how SEED policies are operating in practice, which aspects are working well and which aspects are problematic. It also identified issues of disagreement regarding the rationale behind the policies themselves.

The evaluation involved internal scrutiny of inspection and register data as well as focussed discussions with clinics, recipients of donor gametes, donors and other stakeholder groups.

### Next steps

The results of Phase 1 will be presented at the open Authority meeting in December 2009. Members will be asked to decide which aspects of the SEED policies to take into a more developed and far reaching policy review process.

If you have questions about the SEED evaluation or would like to make a suggestion about this area of work, contact Danielle Hamm, Policy Manager at [Danielle.Hamm@hfea.gov.uk](mailto:Danielle.Hamm@hfea.gov.uk) or phone 020 7291 8253.



## Next multiple births rate to be set

The HFEA will be setting the next maximum multiple births rate in January 2010. Clinics will have three months to prepare before this comes into force in April 2010.

### The current multiple births policy

In January 2009 the HFEA set the maximum multiple birth rate that clinics should not exceed in 2009 at 24 percent.

### How will this change next year?

The HFEA is currently evaluating the first year of the policy in order to set the next maximum multiple births rate for clinics.

## News

# Fertility treatment in 2006: a statistical analysis

In early December we will publish an in depth analysis and interpretation of the national fertility data we hold. The National Perinatal Epidemiology Unit (NPEU) at the University of Oxford carried out the analysis.

### The report

The report looks at a complete year's worth of data (from treatments started in 2006).

The report provides an overview of:

- treatments carried out
- pregnancies, live births and number of babies and donor-conceived babies born
- numbers of embryos created, stored, used in treatment and donated

It analyses each stage of the patient journey, including:

- How likely is it that a treatment cycle will continue to embryo transfer stage and result in a pregnancy?
- Will a baby always be born if a woman becomes pregnant and what are the different outcomes for multiple and singleton pregnancies?

- What is the live birth rate and how likely is it that the birth will be of a singleton full-term baby?
- What is the effect of the number of embryos transferred on pregnancies, births and babies born?
- What about the babies born? Are they term or pre-term and what is the risk of stillbirths or neonatal deaths compared to babies naturally conceived?

The report separately looks at IVF and ICSI treatment, cycles involving fresh and frozen embryos and cycles involving donor eggs. As far as possible the report also examines the effect of the patient's age.

The report will be available on [www.hfea.gov.uk](http://www.hfea.gov.uk) under the 'For media and researchers' section.

For more information contact Helen Richens, Policy Manager at [helen.richens@hfea.gov.uk](mailto:helen.richens@hfea.gov.uk) or phone 020 7291 8236.

We are looking at:

- feedback from clinics and patients
- a statistical analysis of 2009 pregnancy data
- clinic compliance with the policy and the minimisation strategies clinics have been using
- published research around multiple births and single embryo transfer

For more information on the multiple births policy visit [www.hfea.gov.uk/530.html](http://www.hfea.gov.uk/530.html)

### Key dates to remember

#### December 2009:

HFEA discuss analysis of Year 1 of policy

#### January 2010:

HFEA decide Year 2 target

HFEA issue Directions to clinics setting out Year 2 target and requirements of clinics

#### April 2010:

Year 2 target comes into force for clinics

#### What do you think of the HFEA policy?

The HFEA want to hear your feedback about how your clinic has implemented the multiple births policy. How has your minimisation strategy had an impact in your clinic? How have your patients responded to being offered single embryo transfer?

Contact Helen Richens, Policy Manager at [helen.richens@hfea.gov.uk](mailto:helen.richens@hfea.gov.uk) or phone 020 7291 8236

## News

# Review of case by case decision making in embryo testing

On 1 October the HFEA moved to licensing pre-implantation genetic diagnosis (PGD) on a condition by condition basis. This means that once a condition has been licensed by the HFEA, any clinic in the UK licensed for PGD can test for that condition.

However, this decision did not apply to two categories of embryo testing, which will continue to be licensed on a case-by-case basis, for use with a specific family.

### Conditions that will continue to be licensed on a case by case basis

The two conditions are:

- Those defined as 'later onset' and 'lower penetrance.' These are often tests for genes associated with an increased susceptibility to particular forms of cancer. An example is BRCA1, which is linked to an increased risk of breast cancer. The decision to licence these conditions on a case by case basis was made in 2006.
- Embryo testing which involves HLA (human leukocyte antigen) tissue typing for the purposes of conceiving a tissue-matched sibling to provide cord blood (or other tissue) for a sick sibling. The decision to allow HLA testing in isolation from a test for a heritable condition in the embryo was made in 2004.

When the decision to permit the licensing of these conditions on a case by case basis was made, the HFEA agreed to review these decisions after seeing how the licensing process worked in practice.

Over the next few months the HFEA will be evaluating the benefits and drawbacks of licensing these conditions on a case by case basis.

### Review process

The review will be carried out through:

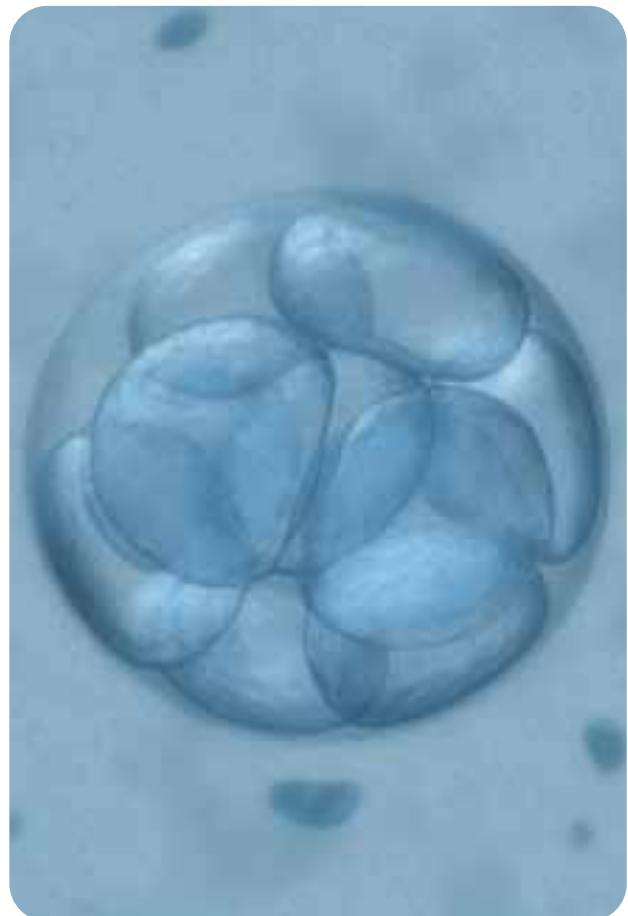
- An analysis of case by case decisions, with evidence gathered from both licence applications and minutes of decisions taken.
- A public event held on 1 December for clinicians, patient groups and other interested parties to get views on the current system, and on proposals for future licensing.

- Gathering the opinions of experts in cancer genetics and consultants involved in the care of children where an HLA tissue-matched sibling is the only available treatment.

This review began in October 2009, and will conclude with decisions taken at the January Authority meeting in 2010.

### Any questions?

If you have questions or would like to make a suggestion about this area of work, contact Danny Edwards, Policy Manager at [danny.edwards@hfea.gov.uk](mailto:danny.edwards@hfea.gov.uk) or phone 020 7291 8239.



## Regulation matters

# Update on the risk tool and the self assessment questionnaire

The HFEA is developing a risk tool, which will be used to monitor centres' compliance and performance and to identify appropriate areas of focus for inspections.

### General performance indicators

Some of the information used to populate the risk tool will be derived from information held by the HFEA about centres' register submissions, outcomes, complaints and incidents, etc. This information, known collectively as general performance indicators (GPIs) will be updated frequently.

Where there are changes in GPIs that cause concern, this may prompt contact between the HFEA and a centre. This continuous monitoring will be important when the HFEA starts to inspect centres once every two years.

### Self assessment questionnaire

Centres will also be asked to complete a self assessment questionnaire (SAQ) to provide information for the risk tool. The SAQ will be used to assess centres' compliance with the 1990 Human Fertilisation and Embryology (HFE) Act and standard licence conditions. The SAQ will replace the pre-inspection questionnaire.

### How the SAQ will work

The questionnaire has been designed in modules that reflect the way information is provided in the 8th Code of Practice. The person most familiar with the activities covered by each module may be the best person to complete the section.

### Your involvement

In **December 2009** all centres will be asked to complete the online version of the SAQ via the clinic portal on the website.

The information submitted will be used as part of a benchmarking exercise. After completing the form for the first time centres will be asked to update their responses to the questionnaire prior to inspection, every two years.

This should ensure that the assessment reflects the centre's practices and enables the task of completing the form to be shared across the team. Feedback from a pilot study suggests that the SAQ takes less time to complete than the pre-inspection questionnaire.

The SAQ does not ask centres to provide evidence of their compliance with the statutory requirements. Review of evidence will be part of the inspection process. Centres will be asked to rank themselves as compliant (Yes or No) or in some cases to rank themselves on a scale of 1-4 (where 4 is fully compliant and 1 is not compliant).

The information provided in the SAQ will be fed into the risk tool along with information on general performance indicators and will be used to help determine where inspections can be most effectively focussed.

## Online applications coming in 2010

By early 2010 it is planned that clinics will be able to submit all licence applications online. The content of the forms will be the same as on the website. Centres will be able to access the forms through the clinic portal and any member of the team will be able to complete the form.

Only the PR will be able to submit an online application form having acknowledged that the information in the form is accurate.

While the majority of forms will not be available to complete online until early 2010, centres are currently able to submit applications for special directions for the import or export of gametes and or embryos through the clinic portal. By trialling the system in this way we hope to ensure that the transition to online applications is as seamless as possible.

New application forms for licence application, renewal and variation are currently available in paper form on the HFEA website and can be submitted electronically to [HFEAcompliance@hfea.gov.uk](mailto:HFEAcompliance@hfea.gov.uk)

## News in brief

### Subscribe to the One at a time e-newsletter

*One at a time Update* is a quarterly e-newsletter that will keep you in touch with changes to the One at a time website.

You will also be able to read about clinics' experiences with their multiple births strategies.

The One at a time website forms part of a wider national strategy to promote the birth of a healthy, singleton child as the aim of all fertility treatment.

To subscribe email [feedback@oneatotime.org.uk](mailto:feedback@oneatotime.org.uk)

**One at a time**   
Better outcomes from fertility treatment



## Upcoming events

### Adverse incident training day

The HFEA are inviting clinics to nominate one member of staff to attend an adverse incident training day in London or Manchester in February/March 2010.

#### The programme will include:

- identifying and reporting adverse incidents to the HFEA,
- investigation techniques and tips, and
- sharing the learning from experience.

The final programme and details for registering will be circulated in January 2010.

If you have any questions contact Carmel Dodson-Brown, Head of Clinical Governance & Patient Safety at [Carmel.Dodson-Brown@hfea.gov.uk](mailto:Carmel.Dodson-Brown@hfea.gov.uk)



### Register for the HFEA Open Authority meeting – 9 December

The next Open Authority meeting will be held on 9 December 2009 at the Vermont Hotel, Castle Garth, Newcastle-upon-Tyne, NE1 1RQ from 9.30am to 1.30pm.

#### Items to be considered at the meeting include:

- plans to move towards a possible Year 2 target for multiple births and
- a look at future policy and consultation work on issues related to sperm, egg and embryo donation (SEED).

The event is free and is open to all clinic staff.

#### To register

Email your name, centre and role to [openmeeting@hfea.gov.uk](mailto:openmeeting@hfea.gov.uk) by **Friday 4 December**.

Confirmation of your attendance and joining instructions will be sent by email. Agenda and papers will be on our website before the meeting.

### Upcoming Open Authority meetings

**24 March 2010 – central London**

For further information contact Alan Tipping on 020 7291 8233 or email [alan.tipping@hfea.gov.uk](mailto:alan.tipping@hfea.gov.uk)