

Welcome...

to the first edition of the HFEA Update for 2009. This edition includes an update on our consultations, new law relating to legal parenthood, the latest about Opening the Register and news of our website upgrade.

Spring 2009

Are you ready? New law relating to legal parenthood

The majority of the Human Fertilisation and Embryology (HFE) Act 2008 will come into force on 1 October 2009. However, new laws relating to legal parenthood (when donor sperm or embryos are used) will be introduced early on 6 April 2009.

This means:

Heterosexual couples

- **Unmarried couples using donor sperm or embryos** – The concept of being 'treated together' under section 28(3) of the HFE Act 1990 will no longer apply. Both partners must consent to the male partner being the father in order for him to be legally recognised and named on the child's birth certificate.
- **Married couples using donor sperm or embryos** – The situation for married couples will be unchanged from the HFE Act 1990. The husband is the legal father of any child born as a result of his wife's treatment, unless it is shown that he did not consent to treatment of his wife.

Same-sex couples

- **For lesbian civil partners**, the partner who does not give birth will be recognised as the legal second parent and named on the child's birth certificate unless she did not consent to her partner's treatment.
- **For lesbian couples not in a civil partnership**, both women must consent to the partner who does not give birth being named as the second legal parent.

From 6 April 2009, make sure consents to parenthood are in place before treatment with donor sperm or embryos - otherwise any child born will not have a second legal parent.

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Are you ready? New law relating to legal parenthood (continued)...

What does this mean for clinics?

From 6 April 2009 clinics will need to:

- Offer implications counselling about consent to parenthood prior to treatment being provided.
- Provide appropriate information to patients and patient partners regarding the implications of treatment following consent to parenthood.
- Obtain consent to parenthood before sperm, egg or embryo transfer from both the woman being treated and her partner.
- Notify patients or patient partners if consent to parenthood is withdrawn or changed.

Clinics will receive a guidance note and consent forms (as well as FAQs and commencement guidance) regarding these parenthood provisions, in the week commencing 23 February. Posters and leaflets will also be provided to inform patients of the changes.



Visit www.hfea.gov.uk/areyouready for more information.

If you have any enquiries please contact Hannah Darby on 020 7291 8237 or email hannah.darby@hfea.gov.uk

News

Core principles agreed for Opening the Register

At the January Authority meeting, the HFEA agreed the core principles that will provide the basis for its approach to Opening the Register (OTR) to people affected by sperm, egg and embryo donation.

They are:

- **Protection of the right of applicants to access information** – to be open about the type of information the HFEA holds and to provide people with accurate information in a timely, secure and considerate manner.
- **Duty of Care** – to treat all applicants sensitively and provide good general information about the possible impact register information can have on people's lives. To provide meaningful signposting to appropriate counselling and support services.
- **Statutory Compliance** – to implement the changes brought about by the Human Fertilisation and Embryology (HFE) Act 2008.

In addition to the implementation of the statutory changes brought about by the HFE Act 2008, the HFEA has decided to continue to provide information access rights to parents of donor-conceived people.

As is currently the case, parents will be able to access anonymous information about their children's donor and any genetically related donor-conceived siblings their children may have, in order to help them inform their children of their origins.

The HFEA is also committed to establishing a Voluntary Sibling Contact Register, which will enable donor-conceived individuals to make contact with their genetically related donor-conceived siblings, from the age of 18, on the basis of mutual consent.

The revised OTR policy will be implemented in October 2009. For more information visit: <http://www.hfea.gov.uk/en/1741.html> or contact Danielle Hamm at danielle.hamm@hfea.gov.uk

News

HFEA consultations update

The HFEA have reached the end of a busy three-month consultation period with clinicians, patients, donors and other stakeholders.

The consultation has focused on the draft HFEA 8th Code of Practice and revised consent forms, and how we present clinic information and data.

Over the last two months we have held events in Manchester, Bristol and London. These were well attended by clinicians, along with patients, donors, researchers and other affected groups.

Participants fed in their views through a choice of interactive workshops on the Code of Practice, demonstrating compliance and presenting information about clinics. We also held a specific event on preimplantation genetic diagnosis (PGD).

These events were complemented by a series of smaller focus groups and stakeholder meetings on the revised consent forms and presenting clinic

information. We also collected useful feedback at Fertility 2009 in Edinburgh.

In addition to these events we had two online questionnaires: one on the draft 8th Code of Practice and consent forms, the other on clinic information and outcome data.

The Code of Practice and consent forms are currently being updated to incorporate feedback collected during the consultation period. We expect these versions will receive final approval in May 2009.

The exception is the parenthood consent forms which we expect will be signed off by our Compliance Committee on 20 February and sent to clinics by the end of February 2009 for introduction on 6 April 2009.

Following the consultation, the HFEA will also agree what information we should present about clinics. We will publish the consultation results and the decisions after May 2009.

HFEA website upgrade – April 2009



The HFEA website is about to undergo a major redesign of its content and visual style, with the new site going live in April 2009.

Some of the improvements include:

- more detailed, informative content for patients, donors and donor-conceived;
- a change in the site's structure to make it easier to find the information you need;
- improved search facility and navigation; and
- a new, fresh layout and design.

To make sure that the new site meets our audiences' needs, we've gathered thoughts and comments from a wide range of users, including clinic staff, via:

- a public survey;
- user testing with clinic staff;
- interviews with stakeholders; and
- workshops.

Thanks to all of you who have helped us so far. The feedback has been, and will be, invaluable in helping us to prepare a site that is both informative and easy to use.

Further changes to the site will be introduced later in the year with the release of the new online Code of Practice and an improved 'Find a Clinic' search.

For more information contact David Williams at david.williams@hfea.gov.uk

Regulation matters

Does your clinic have a Nominal Licensee?

All clinics must have a Person Responsible (PR) in order to obtain a licence. But it is also possible for clinics to appoint a second person as the "Nominal Licensee (NL)".

Having a Nominal Licensee has real benefits for both clinics and the HFEA. It means that two people are available and accountable for the licence, so maintaining business continuity is easier. And if a PR falls ill or is otherwise absent, there is someone who can communicate with the HFEA in an official capacity.

Not having a Nominal Licensee can cause some real difficulties and has some potentially serious consequences for the clinic concerned. Recently, we encountered problems with some clinics (particularly IUI clinics) where the proposed PR had not completed the licence application process, leaving the clinic at risk of committing a criminal offence if they continued to treat patients.

In other cases new PRs failed to apply and obtain approval from a Licence Committee when the former PR was leaving. Operating without a PR is serious breach of the conditions of a licence, and a clinic's licence may be suspended as a result.

Clinics operating within a hospital or other large healthcare organisation have found it advantageous for a member of the Board, the Chief Executive or a senior hospital manager to be put forward as Nominal Licensee. This means that there is another senior person within the organisation who is aware of the legal responsibilities of holding a licence and who can act if the PR is unable to fulfil those responsibilities.

The relevant sections of the **HFE Act are s17, 18 and 19**. These refer to the position of a Nominal Licensee as "a person who may hold a licence whilst not being the person responsible".

In light of these issues, clinics are strongly advised to look carefully at the current arrangements for their Person Responsible and to consider whether a Nominal Licensee should be appointed.

Applications to vary a licence by adding a Nominal Licensee can be found on the HFEA website at <http://www.hfea.gov.uk/en/1585.html>. No fee is required.

If you have any queries, please contact your inspector at regulation.enquiries@hfea.gov.uk

Subscribe to the new HFEA e-newsletter!

Visit our website at www.hfea.gov.uk/e-updates and subscribe to our new email newsletter service, HFEA e-update, which will be sent out every month.

Keep up to date with:

- the latest news from the HFEA;
- upcoming events;
- news from around the fertility sector, and
- changes to the HFEA website.





Regulation matters



New Risk Based Assessment Tool

Last autumn we invited clinics to nominate a member of staff to join an external reference group and attend a workshop in order to gain their views on a risk based approach to inspection.

The external reference group met in December 2008 and participants provided valuable insight into clinics' perspectives. We have also consulted closely with staff from within the HFEA continuously throughout the development phase.

This is to ensure:

- that the risk tool will inform the inspection site visit planning.
- that there is an evidence based, consistent, transparent approach to the decisions which are made.
- that there will be two distinct elements to the tool, an annual self-assessment for centres to complete and an assessment by Compliance to determine the level of inspection.

It is anticipated that the design of the Tool will be delivered in March 2009 – and the IT team will oversee the practical/technical design phase.

Over the next six months we will be undertaking internal testing of the model and then plan to 'pilot' the tool with volunteer clinics from the sector. Final adjustments will be made at the end of the summer and the Assessment tool will be live from 1 October 2009.

If your clinic would like to participate in the 'pilot' phase or you have any queries please contact:

Carmel Dodson-Brown
Head of Clinical Governance & Patient Safety
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London WC1B 3HF



News in brief

HFEA fees review

We are currently conducting a review of our fee charges, which were last reviewed in July 2002 with the view that the new fee charges will be operational from 1 April 2010.

We will be seeking approval of the fee options in May 2009. The consultation on the proposals will commence from early June.

In preparing the fee options for review we will adopt best practice in regulatory fee modelling.

Oneatotime – have you got the information you need?

As part of the national strategy on minimising multiple pregnancies following fertility treatment, oneatotime.org.uk was launched in June last year.

oneatotime.org.uk provides patients and professionals with the latest information on:

- minimising risks from multiple pregnancies
- best practice guidelines
- recent developments and research

Order free promotional material to use in your clinic or organisation:

- post-it notes
- pens
- a leaflet holder with patient leaflets for clinic waiting rooms
- a poster

To order email feedback@oneatotime.org.uk

Am I at risk if an IVF birth results in twins or triplets?

One at a time
The National Strategy on Minimising Multiple Pregnancies



Upcoming events

Open Authority Meeting, London – 18 March

The agenda will include an update on the public consultation on:

- the draft new Code of Practice
- revised consent forms and
- presentation of clinic data.

Venue details and further agenda information to be confirmed.

For more information email openmeeting@hfea.gov.uk

Open Authority Meeting – 8 July

Venue details to be confirmed.

For more information email openmeeting@hfea.gov.uk