

Welcome...

to the spring edition of the HFEA Update. This edition includes an update to the Code of Practice, consent forms and General Directions, the launch of a new Donor Sibling Link service and a new patient publication. Read on to find out more...

Spring 2010



Update to the Code of Practice, consent forms and General Directions

The 8th edition of the HFEA Code of Practice, revised consent forms and General Directions were published in October last year. They have now been updated in response to feedback from centres, new policies and regulations.

Highlights of these updates are:

General Directions

- Changes to requirements for the submission of information about embryo research, payment of HFEA fees and the HFEA's new online licence application system.

Code of Practice 8th edition

- New guidance on two types of embryo testing (exclusion testing and non-disclosure testing) and changes to guidance on multiple birth rates.

Consent forms

- Revisions have been made to ensure consent to storage is obtained, where necessary, when people wish for their gametes or embryos to be used in the event of their mental incapacity or death. There will also be additional guidance on the use of gametes and embryos for training purposes.

The revised General Directions, consent forms and sections of the Code of Practice will be issued to licensed centres at the beginning of March 2010. The revisions will come into force on 6 April 2010.

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News

HFEA to launch Donor Sibling Link

In April 2010, the HFEA will be launching a new service for donor-conceived people to support contact between genetic siblings born as a consequence of the donation of sperm, eggs or embryos after 1 August 1991. This service will be known as the Donor Sibling Link (DSL) and will be available to people 18 or over.



How will the DSL service work?

Applicants will be required to fill out a form indicating whether they are interested in making available their own contact details to donor-conceived genetic siblings, or gaining access to contact information about those siblings who have consented to its disclosure.

Participants in the DSL will need to provide the following information: their name, details about their parents, their contact information, consent for disclosure of personal information and their preferred method of contact. It is the latter, together with their name, that will be passed on to other siblings participating in the scheme.

Anyone can withdraw their consent for disclosure of information at any time and opt out of the DSL scheme.

More details can be found at www.hfea.gov.uk/112.html

Multiple births target lowered

Over the past year clinics have been hard at work implementing their multiple births minimisation strategies. HFEA recognises clinics' achievements in rising to this challenge.

All clinics now have a strategy in place to reduce multiple births. Two thirds of clinics are predicted to be within the Year 1 maximum multiple birth rate of 24% for treatment started in 2009, with many being significantly below this.

In January 2010 the Authority, after careful consideration decided to set the Year 2 maximum multiple birth rate at **20%**. This will come into force on 6 April 2010.

The Authority felt this would maintain the momentum built up in the past year whilst allowing clinics time to review and improve their strategies.



We will be reporting to clinics on how we have assessed their performance against Year 1 of the policy in May.

HFEA will continue to work closely with the sector to review and share multiple births best practice with a series of workshops for clinic staff planned in early March and mid May. Have a look at our 'Upcoming events' page to find out more.

Read more about the multiple births policy in a Chair's letter at www.hfea.gov.uk/5750.html

News

Launch of a new patient publication

HFEA will publish its new patient guide *Getting Started: your guide to fertility treatment*, in April 2010.

Getting Started replaces the old *Guide to Infertility*, and will be available to patients through clinics or directly. It is aimed at people who are starting treatment and those who are at the beginning of their fertility journey.

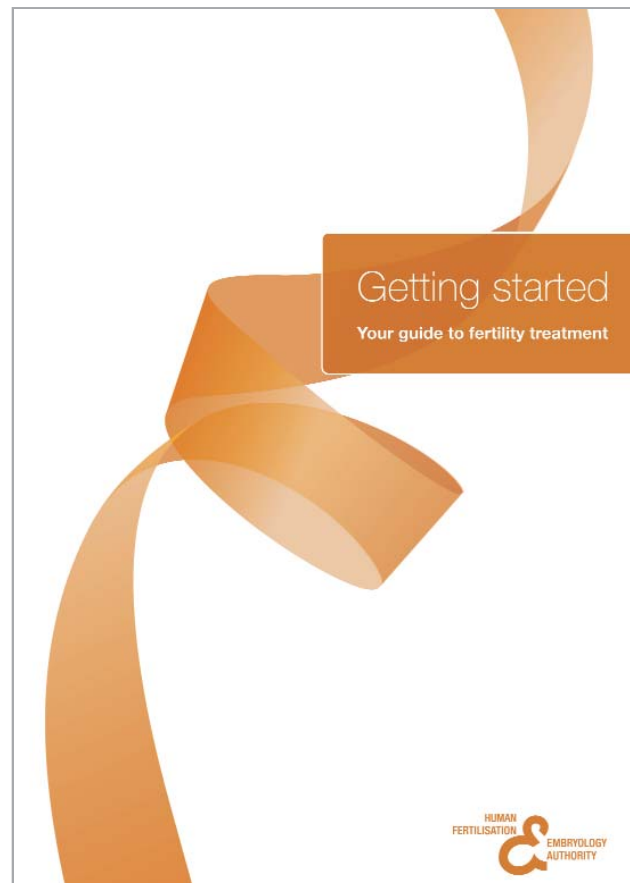
The new publication contains simple, straightforward information on the patient's journey from start to finish. It explains about the different fertility treatments available, how to research a clinic and what to expect. The new guide will include information on freezing and storage, and where to get support. Each section of the guide directs people to the HFEA website for more detailed information.

To ensure it got the new Guide right, HFEA tested it with patients, counsellors and fertility nurses, using their feedback to create an accessible, easy to read and informative publication.

For most patients the start of their journey is in a GP surgery. HFEA has also produced a leaflet promoting the new Guide which will be distributed to GP surgeries nationwide. Prospective patients will be able to order copies of the Guide direct from the HFEA.

Getting Started will also be made available to fertility clinics.

For any further information, contact sharon.neaves@hfea.gov.uk



News

HFEA application procedures online in April

As part of HFEA's commitment to improve application procedures, from 1 April 2010 all treatment or research licence applications will have to be submitted directly to the HFEA via the clinic portal. This includes applications for new licences, renewal, variation, pre-implantation genetic diagnosis, pre-implantation genetic screening and Special Directions applications.

Content of the online forms will be largely the same as those currently on the website. Clinics can 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 the application form, having acknowledged the information in the form is accurate.

The online system should also help us track applications and make sure they are processed efficiently.

There are future plans to allow for application forms to be automatically completed from the data held. This should reduce the amount of time it takes to complete applications and, will help the HFEA make sure that the data held on file is as accurate and up to date as possible.

If you have any queries on completing the new style forms currently on our website at www.hfea.gov.uk/177.html or any questions about the online forms going live in April, contact your inspector.

Seeking patients' views on their treatment

Building on the success of 'Fertility Views', our previous online patients panel, we are now looking to launch a new panel with improved ways of reaching patients.

We will make contact with patients a number of times a year and seek their views on a wide range of issues that will assist the Authority in its decision making process.

Over the coming months, we will be sending you leaflets to display in your waiting rooms to help recruit patients to the panel. We will also be advertising in the media, through patient organisations and in our new patient publication.

For more information contact david.williams@hfea.gov.uk



Compliance matters

Inspection changes: Existing treatment and storage licences

One of the changes to the Human Fertilisation and Embryology Act which came into force in July 2007 as a result of EU Tissues and Cells Directive meant that centres only need to be inspected once every two years.

Thereafter, the Authority agreed that the HFEA should adopt a four year inspection cycle for treatment and storage licences. This will reduce the frequency of inspection for most centres.

Licence renewal year (year 1 of the cycle) – this will involve a full inspection which includes reviewing compliance with all statutory requirements.

Centres with a four year licence - the next inspection will usually be in year 3. This interim inspection will focus on improvements made by the centre following the implementation of recommendations made in the renewal report. The inspection will also focus on themes which the Authority considers a priority, such as witnessing.

Before inspection

All centres will be required to update their self assessment questionnaire (SAQ) before an inspection. Where the SAQ identifies an area that is not fully compliant with the statutory requirements then this area may also be reviewed in the course of an interim inspection.

Non-inspection period

Non-inspection years (years 2 and 4 of the cycle) - the centre's inspector will continue to monitor the centre's activities closely. If concerns arise this may prompt an additional site visit.

Improving the inspection process

These changes should make the inspection process more transparent, proportionate, consistent and targeted.

Inspection will provide centres with an opportunity to demonstrate compliance with the law and the Code of Practice. A finding of non-compliance will only be made after the centre has been given an opportunity to comment or put matters right.

Inspection changes: Research licences and new licence applications

By law, research licences can only be issued for a maximum of three years.

Licence renewal year (year 1 of the inspection cycle) – this involves a full inspection which reviews compliance with all statutory requirements.

Centres with a three year licence - the next inspection will usually be in year 3. As with treatment licences, this will be an interim inspection which will focus on improvements made by the centre following the implementation of recommendations made in the renewal report. Any themes relevant to the research licence and non-compliant areas of practice identified from the centre's SAQ will also be covered.

Year 4 - this would not be inspection free for research licences as this would be the year of licence renewal.

Depending on individual circumstances, new licences for treatment, storage or research or licences issued following substantial variation may be issued for shorter periods than usual. This means that new or varied licences may be subject to more frequent inspection initially.

For more information on these changes contact your inspector.

Upcoming events

HFEA risk management workshops

March will see the HFEA's compliance team provide training workshops on risk management for clinic staff.

Workshop dates

Manchester – already taken place on 1 March

London – Thursday 11 March

The workshops are an opportunity to discuss the benefits and barriers to adverse event reporting at fertility clinics and to identify issues that the HFEA should take into consideration.

To register

Places are limited. To pre-register, email hfeacompliance@hfea.gov.uk and please state which event you wish to attend.

We are inviting clinics to share their learning from adverse events with the sector. If your clinic would like present at the event, please contact: carmel.dodson-brown@hfea.gov.uk

Upcoming Open Authority meeting

24 March 2010 – central London

For further information contact Alan Tipping on 020 7291 8233 or email alan.tipping@hfea.gov.uk



Workshops on multiple births and consent to research

The HFEA will be holding four best-practice workshops in Glasgow, Leeds, Birmingham and London in late March and early May 2010.

The aim for these workshops is to help clinics reduce multiple births and enable them to fully inform patients when discussing consent to release identifying information for researchers.

Members of staff from local clinics will talk about their experiences of working to the new requirements. The multiple births session will also feature lessons from the first year using analysis of HFEA national data and experts from the sector discussing the latest clinical practice in embryo grading and storage.

Who should attend?

All staff involved in these key issues are welcome to join us.

Workshop dates

Birmingham – Tuesday, 23 March

Glasgow – Wednesday, 31 March

London – Wednesday, 5 May

Leeds – Wednesday, 19 May

Register

To register email event@hfea.gov.uk stating which workshop you wish to attend, your role and clinic.

If you have any questions contact Alan Tipping at alan.tipping@hfea.gov.uk or call 020 7291 8233.

The publication of *Getting started*, the launch of the Donor Sibling Link and other communication activities mentioned in this edition of the HFEA Update may be delayed due to the upcoming National Elections.