



## Welcome to the April issue of HFEA Update.

The Update is also available on the HFEA website: [www.hfea.gov.uk/HFEAPublications](http://www.hfea.gov.uk/HFEAPublications)

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#### Focusing regulation where it is needed

#### **Focusing regulation where it is needed**

HFEA is introducing a new risk-based approach for assessing clinic performance alongside inspection this summer, following consultation with the sector. We will be running a six-month trial to ensure the robustness and accuracy of the evaluation the risk matrix provides, so we can consider reducing the frequency of inspections for high performing centres without compromising patient safety.

The risk matrix will provide a clear, focused way of assessing clinics, bringing together information from day-to-day operation, treatment outcomes and complaints. It has been designed to be transparent and easy to use and will enable clinics to assess their own performance.

This will be another step forward in our move to minimize bureaucracy and focus on areas where regulatory activity is really needed to improve the quality of service for patients.

#### In-House Inspectorate

#### **Moving to an in-house inspectorate**

HFEA will be improving consistency, strengthening our independence and minimising the risk of conflicts of interests by moving to an in-house inspectorate. However, we will continue to use a panel of external advisers (formerly known as Inspectors), drawn from staff who work in centres, as their specialist experience is highly valued.

The in-house team will now be known as Inspectors (replacing the previous role of Senior Regulatory Managers). Each Inspector will have a portfolio of centres for which they will be principal contact and lead the inspection team.

The licensing process will be managed by the business systems and information team, including booking inspections and analysing pre-inspection information. (This replaces the role of Regulatory Officers).

We are keen to recruit Inspectors with scientific experience to complete our team. If you are interested in joining us please contact Julie Hegarty in HFEA HR at [julie.hegarty@hfea.gov.uk](mailto:julie.hegarty@hfea.gov.uk) or phone 020 7291 8303.

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#### **Clinics welcome speed and ease of EDI**

Clinic staff using the new Electronic Data Interchange (EDI) system to send patient and treatment information to HFEA are finding it quicker, easier and more useful than the standard paper forms that have been used up until now.

Currently six clinics are trialling the system, which uses terminals in the clinics to send information direct to HFEA instead of using the traditional paper forms. Seven more clinics will be joining the pilot shortly.

People using the new system say it is user-friendly and straightforward to use. It makes supplying information to HFEA much easier because it:

- significantly cuts down paperwork

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- saves writing out the information
- quickly provides information about any corrections needed – with any errors highlighted and sent back to clinic the next day

We have already found a notable improvement in the quality of the information that is sent to HFEA through the EDI system. EDI also provides benefits to clinics themselves, by allowing them to get access to their data that is held at the HFEA. Particular benefits include:

- Reporting – allowing the clinics to run reports on their data, with their own search criteria
- Billing Reports & Automated Billing – this allows clinics to view the status of their billing charges

We hope that all clinics will be using the EDI system by November.

We are listening to the views of the clinics piloting the EDI software and continue to develop the solution with ease of use in mind. This includes the format and data types collected on the new electronic forms. For more information about the EDI system, contact David Moysen in the HFEA's IT team on 020 7291 8307, or email [David.Moysen@hfea.gov.uk](mailto:David.Moysen@hfea.gov.uk)

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## Easier system for PGD approval

We are introducing a new system for processing applications for Preimplantation Genetic Diagnosis (PGD) as part of our commitment to streamlining regulation. This will allow clinics with established expertise in PGD techniques to get quicker approval for tests for new conditions without having to have an application considered by an HFEA licence committee. Guidance on how the new system will work will be issued shortly.

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## Clinic support ensures HAP success

The Historic Audit Project has achieved significant success already thanks to the level of help and support being provided at clinics. By 31 March, the HAP team had already audited about 60,000 forms – 22% of the total – putting us well on target to complete the audit by 31 March 2006. By that date we will have audited all the 270,000 forms relating to treatments resulting in live births between 1 August 1991 and 31 December 2005, with each form sent to the HFEA

checked against the clinics' files and laboratory records.

This significant achievement has only been possible due to the help and co-operation we have had from the clinics with some centres going out of their way to help us in our work. We are very grateful for the positive responses that we have encountered and hope to continue these good working relationships as the project progresses.

Some clinics have also told us that this process has helped them gain a better understanding of the information that the HFEA needs and why it is needed, while we are also using the information gained to modernise the Register. For more information about the HAP project, contact Mike Gilbert at the HFEA on 020 7291 8282, or email [Mike.Gilbert@hfea.gov.uk](mailto:Mike.Gilbert@hfea.gov.uk)

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## Human Tissue Authority – latest developments

Progress is well under way on the setting up of the Human Tissue Authority, which came into effect on 1 April. Baroness Helene Hayman has been appointed as Chair and will oversee the implementation of the HTA. Fourteen other board members have been appointed (the full list can be found in the Press Releases section of the DH website [www.dh.gov.uk/PublicationsAndStatistics/PressReleases](http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases))

Sharmila Nebhrajani and Suzi Leather will sit on the HTA board as well as the HFEA and Baroness Hayman will become a member of the HFEA.

The HTA is currently recruiting a Chief Officer and senior management team, though a number of the HTA's administrative functions will be shared with the HFEA, before the planned merger of the two organisations in 2008. One of the HTA's first acts will be to run a consultation on the proposals for its Code of Practice.

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## Providing information for patients – Opening up the register

The Human Fertilisation and Embryology Act 1990 requires that the HFEA keeps a Register of people who have received regulated treatment or whose gametes have been stored. The Register also records all births that are the result of assisted reproduction. One of the main reasons for collecting this information from clinics is to allow information to be given to people who

have been born through assisted reproduction.

We are currently looking at the key issues involved in making information available in the understanding that the HFEA could receive its first official request for information from August 2007 (for people getting married at 16). As part of our preparation for handling requests for this information, we recognise that we may be dealing with a significant number of telephone enquiries which we will need to ensure that we can cope with.

The issue of how we release information to people is particularly important in the case of identifiable donors. Following the removal of donor anonymity from 1 April 2005, identifying information can be made available to individual offspring when they reach the age of 18 (i.e. from 2023 onwards). However it is possible for people who donated before 1 April to re-register at centres so that they may be identifiable to donor-conceived children once they reach 18. This means that any donors who re-registered could be contactable from 2009 onwards (if the child was born just after the creation of the HFEA in 1991).

We will be considering the need for a publicity campaign (including an internet-based publicity campaign) aimed at donor-conceived children, which is likely to be launched in 2006 once all the data on the Register has been compared to clinical records. This emphasises the need to complete the Historic Audit Project by this time which will bring clear benefit for donors and children for years to come. For further information please contact Karen Jackson Le Mare Records Officer on 020 7291 8291

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## Getting the views of patients

The HFEA is setting up a Panel of patients to help us monitor the views and interests of patients more effectively in our work. We are now starting to recruit to the panel which will be run online.

Panel members will be surveyed four times a year about their views, as well as having the opportunity to give feedback on any issues they wish to raise. This initiative will complement the introduction of patient feedback on inspection reports from June 2004 onwards.

The reports from the panel will be considered by the Authority and published on the HFEA website. The panel will be broadly reflective of the range of different patients at various treatment stages and former patients.

Patients will be recruited through a variety of ways including patient organisations, patient websites and through self-nominations. All clinics will be receiving publicity material shortly to give to patients.

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## The Government's review of the HFE Act

The Department of Health (DH) will be launching a three-month consultation on the review of the HFE Act this summer.

We are advising DH's on necessary changes to the Act. Our initial report to DH focuses on changes which are urgently needed, rather than a wholesale alteration of the entire Act. The report also considered the implications of the EU tissue directive.

Some of the key changes we recommended include:

- A more flexible approach to the Code of Practice and strengthening the role of professional bodies in their responsibility for the technical aspects of guidance and local quality systems
- strengthening the role of the Person Responsible and their responsibilities – including selection, training and commitment to compliance
- relaxing the confidentiality requirements of the Act to help share information with other organisations and registers
- reviewing storage periods
- ensuring regulation of internet providers
- issuing clinical trial licenses to help with introducing new techniques and technologies into clinical procedure

Over the next few months, we will be talking with other organisations to help further develop our guidance on changing the Act.

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## Updating the 'Welfare of the Child' guidance

We have had a good response to the public consultation on the 'Welfare of the Child' guidance, which closed on 7 April.

We have been able to gather the experiences and views of a wide range of individuals and organisations, both from written submissions and from the four consultation meetings that we held across the UK.

This information has been enormously helpful for the development of new guidance, which we expect to be ready in the summer.

For further information on the review please contact Juliet Tizzard, Policy Manager at [juliet.tizzard@hfea.gov.uk](mailto:juliet.tizzard@hfea.gov.uk) or on 020 7291 8232

## Member Focus



### Member Focus

**Hossam Ibrahim Abdalla** MRCOG, Director of the Lister Fertility Clinic

Sam has many years of distinguished work as Clinical Director of the Assisted Conception Unit at The Lister Hospital where he has been at the forefront of new technologies in fertility treatment. His special interest has been in egg donation, with The Lister running a major egg donation programme. His work has resulted in the first baby conceived from a donated embryo which had been frozen, thawed and transferred back to the fallopian tubes. He has also pioneered treatments in therapeutic pelvic surgery. Sam trained in medicine at the University of Baghdad in 1977, moving on to Glasgow where he completed his MRCOG in 1983.

### Help us improve our website

Please fill in our online survey at [www.hfea.gov.uk/sitesurvey](http://www.hfea.gov.uk/sitesurvey)

## The new 'HFEA Guide to Infertility'

The new 'HFEA Guide to Infertility and Directory of Clinics' will be published at the end of May.

The Guide has been planned with input from clinics and patients and, this year, every HFEA-licensed clinic has a full page listing including outcome data for different ages and treatments.

It also provides information about different treatments as well as issues such as the financial and emotional costs of treatments. This edition has been updated to reflect changes such as the lifting of donor anonymity and the move toward the implementation of the NICE guidelines.

We have also produced an interactive version of the guide for the website so that people can search for a clinic according to their own criteria.

We encourage you to make full use of the new Guide and to send copies to people who are enquiring about services. Bulk copies can be ordered by emailing [nathalie.hart@hfea.gov.uk](mailto:nathalie.hart@hfea.gov.uk)

## Contacting the Regulation Department

We have simplified the way that you can contact the Regulation Department following our recent reorganisation. Please use the following numbers:

General Queries (including Import/Export, centre-specific queries, Licensing and Committee queries)	020 7291 8251
Patient Complaints (office hours)	020 7291 8255
Research-related Queries	020 7291 8256
Out-of-hours Incidents number	07717 131244

If we cannot resolve your query at the time of your call, we will take your details and get back to you within three working days.

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

Please contact [benedicte.venn@hfea.gov.uk](mailto:benedicte.venn@hfea.gov.uk)

### Diary Date:

The Authority's next Open Meeting will be held in central Cardiff on the morning of 18 May. If you would like to attend as an observer, please email [openmeeting@hfea.gov.uk](mailto:openmeeting@hfea.gov.uk) for more details and to reserve a place.