



Welcome to the November issue of HFEA Update.

## INSIDE

**The HFEA's Advisory Group on Safety and New Technologies**

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**Patients' complaints to the HFEA**

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**Disclosure of information relating to gamete donation**

This issue informs centres of recent developments such as the newly established Advisory Group on Safety and Technology and offers an overview of the patients' complaints received by the HFEA over the last four years.

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

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### **Advisory Group on Safety and New Technologies**

The HFEA has established an Advisory Group on Safety and New Technologies (SANT). This follows on from previous work looking at risk in ART, and ongoing analysis of reported incidents. It also relates to the forthcoming requirements under the EU Directive on Tissues and Cells concerning labelling, coding, and traceability.

The Group which is chaired by Maybeth Jamieson includes members from within the ART sector, as well as external members with relevant expertise in laboratory solutions and accreditation.

The Group will advise the Executive on ways of improving safety in assisted conception clinics, including the use of technologies that are new to the ART sector. Outputs from the Group will be used by the Executive in developing policies for consideration by the Authority. The Group will not endorse any particular technology or product.

#### **The main tasks of Group are to:**

- Consider the role of new technologies and their application to IVF clinics, taking account of the requirements of the EU Tissues and Cells Directive;
- Consider ways of reducing the risks of mismatching;
- Develop guidance for clinics on risk assessment, clinical governance and handling communication around risk, safety and adverse incidents;
- Look at methods of root cause analysis and associated training needs;
- Advise on the development of an evidence base to support good practice solutions;
- Investigate support required for pre-registered and newly registered embryologists, and andrologists.

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HFEA UPDATE

In its first meeting on 29<sup>th</sup> September the Group agreed to focus on reducing the risk of miss-matched material in the laboratory and to explore how 'new' technologies might affect the HFEA policy on double witnessing. It will also consider solutions in the wake of the labelling, coding and traceability requirements of the Tissue Directive.

The Group is also gathering information on products offering electronic witnessing and inventory checking in dewars, using radio frequency ID and bar coding systems. This includes an assessment of how these technologies might best be used to improve safety in clinics

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## **Patients' complaints to the HFEA**

The HFEA has analysed all the complaints made by patients to the Authority during the period April 2000 to August 2004. Although the number of complaints is relatively small (220, relating to 62 clinics in all), they are a valuable source of feedback from patients, enabling centres to improve the service offered.

The HFEA can only follow up complaints where there is a breach or potential breach of the HF&E Act, or of the Code of Practice. We receive some complaints that do not fall within these criteria and which we do not follow up, although they are noted and can help to inform our inspection process. We recognise that most patients receive excellent care in well-managed centres. However, we thought it would be helpful to share some of the feedback we have received with centres, in the interests of continuing improvement.

The majority of complaints relate to what goes on in the consulting rooms. Interestingly, this contrasts with reported incidents, which mostly occur in the laboratory. Many complaints are multi-faceted, often linking insufficient information and attitude.

### **The four main categories of complaint were:**

- **Consultation** – the subject of by far the greatest number of complaints.

Concerns raised included staffing levels, professionalism and competence, lack of discussion about clinical strategy and anxiety that the consultant was not aware of all the relevant medical information.

- **Information** – we received complaints about both too much and too little information being given, concerns about conflicting information and the time at which the information was provided, and not being able to get through to the right person for information. Complaints were also made about inadequate feedback from clinics about the waiting list position and about results.
- **Finance** – some patients did not understand the justification for particular treatments and the high charges associated. There were also complaints about compensation claims and cost disputes.
- **Attitude** – these complaints were broad-ranging, but revealed strong views. Comments included feeling "part of a conveyor belt system" and being treated "like a slab of meat". Centres seemed only interested in making money, used inappropriate humour, lacked awareness of patients' distress, and were dismissive towards patients.

It is clear from these results that patients want dialogue, not monologue, more attention to privacy, dignity and respect and greater recognition of the stressful nature of IVF treatment.

All centres are being given anonymous details of the distribution of complaints. In addition, the 62 centres will receive information about where they sat on the scale of complaints compared with centres of a similar size.

To read the complaints analysis, click on: <http://www.hfea.gov.uk/AboutHFEA/AuthorityMinutes/2004/October2004/HFEA%20Complaints%20analysis.pdf>

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## **Disclosure of Information relating to gamete donation**

The HFEA has recently advised centres on the information they may disclose to donors, recipients of donor gametes and donor-conceived people. Some of the implications of this letter are set out below.

*Will identifiable donors be informed when someone born as a result of their donation applies to the HFEA register to receive information about them?*

Yes, the HFEA will endeavour to contact donors when someone born as a result of their donation applies for **identifying** information about them. Requests may only be made by those who are over 18 and born as a result of donations from donors who register with clinics after March 31, 2005 (including those born as a result of donations from past donors who re-register after that date). Donors should be encouraged to supply up-to-date contact details. The HFEA will not contact donors when an application for **non-identifying** information has been made.

*Can I tell donors how many live births have resulted from their donations?*

Yes, provided you are satisfied that will not lead to the identification of any of the recipients of the donor's gametes or anyone born as a result.

*Can I give donors any information about the recipients of their gametes?*

Yes, if you are satisfied that the information you give cannot lead to the identification of any of the recipients of the donor's gametes or any offspring.

*Can I give recipients of donated gametes any information about the donor?*

Yes, provided the information you give cannot lead to the identification of the donor. You may give non-identifying information, i.e. the donor's physical characteristics, religion, occupation or interests, and any 'donor code' assigned to the donor by a clinic.

*Can donors and recipients get this information from the HFEA?*

Yes, although the information held by the HFEA will be more limited than that held by clinics. For this reason, and because people making these enquiries are likely to have existing contacts with a clinic, those seeking information about their donations or treatment should first approach their centre.

*What information am I not allowed to give to donors or recipients of donated gametes?*

You may not disclose any information that either identifies, or could lead to the identification of, a person other than the person seeking the information or a member of their family. This includes information that could be used in conjunction with other information that a person might have access to (information in the public domain) to deduce or infer the identity of the person concerned.

*What should I do if I am unsure whether the information required could lead to the identification of a person concerned?*

If you are concerned, you should seek legal advice. If you decide not to give out information because you believe that it is potentially identifying, you should explain your reasons to the person requesting the information.

*What information or counselling am I required to offer or provide for people requesting information?*

There is no formal requirement to offer or provide counselling for people requesting information. However, you should give them the opportunity to consider the consequences of receiving such information (or of the information being unavailable) beforehand. You should also be prepared to answer questions about the disclosure of information and should help them identify a qualified counsellor if needed.

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## Member Focus

### **Professor Neva Haites, Vice-Principal and Head of College of Life Sciences and Medicine, University of Aberdeen**

Neva Haites brings to the HFEA her expertise as a clinical geneticist. She joined the HFEA in 2002 and whilst continuing to work in medical genetics at the University of Aberdeen she manages to travel to London three times a month. Neva has recently taken up the post of Vice-Principal and Head of College of Life Sciences and Medicine – the first woman in the 500 year history of the University of Aberdeen to become Vice-Principal.

Neva now manages four Schools with a total of one thousand staff, still occasionally sees patients and does a little teaching. On top of this, she is the medical genetics advisor to the Chief Medical Officer for Scotland and is a member of a number of other committees such as the Department of Health's advisory group on genetic research.

Originally from Australia, Neva now lives with her family in Aberdeen – where she has been for 30 years. She loves reading, golf, travelling and is a keen member of the local curling team.

Neva decided to become a member of the HFEA because she felt it would be an interesting role to play linking her clinical background to infertility and research. "I like being at the forefront of a challenging field" she says, "I would ideally want to see a move to single embryo transfer."

Neva is the Chair of the HFEA Scientific and Clinical Advances Group and is a member of the Ethics & Law Committee, Information Management Project Board and Licence Committees.

## Giving patients contact details

If you are asking patients to fax any confidential documents to you, please can you aim to confirm the number with them at the time? Due to a technical error on the HFEA website, an incorrect fax number was listed for a clinic, and this was used by a patient, with documents going to a different centre. If you are giving the HFEA number to your patients, would you ensure that you give the switchboard number only (020 7291 8200), rather than any direct lines for staff that you may use. This will prevent situations where patients have to be re-routed within the HFEA.

## SEED review

The HFEA's consultation on the regulation of Sperm, Egg and Embryo Donation (SEED consultation) was launched on 12<sup>th</sup> November. An online questionnaire of the consultation document can be found on [www.hfea.gov.uk/AboutHFEA/Consultations](http://www.hfea.gov.uk/AboutHFEA/Consultations). Paper copies are available on request from the HFEA. Further information about the SEED Review is available at [www.hfea.gov.uk/AboutHFEA/HFEAPolicy/SEEDReview](http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/SEEDReview).

## Staff Changes

**Stephanie Sullivan** joined as Head of Patient Safety & Clinical Governance; **John Paul Maytum** is joining as Head of Media Relations on 29<sup>th</sup> November. **Debra Bloor & Imogen Swann** joined as Regulatory Managers; **Sally Townsend** joined as Head of Finance whilst Rachael Henry is on maternity leave.

**Diary Date:  
HFEA Annual  
Conference  
2005**

*Thursday 15<sup>th</sup>  
March 2005  
(London)*

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

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HFEA PROFILE