



Should embryo screening help parents prevent passing on a wider range of inheritable diseases?

In early November, the HFEA launched a debate to seek the public's views on the appropriateness of using fertility treatment technology to screen out serious genetic disorders such as inherited breast cancer.



The HFEA has launched the debate with a discussion paper *Choices & boundaries* which looks at key questions raised by the embryo testing technique known as preimplantation genetic diagnosis (PGD). People are being asked to give their views on where they feel the boundaries should lie on which conditions PGD can be used to test for.

The paper will be followed by a public discussion meeting in London during December. The outcomes of both the paper and the discussion will be considered by Authority members, who license the specific PGD screening tests that individual clinics can use.

Embryo screening using preimplantation genetic diagnosis (PGD) is already used to enable parents with a family history of serious conditions, such as Cystic Fibrosis and Huntington's disease, to avoid passing the faulty gene which leads to their condition on to their

children. This discussion will focus on those disorders where the conditions are not 'fully penetrant' (i.e. where not all people with the gene will get the disease).

Such diseases include:

- inherited breast cancer
- inherited ovarian cancer
- hereditary Non Polyposis Colon Cancer

The discussion will seek to find out where the majority of people feel the ethical boundaries of PGD lie and will focus on whether it should be used for lower penetrance disorders, such as the cancers above.

In order to take part in the discussion, The Choices and boundaries paper is available to download at www.hfea.gov.uk

To request a place at the PGD meeting in London on December 12, please email pgd@hfea.gov.uk

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HFEA Update

Human Fertilisation and Embryology Authority Newsletter



Update your information

The HFEA is preparing information for the next edition of the **HFEA guide to infertility** to be published in April 2006. The information in the guide should be as accurate as possible and we are asking Centres to verify or correct the following:

- the information that we hold about individual centres
- the information that we hold about treatments relating to the year 2003 / 04.
- spreadsheets showing the raw data for each Centre.
- instructions on how to read the reports and amend information.


You will soon receive an information pack containing:

- a copy of the draft Centre page for the guide.
- exception reports generated against forms received by the HFEA.

In order for the HFEA to meet production deadlines for the next edition of the Guide we need to receive returns by Tuesday 17th January 2006. Your quality audit officers can answer any queries that you may have. If the HFEA does not receive updated information about individual centres these pages may appear blank in the guide.

The HFEA guide to *infertility*

The Human Fertilisation and Embryology Authority has produced a **FREE 'HFEA guide to infertility'**. It is the patient's choice for information about all aspects of infertility.




The guide includes:

- a straight talking introduction to infertility, possible causes, and different treatment options.
- descriptions of the range of treatments available, including IVF, ICSI, IUI and Donor Insemination.
- a listing of all the licensed clinics and treatment centres providing fertility treatment in the UK
- detailed information on the success rates for every clinic, by different treatment and patient age group.
- personal stories by people who have had infertility treatment, and what they learnt from their experience.
- questions for patients to ask their doctor, and issues to consider including treatment costs and emotional support.

Order free copies of the 'HFEA guide to infertility' for your surgery or clinic by emailing admin@hfea.gov.uk or calling 020 7291 8200 mentioning the NHS Alliance.

An interactive version of the guide is available on our secure website at www.hfea.gov.uk. Enter details such as your location, or the required treatment, and age of the patient and the site will provide a list of suitable clinics.

Please call 020 7291 8200 or go to www.hfea.gov.uk



New head of inspection — Marion Witton

Marion has joined the HFEA on secondment from Ofsted. As the Divisional Manager for the South East Region of Ofsted's Early Years Directorate she was responsible for the regulation and inspection of 20,000 children's day care providers through 200 home based inspectors and 100 office-based administrative staff.

Prior to joining Ofsted, Marion was head of the joint inspection unit at the London Borough of Barnet, with responsibility for registering and inspecting residential care homes, nursing homes, clinics, independent hospitals, boarding schools and children's day care services.

In 1994, Marion became the Chair of the National Heads of Inspection and

Registration, a group representing all Inspection Units in England and Wales, with members from each regional group. As a representative of the group, Marion has contributed to major guidance documents, such as 'Eating Well for Children under 5 Years', 'Inspecting Social Services' and the Residential Forum's 'Creating a Home from Home'.



Marion is currently undertaking a part time post graduate diploma in law at BPP law school. Other interests include theatre, gardening, fine wine and she is a Fellow of the Royal Society of Arts.

Review of the Human Fertilisation and Embryology Act – HFEA consultation response



The HFEA has now completed its response to the Department of Health's consultation on the Review of the HFE Act. As a framework, the current model of regulation has worked well and should continue. However, our response also reflects our view that the new Act needs to keep in step with new developments in treatment and research and provide for more proportionate, efficient and flexible regulation.

Safety and consistency of treatment standards are also important concerns. We have recommended the same standards—including the welfare of the child assessment, should apply to treatments using fresh gametes as they do to other forms of licensed treatment. This will help address issues such as the risk of multiple births associated with GIFT and IUI. We also support the government's proposal to regulate the supply of gametes via the internet. To balance this, we recommend more flexibility around the inspection process and the ability to carry out more targeted and risk-based inspections.

In order to facilitate better training practices, we have recommended the introduction of training licences. Similarly, we support the introduction of clinical trials licences for the controlled introduction of new techniques and technologies into clinical practice.

We believe the law should continue to set a framework for maximum storage periods for gametes and embryos but we consider that the current provisions should be made more 'patient-friendly'. For example, it should be possible to extend the storage period for donated sperm for the creation of siblings and we also recommend an extension of storage periods for embryos for surrogacy or donation.

We agree with the government about the importance of a centralised register for information purposes. In addition, we have recommended that information held on the register should be available for future follow-up studies. This would be facilitated by relaxing the existing confidentiality

provisions for assisted reproduction treatments which we believe should be brought into line with the protection given to other medical information.

The consultation includes several proposals on the regulation of embryo research. Our response takes the view that the legislative framework should be broadly permissive of research on human embryos on the condition that this remains within the 14 day limit. We are, however, very aware that public opinion remains cautious and divided over the ethics of human embryo research. We believe before techniques – such as genetic modification of embryos – are used for treatment purposes, there should be an opportunity for wider debate, both by Parliament and the general public. We have recommended the new Act contain regulation making powers to this effect.

We also recommended that the new regulatory body, RATE, should retain certain functions that are distinct to the HFEA's current remit. These should include protecting patient safety and the inclusion of the welfare of the child assessment in all decision making. In order to prepare for the implementation of the Tissues and Cells Directive, we have already started a process of involving the professional bodies in the drawing up of technical standards and we envisage that this process will be formalised under RATE. Not all decision making in this area will be suitable for parliamentary process and we have recommended that the regulator should retain an evidence-based policy making and advisory function. In order to strengthen this role, we have asked for it to be clarified in legislation.

Our full response will be available on our website at www.hfea.gov.uk/response



SEED report launched

Today's sperm donors are much more likely to be family men in their 30s than the old stereotype of hard-up medical students, according to new analysis of information about sperm and egg donors from the HFEA Register.

This analysis was released alongside the conclusions of the Sperm Egg and Embryo Donation report (SEED) following a detailed public consultation earlier in the year.

The analysis showed that in 2004-05:

- more than 2 out of 3 sperm donors (69%) were aged over 30
- the most common age range for sperm donors is 36-40
- more than 2 out of 5 sperm donors (41.5%) already have children of their own
- just under a third of sperm donors (31.4%) have two or more children

The SEED report was designed to ensure the system around donation and donor treatment is as simple and straightforward as possible while ensuring safe and appropriate treatment for donors, patients and donor-conceived children.

The report's conclusions focus on the following areas:

- donor screening – moving towards one set of professional guidance for clinics on screening donors.
- selection of donors - less prescriptive guidance on how clinics must select donors for the treatment of each individual.

- compensation for donors – in addition to the reimbursement of reasonable expenses, donors may receive limited compensation for loss of earnings. Donors may receive discounted treatment as a benefit 'in kind' for donation.
- limits for the use of donor gametes – a donor's gametes may be used to produce children for up to 10 families in the UK. New guidance will also be introduced to help clinics monitor the use of a donor's gametes to ensure that the limit for their use will not be exceeded.
- import of donor gametes from abroad – in order to maintain the high UK standards, donated gametes can only be imported where comparable standards have been met

Full guidance for clinics will be sent out in early 2006. To access the SEED Report in full, and the recent analysis on sperm donors, please visit <http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/SEEDReview>

New system of welfare of the child assessments

The HFEA published the outcome of its review of welfare of the child assessments in licensed centres in early November. Following an extensive period of research and consultation, the HFEA has developed a new system of assessments which is designed to focus attention upon high risk circumstances, leaving the majority of patients to proceed with treatment with the minimum of disruption or delay.

The key aspects of the new system are:

- there should be a presumption to provide treatment, unless there is evidence that the child to be born, or any existing child of the family, is likely to suffer serious medical, physical or psychological harm.
- the factors centres should consider focus upon risk of serious medical, physical or psychological harm to the child. Social factors have been removed from the assessment.
- medical and social information will now be collected from the patient themselves, with follow-up to GPs or other agencies *only* when centres consider that there may be a risk of serious harm.
- donor conception patients should undergo the same assessment process as other patients, but should be provided with information about the implications of treatment. Clinics should encourage and prepare such patients to be open with their children from an early age about the circumstances of their conception.

- patients undergoing unlicensed treatments which involve the handling and manipulation of gametes outside the body for example, IUI and non-donor GIFT should undergo the same assessment as patients having licensed treatment.

A wide range of stakeholders—particularly patients and centre staff, contributed to the review, either through our initial clinic and patient survey, the four consultative meetings or the written consultation process. Their input helped us to understand the limitations of the previous guidance and to develop new guidance which, we hope, is practical, proportionate and fair.

Although centres may implement the new guidance as soon as they wish, the deadline for implementation is 1 January 2006.



More details about the new policy and the evidence base for it can be found in the report of the review, Tomorrow's Children, which is available, with the new guidance, on the HFEA's website at www.hfea.gov.uk

If you have any further questions about the review or the new guidance, please contact either your Inspector or Juliet Tizzard, Policy Manager, on 020 7291 8232 or email juliet.tizzard@hfea.gov.uk



Up and coming projects

Historic Audit Project

The Historic Audit Project recently passed the two thirds mark and has both plans and resources in place to complete the project at centres on time by 31 March 2006.

Parallel to the HAP exercise, we have started to produce reports which identify errors in the Register data. The first of these has been sent to centres for the treatment period April 2003 to March 2004 as part of the 2006 HFEA guide to infertility validation and verification work. We encourage you to treat this as a priority over the Christmas period. We will be publishing the statistics for each clinic in April 2006.

The roll out of Electronic Data Interchange (EDI) is ongoing, with activity increasing each week. Centres are keen to move to EDI although, due to limited staff we have experienced delays in rolling this out. Our priority has been implementing EDI to centres without an Electronic Patient Record (EPR) system.

A strong reliance exists on suppliers of "commercial" EPR systems to modify their products to integrate with the HFEA EDI system. Most suppliers appear confident in making the

necessary software enhancements available to their customers by the end of March 2006. Please contact your supplier for further information.

We would like to thank you for the support, flexibility and positive feedback provided to HAP teams by those centres that we have visited. We look forward to working with the remaining centres.

For more information on HAP please call HFEA on 020 7291 8200 or Email mike.gilbert@HFEA.gov.uk

EDI implementation

EDI standalone service is now being rolled out to clinics without Electronic Patient Record Systems (EPRS). 33 installations have been made with a further 16 more to complete. Feedback from the clinics using EDI is continuing to be positive with clinics using the validation report functionality to help maintain accurate data within the HFEA Register.

We are currently working on an integrated version of EDI with the suppliers of clinic EPRS Systems. This solution will allow you to continue to enter details into the EPRS as usual but the data will be passed from the EPRS to the HFEA's EDI System. The data will be submitted electronically to the HFEA which means you will no longer have to print out the forms and post them into the HFEA. The rollout

timescale depends on your EPRS supplier and the HFEA will encourage them to progress this as a priority.

In both cases the HFEA will supply a PC, keyboard, and screen to every clinic to facilitate EDI.

Completion is due for all clinics by April 2006.



For more information on EDI please call HFEA on 020 7291 8200 or Email david.moyesen@HFEA.gov.uk

Fertility Views - Our virtual Patients Panel

Aims to give patients a greater voice in the affairs of HFEA.

750 prospective, current and past patients on the panel have now given their first responses.

What issues are most important to patients?

The main issues were:

- The financial pressures of the cost of treatment; value for money; why costs vary between clinics
- Success rates: the likelihood of successful treatment; variation in success rates between clinics
- Waiting lists and times
- The availability of, and difficulty of getting, NHS funding
- The emotional effects of fertility treatment

Getting information & choosing a clinic

GPs were rated the most important first port of call for people wanting more information about infertility and advice on next steps. The majority (79%) found success rates helpful when choosing a clinic and (77%) when deciding what questions to ask the clinic. Over half (67%) used them when looking at the chances of getting pregnant and (60%) when asking a GP about treatment options. Half (57%) took them into account when assessing value for money of a clinic's treatment. Our *Guide to Infertility* was welcomed but there was a strong plea to simplify information and how data is presented.

How satisfied are patients?

Over half (60%) rated satisfaction with services 7 or above out of 10, with 10 being the highest rating. Nearly 1 in 5 rated the service 4 or below, with the average rating for a clinic being 6.66.

Suggestions for improving overall services

- Waiting times could be improved
- Better information and advice
- GPs to be more aware of infertility
- Make the service more personal for patients

Getting support

Half (52%) felt they were getting a little or a lot of emotional support from their clinic, 22% felt they were getting no support at all. The majority (61%) are receiving it from their partner, family and friends against only 8% from medical staff, 7% from counsellors and only 2% from patient groups. Panellists considered the 'human' aspects of services, such as emotional support and customer service, to be of greatest value.

How is the HFEA performing?

Most (69%) knew a little about the HFEA, with only 15% knowing a lot about the organisation. Half (50%) believe the HFEA protects the interests of patients, only 12% stated that it does not, 39% didn't know. On scientific advances, more than half of respondents believed that the HFEA is keeping up-to-date, with 39% stating that they didn't know. On the adequacy of ethical scrutiny of fertility treatment: more than 70% believe there is, 7% there is not, and 22% don't know.

Patients wanted a regulator to inspect clinics regularly, ensure safety in clinics, monitor standards and support patients in terms of information. Of these, inspection was regarded as key in providing trust and confidence in the way fertility treatment is regulated in the UK.

What patients want the HFEA to do?

Lastly, the panel were asked what issues we should focus on. The following suggestions were made:

- ensure equality or consistent standards between clinics
- ensure more up-to-date information to patients
- monitor success rates and why they vary and take action against poor performers

The full report can be accessed at www.hfea.gov.uk under Public Events - October 2005 Open Meeting Papers.





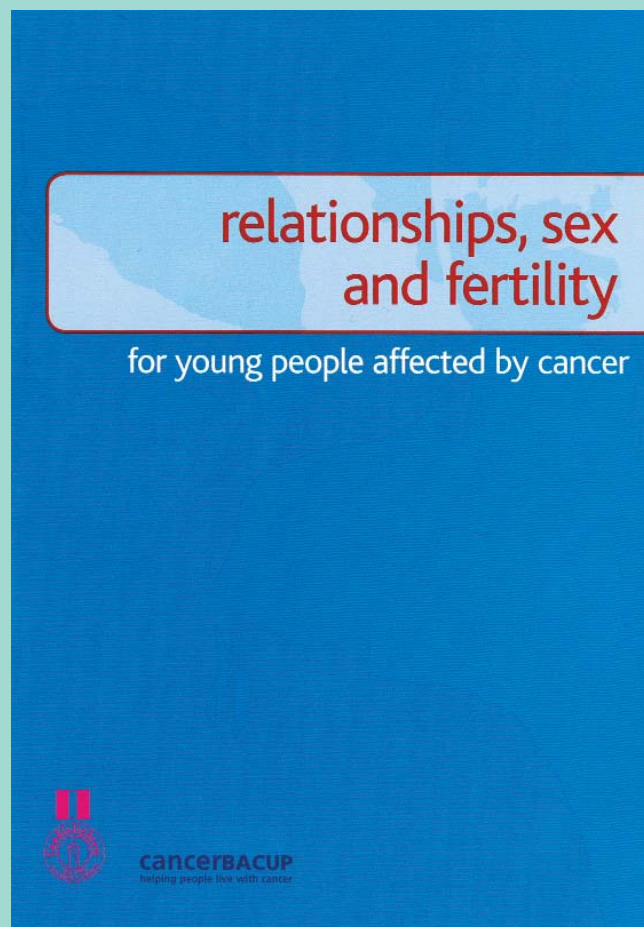
CancerBACUP launches new booklet

CancerBACUP has produced a new booklet *Relationships, sex and fertility— for young people affected by cancer*. The booklet outlines possible fertility complications due to cancer treatments and avoids using complex medical terms.

The idea originally came out of research undertaken by the University of York into the sperm banking experiences of several young men in the Newcastle and Leeds areas. The commitment to develop information materials was included in a follow up study, which is funded by Candlelights' Trust. A survey by CancerBACUP, found that nine out of ten (93%) teenagers with cancer are worried about fertility, and more than seven out of ten (72%) said that the biggest information gap was the effect of cancer on their sex lives.

The booklet was co-authored by scientists, paediatrics oncologists, reproductive physicians, infertility counsellors, social workers and academics. It is designed to help young people at any stage from diagnosis right through to 'late effects', services and adulthood.

The booklet costs £1.95 for clinics and is free to patients. CancerBACUP can supply promotional material including posters and holders for display in your reception area. For more information go to www.click4tic.org.uk



Reminder for centres

Centres are reminded to advise the HFEA of any adverse incidents that occur at the treatment centre within 24 hours. An incident form is available on the centres website. You can fax it to 020 7291 8201 or email it to angela.sanford@hfea.gov.uk

Centres are also reminded that Alerts are published on the centre's website at <http://centres.hfea.gov.uk>. If you require a username and password send an email to paul.davies@hfea.gov.uk