

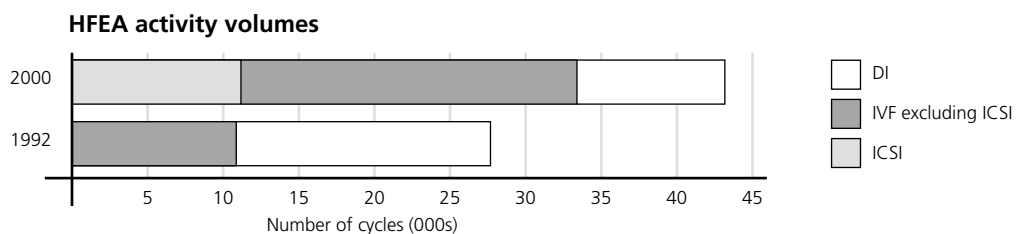
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# HFEA consultation on the modernisation of regulation and new fee strategy

## EXECUTIVE SUMMARY

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- The Human Fertilisation and Embryology Authority has established a strong reputation for the licensing and regulation of treatment and research involving embryos and stored and donated gametes.
- The statutory regulatory responsibilities of the HFEA include: the licensing of clinics and research centres, routine inspection visits and inspections to investigate adverse incidents, data registration and the provision of information.
- The HFEA has managed its first decade as a low cost organisation with a limited infrastructure. The budget has remained constant at around £1.0 – 1.5million since the HFEA was created by the Human Fertilisation and Embryology Act 1990. Recent reviews of the organisation confirm that resource and staffing levels are no longer adequate to meet current workloads, which have expanded rapidly since HFEA was formed, as illustrated below.



- In addition, government and public expectations of regulation have increased and the HFEA needs to improve and modernise its practices to develop a more robust and transparent regulatory framework
- The required improvements will require significant additional funding to increase the budget of the HFEA to about £4 million.
- It is Government policy that the costs of regulation should be met by those being regulated, and that the cost of a service should be reflected directly in the fees charged.
- Traditionally, income to meet the costs of regulation has been derived from fees levied to patients for each cycle of treatment. The fee per cycle of in-vitro fertilisation is small (£40) relative to the cost a patient might expect to pay for the treatment (around £1,200 plus drugs costs). The fee per donor insemination cycle is £20. However, under this system, individual patients bear the costs of a raft of regulatory functions – for example those concerning research or the investigation of adverse incidents – that do not relate directly to their care.

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- The HFEA wishes to devise a new structure of fees to support its regulatory function that is fair and equitable, and that accords with Government policy.

Such an increase in fees would result in significant improvements to the regulatory function that would benefit those who provide and make use of licensed infertility services.

In order to provide fees funding of approximately £4m, the HFEA has considered the following options in relation to the principles set out above.

### **Option 1**

## **Introduction of new licence fees** (HFEA preferred option)

This system would introduce a much increased fee for new licence applications; a fee to be applied to applications for variations; an annual fee for each licensee; and a fee to be applied where HFEA provides an additional inspection. It is estimated that together these fees would raise approximately £2m.

The existing treatment fees would be retained and increased to £50 for IVF and £25 for DI. It is estimated that these fees would raise approximately £2m.

This approach would align fees with the cost of providing services and would lead to a much more transparent link between service and fee charged.

Such a model would be structured around the following components:

### **Initial fees**

**Application fee** Charged to new clinic to cover provision of new licence including: advice; induction; initial inspection; licence committee consideration; interim inspection.

### **Additional fees – Clinics**

**Annual fee** Inspection of clinic and renewal of licence. Provision of range of support services: publications, communications and policy.

**Variation fee – Administration** Variation to statutory information such as change in Person Responsible or registered address.

**Additional Inspection fee** Additional inspection and/ or variation to licence conditions to cover: induction and inspection as appropriate and the monitoring of adverse incidents.

### **Additional fees – Treatment**

**Treatment fees** Contributes to the cost of operating Register and patient information services

Details of proposed fees are shown at Appendix 1 of supporting document.

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# Key objective of this consultation

To design a fee structure to support the licensing and regulatory functions of the HFEA that is equitable, in accordance with Treasury Guidance, and that generates the necessary funding, currently £4 million.

## Option 2

### Present system but with higher treatment fees

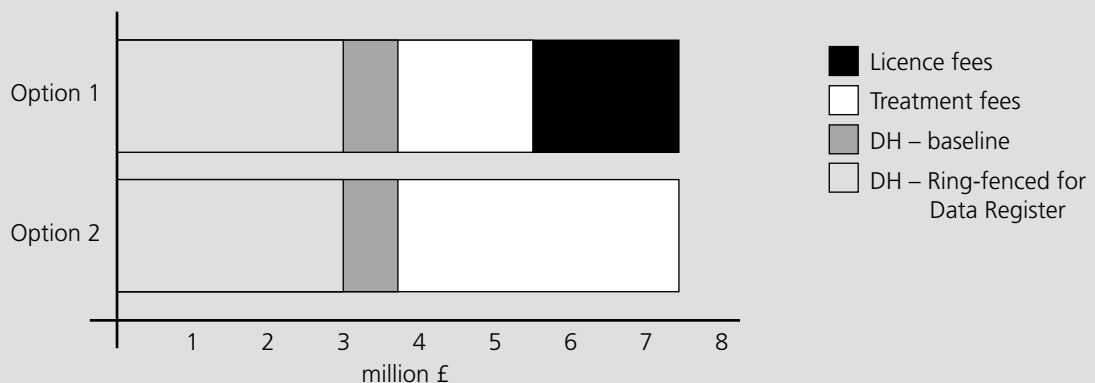
This system is easy to administer but there major disadvantages. In particular the initial application fees are far smaller than the cost of providing this element of service. As a result nearly all the fees are accrued to patients. This leads to the perception of HFEA fees as a 'patient tax' rather than a necessary overhead of the assisted conception service.

This system also means that the cost of novel techniques, new licence applications, and the cost of investigations and additional inspections resulting from poor practice are passed directly to patients in a manner that is far from transparent and in no way linked to clinics with poor practice.

Under this model treatment fees would rise to £100 for IVF and £50 for DI generating a total of nearly £4m.

Research licence fees would continue to generate just £22,000.

Overall the funding of HFEA under these two options would be as follows:



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The HFEA is seeking views on the following questions:

1. Which of the above options is the most appropriate means of raising the income that is required to support its regulatory function?

*The HFEA would also welcome responses to the following supplementary questions, in addition to general observations about the role and organisation of the HFEA.*

2. The proposed fee structure (Option 1) includes a fixed annual fee for treatment clinics. Views are sought on whether a modified approach should be developed, to provide somewhat lower fees for very small clinics engaged in simple processes with a compensating higher fee for large clinics engaged in more advanced techniques.
3. Who should pay for the cost of regulating research licences?
4. How could the HFEA develop its practices to meet more effectively the needs of the clinical and scientific communities, patients involved in assisted reproduction, and policy makers?

A 'response sheet' can be found at page 19 of the supporting document.

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