

HFEA consultation on the modernisation of regulation and new fee strategy

Key objective	2
Introduction	3
HFEA responsibilities	4
Clinic licensing	
HFEA Inspection Visits	
Investigation of adverse incidents	
Data registration	
Provision of information	
Research	
HFEA funding and organisation	7
HFEA funding	
Changing needs and expectations	8
HFEA activity volumes	
Options for new strategies and funding	10
The new HFEA Strategic Mission	
Principles behind the fee strategy review	
Potential changes	
Possible fee options	
Option 1:	
Introduction of new licence fees	
HFEA preferred option	14
Option 2:	
Present system but with higher treatment fees	15
Appendix 1:	
HFEA fees	17
Response sheet	19

The Human Fertilisation and Embryology Authority (HFEA) is committed to furthering best practice in its work. This commitment includes regular consultation with all relevant stakeholders. This consultation paper is a contribution to that dialogue.

It includes a review of existing HFEA practices, some proposed new practices and a structuring of services based upon the ever-increasing demands placed upon the HFEA.

Recommendations are based upon recent reviews and evaluations of the HFEA's work, and its need to keep pace with the rapid scientific, clinical and social developments relating to human fertility and embryology in the UK.

This document is part of a wider consultation process that has involved formal discussions and informal discussions with key stakeholders.

Key objective

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.

Introduction

1. The HFEA was the first statutory body of its kind in the world. In the decade since its creation by the Human Fertilisation and Embryology Act (1990), the HFEA has established a strong national and international reputation for the licensing and regulation of treatment and research involving embryos and stored and donated gametes. It is now recognised as a worldwide authority on infertility regulation.
2. The HFEA model of monitoring and licensing of clinical centres provides a system of checks and measures to ensure the highest possible standards of clinical services. The HFEA's expertise and opinion is sought regularly by Government, the medical profession, the media and the general public. The reputation of the Authority has helped to ensure that the UK is well placed to lead and support the development of international research into embryonic stem cell lines.
3. The HFEA's primary objective and remit remains the licensing and monitoring of clinics and centres carrying out *in vitro* fertilisation, donor insemination and human embryo research. (This includes regulation of the storage of gametes and embryos.) This remit to licence embryo research was expanded to incorporate new regulations passed in January 2001 enabling the use of embryos for research into causes and treatment of serious disease.
4. HFEA's other statutory functions include
 - Producing and updating the HFEA *Code of Practice*.
 - Keeping a register of information about donors, treatments and children born as a result of treatment.
 - Providing advice, information and support to patients, donors and clinics.
 - Reviewing research developments that relate to human embryology, and advising the UK Secretary of State and others on the relevance of this research to existing and new clinical practice and policy.
5. The HFEA's Members determine HFEA policy and also review and evaluate all treatment and research licence applications. Members of the HFEA are appointed by the UK Health Minister in accordance with guidance for the Commissioner of Public Appointments. Membership is not confined to the medical profession, rather membership is actively sought from all stakeholders in the increasingly complex arena of fertilisation and embryology. Lay members must make up a majority of the Authority, and the Chair and deputy Chair are lay members.
6. The HFEA Executive is responsible for implementing HFEA policy, licensing decisions and all other related financial, research, communications and awareness-raising initiatives.

7. Today, the HFEA is a high profile institution working in an area of rapidly evolving public policy and practice. The HFEA seeks to serve the interests of all stakeholders in research and practice, but particularly patients, children, the clinical and scientific community, the Government, and public bodies such as the Medical Research Council (MRC) and the Human Genetics Commission (HGC). The primary focus of the HFEA's work is on the needs of patients and their children, the management of clinics, and addressing public and media anxiety relating to fertilisation and embryology. The HFEA also plays a vital role in informing and – where appropriate – leading public and professional debate on issues arising from developments in infertility treatment and genetics.
8. The HFEA relates to a large number of public and private institutions and groups. The HFEA actively seeks productive and co-operative relationships with relevant stakeholders.

HFEA responsibilities

9. The HFEA has a number of functions that relate to the licensing and regulation of research. It is also involved in the development of policy on ethical as well as scientific matters. This document is largely concerned with the HFEA's licensing and regulatory functions. These include the following activities.

Clinic licensing

10. The regulation of infertility services and related embryo research is the HFEA's central function. The HFEA plays a vital role in promoting good clinical practice and high ethical standards. Naturally, this responsibility involves the promotion and defence of patient needs and patient expectations. The HFE Act requires the HFEA to maintain a *Code of Practice* that gives guidance about the proper conduct of all the activities in licensed centres. Assessment of patients for treatment, counselling, consent and confidentiality are covered in separate sections along with guidance on clinic staffing, facilities and also embryo research.
11. The HFEA's licensing of existing and new clinics is conducted to maintain standards of practice that will advance patient care and create efficient and effective use of existing clinical services throughout the UK. Until recently, licences were renewed on an annual basis, subject to the meeting of centre-specific and general conditions and standards. However, the HFEA now offers established clinics three year licences in the recognition that a number of well-established clinics' compliance with the law and the *Code of Practice* is consistently good.
12. The HFEA is committed to the continual development of its existing licensing systems, and new inspection protocols are introduced as and where appropriate. During 2001, the HFEA assessed licensing and inspection systems in relation to

quality assurance and risk management, and has now incorporated new operational systems to evaluate these particular aspects of clinical and legal compliance.

HFEA Inspection Visits

13. The HFEA has both legal and professional obligations relating to all clinic inspection visits. Inspection visits are designed to take into account factors such as the number of staff, the type of services provided, and clinic practice history.
14. Clinic staff are given the opportunity – either collectively or separately – to discuss any concerns about the running of the clinic and to share their opinions about possible improvements. The inspection also assesses compliance to any previous Licence Committee recommendations, studies the clinic’s arrangements for handling gametes and embryos and evaluates the information given to patients.
15. The Chair of the Inspection Committee ensures that positive observations about clinical practice and procedure are fed back to relevant clinic staff, and also that all staff have the opportunity to provide feedback on the inspection process. The final inspection report is for consideration by the HFEA Licence Committee.

5

Investigation of adverse incidents

16. Clinics and research centres are required to notify the HFEA when an adverse incident occurs. In such an event, or if the HFEA learns about an incident from another source, an inspection team will investigate the cause of the incident. The HFEA will then work with the clinic to ensure measures are put in place to limit the risk of a recurrence. Sometimes such problems require unannounced inspections. If the HFEA is not satisfied that a clinic can meet appropriate requirements it can impose changes (variations) to the licence, or suspend or ultimately withdraw it.

Data registration

17. Under the requirements of the Human Fertilisation and Embryology Act the HFEA receives notification from clinics of all births resulting from fertility treatment with donated gametes or embryos. This data, which includes information on delivery dates and places of births, is placed on an HFEA Register that includes information about the donors. (Since this Register was created under the HFE Act, it only includes information about children conceived after 1 August 1991.)
18. The HFEA is introducing new computer systems for this register, designed to create records that are more comprehensive and easy to use.
19. The HFE Act states that when a child reaches the age of 16, he or she may ask the HFEA whether or not he or she is related to an intended spouse. The Act also

provides for anyone aged 18 to ask the HFEA whether or not he or she was born as the result of infertility treatment using donated gametes or embryos. Additionally, if regulations are made, the Act provides that once a child reaches the age of 18, he or she may be given further information by the HFEA from the Register about his or her genetic parents.

20. Under the existing legislation, the earliest that the HFEA may be required to comply with requests for information about genetic parentage is 1 August 2007, when a 16 year old may intend to marry (some 16 years after the relevant section of the Act was introduced), and 2009 for information to be given to people over the age of 18. In practice, since the first offspring to whom collected information relates to were not born until 1992, information would not be made available until 2008 for 16 year olds and 2010 for 18 year olds.
21. Information about gamete donors could be requested, at the earliest, 18 years after regulations to that effect are made and would only apply to donations made after that date.

Provision of information

22. The HFEA publishes Patients' Guides to IVF and Donor Insemination services. These include the proportion of treatment cycles that result in live births, and also the proportion of multiple pregnancies.
23. The HFEA receives hundreds of individual requests for information each week from members of the public. The press office meets the needs of national and international press and broadcast media for information on assisted reproduction.
24. The HFEA also provides information about regulated activities to parliamentarians and policy makers. The Chair recently gave evidence about the work of the HFEA to the House of Commons Committee for Science and Technology.

Research

25. The HFEA is responsible for the granting of licences in the UK to any research project involving the creation, keeping or use of human embryos outside the body.
26. The HFEA regularly inspects HFEA licensed research centres, and requires regular reports on the progress on the research being conducted in these centres. Upon completion of research programmes, researchers are required to submit a final report to the HFEA.
27. A further consultation is planned on the funding of HFEA activities relating to research.

HFEA funding and organisation

28. The budget for the HFEA has remained fairly constant for a number of years. In the year 2001 – 2002 there was an agreed increase from £1.56 million to £1.9 million: income of £600,000 from the Department of Health grant, £0.325 million from fees raised from NHS trusts and £0.97 million from private clinics. In addition the Department of Health provided special project funding of £1 million.
29. The expectations and workload of HFEA personnel, structure and systems have continued to grow but the resource base has not. In real terms, over the last five years the HFEA's resource base has deteriorated.

7

HFEA Funding

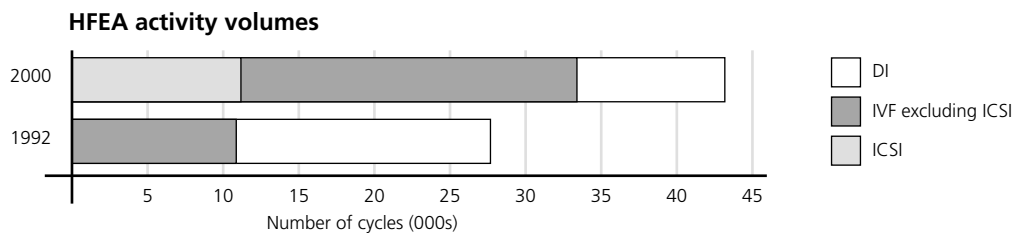
30. Until now HFEA has been required to operate within a strict expenditure control limit. For most of the past ten years this has been set at a level of between £1m and £1.5m. During this time fees have not been increased.
31. The HFEA's current resources are insufficient to meet the demands of the growing workload. Unless resources are increased the HFEA will not be able to fulfil its obligations to the standards required by Government and the public. Additional investment is essential to strengthen the HFEA's key functions, including regulation, policy surveillance, and data collection, evaluation and dissemination.
32. The HFEA is operating in a clinical and scientific field that offers major opportunities, both therapeutic and commercial. However, related regulatory issues present similarly large challenges. HFEA is well placed to spearhead the developments of a modern regulatory system for this new biotechnological world, but developing this system will require organisational and financial changes.
33. In the future, the HFEA must be resourced appropriately to ensure that all HFEA regulatory systems can keep pace with rapid change. Appropriate resources will enable the HFEA to build on its role in safeguarding different public, patient and professional interests, and to maintain public confidence in the regulation of this complex and rapidly evolving area of science and treatment. The modernisation and strengthening of the existing regulation system needs to be developed strategically, but also as a matter of urgency. New models of regulation must include more in-depth inspections, systematic data audits, more timely inspection reports, and more vigorous enforcement of compliance with inspection and HFEA Licence Committee evaluations.

Changing needs and expectations

34. Over the last 10 years, rapid scientific developments have engaged the HFEA in an increasingly large arena of regulation, licensing, education and debate. The HFEA's policy function is constantly expanding to respond to ethical and public health issues. Policy developments in turn impact on the structure of the regulatory function as they suggest developments or changes to 'good practice' in service delivery.
35. Policy issues currently being assessed and evaluated by the HFEA include:
- Implications of stem cell research
 - Implications of Pre implantation Genetic Diagnosis
 - Sex selection
 - Donor information and confidentiality
 - Surveillance of new research and treatment techniques
36. The HFEA seeks to be proactive in its policy development, and to provide timely and accurate advice to Government and others. The environment in which the HFEA operates has changed dramatically since it was set up in 1991. Scientific and clinical developments, public expectations and Government policy are making increasing and very different demands on the HFEA.
37. Biological science and technological advances have seen the development of genetics, the use and transfer of biological techniques from the animal to the human, and the introduction of research into human embryonic stem cells. Policy adopted by the UK Government, allowing regulated research into embryonic stem cells, is likely to lead to increased demands on the HFEA's regulatory function. The HFEA is already involved in discussions with agencies such as the MRC and the MCA about the expansion and regulation of stem cell research.
38. The regulation of stem cell research in embryos is likely to require a cross-governmental partnership between the HFEA and the Department of Trade & Industry (DTI) and the Department of Health (DH). Applications have already been received by the HFEA for the licensing of embryonic stem cell research programmes. This work is likely to increase, driven – in part – by policies already adopted by other countries. The decision by the US Government to limit federal funding to existing stem cell research has already resulted in some relocation of American expertise to this country.
39. The creation of the HFEA reflected public and professional unease about the potential future of human embryo research and infertility treatments, and a widespread desire for statutory regulation in this complex area of healthcare and service provision. This continues to be subject to speculation, questioning and sometimes suspicion, and in the case of the development of embryos for treatment

and research, subject to serious scrutiny and ethical debate in the UK and the rest of the world.

40. Technical advances in treating infertility continue at a rapid pace. Between 1st January 1991 and 31st March 1999, 218,922 IVF cycles, 141,390 Donor Insemination treatments and 35,968 micromanipulation cycles took place. This period saw an increase by 105% in IVF and a 128-fold increase in the use of micromanipulation techniques. A summary of movement in activity levels is shown in the chart below:



41. Developments such as Pre-implantation Genetic Diagnosis (PGD), Intra Cytoplasmic Sperm Injection (ICSI), sex selection and egg sharing have implications for children born from these techniques and for the society as a whole. Strategic policy development and monitoring of these and other key areas, is essential if the HFEA is to be able to fulfil its role as guardian and public protector in this complex arena.
42. There is considerable benefit to the academic community and to the wider national interest in successful research and the accompanying spin-off commercial opportunities. The ability to open up this profitable area rests on confidence in the HFEA's ability to regulate embryo and stem cell research strictly. Any perceived failure in this regulation could undermine public confidence and so limit the potential for further developments.
43. The HFEA was a pioneer in regulation within healthcare. However, expectations on regulation have changed. The Government has put standard-setting, regulation and inspection at the heart of its plans to raise and monitor standards within the NHS. There has also been a trend amongst service providers, patient support groups and others to challenge the HFEA's authority, by subjecting its decisions to judicial review.
44. The public expects health services to be placed under scrutiny and demands robust regulation that is thorough and transparent. This is particularly the case in the sensitive, and sometimes controversial, field of human reproduction.
45. The HFEA needs to be resourced appropriately to ensure the regulatory systems can keep pace with rapid change. This will enable the HFEA to build on its role in safeguarding the different public, patient and professional interests involved, and maintain public confidence in the policing of this complex area of science and treatment.

Options for new strategies and funding

46. The HFEA has managed its first 10 years as a low cost organisation with a limited infrastructure. This structure is no longer tenable. The HFEA now needs to develop corporate functions to support and maintain existing and nascent organisational and service needs. This process of development must include more comprehensive strategic planning, short and long term financial and business planning, and strengthened systems of quality assurance and also risk management.
47. The HFEA has already identified areas where there is a need for improvement in its practice.
- The Tenth Annual Report 2001 notes that the Authority has experienced problems with information technology that have delayed the publication of statistics relating to treatment services.
 - A review of the inspection process suggests there is a need for more detailed inspections, and clinics should be able to expect feedback more quickly.
 - The HFEA wishes to reduce the amount of time it takes to make decisions when it receives an application for a new licence or a variation to an existing licence.
 - The volume of enquiries from the public requires the HFEA to put in place systems to allow it to respond to requests for information and advice.

The new HFEA Strategic Mission

48. The HFEA has adopted a strategic mission that commits it to: modernise, simplify its processes, improve its ability to meet its statutory functions and to better meet the needs of those providing and receiving treatment.

MISSION STATEMENT

The HFEA is committed:

- To fulfilling the obligations laid upon the HFEA in the HFE Act.
- To being a strong, pro-active, modern regulator that inspires the confidence of patients and public, and the respect and co-operation of practitioners and professions.
- To being a transparent organisation, able to communicate with all our stakeholders.
- To informing and supporting the growing public debate about the social, ethical, and epidemiological implications of infertility and biotechnology developments.
- To being a creative, learning organisation, which values its staff, members, and others contributing to the work of the HFEA.

49. This mission reflects the ongoing and new needs and expectations of both the HFEA and the organisations and institutions it seeks to support. Through an ongoing process of consultation, the HFEA seeks practical and sustainable means of building on existing successes and eradicating possible compromises in standards of healthcare, monitoring and also support for relevant research.
50. If the HFEA is to succeed in providing a regulatory framework that is robust and fit for purpose, it will need additional resources. There is an assumption that the costs of policy development and certain core costs should be met by the Department of Health. But it is Government policy that the costs of regulation should be met by those being regulated, and as a Non Departmental Public Body (NDPB) the HFEA is obliged to comply with this policy. HM Treasury Fees and Charges Guide states that the cost of a service should be directly reflected in the fees charged. This means that the cost of improving the regulatory activities must be met by an increase in income derived from fees.
51. The HFEA generates income by two distinct methods

Licence fees

Initial – treatment licence	£500
Renewal – either annual or 3 yearly	£500
Research or storage licence	£200

'Additional' treatment fee per licence treatment

per IVF treatment	£40
per DI treatment	£20

52. Historically licence fees have been paid in advance whilst treatment fees are paid annually in arrears. Treatment fees are to be paid monthly in arrears from May 2002.

Principles behind the fee strategy review

53. The HFEA has begun a review of its fee strategy informed by the following principles:
- The HFE Act defines the services that the HFEA is required to provide;
 - The HFEA should determine the proper interpretation of the Act and ensure that a strategy is developed that provides for the resources required to implement that strategy, including financial resources;
 - All costs of regulation should be met by the service that is being regulated;
 - The fee strategy should be equitable with centres charged in relation to the levels of work carried out;
 - All clinics and research centres should meet minimum required standards to ensure patient safety and good clinical practice;

- The system of licence fees and its collection should be easy to administer;
- The system of licence fees should be open and easy to understand.

Potential changes

54. In identifying potential fee structures, the following have been identified as discrete services:

Initial licence application	<ul style="list-style-type: none"> ● Initial advice and support on establishing a clinic ● Assistance with licence application ● Inspection process ● Licensing Committee
Licence renewal	<ul style="list-style-type: none"> ● Annual inspection ● Licence Committee
Changes to existing licence (processing a 'variation')	<ul style="list-style-type: none"> ● Advice and support ● Inspection process ● Licence Committee
Investigation and management of adverse incidents	<ul style="list-style-type: none"> ● This sometimes requires an additional inspection
Processing treatment forms	<ul style="list-style-type: none"> ● Extraction and storage of data

55. It is recognised that there are a large number of services provided by the HFEA that are not so readily identifiable. These include:

- Formation of general policy;
- Managing enquiries about licensed treatments and matters of policy;
- Briefing policy makers and parliamentarians;
- Public health surveillance.

56. A careful review of the HFEA's funding requirements has concluded that, if it is to develop the corporate functions to meet reasonable expectations of a modern regulatory body, the annual budget must increase from approximately £2 million per annum to over £4 million per annum.

57. Such an increase in funding would result in the following service improvements:

- Faster responses to enquiries
- Faster processing of licence applications and variations
- Improved liaison between clinics and regulatory managers
- More in-depth inspections
- Clearer inspection guidelines and principles of good practice
- Prompt delivery of inspection reports

- Greater transparency in the inspection and licensing processes
 - A revised and simplified data collection process
 - Better support for new centres
 - Greater help in the management of adverse incidents
 - Comprehensive Patient Guide data that is easier to understand
 - Faster publication of statistics
58. To comply with Government policy outlined in paragraph 50 the HFEA must raise the additional income by increasing the portion of funds that is derived from licence fees.
59. Currently, the vast proportion (98.6%) of licence fees is derived from the fees paid per cycle of treatment – usually these are passed on to the patient directly. This means that individual patients bear many of the costs associated with licensing matters and the investigation and management of adverse incidents. The HFEA is concerned to develop a more equitable means of raising income that links fees to the specific areas that they are being raised to fund, but minimises bureaucracy.

Possible fee options

60. The HFEA cannot avoid increasing the level of fees, but it wishes to consult on preferred options for a new structure of fees.
61. The HFEA requires ongoing operational funding of at least £4.5m. The Department of Health has indicated that some £0.6m base line funding will continue to be available to the Authority, but any increase in funding required to improve regulatory services should be obtained through charges. As a result a fees strategy is required that provides £4m.
62. In addition to this operational funding requirement, HFEA requires major new investment in Information Systems and accommodation. The Department of Health has already made available some £3m for these projects during 2001/02 and 2002/03. Further central government funding is being sought to complete these projects; provided the necessary Treasury and ministerial approvals are forthcoming, project funding of about £3m p.a. is likely to continue for a few years.
63. In order to provide fees funding of approximately £4m, the HFEA has considered the following options in relation to the principles set out above.
64. The Authority aims to have a new fees strategy in place by October 2002

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.

Option 2

Present system but with higher treatment fees

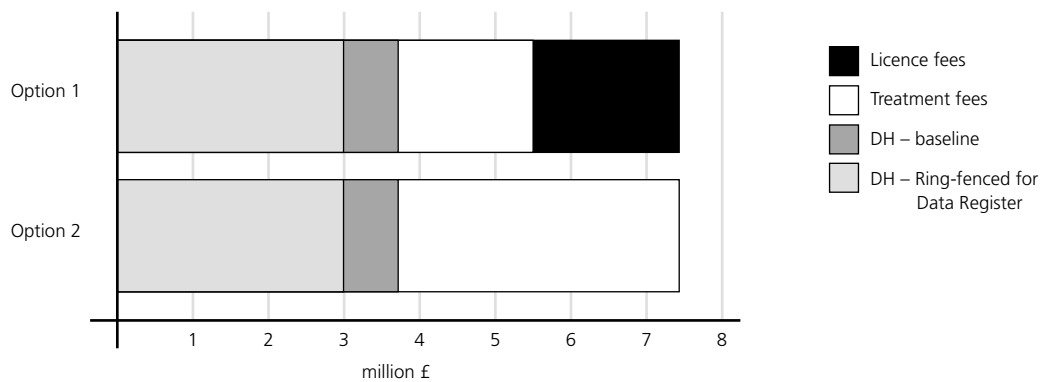
This system is easy to administer but there major disadvantages. In particular the initial application fees are far smaller than the cost of providing this element of service. As a result nearly all the fees are accrued to patients. This leads to the perception of HFEA fees as a ‘patient tax’ rather 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 which generate most work for the HFEA.

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

Licence fees would continue to generate just £22,000.

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



The HFEA has also considered an option where fees would be ‘banded’ according to the size of the clinic. However this option does not comply with Treasury Guidance, as the services provided to small clinics are not necessarily more limited than those provided to larger centres.

66. 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?

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Appendix 1

HFEA fees

Fee Type	Current £	Proposed 1st Oct 2002 £	Notes
Initial fees – Clinics			
Initial/Application Fee – treatment clinics	500	15,000	Payable on application
Initial/Application Fee – storage only clinics & DI only centres	200	1,500	Payable on application
Initial/Application Fee – Research only	200	250	Payable on application Further review to be undertaken following establishment of policy on Stem cell research
Additional fees – Clinics			
Annual fee including inspection – treatment	500	15,000	Payable annually in advance for all clinics licences as at 31st December in previous year. Invoices will be issued dated 1st January and will be payable within 28 days
Annual fee including inspection – storage only clinics	200	1,500	Payable as above
Annual fee including inspection – research	200	250	Payable as above
Variation Fee – administrative	N/A	250	Payable on application
Additional Inspection fee	N/A	1,500	Applicable where additional inspection required in year regarding variation or outcome of earlier inspection or review
Additional Fees – treatment			
IVF fee (incl ICSI)	40	50	Payable monthly in arrears
DI Fee	20	25	Payable monthly in arrears
Other Charges			
Advisory fee	N/A	Available on request	

Response sheet

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

Option 1	or	Option 2
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(delete the option that does not apply)

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.

I am content with a fixed fee	or	I would prefer to see a modified fee structure
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(delete the option that does not apply)

3. Who should pay for the cost of regulating research licences?

I would prefer the cost of research licences to continue to be funded from other fees on the basis that all stakeholders benefit	or	I would prefer to see a more focussed fee structure
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(delete the option that does not apply)

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?

Response:

(continue over if required)

Name and organisation (optional)

Clinic name and number (if appropriate)

Date

Please return to Ann Furedi, Director of Communications, HFEA, Paxton House,
30 Artillery Lane, London E1 7LS by 15 August 2002



