Human Fertilisation and Embryology Authority

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This report covers the year beginning 1 November 1998 with a forward look for the year beginning 1 November 1999.

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CHAIRMAN'S LETTER

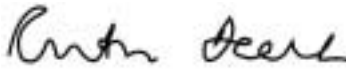
This year marks the tenth anniversary of the Human Fertilisation and Embryology Act 1990. During the past decade assisted reproductive technology has thrown up many difficult and complex social, ethical and regulatory issues. The number of patients seeking infertility treatment continues to grow. Over 50, 000 babies have been born following IVF treatment since the birth of Louise Brown in 1978 and it is to the Authority's credit that it has succeeded in meeting the challenges presented by this new technology. Due to the HFEA's persistent efforts, patients and the public can be assured that infertility treatments offered by licensed clinics conform to the high standards set out in our Code of Practice.

Many licensed clinics are now well established and understand the regulatory standards we expect of them. Taking this into account, the HFEA has introduced three-year licences for such centres. Clinics will, however, continue to be inspected annually. This system allows the HFEA to target its resources more effectively while working to reduce the regulatory burden placed on clinics. Further, a new set of inspection protocols has been introduced to ensure consistency between inspections. The HFEA constantly works with clinics and other interested organisations to improve standards. It will take action to protect patients when evidence shows that this is necessary.

Collecting data and providing information about licensed treatments are two of the HFEA's most important roles. To facilitate the ever increasing volume of data collected, a new Data Register was recently installed. In 1999 we issued our re-designed "Patients' Guide to DI and IVF Clinics". This publication contains comprehensive, impartial advice and information about the many types of licensed treatment available, the issues that patients may wish to consider and detailed statistical information. In addition, we have recently published a variety of patient information leaflets on such subjects as welfare of the child, ICSI and the storage of frozen eggs. All this material is available on our web-site to provide quick access for patients, clinics and academics. We intend to develop our web-site further over the next few years ultimately to include anonymised data held on our Register.

The HFEA is conscious that it has a responsibility to society to keep under review this fast developing area of medical science. We intend shortly to publish the fifth edition of our Code of Practice. This edition, like previous ones, has drawn on exchanges with a variety of professional bodies, and we are grateful for their contributions to our deliberations. We anticipate that the Code's next edition will include guidance on egg sharing and payment of expenses to donors. Our consultations on issues such as cloning, with the Human Genetics Advisory Commission, and pre-implantation genetic diagnosis, with the Advisory Commission on Genetic Testing, have enabled the public to add their voice to these areas of social and ethical concern. We look forward to collaborating with the newly created Human Genetics Commission.

It is with great sadness that we say goodbye to Chief Executive, Suzanne McCarthy, who left the HFEA in October. I would like to thank her for all her hard work and commitment; she has made a significant contribution to the work of the HFEA which is widely appreciated. I know she will be greatly missed by both Members and Executive staff. Hugh Whittall has replaced Suzanne McCarthy as Acting Chief Executive, until a permanent appointment is made. Finally, I would like to thank those Members who have left the HFEA since its last Annual Report: Gulam Bahadur, Brian Lieberman, Joan Stringer and John Williams.



Ruth Deech,
Chairman.

1. THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

The Human Fertilisation and Embryology Authority (HFEA) was established in August 1991 by the Human Fertilisation and Embryology Act 1990 (HFE Act). The first statutory body of its kind in the world, the HFEA's creation reflected public and professional unease about the potential future of human embryo research and infertility treatments, and a widespread desire for statutory regulation of this highly sensitive area. The recommendation for such a body had come from the 1984 report of the Committee of Inquiry into Human Fertilisation and Embryology (the 'Warnock' report).

The HFEA's principal tasks are to license and monitor those clinics that carry out in vitro fertilisation (IVF), donor insemination (DI) and human embryo research. The HFEA also regulates the storage of gametes (sperm and eggs) and embryos.

The HFEA's other statutory functions are:

- to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;
- to keep a formal register of information about donors, treatments and children born from those treatments;
- to publicise its role and provide relevant advice and information to patients, donors and clinics; and
- to keep under review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act and advise the Secretary of State, if asked, about those matters.

Underlying all its activities is the HFEA's determination to safeguard all relevant interests - patients, children, doctors and scientists, the wider public - and future generations.

THE HFEA'S MEMBERSHIP AND ITS EXECUTIVE

HFEA Members are appointed by UK Health Ministers in accordance with the guidance from the Commissioner for Public Appointments (Nolan guidelines). The Members determine the HFEA's policies and scrutinise treatment and research licence applications. In order that a perspective can be maintained which is independent of the medical-scientific view, the HFE Act requires that the Chairman, Deputy Chairman and at least half of the HFEA's Membership are neither doctors or scientists involved in human embryo research or providing infertility treatment. Members are not appointed as representatives of different groups, but bring to the HFEA a broad range of expertise: medical, scientific, social, legal, managerial, religious, and philosophical. Some Members have personal experience of infertility problems.

The HFEA's Executive[1] is responsible for implementing the HFEA's policy and licensing decisions and conducting the HFEA's day-to-day activities.

1. *A list of Executive Staff is at Annex 1.*

QUINQUENNIAL REVIEW

It is a Government requirement that Non- Departmental Public Bodies, such as the HFEA, be independently reviewed every five years. The HFEA is currently undergoing its second Quinquennial Review. The Review's purpose is to consider the HFEA's functions, the extent to which these meet its aims and objectives and the way they are delivered. It is expected that the Reviewers will make recommendations suggesting how the Authority's performance can be further developed and improved. It is anticipated that the Reviewers will submit their report to Department of Health Ministers before autumn 2000. Together with the Department of Health the HFEA will then develop an action plan to implement any agreed recommendations.

PERFORMANCE INDICATORS

The HFEA introduced Performance Indicators for the first time in April 1999 as a means of better assessing the standards of its performance in various areas. Four headline indicators were chosen:

PI 1 Percentage of licence applications dealt with within target timescale

PI 2 Percentage of requests for HFEA publications responded to within three days

PI 3 Data entry unit costs per DI/IVF treatment

PI 4 HFEA performance against Government financial targets including:
- Percentage of creditors paid within 30 days;
- Percentage of debts recovered within 60 and 90 days.

The HFEA's 1999/00 PI data is presented at Annex 7. The data shows that the HFEA met most of its objectives. In areas where this was not the case improvements have been made.

EFFICIENCY SAVINGS

The HFEA is committed to carrying out its duties to the highest standards whilst ensuring the costs are kept to a minimum. The HFEA has, for example, reduced its costs by making changes to its executive structure and administrative savings on stationery, photocopying charges and postage. The latter have mainly resulted from the HFEA's alterations to its licensing process. Thus, the HFEA has been able to achieve efficiency savings of 3.5% during the third year of a capped budget.

LICENCE FEE REVIEW

The HFEA, by agreement with the Department of Health and the Treasury has a financial objective to raise 70% of its annual budget (currently capped at £1,559,000) from licence fees. In order to keep in line with this agreement, in March 2000 the HFEA obtained Department of Health and Treasury agreement to changes to its licence fee levels. This is the first time licence fees have changed since September 1994.

For example, additional licence fees for IVF treatment cycles will be reduced from £40 to £36 for treatments taking place on or after 1st April 2000, while fees for donor insemination treatment cycles will increase from £10 to £14 on or after 1st October 2000 and then to £18 from 1st April 2001. Overall, the effect of the changes will be to reduce the amount of income generated by licence fees and bring fee levels more into line with HFEA costs. The HFEA annually reviews the level of its licence fees, and will continue to make every effort to keep fees as low as possible.

THE CODE OF PRACTICE ON ENFORCEMENT

The HFEA's Code of Practice on Enforcement sets out the level of service that licensed clinics and the public can expect from the HFEA. Every licensed clinic has a copy of this document. It is also available to members of the public on request from the HFEA.

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

Chairman
Ruth Deech, Principal, St Anne's College, Oxford

Deputy Chairman
Jane Denton, Director, The Multiple Births Foundation, Queen Charlotte's & Chelsea Hospital, London

Professor Brenda Almond, Professor of Moral and Social Philosophy, University of Hull

Dr Sue Avery, Scientific Director, Bourn Hall Clinic

Professor David Barlow, Nuffield Professor in Obstetrics and Gynaecology and Head of Department, University of Oxford; Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital, Oxford

Professor Peter Braude, Guys, Kings and St Thomas' School of Medicine; Head of the Division of Women's and Children's Health

Moira Coath, Solicitor; Non-Executive Director, Dorset Healthcare NHS Trust; Previously Chair of 'Child', the National Infertility Support Network

Professor Christine Gosden, Professor of Medical Genetics, University of Liverpool, Liverpool Women's Hospital

Professor Andrew Grubb, Professor of Medical Law, and Head of Department, Cardiff Law School, Cardiff University

Professor Henry Leese, Professor of Biology, University of York

Professor Stuart Lewis, Consultant Psychologist, Ulster Hospital & Community Trust; Formerly, Professor of Psychology Applied to Medicine, The Queen's University, Belfast

Dr Anne McLaren, Principal Research Associate, Wellcome CRC Institute, Cambridge

Dr Sadia Muhammed, General Practitioner, Priory Medical Group, York

Sara Nathan, Freelance Journalist, Previously Editor of Channel 4 News

The Right Reverend Dr Michael James Nazir-Ali, The Lord Bishop of Rochester.

Sharmila Nebhrajani, Finance and Business Affairs Director, BBC New Media

Dr Francoise Shenfield, Clinical Lecturer in Infertility RMU (UCH) and Honorary Lecturer in Medicine (Ethics) (Dept of Medicine RF and UCH Medical School)

Jean Smith, Specialist Social Worker in Adoption, Fostering and Child Protection.

Professor Allan Templeton, Professor of Obstetrics & Gynaecology, University of Aberdeen

Julia Tugendhat, Psychotherapist

Mrs Lis Woods, Formerly Commissioner HM Customs and Excise

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

Audit Committee
Lis Woods (Chair)
Andrew Grubb
Henry Leese
Sharmila Nebhrajani
Jean Smith

Code of Practice Committee
Jane Denton (Chair)
Sue Avery
Andrew Grubb
Anne McLaren
Sadia Muhammed
Allan Templeton
Lis Woods

Communications Steering Group
Sadia Muhammed (Chair)
Moira Coath
Stuart Lewis
Sara Nathan

Ethics Committee
Bishop Michael (Chair)
Brenda Almond
Christine Gosden
Andrew Grubb
Henry Leese
Sara Nathan
Francoise Shenfield
Julia Tugendhat

Information Committee
Stuart Lewis (Chair)
David Barlow
Peter Braude
Moira Coath
Sadia Muhammed
Sara Nathan
Allan Templeton
Julia Tugendhat

Information Committee Co-opted Members
Karin Dawson
Angela Mays
Clare Brown
Richard Flemming
Alison Murdoch

Licensing & Fees Committee
Julia Tugendhat (Chair)
Brenda Almond
David Barlow
Peter Braude
Jane Denton
Christine Gosden
Henry Leese
Stuart Lewis

Organisation & Finance Committee
Ruth Deech (Chair)
Moira Coath
Jane Denton
Sharmila Nebhrajani
Lis Woods

Working Group on New Developments in Reproductive Technology
Anne McLaren (Chair)
Sue Avery
Peter Braude
David Barlow
Jane Denton
Christine Gosden
Henry Leese
Sara Nathan
Francoise Shenfield
Allan Templeton
Elaine Gadd (Observer)

Marcia Fry acts as the Department of Health's observer at HFEA meetings

2. LICENSING AND AUDIT OF LICENSED CLINICS

INTRODUCTION

Every clinic in the UK which offers IVF or DI treatment, the storage of gametes (sperm or eggs) or embryos or which carries out human embryo research is required by law to be licensed by the HFEA. Licensed clinics are inspected annually. Not only does the licensing process ensure that proper standards are maintained, but it also assists in informing the HFEA about current and developing practices. As such it is a useful mechanism for gathering and disseminating information and thereby helps to raise standards of practice. As of 31 August 2000 there were 116 clinics licensed to carry out various activities as shown in Table 1 .

Table 1. **HFEA licensed clinics**

IVF and DI	75
IVF only	0
DI only	29
Storage of sperm only	9
Research licences only	3
Total	116

THE LICENSING AND INSPECTION PROCESS

All licensing decisions are made by HFEA Licence Committees. Each Committee is composed of five HFEA Members who determine whether a licence should be granted, suspended or revoked. If a licence is granted, centre-specific conditions may be attached.

Previously licences were renewed annually. However, following a comprehensive review by the HFEA of its licensing system, the Authority agreed that established clinics could be issued with three-year licences. This recognised the fact that a large percentage of clinics have been licensed by the HFEA for many years, and that in most of these clinics compliance with the law and the Code of Practice is consistently very good. A new clinic normally qualifies for a three-year licence only if it achieves good compliance during its first two years.

Under the HFEA's three-year inspection cycle, each centre receives a broad-based general inspection by a full team once every three years, preceding its licence renewal. Smaller teams for interim or focussed inspections are identified by Licence Committees on a systematic basis according to the nature and licensing history of the clinics. This system means that the Authority can target its resources more effectively while reducing the burden of regulation on clinics as a whole.

2. A list of licensed clinics is at Annex 2

The HFEA currently employs 59 part-time inspectors who assist the HFEA in inspecting clinics. At full inspections the inspection team will normally consist of a clinician, a scientist, a person with a background in another field, such as counselling or nursing, as well as a member of the HFEA's Executive staff. The chairman of the team is usually an HFEA Member. Where an interim inspection is scheduled, a Licence Committee will determine the particular focus as well as the composition of the inspection team.

INSPECTION PROTOCOLS

During 1999 the Authority piloted a new set of inspection protocols aimed at ensuring quality and consistency in the inspection process. These were introduced in May 2000. The protocols are based on the requirements of the HFE Act, the Code of Practice and professional guidelines. They prompt inspectors to cover all relevant areas of compliance whilst also encouraging wider discussion on general issues of good practice. The content of the protocols will be kept under review.

BREACHES AND ENFORCEMENT

Information on alleged or apparent breaches of the HFE Act or the Code of Practice comes to the HFEA from a wide range of sources including HFEA inspections, information from patients, centre staff, analysis of the HFEA's database and from centres themselves.

Once information is received, preliminary investigations are carried out to determine whether there is prima facie evidence of a breach. Where this is the case, the HFEA will often seek specialist advice. All evidence and advice received is then submitted to a Licence Committee which decides whether any action should be taken. Where there is the possibility that a criminal offence may have been committed contrary to the HFE Act, a Licence Committee may decide to refer the matter to the Director of Public Prosecutions.

THE AUDIT PROGRAMME OF LICENSED CLINICS' DATA

The HFEA's five year Audit Programme of clinics data began on the 1st October 1996 and is currently in the fourh year of its five-year programme. The audit programme is used to monitor and improve the standard of the data held on its information register. The audit programme also provides assurance for the National Audit Office regarding the collection of licence fee income.

All licensed clinics are audited during the course of the programme. Feedback is given after every audit including a written report to which the clinic concerned may respond. This report is then considered by a Licence Committee which will direct any follow up action. Approximately 80 audits will have been conducted by October 2000.

Analysis of the data for the first three years of the programme has highlighted centres failing to accurately and completely report to the HFEA patient/partner names, patient reference numbers, treatment dates and the details of sperm donors if used in treatment. Most of the discrepancies found in the donor data arise because centres have failed to agree the characteristics with their donors on their own proformas before completing the HFEA Donor information form or have failed to transcribe these accurately. The current programme will come to an end in the autumn of 2001. The audit programme is currently being reviewed before embarking on a new programme.

3. A list of HFEA Inspectors is at Annex 3

3. THE CODE OF PRACTICE

INTRODUCTION

The HFE Act[4] requires the HFEA to produce a Code of Practice to guide clinics on the standards they should establish in carrying out their licensed activities. It includes guidance on: the selection and screening of sperm donors; payment of expenses to donors; legal requirements for consent; handling and use of gametes and embryos; centre's staff and facilities; welfare of the child; and what information and counselling should be offered.

WELFARE OF THE CHILD

In particular, the Code of Practice provides guidance on the assessment of the welfare of the child. In passing the HFE Act Parliament decided that no category of women should be excluded from treatment. While the offer of treatment is a decision ultimately for the patient's clinician, the HFE Act requires every clinician to make this decision only after "account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth"[5]

The Code of Practice provides guidance on how this assessment should be made. Clinics must bear in mind such factors as the prospective parents' ages and their likely future ability to look after, or provide for, a child's needs, and any risk of harm to the child or children who may be born. Where the child will have no legal father, clinics must pay particular attention to the prospective mother's ability to meet the child's needs throughout its childhood. Clinics must seek to satisfy themselves that the GP of each prospective parent knows of no reason why either of them should not be offered treatment - but they can only do this with their consent. Failure to give consent should be taken into account by the clinician in considering whether or not to offer treatment.

The HFEA does not usually become involved in individual decisions, but it is concerned to ensure that the necessary process is correctly followed and gives guidance on the decision-making process. A clinic's failure to follow the Code of Practice's guidance on the welfare of the child assessment would be a breach of the Code of Practice and would be considered by a Licence Committee.

4. Human Frtilisation and Embryology Act 1990, section 25
5. HFE Act section 13(5)

THE FIFTH EDITION OF THE CODE OF PRACTICE

The Code undergoes regular revisions in the light of technical advances and to deal with issues that emerge from the licensing process. Revisions of the Code must be approved by the Secretary of State and laid before Parliament. The Code's second edition was published in June 1993, the third in December 1995 and the fourth in July 1998. The Code is available on the HFEA's website and from the HFEA on request.

Much of the work on the Code's fifth edition has been completed, and it is anticipated that, subject to Ministerial approval that it will be published by early 2001. As well as a thorough reconsideration of the Code's structure, the next edition of the Code will include new guidance on: egg sharing; payment of expenses to donors; selection and screening of sperm donors; and safe cryopreservation of gametes and embryos.

REVISION OF CONSENT FORMS

The Code of Practice Committee has also recently undertaken a review of the statutory consent forms and has issued new guidance to help centres to complete them. A new consent form has been produced for the Storage of Eggs and Embryos. In addition, a new and simplified consent form designed specifically for patients who are allowed to store their sperm beyond the usual 10 year statutory storage period has been produced.

4. COLLECTING AND PROVIDING DATA

The HFEA has a statutory duty to collect information about licensed treatments and their outcomes and maintains a register of information compiled from data provided by licensed clinics. Information is collected for the following main reasons:

- to provide information to children born as a result of such treatments;
- to monitor the provision of treatments; and
- to assist in the provision of information to the Government, patients, clinics and the general public.

DEVELOPMENT OF THE HFEA'S DATA REGISTER

The HFEA register began operating in 1991 and contains details of licensed treatments and patient characteristics for the whole of the UK. It is the largest database of its kind in the world. During April 1998 to March 1999 details of 35,363 IVF and 7,225 DI treatment forms were added to the register. In 1998 the HFEA adopted a strategy for replacing the original register system that had remained largely unchanged since its introduction. The first phase, a series of consultations with interested parties about the overall plans, began in June 1998. In mid 1999 the HFEA began to introduce the new Register software to deal with treatments carried out from April 1999 onwards.

Since then, there has been a requirement to collect additional information on the Register, especially regarding the storage of eggs and their subsequent use in treatment. Modification of the Register software to deal with this has delayed the introduction of a system for the secure electronic transfer of treatment data from clinics. It is hoped that testing of this system will now begin before the end of 2000 with a view to phasing out paper based input from all but the smallest licensed centres within five years. Similarly, it is hoped that the publication of detailed, non-identifying data sets of treatments and their outcomes on the HFEA's website will begin during 2000.

The following data tables and graphs present data collected for treatment cycles that were carried out during the period 1 April 1998 to 31 March 1999. Unless otherwise stated, the IVF data include treatments involving micromanipulation, such as ICSI or SUZI, and frozen embryo replacements. The DI data includes cycles involving GIFT and intrauterine insemination (IUI) using donor gametes.

IVF DATA

During the period 1998/9 27,151 patients received IVF treatment. There were a total of 35,363 cycles started, including frozen embryo replacements, of which 30,520 reached embryo transfer. There were 7,762 clinical pregnancies (21.9% of treatments started) which led to 6,450 live birth events (18.2% of treatments started). The number of clinical pregnancies where no outcomes or incomplete information was received was 212 or 2.7% of all pregnancies reported. Table 4.1 shows that the number of conventional IVF cycles (those not involving micromanipulation) has decreased for the second consecutive year and stands at 86.6% of its peak in 1996/7. Conversely, the number of cycles involving micromanipulation continues to increase, although at a much lower rate than previously (14.4% rise on the 1997/8 figure compared to 39.7% on the rise between1996/7 and 1997/8). The increased use and success of micromanipulation (figure 4.1) has been behind the rise in the total IVF live birth rate seen since 93/94 (table 4.4), although this appears now to have levelled off. Success with micromanipulation seems higher than with IVF, although this may not be the case when corrected for female factors (figures 4.1 and 4.2)
Analysis of the tables shows:

- Live birth rates for IVF and micromanipulation both decrease steadily after women pass the age of 30 (figure 4.2)
- IVF frozen embryo transfer cycles (table 4.1) have significantly lower pregnancy and live birth rates than those involving fresh embryos (table 4.13)

MULTIPLE BIRTHS AND TWO AND THREE EMBRYO TRANSFER

The incidence of multiple births (and attendant risk to maternal and infant health) as a result of IVF and micromanipulation remains high (table 4.1 - see also tables 4.6-4.10). For example, table 4.6 shows that 47% of individual babies born from all types of IVF come from a multiple pregnancy (3,873 out of 8,337) This figure has remained virtually unchanged during the period 1994 to 1999[6]. The stillbirth and neonatal death rate for a triplet pregnancy with one or more of the babies dying is 59.6 per 1000 birth events (6.0%) compared to 9.9 per 1000 (1.0%) for singleton pregnancies.

Table 4.9 shows that reducing the number of embryos transferred in the majority of cases[7], reduces the risk of a multiple birth (particularly of triplets - see table 4.10) without reducing the chance of giving birth to at least one child.

Encouragingly, the number of embryo transfers where the maximum of three embryos were replaced has fallen steadily from 68.6% in 1995/6 to 50.5% in 1998/9[8]. Conversely, the number of transfers where only two embryos were replaced has risen from 30.9% to 48.6% during the same period.

6. HFEA Annual Reports 1996 - 2000.
7. Where more than four embyos have been created.
8. Where more than four embryos have been created. HFEA Annual Reports 1997 - 2000.

DONOR INSEMINATION DATA

During the period 1998/9, 4,338 patients received treatment involving DI or GIFT using donated gametes. Table 4.18 shows that 11,035 cycles were started which led to 1,332 clinical pregnancies (12.1%) and 1,087 live births (9.9%). The number of clinical pregnancies for which no outcome or incomplete information was submitted totalled 50 or 3.8% of all pregnancies reported.

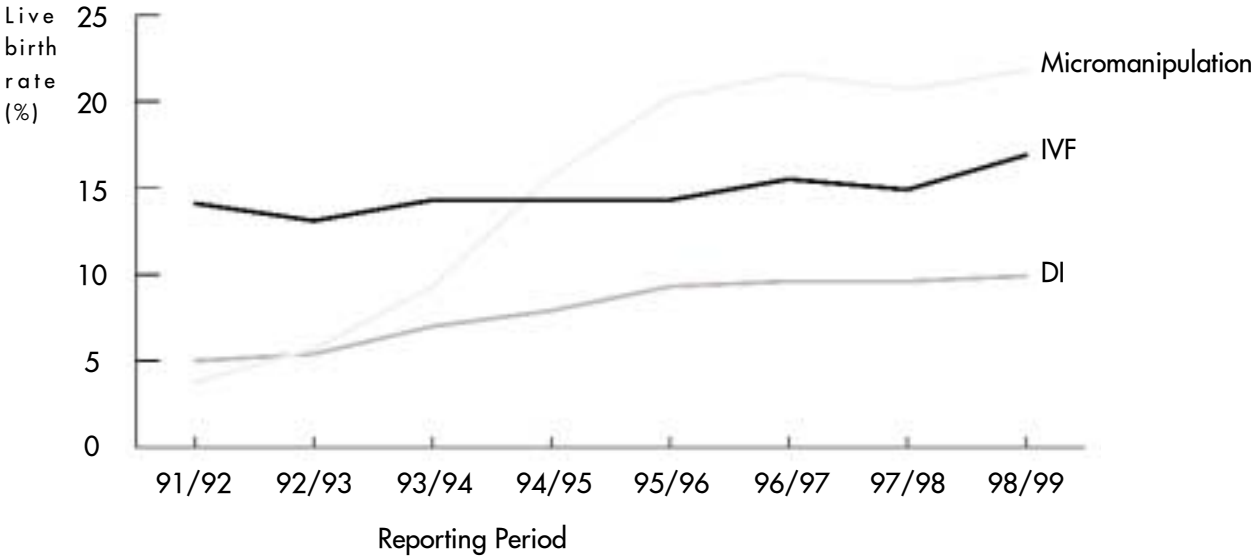
- The number of DI cycles carried out annually has dropped by 57% since the 1992/3 reporting period (from 25,623 to 11,035) (table 4.18).
- Live birth rates for DI decrease with age, and increasingly so after the age of 35 (table 4.21).

Table 4.1. Live birth and multiple birth rates for IVF, micromanipulation and DI, 1991-1999

	IVF [1]			Micromanipulation[2]			DI [3]		
Reporting period	Number of treatment cycles	Live Birth Rate per treatment cycle (%)	Multiple Live Birth Rate per live birth event (%)	Number of treatment cycles	Live Birth Rate per treatment cycle (%)	Multiple Live Birth Rate per live birth event (%)	Number of treatment cycles	Live Birth Rate per treatment cycle (%)	Multiple Live Birth Rate per live birth event (%)
91/92[4]	10434	14.0	27.3	80	3.8	33.0	16299	5.0	7.3
92/93	19309	13.1	28.1	244	5.7	35.7	25623	5.4	6.7
93/94	21726	14.3	27.6	798	9.3	25.7	23869	7.0	8.3
94/95	24193	14.3	27.7	1685	15.7	26.4	20604	7.9	7.2
95/96	25781	14.3	29.6	4651	20.2	28.9	16874	9.3	8.3
96/97	26865	15.5	26.8	6652	21.6	29.1	14333	9.6	6.5
97/98	24889	14.9	27.3	9295	20.7	27.4	12753	9.6	7.0
98/99	23254	16.9	27.3	10630	21.8	26.9	11035	9.9	6.4

1 In this table, IVF data does not include cycles involving micromanipulation. Frozen embryo transfers are included.
2 Frozen embryo transfers are excluded from cycles involving micromanipulation.
3 DI data includes GIFT using donor gametes and intra uterine insemination.
4 1991/2 data for eight months only.

Figure 4.1 Live birth rates per Treatment Cycle for Licensed Treatments 1991 - 1999



Notes
Micromanipulation data include ICSI treatments
The 'IVF' line does not include micromanipulation data

Table 4.2 Number of boys and girls born following IVF and DI treatments

	Boys	Girls	Total
DI	594(51.2%)	567(48.8%)	1161
IVF	4228(50.7%)	4109(49.3%)	8337

Table 4.3 Mean clinical pregnancy and live birth rates for female causes of infertility
(All percentages are of number of treatment cycles)

Factor	Number of cycles	% of all cycles	Clinical pregnancy rate (%)	Live Birth rate (%)
Tubal Disease	10923	30.9	19.5	15.9
Endometriosis	3194	9.0	21.9	18.2
Unexplained	16508	46.7	23.0	19.4
Other	8183	23.1	22.8	18.5

Note: the total number of cycles in this table does not equal 35,363 because some patients have more than one cause of infertility

Table 4.4 IVF clinical pregnancy and live birth rates :1/8/1991 - 31/3/1999
(including micromanipulation treatments but excluding frozen embryo replacements)

Reporting period	Number of treatment cycles	Clinical Pregnancy Rate per treatment cycle (%)	Live Birth Rate per treatment cycle (%)
01/08/91 to 31/03/92[1]	9284	18.0	14.0
01/04/92 to 31/03/93	17031	17.3	13.2
01/04/93 to 31/03/94	19376	18.3	14.5
01/04/94 to 31/03/95	22153	18.4	14.9
01/04/95 to 31/03/96	25494	19.2	15.8
01/04/96 to 31/03/97	27288	21.5	17.9
01/04/97 to 31/03/98	28550	21.0	17.6
01/04/98 to 31/03/99	28689	23.4	19.6

1. Data for eight months only

Table 4.5 Live birth rates by age of woman

a) IVF (using own eggs - excluding micromanipulation but including frozen embryo replacements)

	Under 27	27 - 28	29 - 30	31 - 32	33 - 34	35 - 36	37 - 38	39 - 40	41 - 42	43 - 44	45 and over	all patients
Treatment Cycles	862	1362	2319	3255	3651	3577	2999	2057	1037	404	210	21733
Live Birth Rate per treatment cycle (%)	17.6	20.7	19.0	19.0	20.1	18.1	15.2	9.5	7.3	3.0	0.5	16.6

b) Micromanipulation using own eggs (including frozen embryo replacements)

	Under 27	27 - 28	29 - 30	31 - 32	33 - 34	35 - 36	37 - 38	39 - 40	41 - 42	43 - 44	45 and over	all patients
Treatment Cycles	607	867	1447	1860	2092	1869	1398	896	383	166	44	11629
Live Birth Rate per treatment cycle (%)	25.2	24.1	25.6	24.1	23.0	21.5	16.8	11.2	5.5	2.4	2.3	20.9

Note: There were 433 micromanipulation cycles using donated eggs resulting in 85 live birth events
All tables exclude treatments using donated embryos

Figure 4.2 Live birth rates per Treatment Cycle by age of woman

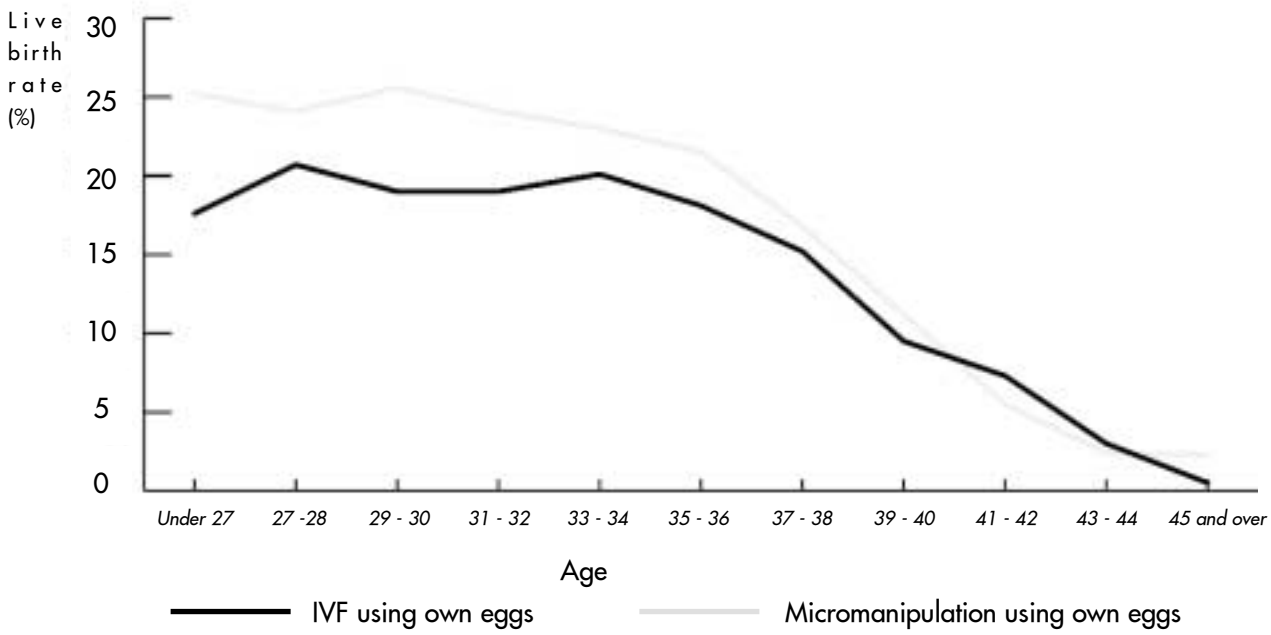


Table 4.6 Single and Multiple Clinical Pregnancy Outcomes after IVF or Frozen Embryo Transfers

	Clinical Pregnancies	Live Births	Miscarriages	Terminations	Ectopics	Unknown Outcomes	Babies Born	Still Birth and Neonatal Deaths (per thousand birth events)
Singleton	5395	4457	638	44	175	38	4464	9.9
Twin	1891	1756	280	14	7	12	3254	43.8
Triplet	261	235	62	34	1	2	613	59.6
Quads	3	2	1	2	-	-	6	-
Totals	7550	6450	981	94	183	52	8337	20.9

Notes:
Twin and triplet pregnancies do not add up because a multiple pregnancy may have more than one outcome

The number of babies born represents all the babies born for the type of pregnancies. For example, babies born for twin pregnancies (two gestational sacs) will include birth events in which only one baby was born and babies born from singleton pregnancy (one gestational sac on an early scan) may include two babies.

The total number of clinical pregnancies shown here is less than the total given in other tables because there were 212 clinical pregnancies reported for which no outcome form was received.

Table 4.7 IVF clinical pregnancy and multiple clinical pregnancy by the number of embryos transferred (including frozen embryo transfers)

Embryos Transferred	No of cycles	Number of clinical pregnancies			Clinical Pregnancy Rate (% of treatment cycles)	Multiple Clinical Pregnancy (% of clinical pregnancies)
		Singleton	Twin	Triplet or greater		
One	2977	276	8	1	9.5	3.2
Two	14144	2721	959	15	26.1	26.4
Three	13399	2398	924	248	26.4	33.1
Total	30520	5395	1891	264	24.6	28.7

Notes:
The total number of clinical pregnancies is less than the total given in other tables because there were 212 clinical pregnancies reported for which no outcome form was received.

Table 4.8 IVF live birth and multiple live birth rate by the number of embryos transferred (including frozen embryo transfers)

Embryos Transferred	No of cycles	Number of live births			Live Birth Rate (% of treatment cycles)	Multiple Birth Rate (% of live birth events)	Stillbirths and neonatal deaths per 1000 birth events
		Singleton	Twin	Triplet or greater			
One	2977	232	6	1	8.0	2.9	8.4
Two	14144	2423	786	9	22.8	24.7	20.8
Three	13399	2065	782	146	22.3	31.0	22.1
Total	30520	4720	1574	156	21.1	26.8	20.9

Table 4.9 Two and three embryo transfers for fresh stimulated IVF (where more than four embryos were created)

Number of embryos transferred	Number of cycles	Live birth rate (% of number of cycles)	Multiple birth rate (% of number of live births)
2	6838	28.6	26.4
3	7102	25.8	34.9

There were 123 cycles where 1 embryo was transferred.

Table 4.10 IVF live birth rates and multiple birth rates by age and number of embryos transferred (Fresh stimulated IVF including micromanipulation. Where more than four embryos were created)

a) All embryo transfers

Age	Number of cycles	Number of live births	Live birth rate per treatment cycle	Number of multiple births (twins triplets and quads)	Multiple birth rate per live birth event (twins, triplets and quads)	Number of triplets and quads	Triplet and quad birth rate per live birth event
<25	216	61	(28.2%)	18	(29.5%)	1	(1.6%)
25-29	2346	734	(31.3%)	241	(32.8%)	25	(3.4%)
30-34	5891	1752	(29.7%)	570	(32.5%)	55	(3.1%)
35-39	4578	1143	(25.0%)	317	(27.7%)	24	(2.1%)
40-44	971	120	(12.4%)	14	(11.7%)	1	(0.8%)
45+	27	1	(3.7%)	-	-	-	-
Total	14029	3811	(27.2%)	1160	(30.4%)	106	(2.8%)

b) Two embryo transfer

<25	162	47	(29.0%)	13	(27.7%)	-	-
25-29	1504	473	(31.4%)	126	(26.6%)	2	(0.4%)
30-34	3283	987	(30.1%)	275	(27.9%)	1	(0.1%)
35-39	1740	428	(24.6%)	99	(23.1%)	2	(0.5%)
40-44	136	20	(14.7%)	4	(20.0%)	-	-
45+	8	1	(12.5%)	-	-	-	-
Total	6833	1956	(28.6%)	517	(26.4%)	5	(0.3%)

c) Three embryo transfer

<25	54	14	(25.9%)	5	(35.7%)	1	(7.1%)
25-29	835	259	(31.0%)	115	(44.4%)	23	(8.9%)
30-34	2546	755	(29.7%)	291	(38.5%)	53	(7.0%)
35-39	2791	704	(25.2%)	217	(30.8%)	22	(3.1%)
40-44	828	99	(12.0%)	10	(10.1%)	1	(1.0%)
45+	19	-	-	-	-	-	-
Total	7073	1831	(25.9%)	638	(34.8%)	100	(5.5%)

Table 4.11 Clinical Pregnancy and Live Birth Rates (Frozen embryo replacements)
(All percentages are of number of treatment cycles)

	Treatment		Clinical			Babies
	Patients	Cycles	Embryo Transfers	Pregnancies	Live Births	Born
Own Gametes	4917	5742	5192 (90.4%)	861 (15.0%)	699 (12.2%)	827
Donated Sperm	255	295	262 (88.8%)	50 (16.9%)	34 (11.5%)	41
Donated Eggs	397	449	409 (91.1%)	85 (18.9%)	66 (14.7%)	78
Donated Embryos	157	188	172 (91.5%)	41 (21.8%)	35 (18.6%)	42
Totals	5726	6674	6035 (90.4%)	1037 (15.5%)	834 (12.5%)	988

Table 4.12 Treatments using micromanipulation
(including ICSI)

Clinics	69
Patients	9776
Number of cycles	12109
Number of embryo transfers	11481
Clinical pregnancies	2997
Clinical pregnancy rate (%)	24.8
Total live births	2522
Live birth rate (%)	20.8
Miscarriages	421
Terminations	40
Ectopics	51
Unknown	22
Babies born	3232
Stillbirths and neonatal deaths (per thousand birth events)	22.2

The number of cycles excludes those which were abandoned prior to egg collection.
The data includes the results from 1479 frozen embryo transfers.

Table 4.13 Results of stimulated IVF and fresh embryo transfer cycles
(All percentages are of number of treatment cycles)

	Treatment		Clinical				Babies
	Patients	Cycles	Embryo Transfers		Pregnancies		Live Births		Born
Own Gametes	21898	26056	22083	(84.8%)	5991	(23.0%)	5012	(19.2%)	6526
Donated Sperm	1023	1174	1088	(92.7%)	354	(30.2%)	292	(24.9%)	410
Totals	22921	27230	23171	(85.1%)	6345	(23.3%)	5304	(19.5%)	6936

Table 4.14 Results of unstimulated IVF and fresh embryo transfer cycles
(All percentages are of number of treatment cycles)

	Treatment		Clinical				Babies
	Patients	Cycles	Embryo Transfers		Pregnancies		Live Births		Born
Own Gametes	76	86	38	(44.2%)	4	(4.7%)	2	(2.3%)	2
Donated Sperm	9	9	4	(44.4%)	-	-	-	-	-
Totals	85	95	42	(44.2%)	4	(4.2%)	2	(2.1%)	2

Table 4.15 Results of IVF and fresh embryo transfer cycles using donated eggs or donated embryos
(All percentages are of number of treatment cycles)

	Treatment		Clinical				Babies
	Patients	Cycles	Embryo Transfers		Pregnancies		Live Births		Born
Donated Eggs	1161	1253	1166	(93.1%)	345	(27.5%)	282	(22.5%)	373
Donated Embryos	104	111	106	(95.5%)	31	(27.9%)	28	(25.2%)	38
Totals	1265	1364	1272	(93.3%)	376	(27.6%)	310	(22.7%)	411

Table 4.16 Clinical IVF pregnancy and live birth rates with fresh embryo transfer

a) Stimulated IVF

		Pregnancy rate %			Live birth rate %		
	Number of treatment cycles	Per treatment cycle	Per egg collection	Per embryo transfer	Per Treatment Cycle	Per egg collection	Per embryo transfer
Own Gametes	26056	23.0	25.0	27.1	19.2	20.9	22.7
Donated Sperm	1174	30.2	30.4	32.5	24.9	25.1	26.8
Totals	27230	23.3	25.2	27.4	19.5	21.1	22.9

b) Unstimulated IVF

		Pregnancy rate %			Live birth rate %		
	Number of treatment cycles	Per treatment cycle	Per egg collection	Per embryo transfer	Per Treatment Cycle	Per egg collection	Per embryo transfer
Own Gametes	86	4.7	9.3	10.5	2.3	4.7	5.3
Donated Sperm	9	-	-	-	-	-	-
Totals	95	4.2	8.2	9.5	2.1	4.1	4.8

c) Cycles using donated eggs or donated embryos

		Pregnancy rate %			Live birth rate %		
	Number of treatment cycles	Per treatment cycle	Per egg collection	Per embryo transfer	Per Treatment Cycle	Per egg collection	Per embryo transfer
Donated Eggs	1253	27.5	n/a	29.6	22.5	n/a	24.2
Donated Embryos	111	27.9	n/a	29.2	25.2	n/a	26.4
Totals	1364	27.6	n/a	29.6	22.7	n/a	24.4

Table 4.17 Developmental defects and syndromes

Chromosomal syndromes	Total	Fresh IVF	Frozen IVF	DI	Micro-manipulation
Down's Syndrome	8	1		2	5
Other chromosomal abnormalites	8	3	1	1	3

Congenital abnormalities	Total	Fresh IVF	Frozen IVF	DI	Micro-manipulation
Cleft lip	5	2	1		2
Cleft palate	2	2			
Cleft lip with cleft palate	5	2			3
Tracheo-oesophageal fistula, oesophageal atresia and stenosis	1	1			
Atresia and Stenosis of the large intestine, rectum and anal canal	4	4			
Anomalies of the alimentary system	5	1		1	3
Cardiac murmurs	6	3			3
Ventricular septal defect	5	2	1	2	
Other congenital cardiac anomalies	12	4	2	3	3
Other anomalies of the cardiac septa	1				1
Patent Ductus	3	1			2
Anomalies of the cardiovascular system	4	1			3
Hypospadias, Epispadias	2	1		1	
Anomalies of the male external genitalia	1				1
Renal anomalies	13	3	3	1	6
Polydactyly or syndactyly	6	3		2	1
Reduction deformities of the limbs	1	1			
Talipes	9	2		2	5
Congenital dislocation of the hip	2	1			1
Other anomalies of the limbs or limb girdle	2	1			1
Anomalies of the nose, face, neck and skull	2	1		1	
Anomalies of the abdominal wall	1				1
Ear anomalies	7		1		6
Spina bifida					
Exomphalos	5	1			4
Anomalies of the tongue, branchial cleft and auricular sinus					
Total number of children born	120	41	9	16	54
As a percentage of total number of babies born as a result of each type of licensed treatment	1.3	0.9	1.2	1.4	1.7

Note: Some children are born with more than one chromosmal or congenital abnormality

Table 4.18 DI clinical pregnancy & live birth rates per treatment cycle 1/8/1991 to 31/3/1999
(Data includes GIFT using donor gametes and Intra Uterine Insemination)
(All percentages are of number of treatment cycles)

Reporting period	Number of treatment cycles	Clinical Pregnancy Rate per treatment cycle (%)	Live Birth Rate per treatment cycle (%)
01/08/91 to 31/03/92[1]	16299	6.6	5.0
01/04/92 to 31/03/93	25623	6.9	5.4
01/04/93 to 31/03/94	23869	8.6	7.0
01/04/94 to 31/03/95	20604	9.7	7.9
01/04/95 to 31/03/96	16874	11.2	9.3
01/04/96 to 31/03/97	14333	11.6	9.6
01/04/97 to 31/03/98	12753	11.6	9.6
01/04/98 to 31/03/99	11035	12.1	9.9

1. Data for eight months only

Table 4.19 Donor Insemination Data

Stimulated DI		Unstimulated DI	
Number of Centres	103	Number of Centres	97
Number of Patients	2330	Number of Patients	2573
Number of Treatment Cycles	4713	Number of Treatment Cycles	6322
Total Clinical Pregnancies	642	Total Clinical Pregnancies	690
Clinical Pregnancy Rate per Cycle	13.6%	Clinical Pregnancy Rate per Cycle	10.9%
Total Miscarriages	68	Total Miscarriages	78
Total Terminations	12	Total Terminations	6
Total Ectopics	9	Total Ectopics	2
Total Live Births	517	Total Live Births	570
Live Birth Rate per Cycle	11.0%	Live Birth Rate per Cycle	9.0%
Total stillbirths and neonatal deaths	8	Total stillbirths and neonatal deaths	4

Table 4.20 Single and multiple clinical pregnancy outcome

a) Stimulated DI

	Clinical Pregnancies	Live Births	Miscarriages	Terminations	Ectopics	Unknown Outcomes	Babies Born	Stillbirths and Neonatal Deaths (per thousand birth events)
Singleton	539	450	58	9	9	10	451	6.7
Twin	60	57	7	-	-	1	108	17.5
Triplet	9	8	2	1	-	-	18	500.0[1]
Quad	3	2	1	2	-	-	6	-
Totals	611	517	68	12	9	11	583	15.5

1. Four out of eight.

b) Unstimulated DI

	Clinical Pregnancies	Live Births	Miscarriages	Terminations	Ectopics	Unknown Outcomes	Babies Born	Stillbirths and Neonatal Deaths (per thousand birth events)
Singleton	662	562	77	6	2	11	562	7.1
Twin	9	8	1	-	-	-	16	-
Totals	671	570	78	6	2	11	578	7.0

Note: There were 50 clinical pregnancies for which no outcome form was received

Table 4.21 DI live birth rate by woman's age

	Under 25	25 - 29	30 -34	35 - 39	40 - 44	45 and over
Number of cycles	358	2210	4200	3299	927	41
Live Birth Rate per cycle	8.7	11.8	11.4	8.4	3.9	2.4

5. RESEARCH

INTRODUCTION

Research is vital for the advancement of clinical medicine. Early knowledge of human embryology was based entirely on the physical description of embryos at different stages of development and comparison with processes in other species, mainly the mouse. The first successful in vitro fertilisation of mouse ova was achieved in 1958 and was followed ten years later by the successful fertilisation of human eggs. With the ability to freeze and store embryos, the possibilities for research have risen significantly in the past few years.

Any research project[9] involving the creation, keeping or using of human embryos outside the body must be licensed by the HFEA . To grant a research licence, the HFEA must be satisfied that the research is "necessary or desirable", and that the use of human embryos is essential. The HFEA may grant licences for research projects only for the following specified purposes[10]:

- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of congenital disease;
- increasing knowledge about the causes of miscarriages;
- developing more effective techniques of contraception; or
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Human embryos obtained with appropriate consent for a research project may not be used for any other purpose. The following activities involving human embryos are not permitted under UK law:

- keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier;
- placing a human embryo in an animal;
- replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or a subsequent development of an embryo;
- altering the genetic structure of any cell while it forms part of an embryo; and
- using embryos for any other purposes except in pursuance of a licence.

It is also the HFEA's policy not to licence research projects involving embryo splitting with the intention of increasing the number of embryos for transfer[11].

9. HFE Act 1990 s.3(1).
10. HFE Act 1990 Schedule 2, para. 3(2).
11. HFEA Code of Practice paragraph 10.5.

LICENSED RESEARCH PROJECTS

As of 31st August 2000 the HFEA had received 131 applications for research licences since 1991. Of these, 111 were granted and work has been completed on 70 projects.

As of 31st August 2000 there were 32 licensed research projects ongoing at 20 different centres. Of these research projects, 26 are ongoing and 6 are new. A full list of the projects currently licensed by the HFEA can be found at Annex 4. The main objective of the majority of the projects currently licensed by the HFEA is to promote advances in the treatment of infertility.

THE RESEARCH LICENSING PROCESS

Approval by a properly constituted external Research Ethics Committee is a prerequisite to the HFEA considering an application for a research licence. The HFEA's Code of Practice provides guidance on the use and constitution of such ethics committees[12]. An application for a research licence must contain a range of information on the proposed project including its objectives, protocols to be used and why the use of sperm, oocytes or embryos is necessary.
When an application for a research licence is received, it is sent out to Peer Review. A full list of the HFEA's Peer Reviewers can be found at Annex 5. Peer Reviewers are asked to recommend whether the project should be licensed and to comment in particular on:

- whether the proposed research falls under the purposes listed above;
- the potential importance of the research to the particular field;
- whether the research has previously been undertaken elsewhere;
- whether the use of human embryos is justified in furthering knowledge in the field;
- the suitability of the methods to be used for achieving the stated aims of the research;
- whether the proposed numbers of gametes or embryos are realistic and are likely to give meaningful results
- the suitability of the proposed length of the study; and
- the suitability of the applicant's qualifications and professional background to undertaking research on human embryos.

Comments made by Peer Reviewers may be fed back to applicants to give them opportunity to clarify any issues raised before a Licence Committee considers whether a licence should be granted. The Licence Committee will consider the issues listed above as well as issues such as the information given to patients donating sperm, oocytes or embryos to the research project.

The HFEA inspects centres at which licensed research is carried out and requires reports to be submitted on the progress of projects. At the end of a research project the researchers are required to submit a final report containing the the number of embryos used, the results and conclusions of the project and references to any publications resulting from the work.

12.HFEA Code of Practice paragraph10.8

6. POLICY UPDATE AND ISSUES FOR THE COMING YEAR

In addition to subjects covered elsewhere in this report, the HFEA is considering, or has recently considered the following issues.

PREIMPLANTATION GENETIC DIAGNOSIS (PGD)

PGD is a technique used to detect whether an embryo created *in vitro* is carrying a genetic defect that will give rise to a serious inherited genetic disorder. It can also be used to determine the sex of an embryo where a family is at risk of passing on a serious sex-linked disorder, such as Duchenne's Muscular Dystrophy. Four centres are currently licensed to carry out PGD with one other centre licensed only to carry out the embryo biopsy procedure. PGD is currently practised on a small scale, but demand is expected to grow as knowledge about the genes responsible for different conditions increases and the techniques involved continue to develop. The HFEA and the Advisory Committee on Genetic Testing (ACGT) (a body that has been absorbed by the newly created Human Genetics Commission (HGC)) issued a consultation paper on the issues surrounding the use of PGD at the end of 1999. A total of 171 responses were received including replies from individuals and organisations. The HFEA and the HGC are currently preparing their conclusions and recommendations based on this consultation exercise. It is expected that these will be published in 2001.

EGG FREEZING

After due consideration, the HFEA decided to allow the carefully controlled use of frozen eggs in fertility treatment. Certain clinics had previously been allowed to freeze and store human eggs, but the HFEA was not satisfied that there was enough medical research to show that their use in treatment was sufficiently safe. After hearing expert evidence and following a report, specially commissioned by the HFEA, it was decided that the science had progressed sufficiently to support the licensing of this procedure and allow frozen eggs to be used in IVF treatment. In doing so the HFEA recognised that this technique could offer hope to women who risk losing their fertility due to a medical condition or treatment. The HFEA has insisted that clinics offering this treatment must inform patients of any risks involved and also give clear information about the success rate that is currently very low. The HFEA has produced a patient information leaflet about this procedure. Seven centres are currently licensed to carry out egg freezing.

CLONING

In 1998 the HFEA held a joint consultation with the Human Genetics Advisory Commission on human cloning. The ensuing report distinguished between reproductive cloning and in vitro work using cell nucleus replacement technology with a therapeutic aim. The report recommended that, while reproductive cloning should not take place, therapeutic cloning may hold promise for the treatment of serious illnesses.

Specifically the report recommended to the Secretary of State that consideration should be given to specifying in Regulations two further categories for which HFEA licensed embryo research may take place:

- Developing methods of therapy for mitochondrial diseases; and
- Developing methods of therapy for diseased or damaged tissues or organs.

In June 1999 the Government announced the creation of an advisory group under the Chief Medical Officer to examine further the potential benefits, risks and alternatives to therapeutic cloning. That group's recomendations were endorsed by the Government in August 2000 and closely reflected the conclusions of the HFEA/HGAC report. It is now for Parliament to decide whether all, or some, of these recommendations should be implemented.

EGG SHARING

Egg sharing is an arrangement whereby a woman may receive free or subsidised IVF treatment in return for donating her surplus eggs. The HFEA was persuaded that, if properly regulated and monitored, the practice could, in some cases, be beneficial to participants. The HFEA decided to allow egg sharing to continue, but only on condition that strict guidelines were prepared to protect all those involved in such arrangements. Guidance has been drafted with the assistance of BFS and RCOG representatives. The HFEA anticipates issuing the guidance to licensed centres shortly.

PAYMENT OF EXPENSES TO DONORS

Following consultation, the HFEA decided to allow the current limited payment to sperm and egg donors of up to £15 to continue and that donors' reasonable expenses should be reimbursed. To help centres the Code of Practice Committee has drafted guidelines for the payment of expenses to donors covering, for example, travel and subsistence.

HFEA INFORMATION FOR TREATMENT ETHICS COMMITTEES

Ethics committees for treatment are not mandatory either under the HFE Act or through the HFEA's Code of Practice. The HFEA, however, encourages licensed clinics to have active ethics committees and to seek their advice whenever necessary. The HFEA has recently circulated guidelines for members of ethics committees. These concern their role in the decision making process of the licensed clinic, the welfare of the child assessment and recommendations as to their constitution.

SCREENING OF SPERM DONORS

Following the publication of the new 1999 British Andrology Society (BAS) guidelines on the screening of sperm donors, the Code of Practice Committee has been considering the possibility of revising the guidance given in the Code. Any changes agreed by the HFEA will be reflected in the Code's next edition.

BULK IMPORT

In 1999 the HFEA granted a licensed centre a Special Direction for the bulk import of sperm. This was prompted by a shortage of sperm donors in its area, and was granted on condition that the clinic abroad adhered to the high safety standards enforced by the HFEA in the UK. The overseas clinic was also required to provide their donors with information about the legal situation in the UK with respect to legal parentage, anonymity and the keeping of information about donors on the HFEA's Register.

STORAGE OF OVARIAN AND TESTICULAR TISSUE

The HFEA licences the storage of sperm and eggs including ovarian and testicular tissue where mature gametes are, or might be, present - that is, testicular tissue where boys have reached puberty and ovarian tissue from girls or women where a mature egg may be present. The Department of Health is currently considering a scheme for the regulation of the storage of human tissue, which would include ovarian and testicular tissue where no mature gametes are present. The Authority is following this initiative closely to ensure that this system will operate smoothly alongside the HFEA's own licensing process.

THE STATUTORY STORAGE PERIOD FOR GAMETES AND EMBRYOS

The statutory storage period for gametes and embryos is ten and five years respectively. Regulations allow the storage period for sperm and embryos to be extended in certain circumstances. The first ten year period since the 1990 Act's implementation will end in August 2001. The HFEA plans to issue advice to centres on how they should prepare for this. The HFEA has issued a new consent form that can be completed by men eligible for storage of sperm beyond the statutory storage period of ten years in accordance with Regulations.

MIXED IVF/ICSI EMBRYO TRANSFERS

In 2000 the HFEA reviewed its policy regarding the replacement of embryos produced by ICSI together with IVF embryos in a single embryo transfer. The HFEA recognised that, despite concerns about the effect mixed embryo transfers may have on the monitoring of ICSI practice, a mixed embryo transfer might be beneficial to some patients in exceptional circumstances. Centres may now, therefore, carry out mixed embryo transfers up to a limit of 2% of all ICSI embryo transfers per annum.

WORKING GROUP ON NEW DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY

The Working Group on New Developments in Reproductive Technology (WGNDRT) advises the Authority on progress in, and the safety of, new clinical and scientific techniques that fall within the HFEA's remit. The WGNDRT also advises on the training standards for practitioners of techniques such as embryo biopsy, which is required for pre-implantation genetic diagnosis (PGD), and keeps newly licensed techniques such as laser assisted hatching under review.

In considering whether a new technique should be licensed by the HFEA, the WGNDRT explores:

- the biological basis of the procedure;
- evidence from animal research;
- evidence from human embryo research;
- evidence from clinical research; and
- evidence of expertise/competence of the practitioner.

Some issues that have been considered by the WGNDRT during the period of this report are summarised below.

FRAGMENT REMOVAL IN ASSISTED HATCHING

Assisted hatching involves making a small hole in the shell (zona pellucida) of the embryo created in vitro. The aim is to help the embryo hatch out of its shell and increase the chance of implantation into the lining of the uterus. The hole in the shell can be made mechanically, chemically or by using a laser.

During the development of an embryo, fragments of cell debris may be produced within the embryo. It has been suggested that the presence of such fragments may impair the ability of the embryo to develop. The technique of fragment removal involves inserting a micropipette into the embryo via the hole made for assisted hatching and removing the fragments.

The WGNDRT considered the published scientific evidence on the use of fragment removal in assisted hatching. It agreed that there was little evidence to suggest that this procedure was beneficial and some evidence to suggest it might be harmful. The WGNDRT noted that the degree of harm would relate to operator expertise and the degree of fragment removal undertaken. The WGNDRT therefore recommended that the technique should not be licensed.

RE-INSEMINATION BY SUZI OF FAILED TO FERTILISE EGGS

SUZI (sub-zonal insemination) is the microinjection of a small number of sperm through the zona pellucida into the space between the egg and the zona pellucida. The WGNDRT considered the use of this technique on eggs that have failed to fertilise by 24 hours after being incubated with sperm, as happens in standard IVF. It agreed that this procedure could be of benefit to patients and did not feel that there were any new safety concerns. The WGNDRT felt that that patient information should inform patients of the low success rate of this procedure, but recommended that the practice should be allowed to continue.

7. COMMUNICATIONS

INTRODUCTION

The HFE Act requires the HFEA to "publicise the services provided to the public by the HFEA or provided in pursuance of licences" and to "provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos ... or may wish to do so." In fulfilling this function the HFEA offers a comprehensive range of information for current or prospective patients, donors and the general public (listed at the end of this chapter). The HFEA receives, on average, 250 requests per week for its publications. About twice a year the HFEA circulates a newsletter, 'HFEA Update', to licensed clinics and interested bodies, informing them of recent policy decisions and discussing areas of concern.

The HFEA works closely with journalists and media researchers and supplies speakers for national and international conferences and for press, radio and television interviews. In addition, HFEA Members and staff have written articles for mainstream, specialist and patient publications. The HFEA's website (www.hfea.gov.uk) now includes its Patients' Guide, Annual Reports and Code of Practice, as well as recent press releases and summary minutes of HFEA meetings.

THE PATIENTS' GUIDE TO DI AND IVF CLINICS

Since 1995 the HFEA has produced a 'Patients' Guide to DI and IVF Clinics' to provide advice and information to those people seeking infertility treatment. The HFEA understands how important it is for patients to receive impartial information that is easily accessible. To that end, and following responses from patients and others, the Guide has been fundamentally redesigned. The Guide is now separated into three booklets: 'The Patients' Guide to Infertility and IVF', 'The Patients' Guide to IVF Clinics' and 'The Patients' Guide to DI'. The new clinic data tables are presented in a more user friendly format with a clearer layout and annotated explanation. The data tables are updated every year.

A leaflet entitled, 'Who we are and what we do', has also been produced explaining the HFEA's role and responsibilities and publicising the existence of the Patients' Guide. Following a survey of licensed clinics, the HFEA has produced a similar leaflet in a number of minority languages.

THE HFEA ANNUAL CONFERENCE

The HFEA's Annual Conference provides a forum for informed discussion and debate in the field of regulated fertility treatment. This one day conference gives the staff of licensed clinics, HFEA's Members, Executive staff, Inspectors and other delegates an opportunity to discuss issues of mutual interest and to exchange views and ideas.

The 1999 HFEA Annual Conference was held in Manchester and was attended by over 250 delegates. The Deputy Chief Medical Officer discussed the relationship between the Department of Health and the HFEA and Mr Hossam Abdalla, Dr Liz Lenton and Professor Allan Templeton discussed moving towards two embryo replacement as a way of reducing multiple births. There were also workshops on the new licensing system and HFEA inspections, the new data register, egg sharing and meeting patients' needs. The 2000 HFEA Annual Conference will take place in London in December and the programme will include sessions on Human Rights, Egg Freezing, Storage of Ovarian and Testicular Tissue and Patients' Satisfaction.

REGIONAL AND OTHER MEETINGS

The HFEA recognises the importance of maintaining a continual dialogue with those involved, or interested in, the area of assisted reproduction. In line with this policy the HFEA has this year organised regional meetings in London and York. These meetings provide an opportunity for patients, nurses, clinicians, researchers and counsellors to meet with HFEA representatives to discuss HFEA policy. This year the HFEA's Chairman, Deputy Chairman and Chief Executive also met with representatives of various groups opposed to practices allowed by the 1990 Act that the HFEA has a statutory duty to regulate.

In addition, HFEA representatives have continued their regular meeting with the British Fertility Society and the Royal College of Obstetricians and Gynaecologists. There is also ongoing contact with other organisations including the patient representative groups, Child and Issue as well as the British Medical Association, the Family Planning Association, Progress, Donor Conception Network, the National Gamete Donation Trust, the Medical Research Council, the British Infertility Counselling Association, The Wellcome Trust, the British Andrology Society, the Association of Clinical Embryologists and the Royal College of Nursing. The HFEA also works closely with the Department of Health on many areas of mutual concern.

INFORMATION AVAILABLE TO THE PUBLIC

The HFEA provides information that is available to prospective patients, interested organisations and the general public. Those requiring any of the following publications should contact the HFEA. The following information can be found on the HFEA's website www.hfea.gov.uk.

Annual Reports 1992 - 2000

(The 1998 and 1999 Annual Reports are available from the Stationery Office priced £10)

The Patients' Guide to DI and IVF Clinics

Pack Includes:

- The Patients' Guide to Infertility and IVF
- The Patients' Guide to IVF Clinics 2000
- The Patients' Guide to DI 2000

Information Leaflets:

- HFEA: Who we are and what we do
- Egg Donation
- Sperm and Egg Donors and the Law
- Embryo storage
- Welfare of the Child: Information for GPs
- Welfare of the Child: Information for Patients
- Intra Cytoplasmic Sperm Injection (ICSI): Information for Patients
- Storage and Use of Frozen Eggs
- Consent to the Use and Storage of Gametes and Embryos

Code of Practice Fourth Edition

(Fifth edition is expected to be published during 2001)

The following lists are produced:

- Centres who do IVF with donor eggs
- Sperm donor recruitment centres
- PGD clinics
- Egg freezing centres
- Storage of sperm centres

Videos:

- In Vitro Fertilisation
- Donor Insemination
- (Supplied for educational purposes only)

Website:

http://www.hfea.gov.uk

ANNEXES

1 EXECUTIVE STAFF Main telephone no: 0207 377 5077

	Job Title	Telephone Number
Senior Managers		
Hugh Whittall	Acting Chief Executive	020 7539 3303
Derek Hodge	Personnel & Resources Manager	020 7539 3330
Mark Salmon	On Secondment	
Allan Wright	IT Manager	020 7539 3307
Office Administration		
Julie Jones	Executive Assistant/ PA to Hugh Whitall	020 7539 3303
Paul Allum	Administration Officer	020 7539 3319
Dilpha Patel	Administration Assistant	020 7539 3318
Communications		
James Yeandel	Director of Communications	020 7539 3306
Data		
Dr Richard Baranowski	Deputy Information Manager	020 7539 3329
Christine Poole	Data Register Manager	020 7539 3327
Tina Kundu	IT Support and Research Assistant	020 7539 3310
Maureen Goodman	Data Officer	020 7539 3331
Patricia Honnor	Data Officer	020 7539 3321
Gaby Jeremiah	Data Officer	020 7539 3321
Sandy Lathleiff	Data Officer	020 7539 3331
Michael Lench	Data Officer	020 7539 3332
Andrew Brown	Data Officer	020 7539 3332
Sally Payne	Data Administrator	0207 539 3332
Finance		
Gill Davidson	Finance Manager	020 7539 3305
Wilhelmina Crown	Deputy Finance Manager	020 7539 3302
Licensing		
Dr Debbie Jaggers	Licensing Manager	020 7539 3322
Dr Mary Wall	Licensing Business Manager	020 7539 3315
Dr Joanne Rippington	Inspector Co-ordinator	020 7539 3328
Elizabeth Asung	Auditor/Inspector Co-ordinator	020 7539 3323
Kim Hayes	Inspector Co-ordinator	020 7539 3312
Jennifer Dimond	Inspector Co-ordinator/Auditor	020 7539 3313
Dr Christine O'Toole	Inspector Co-ordinator	020 7539 3324
Kerri Treston	Licence Administrator	020 7539 3317
Diane Lowe	Licence Administrative Assistant	020 7539 3326
Policy		
Dr Virginia Shires	Senior Policy Manager	020 7539 3311
Dr Peter Mills	Policy Manager	020 7539 3308
Myfanwy Milton	Policy Manager	020 7539 3320

2 LIST OF LICENSED CLINICS
(as of 31 August 2000)

Avon
Centre for Reproductive Medicine, Bristol University.
Royal United Hospital, Bath.
Southmead General Hospital, Bristol.
St Michael's Hospital, Bristol.
Tower House Clinic, Bristol.
University of Bristol IVF Service, The BUPA Hospital, Bristol.

Buckinghamshire
BMI Chiltern Hospital, Great Missenden.
Thames Valley Nuffield Hospital.

Cambridgeshire
Bourn Hall Clinic, Bourn.
Peterborough District Hospital.
Rosie Maternity Hospital, Cambridge.

Cleveland
Cleveland Fertility Centre, Stokesley.
Hartlepool General Hospital.
South Cleveland Hospital, Middlesborough.
Derbyshire.
Derby City General Hospital.

Devon
Derriford Hospital, Plymouth.
Heavitree Hospital, Exeter.

Dorset
Winterbourne Hospital, Dorchester.

Durham
Bishop Auckland General Hospital.

East Sussex
Esperance Private Hospital, Eastbourne.

Essex
Brentwood Fertility Centre.
Essex Fertility Centre, Buckhurst Hill.
North East London Fertility Services, Ilford.
The Oaks Hospital, Colchester.

Greater Manchester
Billinge Hospital, Wigan.
Centres for Assisted Reproduction Ltd. (CARE) at the Alexandra Victoria Park Hospital, Manchester.
Manchester Fertility Services, BUPA Manchester Hospital.
Regional IVF & DI Unit, St Mary's Hospital, Manchester.
Salford Royal IVF and Fertility Centre, Hope Hospital, Salford.

Hampshire
BUPA Chalybeate Hospital, Southhampton.
North Hampshire Fertility Centre, North Hampshire Hospital, Basingstoke.
The Hampshire Clinic, Baskingstoke.
Wessex Fertility Services, Princess Ann Hospital, Southampton.

Herfordshire
Watford General Hospital.

Humberside
Princess Royal Hospital, Hull.

Kent
BMI The Chaucer Hospital, Canterbury.
BMI Chelsfield Park Hospital.
Maidstone Hospital.
Queen Mary's Hospital, Sidcup.

Leicestershire
Leicester Royal Infirmary.
Middle England Fertility Centre, BUPA Hospital, Leicester.

London
Assisted Conception Unit, University College Hospital.
Assisted Reproduction and Gynaecology Centre.
Chelsea & Westminster Hospital.
Cromwell Hospital.
Dr Louis Hughes,
Fertility Unit, The Portland Hospital.
London Fertility Centre.
London Women's Clinic/Hallam Medical Centre.
London Women's Clinic, The Portland Hospital.
Reproductive Medicine Unit, University College Hospital.
Seymour Clinic, St Mary's Hospital.
St Bartholomew's Hospital.
St Thomas' Hospital.

The Bridge Centre.
The Harley Street Fertility Centre.
The Harley Street Clinic.
The Lister Hospital.

London (East)
Homerton Hospital.
Newham General Hospital.

London (North)
London Female and Male Fertility Centre, Highgate Private Hospital.

London (South)
Diana, Princess of Wales Centre for Reproductive Medicine, St George's Hospital, Tooting.
King's College Hospital.

London (West)
West Middlesex University Hospital.
Wolfson Family Clinic, Hammersmith Hospital.

Merseyside
BUPA Murrayfield Hospital, Wirral.
Liverpool Women's Hospital.
University Hospital Aintree, Liverpool.

Northern Ireland
Royal Maternity Hospital, Belfast.

Norfolk
James Paget Healthcare NHS Trust, Great Yarmouth.
Northamptonshire.
BMI Three Shires Hospital, Cliftonville.

Nottinghamshire
Centres for Assisted Reproduction Ltd. (CARE) at the Park Hospital, Arnold.
NURTURE, University of Nottingham.
Queen's Medical Centre, Nottingham.

Oxfordshire
John Radcliffe Maternity Hospital, Oxford.

Scotland - Grampian
University of Aberdeen.

Scotland - Lothian
Royal Infirmary of Edinburgh.
Western General Hospital, Edinburgh.

Scotland - Orkney
Balfour Hospital, Orkney.

Scotland - Strathclyde
BMI Ross Hall Hospital, Glasgow.
Glasgow Nuffield Hospital.
Glasgow Royal Infirmary.
Monklands Hospital Acute NHS Trust, Airdrie.

Scotland - Tayside
Ninewells Hospital and Medical School, Dundee.

Shropshire
Shropshire and Mid-Wales Fertility Centre, Royal Shrewsbury Hospital.

Staffordshire
North Staffordshire Nuffield Hospital, Newcastle-under-Lyme.
Queen's Hospital, Burton-upon-Trent.

Surrey
Shirley Oaks Hospital, Croydon.
Woking Nuffield Hospital.

Tyne and Wear
Cromwell IVF & Fertility Centre, The BUPA Washington Hospital.
Queen Elizabeth Hospital, Gateshead.
Sunderland Royal Hospital.
The International Centre for Life, Newcastle-upon-Tyne.

Wales (South Glamorgan)
BUPA Hospital Cardiff.
University Hospital of Wales, Cardiff.

Wales (West Glamorgan)
Cromwell IVF and Fertility Centre, Singleton Hospital, Swansea.
Neath General Hospital.

West Midlands

Birmingham Women's Hospital.
BMI Priory Hospital, Birmingham.
Midland Fertility Services, Aldridge.
New Cross Hospital, Wolverhampton.
Walsgrave Hospital, Coventry.

Yorkshire (South)

Jessop Hospital for Women, Sheffield.
Sheffield Fertility Centre.

Yorkshire (West)

Clarendon Wing, Leeds General Infirmary.
St James' University Hospital Leeds.

Clinics with Storage Licences only

Andrology Unit, Hammersmith Hospital.
Bridge Centre Cryoservices, London.
Cheltenham General Hospital.
Christie Hospital NHS Trust.
North West Wales Fertility Centre, Gwynedd Hospital, Bangor.
Nottingham City Hospital.
Royal Surrey County Hospital, Guildford.
Singleton Hospital, Swansea.
Yorkshire Regional Tissue Bank, Wakefield.

3 LIST OF INSPECTORS
(as of 31 August 2000)

Clinicians

Mr Masoud Afnan
Consultant Obstetrician & Gynaecologist,
Honorary Senior Lecturer,
Director of ACU, Birmingham Maternity Hospital.

Mr Peter Brinsden
Medical Director, Bourn Hall Clinic,
Affiliated Lecturer, Department of Obstetrics & Gynaecology, University of Cambridge.

Mr Chris Chandler
Clinical Director, Consultant Obstetrician & Gynaecologist, Billinge Hospital, Wigan.

Dr Ruth Curson
Associate Specialist, King's College Hospital, London.

Mr Robert Forman
Medical Director, Centre for Reproductive Medicine, London.

Professor Stephen Franks
Professor of Reproductive Endocrinology, St Mary's ICSM Campus, London.

Dr Mark Hamilton
Consultant Obstetrician & Gynaecologist,
Clinical Senior Lecturer, University of Aberdeen.

Mr Richard Kennedy
Consultant Obstetrician & Gynaecologist,
Walsgrave Hospital, Coventry.

Mr Charles Kingsland
Consultant Obstetrician & Gynaecologist,
Honorary Lecturer,
The Women's Hospital Liverpool.

Dr Martin Lees
Consultant Obstetrician & Gynaecologist,
Senior Lecturer, Royal Infirmary of Edinburgh NHS Trust.

Dr John Mills
Consultant Obstetrician & Gynaecologist,
Ninewells Hospital, Dundee.

Dr Alison Murdoch
Consultant Obstetrician & Gynaecologist,
Honorary Senior Lecturer,
Director of the Centre for Reproductive Medicine, International Centre for Life, Newcastle upon Tyne.

Mr Roger Neuberg
Consultant Obstetrician & Gynaecologist,
Director of Infertility Service, Leicester Royal Infirmary,
Co-Director of BUPA Leicester.

Mr Julian Pampiglione
Consultant Obstetrician & Gynaecologist, The Royal Bournemouth Hospital.

Mr John Parsons
Senior Lecturer.
Honorary Consultant, King's College Hospital, London.

Dr Elizabeth Pease
Consultant, St Mary's Hospital, Manchester.

Dr David Polson
Consultant in Obstetrics & Gynaecology,
Salford Royal IVF & Fertility Centre.

Mr Anthony Rutherford
Consultant Obstetrician & Gynaecologist,
The Leeds Teaching Hospitals NHS Trust.

Mr Robert Sawers
Consultant Obstetrician & Gynaecologist,
Programme Director, BMI Priory Hospital, Birmingham.

Mr Eric Simons
Medical Director,
Cromwell Hospital, London.

Dr Alison Taylor
Consultant,
Senior Lecturer, Guy's and St Thomas' Hospital, London.

Mr Peter Wardle
Consultant & Senior Lecturer in Obstetrics & Gynaecology, Southmead Hospital, Bristol.

Dr Christine West
Consultant Obstetrician & Gynaecologist,
Royal Infirmary, Edinburgh.

Dr Robin Yates
Medical Research Director,
Assisted Conception Unit, Royal Infirmary, Glasgow.

Scientists

Dr Linda Baggott
Lecturer in Biology and Education,
University of Exeter.

Dr Virginia Bolton
Senior Lecturer,
King's College Hospital, London.

Dr John Clarke
Retired Lecturer in Zoology,
University of Oxford.

Dr John Coutts
Retired Reader in Reproductive Endocrinology.

Ms Karin Dawson
Consultant Embryologist,
Hammersmith Hospital, London.

Dr Simon Fishel
Managing Director,
Centres for Assisted Reproduction Ltd. (CARE), Park Hospital, Arnold, Nottingham.

Professor Tom Fleming
Cell Sciences Division, School of Biological Sciences, University of Southampton.

Professor Lynn Fraser
Professor of Reproductive Biology, King's College, London.

Dr Ceinwen Gearon
IVF Laboratory Director, Lister Hospital, London.

Dr May-Beth Jamieson
Senior Embryologist
University Department of Obstetrics & Gynaecology, Glasgow Royal Infirmary.

Dr John Keith
Senior Scientist,
Edinburgh Assisted Conception Unit.

Mr Terry Leonard
Co-Director, ISIS Fertility Centre, Colchester.

Dr Alan McDermott
Director, Regional Cytogenetics Centre, Southmead Hospital Bristol.

Dr Dave Morroll
Senior Clinical Embryologist,
NURTURE, Nottingham.

Ms Barbara Ray
Principal Embryologist,
University of Bristol, BUPA Hospital, Bristol.

Dr John Robinson
Scientific Director,
Hull IVF Unit.

Reverend Professor Mary Seller
Professor of Development Genetics,
Medical & Molecular Genetics, Guy's Hospital, London.

Dr Arasaratnam Srikanthrarajah
Research Embryologist,
University of Aberdeen.

Mr Stephen Troup
Scientific Director,
Liverpool Women's Hospital.

Dr Karen Turner
Senior Clinical Embryologist,
Queen's Hospital, Burton-on-Trent.

Dr Maureen Wood
Research Fellow,
Department of Anatomy and Developmental Biology, St George's Hospital Medical School, London.

Social and ethical inspectors

Mrs Sarah Biggs
Member of King's Fund Committee on Counselling, London.

Mrs Linda Breeze
Relate.
Psychosexual Therapist and Fertility Counsellor at Royal Devon and Exeter Hospital

Ms Jennifer Clifford
Counsellor.

Mrs Elizabeth Corrigan
Nursing Director,
St Michael's and BUPA Hospital, Bristol.

Ms Marilyn Crawshaw
Social Worker.

Mrs Heideh Hillier
IVF Nurse Manager,
Edinburgh Assisted Conception Unit.

Ms Jennifer Hunt
Senior Infertility Counsellor,
Hammersmith Hospital, London.

Ms Margaret Inglis
Counsellor,
Royal Free Hospital, London.

Ms Janice Kerr
Services Manager, Clinical Nurse Specialist (Infertility),
Leeds General Hospital.

Ms Kathryn Mangold
Unit Manager of IVF & OPD, BMI Portland Hospital, London.

Dr Jim Monach
Lecturer,
SCHARR, University of Sheffield.

Mrs Roz Shaw-Smith
Counselling Psychologist,
John Radcliffe Hospital, Oxford.

Ms Jennifer Speirs
Freelance Infertility Counsellor and Social Work Consultant, Edinburgh.

4 LIST OF RESEARCH PROJECTS
(as of 31 August 2000)

Bourn Hall Clinic

Oocyte preservation

Centre for Genome Research, University of Edinburgh

Culture of multipotential human embryo cells

Glasgow Royal Infirmary

Detection of autosome and sex chromosome abnormalities in human pre-implantation embryos using FISH and the PCR

Clarendon Wing - Leeds

Diagnosis of trisomies and DNA fingerprinting in human blastomeres to improve pre-implantation genetic diagnosis

Maturation and fertilisation of human eggs in vitro

Study of human eggs matured in vitro and in vivo

Segregation of mitochondrial DNA (MTDNA) in human embryos

Guy's and St Thomas' Hospital, London

Improving methods for the biopsy and diagnosis of inherited genetic disease of human pre-implantation embryos

The Hammersmith Hospital, London

Pre-implantation genetic diagnosis - parallel investigations

To measure the activity of enzymes implicated in genetic disorders

To measure the activity of metabolic enzymes in spare human pre-implantation embryos

International Centre for Life, Newcastle

An investigation of the use of laser biopsied blastocytes for pre-implantation diagnosis

Isolation and characterisation of cell lines from human pre-implantation embryos. Study of the involvement of the cellular stress response in the cause of embryo attrition and developmental defects in the human using human embryonic stem cells.

Jessop Hospital

An investigation of embryonic-endometrial dialogue during the peri-implantation period in vitro (with Sheffield Fertility Centre)

Liverpool Women's Hospital

Biopsy practice of three pronucleate embryos

Manchester Fertility Services

In vitro development and implantation of normal human pre-embryos and comparison with uni- or poly-nucleate pre-embryos (with St Mary's Hospital, Manchester and University of Manchester)

NURTURE, University of Nottingham

Fluorescent in-situ hybridisation (FISH) analysis of: failed-to-fertilise oocytes; embryos donated for research and failed thaw embryos

In-vitro maturation and cyropreservation of immature and mature human oocytes

Oxford Fertility Unit

Segregation of mitochondrial DNA in human embryos (with Walsgrave Hospital)

Development of a model to study implantation in the human

Royal Infirmary of Edinburgh

Cell biology of human spermatozoa

Sheffield Fertility Centre

An investigation of embryonic-endometrial dialogue during the peri-implantation period in vitro (with Jessop Hospital)

St Mary's Hospital, Manchester

In vitro development and implantation of normal human pre-embryos and comparison with uni- or poly-nucleate pre-embryos (with Manchester Fertility Services and University of Manchester)

University College Hospital, London

The development of novel PGD procedures and the study of early human development

University of Aberdeen

Metabolism of human embryos as an index of quality

University of Manchester

In vitro development and implantation of normal human pre-embryos and comparison with uni- or poly-nucleate pre-embryos (with Manchester Fertility Services and St Mary's Hospital)

University of York

Biochemistry of early human embryos

Walsgrave Hospital, Coventry

A study of the effects of cell death on the further development of human embryos in vitro

In vitro maturation and fertilisation of oocytes from women with polycystic ovarian disease

Segregation of mitochondrial DNA in human embryos (with Oxford Fertility Unit)

In vitro maturation and fertilisation of immature oocytes from women under going ICSI treatment

Randomised controlled clinical trial of blastocytes vs. cleaving embryo transfer

5.LIST OF PEER REVIEWERS

Professor Jonathan Aitken
Head of Department of Biological Sciences, University of Newcastle, New South Wales, Australia.

Dr Gulam Bahadur
Clinical Biochemist,
Head of Fertility Laboratories,
University College London,
Medical School/University College, London Hospital Trust.

Mr Adam Balen
Consultant Obstetrician & Gynaecologist and Sub-specialist in Reproductive Medicine, Leeds General Infirmary.

Professor David Barlow
Nuffield Professor of Obstetrics & Gynaecology, University of Oxford, Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital, Oxford.

Dr Siladitya Bhattacharya
Lecturer in Obstetrics & Gynaecology, University of Aberdeen.

Dr Virginia Bolton
Senior Lecturer, King's Assisted Conception Unit.

Professor Peter Braude
Head of the Division of Women's and Children's Health, Guy's, Kings and St Thomas' School of Medicine, London.

Professor Nigel A Brown
Professor of Developmental Biology, Department of Anatomy and Developmental Biology, St George's Hospital Medical School, London.

Professor Iain Cameron
Head of Department, Department of Obstetrics & Gynaecology, University of Southampton.

Dr John Carroll
Department of Anatomy & Developmental Biology, University College, London.

Professor Tim Chard
Department of Reproductive Physiology, St Bartholomew's Hospital Medical College, London.

Dr J R T Coutts
Retired Reader, Division of Biochemistry and Molecular Biology, University of Glasgow

Professor Mark Curry
Senior Lecturer in Equine Science, Department of Agriculture and Horticulture, De Montford University.

Ms Karin Dawson
Consultant Embryologist, Hammersmith Hospital, London.

Professor Joy Delhanty
Professor of Human Genetics, University College, London.

Dr Simon Fishel
Managing Director, CARE at the Park Hospital, Arnold, Nottingham

Dr Richard Fleming
Department of Obstetrics & Gynaecology, Glasgow Royal Infirmary.

Professor Stephen Franks
Professor of Reproductive Endocrinology, St Mary's Hospital Medical School, London.

Professor Lynn Fraser
Professor of Reproductive Biology,
King's College, London.

Dr Rafet Gazvani
Lecturer in Obstetrics & Gynaecology, University of Aberdeen.

Professor Christine Gosden
Professor of Medical Genetics, University of Liverpool, Liverpool Women's Hospital.

Professor Roger Gosden
Professor of Reproductive Biology, University of Leeds.

Dr Mark Hamilton
Clinical Science Lecturer, Department of Obstetrics & Gynaecology, University of Aberdeen.

Dr Joyce Harper
University College London.

Dr Geraldine Hartshorne
Scientific Director, Walsgrave Hospital Assisted Conception Unit, Coventry, Principal Research Fellow, Department of Biological Sciences, University of Warwick.

Professor Alan Handyside
School of Biochemistry and Molecular Biology, University of Leeds.

Mr Jonathan Hewitt
Consultant Obstetrician & Gynaecologist, Chairman of Medical Committee, Liverpool Women's Hospital.

Dr Mark Johnson
Senior Lecturer in Obstetrics, Chelsea & Westminster Hospital.

Professor Martin Johnson
Professor of Reproductive Sciences, University of Cambridge.

Professor M H Kaufman
Professor of Anatomy, University of Edinburgh.

Dr Sue Kimber
Senior Lecturer, University of Manchester.

Mr Charles Kingsland
Consultant in Obstetrics & Gynaecology, Liverpool Women's Hospital.

Professor G E Lamming
Department of Physiology and Environmental Science, University of Nottingham.

Professor Henry Leese
Department of Biology, University of York.

Dr Brian Lieberman
Medical Director, Regional IVF and DI Unit, St Mary's Hospital, Manchester.

Dr Alan McDermott
Director, Regional Cytogenetics Centre, Southmead Hospital, Bristol.

Dr Anne McLaren
Principal Research Associate, Wellcome/CRC Institute, Cambridge.

Professor Alan McNeilly
Deputy Director and Senior Scientist, MRC Reproductive Biology Unit, Edinburgh.

Dr Tony Michael
Lecturer in Biochemistry, Department of Biochemistry & Molecular Biology, Royal Free & University College Medical School, London.

Professor Marilyn Monk
Head of Molecular Embryology Unit, Institute of Child Health, London.

Professor R Moor
Babraham Institute, Cambridge.

Professor H D M Moore
Professor of Reproductive Biology, Department of Molecular Biology and Biotechnology, University of Sheffield.

Professor David Pegg
Director, Medical Cryobiology Unit, Biology Department, University of York.

Dr Ian Sargent
John Radcliffe Hospital, Oxford.

Dr Karl Swann
Reader in Cell Physiology, University College, London.

Professor Allan Templeton
Professor of Obstetrics & Gynaecology, University of Aberdeen.

Professor Robert Webb

Professor of Animal Production, Department of Agriculture and Horticulture, University of Nottingham.

Dr Maureen Wood

Research Fellow, Department of Anatomy and Developmental Biology, St George's Hospital Medical School, London.

Professor Michael Whitaker

Head of Department, Department of Physiological Sciences, University of Newcastle.

Professor David Whittingham

Emeritus Professor of Experimental Embryology, St George's Hospital Medical School.

6 LIST OF MEMBERS' INTERESTS

Ruth Deech

Principal, St Anne's College, Oxford.

Shares in Glaxo (through a PEP) and Oxford Glycobiology

Member - United Oxford & Cambridge Club;

St Anne's College has shares in London International GP, Glaxo, Smithkline Beecham, Zeneca GP, Nyomed Amersham

Rolls Royce - Supports engineering at St Anne's College

Linnells Solicitors (Dr John Deech, Partner)

Jane Denton

Director, The Multiple Births Foundation, Queen Charlotte's & Chelsea Hospital, London.

Editorial Board Member, Human Fertility

The MBF receives grants from the Gatsby Charitable Foundation, Smiths Charity, Department of Health (section 64)

RCOG Infertility Guidelines Development Group Member

Brenda Almond

Professor of Moral and Social Philosophy, University of Hull.

Sue Avery

Scientific Director, Bourn Hall.

Executive Committee Member of Association of Clinical Embryologists

Bourn Hall is owned by Ares-Serono

Occasional consultancy work for Wallace Womens Health Care

David Barlow

Nuffield Professor of Obstetrics and Gynaecology and Head of Department, University of Oxford. Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital, Oxford

Consultancy with Pharmaceutical Industry: Novo-Nordisk, Zeneca

Intermittent involvement with advisory committees and expert reports for pharmaceutical industry: Novo-Nordisk; Zeneca; Proctor & Gamble; Ely Lilly; Pharmacia Upjohn; MHR

Board or Council positions on public organisations (unpaid): RCOG; National Osteoporosis Society; British Menopause Society; National Endometriosis Society; Pernell Initiative

Membership of research grant awarding bodies (no personal gain): Wellbeing (Chairman); South East Region NHS R&D committee

Department receives research grants from many sources (no personal gain): The Wellcome Trust; Action Research; WellBeing; MRC; EU; OXAGEN; NHS R&D Programme; Schering; Searle; Serono; Organon; Zeneca; Wyeth; Jansen-Cilag; Pharmacia-Leiras

Peter Braude

Guy's, Kings and St Thomas' School of Medicine, Head of the Division of Women's and Children's Health.

Intermittent involvement and expert advisor to Serono Pharmaceuticals, Ares Serono, Tommy's Campaign and Wellbeing

Shares in Marks & Spencer, Centrica

Dept. holds grants from Tommy's Campaign, MRC, BHF, Organon, Ares Serono, Serono Pharmaceuticals UK, Welch Allen, Sir Jules Thorn Trust, Zeneca

Intermittent writing/editing Mosby, Harcourt-Brace, RCOG, OUP

Moira Coath

Solicitor.

Administrator, Simon Coath, Legal Training Consultancy

Non-Executive Director, Dorset Healthcare NHS trust

Mental Health Act Manager

Previously Chair of "Child", the National Infertility Support Network

Christine Gosden

Professor of Medical Genetics, University of Liverpool, Liverpool Women's Hospital. Honorary Consultant, Liverpool Women's Hospital, NHS Trust

Intermittent writing/publishing: Oxford University Press, Blackwells, Churchill Livingstone, Wiley Saunders, Times Higher Education Supplement, Washington Post

Commissions for filming/interviews/articles, CBS, Channel 4

Holder of research grants; Wellbeing, North West Cancer Research Fund, Roy Castle International Foundation for lung cancer research, NHS NW R&D Research funding, Humanitas, UK Department for International Development, US State Department

Fees received for lectures on cancer, fetal medicine,

human rights, genocide

Small personal shareholdings; Abbey National, Scottish Power

Andrew Grubb

Professor of Medical Law and Head of Department, Cardiff Law School, Cardiff University.

Various author and editorial royalties from academic publishers

Henry Leese

Professor of Biology, University of York.

Director and shareholder in Cellutions Ltd, a company that will develop embryo culture media (part funded by a grant from DTI)

Research grants from the following: European Commission, Medical Research Council (no personal gain)

Editor in Chief, Human Fertility

Committee Member: British Fertility Society

Small personal shareholdings: Natwest, Zeneca

Wife is at National Primary Care R&D Centre funded by the Department of Health

Stuart Lewis

Consultant Psychologist, Ulster Hospital & Community Trust; Formerly, Professor of Psychology applied to Medicine, The Queen's University, Belfast.

Sessional Consultant at Ulster, North Down & Ards Hospital Trust; Homefirst Hospital Trust; Mountsandal GP Surgery

Anne McLaren

Principal Research Associate, Wellcome/CRC Institute, Cambridge.

Member of Progress Educational Trust, British Society of Developmental Biology, European Society for Human Reproduction and Embryology and Genetical Society

Trustee of Society for the Study of Fertility, British Fertility Society, Novartis Foundation and Oxford International Biomedical Centre

European Developmental Biology Organisation (President)

Royal Society (Fellow)

Royal College of Obstetrics & Gynaecology (Fellow)

Wellcome Trust Population Panel (Member)

Project Grant Holder from Wellcome Trust (including post-retirement stipend)

Sadia Muhammed

General Practitioner, Priory Medical Group, York.

Forensic medical examiner on retained and fee basis, North Yorkshire Police

Member of North Yorkshire Health Authority Expert Sub-Fertility Group

Sara Nathan

Freelance journalist, previously Editor of Channel 4 News.

Freelance journalism for Assorted Publications and Broadcasters

Shareholdings in Williams, Rio Tinto, Shell, Imperial Chemical, Cookson Group, Diageo, Glaxo Wellcome

Council Member, Jewish Museum

Member of Radio Authority

Lay Member, Professional Conduct Committee of the Bar Council

Assorted Broadcasting Consultancies

Member of Criminal Injuries Compensation Appeals Panel

Chair, Lambeth's Children First Comission

Member, Home Office Gambling Review Body

Michael Nazir-Ali

Lord Bishop of Rochester; Director, Diocesan Board of Finance; President, Diocesan Board of Education.

Harper Collins; SPCK; Paternoster; Publishers of books

Fellow, St Edmund Hall, Oxford University

Endowed lectureshsips; University of Cambridge; University of Oxford; Queen's Belfast; Wycliffe College, Toronto; St John's, Auckland, NZ

Visiting Professor, Faculty of Humanities, University of Greenwich

Chairman of Council, Trinity College, Bristol

Sharmila Nebhrajani

Director of Finance and Business Affairs, BBC New Media.

KPMG (Husband, Peter Wallace, is an Executive Consultant)

Francoise Shenfield

Clinical lecturer in infertility RMU (UCH) and honorary lecturer in medicine (ethics) (dept of Medicine RF and UCH medical School)

Progress Educational Trust Board Member

Member of the Scientific Committee of "La Revue du

Practicien-Gynecologie et Obstetrique"
Lecturer on Ethics for the International Academic Advisory Board of the Austrian Danube University of Krems

Jean Smith

Specialist Social Worker in Adoption, Fostering and Child Protection.

Retired Head of Social Work Dept, Hull Maternity Hospital
Director, Linnaeus House Family Assessment Unit, Hull
Committee Member, Family Conciliation Service, Hull
Lay Member/V. Chair, Yorkshire Wolds and Coast Primary Care Group

Allan Templeton

Professor of Obstetrics & Gynaecology and Head of Department, University of Aberdeen.
Honorary Secretary, RCOG

Grant from EU Biomed on the prevention of pelvic infection
Chairman: Guidelines and Audit Subcommittee RCOG
Chairman: Infertility Guidelines Development Group RCOG
Member: CMOS Expert Advisory Group on Chlamydia Trachomatis
MRC Advisory Board
Committee Member: British Fertility Society
Recent Chairman: Society for the Study of Fertility
Project Grant Holder: EU Biomed on the prevention of pelvic infection
Dept. holds grants from MRC, Scottish Office, DiFid, BBSRC

Julia Tugendhat

Psychotherapist in Private Practice.

Vice President: British Association of Counselling
Shares in Norwich Union; Abbey National; Diaglo; PLC; MEP; BT; Bablock Int; Selfridges; Sears; Merit Zero Dividend prefs

Lis Woods

Formerly, Commissioner HM Customs and Excise.

Occasional management consultancy projects for Department of Health and others

7: DETAILS OF PERFORMANCE INDICATORS

Percentage of licence applications dealt with within target timescale

i) New treatment licences

Month	No of applications received	No of applications precessed within timescale
April 1999 - March 2000	5	4

Summary: The data above indicates that the Authority dealt with 80% of new treatment licence applications within the allowed time period. In the coming year we have set a target of clearing 90% within the set period

ii) Renewal

Month	Total no of applications received	No of applications delayed due to factors outside HFEA control	No of applications processed within timescale
April 1999 - March 2000	112	16	81 out of 96 - 84%

Summary: During the period 112 applications for licence renewal were received, 81 out of 96 within the HFEA's control (84%) were processed within the allowed time period. This rate has improved significantly during the last five months of this accounting period as a result of changes being introduced and new tighter procedures and internal time limits being imposed. In the second year we aim to clear 90% within the set period

iii) Research

Month	No of applications received	No of applications delayed due to factors outside HFEA control	No of applications processed within timescale
April 1999 - March 2000	12	10	2 out of 2 - 100%

Summary: Delays within the sole control of clinics or due to late receipt of information from peer reviewers were the reasons why 10 applications failed to be processed within the timescale set. We aim to reach a target of 90% in the second year

Number of extensions granted to renewal licences caused by delays within the HFEA

Month	No of applications dealt with
April 1999 - March 2000	6

Summary: 6 temporary licences were granted because of delays. Most occurred early in the accounting year and, as stated in ii above, changes were made to the procedures as a direct consequence of the introduction of PIs.

b) Percentage of requests for HFEA publications responded to within three days

Month	Average % of publications dealt with within 3 days
April 1999 - March 2000	80%

Summary: This data shows that the great majority of HFEA publications are despatched within the time period allowed. The target is now 85%.

c) Data entry unit costs per DI/IVF treatment

Month	Average Unit Cost per data entry for DI/IVF over 12 months
April 1999 - March 2000	£1.20

Summary: The verification process and the introduction of forms designed for the new Register have contributed to significant monthly variations in the cost of data input during this first year of PIs. We are introducing a staggered reduction in costs with the aim of eventually setting the unit costs at 0.70p.

d) HFEA performance against Government financial targets including:

Percentage of creditors paid with 30 days;

Month	Average % of creditors paid within 30 days
April 1999 - March 2000	90%

Percentage of Debts recovered within 60 and 90 days

Month	Average % of debts recovered within 60/90 days
April 1999 - March 2000	84%/95%

Summary: The above figures compare favourably with other public sector organisations. We aim to improve upon the above figures.

Human Fertilisation and Embryology Authority

ACCOUNTS 1999/2000

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

ACCOUNTS 1999-2000

FOREWORD

Background

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7 November 1990 and began operating on 1st August 1991. The HFEA was created by the Human Fertilisation and Embryology Act 1990 to license and regulate human embryo research and specified forms of infertility treatment.

The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health.

Statutory Remit

One of the main statutory functions of the HFEA is to regulate, by means of a licensing system, centres undertaking infertility treatments involving the creation or use of human embryos outside the body, the storage or donation of embryos or gametes or research involving human embryos.

The HFEA is also required to maintain a register of information about all licensed treatments performed in the United Kingdom. This contains information about those receiving treatment, donors of gametes and embryos and any children born as a result of such treatments. At the age of 18 (or 16 if wishing to marry), people may enquire as to whether information held on the register shows that they were born as a result of this treatment, and, if so, whether they are related to a prospective spouse.

In addition, the HFEA has other statutory responsibilities including:

- publicising the services provided by it and by the centres it licenses;
- publishing a Code of Practice giving guidance to centres on how they should carry out licensed activities;
- giving information and advice to donors, to people seeking treatment or storage or to people considering such action; and
- keeping the field under review and providing advice to the Secretary of State for Health, if so requested.

PRINCIPAL ACTIVITIES

Licensing:

Below is a summary of the licensing activities undertaken from 1 April 1999 to 31 March 2000:

Inspections	2000	1999
No. of licenced centres at 31 March	116	119
No. of inspection visits during year	109	106
No. of audit visits during year	25	28
No. of ICSI Practitioners inspected	22	35
No. of PGD Practitioners inspected	1	0

Issue of licences	2000	1999
No. of Licence Committee meetings	39	32
No. of items considered	328	315
No. of licences issued (Treatment and Storage)	110	92
No. of licences issued (Storage)	8	6
No. of licences issued (Research)	10	16

Established centres are subject to a three year licensing cycle composed of one full and two interim inspections.

The HFEA's Systems and Data Audit five year programme, commenced in October 1996, completed its third year. At 31st March 2000 a total of 74 audits had been carried out. The programme was established to ensure that centres and the HFEA are complying with their statutory obligations.

Information:

The HFEA collects data from all licensed centres about IVF and donor insemination treatments, their outcomes and about every donor. The HFEA published a Patients' Guide for 1999 giving the outcome data for individual clinics. This information is also published on the HFEA's website (www.hfea.gov.uk).

In order to ensure the long term accuracy of the data, to maintain relevance of data collected and to keep pace with the growing size of the register, the HFEA has developed a replacement database program. The introduction of this commenced in April 1999.

Policy:

Preparations were made during the year for the publication in 2000/01 of the 5th edition of the Code of Practice. The Code of Practice Committee also made preparations for the production of guidance on payment of expenses to donors and on egg sharing. A consultation document on pre-implantation genetic diagnosis (PGD) was issued jointly with the Advisory Commission on Genetic Testing in November 1999.

FINANCIAL REPORT

Overall Results

The operating deficit for the year amounted to £116,736.

Performance against key financial targets

The HFEA is required to meet two key financial targets.

1. Expenditure

The HFEA must ensure that it remains within the cash limit set by the Department of Health which, in 1999/2000, was £1,586,097. (Allocated cash limit of £1,601,600 less adjustment of £15,503 relating to 1998/99). The HFEA's cash expenditure for 1999/2000 was £1,598,465 being 100.8% of the adjusted cash limit of £1,586,097.

In Government Accounting terms, the *cash limit* refers to the total receipts of an organisation (from any source) which are either spent or *retained* during the relevant year. Because of a large receipt on the very last day of 1999/2000 that was received too late to be surrendered to the Department of Health, the HFEA received total resources of £1,618,664. This exceeded the adjusted cash limit for 1999/2000 by £32,567. The Department of Health is shown in the balance sheet as a creditor for this amount and an appropriate adjustment will be made to the HFEA's grant in 2000/2001.

2. Licence Fees

The HFEA's second financial objective for the period 1998/99 to 2000/01 was to raise 70% of its cash limit through the collection of licence fees. The amount raised in cash from licence fees in 1999/2000 was £1,612,328 which was 101.7% of the cash limit.

With effect from 1 April 1998 licence fee income has been reclassified by the Treasury as appropriations in aid. Licence fee income is no longer required to be surrendered to the Consolidated Fund, but is retained by the Department of Health to offset the cost of the HFEA to the Exchequer. Where licence fee income receipts exceed 70% of the cash limit, the Department of Health must surrender these receipts to the Treasury.

The fee structure is made up of an initial and an additional fee. Each centre is required to pay an initial fee on application. During 1999/2000 this fee was set at £250 for a treatment licence and £100 for a research or storage licence. The additional fee is payable on acceptance of the terms and conditions attached to a treatment licence.

The level of additional fees was last changed on 1 September 1994. When each centre applies to have its licence renewed the total number of donor insemination and IVF cycles held on the HFEA's register carried out after 1 September 1994 is identified. Donor insemination cycles were charged at £10 and IVF cycles at £40 during 1999/2000. From this total was subtracted the additional fees previously invoiced to give the additional fee payable. Those IVF cycles that are abandoned prior to eggs being mixed with sperm or embryo thawing are not included in the calculation.

In March 2000 the HFEA obtained Treasury and Department of Health agreement to its proposed revised licence fee levels which are to be introduced during 2000/2001.

Payment of Creditors

The HFEA has adopted the Treasury's guidance on prompt payment, and works to ensure that all undisputed invoices are paid within 30 days. In 1999/2000 the HFEA paid 88% of invoices within 30 days (1998/99 88%) and 99% were paid within 60 days (1998/99 99%).

Charitable Donations

There have been no charitable donations.

Equal Opportunities

The HFEA is an equal opportunities employer with a policy of providing equality of opportunity for all staff members and job applicants. The HFEA does not discriminate against anyone on the grounds of age, race, colour, ethnic or national origin, gender, marital status, responsibility for children or dependants, disability, sexual orientation or religious or political beliefs.

Consultation with Employees

The HFEA's policy is to involve staff and to consult them on relevant matters such as health, safety and welfare. New policies on health and safety, parental leave, working time regulations and whistleblowing were introduced during the year. Issues which may be of interest or concern are discussed at regular staff meetings.

HFEA Membership

The HFEA's full complement is a Chairman, Deputy Chairman and nineteen members. Members who have served the HFEA for some period of the year 1999/2000 are listed in Annex A.

FUTURE DEVELOPMENTS

In addition to the work involved in licensing, policy, information and communications, the following are some of the high priority issues being taken forward by the HFEA in the financial year 2000/2001:

- to monitor the effectiveness and financial costs of the improved licensing system
- to review the systems and data audit programme
- to publish the fifth edition of the Code of Practice
- following discussion with the Human Genetics Commission, to work towards the formulation of the HFEA's policy on the licensing of pre-implantation genetic diagnosis
- to continue closely to consider developments in various aspects of tissue and gamete storage
- to consider and take forward, as appropriate, the recommendations of the second Quinquennial Review. The review's recommendations are expected to be announced during 2000/01. The review was started towards the end of 1999/2000 and will continue into the next financial year.

Signed:	Suzanne McCarthy	
Position:	Chief Executive	Date: 12 July 2000

ANNEX A

Membership of the Human Fertilisation and Embryology Authority 1999/2000

Mrs Ruth Deech (Chairman)
Mrs Jane Denton (Deputy Chairman)
Professor Brenda Almond
Dr Sue Avery (appointed November 1999)
Dr Gulam Bahadur (retired November 1999)
Professor David Barlow
Professor Peter Braude (appointed November 1999)
Mrs Moira Coath
Professor Christine Gosden
Professor Andrew Grubb
Professor Martin Johnson (retired April 1999)
Professor Henry Leese
Professor Stuart Lewis
Dr Brian Lieberman (retired November 1999)
Dr Anne McLaren
Dr Sadia Muhammed
Ms Sara Nathan
Ms Sharmila Nebhrajani
Rt Rev'd Dr Michael Nazir-Ali
Dr Françoise Shenfield (appointed November 1999)
Dr Joan Stringer (retired November 1999)
Professor Allan Templeton
Lady Julia Tugendhat
Professor John Williams (retired November 1999)
Mrs Lis Woods (appointed November 1999)

STATEMENT OF AUTHORITY'S AND CHIEF EXECUTIVE'S RESPONSIBILITIES

Under section 6(1) of the Human Fertilisation and Embryology Act 1990 the Human Fertilisation and Embryology Authority is required to prepare a statement of accounts for each financial year in the form and on the basis determined by the Secretary of State, with the consent of the Treasury. The accounts are prepared on an accruals basis, and must show a true and fair view of the Authority's state of affairs at the year end and of its income and expenditure, total recognised gains and losses and cash flow for the financial year.

In preparing the accounts the Authority is required to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed, and disclose and explain any material

departures in the financial statements;
- prepare the financial statements on the going concern basis, unless it is inappropriate to presume that the Authority will continue in operation.

The Accounting Officer of the Department of Health has designated the Chief Executive of the Human Fertilisation and Embryology Authority as the Accounting Officer for the Authority. Her relevant responsibilities as Accounting Officer, including her responsibility for the propriety and regularity of the public finances for which she is answerable and for the keeping of proper records, are set out in the Non-Departmental Public Bodies' Accounting Officer Memorandum.

STATEMENT ON THE SYSTEM OF INTERNAL FINANCIAL CONTROL

As Accounting Officer I acknowledge my responsibility for ensuring that an effective system of internal financial control is maintained and operated by the HFEA.

The system can provide only reasonable, and not absolute, assurance that assets are safeguarded, transactions authorised and properly recorded and that material errors or irregularities are either prevented or would be detected within a timely period.

The system of internal financial control is based on a framework of regular management information, administrative procedures, including the segregation of duties, and a system of delegation and accountability. In particular, it includes:

- comprehensive budgeting systems with an annual budget report which is reviewed by the Organisation and Finance Committee (OFC) and agreed by the Authority. In addition, the OFC receives a biannual budget report;

- regular reviews by senior managers of monthly and biannual financial reports which indicate financial performance against forecasts;

- setting targets to measure financial and other performance; and

- clearly defined capital investment procedures.

The accountancy firm, KPMG, is the HFEA's internal auditor, and operates to standards defined in the Government Internal Audit Manual. The work of the internal auditor is informed by an analysis of the risk to which the body is exposed, and annual internal audit plans are based on this analysis. The analysis of risk and the internal audit plans are approved by both the HFEA's Audit Committee and by me. A report on internal audit activity in the HFEA is provided to the Audit Committee. The report includes an assessment of the adequacy and effectiveness of the body's system of internal financial control.

My review of the effectiveness of the system of internal financial control is informed by the work of the internal auditors, the Audit Committee, which oversees the work of the internal auditors, those HFEA executive managers who have responsibility for the development and maintenance of the financial control framework and comments made by the external auditors in their management letter and other reports.

Where recommendations are made by the internal or external auditors, action plans are agreed by senior managers and myself for implementation of those recommendations. The plans set out the action to be taken and the timetable for implementation. Progress against an action plan is monitored by senior managers and by the HFEA's Audit Committee, which considers all audit reports and the actions undertaken by management to correct weaknesses highlighted. Internal and external auditors also follow up recommendations made in previous reports.

Formal procedures for Finance and Audit have been drawn up and are incorporated in the staff manual. The HFEA regularly reviews and updates these procedures to improve and strengthen its system of internal controls. The finance procedures were updated in 1999/2000.

As Accounting Officer I am aware of the recommendations of the Turnbull Committee and I am taking reasonable steps to comply with the Treasury's requirement for a statement of internal control to be prepared for the year ended 31 March 2002 in accordance with guidance to be issued by them.

Signed: Suzanne McCarthy
Position: Chief Executive Date: 12 July 2000

THE CERTIFICATE OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

I certify that I have audited the financial statements on pages 60 to 63 under Section 6(4) of the Human Fertilisation and Embryology Act 1990. These financial statements have been prepared under the historical cost convention as modified by the revaluation of certain fixed assets and the accounting policies set out on pages 64 and 65.

Respective responsibilities of the Authority, the Chief Executive and Auditor

As described on pages 56 and 57 the Authority and Chief Executive are responsible for the preparation of the financial statements and for ensuring the regularity of financial transactions. The Authority and Chief Executive are also responsible for the preparation of the Foreword. My responsibilities, as independent auditor, are established by statute and guided by the Auditing Practices Board and the auditing profession's ethical guidance.

I report my opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and the Secretary of State for Health directions made thereunder, and whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

I also report if, in my opinion, the Foreword is not consistent with the financial statements, if the Authority has not kept proper accounting records, or if I have not received all the information and explanations I require for my audit.

I review whether the statement on pages 57 and 58 reflects the Authority's compliance with Treasury's guidance 'Corporate governance: statement on the system of internal financial control'. I report if it does not meet the requirements specified by Treasury, or if the statement is misleading or inconsistent with other information I am aware of from my audit of the financial statements.

Basis of opinion

I conducted my audit in accordance with Auditing Standards issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Authority and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Human Fertilisation and Embryology Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by error, or by fraud or other irregularity and that, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I have also evaluated the overall adequacy of the presentation of information in the financial statements.

Opinion

In my opinion:

- the financial statements give a true and fair view of the state of affairs of the Human Fertilisation and Embryology Authority at 31 March 2000 and of the deficit, total recognised gains and losses and cash flows for the year then ended and have been properly prepared in accordance with Section 6(2) of the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State for Health; and

- in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

I have no observations to make on these financial statements.

John Bourn
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON,SW1W 9SP

Date: 14 July 2000

Income and Expenditure Account for the year ended 31 March 2000

	Notes	£	1998/99 £
Gross income	2	1,530,960	1,370,550
Transfer from Deferred Government Grant	11	58,961	37,950
		1,589,921	1,408,500
Expenditure			
- Staff Costs	3	932,093	848,288
- Other Operating Charges	4	733,610	666,671
- Depreciation	5	40,954	37,950
Total Expenditure		1,706,657	1,552,909
Operating (Deficit)	6	(116,736)	(144,409)
- Notional Interest(Capital Charges)	1	(23,200)	(25,800)
(Deficit) on Ordinary Activities		(139,936)	(170,209)
- Write back of Notional Interest		23,200	25,800
- Write back of Notional Superannuation		79,336	78,400
Deficit for the financial year		(37,400)	(66,009)
Retained surplus brought forward		249,448	315,457
Retained surplus carried forward		212,048	249,448

All operations are continuing

The notes on pages 64 to 75 form part of these accounts

Statement of Total Recognised Gains and Losses for the year ended 31 March 2000

	Notes		1998/99
		£	£
Deficit for the financial year		(37,400)	(66,009)
Revaluation of fixed assets	5	(1,085)	228
Total recognised losses for the year		(38,485)	(65,781)

The notes on pages 64 to 75 form part of these accounts

Balance Sheet as at 31 March 2000

	Notes	£	31 March 1999 £
Fixed Assets	5	138,677	159,363
Current Assets			
- Debtors: Amounts falling due within one year	7	195,731	225,950
- Cash at bank and in hand		79,054	58,794
Creditors: Amounts falling due within one year	8	(62,738)	(21,775)
Net Current Assets		212,047	262,969
Total Assets less Current Liabilities		350,724	422,332
Financed By			
Accruals and Deferred Income - Deferred government grant	11	128,565	161,688
Capital and Reserves			
- Income and Expenditure account	11	212,048	249,448
- Revaluation Reserve	11	10,111	11,196
		350,724	422,332

The notes on pages 64 to 75 form part of these accounts

Signed: Suzanne McCarthy
Position: Chief Executive Date: 12th July 2000

Cash Flow Statement for the year ended 31 March 2000

	Notes	£	1998/99 £
Operating Activities			
Net Cash Inflow	18	20,260	21,069
Capital Expenditure			
- Purchase of Fixed Assets	5	(25,838)	(89,158)
Net Cash (Outflow) before financing		(5,578)	(68,089)
Financing			
- Receipts of Government Grants for fixed assets	11	25,600	25,600
- Transfer from revenue grant	11	238	63,558
Net cash inflow from financing		25,838	89,158
Increase in Cash	18	20,260	21,069

The notes on pages 64 to 75 form part of this account

NOTES TO THE ACCOUNT

1. Accounting policies

(a) Accounting convention

The HFEA's accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Determination issued by the Secretary of State for Health in May 1997 (reproduced as an appendix to these accounts).

These accounts are prepared, in accordance with applicable accounting standards, under the historical cost convention modified to allow for the revaluation of fixed assets. Without limiting the information given, the accounts meet the accounting and disclosure requirements of the Companies Acts and accounting standards issued or adopted by the Accounting Standards Board so far as those requirements are appropriate.

(b) Fixed assets

Fixed Assets include tangible fixed assets and the costs of acquiring or creating computer systems or software. Only items, or groups of related items, costing £1,000 or more, are capitalised. Those costing less are treated as revenue expenditure. Assets are indexed annually using the Central Statistical Office Index for computers and other information processing equipment, and appropriate Health Service Cost indices for other assets. Gains and losses arising on indexation are normally taken to the revaluation reserve. However, deferred government grant is released to match downward indexation of particular assets when there are no related existing credits within the revaluation reserve.

(c) Depreciation

Depreciation is provided on all tangible fixed assets at rates calculated to write off the cost of each asset evenly over its expected useful life. Expected useful lives are as follows:

Computer equipment and software	3 years
Office Equipment	4 years
Furniture, fixture and fittings	4 years
Installations	10 years

Improvements to leasehold property included in installations are depreciated over the remainder of the lease term, if less than 10 years.

(d) Operating leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

(e) Register of information

Expenditure on development of the computer programme for the Register of Information is charged to the Income and Expenditure Account as it is incurred.

(f) Government grants

Government grants received for revenue expenditure are credited to income in the year to which they relate. Government grants received for capital expenditure are credited to a Deferred Government Grant Reserve and released to the Income and Expenditure Account to match depreciation and downward indexation, where appropriate.

(g) Notional charges

In order to give full costs, a notional charge for superannuation has been charged in the Income and Expenditure Account amounting to £79,336 (1998/99 - £78,400). This notional charge has been assessed by the Government Actuary for the year 1999/2000. See also Note 9.

In accordance with Treasury guidance, notional interest at 6% of the average capital employed has been charged in the Income and Expenditure Account amounting to £23,200 (1998/99 - £25,800).

2. Gross Income

The gross income is made up of Government grants, made on a cash basis, which are offset by licence fee and other income which are recorded on an accruals basis. Government grants received for capital expenditure are credited to a Deferred Government Grant Reserve (note 1). Where licence fee income collected exceeds 70% of cash limit, the balance is surrendered to the Department of Health.

	1999/2000	1998/99
	£	£
Department of Health Class II, Vote 2	1,299,000	1,260,100
Scottish Office, Home and Health Dept. Class XIII, Vote 1	146,000	153,300
Welsh Office Class XIV, Vote 1	74,000	76,700
Department of Health and Social Services, Northern Ireland, Class XV, Vote 1	41,000	42,900
	1,560,000	1,533,000
Less transfer to Deferred Government Grant	(238)	(63,558)
	1,559,762	1,469,442
Cash/Accruals Adjustment	(28,802)	(98,892)
Gross Income reported in Income and Expenditure Account	1,530,960	1,370,550

Analysis of Income

Recovered in Licence Fee Income	1,583,760	1,334,770
Other Income	728	1,805
Superannuation Receipts	40,877	8,133
Capital grant	(25,838)	(89,158)
Cash to be surrendered to Department of Health	(68,567)	-
Cash received from Department of Health	-	115,000
	1,530,960	1,370,550

3. Staff Costs

	1999/2000 £	1998/1999 £
All Staff		
Salaries - HFEA Staff	637,581	561,994
Salaries - Seconded Staff	61,687	60,895
Social Security Costs	53,044	44,437
Superannuation Costs - Seconded Staff	10,894	8,911
Net Superannuation Costs - Executive Staff	0	13,458
Notional Superannuation Charge	79,336	78,400
Agency/Temporary Staff	19,048	10,748
	861,590	778,843

The average monthly number of staff employed, including secondees, during the year was as follows:

	1999/2000 No.	1998/99 No.
Management	5	5
Administrative	28	26
	33	31

Remuneration of key management

Chief Executive

Emoluments (excluding pension fund contributions):

Salary	53,495	49,851
Bonus payments	250	750
Total	53,745	50,601

Pension entitlements

The Chief Executive is an ordinary member of the Principal Civil Service Pension Scheme (see also note 9). Contributions in 1999/2000 amounted to £9,556 (1998/99 - £8,911). The total accrued pension disclosed below excludes pension benefits arising from the purchase of added years or additional voluntary contributions. It also excludes the value of pension benefits transferred from other schemes. The liability for the Chief Executive's pension entitlements lies wholly with the Home Office.

	£
Real increase in pension at 60 during 1999/2000	944
Total accrued pension at 60 as at 31/03/00	6,488

Remuneration of Authority Members

Chairman	1999/2000	1998/99
	£	£
Remuneration	8,440	8,210

No pension contributions were made on behalf of the Chairman in 1999/2000 (1998/99 - nil)

Members	£	£
Total fees paid to members including Chairman	68,401	67,307
Social Security Costs	2,102	2,138
	70,503	69,445

The Deputy Chairman received a fee of £147 per day (1998/99 £143). Other Board Members received a fee of £135 per day (1998/99 £131). No pension contributions were paid on behalf of any Board Member. Total remuneration paid to individual Members during the financial year was as follows:-

	£
Mrs Jane Denton (Deputy Chairman)	7,962
Professor Brenda Almond	2,025
Dr Sue Avery (appointed November 1999)*	1,755
Dr Gulam Bahadur (retired November 1999)	2,430
Professor David Barlow	1,890
Professor Peter Braude (appointed November 1999)	675
Mrs Moira Coath	1,886
Professor Christine Gosden	4,320
Professor Andrew Grubb	3,375
Professor Martin Johnson (retired April 1999)	0
Professor Henry Leese *	5,126
Professor Stuart Lewis	3,510
Dr Brian Lieberman (retired in November 1999)**	1,342
Dr Anne McLaren	1,620
Dr Sadia Muhammed *	2,430
Ms Sara Nathan	5,805
Ms Sharmila Nebhrajani	1,620
Rt Rev'd Dr Michael Nazir-Ali	1,215
Dr Françoise Shenfield (appointed November 1999)	540
Dr Joan Stringer (retired November 1999)	540
Professor Allan Templeton	1,346
Lady Julia Tugendhat	3,780
Mr John Williams (retired November 1999)	1,485
Mrs Lis Woods(appointed November 1999)	1,080

* Fees were paid to Members' main employer

** Fees were paid to charitable trust

4. Other Operating Charges

	1999/00	1998/99
Operating lease payments		
- land and buildings	110,450	110,659
- other leases	17,406	8,740
Accommodation	90,730	100,312
Travel & subsistence	101,448	91,163
Attendance fees - Inspectors	23,401	19,020
Professional & administrative fees	134,136	76,273
Audit fees	11,500	11,500
Register of information	10,691	(14,177)
Stationery,photocopying & printing	96,493	58,252
Telephones & postage	42,979	39,675
Training & development	17,585	41,734
Recruitment & advertising	17,065	14,804
Conferences & meeting expenses	12,418	16,720
Library & reading materials	9,436	9,030
Sundry office equipment	19,456	53,312
Miscellaneous	13,931	14,944
Permanent diminution in value of fixed assets	4,485	4,495
Provision for Doubtful Debts		10,215
Total	**733,610**	**666,671**

5. Fixed Assets as at 31 March 2000

	Computer Equipment	Office Equipment	Furniture & Fittings	Installations	Totals
	£	£	£	£	£
Cost/valuation as at 31 March 1999	116,542	45,263	108,496	120,032	390,333
Additions	11,691	14,147	-	-	25,838
Disposals	(40,075)	(1,491)	(9,349)	-	(50,915)
Revaluation	(8,006)	(232)	(1,031)	(1,248)	(10,517)
As at 31 March 1999	80,152	57,687	98,116	118,784	354,739
Depreciation as at 31 March 1999	73,707	20,523	100,567	36,173	230,970
Charge for the year	17,485	7,664	3,751	12,054	40,954
Disposals	(40,075)	(1,491)	(9,349)	-	(50,915)
Revaluation	(3,521)	(101)	(949)	(376)	(4,947)
As at 31 March 1999	47,596	26,595	94,020	47,851	216,062
Net Book Value (NBV)					
At 31 March 2000	32,556	31,092	4,096	70,933	138,677
At 31 March 1999	42,835	24,740	7,929	83,859	159,363
Increase (Decrease) in NBV	(10,279)	6,352	(3,833)	(12,926)	(20,686)

6. Operating (Deficit)/Surplus

The activities of the Authority have contributed to the Operating (Deficit)/Surplus as follows:

	LICENSING		OTHERS		TOTAL	
	1999/2000	1998/99	1999/2000	1998/99	1999/2000	1998/99
	£	£	£	£	£	£
INCOME						
Licence Fees	1,583,760	1,334,770			1,583,760	1,334,770
Other			41,605	9,938	41,605	9,938
Cash surrendered to/received from the Department of Health			(68,567)	115,000	(68,567)	115,000
Transfer to Deferred Government Grant			(25,838)	(89,158)	(25,838)	(89,158)
Transfer from Deferred Government Grant	29,481	18,975	29,481	18,975	58,961	37,950
Total	1,613,241	1,353,745	(23,320)	54,755	1,589,921	1,408,500
EXPENDITURE						
Staff Costs	(585,940)	(496,742)	(346,153)	(351,546)	(932,093)	(848,288)
Depreciation	(20,477)	(18,975)	(20,477)	(18,975)	(40,954)	(37,950)
Other Charges	(509,560)	(416,496)	(224,051)	(250,176)	(733,611)	(666,671)
Total	(1,115,977)	(932,213)	(590,680)	(620,697)	(1,706,657)	(1,552,909)
Operating (Deficit)/Surplus	497,263	421,533	(614,000)	(565,942)	(116,736)	(144,409)

The above information is given to satisfy the disclosures required by HM Treasury Fees and Charges Guide not those required by Statement of Standard Accounting Practice No 25 (SSAP 25), "Segmental Reporting".

Statutory activities classified as "other" include maintaining the Register of Information, publishing a Code of Practice, publicising the Authority's services, giving advice and reviewing the field of human fertilisation and embryology.

7. Debtors

		31 March 1999
	£	£
Licence fee	97,502	126,109
Other debtors	14,394	14,951
Pre-payments	83,835	84,890
	195,731	225,950

8. Creditors: Amounts falling due within one year

		31 March 1999
	£	£
Trade creditors	1,743	1,515
Other taxes and social security	2,680	91
Department of Health	32,567	
Accruals	25,748	20,169
	62,738	21,775

9. Pension Arrangements

Seconded staff belong to the Principal Civil Service Pension Scheme. For 1999/2000, contributions of £10,894 (1998/99 £8,911) were made to the Paymaster General for seconded staff at rates determined from time to time by the Government Actuary and advised by the Treasury. The rate for 1999/2000 for non-industrial staff in salary band 3 (£29,001 to £50,000) is 16.5% and in salary band 4 (£50,001 and over) is 18.5%.

For its own staff the HFEA operates its own pay-as-you-go scheme to provide retirement and related benefits based on individual final emoluments to all eligible employees. The scheme is non-contributory and is analagous to the Principal Civil Service Pension Scheme. The scheme is funded on a pay-as-you-go basis from Grant in Aid. Pension liabilities are charged to the Income and Expenditure Account in the year of account.

Members contribute 1.5% of annual salary to cover spouses' pensions. These contributions (1999/2000 £9,160; 1998/99 £8,133) are classified as current income and any benefits paid are treated as current expenditure (1999/2000 - £778, 1998/99 - £0).

Transfer values received from other organisations are also treated as current income. During the year receipts amounted to £32,495 (1998/99 -£22,836). There were no transfer payments to other organisations (1998/99 - £36,294).

The Government Actuary has carried out an approximate actuarial valuation of the liabilities of the Human Fertilisation & Embryology Authority Pension Scheme as at 31 March 2000. The capitalised value as at 31 March 2000 for benefits accrued in respect of employment (or former employment) prior to 31 March 2000 has been assessed as follows:-

Value of Liabilities	£ 000
Pensions in Payment	0
Deferred Pensions	105
Active Members (Past Service)	433
Total	538

10. Post balance sheet events

The HFEA is planning to apply for bulk admission of its existing staff to the Principal Civil Service Pension Scheme (PCSPS) in 2000/2001 and an application is being prepared with the support of the Department of Health. The Government Actuary has advised that, if admission were approved, a sum of approximately £543,000 would be payable to the PCSPS to cover the cost of transfer of accrued pension liabilities. The Treasury has confirmed to the Department of Health that it is prepared to cover this cost.

Under the current superannuation scheme only a notional charge is made to the Income and Expenditure Account. From the date of transfer, the HFEA would pay annually to the PCSPS accruing superannuation liability contributions (ASLCs), calculated as a percentage of salary.

11. Deferred Government Grant, Capital and Reserves

	Deferred Government Grant £	Income and Expenditure £	Revaluation Reserve £
Balance at 31 March 1999	161,688	249,448	11,196
Movements in Year:			
Revaluation of fixed assets			(1,085)
1999/2000 capital grant	25,600		
Transfer from revenue grant	238		
Transfer to income & expenditure	(58,961)		
(Deficit) for the year			(37,400)
Balance at 31 March 1999	**128,565**	**212,048**	**10,111**

12. Financial commitments

The HFEA is committed to make the following operating lease payments during the next financial year.

	1999/2000 £	1998/1999 £
Land and Buildings		
Leases which expire in over 5 years	110,450	110,450
Other Leases		
Leases which expire within 1 year	0	807
Leases which expire within 2 to 5 years	12,204	12,204

13. Capital Commitments

At the balance sheet date the HFEA had no capital commitments.

14. Contingent Liabilities

The HFEA had no contingent liabilities at the balance sheet date.

15. Material Losses

The HFEA had no material losses in the year 1999/2000.

16. Related Party Transactions

The Department of Health is regarded as a related party. During the year the HFEA has had various material transactions with the Department. In addition, the HFEA has had a small number of material transactions with other government departments.

None of the HFEA Members, key managerial staff or other related parties have undertaken any material transactions with the HFEA during the year.

17. Performance against key financial targets

The HFEA has two key financial targets .

(a) The HFEA must ensure that its cash expenditure remains within the cash limit set by the Department of Health. In the year 1999/00, actual cash expenditure was £1,598,465 which was 100.8% of the adjusted cash limit of £1,586,097. (See the Foreword, page 54).

(b) The HFEA was also required to raise 70% of its cash limit from licence fees. The amount raised in cash from licence fees in 1999/00 was £1,612,328 which was 101.7 % of the adjusted cash limit.

18. Notes to the Cash Flow Statement

1. Reconciliation of operating deficit to net cash inflow from operating activities:

	£	1998/99 £
Operating (deficit)	(116,736)	(144,409)
Notional superannuation charge	79,336	78,400
Depreciation charges	40,954	37,950
Downward indexation charge	4,485	4,495
Decrease in debtors	30,219	123,409
Increase (decrease) in creditors	40,963	(40,826)
Transfer from deferred government grant	(58,961)	(37,950)
Net cash inflow from operating activities	20,260	21,069

2. Analysis of changes in cash

	At 31 March 1999	Cash Flows	At 31 March 2000
Cash at bank and in hand	58,794	20,260	79,054

APPENDIX

THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

ACCOUNTS DETERMINATION

The Secretary of State, with the approval of the Treasury, in pursuance of section 6 of the Human Fertilisation and Embryology Act 1990, hereby gives the following determination:

1. In this determination "the Authority" means the Human Fertilisation and Embryology Authority.

2. Direction given by the Secretary of State

The Authority shall prepare accounts for the financial year ended 31 March 1997 and subsequent financial years comprising:

a) a foreword;
b) an income and expenditure account;
c) a balance sheet;
d) a cash flow statement; and
e) a statement of total recognised gains and losses;

including such notes as may be necessary for the purposes referred to in the following paragraphs.

3. Form of Accounts

The accounts shall give a true and fair view of the income and expenditure and cash flows for the financial year, and the state of affairs as at the end of the financial year.

4. Subject to this requirement, the accounts shall be prepared in accordance with:

a) generally accepted accounting practice in the United Kingdom (UK GAAP);
b) The disclosure and accounting requirements contained in "The Fees and Charges Guide" (in particular those relating to the need for appropriate segmental information for services or forms of service provided) and in other guidance which the Treasury or the Secretary of State may issue from time to time in respect of accounts which are required to give a true and fair view;
c) The accounting and disclosure requirements given in "Government Accounting" and in "Executive NDPBs: Annual Reports and Accounts guidance, as amended or augmented from time to time:

insofar as these are appropriate to the Authority and are in force for the financial year for which the statement of accounts is to be prepared.

5. Clarification of the application of the accounting and disclosure requirements of the Companies Act and accounting standards is given in Schedule 1 attached. Additional disclosure requirements are set out in Schedule 2 attached.

6. The income and expenditure account and balance sheet shall be prepared under the historical cost convention modified by the inclusion of:

a) fixed assets at their value to the business by reference to current costs; and
b) stocks valued at the lower of net current replacement cost (or historical cost if this is not materially different) and net realisable value.

7. This accounts determination supersedes that dated 26 April 1996 and shall be reproduced as an appendix to the accounts.
Date: 6 May 1997
Signed by the authority of the Secretary of State for Health

P. KENDALL
Branch Head (RMF-EAC Division)
Department of Health

SCHEDULE 1

APPLICATION OF THE ACCOUNTING AND DISCLOSURE REQUIREMENTS OF THE COMPANIES ACT AND ACCOUNTING STANDARDS

Companies Act

1. The disclosure exemptions permitted by the Companies Act shall not apply to the Authority unless specifically authorised by the Secretary of State with the approval of the Treasury.

2. The Companies Act requires certain information to be disclosed in the Directors' Report. To the extent that it is appropriate, the information relating to the Authority shall be contained in the foreword.

3. When preparing its income and expenditure account, the Authority shall have regard to the profit and loss format 2 prescribed in Schedule 4 to the Companies Act 1985 (as amended).

4. When preparing its balance sheet, the Authority shall have regard to the balance sheet format 1 prescribed in Schedule 4 to the Companies Act 1985 (as amended). The balance sheet totals shall be struck at 'Total assets less current liabilities'.

5. The Authority is not required to provide the additional information required by paragraph 33 (3) of Schedule 4 to the Companies Act 1985.

6. The foreword and balance sheet shall be signed by the Chief Executive to the Authority and dated.

Accounting standards

7. The Authority is not required to include a note showing historical cost profits and losses a described in FRS3.

8. The Authority shall not adopt the Financial Reporting Standard for Smaller Entities unless specifically approved by the Treasury.

SCHEDULE 2

ADDITIONAL DISCLOSURE REQUIREMENTS

1. The foreword shall, inter alia:

   a) State that the accounts have been prepared in a form determined by the Secretary of State with the approval of the Treasury in accordance with Section 6 of the Human Fertilisation and Embryology Act 1990;

   b) Include a brief history of the Authority and its statutory background.

2. The notes to the accounts shall, inter alia:

   a) Include details for the accounting policies adopted;

   b) Provide further explanations of figures in the accounts where it is considered appropriate for a proper understanding of the accounts;

   c) Include details of the key corporate financial targets set by Ministers together with the performance achieved.