This report covers the year beginning 1 November 1998 with a forward look for the year beginning 1 November 1999.
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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 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 Muhamed, General Practitioner, Priory Medical Group, York

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


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

Dr Françoise 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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVF and DI</td>
<td>75</td>
</tr>
<tr>
<td>IVF only</td>
<td>0</td>
</tr>
<tr>
<td>DI only</td>
<td>29</td>
</tr>
<tr>
<td>Storage of sperm only</td>
<td>9</td>
</tr>
<tr>
<td>Research licences only</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>116</strong></td>
</tr>
</tbody>
</table>

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 fourth 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 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”.

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.

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 between 1996/7 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. 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 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. Conversely, the number of transfers where only two embryos were replaced has risen from 30.9% to 48.6% during the same period.

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7. Where more than four embryos 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

<table>
<thead>
<tr>
<th>Reporting period</th>
<th>IVF ¹</th>
<th>Micromanipulation ²</th>
<th>DI ³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of treatment cycles</td>
<td>Live Birth Rate per treatment cycle (%)</td>
<td>Multiple Live Birth Rate per live birth event (%)</td>
</tr>
<tr>
<td>91/92 ²</td>
<td>10434</td>
<td>14.0</td>
<td>27.3</td>
</tr>
<tr>
<td>92/93</td>
<td>19309</td>
<td>13.1</td>
<td>28.1</td>
</tr>
<tr>
<td>93/94</td>
<td>21726</td>
<td>14.3</td>
<td>27.6</td>
</tr>
<tr>
<td>94/95</td>
<td>24193</td>
<td>14.3</td>
<td>27.7</td>
</tr>
<tr>
<td>95/96</td>
<td>25781</td>
<td>14.3</td>
<td>29.6</td>
</tr>
<tr>
<td>96/97</td>
<td>26865</td>
<td>15.5</td>
<td>26.8</td>
</tr>
<tr>
<td>97/98</td>
<td>24889</td>
<td>14.9</td>
<td>27.3</td>
</tr>
<tr>
<td>98/99</td>
<td>23254</td>
<td>16.9</td>
<td>27.3</td>
</tr>
</tbody>
</table>

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

![Graph showing live birth rates per treatment cycle for Licensed Treatments 1991-1999. The graph indicates trends for IVF, Micromanipulation, and DI treatments over the years.]

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

<table>
<thead>
<tr>
<th></th>
<th>Boys</th>
<th>Girls</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>DI</td>
<td>594(51.2%)</td>
<td>567(48.8%)</td>
<td>1161</td>
</tr>
<tr>
<td>IVF</td>
<td>4228(50.7%)</td>
<td>4109(49.3%)</td>
<td>8337</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Factor</th>
<th>Number of cycles</th>
<th>% of all cycles</th>
<th>Clinical pregnancy rate (%)</th>
<th>Live Birth rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubal Disease</td>
<td>10923</td>
<td>30.9</td>
<td>19.5</td>
<td>15.9</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>3194</td>
<td>9.0</td>
<td>21.9</td>
<td>18.2</td>
</tr>
<tr>
<td>Unexplained</td>
<td>16508</td>
<td>46.7</td>
<td>23.0</td>
<td>19.4</td>
</tr>
<tr>
<td>Other</td>
<td>8183</td>
<td>23.1</td>
<td>22.8</td>
<td>18.5</td>
</tr>
</tbody>
</table>

Note: the total number of cycles in this table does not equal 35,363 because some patients have more than one cause of infertility.
(including micromanipulation treatments but excluding frozen embryo replacements)

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

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)

<table>
<thead>
<tr>
<th>Treatment Cycles</th>
<th>Under 27</th>
<th>27 - 28</th>
<th>29 - 30</th>
<th>31 - 32</th>
<th>33 - 34</th>
<th>35 - 36</th>
<th>37 - 38</th>
<th>39 - 40</th>
<th>41 - 42</th>
<th>43 - 44</th>
<th>45 and over</th>
<th>all patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live Birth Rate per treatment cycle (%)</td>
<td>17.6</td>
<td>20.7</td>
<td>19.0</td>
<td>19.0</td>
<td>20.1</td>
<td>18.1</td>
<td>15.2</td>
<td>9.5</td>
<td>7.3</td>
<td>3.0</td>
<td>0.5</td>
<td>16.6</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Treatment Cycles</th>
<th>Under 27</th>
<th>27 - 28</th>
<th>29 - 30</th>
<th>31 - 32</th>
<th>33 - 34</th>
<th>35 - 36</th>
<th>37 - 38</th>
<th>39 - 40</th>
<th>41 - 42</th>
<th>43 - 44</th>
<th>45 and over</th>
<th>all patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live Birth Rate per treatment cycle (%)</td>
<td>25.2</td>
<td>24.1</td>
<td>25.6</td>
<td>24.1</td>
<td>23.0</td>
<td>21.5</td>
<td>16.8</td>
<td>11.2</td>
<td>5.5</td>
<td>2.4</td>
<td>2.3</td>
<td>20.9</td>
</tr>
</tbody>
</table>

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

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

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)

<table>
<thead>
<tr>
<th>Embryos Transferred</th>
<th>No of cycles</th>
<th>Number of clinical pregnancies</th>
<th>Clinical Pregnancy Rate (% of treatment cycles)</th>
<th>Multiple Clinical Pregnancy (% of clinical pregnancies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>2977</td>
<td>276</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Two</td>
<td>14144</td>
<td>2721</td>
<td>959</td>
<td>15</td>
</tr>
<tr>
<td>Three</td>
<td>13399</td>
<td>2398</td>
<td>924</td>
<td>248</td>
</tr>
<tr>
<td>Total</td>
<td>30520</td>
<td>5395</td>
<td>1891</td>
<td>264</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Embryos Transferred</th>
<th>No of cycles</th>
<th>Number of live births</th>
<th>Live Birth Rate (% of treatment cycles)</th>
<th>Multiple Birth Rate (% of live birth events)</th>
<th>Stillbirths and neonatal deaths per 1000 birth events</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>2977</td>
<td>232</td>
<td>6</td>
<td>1</td>
<td>8.0</td>
</tr>
<tr>
<td>Two</td>
<td>14144</td>
<td>2423</td>
<td>786</td>
<td>9</td>
<td>22.8</td>
</tr>
<tr>
<td>Three</td>
<td>13399</td>
<td>2065</td>
<td>782</td>
<td>146</td>
<td>22.3</td>
</tr>
<tr>
<td>Total</td>
<td>30520</td>
<td>4720</td>
<td>1574</td>
<td>156</td>
<td>21.1</td>
</tr>
</tbody>
</table>
Table 4.9  Two and three embryo transfers for fresh stimulated IVF (where more than four embryos were created)

<table>
<thead>
<tr>
<th>Number of embryos transferred</th>
<th>Number of cycles</th>
<th>Live birth rate (% of number of cycles)</th>
<th>Multiple birth rate (% of number of live births)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>6838</td>
<td>28.6</td>
<td>26.4</td>
</tr>
<tr>
<td>3</td>
<td>7102</td>
<td>25.8</td>
<td>34.9</td>
</tr>
</tbody>
</table>

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

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

### b) Two embryo transfer

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of cycles</th>
<th>Number of live births</th>
<th>Live birth rate per treatment cycle</th>
<th>Number of multiple births (twins, triplets and quads)</th>
<th>Multiple birth rate per live birth event (twins, triplets and quads)</th>
<th>Number of triplets and quads</th>
<th>Triplet and quad birth rate per live birth event</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>162</td>
<td>47</td>
<td>(29.0%)</td>
<td>13</td>
<td>(27.7%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>25-29</td>
<td>1504</td>
<td>473</td>
<td>(31.4%)</td>
<td>126</td>
<td>(26.6%)</td>
<td>2</td>
<td>(0.4%)</td>
</tr>
<tr>
<td>30-34</td>
<td>3283</td>
<td>987</td>
<td>(30.1%)</td>
<td>275</td>
<td>(27.9%)</td>
<td>1</td>
<td>(0.1%)</td>
</tr>
<tr>
<td>35-39</td>
<td>1740</td>
<td>428</td>
<td>(24.6%)</td>
<td>99</td>
<td>(23.1%)</td>
<td>2</td>
<td>(0.5%)</td>
</tr>
<tr>
<td>40-44</td>
<td>136</td>
<td>20</td>
<td>(14.7%)</td>
<td>4</td>
<td>(20.0%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>45+</td>
<td>8</td>
<td>1</td>
<td>(12.5%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>6833</td>
<td>1956</td>
<td>(28.6%)</td>
<td>517</td>
<td>(26.4%)</td>
<td>5</td>
<td>(0.3%)</td>
</tr>
</tbody>
</table>

### c) Three embryo transfer

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of cycles</th>
<th>Number of live births</th>
<th>Live birth rate per treatment cycle</th>
<th>Number of multiple births (twins, triplets and quads)</th>
<th>Multiple birth rate per live birth event (twins, triplets and quads)</th>
<th>Number of triplets and quads</th>
<th>Triplet and quad birth rate per live birth event</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>54</td>
<td>14</td>
<td>(25.9%)</td>
<td>5</td>
<td>(35.7%)</td>
<td>1</td>
<td>(7.1%)</td>
</tr>
<tr>
<td>25-29</td>
<td>835</td>
<td>259</td>
<td>(31.0%)</td>
<td>115</td>
<td>(44.4%)</td>
<td>23</td>
<td>(8.9%)</td>
</tr>
<tr>
<td>30-34</td>
<td>2546</td>
<td>755</td>
<td>(29.7%)</td>
<td>291</td>
<td>(38.5%)</td>
<td>53</td>
<td>(7.0%)</td>
</tr>
<tr>
<td>35-39</td>
<td>2791</td>
<td>704</td>
<td>(25.2%)</td>
<td>217</td>
<td>(30.8%)</td>
<td>22</td>
<td>(3.1%)</td>
</tr>
<tr>
<td>40-44</td>
<td>828</td>
<td>99</td>
<td>(12.0%)</td>
<td>10</td>
<td>(10.1%)</td>
<td>1</td>
<td>(1.0%)</td>
</tr>
<tr>
<td>45+</td>
<td>19</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>7073</td>
<td>1831</td>
<td>(25.9%)</td>
<td>638</td>
<td>(34.8%)</td>
<td>100</td>
<td>(5.5%)</td>
</tr>
</tbody>
</table>
Table 4.11  Clinical Pregnancy and Live Birth Rates (Frozen embryo replacements)
(All percentages are of number of treatment cycles)

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

Table 4.12  Treatments using micromanipulation
(including ICSI)

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

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)

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>Clinical</th>
<th>Babies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>Cycles</td>
<td>Embryo Transfers</td>
</tr>
<tr>
<td>Own Gametes</td>
<td>21898</td>
<td>26056</td>
<td>22083 (84.8%)</td>
</tr>
<tr>
<td>Donated Sperm</td>
<td>1023</td>
<td>1174</td>
<td>1088 (92.7%)</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>22921</strong></td>
<td><strong>27230</strong></td>
<td><strong>23171 (85.1%)</strong></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>Clinical</th>
<th>Babies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>Cycles</td>
<td>Embryo Transfers</td>
</tr>
<tr>
<td>Own Gametes</td>
<td>76</td>
<td>86</td>
<td>38 (44.2%)</td>
</tr>
<tr>
<td>Donated Sperm</td>
<td>9</td>
<td>9</td>
<td>4 (44.4%)</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>85</strong></td>
<td><strong>95</strong></td>
<td><strong>42 (44.2%)</strong></td>
</tr>
</tbody>
</table>

### 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)

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>Clinical</th>
<th>Babies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>Cycles</td>
<td>Embryo Transfers</td>
</tr>
<tr>
<td>Donated Eggs</td>
<td>1161</td>
<td>1253</td>
<td>1166 (93.1%)</td>
</tr>
<tr>
<td>Donated Embryos</td>
<td>104</td>
<td>111</td>
<td>106 (95.5%)</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>1265</strong></td>
<td><strong>1364</strong></td>
<td><strong>1272 (93.3%)</strong></td>
</tr>
</tbody>
</table>
Table 4.16  Clinical IVF pregnancy and live birth rates with fresh embryo transfer

a) Stimulated IVF

<table>
<thead>
<tr>
<th></th>
<th>Number of treatment cycles</th>
<th>Per egg collection</th>
<th>Per embryo transfer</th>
<th>Per Treatment Cycle</th>
<th>Per egg collection</th>
<th>Per embryo transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own Gametes</td>
<td>26056</td>
<td>23.0</td>
<td>25.0</td>
<td>27.1</td>
<td>19.2</td>
<td>20.9</td>
</tr>
<tr>
<td>Donated Sperm</td>
<td>1174</td>
<td>30.2</td>
<td>30.4</td>
<td>32.5</td>
<td>24.9</td>
<td>25.1</td>
</tr>
<tr>
<td>Totals</td>
<td>27230</td>
<td>23.3</td>
<td>25.2</td>
<td>27.4</td>
<td>19.5</td>
<td>21.1</td>
</tr>
</tbody>
</table>

b) Unstimulated IVF

<table>
<thead>
<tr>
<th></th>
<th>Number of treatment cycles</th>
<th>Per egg collection</th>
<th>Per embryo transfer</th>
<th>Per Treatment Cycle</th>
<th>Per egg collection</th>
<th>Per embryo transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own Gametes</td>
<td>86</td>
<td>4.7</td>
<td>9.3</td>
<td>10.5</td>
<td>2.3</td>
<td>4.7</td>
</tr>
<tr>
<td>Donated Sperm</td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Totals</td>
<td>95</td>
<td>4.2</td>
<td>8.2</td>
<td>9.5</td>
<td>2.1</td>
<td>4.1</td>
</tr>
</tbody>
</table>

c) Cycles using donated eggs or donated embryos

<table>
<thead>
<tr>
<th></th>
<th>Number of treatment cycles</th>
<th>Per egg collection</th>
<th>Per embryo transfer</th>
<th>Per Treatment Cycle</th>
<th>Per egg collection</th>
<th>Per embryo transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donated Eggs</td>
<td>1253</td>
<td>27.5</td>
<td>n/a</td>
<td>29.6</td>
<td>22.5</td>
<td>n/a</td>
</tr>
<tr>
<td>Donated Embryos</td>
<td>111</td>
<td>27.9</td>
<td>n/a</td>
<td>29.2</td>
<td>25.2</td>
<td>n/a</td>
</tr>
<tr>
<td>Totals</td>
<td>1364</td>
<td>27.6</td>
<td>n/a</td>
<td>29.6</td>
<td>22.7</td>
<td>n/a</td>
</tr>
</tbody>
</table>
### Table 4.17 Developmental defects and syndromes

<table>
<thead>
<tr>
<th>Chromosomal syndromes</th>
<th>Total</th>
<th>Fresh IVF</th>
<th>Frozen IVF</th>
<th>DI</th>
<th>Micro-manipulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Down's Syndrome</td>
<td>8</td>
<td>1</td>
<td>2</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Other chromosomal abnormalities</td>
<td>8</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Congenital abnormalities</th>
<th>Total</th>
<th>Fresh IVF</th>
<th>Frozen IVF</th>
<th>DI</th>
<th>Micro-manipulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleft lip</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Cleft palate</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Cleft lip with cleft palate</td>
<td>5</td>
<td>2</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Tracheo-oesophageal fistula, oesophageal atresia and stenosis</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atresia and Stenosis of the large intestine, rectum and anal canal</td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anomalies of the alimentary system</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Cardiac murmurs</td>
<td>6</td>
<td>3</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Ventricular septal defect</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Other congenital cardiac anomalies</td>
<td>12</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Other anomalies of the cardiac septa</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patent Duct</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anomalies of the cardiovascular system</td>
<td>4</td>
<td>1</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Hypospadias, Epispadias</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Anomalies of the male external genitalia</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal anomalies</td>
<td>13</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Polydactyly or syndactyly</td>
<td>6</td>
<td>3</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Reduction deformities of the limbs</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talipes</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Congenital dislocation of the hip</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Other anomalies of the limbs or limb girdle</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Anomalies of the nose, face, neck and skull</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Anomalies of the abdominal wall</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Ear anomalies</td>
<td>7</td>
<td></td>
<td>1</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Spina bifida</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exomphalos</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Anomalies of the tongue, branchial cleft and auricular sinus</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total number of children born: 120 as a percentage of total number of babies born as a result of each type of licensed treatment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Fresh IVF</th>
<th>Frozen IVF</th>
<th>DI</th>
<th>Micro-manipulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh IVF</td>
<td>41</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frozen IVF</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micro-manipulation</td>
<td>54</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Some children are born with more than one chromosomal 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)

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

1. Data for eight months only

Table 4.19  Donor Insemination Data

<table>
<thead>
<tr>
<th>Stimulated DI</th>
<th>Unstimulated DI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Centres</td>
<td>103</td>
</tr>
<tr>
<td>Number of Patients</td>
<td>2330</td>
</tr>
<tr>
<td>Number of Treatment Cycles</td>
<td>4713</td>
</tr>
<tr>
<td>Total Clinical Pregnancies</td>
<td>642</td>
</tr>
<tr>
<td>Clinical Pregnancy Rate per Cycle</td>
<td>13.6%</td>
</tr>
<tr>
<td>Total Miscarriages</td>
<td>68</td>
</tr>
<tr>
<td>Total Terminations</td>
<td>12</td>
</tr>
<tr>
<td>Total Ectopics</td>
<td>9</td>
</tr>
<tr>
<td>Total Live Births</td>
<td>517</td>
</tr>
<tr>
<td>Live Birth Rate per Cycle</td>
<td>11.0%</td>
</tr>
<tr>
<td>Total stillbirths and neonatal deaths</td>
<td>8</td>
</tr>
</tbody>
</table>
Table 4.20  Single and multiple clinical pregnancy outcome

a) Stimulated DI

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

¹. Four out of eight.

b) Unstimulated DI

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

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

Table 4.21  DI live birth rate by woman’s age

<table>
<thead>
<tr>
<th></th>
<th>Under 25</th>
<th>25 - 29</th>
<th>30 - 34</th>
<th>35 - 39</th>
<th>40 - 44</th>
<th>45 and over</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cycles</td>
<td>358</td>
<td>2210</td>
<td>4200</td>
<td>3299</td>
<td>927</td>
<td>41</td>
</tr>
<tr>
<td>Live Birth Rate per cycle</td>
<td>8.7</td>
<td>11.8</td>
<td>11.4</td>
<td>8.4</td>
<td>3.9</td>
<td>2.4</td>
</tr>
</tbody>
</table>
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 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:

- 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.

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 committees12. 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 number of embryos used, the results and conclusions of the project and references to any publications resulting from the work.
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 recommendations 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
<table>
<thead>
<tr>
<th>Job Title</th>
<th>Telephone Number</th>
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<tbody>
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<td>Myfanwy Milton Policy Manager</td>
<td>020 7539 3320</td>
</tr>
</tbody>
</table>
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, Southampton.
North Hampshire Fertility Centre, North Hampshire Hospital, Basingstoke.
The Hampshire Clinic, Basingstoke.
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 - 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, NUPTURE, 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 Arasaratanam 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.
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 autosomal 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 blastocysts 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 cryopreservation 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 undergoing ICSI treatment
   Randomised controlled clinical trial of blastocysts 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 Couts**  
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
Commissions for filming/interviews/articles, CBS, Channel 4
Holder of research grants; Wellbeing, North West Cancer Research Fund, Ray 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 Commission
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 lectureships; 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

Lisa 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

<table>
<thead>
<tr>
<th>Month</th>
<th>No of applications received</th>
<th>No of applications processed within timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Month</th>
<th>Total no of applications received</th>
<th>No of applications delayed due to factors outside HFEA control</th>
<th>No of applications processed within timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>112</td>
<td>16</td>
<td>81 out of 96 - 84%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Month</th>
<th>No of applications received</th>
<th>No of applications delayed due to factors outside HFEA control</th>
<th>No of applications processed within timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>12</td>
<td>10</td>
<td>2 out of 2 - 100%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Month</th>
<th>No of applications dealt with</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>6</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Month</th>
<th>Average % of publications dealt with within 3 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>80%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Month</th>
<th>Average Unit Cost per data entry for DI/IVF over 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>£1.20</td>
</tr>
</tbody>
</table>

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;

<table>
<thead>
<tr>
<th>Month</th>
<th>Average % of creditors paid within 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>90%</td>
</tr>
</tbody>
</table>

Percentage of Debts recovered within 60 and 90 days

<table>
<thead>
<tr>
<th>Month</th>
<th>Average % of debts recovered within 60/90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1999 - March 2000</td>
<td>84%/95%</td>
</tr>
</tbody>
</table>

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
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:

<table>
<thead>
<tr>
<th>Inspections</th>
<th>2000</th>
<th>1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of licenced centres at 31 March</td>
<td>116</td>
<td>119</td>
</tr>
<tr>
<td>No. of inspection visits during year</td>
<td>109</td>
<td>106</td>
</tr>
<tr>
<td>No. of audit visits during year</td>
<td>25</td>
<td>28</td>
</tr>
<tr>
<td>No. of ICSI Practitioners inspected</td>
<td>22</td>
<td>35</td>
</tr>
<tr>
<td>No. of PGD Practitioners inspected</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Issue of licences</th>
<th>2000</th>
<th>1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Licence Committee meetings</td>
<td>39</td>
<td>32</td>
</tr>
<tr>
<td>No. of items considered</td>
<td>328</td>
<td>315</td>
</tr>
<tr>
<td>No. of licences issued (Treatment and Storage)</td>
<td>110</td>
<td>92</td>
</tr>
<tr>
<td>No. of licences issued (Storage)</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>No. of licences issued (Research)</td>
<td>10</td>
<td>16</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross income</td>
<td>2</td>
<td>1,530,960</td>
<td>1,370,550</td>
<td></td>
</tr>
<tr>
<td>Transfer from</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deferred Government Grant</td>
<td>11</td>
<td>58,961</td>
<td>37,950</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,589,921</td>
<td>1,408,500</td>
<td></td>
</tr>
</tbody>
</table>

### Expenditure

- **Staff Costs** | 3 | 932,093 | 848,288 |
- **Other Operating Charges** | 4 | 733,610 | 666,671 |
- **Depreciation** | 5 | 40,954 | 37,950 |

**Total Expenditure**

<table>
<thead>
<tr>
<th>1,706,657</th>
<th>1,552,909</th>
</tr>
</thead>
</table>

**Operating (Deficit)** | 6 | (116,736) | (144,409) |

- **Notional Interest(Capital Charges)** | 1 | (23,200) | (25,800) |

**(Deficit) on Ordinary Activities**

<table>
<thead>
<tr>
<th>(139,936)</th>
<th>(170,209)</th>
</tr>
</thead>
</table>

- **Write back of Notional Interest**
- **Write back of Notional Superannuation**

**Deficit for the financial year**

<table>
<thead>
<tr>
<th>(37,400)</th>
<th>(66,009)</th>
</tr>
</thead>
</table>

**Retained surplus brought forward**

<table>
<thead>
<tr>
<th>249,448</th>
<th>315,457</th>
</tr>
</thead>
</table>

**Retained surplus carried forward**

<table>
<thead>
<tr>
<th>212,048</th>
<th>249,448</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Notes</th>
<th>1998/99</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deficit for the financial year</td>
<td>(37,400) (66,009)</td>
</tr>
<tr>
<td>Revaluation of fixed assets</td>
<td>5</td>
</tr>
<tr>
<td>Total recognised losses for the year</td>
<td>(38,485)</td>
</tr>
</tbody>
</table>

The notes on pages 64 to 75 form part of these accounts.
Balance Sheet as at 31 March 2000

31 March 1999

<table>
<thead>
<tr>
<th>Notes</th>
<th>£</th>
<th>£</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>£</th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating Activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net Cash Inflow</td>
<td>20,260</td>
<td>21,069</td>
</tr>
<tr>
<td><strong>Capital Expenditure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Purchase of Fixed Assets</td>
<td>(25,838)</td>
<td>(89,158)</td>
</tr>
<tr>
<td><strong>Financing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Receipts of Government Grants for fixed assets</td>
<td>25,600</td>
<td>25,600</td>
</tr>
<tr>
<td>- Transfer from revenue grant</td>
<td>238</td>
<td>63,558</td>
</tr>
<tr>
<td><strong>Net cash inflow from financing</strong></td>
<td>25,838</td>
<td>89,158</td>
</tr>
<tr>
<td><strong>Increase in Cash</strong></td>
<td>20,260</td>
<td>21,069</td>
</tr>
</tbody>
</table>

*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.

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

**Analysis of Income**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovered in Licence Fee Income</td>
<td>1,583,760</td>
<td>1,334,770</td>
</tr>
<tr>
<td>Other Income</td>
<td>728</td>
<td>1,805</td>
</tr>
<tr>
<td>Superannuation Receipts</td>
<td>40,877</td>
<td>8,133</td>
</tr>
<tr>
<td>Capital grant</td>
<td>(25,838)</td>
<td>(89,158)</td>
</tr>
<tr>
<td>Cash to be surrendered to Department of Health</td>
<td>(68,567)</td>
<td>-</td>
</tr>
<tr>
<td>Cash received from Department of Health</td>
<td>-</td>
<td>115,000</td>
</tr>
<tr>
<td></td>
<td>1,530,960</td>
<td>1,370,550</td>
</tr>
</tbody>
</table>
3. Staff Costs

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

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td>Management</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Administrative</td>
<td>28</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>31</td>
</tr>
</tbody>
</table>

Remuneration of key management

Chief Executive

Emoluments (excluding pension fund contributions):

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Salary</td>
<td>53,495</td>
<td>49,851</td>
</tr>
<tr>
<td>Bonus payments</td>
<td>250</td>
<td>750</td>
</tr>
<tr>
<td>Total</td>
<td>53,745</td>
<td>50,601</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th></th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real increase in pension at 60 during 1999/2000</td>
<td>944</td>
</tr>
<tr>
<td>Total accrued pension at 60 as at 31/03/00</td>
<td>6,488</td>
</tr>
</tbody>
</table>
Remuneration of Authority Members

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Remuneration</td>
<td>£8,440</td>
<td>£8,210</td>
</tr>
</tbody>
</table>

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

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:

<table>
<thead>
<tr>
<th>Member</th>
<th>1999/2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Jane Denton (Deputy Chairman)</td>
<td>£7,962</td>
</tr>
<tr>
<td>Professor Brenda Almond</td>
<td>£2,025</td>
</tr>
<tr>
<td>Dr Sue Avery (appointed November 1999)*</td>
<td>£1,755</td>
</tr>
<tr>
<td>Dr Gulam Bahadur (retired November 1999)</td>
<td>£2,430</td>
</tr>
<tr>
<td>Professor David Barlow</td>
<td>£1,890</td>
</tr>
<tr>
<td>Professor Peter Braude (appointed November 1999)</td>
<td>£675</td>
</tr>
<tr>
<td>Mrs Moira Coath</td>
<td>£1,886</td>
</tr>
<tr>
<td>Professor Christine Gosden</td>
<td>£4,320</td>
</tr>
<tr>
<td>Professor Andrew Grubb</td>
<td>£3,375</td>
</tr>
<tr>
<td>Professor Martin Johnson (retired April 1999)</td>
<td>£0</td>
</tr>
<tr>
<td>Professor Henry Leese *</td>
<td>£5,126</td>
</tr>
<tr>
<td>Professor Stuart Lewis</td>
<td>£3,510</td>
</tr>
<tr>
<td>Dr Brian Lieberman (retired in November 1999)**</td>
<td>£1,342</td>
</tr>
<tr>
<td>Dr Anne McLaren</td>
<td>£1,620</td>
</tr>
<tr>
<td>Dr Sadia Muhammed *</td>
<td>£2,430</td>
</tr>
<tr>
<td>Ms Sara Nathan</td>
<td>£5,805</td>
</tr>
<tr>
<td>Ms Sharmila Nebhrajani</td>
<td>£1,620</td>
</tr>
<tr>
<td>Rt Rev’d Dr Michael Nazir-Ali</td>
<td>£1,215</td>
</tr>
<tr>
<td>Dr Francoise Shenfield (appointed November 1999)</td>
<td>£540</td>
</tr>
<tr>
<td>Dr Joan Stringer (retired November 1999)</td>
<td>£540</td>
</tr>
<tr>
<td>Professor Allan Templeton</td>
<td>£1,346</td>
</tr>
<tr>
<td>Lady Julia Tugendhat</td>
<td>£3,780</td>
</tr>
<tr>
<td>Mr John Williams (retired November 1999)</td>
<td>£1,485</td>
</tr>
<tr>
<td>Mrs Lis Woods (appointed November 1999)</td>
<td>£1,080</td>
</tr>
</tbody>
</table>

* Fees were paid to Members' main employer
** Fees were paid to charitable trust
4. Other Operating Charges

<table>
<thead>
<tr>
<th>Description</th>
<th>1999/00</th>
<th>1998/99</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease payments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- land and buildings</td>
<td>110,450</td>
<td>110,659</td>
</tr>
<tr>
<td>- other leases</td>
<td>17,406</td>
<td>8,740</td>
</tr>
<tr>
<td>Accommodation</td>
<td>90,730</td>
<td>100,312</td>
</tr>
<tr>
<td>Travel &amp; subsistence</td>
<td>101,448</td>
<td>91,163</td>
</tr>
<tr>
<td>Attendance fees - Inspectors</td>
<td>23,401</td>
<td>19,020</td>
</tr>
<tr>
<td>Professional &amp; administrative fees</td>
<td>134,136</td>
<td>76,273</td>
</tr>
<tr>
<td>Audit fees</td>
<td>11,500</td>
<td>11,500</td>
</tr>
<tr>
<td>Register of information</td>
<td>10,691</td>
<td>(14,177)</td>
</tr>
<tr>
<td>Stationery, photocopying &amp; printing</td>
<td>96,493</td>
<td>58,252</td>
</tr>
<tr>
<td>Telephones &amp; postage</td>
<td>42,979</td>
<td>39,675</td>
</tr>
<tr>
<td>Training &amp; development</td>
<td>17,585</td>
<td>41,734</td>
</tr>
<tr>
<td>Recruitment &amp; advertising</td>
<td>17,065</td>
<td>14,804</td>
</tr>
<tr>
<td>Conferences &amp; meeting expenses</td>
<td>12,418</td>
<td>16,720</td>
</tr>
<tr>
<td>Library &amp; reading materials</td>
<td>9,436</td>
<td>9,030</td>
</tr>
<tr>
<td>Sundry office equipment</td>
<td>19,456</td>
<td>53,312</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>13,931</td>
<td>14,944</td>
</tr>
<tr>
<td>Permanent diminution in value of fixed assets</td>
<td>4,485</td>
<td>4,495</td>
</tr>
<tr>
<td>Provision for Doubtful Debts</td>
<td></td>
<td>10,215</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>733,610</strong></td>
<td><strong>666,671</strong></td>
</tr>
</tbody>
</table>
5. Fixed Assets as at 31 March 2000

<table>
<thead>
<tr>
<th></th>
<th>Computer Equipment</th>
<th>Office Equipment</th>
<th>Furniture &amp; Fittings</th>
<th>Installations</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Cost/valuation as at 31 March 1999</td>
<td>116,542</td>
<td>45,263</td>
<td>108,496</td>
<td>120,032</td>
<td>390,333</td>
</tr>
<tr>
<td>Additions</td>
<td>11,691</td>
<td>14,147</td>
<td>-</td>
<td>-</td>
<td>25,838</td>
</tr>
<tr>
<td>Disposals</td>
<td>(40,075)</td>
<td>(1,491)</td>
<td>(9,349)</td>
<td>-</td>
<td>(50,915)</td>
</tr>
<tr>
<td>Revaluation</td>
<td>(8,006)</td>
<td>(232)</td>
<td>(1,031)</td>
<td>(1,248)</td>
<td>(10,517)</td>
</tr>
<tr>
<td>As at 31 March 1999</td>
<td>80,152</td>
<td>57,687</td>
<td>98,116</td>
<td>118,784</td>
<td>354,739</td>
</tr>
<tr>
<td>Depreciation as at 31 March 1999</td>
<td>73,707</td>
<td>20,523</td>
<td>100,567</td>
<td>36,173</td>
<td>230,970</td>
</tr>
<tr>
<td>Charge for the year</td>
<td>17,485</td>
<td>7,664</td>
<td>3,751</td>
<td>12,054</td>
<td>40,954</td>
</tr>
<tr>
<td>Disposals</td>
<td>(40,075)</td>
<td>(1,491)</td>
<td>(9,349)</td>
<td>-</td>
<td>(50,915)</td>
</tr>
<tr>
<td>Revaluation</td>
<td>(3,521)</td>
<td>(101)</td>
<td>(949)</td>
<td>(376)</td>
<td>(4,947)</td>
</tr>
<tr>
<td>As at 31 March 1999</td>
<td>47,596</td>
<td>26,595</td>
<td>94,020</td>
<td>47,851</td>
<td>216,062</td>
</tr>
</tbody>
</table>

Net Book Value (NBV)

<table>
<thead>
<tr>
<th></th>
<th>At 31 March 2000</th>
<th>At 31 March 1999</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td></td>
<td>32,556</td>
<td>42,835</td>
</tr>
<tr>
<td></td>
<td>31,092</td>
<td>24,740</td>
</tr>
<tr>
<td></td>
<td>4,096</td>
<td>7,929</td>
</tr>
<tr>
<td></td>
<td>70,933</td>
<td>83,859</td>
</tr>
<tr>
<td>Increase (Decrease) in NBV</td>
<td>(10,279)</td>
<td>6,352</td>
</tr>
<tr>
<td></td>
<td>(3,833)</td>
<td>(12,926)</td>
</tr>
<tr>
<td></td>
<td>(20,686)</td>
<td></td>
</tr>
</tbody>
</table>

70
### 6. Operating (Deficit)/Surplus

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

<table>
<thead>
<tr>
<th></th>
<th>LICENSING</th>
<th>OTHERS</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income</td>
<td>£</td>
<td>£</td>
<td>£ £</td>
</tr>
<tr>
<td>Licence Fees</td>
<td>1,583,760</td>
<td>1,334,770</td>
<td>1,583,760 1,334,770</td>
</tr>
<tr>
<td>Other</td>
<td>41,605</td>
<td>9,938</td>
<td>41,605 9,938</td>
</tr>
<tr>
<td>Cash surrendered to/received from the Department of Health</td>
<td>(68,567)</td>
<td>115,000</td>
<td>(68,567) 115,000</td>
</tr>
<tr>
<td>Transfer to Deferred Government Grant</td>
<td>(25,838)</td>
<td>(89,158)</td>
<td>(25,838) (89,158)</td>
</tr>
<tr>
<td>Transfer from Deferred Government Grant</td>
<td>29,481</td>
<td>18,975</td>
<td>29,481 18,975</td>
</tr>
<tr>
<td>Total</td>
<td>1,613,241</td>
<td>1,353,745</td>
<td>(23,320) 54,755</td>
</tr>
</tbody>
</table>

| Expenditure        | £         | £      | £ £            |
| Staff Costs        | (585,940) | (496,742) | (346,153) (351,546) |
| Depreciation       | (20,477)  | (18,975) | (20,477) (18,975) |
| Other Charges      | (509,560) | (416,496) | (224,051) (250,176) |
| Total              | (1,115,977)| (932,213) | (590,680) (620,697) |

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

<table>
<thead>
<tr>
<th></th>
<th>£</th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence fee</td>
<td>97,502</td>
<td>126,109</td>
</tr>
<tr>
<td>Other debtors</td>
<td>14,394</td>
<td>14,951</td>
</tr>
<tr>
<td>Pre-payments</td>
<td>83,835</td>
<td>84,890</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>195,731</td>
<td>225,950</td>
</tr>
</tbody>
</table>

8. Creditors: Amounts falling due within one year

<table>
<thead>
<tr>
<th></th>
<th>£</th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade creditors</td>
<td>1,743</td>
<td>1,515</td>
</tr>
<tr>
<td>Other taxes and social security</td>
<td>2,680</td>
<td>91</td>
</tr>
<tr>
<td>Department of Health</td>
<td>32,567</td>
<td></td>
</tr>
<tr>
<td>Accruals</td>
<td>25,748</td>
<td>20,169</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>62,738</td>
<td>21,775</td>
</tr>
</tbody>
</table>

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 analogous 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

<table>
<thead>
<tr>
<th></th>
<th>£ 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pensions in Payment</td>
<td>0</td>
</tr>
<tr>
<td>Deferred Pensions</td>
<td>105</td>
</tr>
<tr>
<td>Active Members (Past Service)</td>
<td>433</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>538</strong></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Deferred Government Grant</th>
<th>Income and Expenditure</th>
<th>Revaluation Reserve</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Balance at 31 March 1999</td>
<td>161,688</td>
<td>249,448</td>
<td>11,196</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th></th>
<th>Deferred Government Grant</th>
<th>Income and Expenditure</th>
<th>Revaluation Reserve</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Balance at 31 March 1999</td>
<td>128,565</td>
<td>212,048</td>
<td>10,111</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Land and Buildings</td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td>Leases which expire in over 5 years</td>
<td>110,450</td>
<td>110,450</td>
</tr>
<tr>
<td>Other Leases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leases which expire within 1 year</td>
<td>0</td>
<td>807</td>
</tr>
<tr>
<td>Leases which expire within 2 to 5 years</td>
<td>12,204</td>
<td>12,204</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th></th>
<th>1998/99</th>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating (deficit)</td>
<td>(116,736)</td>
<td>(144,409)</td>
</tr>
<tr>
<td>Notional superannuation charge</td>
<td>79,336</td>
<td>78,400</td>
</tr>
<tr>
<td>Depreciation charges</td>
<td>40,954</td>
<td>37,950</td>
</tr>
<tr>
<td>Downward indexation charge</td>
<td>4,485</td>
<td>4,495</td>
</tr>
<tr>
<td>Decrease in debtors</td>
<td>30,219</td>
<td>123,409</td>
</tr>
<tr>
<td>Increase (decrease) in creditors</td>
<td>40,963</td>
<td>(40,826)</td>
</tr>
<tr>
<td>Transfer from deferred government grant</td>
<td>(58,961)</td>
<td>(37,950)</td>
</tr>
</tbody>
</table>

Net cash inflow from operating activities | 20,260 | 21,069 |

2. Analysis of changes in cash

<table>
<thead>
<tr>
<th></th>
<th>At 31 March 1999</th>
<th>Cash Flows</th>
<th>At 31 March 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash at bank and in hand</td>
<td>58,794</td>
<td>20,260</td>
<td>79,054</td>
</tr>
</tbody>
</table>
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 as 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.