Master Copy

Communications

Fertilisation and Embryology

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY
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This report covers the year beginning 1 November 1995 with a forward look for the year beginning 1 November 1996.

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1 Chairman's letter

The Human Fertilisation and Embryology Authority remains one of the few statutory bodies in the world regulating assisted reproduction technology and human embryo research. Our purpose is to facilitate and to promote good practice both clinically and in research. We exist to safeguard and protect.

From the beginning our aim has been that patients should receive the best possible treatment and that the welfare of any potential child be fully considered in advance of treatment being offered.

During the past year our workload has grown rapidly. This is in response to the ever-increasing demand for licensed infertility services and information about them. We have to balance growing public concern with the tireless drive of scientific progress. To do this we seek to stimulate and lead public debate in order to provide a framework in which science can advance with public confidence.

We are concerned that some research and treatment innovations which are prohibited in the UK are being sought and provided abroad where standards may be lower. This development is unwelcome because we believe it exposes patients and children to risks.

Times change, and the medical and ethical worlds move on. We recognise the need regularly to update our views and advice and the Authority is considering a number of topics with wide ethical implications. For example, pre-implantation genetic diagnosis is a powerful technique which enables an in vitro embryo to be screened for genetic defects. Demand for this service is likely to grow, and we are looking at the subject jointly with the Advisory Committee on Genetic Testing.

The safe cryopreservation of sperm and embryos has also concerned the Authority. Our working group has pointed to a lack of research in this area, and has recommended consultation with professional organisations to ensure that our policies meet the demands posed by these issues. We are now taking this forward.

Cloning has raced up the list of ethical concerns as a result of the Roslin Institute's experiment with sheep, and we are actively debating the implications for the Authority with other interested parties, particularly the Department of Health and the Human Genetics Advisory Commission.

There has been wide public debate on the distressing and difficult circumstances in which Diane Blood found herself, her late husband not having been able to give written consent to the storage of his sperm or its use for treatment. We were concerned throughout to uphold the integrity of the Human Fertilisation and Embryology Act 1990 and its requirement for informed written consent. We were pleased that the Court of Appeal unequivocally confirmed this and made it clear that a similar situation should not recur.

One of the HFEA's prime functions is to set proper standards and practicable guidelines for clinics. The Authority does this through its Code of Practice, which is continually reviewed and regularly updated, and implemented through annual licensing inspections. The fourth edition will shortly be submitted to the Secretary of State incorporating policy decisions made since December 1995 including the Authority's guidance on the statutory storage period for embryos. The changes in the Code reflect the Authority's objective of keeping closely in touch with advances in scientific techniques and issues affecting the licensing process.

As Chairman of the HFEA I am proud of its accomplishments. The Quinquennial Review of the Authority, presented to the Government in July 1996, was very positive about our work. It confirmed the need for the Authority and complimented it on its cost-effectiveness.

As the accomplishments of the HFEA grow, an ever-greater workload falls upon Members. I am grateful for the many days of work that they undertake annually on behalf of the Authority, and for their commitment to fulfilling the role set for them by Parliament. In particular I would like to pay tribute to the work done by those individuals who have recently left the Authority: Sam Berry, Joan Harbison, Stephen Hillier, Penelope Keith and Jeanette Naish.

There are many things which the Authority would like to do. Our finite resources, however, by necessity restrict our overall activities. Nevertheless, we have reached our sixth birthday with our fund of knowledge, breadth of responsibility and public profile greatly increased and still growing. Medical progress becomes more insistent, and the press and public ever more interested in our work. We are committed to our roles of regulator and arbiter between scientific progress and public concern.

RUTH DEECH
Chairman

2 The Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority was the first statutory body in the world established to regulate and monitor certain fertility treatments and human embryo research.

Ruth Deech
Chairman

Suzanne McCarthy
Chief Executive

ORGANISATION AND FINANCE COMMITTEE

Ruth Deech
Chairman

Diana Brittan

David Greggains

Richard Jones

Joan Stringer

AUDIT COMMITTEE

Julia Tugendhat
Chairman

Gulam Bahadur

David Greggains

John Williams

A product of the 1984 Warnock Committee's report[1], the Authority was created by the Human Fertilisation and Embryology Act 1990 and assumed its full powers on 1 August 1991.

The Authority's Role

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

Underlying all its activities is the Authority's primary aim – to safeguard all relevant interests: patients; children; the wider public; and future generations. Its objectives are to ensure that both treatment and research are undertaken with the utmost respect and responsibility.

The HFEA's other main functions under the 1990 Act are:

- to keep a formal register of information about donors, treatments and children born from those treatments. This is so that children born as a result of donated eggs or sperm can find out, if they wish, something about their genetic history;
- to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;
- to publicise its role and provide relevant advice and information to patients and donors and clinics;
- to keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by the 1990 Act and advise the Secretary of State if he asks about those matters.

The Authority's Membership

The Authority's 21 Members are appointed by UK Health Ministers. The 1996 appointments were made for the first time after national advertising and in accordance with Nolan guidelines.

Authority Members determine the Authority's policies and scrutinise treatment and research licence applications. They are not appointed as representatives of different groups, but bring to the Authority a broad range of medical, scientific, social, legal, religious and philosophical knowledge and experience. In order that an independent perspective can be maintained, the 1990 Act requires that the Chairman, Deputy

[1]Committee of Inquiry into Human Fertilisation and Embryology.

Chairman and at least half of the Authority's Membership are neither doctors nor scientists involved in research or practice relevant to infertility.[2]

The Authority's Executive

The Authority has an Executive composed of 29 staff who are responsible for implementing the Authority's policies and licensing decisions and conducting the Authority's day-to-day activities.[3]

The Executive is divided into seven sections, each of which reports to particular HFEA standing committees and working groups as follows:

Audit reporting to the Audit Committee;

Communications reporting to the Communications Steering Group;

Data management reporting to the Information Committee;

Finance reporting to the Organisation and Finance Committee and the Audit Committee;

Licensing reporting to the Licensing and Fees Committee and the Working Group on New Developments in Reproductive Technology;

Policy reporting to the Code of Practice Committee and the Ethics Committee; and

Resources reporting to the Organisation and Finance Committee and the Audit Committee.

[2]A full list of Members is at Annex 1, with Committee and Working Group membership at Annex 2.

[3]A list of Executive Staff is at Annex 3.

The Quinquennial Review

In accordance with the requirement that every Non-Departmental Public Body (NDPB) be reviewed every five years, the Authority's first Quinquennial Review was carried out during 1996.[4]

The Review asked certain pertinent questions about the Authority including;

- whether the functions of the Authority were still required and the appropriateness of its aims and objectives;
- whether an NDPB was the best vehicle for meeting the Government's objectives in issues of human fertilisation and embryology; and
- how effectively, efficiently and economically the Authority achieved its aims and objectives.[5]

The Review concluded that the case for an independent statutory body remained valid and that there was no other body which might perform the functions of the HFEA more cost-effectively.

The Authority's Income

The Authority's budget for the financial year 1996/97 was £1,501,242. The Authority's objectives are to make the most efficient and cost-effective use of its resources and to increase the value for money of the services it provides in order to limit the level of licence fees and the charge to the taxpayer.

[4]First Quinquennial Review of the Human Fertilisation and Embryology Authority; Report to UK Health Ministers by Mr M Lillywhite, July 1996.

[5]The Quinquennial Review also drew on the Financial Appraisal of the Human Fertilisation and Embryology Authority carried out by the Department of Health's Internal Audit Branch, 1996.

The Authority, by agreement with the Department of Health and the Treasury, has a financial objective to raise 70% of its income from licence fees during 1996/97 and 1997/98. The fees charged to clinics remain as settled by the Authority in 1994 being £40 per IVF cycle and £10 per DI cycle. Once the Authority's licence fee income target for 1998/99 has been settled the Authority intends reviewing fee levels and the system for fees collection. The Authority will give clinics as much notice as possible before introducing any changes in its fees.

The Code of Practice on Enforcement

The Authority's Code of Practice on Enforcement (CPE) sets out the level of service that licensed clinics and the public can expect from the Authority. It specifically states how fast the Authority aims to process licence applications and the procedures for making complaints about the Authority. It is sent to licensed clinics and is available to members of the public on request. Since the publication of the last Annual Report in July 1996 no formal complaints have been made about the Authority under this procedure.

3 Licensing and Audit of Licensed Centres

All licensing decisions are made by Authority licence committees.

LICENSING AND FEES COMMITTEE

Diana Brittan
Chairman

Jane Denton

Christine Gosden

David Greggains

Richard Jones

Brian Lieberman

Angela Mays

Licence Committees

Each committee is composed of at least three Authority Members who determine the type of inspection required and whether a licence should be revoked, suspended or granted. If a licence is granted, specified conditions may be attached. Where there is the possibility that a criminal offence has been committed contrary to the 1990 Act, a licence committee will decide what further action should be taken including whether the police should be involved or the matter referred to the Director of Public Prosecutions.

Licences

Each clinic in the UK which offers IVF or DI clinical treatments, storage of gametes or embryos or which carries out embryo research must be licensed by the HFEA. (Research licensing is considered in section 4).

As of 31 July 1997 there were 117 clinics licensed for treatment and/or storage of gametes and embryos.[6] Of these, 74 are licensed for IVF and DI, 2 for IVF only and 31 for DI only. There are 10 clinics licensed only for the storage of sperm. Of the 76 clinics offering IVF, 93% are licensed for embryo storage and 62% for Intra Cytoplasmic Sperm Injection (ICSI).

During the period 1 November 1995 to 31 October 1996, 4 centres originally licensed only for DI expanded their services to include IVF, 5 new centres were granted licences, 2 centres closed and 1 DI centre merged with an associated IVF centre.

[6] Full details of licensed clinics and the services they offer can be found in the Authority's Patients' Guide to DI and IVF Clinics (third edition). A list of licensed clinics is also at Annex 4 of this Report.

The New Licensing System

The Authority is modifying its system to make it more efficient and to contain costs. The Authority's Fifth Annual Report (1996) stated that the Authority was refining its licensing system with the introduction of a three year licensing cycle for each centre. This cycle consists of a broad-based general inspection by a full team once every three years combined with highly focused inspections as directed by licence committees during the intervening years. This new system formally started on 1 May 1997. The Authority intends reviewing the system's progress in December 1997.

A further development is the use, but only at a licence committee's discretion, of a shortened application for licence renewals if these are based on focused inspections. This change in procedure recognises that a centre may not have altered radically since its licence was last renewed.

Breaches and Enforcement

Information on alleged or apparent breaches of the 1990 Act or the Code of Practice comes to the Authority from a wide range of sources including Authority

inspections, information from patients, centre staff, the Authority's database and from the centres themselves. The Authority has investigated 14 such incidents during the period of this Annual Report. Once information is received preliminary investigations are carried out to determine whether there is prima facie evidence of a breach. Where this is found the Authority often seeks specialist advice. All evidence and advice received is submitted to a licence committee which decides whether any further action should be taken.

The Audit Programme of Licensed Clinics

The National Audit Office (NAO) strongly recommended during its annual inspection of the Authority that the HFEA should employ an auditor in order to assure itself of the accuracy and completeness of the data collected from clinics. The NAO would normally perform this service itself, but the 1990 Act's requirements of confidentiality make this impossible.

A Systems and Data Auditor (SDA) was duly appointed in April 1996 to design and implement a programme of audits. The first full programme, started in October 1996, will take five years to complete. New centres will be incorporated into the programme after they have been licensed for three years in order to allow such centres time to develop their systems and become familiar with the licensing process.

Prior to auditing a centre the SDA extracts, using random sampling, a data set from the Authority's register which is checked against patient/donor records at the centre. When the SDA visits a centre this process is reversed: the sample being extracted from the patient files held there which are later checked against the data held in the register. Feedback is given after every audit including a formal audit report. Clinics are given the opportunity to respond to this report which is then considered by a licence committee.

It should be stressed that, while the audit programme is under the remit of the licensing section, the audit function is completely separate from that of the inspection process. As of 1 October 1997 approximately 20 audits will have been carried out.

Licensing of Intra Cytoplasmic Sperm Injection (ICSI)

ICSI is a relatively new IVF technique in which a single sperm is injected into the cytoplasm of an egg using microinjection equipment. The skills and experience of the practitioner are key factors in the successful application of this technique. The Authority has therefore introduced competency assessment for licensing clinical ICSI treatment.

When the ICSI licensing system was started in July 1995 two ICSI inspectors were appointed. In order to meet the expected demand for the assessment of prospective ICSI practitioners, the Authority appointed 9 more ICSI inspectors in 1996. As of July 1997, 47 centres are licensed to offer ICSI and there are 110 recognised practitioners.

During the period 1 November 1995 to 31 October 1996, one ICSI practitioner's recognition was withdrawn at the time of the centre's licence renewal. It was subsequently reinstated following a further inspection.

On examining the operation of the new system, the Authority's Licensing and Fees Committee recognised that there were some inconsistencies with respect to both the licensing of practitioners and facilities. In light of this, the Authority set up an ICSI Advisory Group composed of experts in the field and a representative from the Association of Clinical Embryologists to examine the licensing of ICSI.[7] The Advisory Group's deliberations resulted in the publication in 1996 of, *"Guidelines for the Inspection of ICSI Facilities and Practitioners: Standards for Criteria and Assessment,"* which the Authority has implemented.

Clinical Frontiers

There are a number of clinical procedures which, while technically possible, are still unproven. Before clinical applications can be considered the Authority must be in posession of research evidence demonstrating both medical safety and effectiveness. These techniques include:

Use of spermatids in ICSI

Spermatids are immature sperm. Few babies have been born as a result of this technique, and the Authority considers that there is insufficient evidence from animal studies and from research on human embryos to demonstrate its safety and efficacy. The Authority has granted a research licence to enable such evidence to be obtained.

Oocyte cryopreservation

The use of a frozen egg in a successful live birth was reported in 1986. It has not been possible to repeat the event, and the cryopreservation of eggs for routine clinical purposes is not yet a practical proposition.

[7] Steven Hillier, Steve Troup, Bert Stewart, Alan McDermott, Ceinwen Gearon and Karin Dawson

4 Research

Any research project which involves the creation, keeping or use of human embryos outside the body must be licensed by the Authority.

Introduction

For a research licence to be granted the HFEA must be satisfied that the use of human embryos is "necessary or desirable" for at least one of the following purposes:[8]

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

The following activities involving human embryos are not permitted in the UK:

- 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 a nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or 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.[9]

The HFEA Code of Practice states that the Authority will not licence research projects involving embryo splitting with the intention of increasing the number of embryos for transfer.

The Human Embryo Research Licensing Process

Approval by a properly constituted external ethics committee is a necessary prerequisite to the Authority considering an application for a research licence. Centres within the NHS refer research projects to the Local Research Ethics Committee of the relevant District Health Authority. The Code of Practice provides guidance on the use and constitution of ethics committees for centres outside the NHS.

In addition, all applications for research licences are submitted for peer review.[10] Peer reviewers comment on a number of issues including the importance of the work's originality and justification for it. Their recommendations are submitted to a licence committee which will decide whether a licence should be granted. The Committee

[8] HFE Act 1990, Schedule 2, para 3(2).

[9] The commission of any of these activities is a criminal offence.

[10] The Authority's panel of peer reviewers is at Annex 7. The panel is currently being reviewed by the Authority.

will take into account all the information presented and consider issues such as the information to be given to patients who might wish to be involved in the project and the consent forms they will sign.

Licensed Research Projects – An Update[11]

The Authority has 26 licensed research projects at 19 different centres. Of those currently licensed, 5 were licensed for the first time and 21 were licensed as ongoing projects.

[11] A list of current research projects as of 31 July 1997 is at Annex 6.

5 The Code of Practice

From the outset one of the HFEA's primary aims has been to set proper standards and practicable guidelines for clinics. All licensed clinics and research centres are expected to follow the professional, legal and ethical standards set out in the Code.

CODE OF PRACTICE COMMITTEE

Jane Denton
Chairman

Gulam Bahadur

Ruth Chambers

Richard Holloway

Anne McLaren

Rory Nicol

Allan Templeton

The 1990 Act[12] requires the Authority to produce a Code of Practice to guide clinics on how they should carry out their licensed activities. The Code provides part of the framework for the Authority's monitoring activities.

The Code is reviewed regularly and updated in the light of advances in techniques and to deal with issues which emerge from the licensing process. The Code's second edition was published in June 1993, the third in December 1995 and the fourth is expected to be published in early 1988. Revisions of the Code must be approved by the Secretary of State and laid before Parliament. Copies of the Code are available from the HFEA upon request.

Fourth edition of the Code

The present revision will incorporate those policy decisions which the Authority has made since December 1995. In preparing this latest revision the Authority carried out consultations with both clinics and interested organisations on two issues: the upper age limit for sperm donors and the screening of donors for cystic fibrosis. In addition, the latest revision also includes the Authority's policy on the statutory storage period for embryos and the treatment of HIV antibody positive patients.

Upper Age Limit for Sperm Donors

The Authority decided to review the evidence that was available on the genetic effects of paternal age. In particular, there is some evidence that the incidence of serious non-chromosomal birth defects, especially those arising from new autosomal mutations, increases with age. The responses received all agreed that the upper age limit should be lowered if there was evidence to support it. Because of the lack of compelling evidence the Authority decided not to lower the current upper age limit of 55 years at this time. It will, however, continue to monitor published evidence on this subject.

[12] Section 25.

Screening Donors for Cystic Fibrosis

Cystic fibrosis is the most common autosomal recessive condition in northern Europeans, and screening gamete donors for cystic fibrosis has increasingly become standard practice at licensed clinics. The consultation responses received generally favoured making the screening of donors mandatory, although there was some concern about the way in which such a policy should be implemented. For example, the test that is used to identify cystic fibrosis carrier status will detect approximately 85% of all carriers. Thus, even where all donors have been screened, there remains a risk that a cystic fibrosis carrier's donation might be used unknowingly in a patient's treatment.

The provision of information and support to all individuals undergoing genetic tests and/or receiving gametes from donors was a major consideration in developing the Authority's policy. The Authority was anxious both that patients should be made aware of the risks still present even if testing was carried out, and that the concerns of donors undergoing the test should be addressed.

The Authority decided to recommend strongly to clinics that cystic fibrosis screening should be carried out on all sperm and egg donors. In line with this, all licensed clinics are now required to inform patients whether or not a donor has been tested for cystic fibrosis, and of the risks for any child who may be born from fertility treatment.

In addition, the Authority encourages clinics to offer testing to couples. Should they wish to undergo such a test, the Authority recommends that they should be offered genetic counselling. It was also decided that donors should be offered genetic counselling if they agreed to be tested for cystic fibrosis, and be provided with information about the implications for themselves and their family if they were found to be carriers.

The Authority also considered the wider implications of genetic testing and decided that testing for other disorders was appropriate if there was an accurate test available and it would help to prevent the transmission of a serious condition.

Statutory Storage Period for Embryos

In February 1996 the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations [1996], were laid before Parliament. These extended, in certain circumstances, the statutory storage period for embryos in the 1990 Act from five years to ten years. Special provision was made for some women, including those undergoing cancer treatment or suffering from premature menopause, to store embryos until their 55th birthdays. The Regulations took effect in May 1996, and the Authority issued new consent and storage forms so that couples placing embryos into storage for the first time could consent to more than five years storage if this was appropriate. Couples who had placed embryos in storage before May 1996 were required to renew their consents to storage if they wished to store their embryos for more than five years. The Authority issued guidance to clinics on how to deal with these situations, and this has now been incorporated into the Code of Practice. In accordance with the Act, emphasis is placed on ensuring that couples give informed consent and on the importance of counselling. The Authority also produced a new leaflet on consent, *"Consent to the Use and Storage of Gametes and Embryos"*, which addresses these issues.

When embryos in store reach the end of their storage period they must be removed from storage and either used in accordance with the couple's wishes or allowed to perish. Clinics are required to deal with the disposal of embryos sensitively, and couples should, if possible, be made aware of the event. Couples are encouraged to keep in contact with clinics where they have stored embryos.

Treatment of HIV Antibody Positive Patients

The Authority reviewed its guidance on the welfare of the potential child to see whether this should be amended, in the light of treating HIV antibody positive patients. The Authority concluded that this question raised several general issues as there are other diseases or viruses which may be transmitted to a potential child through pregnancy. In addition, one parent might be suffering from, or at risk of, another life-threatening disorder. In acknowledgement of this, the Code of Practice has been amended to make it clear that, before agreeing to proceed, the clinics should consider the welfare of any potential child and take into account the health of the couple requiring treatment.

Other Changes

The fourth edition also contains a number of smaller changes which mostly serve to clarify current

policy including, for example, factors to be taken into account when making the welfare of the child assessment, and the information that should be given to patients on the implications of multiple pregnancy. These have been included in response to comments from clinics or because the Authority has become aware that more detail is necessary.

The Code's Fifth Edition

Work on the fifth edition will start shortly. The Authority's main objective for this revision is to undertake a thorough reconsideration of the Code's structure. Although it is perhaps inevitable that the Code of Practice will grow more lengthy and complicated as the number of techniques and issues covered multiply, there is a concern that it might consequently become increasingly difficult to use. This would be undesirable. As part of this review process the Authority will be seeking the views of clinics, as the main users of the Code, on how the material in the Code of Practice might be organised more effectively.

6 Ethical Issues

Ethical issues are always being considered by the HFEA. Current concerns include pre-implantation genetic diagnosis, payment to gamete donors, safe cryopreservation of sperm and embryos, and cloning.

ETHICS COMMITTEE

Richard Holloway
Chairman

Liz Forgan

Christine Gosden

Stuart Lewis

Anthony Thiselton

Julia Tugendhat

John Williams

Pre-Implantation Genetic Diagnosis (PGD)

PGD is a technique used to detect whether an embryo created *in vitro* is carrying a genetic defect which will give rise to a serious inherited 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, to a male child. Four centres are licensed to carry out this technique clinically while four others hold Authority research licenses.

While PGD is now practised on a small scale, it is expected that, as knowledge about the genes responsible for different conditions increases and people become more aware of genetics, demand will grow. The Authority, and its Ethics Committee in particular, have been considering the issues surrounding PGD in order to determine what guidance should be produced and what criteria should be used in deciding when PGD is, and is not, acceptable. As part of this exercise a joint working group has been established with the Advisory Committee on Genetic Testing.

Payments to Gamete Donors

Under the 1990 Act, payments to donors may only be made if authorised by the Authority. The Authority's first working group on this subject developed two broad principles which have guided the Authority on this issue:

- fully informed consent, free from any inducement and pressure, is fundamental to gamete donation; and,
- the potential for human life inherent in a donation made with the specific intent of producing children should be respected.

The Authority is still considering the implications surrounding the withdrawal of payments for donors and intends to consult before taking any final decisions. If changes are made to the present system, these will not be introduced until after responses to the consultation have been discussed in depth by the Authority, and clinics will be given sufficient time to prepare for such changes.

Safe Cryopreservation of Sperm and Embryos

A working group was created in September 1995 to examine the safe cryopreservation of sperm and embryos following an incident of cross contamination with hepatitis B in the storage of bone marrow. While it is not known what the precise risk of cross contamination is with gametes and embryos, the Authority concluded that the potential risks had to be taken very seriously. The Authority's Fifth Annual Report (1996) stated that the working group hoped shortly to be able to issue guidance. The issues have, however, proved particularly complex, and progress has been hindered by the lack of research in this area.

The working group has therefore recommended to the Authority that consultation should take place with relevant professional organisations such as the British Fertility Society, the Association of Clinical Embryologists, the Royal College of Obstetricians and Gynaecologists and the Royal College of Pathologists. It is expected that a consultation document will be circulated by the beginning of September 1997, and that a final report containing recommendations will be considered by the Authority by May 1998.

Cloning

The 1990 Act prohibits cloning by nuclear replacement and bringing about the creation, keeping or using of an embryo except in accordance with a licence from the Authority.[13] The Authority decided in 1994 that it would not license embryo splitting for treatment purposes or for research where the intention is to increase the number of embryos for replacement (transfer).

In February 1997 the Roslin Institute (Edinburgh) reported the cloning of Dolly the sheep.[14] Their research provoked a public response which focused almost entirely on the possibility of using the Roslin technique for human cloning.

This experiment prompted the House of Commons' Science and Technology Committee to conduct an inquiry into the Roslin experiment. In particular, the Committee wished to explore, "the adequacy of the law relating to cloning and related issues in both animals and humans".

In giving evidence to the Committee, the Authority's Chairman said that much depended on the definition of "embryo" as contained in the 1990 Act. The Authority informed the Committee that it was taking legal advice with the Department of Health on this point.[15]

[13] Section 3 HFE Act 1990.

[14] Nature, volume 385, 27 February, 1997.

[15] Science and Technology Committee, Fifth Report, The Cloning of Animals from Adult Cells, HC 373-I, 18 March 1997.

Review of Written Consent Provisions

a) The Diane Blood Case

Sperm were taken from the late Mr Blood while he was in a coma. He died shortly afterwards without regaining consciousness and thus had no opportunity to give the informed, written consent required by the 1990 Act for storage or use of sperm. The Authority was asked to exercise its discretion to allow the export of the sperm, but refused this request. An application was made to the High Court. The President of the Family Division rejected the application and an appeal against that decision was made to the Court of Appeal.

The Court of Appeal in its ruling confirmed that a person's gametes must not be stored or used in the UK (whether or not for export) without that person's informed written consent. In light of the judgement, the Authority decided to exercise its discretion and allowed the export of Mr Blood's sperm for Mrs Blood's treatment abroad.

b) The Review of Written Consent Provisions

As a consequence of the issues raised in the case, the Government in February 1997 announced that Professor Sheila McLean, Professor of Law and Ethics in Medicine at the University of Glasgow, had agreed to undertake a review for the UK Health Ministers of the written consent requirements for the storage and use of gametes (sperm or eggs) contained in the Human

Fertilisation and Embryology Act 1990[16]. The Authority welcomes this review. A working group of Authority Members chaired by the Authority Chairman has been set up to prepare the Authority's response.

[16]The Review's Terms of Reference are: to review whether – and in which circumstances – explicit consent under the common law to the removal of gametes might be waived; to consider in the light of the above whether changes are required to the Human Fertilisation and Embryology Act 1990 whereby effective consent to storage and use of gametes must always be given in writing; to consider the implications of any changes to the present consent regime in the Human Fertilisation and Embryology Act 1990 for the remainder of that Act including for the operation of the Human Fertilisation and Embryology Authority; and to consider the implications for the above of the judgement given by the Court of Appeal in the case of *R v Human Fertilisation and Embryology Authority ex parte Diane Blood.*

7 Collecting and Providing Data

The Authority has a statutory duty to collect information about licensed treatments and their outcomes in order to provide information to children born as a result of such treatments.

INFORMATION COMMITTEE

John Williams
Chairman

Ruth Chambers

Jane Denton
(until 31 Dec 1996)

Martin Johnson

Rory Nicol

Allan Templeton

Julia Tugendhat

co-opted members:
Claire Brown
Ian Cooke
(until 27 Mar 1997)
Joan Morris
Alison Murdoch
(from 16 June 1996)
Tony Rutherford

Introduction

The Authority maintains a register of information compiled from data provided by licensed clinics. The data collected are also used to monitor the provision of IVF and DI given at clinics.

The Authority is in the process of redeveloping its computer database, and this will continue to be one of its major projects during the coming year. The Authority will also be reviewing its data collection systems and the new IVF, DI and outcome forms introduced last year. One of the Authority's aims is to increase the accuracy and timely return of data forms.

Publishing Data

The HFEA register is a powerful resource for investigating the outcomes of licensed treatments for the benefit of future patients. It holds an unique record of treatments and patient characteristics for the whole of the UK, and is the largest database of its kind in the world. Based on statistical analysis of the register's data, a study co-authored by an Authority Member, the Authority's Statistics Consultant and a member of staff titled, *"Factors that affect outcome of in-vitro fertilisation treatment"*, was published in 1996[17]. This paper drew upon the Authority's records of all IVF treatments carried out since August 1991. Age, duration of infertility, previous pregnancy and previous IVF treatments were identified as the most significant factors affecting outcome.

Subjects currently being explored for possible future publications are the factors that affect the incidence of multiple birth, factors that affect the outcome of treatments employing ICSI and factors that affect the outcome of DI treatments.

[17]Allan Templeton, Joan Morris, Bill Parslow, Lancet, Vol.348, 23 November 1996.

Data Tables in this section

The data tables in this section and in Annex 8 show data collected for treatment cycles that were carried out during the 15 month period from 1 January 1995 to 31 March 1996. The Authority is reporting an additional three months' data in this report in order that data presented in future Annual Reports and Patients' Guides are synchronised. The basic treatment data are shown in tables 1 to 4 on pages 13 and 14. The remaining data tables are in Annex 8 (pages 26-31).

Data tables in Annex 8

Analysis of the tables given in Annex 8 enables the identification of several other interesting trends:

- the stillbirth and neonatal death rate for a triplet pregnancy with one or more of the babies dying is 82.6 per 1000 birth events compared to 8.8 per 1,000 for singleton pregnancies [Table 3];
- there has been a large increase in the number of cycles involving micromanipulation. Excluding cycles which were abandoned prior to egg collection and frozen embryo cycles, there were 1,356 such cycles in 1994 and 5,209 cycles in this period. The live birth rate has also increased in the same period from 14.8% to 19.6% [Table 4];
- the live birth rate for conventional IVF per embryo transfer, excluding frozen embryo transfers, is 19.5% compared to a rate of 21.0% per fresh embryo transfer for cycles in which the embryo was created through micromanipulation [Tables 4, 8 and 9]; and

Clinical pregnancy and live birth rate for IVF (1.1.1985 to 31.3.1996)

Table 1 shows that during the period 1 January 1995 to 31 March 1996, there were a total of 36,994 IVF cycles started in 26,967 patients of which 30,354 reached embryo transfer. There were 6,827 clinical pregnancies (18.5%) and 5,542 live birth events (15.0%). The number of pregnancies where no outcome or incomplete information was received totalled 106 or 1.6% of all pregnancies reported. This table shows the continued yearly increase in IVF treatment carried out in the UK.

TABLE 1
IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES: 1.1.1985 TO 31.3.1996
(for all IVF treatment cycles including frozen embryo replacements, and micromanipulation)

Year	*Number of treatment cycles*	*Clinical Pregnancy Rate per treatment cycle (%)*	*Live Birth Rate per treatment cycle (%)*
1985	4308	11.2	8.6
1986	7043	9.9	8.6
1987	8899	12.5	10.1
1988	10489	12.9	9.1
1989	10413	15.4	11.1
1990	11583	17.3	12.5
1991	6653*	17.8	13.9
1992	18224	16.9	12.7
1993	21823	18.0	14.2
1994	24672	18.0	13.8
1995	29185	18.4	14.9
31/1/1995 to 31/3/96	*36994*	*18.5*	*15.0*

* *Data available for 1 August to 31 December only*

Clinical pregnancy and live birth rate for DI (1.8.1991 to 31.3.1996)

During the period 1 January 1995 to 31 March 1996, 7,136 patients received treatment involving DI or GIFT using donated gametes. Table 2 shows that a total of 21,760 cycles were started which led to 2,385 clinical pregnancies (11.0%) and 1,955 live births (9.0%). The number of clinical pregnancies reported for which no outcome or incomplete information was submitted totalled 57, or 2.4% of clinical pregnancies.

The data from 1995 alone shows that the number of DI cycles started continues to decline, dropping by more than 3,000 in 1995. The number of patients receiving donor insemination during the same period decreased by only 1,000.

TABLE 2
DI CLINICAL PREGNANCY & LIVE BIRTH RATES PER TREATMENT CYCLE 1.8.1991 TO 31.3.1996
(Data includes GIFT using donor gametes and Intra Uterine insemination)
(% are of number of treatment cycles)

Year	*Cycles*	*Clinical Pregnancy Rate (%)*	*Live Birth Rate (%)*
1991*	9262	6.5	4.9
1992	26063	6.7	5.0
1993	24035	7.9	6.5
1994	21180	9.7	7.9
1995	17857	10.6	8.7
1/1/1995 to 31/3/96	*21760*	*11.0*	*9.0*

* *Data only available for 1 August to 31 December*

- the difference in multiple birth rates between stimulated and unstimulated DI. For example, the triplet live birth rate (as a proportion of the total live births) is 2.3% for stimulated DI compared to 0.2% for unstimulated DI [Tables 5 and 6].

Two and three embryo transfer

Analysis of the data held on the Register has provided valuable new information regarding the live birth rate and the relative risk of multiple births in relation to the number of embryos replaced in treatment cycles. Table 3 shows that, in cases where more than four embryos have been created, the replacement of three embryos in many circumstances does not enhance the live birth rate, but merely increases the risk of a multiple birth, particularly of triplets. Research is presently underway to examine this effect in more detail.

TABLE 3
IVF TWO AND THREE EMBRYO TRANSFERS FOR FRESH STIMULATED IVF ONLY

*Number of embryos transferred**	*Number of cycles*	*Live Birth Rate (% of number of cycles)*	*Multiple Birth Rate (% of the number of cycles)*
2	4271	23.4	6.6
3	9497	24.4	9.2

*Where more than four embryos were created

Clinical pregnancy and live birth rate by number of embryos transferred

Tables 4a and 4b compare the pregnancy rates and live birth rates where one, two or three embryos are transferred. These tables do not take into consideration the number of embryos that were created prior to embryo transfer. They indicate that there is a higher live birth rate where three embryos are transferred, but also show that the multiple birth rate (and attendent risk to maternal and infant health) rises from 23.4% for two embryo transfers to 32.9% for three embryo transfers. The table also shows that currently the maximum number of three embryos is replaced in 55% of all treatment cycles.

TABLE 4A
IVF CLINICAL PREGNANCY AND MULTIPLE CLINICAL PREGNANCY BY THE NUMBER OF EMBRYOS TRANSFERRED
(the data includes frozen embryo transfers)

		Number of clinical pregnancies		
Embryos Transferred	*Number of cycles*	*Singleton*	*Twin*	*Triplet or greater*
One	3306	265	10	3
Two	10376	1587	505	5
Three	16672	2930	1163	253*
Total	30354	4782	1678	261

*Includes 6 sets of quads

The total number of clinical pregnancies is less than that stated elsewhere in this section because there were 106 clinical pregnancies reported for which no outcome form was received.

TABLE 4B
IVF CLINICAL PREGNANCY AND MULTIPLE CLINICAL PREGNANCY RATES AND LIVE BIRTH RATE BY THE NUMBER OF EMBRYOS TRANSFERRED
(the data includes frozen embryo transfers)

Embryos Transferred	*Clinical Pregnancy Rate (% of treatment cycles)*	*Live Birth Rate (% of treatment cycles)*	*Multiple Clinical Pregnancies (% of clinical pregnancies)*	*Multiple Birth Rate (% of live birth events)*	*Stillbirth and neonatal deaths (per thousand birth events)*
One	8.4	6.8	4.7	4.0	17.8
Two	20.2	16.8	24.3	23.4	22.4
Three	26.0	21.4	32.6	32.9	22.7

8 Communications

The HFEA offers a comprehensive range of information.

COMMUNICATIONS STEERING GROUP

Diana Brittan
Chairman

Liz Forgan

Stuart Lewis

Brian Lieberman

Angela Mays

Anthony Thiselton

Joan Stringer

The 1990 Act requires the Authority to "publicise the services provided to the public by the Authority or provided in pursuance of licences."[18] In fulfilling this function the HFEA offers a comprehensive range of information.[19] The Authority receives on average 150 requests per week for its publications. In addition, every year the HFEA supplies speakers for national and international conferences and for press, radio and television interviews. We keep the public and media continuously informed about ongoing developments, and new data.

The Patients' Guide to DI and IVF Clinics

The Patient's Guide gives general information about DI and IVF treatments as well as specific information about each licensed clinic. The third edition of the Guide will be published in October 1997.

The HFEA aims to make the Guide as comprehensible and as user friendly as possible. For this reason, the Authority has decided to undertake a thorough review of the Guide's format and design. Therefore the Guide's fourth edition is not expected to be published until autumn 1999.

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, the HFEA's Members, its Executive staff, its Inspectors and other delegates an opportunity to discuss issues of mutual interest and to exchange views and ideas.

The main plenary sessions of the 1996 conference were devoted to two topics: issues of consent; and payment of sperm and egg donors. Smaller workshops were also held on HIV testing and subfertility developments in inspections and licensing and an update on the safety of embryo freezing and storage.

The 1997 Conference is planned for December. The programme will include a special session on the ethical implications of ICSI.

Other Meetings

The Authority recognises the importance of maintaining a continuing dialogue with all those involved in, or concerned about, the area of assisted reproduction. In order to achieve this the Authority is planning a number of meetings including regional meetings with local clinicans and other professionals and interested individuals.

[18] Section 8 HFE Act 1990.

[19] see Annex 9.

Organisations Consulted

The Authority makes a concerted effort to be conscious of, and sensitive to, the views, opinions and comments of others. The HFEA frequently consults both formally and informally. As mentioned in this Report, it will be leading, involved in or responding to a number of consultations during 1997/98.

The list below gives a number of the professional bodies and organisations which the Authority has consulted during the period of this report. The list is not meant to be exhaustive.

Advisory Committee on Genetic Testing

Association of Clinical Embryologists

British Andrology Society

British Fertility Society

British Infertility Counselling Association

British Medical Association

CHILD

Department of Health

DI Network

General Medical Council

Human Genetics Advisory Commission

ISSUE

Multiple Births Foundation

National Egg and Embryo Donation Society

Nuffield Council on Bioethics

Progress Educational Trust

Project Group on Assisted Reproduction

Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

9 Main Issues for the Coming Year

As mentioned previously in this Report, the following have been identified as future areas of discussion for the Authority.

Fifth Edition of the Code of Practice

Assisted reproduction technology makes constant and rapid advances. As with any other field of science or medicine, good practice needs to be regularly reviewed and updated. It is for this reason that the Authority has always said that the Code of Practice should be subject to regular review and discussion. Work on the fifth edition of the Code is planned to start in autumn 1997.

Pre-Implantation Genetic Diagnosis (PGD)

The Authority's Ethics Committee will continue to examine PGD, as explained in section 6 of this Report.

Report on Safe Cryopreservation

The Authority is planning to give further guidance to clinics on safe cryopreservation of gametes and embryos. This is also covered in section 6.

Review of the Level of Fees

The level of fees charged for licences is clearly of great interest to both clinics and to patients. The Authority tries to keep its costs, and consequently the fees it has to charge, to a minimum. The Government determines how much of the Authority's income must be generated by licence fees. The Authority intends shortly to undertake a review of fee levels and fee collection.

Review of the Written Requirements for Consent

The Authority intends to contribute to Professor McLean's review of the 1990 Act's requirement for written consent. As described in section 6, an Authority working party has been created to prepare the Authority's response.

Examination of the Implementation of the Authority's Policy on Non-Payment of Donors

As mentioned in Section 6, a consultation exercise on the implications of implementation is planned.

Review of Patient Data Forms and Collection Process

The Authority is concerned with the number of data forms incorrectly completed by centres. It intends to analyse returned forms in order to identify problems which can then be addressed.

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

CHAIRMAN
Mrs Ruth Deech
Principal,
St Anne's College, Oxford

DEPUTY CHAIRMAN
Diana Brittan*
Member of the Lord Chancellor's Advisory Committee on
Legal Education and Conduct
Magistrate, City of London, Chairman, Rathbone CI
Former Deputy Chairman, Equal Opportunities Commission

MEMBERS

Dr Gulam Bahadur
Clinical Biochemist
Head of Fertility
Laboratories,
UCLMS/UCLH Trust,
London

Professor Martin Johnson
Professor of
Reproductive Sciences,
University of Cambridge

Dr Joan Stringer
Principal and Vice Patron,
Queen Margaret College,
Edinburgh

Professor Ruth Chambers
GP and Professor of
Health Commissioning,
Primary Care
Development Unit,
School of Health,
Staffordshire University

Richard Jones
Legal Consultant

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

Mrs Jane Denton
Nursing Director, The
Multiple Births Foundation,
Queen Charlottes &
Chelsea Hospital,
London

Professor Stuart Lewis
Professor of Psychology
Applied to Medicine
The Queen's University,
Belfast

Professor the Reverend
Canon Anthony Thiselton
Head of the Department
of Theology,
The University
of Nottingham
Canon Theologian of
Leicester Cathedral

Ms Liz Forgan
Broadcaster, journalist and
media consultant

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

Julia Tugendhat
Family Therapist

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

Mrs Angela Mays*
Management Consultant

John Williams
Dean, Faculty of Economic
and Social Studies,
University of Wales,
Aberystwyth

Mr David Greggains
Director,
Gorham Partners Ltd

Dr Anne McLaren
Principal Research Associate,
Wellcome CRC Institute

The Most Reverend
Richard Holloway*
Bishop of Edinburgh

Professor Rory Nicol*
Professor of Child
Psychiatry,
The Greenwood Institute
of Child Health,
University of Leicester

* *Members who will be ending their appointments in 1997.*

ANNEX 2

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

STANDING COMMITTEES

Audit Committee

Julia Tugendhat *(Chairman)*
Gulam Bahadur
David Greggains
John Williams

Code of Practice Committee

Jane Denton *(Chairman)*
Gulam Bahadur
Ruth Chambers
Richard Holloway
Anne McLaren
Rory Nicol
Allan Templeton

Communications Steering Group

Diana Brittan *(Chairman)*
Liz Forgan
Stuart Lewis
Brian Lieberman
Angela Mays
Anthony Thiselton
Joan Stringer

Ethics Committee

Richard Holloway *(Chairman)*
Liz Forgan
Christine Gosden
Stuart Lewis
Anthony Thiselton
Julia Tugendhat
John Williams

Information Committee

John Williams *(Chairman)*
Ruth Chambers
Jane Denton *(until 31 Dec 1996)*
Martin Johnson
Rory Nicol
Allan Templeton
Julia Tugendhat

Co-opted members:
Claire Brown
Ian Cooke *(until 27 March 1997)*
Joan Morris
Alison Murdoch *(from 16 June 1997)*
Tony Rutherford

Licensing and Fees Committee

Diana Brittan *(Chairman)*
Jane Denton
Christine Gosden
Richard Jones
Brian Lieberman
Angela Mays
David Greggains

Organisation and Finance Committee

Ruth Deech *(Chairman)*
Diana Brittan
David Greggains
Richard Jones
Joan Stringer

Working Group on New Developments in Reproductive Technology

Anne McLaren *(Chairman)*
Jane Denton
Christine Gosden
Martin Johnson
Richard Jones
Brian Lieberman
Allan Templeton
Observer: Elaine Gadd

AD HOC COMMITTEES

Working Group on the Effect of Removing Payment from Donors

Martin Johnson *(Chairman)*
Jane Denton
Liz Forgan
Brian Lieberman
Angela Mays

Advisory Group on Safe Cryopreservation

Jane Denton *(Chairman)*

Co-opted members:
Ian Cooke
Karin Dawson
Lynn Fraser
Stephen Hillier *(Chairman until November 1996)*
Stewart Irvine
John Mills *(to November 1996)*
David Pegg
Richard Tedder
Maureen Wood

Advisory Group on ICSI

Co-opted members:
Stephen Hillier *(Chairman)*
Karin Dawson
Ceinwen Gearon
Alan Mc Dermott
Bert Stewart
Steve Troup

Working Group on Requirement for Written Consent

Ruth Deech *(Chairman)*
Liz Forgan
Anne McLaren
Allan Templeton

Co-opted members:
Graham Miles *(Legal Adviser)*

Advisory Working Group on Pre-Implantation Genetic Diagnosis

Allan Templeton *(Chairman)*
Liz Forgan
Christine Gosden
Stuart Lewis
Hillary Harris*
Philip Webb*

* *Members from the Advisory Committee on Genetic Testing.*

THE AUTHORITY'S EXECUTIVE STAFF

Main telephone no: 0171-377 5077

Senior Managers	Job Title	Tel/Ext
Suzanne McCarthy	Chief Executive	202
Linda Heiden	Information & Resources Manager	206
Mark Salmon	Policy & Finance Manager	208
Dr David Thorne	Licensing Manager	215
Administration		
Derek Hodge	Personnel and Facilities Manager	229
Melle Stripp	Office Manager	201
Tony Burkett	Administration Officer	218
Julie Jones	Administration Officer/PA to Suzanne McCarthy	202
Dilpha Patel	Administration Assistant	217
Audit		
Katy Lloyd	Head of Internal Audit	222
Jane Davis	Systems & Data Auditor	212
Communications		
Barney Wyld	Director of Communications	205
Data		
Richard Baranowski	Deputy Information Manager	228
Joanna Thompson	Deputy Information Manager	209
Rob Aitchison	Data Officer	220
Maureen Goodman	Data Officer	231
Patricia Honnor	Data Officer	220
Gaby Jeremiah	Data Officer	220
Sandy Lathleiff	Data Officer	220
Doug Pearce	Data Officer	220
Finance		
David Axworthy	Finance Manager	204
Tony Smith	Accounts Manager	200
Licensing		
Kim Hayes	Inspector Co-ordinator	211
Nan Hume	Inspector Co-ordinator	213
Katy Lloyd	Inspector Co-ordinator	222
(Two further Inspector Co-ordinators to be appointed)		
Kerri Treston	Licence Administrator	216
Policy		
Bea Heales	Policy Manager	207
Derek Hodge	Policy Manager	229
Carol Perkins	Policy Manager	219

ANNEX 4

LIST OF LICENSED CLINICS
(as of 31 July 1997)

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

Berkshire
Belmore Park Health Centre, Reading
Orchid Centre, BUPA Dunedin Hospital, Reading

Buckinghamshire
BMI Chiltern Hospital, Great Missenden

Cambridgeshire
Bourn Hall Clinic, Cambridge
Rosie Maternity Hospital, Cambridge

Cleveland
Hartlepool General Hospital
South Cleveland Hospital, Middlesborough
North Tees General Hospital, Stockton-on-Tees
Cleveland Fertility Centre, Stokesley

Derbyshire
Derby City General Hospital

Devon
Royal Devon and Exeter Hospital, Exeter
Nuffield Hospital, Plymouth

Dorset
Winterbourne Hospital, Dorchester

Durham
Bishop Auckland General Hospital

East Sussex
Esperance Private Hospital, Eastbourne

Essex
Holly House Hospital, Buckhurst Hill
The BUPA Roding Hospital, Ilford
North East London Fertility Services, Ilford

Greater Manchester
Manchester Fertility Services, BUPA Manchester Hospital
Regional IVF & DI Unit, St Mary's Hospital, Manchester
Withington Hospital, Manchester
Salford Royal IVF And Fertility Centre, Hope Hospital, Salford
Billinge Hospital, Wigan

Hampshire
North Hampshire Fertility Centre, North Hampshire Hospital
The Hampshire Clinic, Basingstoke
BUPA Chalybeate Hospital, Southampton
Wessex Fertility Services, Princess Anne Hospital, Southampton

Hertfordshire
Watford General Hospital

Humberside
Princess Royal Hospital, Hull

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

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

London (Central)
The Portland Hospital
Bridge Fertility Centre, London Bridge Hospital
Chelsea & Westminster Hospital
Churchill Clinic
Cromwell Hospital
Dr Louis Hughes
Dr Katz, University College Hospital
Lister Hospital
London Gynaecology and Fertility Centre
Assisted Reproduction and Gynaecology Centre, London Welbeck Hospital
London Womens' Clinic/ Hallam Medical Centre (2)
Reproductive Medicine Unit, Obstetric Hospital, UCH
St Bartholomew's Hospital
Seymour Clnic, St Mary's Hospital
UM&DS - St Thomas' Hospital
Assisted Conception Unit, University College Hospital

London(East)
Homerton Hospital
Multicare International Harbour Exchange
Newham General Hospital

London (North)
Highgate Private Hospital

London (South)

King's College Hospital

London (West)

West Middlesex University Hospital
Wolfson Family Clinic, Hammersmith Hospital

Merseyside

Fazakerley Hospital, Liverpool
Liverpool Women's Hospital
BUPA Murrayfield Hospital, Wirral

Northern Ireland

Royal Maternity Hospital, Belfast

Norfolk

BUPA Hospital, Norwich

Northamptonshire

Three Shires Hospital, Cliftonville

Nottinghamshire

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

Oxfordshire

John Radcliffe Maternity Hospital, Oxford

Scotland-Grampian

University of Aberdeen

Scotland-Lothian

Royal Infirmary of Edinburgh
Western General Hospital, Edinburgh

Scotland-Orkney

Balfour Hospital, Orkney

Scotland-Strathclyde

Monklands and Belshill NHS Trust, Airdrie
BMI Ross Hall Hospital, Glasgow
Glasgow Nuffield Hospital
Glasgow Royal Infirmary

Scotland-Tayside

Ninewells Hospital and Medical School, Dundee

Shropshire

Royal Shrewsbury Hospital

Staffordshire

North Staffordshire Hospital, Stoke on Trent

Surrey

Shirley Oaks Hospital, Shirley
Woking Nuffield Hospital

Tyne and Wear

Royal Victoria Infirmary, Newcastle upon Tyne
Sunderland District General Hospital
Cromwell IVF & Fertility Centre, Washington Hospital
Queen Elizabeth Hospital, Gateshead

Wales (South Glamorgan)

University Hospital of Wales,Cardiff
BUPA Hospital Cardiff

Wales (West Glamorgan)

Neath General Hospital
Cromwell IVF and Fertility Centre, Singleton Hospital, Swansea

West Midlands

Midland Fertility Services, Aldridge
Birmingham Maternity Hospital
BMI Priory Hospital, Birmingham
New Cross Hospital, Wolverhamption
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

North West Wales Fertility Centre, Gywnedd Hospital, Bangor

Cheltenham General Hospital

Danum Lodge Nursing Home, Doncaster

Royal Surrey County Hospital, Guildford

Bridge Centre Cryoservices, London

Queen Charlotte's and Chelsea Hospital, London

Newcastle General Hospital, Newcastle upon Tyne

Nottingham City Hospital

Singleton Hospital, Swansea

Yorkshire Regional Tissue Bank, Wakefield

LIST OF HFEA INSPECTORS

(as of 31 July 1997)

Clinicians

Mr Masoud Afnan
Consultant in Obstetrics & Gynaecology, Senior Lecturer
Director of ACU, Birmingham Maternity Hospital

Professor David Barlow
Professor of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxfordshire

Professor Peter Braude
Chairman, Division of Obstetrics & Gynaecology, UMDS of Guy's & St Thomas' Hospitals, London

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

Mr Chris Chandler
Clinician, Billinge Hospital, Wigan

Dr Ruth Curson
Associate Specialist
Kings College Hospital, London

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

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

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

Mr Richard Kennedy
Consultant Obstetrician & Gynaecologist, Walsgrave Hospital

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

Dr Martin Lees
Consultant in Obstetrics & Gynaecology
Senior Lecturer, Royal Infirmary of Edinburgh NHS Trust

Dr John Mills
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Ninewells Hospital, Dundee

Dr Alison Murdoch
Consultant Obstetrician & Gynaecologist
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Head of Department of Reproductive Medicine,
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Mr Roger Neuberg
Consultant of Obstetrics & Gynaecology,
Director of Infertility Service,
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Mr Anthony Rutherford
Counsultant of Obstetrics & Gynaecology, United Leeds Teaching Hospitals NHS Trust

Mr Robert Sawers
Consultant of Obstetrics & Gynaecology
Porgramme Director, Birmingham & Midland Hospital for Women

Dr Francoise Shenfield
Reproductive Medicine Unit,
University College Medical School

Mr Eric Simons
Medical Director
Cromwell Hospital, London

Dr Alison Taylor
Senior Registrar
Lecturer, St Thomas's Hospital

Dr Sheila Walker
Senior Lecturer
Honorary Conusultant,
University Hospital of Wales

Mr Peter Wardle
Consultant & Senior Lecturer in Obstetrics and Gynaecology
St Michael's Hospital, Bristol

Dr John Waterstone
Senior Registrar
Lewisham Hospital NHS Trust

Dr Christine West
Consultant Obstetrician & Gynaecologist
Royal Infirmary, Edinburgh

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

Scientists

Dr Sue Avery
Principal Scientist
Bourn Hall, Cambridge

Dr Linda Baggott
Lecturer in Biology & 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
Reader in Reproductive Endocrinology, Glasgow Royal Infirmary

Ms Diane Critchlow
Senior Clinical Embryologist, St Mary's Hospital, Manchester

Ms Karin Dawson
Consultant Embryologist, Hammersmith Hospital, London

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

Dr Richard Fleming
Scientist, Glasgow Royal Infirmary

Dr Tom Fleming
Reader, Department of Biology, 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 Henry Leese
Scientist, Department of Biology, University of York

Dr Elizabeth Lenton
Senior Lecturer in Reproductive Endocrinology, Director of Sheffield Fertility Centre

Mr Terry Leonard
Senior Embryologist, Northamptonshire Fertility Services

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

Ms Barbara Ray
Senior Clinical Scientist, Southmead Hospital, Bristol

Dr John Robinson
Scientific Director, Hull IVF Unit

Dr Mary Seller
Reader in Development Genetics, Medical & Molecular Genetics, Guy's Hospital, London

Dr Arasaratnam Srikanthrarajah
Research Embryologist, University of Aberdeen

Dr Bert Stewart
Scientific Director, Midland Fertility Services

Dr Stephen Troup
Senior Clinical Embryologist, Manchester Fertility Services

Reverend Professor Paul Watson
Professor of Reproductive Cryobiology, Royal Veterinary College, London

Dr Maureen Wood
Senior Scientific Officer, MRC Experimental Embryology and Teratology Unit, St George's Hospital Medical School, London

Social and Ethical Inspectors

Mrs Sarah Biggs
Member of Kings Fund Committee on Counselling

Mrs Linda Breeze
Counsellor for National Childbirth Trust and RELATE

Dr Elizabeth Bryan
Medical Director, Multiple Births Foundation, Queen Charlotte's & Chelsea Hospital, London

Ms Jennifer Clifford
Counsellor

Mrs Elizabeth Corrigan
Nursing Director, St Michaels and BUPA Hospital, Bristol

Ms Marilyn Crawshaw
Social Worker

Ms Hilary Everett
Social Worker/Counsellor, St Bartholomew's Hospital, London

Ms 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
Clinical Nurse Specialist, (Infertility), Leeds General Hospital

Dr Jim Monach
Lecturer, SCHARR, University of Sheffield

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

Ms Annette Sayburn
Director of Clinical Services, BMI Portland Hospital, London

Mrs Roz Shaw-Smith
Counselling Psychologist, John Radcliffe Hospital, London

Ms Jennifer Speirs
Director of Family Care, Edinburgh

LIST OF RESEARCH PROJECTS
(as of July 1997)

Centre for Genome Research, University of Edinburgh
Culture of multipotential human embryos

Centres for Assisted Reproduction Ltd (CARE), Park Hospital, Nottinghamshire
Diagnosis of the common aneuploidies in human pre-implantation embryos using fluorescent *in situ* hybridisation (FISH)

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*

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

Kings College Hospital, London
Cytogenetic analysis of human pre-implantation embryos following ICSI

Investigation of the effects of co-culture with the endometrial cells on the viability of human pre-implantation embryos

Newham General Hospital
Effects of angiotensin II on *in vitro* sperm capacitation and egg penetration in the golden hamster

NURTURE, University of Nottingham
Evaluation and use of the hamster egg penetration test

Evaluation on the use of spermatids for achieving conception *in vitro*

Oxford IV Unit
The use of growth factors to improve human embryo cultures for *in vitro* fertilisation

The Portland Hospital, London
The role of a protein from human sperm that triggers cytosolic calcium oscillations in eggs: effects on fertilisation and embryo development

Royal Infirmary of Edinburgh
Cell biology of human spermatozoa.

ICSI: Studies on cellular events following sperm injection

Royal Victoria Infirmary, Newcastle Upon Tyne
Human implantation *in vitro*

South West Regional Cytogenetics Centre, Bristol
To study the effects of cryopreservation on cyto genetic abnormalities in pre-implantation embryos

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

St Thomas' Hospital, London
Improving methods for the biopsy and diagnosis of inherited genetic disease of human pre-implantation embryos

University of Aberdeen
A comparison of human oocyte cryopreservation methods on the outcome of *in vitro* fertilisation

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

University of Warwick
A two part study of human sperm injected into human eggs (in conjunction with Walsgrave Hospital)

University of York
The 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

A two part study of human sperm injected into human eggs (in conjunction with University of Warwick)

LIST OF PEER REVIEWERS

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DATA TABLES

The following data cover the 15 month period (1.1.1995 to 31.3.1996)

IVF data

The tables which follow are based on treatment data from 1 January 1995 to 31 March 1996 and their outcomes. Unless otherwise stated the IVF data include treatments involving micromanipulation, such as ICSI or SUZI, and frozen embryo replacements.

During this period 26,967 patients received IVF treatment. There were a total of 36,994 cycles started, including frozen embryo replacements, of which 30,354 reached embryo transfer. There were 6,827 clinical pregnancies (18.5% of treatments started) which led to 5,542 live birth events (15.0% of treatments started).

TABLE 1
IVF CLINICAL PREGNANCY AND LIVE BIRTH RATE FOR FEMALE CAUSES OF INFERTILITY
(% are of number of treatment cycles)

Factor	*Number of cycles*	*% of all cycles*	*Clinical Pregnancy Rate (%)*	*Live Birth Rate (%)*
Tubal Disease	14667	39.6	16.9	13.3
Endometriosis	3663	9.9	18.6	15.0
Unexplained	15627	42.2	19.0	15.9
Other	5887	15.9	20.6	16.4

The total number of cycles in this table does not equal 36,994 because some patients have more than one cause of infertility.

TABLE 2
IVF LIVE BIRTH RATES BY WOMEN'S AGE

Using own eggs

	Under 25	*25-29*	*30-34*	*35-39*	*40-44*	*45 and over*
Treatment Cycles	536	5617	14137	11646	3175	229
Live Birth Rate *(% per treatment cycle)*	16.4	18.2	17.2	13.0	5.5	2.2

Using donor eggs

	Under 25	*25-29*	*30-34*	*35-39*	*40-44*	*45 and over*
Treatment Cycles	10	112	251	325	384	272
Live Birth Rate *(% per treatment cycle)*	20.0	17.0	21.9	18.5	17.7	16.5

This table excludes treatments using donated embryos

TABLE 3
SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES AFTER IVF OR FROZEN EMBRYO TRANSFERS (for all centres)

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Stillbirths and Neonatal Deaths (per thousand birth events)*
Singleton	4782	3764	727	32	153	77	3775	8.8
Twin	1678	1539	196	10	10	27	2896	46.8
Triplet	255	230	43	24	3	5	619	82.6
Quad	6	5	1	2	0	0	13	–
Totals	6721	5538	967	68	166	109	7303	22.4

NOTES

Twins 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 that stated elsewhere in this section because there were 106 clinical pregnancies reported for which no outcome form was received.

Four live births were reported which are not included in this table as the number of fetal sacs was not recorded.

TABLE 4
TREATMENTS USING MICROMANIPULATION

Clinics	*Patients*	*Number of cycles**	*Number of embryo transfers*	*Clinical Pregnancies*	*Clinical Pregnancy Rate (%)*	*Total Live Births*	*Live Birth Rate (%)*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown*	*Babies Born*	*Stillbirths & Neonatal Deaths (per thousand birth events)*
43	4406	5209	4848	1207	23.2	1022	19.6	182	10	14	13	1362	19.6

*The number of cycles excludes those which were abandoned prior to egg collection

DI data

The data in these tables are for treatments carried out during the period 1 January 1995 to 31 March 1996. The data includes cycles involving GIFT and intrauterine insemination (IUI) using donor gametes.

There were 7,136 patients who received treatment during this period. A total of 21,760 cycles were started which led to 2,385 clinical pregnancies (11.0%) and 1,955 live birth events (9.0%).

TABLE 5
DONOR INSEMINATION DATA (for all centres)

Stimulated DI		**Unstimulated DI**	
Number of Centres	101	Number of Centres	96
Number of Patients	3602	Number of Patients	4563
Number of Treatment Cycles	8965	Number of Treatment Cycles	12795
Total Clinical Pregnancies	1074	Total Clinical Pregnancies	1311
Clinial Pregnancy Rate per Cycle	12.0%	Clinical Pregnancy Rate per Cycle	10.2%
Total Miscarriages	139	Total Miscarriages	163
Total Terminations	11	Total Terminations	8
Total Ectopic Pregnancies	11	Total Ectopic Pregnancies	9
Total Live Births	870	Total Live Births	1085
Live Birth Rate per Cycle	9.7%	Live Birth Rate per Cycle	8.5%
Total Stillbirths and Neonatal Deaths	16	Total Stillbirths and Neonatal Deaths	10

TABLE 6
SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR STIMULATED DI

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Stillbirths and Neonatal Deaths (per thousand birth events)*
Singleton	884	717	125	8	11	14	718	12.6
Twin	141	132	13	1	0	0	253	45.5
Triplet	20	20	0	2	0	0	57	50.0
Quad	2	1	1	0	0	0	4	0
Totals	1047*	870	139	11	11	14	1032	18.4

* 27 clinical pregnancies recorded with no outcome form received

SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR UNSTIMULATED DI

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Stillbirths and Neonatal Deaths (per thousand birth events)*
Singleton	1257	1063	162	7	8	7	1064	9.4
Twin	22	20	1	1	1	0	39	0
Triplet	2	2	0	0	0	0	6	0
Totals	1281*	1085	163	8	9	7	1109	9.2

* 30 Clinical pregnancies recorded with no outcome form received

TABLE 7
DI LIVE BIRTH RATE BY WOMAN'S AGE

	Under 25	*25-29*	*30-34*	*35-39*	*40-44*	*45 and over*
Number of Cycles	951	5120	8799	5408	1378	93
Live Birth Rate *(% per treatment cycle)*	10.7	11.4	9.8	6.8	2.7	2.2

TABLE 8
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES
(all percentages are of the number of treatment cycles)

(a) All centres

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	22171	27484	21805 (79.3%)	5192 (18.9%)	4219 (15.4%)	5621
Donated Sperm	1621	1934	1732 (89.6%)	449 (23.2%)	384 (19.9%)	518
Donated Eggs	91	96	80 (83.3%)	33 (34.4%)	21 (21.9%)	28
Donated Embryos	18	18	17 (94.4%)	5 (27.8%)	4 (22.2%)	8
Totals	23901	29532	23634 (80.0%)	5679 (19.2%)	4628 (15.7%)	6175

(b) Large centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	19385	24218	19333 (79.8%)	4673 (19.3%)	3806 (15.7%)	5049
Donated Sperm	1395	1674	1491 (89.1%)	396 (23.7%)	337 (20.1%)	457
Donated Eggs	81	86	73 (84.9%)	30 (34.9%)	19 (22.1%)	25
Donated Embryos	18	18	17 (94.4%)	5 (27.8%)	4 (22.2%)	8
Totals	20879	25996	20914 (80.8%)	5104 (19.6%)	4166 (16.0%)	5539

(c) Small centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	2786	3266	2472 (75.7%)	519 (15.9%)	413 (12.6%)	572
Donated Sperm	226	260	241 (92.7%)	53 (20.4%)	47 (18.1%)	61
Donated Eggs	10	10	7 (70.0%)	3 (30.0%)	2 (20.0%)	3
Donated Embryos	0	0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0
Totals	3022	3536	2720 (76.9%)	575 (16.3%)	462 (13.1%)	636

* A large centre is one which carries out 200 or more cycles per year, a small centre is one which carries out fewer than 200 cycles per year.

TABLE 9
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES
(all percentages are of the number of treatment cycles)

(a) All centres

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	412	434	83 (19.1%)	13 (3.0%)	8 (1.8%)	9
Donated Sperm	26	31	9 (29.0%)	2 (6.5%)	0 (0.0%)	0
Totals	438	465	92 (19.8%)	15 (3.2%)	8 (1.7%)	9

(b) Large centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	372	394	79 (20.1%)	13 (3.3%)	8 (2.0%)	9
Donated Sperm	21	25	9 (36.0%)	2 (8.0%)	0 (0.0%)	0
Totals	393	419	88 (21.0%)	15 (3.6%)	8 (1.9%)	9

(c) Small centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	40	40	4 (10.0%)	0 (0.0%)	0 (0.0%)	0
Donated Sperm	5	6	0 (0.0%)	0 (0.0%)	0 (0.0%)	0
Totals	45	46	4 (8.7%)	0 (0.0%)	0 (0.0%)	0

* A large centre is one which carries out 200 or more cycles per year, a small centre is one which carries out fewer than 200 cycles per year.

TABLE 10
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES
(all percentages are of the number of treatment cycles)

(a) All centres

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Donated Eggs	826	916	802 (87.6%)	226 (24.7%)	180 (19.7%)	244
Donated Embryos	106	115	99 (86.1%)	32 (27.8%)	27 (23.5%)	34
Totals	932	1031	901 (87.4%)	258 (25.0%)	207 (20.1%)	278

(b) Large centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Donated Eggs	759	841	739 (87.9%)	219 (26.0%)	174 (20.7%)	238
Donated Embryos	79	87	74 (85.1%)	23 (26.4%)	19 (21.8%)	23
Totals	838	928	813 (87.6%)	242 (26.1%)	193 (20.8%)	261

(c) Small centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Donated Eggs	67	75	63 (84.0%)	7 (9.3%)	6 (8.0%)	6
Donated Embryos	27	28	25 (89.3%)	9 (32.1%)	8 (28.6%)	11
Totals	94	103	88 (85.4%)	16 (15.5%)	14 (13.6%)	17

* A large centre is one which carries out 200 or more cycles per year, a small centre is one which carries out fewer than 200 cycles per year.

TABLE 11
RESULTS OF FROZEN EMBRYO TRANSFER CYCLES
(all percentages are of the number of treatment cycles)

(a) All centres

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	4137	5023	4824 (96.0%)	701 (14.0%)	558 (11.1%)	673
Donated Sperm	394	470	450 (95.7%)	85 (18.1%)	71 (15.1%)	90
Donated Eggs	298	342	331 (96.8%)	64 (18.7%)	48 (14.0%)	56
Donated Embryos	110	131	122 (93.1%)	25 (19.1%)	22 (16.8%)	26
Totals	4939	5966	5727 (96.0%)	875 (14.7%)	699 (11.7%)	845

(b) Large centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	3596	4389	4208 (95.9%)	622 (14.2%)	496 (11.3%)	600
Donated Sperm	322	378	362 (95.8%)	73 (19.3%)	60 (15.9%)	77
Donated Eggs	263	296	285 (96.3%)	58 (19.6%)	44 (14.9%)	51
Donated Embryos	103	122	114 (93.4%)	25 (20.5%)	22 (18.0%)	26
Totals	4284	5185	4969 (95.8%)	778 (15.0%)	622 (12.0%)	754

(c) Small centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	541	634	616 (97.2%)	79 (12.5%)	62 (9.8%)	73
Donated Sperm	72	92	88 (95.7%)	12 (13.0%)	11 (12.0%)	13
Donated Eggs	35	46	46 (100.0%)	6 (13.0%)	4 (8.7%)	5
Donated Embryos	7	9	8 (89.0%)	0 (0.0%)	0 (0.0%)	0
Totals	655	781	758 (97.1%)	97 (12.4%)	77 (9.9%)	91

* A large centre is one which carries out 200 or more cycles per year, a small centre is one which carries out fewer than 200 cycles per year.

TABLE 12
IVF CLINICAL PREGNANCY RATES AND LIVE BIRTH RATES BY NUMBER OF PREVIOUS ATTEMPTS (for all centres)
(all percentages are of the number of treatment cycles)

	0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*10+*
Patients Treated	15451	9542	4663	2417	1245	723	396	247	154	107	51	84
Pregnancy Rates per cycle %	19.7	18.4	17.5	17.4	16.0	15.8	13.0	13.5	12.2	15.8	11.3	5.9
Live Birth Rates per cycle %	16.2	14.9	14.4	13.4	12.5	12.4	11.1	9.2	7.9	13.2	11.3	4.2

DI CLINICAL PREGNANCY RATES AND LIVE BIRTH RATES BY NUMBER OF PREVIOUS ATTEMPTS (for all centres)
(all percentages are of the number of treatment cycles)

	0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*10+*
Patients Treated	3083	2830	2513	2057	1734	1500	1236	1062	871	742	615	1108
Pregnancy Rates per cycle%	12.2	11.9	11.2	10.9	9.7	11.0	12.0	10.4	10.8	10.8	9.7	9.6
Live Birth Rates per cycle%	10.3	9.8	9.0	9.0	7.8	9.5	9.8	8.4	8.9	8.4	8.1	7.5

TABLE 13
NUMBER OF BOYS AND GIRLS BORN FOLLOWING IVF AND DI TREATMENTS

	Boys		*Girls*		*Total*
DI	1073	(50.1%)	1068	(49.9%)	2141
IVF	3815	(52.2%)	3492	(47.8%)	7307

TABLE 14
MEAN CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR STIMULATED IVF WITH FRESH EMBRYO TRANSFER

		Pregnancy Rates %			Live Birth Rates %		
	Number of Treatment Cycles	*Per Treatment Cycle (%)*	*Per Egg Collection (%)*	*Per Transfer (%)*	*Per Treatment Cycle (%)*	*Per Egg Collection (%)*	*Per Transfer (%)*
Own Gametes	27484	18.9	20.9	23.8	15.4	17.0	19.3
Donated Sperm	1934	23.2	23.3	25.9	19.9	19.9	22.2
Donated Eggs	96	34.4		41.3	21.9		26.3
Donated Embryos	18	27.8		29.4	22.2		23.5
All	29532	19.2	21.0	24.0	15.7	17.2	19.6

MEAN CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR UNSTIMULATED IVF WITH FRESH EMBRYO TRANSFER CYCLES (for all centres)

		Pregnancy Rates %			Live Birth Rates %		
Collection (%)	*Number of Treatment (%)*	*Per Treatment 4*	*Per Egg Cycles*	*Per Transfer Cycle (%)*	*Per Treatment Collection (%)*	*Per Egg (%)*	*Per Transfer Cycle (%)*
Own Gametes	434	3.0	11.1	15.7	1.8	6.8	9.6
Donated Sperm	31	6.5	15.4	22.2	0.0	0.0	0.0
Donated Eggs	916	24.7		28.2	19.7	–	22.4
Donated Embryos	115	27.8		32.3	23.5	–	27.3
All	1496	18.2	11.5	27.5	14.4	6.2	21.7

MEAN PREGNANCY AND LIVE BIRTH RATES FOR FROZEN EMBRYO TRANSFER CYCLES (all centres)

		Pregnancy Rates %	Live Birth Rates %
	Number of Treatment Cycles	*Per Treatment Cycle (%)*	*Per Treatment Cycle (%)*
Own Gametes	5023	14.0	11.1
Donated Sperm	470	18.1	15.1
Donated Eggs	342	18.7	14.0
Donated Embryos	131	19.1	16.8
All	5966	14.7	11.7

TABLE 15
DEVELOPMENTAL DEFECTS AND SYNDROMES

Chromosomal Syndromes	*Total*	*Fresh IVF*	*Frozen IVF*	*DI*	*Micromanipulation*
Downs' Syndrome	7	4		2	1
Other chromosomal abnormalities	4	2	1	1	

Congenital Abnormalities	*Total*	*Fresh IVF*	*Frozen IVF*	*DI*	*Micromanipulation*
Cleft lip	2	2			
Cleft palate	3	3			
Cleft lip with cleft palate	7	4		3	
Tracheo-oesophageal fistula, oesophageal atresia and stenosis	2			1	1
Atresia and Stenosis of the large intestine, rectum and anal canal	2	2			
Anomalies of the alimentary system	2	2			
Cardiac murmurs	7	4		2	1
Ventricular septal defect	2	1	1		
Other congenital cardiac anomalies	8	7		1	
Other anomalies of the cardiac septa	2	1			
Patent Ductus	2	2			
Anomalies of the cardiovascular system	2	1			1
Hypospadias, Epispadias	7	2	2	2	1
Anomalies of the male external genitalia	1	1			
Renal anomalies	7	6			1
Polydactyly or syndactyly	5		2	1	2
Reduction deformities of the limbs	1				1
Talipes	14	11		1	2
Congenital dislocation of the hip	4	3		1	
Other anomalies of the limbs or limb girdle	1	1			
Anomalies of the nose, face and skull	1	1			
Anomalies of the abdominal wall	3	1	1		1
Ear anomalies	2		1	1	
Spina bifida	2	1		1	
Exomphalos	2	1	1		
Anomalies of the tongue, branchial cleft and auricular sinus	1	1			
TOTAL NUMBER OF CHILDREN BORN	91	55	8	16	12
As a percentage of total numbers of babies born as a result of each type of licensed treatment	0.8	0.9	0.9	0.7	0.9

NB Some children were born with more than one chromosomal or congenital abnormality

INFORMATION AVAILABLE TO THE PUBLIC

The HFEA provides information which is available to prospective patients, interested organisations and the general public. If you require any of the following information please contact the HFEA.

Annual Reports: 1992-97

Patients' Guide to DI and IVF Clinics *(1997 Edition)*
(Comprehensive information about the treatments of, and outcomes for, each licensed centre)

List of all licensed clinics

List of sperm donor recruitment centres

List of egg donation centres

List of ICSI centres

Code of Practice *(Fourth Edition)*

Code of Practice on Enforcement

Information Leaflets:

- Consent to the Use and Storage of Gametes and Embryos
- Donor Insemination
- Egg Donation
- Embryo Storage
- *In Vitro* Fertilisation
- The Role of the HFEA
- Sperm and Egg Donors and the Law
- Treatment Clinics: Questions to Ask.

Videos (on *In Vitro* Fertilisation and Donor Insemination; supplied for education purposes only)

Consultation documents

- Sex selection *(published 1993)*
- Donated Ovarian Tissue in Embryo Research and Assisted Conception (consultation document and report available) *(published 1994)*
- The publication of Centres' Success Rates for *in vitro* Fertilisation and Donor Insemination *(published 1995)*

Financial Report 1995-1996

FOREWORD

a) Overall Results

The operating deficit for the year amounted to £22,738.

b) Expenditure

The Authority is committed to carrying out its duties to the highest standards, whilst ensuring the costs of its work are kept to a minimum. Expenditure is constantly monitored and performance indicators across all aspects of the Authority's business will continue to be developed. Ways of reducing costs, wherever possible, are always being considered, and, wherever possible, introduced.

c) Licence Fees

In the year, the Authority's financial objective was to raise 70% of its income from licence fees. This level is set for 1996/97 and for 1997/98. The actual percentage raised through fees in 1995/96 was 70.7%.

The fee structure is made up of an initial and an additional fee. Each centre is required to pay an initial fee on application. This fee remains at £100 for a research or storage licence and £250 for a treatment 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 cycles held on the register are identified and IVF cycles are charged at £30 per cycle for cycles taking place before 1 September 1994 and £40 for those carried out after this date. Similarly, DI cycles carried out before 1 September 1994 incur a charge of £7 and after this date £10 per cycle. From this total is subtracted the additional fees previously invoiced to give the current additional fee. IVF cycles abandoned prior to eggs being mixed with sperm or embryo thawing are not included in the calculation if they were performed after 1 September 1994.

The Authority will review both the structure of fee collection and the level of fees when the new Treasury targets for 1998/99 onwards have been issued. Charges for treatment cycles will also continue to be reviewed on a regular basis in order to ensure that the Authority's financial targets are met.

STATEMENT OF AUTHORITY'S AND CHIEF EXECUTIVE 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 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.

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

I certify that I have audited the financial statements on pages 36 to 41 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 page 39.

As described on page 34 the Authority and Chief Executive are responsible for the preparation of the financial statements and for ensuring the regularity of financial transactions. It is my responsibility to form an independent opinion, based on my audit, on those statements and on the regularity of the financial transactions included in them and to report my opinion to you.

I conducted my audit in accordance with Auditing Standards issued by the Audit 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.

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 1996 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;
- 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

16 October 1996

National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31 MARCH 1996

	NOTES	£	1995/96 £	1994/95 £
Gross Income				
Government grants	2		329,130	459,078
Income from licensing			1,004,158	884,289
Income from other sources			1,177	8,686
			1,334,465	1,352,053
Transfer from reserves			51,856	49,177
			1,386,321	1,401,230
Expenditure				
Staff costs	3	586,358		597,365
Depreciation	5	51,856		49,177
Other operating charges	4	752,345		676,987
Notional interest	9	18,500		0
			1,409,059	1,323,529
(Deficit)/surplus for the financial year	6		(22,738)	77,701
Appropriations	7		0	(7,732)
			(22,738)	69,969
Retained surplus/(deficit) brought forward			48,827	(21,142)
Retained surplus carried forward			26,089	48,827

STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES FOR THE YEAR ENDED 31 MARCH 1996

	1995/96 £	1994/95 £
(Deficit)/surplus for financial year	(22,738)	77,701
Revaluation of fixed assets	3,654	4,630
Total recognised (losses)/gains for the year	(19,084)	82,331

The notes on pages 39 to 41 form part of these accounts

BALANCE SHEET AS AT 31 MARCH 1996

	NOTES	£	1995/96 £	1994/95 £
Assets employed				
Fixed assets				
Tangible assets	5		121,191	135,625
Current assets				
Debtors	8	244,113		201,616
Cash at bank and in hand		32,138		41,720
		276,251		243,336
Creditors: amounts falling due within one year	10	(74,848)		(82,180)
Net current assets			201,403	161,156
Total assets less current liabilities			322,594	296,781
Financed by				
Accrued and deferred income				
Deferred government grant	13		112,908	130,995
Capital and reserves				
Income and expenditure account			26,089	48,827
Revaluation reserve			8,284	4,630
Notional superannual costs			156,813	112,329
Notional interest costs			18,500	–
			322,594	296,781

Suzanne McCarthy
Chief Executive
9 October 1996

The notes to the accounts (pages 39 and 41) form part of these accounts.

CASH FLOW STATEMENT FOR THE YEAR ENDED 31 MARCH 1996

	NOTES	£	1995/96 £	£	1994/95 £
Net cash outflow from operating activities	17		(28,083)		(2,770)
Investing activities:					
Purchase of tangible fixed assets	5	(33,769)		(66,660)	
Net cash outflow from investing activities			(33,769)		(66,660)
Net cash outflow before financing			(61,852)		(69,430)
Financing:					
Receipts of Government grants for fixed assets	14	21,898		41,898	
Transfer from revenue grant	13	11,871		24,762	
Net cash inflow from financing			33,769		66,660
Decrease in cash and cash equivalents			(28,083)		(2,770)

Note 17 (page 41) forms part of the Cash Flow Statement

Notes to the Accounts

1 Accounting policies

a) Accounting convention

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. The accounts are also consistent, where appropriate, with the guidance given in the Statements of Recommended Practice.

(b) Tangible fixed assets

All tangible fixed assets over £1,000 are capitalised and some items are capitalised in groups where the individual cost of each item is £250 or more. Individual items not falling into either of these categories are charged to the Income and Expenditure Account in the year of purchase. Assets are revalued annually using the Central Statistical Office Index of Data Processing and Office Equipment for computers and office equipment and appropriate Health Services Prices indices for other assets.

(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. Depreciation charges are made from the month in which the invoice for the item is received. Expected useful lives are as follows:

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

(d) 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.

(e) Government grants

Government grants receivable for revenue expenditure are credited to income in the year to which they relate.

Government grants receivable for capital expenditure are credited to a Deferred Government Grant Reserve and released to the Income and Expenditure Account in equal annual instalments over the expected useful lives of the relevant assets purchased.

(f) Notional charges

In order to give full costs, the accounts include a notional charge for superannuation on HFEA employees' salaries. This notional charge is calculated at 13.5% of basic salaries and is included under Staff Costs.

2 Gross Income

Revenue grant received	1995/96 £	1994/95 £
Department of Health Class XII. Vote 2. Subhead H(1)	1,101,762	1,124,732
Less: Licence fees retained, payable to the Department of Health	1,004,158	884,289
	97,604	240.443
Scottish Office. Department of Health.. Class XIV, Vote 10, Subhead K6(4)	136,740	136,740
Welsh Office Class XV, Vote 5, Subhead F10	68,370	68,370
Department of Health and Social Services. Northern Ireland Vote 3, Subhead F7.10	38,287	38,287
	341,001	483,840
Less transfer to Deferred Government Grant Reserve (Note 13)	11,871	24,762
	329,130	459,078

3 Staff Costs

	1995/96 £	1994/95 £
(a) Remuneration of Authority Members		
Fees paid to members including Chairman	67,716	62,686
Social security costs	1,815	2,302
	69,531	64,988
(b) Salaries – HFEA staff	334,226	327,191
Salaries-seconded staff	89,067	106,473
Social security costs	36,602	36,789
Superannuation contributions	54,592	60,665
Agency staff	2,340	17,626
	516,827	548,744

The Superannuation contributions include a notional charge of £44,484 for Authority employees (Note 12)

(c) The average number of staff employed, including secondees, during the year was made up as follows:

	1995/96 No.	1994/95 No.
Management	4	4
Administrative	22	20
	26	24

(d) The remuneration of the Chief Executive for the year was £58,720. The Chief Executive is an ordinary member of the Principal Civil Service Pension Scheme.

The remuneration of the Deputy Chief Executive for the year was £32,978. The Deputy Chief Executive is an ordinary member of the Principal Civil Service Pension Scheme.

No other employee received remuneration of more than £30,000.

4 Other Operating Charges

	1995/96	1994/95
Accommodation	214,115	208,724
Travel and subsistence – employees	4,350	7,472
Travel and subsistence – members	36,246	29,169
Travel and subsistence – inspectors	28,986	47,018
Attendance fees – inspectors	22,282	27,749
Professional and administrative fees	114,755	119,994
Audit fees	10,000	8,029
Register of Information	56,196	35,381
Stationery and printing	102,491	92,864
Photocopying charges	19,757	7,281
Telephones and postage	29,531	30,847
Communications	2,556	3,673
Training and staff development	28,368	20,049
Recruitment and advertising	42,705	7,540
Conferences and meeting expenses	19,817	17,327
Library and reading materials	6,270	4,857
Sundry office equipment	12,523	8,447
Miscellaneous	1,397	203
Bad debts	–	363
Total	752,345	676,987

5 Tangible Fixed Assets as at 31 March 1996

	Computer equipment	Office equipment	Furniture & fittings	Installations	Totals
	£	£	£	£	£
Cost					
As at 1 April 1995	101,193	23,593	84,885	49,267	258,938
Additions	29,758	2,921	–	1,090	33,769
Disposals	(1,696)	(3,404)	–	–	(5,100)
Revaluation	(4,039)	(820)	6,048	3,512	4,701
As at 31 March 1996	**125,216**	**22,290**	**90,933**	**53,869**	**292,308**
Depreciation					
As at 1 April 1995	59,751	10,982	47,713	4,868	123,314
Charge for the year	18,589	5,288	22,592	5,387	51,856
Disposals	(1,696)	(3,404)	–	–	(5,100)
Revaluation	(2,380)	(363)	3,443	347	1,047
As at 31 March 1996	**74,264**	**12,503**	**73,748**	**10,602**	**171,117**
Net Book Value (NBV)					
At 31 March 1996	50,952	9,787	17,185	43,267	121,191
At 31 March 1995	41,442	12,611	37,172	44,399	135,624
Increase/(Decrease) in NBV	**9,510**	**(2,824)**	**(19,987)**	**(1,132)**	**(14.433)**

6 Operating deficit

The activities of the Authority have contributed to the operating deficit as follows:

	Licensing 1995/96	1994/95	Others 1995/96	1994/95	Total 1995/96	1994/95
	£	£	£	£	£	£
Income						
Government grant	–	–	329,130	459,078	329,130	459,078
Licence fees	1,004,158	884,289	–	–	1,004,158	884,289
Other	–	–	1,177	8,686	1,177	8,686
Transfer from reserves	25,928	24,589	25,928	24,588	51,856	49,177
Total	1,030,086	908,878	356,235	492,352	1,386,321	1,401,230
Expenditure						
Staff costs	(242,645)	(296,326)	(343,713)	(301,039)	(586,358)	(597,365)
Depreciation	(25,928)	(24,589)	(25,928)	(24,588)	(51,856)	(49,177)
Other charges	(402,747)	(411,621)	(349,598)	(265,366)	(752,345)	(676,987)
Notional interest	(9,250)	–	(9,250)	–	(18,500)	–
Total	(680,570)	(732,536)	(728,489)	(590,993)	(1,409,059)	(1,323,529)
Surplus/(deficit)	349,516	176,342	(372,254)	(98,641)	(22,738)	77,701

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 Appropriations

There were no pension transfer receipts payable to the Consolidated Fund via the Department of Health.

8 Debtors

	1995/96	1994/95
Debtors (Licence fees)	123,877	112,118
Other debtors	4,447	1,314
Prepayments	115,789	88,184
	244,113	201,616

9 Interest on capital employed

In accordance with Treasury guidance notional interest at 6% of the average capital employed has been charged in the Income & Expenditure Account, amounting to £18,500. This is the first year in which this charge has been made.

10 Creditors: Amounts falling due within one year

	1995/96	1994/95
	£	£
Trade creditors	–	2,490
Other taxes and social security	41,725	39,681
Accruals	33,123	40,009
	74,848	82,180

11 Reserves

	Notional Superannuation
Balance at 1 April 1995	112,329
Increase in year	44,484
Balance at 31 March 1996	156,813

12 Pension arrangements

Seconded staff belong to the Principal Civil Service Pension Scheme. For 1995/96 contributions of £12,210 were made to the Paymaster General at rates determined from time to time by the Government Actuary and advised by the Treasury. For 1995/96 these rates were 13.5% for non-industrial staff. For its own employees, the Authority operates an analogous non-contributory scheme, to which the conditions of the Superannuation Act 1965 and subsequent amendments apply. In 1995/96 a notional charge was made and provided for at a rate of 13.5%.

13 Deferred Government grant, capital and reserves

	Deferred Government Grant £	Income and Expenditure £	Revaluation Reserve £
Balance brought forward	130,995	48,827	4,630
Revaluation of fixed assets	0	0	3,654
1995/96 capital grant	21,898	0	0
Transfer from revenue grant	11,871	0	0
Transfer to Income & Expenditure	(51,856)	0	0
Deficit for the year	0	(22,738)	0
Balance carried forward	112,908	26,089	8,284

14 Government grants for capital

	1995/96 £	1994/95 £
Department of Health		
Class XII, Vote 2, Subhead H(7) (Note 13)	21,898	41,898
Transfer from Revenue Grant	11,871	24,762
	33,769	66,660

15 Capital commitments

At the balance sheet date the Authority had capital commitments amounting to £4,303.

16 Contingent liabilities

At the balance sheet date the Authority had no contingent liabilities.

17 Notes to the Cash Flow Statement

	1995/96 £	1994/95 £
1 Reconciliation of operating deficit to net cash outflow from operating activities		
Operating (Deficit)/surplus	(22,738)	77,701
Depreciation charges	51,856	49,177
Increase in debtors	(42, 497)	(94,227)
Decrease in creditors	(7,332)	(23,791)
Increase in reserves	44,484	45,279
Transfer from reserves	(51,856)	(49,177)
Appropriations payable to the Consolidated Fund	0	(7,732)
Net cash outflow from operating activities	(28,083)	(2,770)
2 Analysis of changes in cash and cash equivalents during the year		
Balance at 1 April 1995	41,720	44,490
Net cash outflow	(9,582)	(2,770)
Balance at 31 March 1996	32,138	41,720
3 Analysis of balances of cash and cash equivalents as shown in the Balance Sheet		
Cash at bank and in hand at 1 April 1995	41,720	44,490
Balance at 31 March 1996	32,138	41,720
Change in Year	(9,582)	(2,770)

Appendix to the Account

ACCOUNTS DIRECTION

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 direction:

1 In this direction, unless the context otherwise requires – "the Act" means the Human Fertilisation and Embryology Act 1990; "the Authority" means the Human Fertilisation and Embryology Authority.

Form of Accounts

2 The statement of accounts which it is the duty of the Authority to prepare in respect of the financial year ended 31 March 1996 shall be as set out in the following paragraph and Schedule:

Accounts of the Authority

3 The statement of accounts of the Authority shall comprise;

(a) a foreword;

(b) an income and expenditure account;

(c) a balance sheet;

(d) a cash flow statement;

(e) a statement of total recognised gains and losses;

(f) such notes as may be necessary for the purposes referred to in paragraph 4 below.

4 The statement of accounts shall give a true and fair view of the income and expenditure and cash flow for the year and the state of affairs as at the end of the financial year. subject to the foregoing requirement, the statement of accounts shall also, without limiting the information given and as described in the Schedule, meet:

(a) the accounting and disclosure requirements of the Companies Act. The disclosure exemptions permitted by the Companies Act will not apply unless specifically authorised by the Secretary of State with the approval of the Treasury;

(b) best commercial accounting practice including accounting standards issued or adopted by the Accounting Standards Board;

(c) all relevant guidance given in "*Government Accounting*" and "Trading Accounts: A Guide for Government Departments and Non-Departmental Public Bodies";

(d) any additional disclosure requirements contained in "The Fees and Charges Guide" in particular those relating to the need for appropriate segmental information for different services provided;

(e) any disclosure and accounting requirements which the Secretary of State or Treasury may issue from time to time;

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

5 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, if any, valued at the lower of cost, or current replacement cost where materially different, and net realisable value.

6 This accounts direction supersedes that dated March 1992.

Date 26 April 1996

Signed by the authority of the Secretary of State for Health

JM Brownlee
Branch Head (RM&F Division)
Department of Health

SCHEDULE

Foreword

1 The foreword shall include a statement that the account had been prepared in accordance with a direction given by the Secretary of State.

2 The foreword shall describe the statutory background and main functions of the Authority and shall contain the information required by the Companies Act to be disclosed in the Directors' Report, to the extent that such requirements are appropriate to the Authority.

3 The foreword shall be dated and signed by the Chief Executive of the Authority.

Income and Expenditure Sheet

4 The income and expenditure account and balance sheet shall follow the prescribed format shown in Annex C to the "Trading Accounts" booklet, modified as appropriate and shall meet the requirements of formats 2 and 1 respectively prescribed in Schedule 4 to the Companies Act, to the extent that such requirements are appropriate to the Authority.

5 Although the Authority prepares its accounts under the modified historical cost convention, it is exempt from providing the additional information required by paragraph 33 (3) of Schedule 4 to the Companies Act.

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

Cash Flow Statement

7 The recommendations of Financial Reporting Standard No.1 shall be followed in the preparation of the cash flow statement.

Statement of Total Recognised Gains and Losses

8 The recommendations of Financial Reporting Standard No3 shall be followed in the preparation of the statement of total recognised gains and losses (with the exception of the requirement contained in FRS 3 for the inclusion of a note showing historical of profits and losses).

Notes to the Accounts

9 The notes to the accounts shall, inter alia, include details of the accounting policies adopted.

10 Notes providing further explanations of figures in the accounts shall be made where it is considered appropriate for a proper understanding of the accounts.

11 The accounts direction shall be reproduced as an appendix to the accounts.

GLOSSARY OF TERMS

Autosomal
Pertaining to any chromosome that occurs in the nucleus, except for the sex chromosomes.

Chromosome
Small bodies within the nucleus of every cell in the body. They contain the genes.

Clinical pregnancy
Ultrasound evidence of a fetal heart.

Clinical pregnancy rate
This is calculated as a proportion of pregnancies for every 100 treatment cycles commenced.

Congenital abnormalities
Deformities or diseases which are either present at birth or show themselves soon after birth.

Cytoplasm
The material between the nucleus and the cell surface.

Cryopreservation
The freezing of oocytes, spermatozoa or embryos and their storage in liquid nitrogen.

Cystic fibrosis
A disorder of the mucus-secreting glands of the lungs, the pancreas, the mouth and the gastro-intestinal tract. The commonest serious genetic disease in Caucasian children.

Directions
The Act allows the Authority to impose additional conditions on licensed activities. These Directions cover areas where primary legislation would be inappropriate because of the need for flexibility. Directions can be applied to an individual clinic or generally.

Donor insemination (DI)
The insemination into a woman of donor sperm (at the cervical opening or into the cervical canal).

Embryo
A fertilised egg up to eight weeks of development. At two weeks it is approximately 1-1.5mm in diameter.

Embryo transfer
The transfer of one or more embryos to the uterus.

Embryologist
A scientist who creates, cultures and studies embryos in a clinical or research laboratory.

Female factor
This term covers any reason why a woman is infertile, such as ovulation failure or damage to the fallopian tubes.

Gamete
The male sperm or the female egg.

GIFT
Gamete Intra-fallopian Transfer. Sperm and a maximum of three eggs are mixed together and transferred to one or both of a woman's fallopian tubes. GIFT is a fertility treatment only licensed by the Authority if donor gametes are used.

Hepatitis
Refers to infection with one of the hepatitis viruses which causes acute or chronic inflammation of the liver cells.

Intra Cytoplasmic Sperm Injection (ICSI)
A micromanipulation technique. A variation of IVF treatment where a single sperm is injected into the inner cellular structure of the egg. This technique is used for couples in which the male partner has severely impaired or few sperm.

Intrauterine insemination (IUI)
The insemination of specially prepared sperm through the cervical canal into the uterine cavity.

***In vitro* fertilisation (IVF)**
Sperm and eggs are collected and put together to achieve fertilisation outside the body. Up to three of the resulting embryos can be transferred into a woman's uterus.

Live birth
The delivery of one or more babies from a pregnancy.

Live birth rate
This is calculated as a proportion of live births for every 100 treatment cycles commenced.

Male factor
This term covers any reason why the male partner's sperm may be less effective or incapable of fertilisation, including the absence of viable sperm and a failed reversal of a vasectomy.

Micromanipulation
This term covers any technique used in IVF to bypass the zona pellucida (protein shell) which surrounds the egg, as this frequently prevents sperm which have poor motility or morphology from penetrating and fertilising the egg.

Miscarriage
Spontaneous complete loss of a pregnancy before 24 weeks.

Multiple birth
Birth of more than one baby from a pregnancy. Such an event is counted as a single live birth outcome for the pregnancy, irrespective of the number of babies.

Multiple birth rate
This rate is calculated as a proportion of all births.

Muscular dystrophy
A hereditary condition where muscles slowly waste away.

Oocyte
Another name for an egg.

Neonatal death
The death of a baby within 27 complete days of delivery.

Pre-Implantation genetic diagnosis
After IVF, one or two cells are removed from embryos *in vitro* and tested to detect their sex or genetic makeup of the embryo.

Primitive streak
This develops in an embryo by day 14 when the cells which form the fetus separate from those which form the placenta and umbilical cord.

Spermatid
An immature sperm cell.

Still Birth
The birth of a dead infant.

Stimulated cycle
A treatment cycle in which the woman's ovaries are stimulated with superovulatory drugs to produce more than one egg.

Sub zonal insemination (SUZI)
A micromanipulation technique. A variation of IVF treatment where a single sperm is deposited just beneath the zona pellucida (protein shell). This technique is aimed at patients who have sperm which fail to penetrate the zona.

Transport (or Satellite) IVF
An arrangement whereby IVF is carried out at a primary centre (HFEA licensed) but other parts of the treatment (eg ovulation induction or egg retrieval) are performed at a secondary centre (not necessarily HFEA licensed). The embryology and embryo transfer takes place at the primary centre.

Treatment cycle
a) IVF with fresh embryos: a cycle begins with the administration of drugs for the purpose of superovulation, or, if no drugs are used, with the attempt to collect eggs.

b) IVF with frozen-thawed embryos: a cycle begins with the removal of the stored embryos in order to be thawed and then transferred.

For DI a treatment cycle begins when the first insemination with donor sperm takes place.

Unstimulated ('natural')
No superovulatory drugs were given to stimulate the cycle.