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HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Human Fertilisation and Embryology Authority

SEVENTH

ANNUAL REPORT & ACCOUNTS

1998


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This report covers the year beginning 1 November 1996 with a forward look for the year beginning 1 November 1997.

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The Human Fertilisation and Embryology Authority

THE HFEA'S ROLE

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

In 1996 the HFEA was the subject of a Quinquennial Review[1]. The Review concluded that the case for an independent, statutory body doing the job performed by the HFEA remained valid, and that there was no other body which might perform the functions of the HFEA more cost effectively.

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

The HFEA's other statutory functions are:

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

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1 *First Quinquennial Review of the Human Fertilisation and Embryology Authority; Report to UK Health Ministers* by Mr M Lillywhite, July 1996. It is a requirement that every executive Non-Departmental Public Body is reviewed at five year intervals.

Underlying all its activities is the HFEA's determination to safeguard all relevant interests – patients, children, doctors and scientists, the wider public, and future generations. Its objectives are to ensure that both treatment and research are undertaken with the utmost respect and responsibility.

THE HFEA'S MEMBERSHIP AND ITS EXECUTIVE

The HFEA's 21 Members[2] are appointed by UK Health Ministers in accordance with the guidance from the Commissioner for Public Appointments (Nolan guidelines). They determine all of the HFEA's policies and scrutinise treatment and research licence applications. Members are not appointed as representatives of different groups, but bring to the HFEA a broad range of specialisms, for example medical, scientific, social, legal, managerial, religious and philosophical. Some Members have personal experience of infertility problems. In order that a perspective can be maintained which is independent of the medical-scientific view, the HFE Act requires that the Chairman, Deputy Chairman and at least half of the HFEA's Membership are neither doctors nor scientists involved in human embryo research or providing infertility treatment.

The HFEA has an Executive[3] which is responsible for implementing the HFEA's policy and licensing decisions and conducting the HFEA's day-to-day activities.

THE CODE OF PRACTICE ON ENFORCEMENT

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

2 A list of Members is at Annex 1. Committee and Working Group membership is at Annex 2.

3 A list of Executive Staff is at Annex 3.

Chairman's Letter

On the twentieth anniversary of Steptoe and Edwards' first IVF success, society continues to be confronted with complex ethical and social questions presented by assisted conception techniques. The fact that legislation and a regulatory structure for the field were not implemented until after Louise Brown's thirteenth birthday perhaps illustrates how contentious these issues were and are.

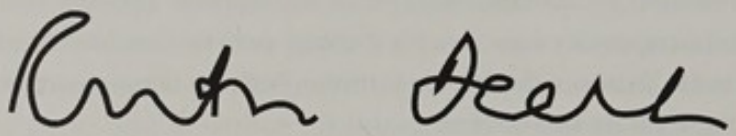
30,000 IVF babies later, many challenges still confront us. The HFEA exists to safeguard, protect and reassure patients, professionals and the public about licensed infertility treatments and human embryo research. Despite concerns on issues as varied as cloning, preimplantation genetic diagnosis and fertility treatment for older and single women, the UK's regulatory structure enables society's anxieties to be considered and reflected in new guidance and policy.

The HFEA continues to monitor all licensed treatment centres and to inspect them annually, requiring and helping all centres to achieve, and adhere to, the highest standards in our Code of Practice. We can, and do, take action if we are not satisfied. We provide detailed advice and information to people treading their way through the maze of clinics and treatments. We remain one of the few statutory bodies of our kind in the world, and regularly attract official visitors from other countries interested in the UK's experience.

The HFEA's policy of public consultation has earned us respect and approval, if not always agreement, in most quarters. We have published consultations on cloning (working with the Human Genetics Advisory Commission), the implementation of the withdrawal of payments for donors, the safe cryopreservation of gametes and embryos, and our Patient's Guide. We are working with the Advisory Committee on Genetic Testing on a forthcoming consultation document on preimplantation genetic diagnosis.

I am extremely grateful to all of the HFEA Members and staff for coping with the ever-increasing workload. I would particularly like to pay tribute to those Members who have left the Authority since the last Annual report, and thank them for their years of service: Diana Brittan, Richard Holloway, Angela Mays and Rory Nicol. I am sure that their successors will carry on their fine work.

We continue to work closely with the Department of Health, as well as with the British Fertility Society, the Royal College of Obstetricians and Gynaecologists, the patient groups and many other relevant organisations. I would like to thank all of them for working with us so constructively in this most sensitive of areas, and for enabling us to perform our very public role as effectively as possible.



Ruth Deech
Chairman

Licensing and Audit of Licensed Clinics

1

INTRODUCTION

Every clinic in the UK which offers IVF or DI treatment, the storage of gametes or embryos or which carries out human embryo research is required by law to be licensed by the HFEA. Not only does the licensing process ensure that proper standards are maintained, but it also assists in informing the HFEA about current and developing practices. As such it is a useful mechanism for gathering and disseminating information and thereby helps raise standards of practice. As of 30 September 1998 there were 114 clinics licensed to carry out various activities as shown in Table 1[4].

Table 1

HFEA licensed clinics

IVF and DI	72
IVF only	1
DI only	31
Storage of sperm only	8
Research licences only	2
Total	**114**

THE LICENSING AND INSPECTION PROCESS

All licensing decisions are made by HFEA Licence Committees. Each committee is composed of at least three HFEA Members who determine the type of inspection required and whether a licence should be granted, suspended or revoked. If a licence is granted, conditions may be attached.

During 1997–8 the HFEA has continued to modify its licensing system to make it more efficient and cost effective. A three year licensing cycle for each centre was introduced consisting 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. In addition, there has been an increased use of shortened applications for licence renewals during 1997/8. This recognises that a centre may not have altered radically since its licence was last renewed. During 1998/99 the HFEA will be considering how it might be able further to refine its inspections and licensing system in order to ensure that its resources are best directed.

4 A list of licensed clinics is at Annex 4.

The HFEA currently employs 68 part-time inspectors[5] who assist the HFEA in inspecting clinics. At full inspections, the inspection team will normally consist of a clinician, a scientist, and a person who may have a background in another field such as counselling, as well as a member of the HFEA's Executive staff. One of the team will be an HFEA Member. Where a focussed inspection is scheduled, a License Committee will determine the particular focus as well as the composition of the inspection team.

BREACHES AND ENFORCEMENT

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

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

THE AUDIT PROGRAMME OF LICENSED CLINICS' DATA

The HFEA's five year Audit Programme of clinics' data began on 1st October 1996. Using audit as a management tool, the HFEA is committed to monitoring and improving the standard of the data held on its information register. Further, the audit programme enables the HFEA to meet the National Audit Office's requirement for assurance regarding the collection of licence fee income and provides the HFEA with assurance regarding the quality of the data it receives from clinics. Feedback is given after every audit including a formal audit report to which clinics may respond. The report is then considered by a Licence Committee. Approximately 40 audits will have been carried out by 1 October 1998.

5 A list of HFEA Inspectors is at Annex 5.

The Code of Practice

2

INTRODUCTION

The HFE Act[6] requires the HFEA to produce a Code of Practice to guide clinics on the standards they should establish in carrying out their licensed activities. The Code provides part of the framework for the HFEA's monitoring activities. It includes guidance on: welfare of the child, clinics' staff and facilities; the assessment of donors; what information and counselling should be offered; legal requirements for consent; and the storage, handling and use of gametes and embryos.

The Code is reviewed regularly and updated in the light of technical advances and to deal with issues which emerge from the licensing process. Revisions of the Code must be approved by the Secretary of State[7] and laid before Parliament. The Code's second edition was published in June 1993, the third in December 1995 and the fourth in July 1998. Copies of the fourth edition are available from the HFEA upon request.

'WELFARE OF THE CHILD'

In particular, the Code of Practice provides guidance on the assessment of the welfare of the child. In passing the HFE Act, Parliament decided that no category of woman should be excluded from treatment. While the offer of treatment is a decision ultimately for the patient's clinician, the HFE Act requires every clinician to make this decision only after 'account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth'[8].

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

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6 Human Fertilisation and Embryology Act 1990, section 25.

7 HFE Act, section 26(4).

8 HFE Act, section 13(5).

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

FIFTH EDITION OF THE CODE

Work has now started on the Code's fifth edition and will include a thorough reconsideration of the Code's structure. Issues which have already been identified for consideration include: contacting patients' GPs and what to do if permission is refused, or if a GP does not respond; genetic testing; the status of donors; and the number of embryos that may be transferred in a treatment cycle.

a) Genetic Testing

Following the recommendation in the fourth edition that donors should be tested for cystic fibrosis carrier status, the Code of Practice Committee will be considering whether genetic guidance for donors and patients will need to be further updated. The Committee is working closely with the Advisory Committee on Genetic Testing (ACGT) whose remit is to advise on good practice in all areas of genetic testing. The genetic testing of patients may also need to be considered in cases where their sub-fertility has a genetic component.

b) Number of Embryos Transferred in Each Treatment Cycle

The Code of Practice limits the number of embryos that may be transferred in a single treatment cycle to three. The reason for setting such a limit is to maximise the chances of pregnancy but minimise the risk of multiple pregnancies. These are associated with premature birth, low birth weight babies, a higher rate of stillbirth and neonatal death and long term disability such as cerebral palsy, as well as continuing social and psychological difficulties. HFEA data shows that the multiple pregnancy rate remains high (almost half of all IVF babies come from a multiple birth)[9]. In addition, the data show that, where there are four or more embryos available to a patient, the chances of a live birth are no greater for three than for two embryo transfer, but that the multiple pregnancy rate increases significantly with the former[10]. The British Fertility Society have recently recommended that two embryo transfer should be the usual practice and the HFEA welcomes this. We shall be considering whether, in the light of published evidence, the guidelines in the Code should be changed.

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9 See Table 3.7, page 12

10 See Tables 3.10 and 3.11, pages 13–14

Collecting and Providing Data

3

INTRODUCTION

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

- to provide information to children born as a result of such treatments; [11]
- to monitor the provision of treatments; and
- to assist in the giving of information to the Government, patients, clinics and the general public.

The HFEA is in the process of redeveloping its Register. As part of this programme the HFEA is considering introducing electronic transfer of data from clinics. A new Register should be in place by April 1999.

The HFEA Register holds the largest database of its kind in the world, being a complete record of treatments and patient characteristics for the whole of the UK. As part of the Register's redevelopment the HFEA intends by early 2000 to put in place a system for publishing detailed, non-identifying information about treatments and their outcomes. It is hoped that these data can be made available on the HFEA's website.

Unless otherwise stated, the data tables and graphs show data collected for treatment cycles that were carried out during the 12 month period from 1 April 1996 to 31 March 1997.

Unless otherwise stated the IVF data include treatments involving micromanipulation, such as ICSI or SUZI, and frozen embryo replacements.

The DI data includes cycles involving GIFT and intrauterine insemination (IUI) using donor gametes. The form of reporting does not permit separation of this data, although this issue is being actively addressed in the redevelopment of the Register.

11 First information to be given to 16 year old enquirers, who intend to marry, in 2007

COMPARABLE DATA ON LICENSED TREATMENTS

There are several important trends:

- The incidence of multiple births (and attendant risk to maternal and infant health) as a result of IVF and micromanipulation remains high (table 3.1 – see also pages 12–14).
- There has been an increase in the number of IVF cycles in recent years, mainly as a result of a rapid increase in micromanipulation treatments. Excluding cycles which were abandoned prior to egg collection and frozen embryo cycles, there were 1,685 micromanipulation cycles in the 1994/1995 reporting period, 4,651 cycles during 1995/1996 and 6,652 cycles in the current period (table 3.1). After a relatively rapid increase, the live birth rate appears to be levelling off and is currently at 21.6% (Figure 3.1).
- Increases in the overall IVF live birth rates are almost exclusively due to the increased use and success of micromanipulation. Success with micromanipulation seems higher than with IVF, although this may not be the case when corrected for female factors (figures 3.1 and 3.2).
- With IVF, micromanipulation and DI, the 1st cycle of treatment is statistically the most successful (table 3.2).

Table 3.1 Live birth and multiple birth rates for IVF, micromanipulation and DI, 1991–1997

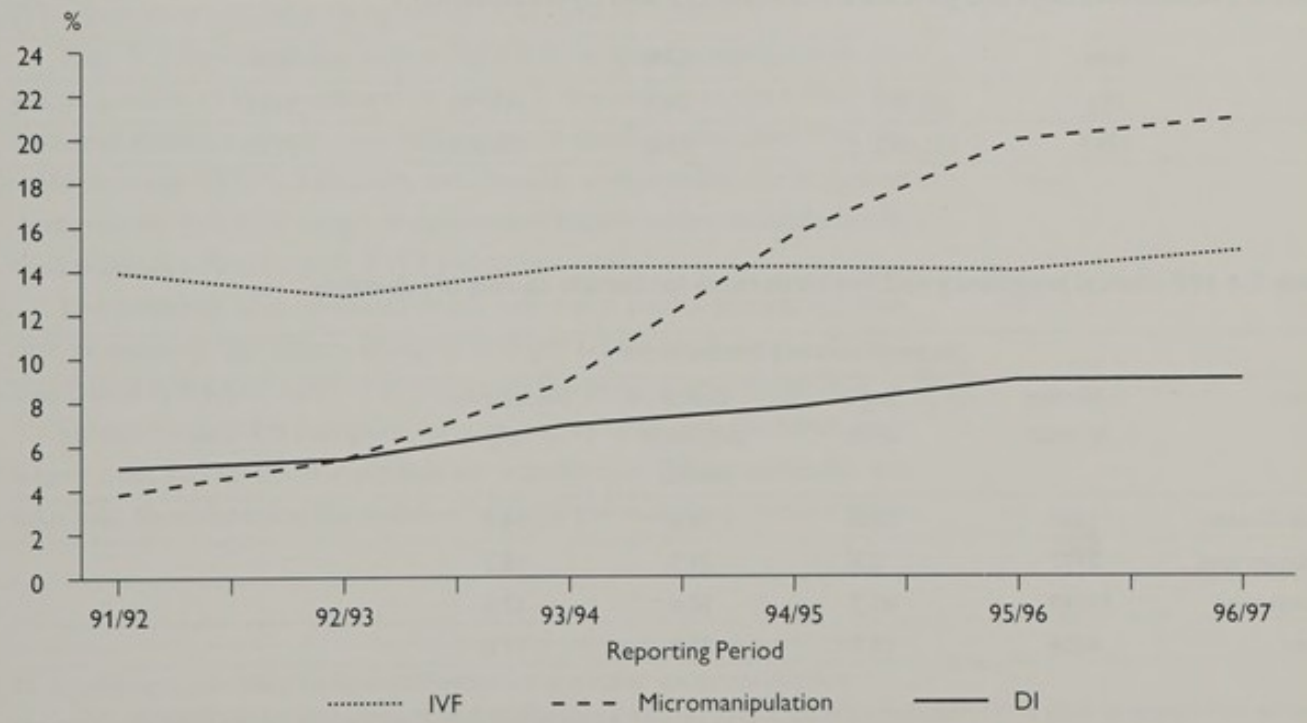
	IVF[1]			MICROMANIPULATION			DI[2]		
Reporting period	Number of treatment cycles	Live Birth Rate per treatment cycle (%)	Multiple Birth Rate per live birth event (%)	Number of treatment cycles	Live Birth Rate per treatment cycle (%)	Multiple Birth Rate per live birth event (%)	Number of treatment cycles	Live Birth Rate per treatment cycle (%)	Multiple Birth Rate per live birth event (%)
91/92[3]	10434	14.0	27.3	80	3.8	33.0	16299	5.0	7.3
92/93	19309	13.1	28.1	244	5.7	35.7	25623	5.4	6.7
93/94	21726	14.3	27.6	798	9.3	25.7	23869	7.0	8.3
94/95	24193	14.3	27.7	1685	15.7	26.4	20604	7.9	7.2
95/96	25781	14.3	29.6	4651	20.2	28.9	16874	9.3	8.3
96/97	26868	15.5	26.8	6652	21.6	29.1	14333	9.6	6.5

1 In this table, IVF data does not include cycles involving micromanipulation. Frozen embryo transfers are included.

2 DI data includes GIFT using donor gametes and intra uterine insemination.

3 1991/2 data for eight months only

Figure 3.1 Live birth rates per Treatment Cycle for Licensed Treatments 1991–1997



Notes

1. Micromanipulation data include ICSI treatments

2. The 'IVF' line does not include micromanipulation data

Table 3.2 Live Birth Rates by number of attempts

a) IVF (fresh embryo transfers only, not including micromanipulation)

	1st	*2nd*	*3rd*	*4th*	*5th*	*6th*	*7th–10th*	*11th+*
Patients Treated	10147	4938	2459	1212	599	360	408	69
Pregnancy Rates per Cycle %	21.2	19.6	19.5	19.6	18.7	17.5	18.8	11.1
Live Birth Rates per Cycle %	17.4	16.1	16.3	16.5	14.4	12.6	13.8	8.6

b) Micromanipulation (including ICSI)

	1st	*2nd*	*3rd*	*4th*	*5th–8th*	*9th+*
Patients Treated	2852	1751	918	500	485	56
Pregnancy Rates per Cycle %	27.6	25.1	22.5	20.9	23.1	18.3
Live Birth Rates per Cycle %	24.1	21.3	19.2	17.1	18.5	15.0

c) Donor Insemination

	1st	*2nd*	*3rd*	*4th*	*5th*	*6th–8th*	*9th–11th*	*12th+*
Patients Treated	2228	1913	1658	1382	1173	2424	1447	740
Pregnancy Rates per Cycle %	13.8	12.8	12.2	11.5	9.7	11.1	11.5	9.2
Live Birth Rates per Cycle %	11.2	10.3	10.5	9.4	8.6	9.4	9.6	7.4

Table 3.3 Number of boys and girls born following IVF and DI treatments

	Boys		*Girls*		*Total*
DI	752	(50.3%)	743	(49.7%)	1495
IVF	3747	(51.4%)	3546	(48.6%)	7293

Table 3.4 IVF clinical pregnancy and live birth rates for female causes of infertility

		(%s are of number of treatment cycles)		
Factor	*Number of cycles*	*% of all cycles*	*Clinical pregnancy rate (%)*	*Live birth rate (%)*
Tubal Disease	11984	35.8	18.6	14.9
Endometriosis	2777	8.3	21.5	18.2
Unexplained	15149	45.2	20.6	17.5
Other	6206	18.5	21.8	17.6

Note: The total number of cycles in this table does not equal 33,520 because some patients have more than one cause of infertility.

IVF DATA

During the period 1996/7, 25,565 patients received IVF treatment. There were a total of 33,520 cycles started, including frozen embryo replacements, of which 27,981 reached embryo transfer. There were 6,755 clinical pregnancies (20.2% of treatments started) which led to 5,601 live birth events (16.7% of treatments started). The number of clinical pregnancies where no outcomes or incomplete information was received was 37 or 0.5% of all pregnancies reported. The annual difference between the clinical pregnancy rate and live birth rate remains within the range 3.3%–4.0%.

Analysis of the tables has identified several interesting trends:

- Live birth rates for IVF and micromanipulation both decrease steadily after women pass the age of 30 (Figure 3.2).
- The live birth rate for IVF decreases markedly in women over the age of 34 using their own eggs (table 3.6, Figure 3.2).
- IVF frozen embryo transfer cycles have significantly lower pregnancy and live birth rates than those involving fresh embryos (particularly when the couple's own gametes are used) (table 3.12).

Multiple births and two and three embryo transfer

There remains a high incidence of multiple births as a result of licensed infertility treatment, and IVF in particular. For this reason we include several tables exploring the issue with the latest data.

Table 3.7 shows that 47% of individual babies born from all types of IVF come from a multiple pregnancy (3,417 out of 7,292).

Table 3.7 shows that there were 262 triplet or quad pregnancies in the UK as a result of IVF treatment in 1996/7. According to the Office for National Statistics, there were 328 triplet or quad 'maternities'[12] in the calendar year 1997[13]. Although not directly comparable, these figures demonstrate that a very high proportion of higher order multiple births took place as a direct result of IVF treatment.

The stillbirth and neonatal death rate for a triplet pregnancy with one or more of the babies dying is 87.0 per 1,000 birth events (8.7%) compared to 9.6 per 1,000 (1%) for singleton pregnancies (table 3.7).

Tables 3.8 and 3.9 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

12 According to the Office for National Statistics, a 'maternity' is a 'pregnancy that resulted in the birth of one or more live or stillborn children'

13 *House of Commons Written Answers*, 25 June 1998, Hansard col 581; 29 June 1998 cols. 3 and 61; 1 July 1998 col. 197

to embryo transfer. They indicate that there is only a slightly higher live birth rate where three embryos are transferred, but also show that the multiple birth rate per live birth event rises from 22.4% for two embryo transfers to 32.2% for three embryo transfers.

The tables show that during the 1996/1997 reporting period the maximum number of three embryos was replaced in 52% of all treatment cycles which reached embryo transfer. Encouragingly, they show that the number of cycles in which two embryos are replaced increased by 379 (8.2%) since the 1995/1996 reporting period whereas the number of cycles in which three embryos are replaced fell by 1,339 (5.8%).

Table 3.10 shows that, in the majority of cases where more than four embryos have been created, the replacement of three embryos does not enhance the live birth rate, but merely increases the risk of a multiple birth, particularly of triplets. In such cases where women under the age of 35 have had three embryos transferred, four out of ten births have been multiples (table 3.11).

Table 3.5 IVF clinical pregnancy and live birth rates: 1/8/1991–31/3/1997

(including micromanipulation treatments but excluding frozen embryo replacements)

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

[1] *Data for eight months only*

Table 3.6 Live birth rates by age of woman

a) IVF (using own eggs – not including micromanipulation)

	Under 27	*27–28*	*29–30*	*31–32*	*33–34*	*35–36*	*37–38*	*39–40*	*41–42*	*43–44*	*45 and over*	*All patients*
Treatment Cycles	1149	1723	2833	4015	4472	4030	3201	2134	1040	482	202	25281
Live Birth Rate	18.0	17.4	20.1	18.5	17.5	14.4	12.7	9.7	5.2	2.7	1	15.3

b) Micromanipulation using own eggs

	Under 27	*27–28*	*29–30*	*31–32*	*33–34*	*35–36*	*37–38*	*39–40*	*41–42*	*43–44*	*45 and over*	*All patients*
Treatment Cycles	361	448	828	1098	1173	1021	717	483	244	79	32	6484
Live Birth Rate	26.6	27.9	28.1	23.6	22.8	21.5	16.9	12	8.2	3.8	3.1	21.6

Note: There were 151 micromanipulation cycles using donated eggs resulting in 38 live birth events

All tables exclude treatments using donated embryos

Figure 3.2

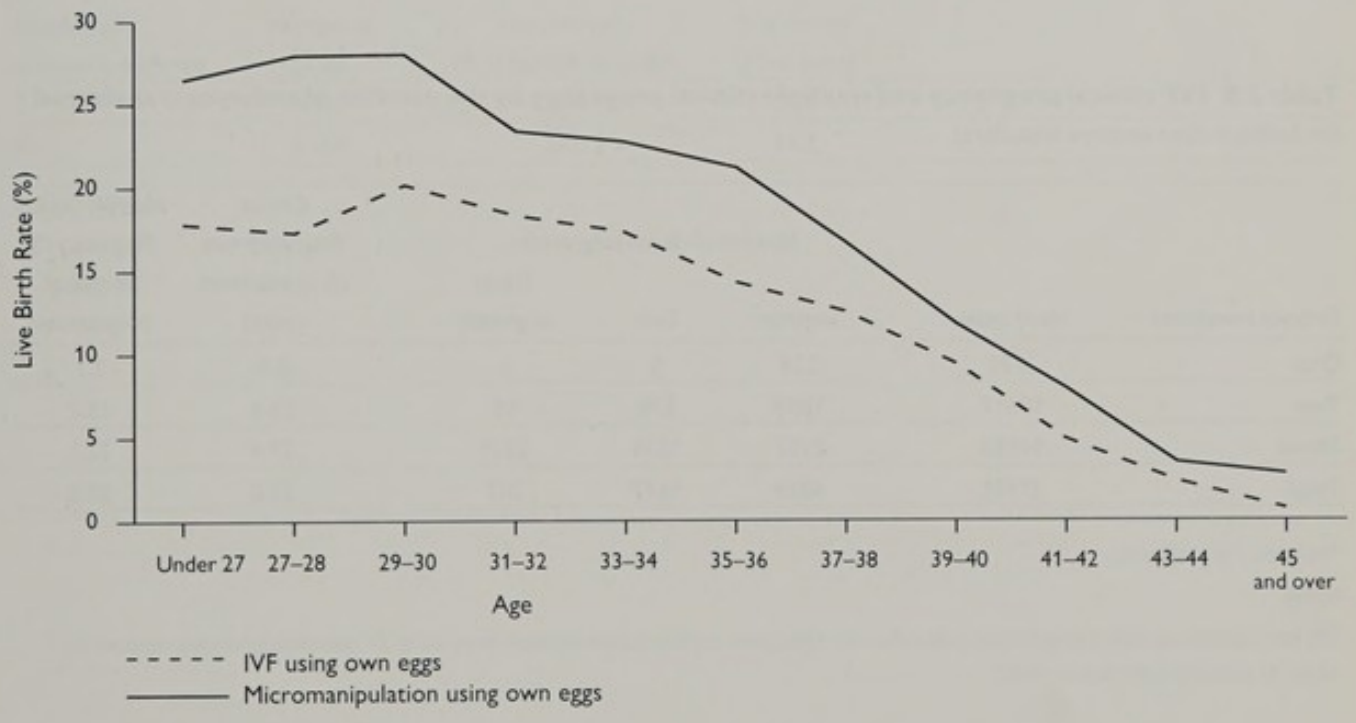


Table 3.7 Single and Multiple Clinical Pregnancy Outcomes after IVF or Frozen Embryo Transfers

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Still Birth and Neonatal Deaths (per thousand birth events)*
Singleton	4839	3867	674	31	140	90	3875	9.6
Twin	1617	1502	218	9	8	14	2809	44.6
Triplet	260	230	59	37	-	5	602	87.0
Quads	2	2	-	-	-	-	6	500.0
Totals	6718	5601	951	77	148	109	7292	22.3

Notes:

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

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

The total number of clinical pregnancies shown here is less than the total given in other tables because there were 308 clinical pregnancies reported for which no outcome form was received.

Table 3.8 IVF clinical pregnancy and multiple clinical pregnancy by the number of embryos transferred (including frozen embryo transfers)

		Number of clinical pregnancies			*Clinical Pregnancy rate (% of treatment cycles)*	*Multiple Clinical Pregnancy (% of clinical pregnancies)*
Embryos transferred	*No of cycles*	*Singleton*	*Twin*	*Triplet or greater*		
One	2781	234	5	-	8.6	2.1
Two	10617	1898	578	10	23.4	23.7
Three	14583	2707	1034	252*	27.4	32.2
Total	27981	4839	1617	262	24.0	28.0

**Includes 2 sets of quads*

Notes:

The total number of clinical pregnancies is less than the total given in other tables because there were 37 clinical pregnancies reported for which no outcome form was received.

Table 3.9 IVF live birth and multiple live birth rate by the number of embryos transferred (including frozen embryo transfers)

		Number of live births			Live birth rate (% of treatment cycles)	Multiple birth rate (% of live birth events)	Stillbirths and neonatal deaths per 1000 birth events
	No of cycles	Singleton	Twin	Triplet or greater			
One	2781	201	3	-	7.3	1.5	9.8
Two	10617	1644	471	6	20.0	22.4	20.3
Three	14583	2222	904	150*	22.5	32.2	24.4
Total	27981	4067	1,378	156	20.0	27.4	22.3

Includes 1 set of quads

Table 3.10 Two and three embryo transfers for fresh stimulated IVF only
(where more than four embryos were created)

Number of embryos transferred	Number of cycles	Live birth rate (% of number of cycles)	Multiple birth rate (% of number of live births)
2	4650	26.4	26.0
3	8158	26.0	34.3

Table 3.11 IVF live birth and multiple birth rates by age and number of embryos transferred
(Data for 2 year period 01/04/95–31/03/97. Fresh stimulated IVF only, including micromanipulation. Where more than four embryos were created)

a) All embryo transfers

Age	Number of cycles	Number of live births	Live birth rate per treatment cycle	Number of multiple births (twins, triplets and quads)	Multiple birth rate per live birth event (twins, triplets and quads)	Number of triplets and quads	Triplet and quad birth rate per live birth event
<25	436	112	(25.7%)	41	(36.6%)	3	(2.7%)
25-29	4376	1233	(28.2%)	442	(35.8%)	53	(4.3%)
30-34	10530	2968	(28.2%)	1008	(34.0%)	120	(4.0%)
35-39	7285	1618	(22.2%)	465	(28.7%)	48	(3.0%)
40-44	1543	181	(11.7%)	31	(17.1%)	3	(1.7%)
45+	96	10	(10.4%)	2	(20.0%)	-	-
Total	24266	6122	(25.2%)	1989	(32.5%)	227	(3.7%)

b) Two embryo transfer

Age	Number of cycles	Number of live births	Live birth rate per treatment cycle	Number of multiple births (twins, triplets and quads)	Multiple birth rate per live birth event (twins, triplets and quads)	Number of triplets and quads	Triplet and quad birth rate per live birth event
<25	205	54	(26.3%)	16	(29.6%)	-	-
25-29	1955	546	(27.9%)	160	(29.3%)	2	(0.4%)
30-34	3926	1053	(26.8%)	285	(27.1%)	2	(0.2%)
35-39	1939	403	(20.8%)	88	(21.8%)	-	-
40-44	183	15	(8.2%)	-	-	-	-
45+	10	-	-	-	(0.0%)	-	-
Total	8218	2071	(25.2%)	549	(26.5%)	4	(0.2%)

c) Three embryo transfer

Age	Number of cycles	Number of live births	Live birth rate per treatment cycle	Number of multiple births (twins, triplets and quads)	Multiple birth rate per live birth event (twins, triplets and quads)	Number of triplets and quads	Triplet and quad birth rate per live birth event
<25	228	58	(25.4%)	25	(43.1%)	3	(5.2%)
25-29	2400	684	(28.5%)	281	(41.1%)	51	(7.5%)
30-34	6539	1902	(29.1%)	721	(37.9%)	117	(6.2%)
35-39	5290	1203	(22.7%)	374	(31.1%)	48	(4.0%)
40-44	1353	166	(12.3%)	31	(18.7%)	3	(1.8%)
45+	86	10	(11.6%)	2	(20.0%)	-	-
Total	15896	4023	(25.3%)	1434	(35.6%)	222	(5.5%)

Table 3.12 IVF Clinical Pregnancy and Live Birth Rates (Frozen embryo replacements)
(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregs*	*Live Births*	*Babies Born*
Own Gametes	4331	5134	4646 (90.5%)	684 (13.3%)	563 (11.0%)	671
Donated Sperm	399	455	420 (92.3%)	81 (17.8%)	62 (13.6%)	79
Donated Eggs	379	437	405 (92.7%)	74 (16.9%)	58 (13.3%)	68
Donated Embryos	173	206	191 (92.7%)	49 (23.8%)	40 (19.4%)	50
Totals	**5282**	**6232**	**5662 (90.9%)**	**888 (14.2%)**	**723 (11.6%)**	**868**

Table 3.13 Treatments using micromanipulation
(including ICSI)

Clinics	47
Patients	5828
Number of cycles *	6652
Number of embryo transfers	6194
Clinical pregnancies	1674
Clinical pregnancy rate (%)	25.2
Total live births	1438
Live birth rate (%)	21.6
Miscarriages	229
Terminations	10
Ectopics	18
Unknown	25
Babies born	1896
Stillbirths and neonatal deaths (per thousand birth events)	20.2

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

Table 3.14 Results of stimulated IVF and fresh embryo transfer cycles
(All percentages are of number of treatment cycles)

a) All centres

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	20646	24635	20033 (81.3%)	5182 (21.0%)	4322 (17.5%)	5678
Donated Sperm	1216	1409	1252 (88.9%)	382 (27.1%)	321 (22.8%)	429
Donated Eggs	238	246	209 (85.0%)	55 (22.4%)	44 (17.9%)	54
Donated Embryos	29	30	27 (90.0%)	8 (26.7%)	6 (20.0%)	8
Totals	**22129**	**26320**	**21521 (81.8%)**	**5627 (21.4%)**	**4693 (17.8%)**	**6169**

b) Large centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical pregnancies*	*Live Births*	*Babies Born*
Own Gametes	18023	21557	17570 (81.5%)	4591 (21.3%)	3828 (17.8%)	5032
Donated Sperm	1008	1172	1036 (88.4%)	325 (27.7%)	271 (23.1%)	360
Donated Eggs	207	214	185 (86.4%)	51 (23.8%)	40 (18.7%)	50
Donated Embryos	23	23	21 (91.3%)	6 (26.1%)	5 (21.7%)	7
Totals	**19261**	**22966**	**18812 (81.9%)**	**4973 (21.7%)**	**4144 (18.0%)**	**5449**

c) Small centres*

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical pregnancies*	*Live Births*	*Babies Born*
Own Gametes	2623	3078	2463 (80.0%)	591 (19.2%)	494 (16.0%)	646
Donated Sperm	208	237	216 (91.1%)	57 (24.1%)	50 (21.1%)	69
Donated Eggs	31	32	24 (75.0%)	4 (12.5%)	4 (12.5%)	4
Donated Embryos	6	7	6 (85.7%)	2 (28.6%)	1 (14.3%)	1
Totals	**2868**	**3354**	**2709 (80.8%)**	**654 (19.5%)**	**549 (16.4%)**	**720**

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

Table 3.15 Unstimulated IVF: own gametes and donated sperm
(All percentages are of number of treatment cycles)

a) All centres

	Patients	Treatment Cycles	Embryo Transfers		Clinical pregnancies		Live Births		Babies Born
Own Gametes	133	140	46	(32.9%)	5	(3.6%)	3	(2.1%)	5
Donated Sperm	11	11	3	(27.3%)	1	(9.1%)	1	(9.1%)	1
Totals	**144**	**151**	**49**	**(32.5%)**	**6**	**(4.0%)**	**4**	**(2.6%)**	**6**

b) Large centres*

	Patients	Treatment Cycles	Embryo Transfers		Clinical pregnancies		Live Births		Babies Born
Own Gametes	121	128	45	(35.2%)	5	(3.9%)	3	(2.3%)	5
Donated Sperm	7	7	2	(28.6%)	0	(0.0%)	0	(0.0%)	0
Totals	**128**	**135**	**47**	**(34.8%)**	**5**	**(3.7%)**	**3**	**(2.2%)**	**5**

c) Small centres*

	Patients	Treatment Cycles	Embryo Transfers		Clinical pregnancies		Live Births		Babies Born
Own Gametes	12	12	1	(8.3%)	0	(0.0%)	0	(0.0%)	0
Donated Sperm	4	4	1	(25.0%)	1	(25.0%)	1	(25.0%)	1
Totals	**16**	**16**	**2**	**(12.5%)**	**1**	**(6.3%)**	**1**	**(6.3%)**	**1**

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

Table 3.16 Unstimulated IVF using donated eggs or donated embryos
(All percentages are of number of treatment cycles)

a) All centres

	Patients	Treatment Cycles	Embryo Transfers		Clinical pregnancies		Live Births		Babies Born
Donated Eggs	683	731	674	(92.2%)	212	(29.0%)	165	(22.6%)	225
Donated Embs	81	86	75	(87.2%)	22	(25.6%)	16	(18.6%)	24
Totals	**764**	**817**	**749**	**(91.7%)**	**234**	**(28.6%)**	**181**	**(22.2%)**	**249**

b) Large centres*

	Patients	Treatment Cycles	Embryo Transfers		Clinical pregnancies		Live Births		Babies Born
Donated Eggs	627	671	622	(92.7%)	197	(29.4%)	153	(22.8%)	208
Donated Embs	66	71	62	(87.3%)	21	(29.6%)	16	(22.5%)	24
Totals	**693**	**742**	**684**	**(92.2%)**	**218**	**(29.4%)**	**169**	**(22.8%)**	**232**

c) Small centres*

	Patients	Treatment Cycles	Embryo Transfers		Clinical pregnancies		Live Births		Babies Born
Donated Eggs	56	60	52	(86.7%)	15	(25.0%)	12	(20.0%)	17
Donated Embs	15	15	13	(86.7%)	1	(6.7%)	0	(0.0%)	0
Totals	**71**	**75**	**65**	**(86.7%)**	**16**	**(21.3%)**	**12**	**(16.0%)**	**17**

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

Table 3.17 Clinical IVF pregnancy and live birth rates with fresh embryo transfer

a) Stimulated IVF

		Pregnancy rate %			*Live birth rate*		
	Number of treatment cycles	*Per treatment cycle*	*Per egg collection*	*Per embryo transfer*	*Per treatment cycle*	*Per egg collection*	*Per embryo transfer*
Own Gametes	24635	21.0	23.2	25.9	17.5	19.4	21.6
Donated Sperm	1409	27.1	27.6	30.5	22.8	23.2	25.6
Donated Eggs	246	22.4	n/a	26.3	17.9	n/a	21.1
Donated Embryos	30	26.7	n/a	29.6	20.0	n/a	22.2
All	**26320**	**21.4**	**n/a**	**26.1**	**17.8**	**n/a**	**21.8**

b) Unstimulated IVF

		Pregnancy rate %			*Live birth rate*		
	Number of treatment cycles	*Per treatment cycle*	*Per egg collection*	*Per embryo transfer*	*Per treatment cycle*	*Per egg collection*	*Per embryo transfer*
Own Gametes	140	3.6	8.2	10.9	2.1	4.9	6.5
Donated Sperm	11	9.1	33.3	33.3	9.1	33.3	33.3
Donated Eggs	731	29.0	n/a	31.5	22.6	n/a	24.5
Donated Embryos	86	25.6	n/a	29.3	18.6	n/a	21.3
All	**968**	**24.8**	**n/a**	**30.1**	**19.1**	**n/a**	**23.2**

Table 3.18 Developmental defects and syndromes

	Total	Fresh IVF	Frozen IVF	DI	Micro-manipulation
Chromosomal syndromes					
Downs' Syndrome	8	4		3	1
Other chromosomal abnomalites	3	2			1
Congenital abnormalities					
Cleft lip	3	3			
Cleft palate	5	1	3	1	
Cleft lip with cleft palate	5	5			
Tracheo-oesophageal fistula, oesophageal atresia and stenosis	0				
Atresia and Stenosis of the large intestine, rectum and anal canal	2	2			
Anomalies of the alimentary system	3	1			2
Cardiac murmurs	13	7	3	2	1
Ventricular septal defect	4	2	2		
Other congenital cardiac anomalies	5	3			2
Other anomalies of the cardiac septa	2		1	1	
Patent Ductus	1	1			
Anomalies of the cardiovascular system	3	1		2	
Hypospadias, Epispadias	2		1	1	
Anomalies of the male external genetalia	2	1		1	
Renal anomalies	9	2	2	1	4
Polydactyly or syndactyly	3	1		1	1
Reduction deformities of the limbs	3			3	
Talipes	6	5		1	
Congenital dislocation of the hip	1	1			
Other anomalies of the limbs or limb girdle	2		1	1	
Anomalies of the nose, face, neck and skull	5	3	1	1	
Anomalies of the abdominal wall	4	1		1	2
Ear anomalies	0				
Spina bifida	0				
Exomphalos	0				
Anomalies of the tongue, branchial cleft and auricular sinus	0				
Total number of children born	**84**	**42**	**12**	**17**	**13**
As a percentage of total number of babies born as a result of each type of licensed treatment	0.8	0.6	1.4	1.1	0.9

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

DONOR INSEMINATION DATA

During the period 1 April 1996 to 31 March 1997, 5,439 patients received treatment involving DI or GIFT using donated gametes. Table 3.19 shows that 14,333 cycles were started which led to 1,661 clinical pregnancies (11.6%) and 1,379 live births (9.6%). The number of clinical pregnancies for which no outcome or incomplete information was submitted totalled 30 or 1.8% of all pregnancies reported.

- The live birth rate for DI has increased steadily over the last 5 years, and has almost doubled since 1992 (table 3.19).
- The number of DI cycles carried out annually has dropped by 44% since the 1992/3 reporting period (from 25,623 to 14,333) (table 3.19).
- Live birth rates for DI decrease with age, and increasingly so after the age of 35 (table 3.22).

Table 3.19 DI clinical pregnancy & live birth rates per treatment cycles 1/8/91 – 31/3/97 (Data includes GIFT using donor gametes and Intra Uterine insemination)

(Percentages are of number of treatment cycles)

	Number of treatment cycles	*Clinical pregnancy rate per treatment cycle (%)*	*Live birth rate per treatment cycle (%)*
01/08/91 to 31/03/92	16299	6.6	5.0
01/04/92 to 31/03/93	25623	6.9	5.4
01/04/93 to 31/03/94	23869	8.6	7.0
01/04/94 to 31/03/95	20604	9.7	7.9
01/04/95 to 31/03/96	16874	11.2	9.3
01/04/96 to 31/03/97	14333	11.6	9.6

Table 3.20 Donor Insemination Data

Stimulated DI		*Unstimulated DI*	
Number of Centres	102	Number of Centres	97
Number of Patients	2732	Number of Patients	3396
Number of Treatment Cycles	5884	Number of Treatment Cycles	8449
Total Clinical Pregnancies	739	Total Clinical Pregnancies	922
Clinical Pregnancy Rate per Cycle	12.6%	Clinical Pregnancy Rate per Cycle	10.9%
Total Miscarriages	91	Total Miscarriages	112
Total Terminations	7	Total Terminations	6
Total Ectopics	8	Total Ectopics	5
Total Live Births	606	Total Live Births	773
Live Birth Rate per Cycle	10.3%	Live Birth Rate per Cycle	9.1%
Total stillbirths and neonatal deaths	9	Total stillbirths and neonatal deaths	4

Table 3.21 Single and multiple clinical pregnancy outcome

a) Stimulated DI

	Clinical pregnancies	*Live births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown outcomes*	*Babies born*	*Stillbirths and neonatal deaths (per thousand birth events)*	
Singleton	635	525	85	5	8	8	527	7.6	
Twin	68	65	5	1	0	0	125	46.2	
Triplet	13	13	1	1	0	0	34	153.8	(2 out of 13)
Quad	2	2	0	0	0	0	8	-	
Totals	**718**	**605**	**91**	**7**	**8**	**8**	**694**	**14.9**	

b) Unstimulated DI

	Clinical pregnancies	*Live births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown outcomes*	*Babies born*	*Stillbirths and neonatal deaths (per thousand birth events)*	
Singleton	896	759	110	6	5	13	760	4.0	
Twin	15	14	2	0	0	0	26	71.4	(1 out of 14)
Triplet	0	0	0	0	0	0	0	0	
Totals	**911**	**773**	**112**	**6**	**5**	**13**	**786**	**5.2**	

Table 3.22 DI live birth rate by woman's age

	Under 25	*25–29*	*30–34*	*35–39*	*40–44*	*45 and over*
Number of cycles	630	3262	5557	3766	1046	62
Live Birth Rate per cycle	11.7	11.3	10.2	8.8	3.7	1.6

4 *Research*

INTRODUCTION

Much valuable knowledge has been gained through human embryo research. Any research project which involves the creation, keeping or use of embryos outside the body must be licensed by the HFEA[14]. 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[15]:

- 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.

Embryos obtained with appropriate consent for a research project may not be used for any other purpose.

While encouraging research, UK law does not permit certain activities involving human embryos. These include:

- 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; or
- using embryos for any other purposes except in pursuance of a licence.

THE RESEARCH LICENSING PROCESS

In addition, the HFEA's Code of Practice states the HFEA's policy not to license research projects involving embryo splitting with the intention of increasing the number of embryos for transfer.

The HFEA has 24 licensed research projects at 18 different centres. Of those currently licensed, 8 were licensed for the first time and 16 were licensed as ongoing projects.

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14 A list of HFEA licensed research projects is at Annex 6.

15 HFE Act, schedule 2, para 3(2).

Approval by a properly constituted external ethics committee is a necessary prerequisite to the HFEA 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 or, under Health Service Guidelines (97)23, a Multi-Centre REC if five or more centres are involved. The HFEA's Code of Practice provides guidance on the use and constitution of ethics committees for centres outside the NHS.

An application for a research licence must provide a range of information on the proposed project including its objectives and duration, reasons why the use of sperm, oocytes and embryos is essential, methodology and relevant protocols. The HFEA does not have the remit to license clinical trials.

In addition, all applications for research licences are submitted for peer review[16]. Peer reviewers comment on a number of issues including the work's originality and the justification for it. Their recommendations are submitted to a Licence Committee which will decide whether a research licence should be granted. In coming to their decision Licence Committees will, in particular, take into account all the information presented and consider such issues as the information to be given to patients who might wish to be involved in the project and the consent forms they will be asked to sign.

16 The HFEA's panel of peer reviewers is at Annex 7.

5 *Policy update and issues for the coming year*

The HFEA is considering, or has recently considered, the following ethical issues.

PAYMENTS TO SPERM AND EGG DONORS [17]

In 1996 the HFEA decided that, except for expenses, there should be no payments made to egg and sperm donors. In February 1998 an HFEA consultation paper was circulated to seek views on the best way to implement this policy and discussing options as to how payments could be withdrawn without adversely affecting the supply of donors. Among issues covered in the consultation were:

- whether any changes in the public perception of donation could increase the number of donors;
- whether a national gamete donor recruitment service would help to increase public awareness of gamete donation and assist implementation; and
- the development of a new system of expenses payments.

The consultation period ended on 31 July 1998, and the HFEA is now in the process of analysing the responses received. Copies of the consultation document are still available from the HFEA on request. Clinics will be given sufficient time to prepare for any changes.

PREIMPLANTATION GENETIC DIAGNOSIS (PGD)

PGD is a technique used to detect whether an embryo created in vitro is carrying a genetic defect that will give rise to a serious inherited 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 muscular dystrophy, to a male child. The HFEA is monitoring developments in this area very closely and licenses appropriate research and treatment. Four centres are currently licensed to carry out this technique and one to carry out the embryo biopsy part of the procedure. Eight centres hold HFEA research licences in this area.

PGD is currently practised on a small scale. However, it is expected that demand will grow as knowledge about the genes responsible for different conditions increases and the techniques involved develop. The latest data show that around 150 babies have so far been born world-wide as a result of PGD.

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17 Under Section 12(e) of the HFE Act, payments to donors may only be made if authorised by the HFEA

The HFEA established a joint Working Group with the Advisory Committee on Genetic Testing which is preparing a public consultation document on the use of PGD.

In addition, a Working Group on Embryo Biopsy was set up to devise guidelines for assessing practitioners who perform the embryo biopsy part of the PGD procedure.

CLONING

In February 1997 the Roslin Institute and PPL Therapeutics reported the birth of Dolly the sheep following nuclear replacement of an egg[18]. Dolly represented a scientific breakthrough as it was the first time an adult mammal had been cloned by nuclear replacement. However, there was widespread concern that developments in animal cloning would inevitably lead to human beings being cloned.

The HFE Act covers all forms of cloning which involve the creation and use of human embryos outside the body, and one type of cloning, nuclear replacement into embryos, is specifically prohibited. It is currently unlawful to apply the technique which was used to produce Dolly to humans in the UK as the HFEA has not issued a licence for the technique. The HFEA has made it clear that it is opposed to the deliberate creation of cloned human fetuses or babies and will not issue a licence which has this as its aim.

It has been suggested that the technology which produced Dolly could in the future be used for therapeutic purposes. The HFEA is concerned that the issues surrounding the potential therapeutic use of cloning technology, and the research that would be required to develop such use, are carefully considered before decisions are made. To that end a consultation document jointly produced by the Human Genetics Advisory Commission (HGAC) and the HFEA was published in January 1998.

The consultation's primary aim was to inform the HFEA and the HGAC of possible scientific developments in this area and the associated ethical concerns. In particular, the consultation sought views on whether a distinction could be drawn between the creation of human clones ('reproductive cloning') and in vitro work using the nuclear replacement technology with a therapeutic aim ('therapeutic cloning'). The HFEA and HGAC have been analysing the responses received and will be reporting their findings to the Government.

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18 I. Wilmut et al, *Viable offspring derived from fetal and adult mammalian cells*, Nature, vol. 385, 27 February 1997, 810-813

CRYOPRESERVATION OF SPERM AND EMBRYOS

An HFEA working group was set up in 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 the precise risk of cross contamination is not known with gametes and embryos, the HFEA concluded that the potential risks, while very low, had to be taken seriously. The issues proved particularly complex, hindered by the lack of research in this area.

A consultation paper on this subject was issued in June 1998 and sent to licensed centres and relevant experts and professional organisations. Responses have been requested by the end of October 1998. The Working Group will reconvene to analyse the responses and produce a report to be considered by the full Authority.

STORAGE AND USE OF TESTICULAR AND OVARIAN TISSUE

The HFE Act gives the HFEA jurisdiction over the storage and use of live human gametes and human embryos created *in vitro* and requires a patient's written consent to the storage of such gametes or embryos. The definition of 'gamete' to which the HFEA works is:

> *a reproductive cell, such as as ovum or a spermatozoon, which has a haploid set of chromosomes and which is able to take part in fertilisation with another of the opposite sex to form a zygote.*

a) Testicular tissue

Using this definition in conjunction with the six grades of puberty described by Professor Tanner[19], the storage of testicular tissue from boys who have reached Tanner stage G2 or beyond would require a licence from the HFEA.

b) Ovarian tissue

For much of the menstrual cycle, ovarian tissue will not contain gametes according to the definition above. Any gamete or gametes that are present will be localised in certain parts of the ovary. Clinicians will need to consider on a case by case basis whether ovarian tissue contains any viable gametes either by reference to the stage of the woman's cycle or by appropriate testing or assessment of the tissue itself. If a gamete or gametes are present, storage of such tissue would require a licence.

c) Consent to storage and use

Substituted consent is not possible under the HFE Act. Thus consent to storage cannot be given by a person with parental responsibility on behalf of any boy who has reached Tanner stage G2, nor for any girl whose tissue contains gametes. However, a child under the age of 16 can give an effective consent in accordance with the HFE Act's requirements

19 Tanner J.M. *Foetus into man: physical growth from conception to maturity*, 2nd ed. Castlemead, 1989

if he or she is competent in law to consent, i.e. if he or she is capable of understanding the implications of the proposed course of action.

If a boy is pre-pubertal (pre Tanner stage G2), or the girl's tissue does not contain a gamete or gametes, the HFE Act does not apply. However if, in the future, such material were to be developed *in vitro* in some way so as to create a gamete or gametes within the definition above, the storage or use of that material would require a licence. At that stage an effective consent would also be required in accordance with the HFE Act.

As distinct from storage and use, the common law on consent applies to the *removal* of testicular or ovarian tissue. Section 8 of the Family Law Reform Act 1969 provides that anyone who has attained the age of 16 years may give a legally valid consent to surgical or medical treatment or procedures. Some children, though under the age of 16, are perfectly able to understand the implications of medical decisions that affect them and are legally capable of giving or refusing consent to treatment. Their consent should always be sought. For those children who cannot understand, it would be for the person with parental responsibility to consent to the medical procedure where this would be in the child's best interests.

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. Concerns have been raised regarding the genetic consequences of the use of ICSI and the development of infants conceived by ICSI. The HFEA's Working Group on New Developments in Reproductive Technology (WGNDRT) has been considering these issues, and the HFEA has issued information to clinics addressing the risks of ICSI and providing guidance to centres on ICSI treatment.

In addition, because of the increased concern over risks associated with ICSI, the HFEA is keen to work with others to follow up children born as a result of this technique. During 1998 the WGNDRT wrote to selected centres inviting responses on this proposal and any other possible areas of follow up study in which the HFEA may be able to become involved. A meeting was held in September 1998 with experts from the UK and abroad to discuss these concerns and possibilities.

At the present time, a standard licence condition prohibits the transfer to the uterus of an embryo produced using ICSI in the same treatment cycle as any embryos produced by other means. This policy enables the identification of babies born as a result of ICSI, thereby enabling accurate follow up studies to be undertaken and meaningful information about the performance of ICSI in individual centres to be collected. However, a number of licensed centres have expressed their

concern about this licence condition, arguing that the restriction on mixing embryos is not in the best interests of patients. In light of this, the HFEA invited views from clinics performing ICSI about this condition and how its implementation has affected their practices, and we are currently considering the responses.

DEPARTMENT OF HEALTH'S CONSULTATIONS

In February 1997 the then Government commissioned Professor Sheila McLean of Glasgow University to conduct a review on the HFE Act's requirements for written consent[20]. In June 1997 Tessa Jowell, Minister for Public Health, announced that there would be a review of the law covering surrogacy. A consultation document was published by the surrogacy review team in October 1997[21]. The HFEA has responded to both these reviews.

20 Consent and the Law: Review of the current provisions in the Human Fertilisation and Embryology Act 1990, September 1997

21 Surrogacy: review for the UK Health Ministers of current arrangements for payments and regulation, Professor Margaret Brazier, Professor Susan Golombok and Professor Alastair Campbell, October 1997

Communications

6

INTRODUCTION

The HFE Act requires the HFEA to 'publicise the services provided to the public by the HFEA or provided in pursuance of licences' and to 'provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos ... or may wish to do so.'[22] In fulfilling this function the HFEA offers a comprehensive range of information for actual or prospective patients and donors and the general public[23]. We receive, on average, 150 requests per week for our publications. About once a year the HFEA sends a 'Chairman's letter' to licensed clinics, informing them of recent policy decisions and discussing areas of concern. This is to be replaced by a newsletter allowing broader coverage of HFEA news.

The HFEA works closely with many journalists and media researchers and supplies speakers for national and international conferences and for press, radio and television interviews. In addition, HFEA Members and staff have written dozens of articles for mainstream, specialist and patient publications. This year the HFEA went online (www.hfea.gov.uk), with comprehensive information for people considering or undergoing treatment. The contents of the website will be expanded in 1998/9.

REVIEW OF THE PATIENTS' GUIDE TO DI AND IVF CLINICS AND OTHER PATIENT LITERATURE

The HFEA aims to make its literature as comprehensible and as user friendly as possible, and is currently reviewing its format, design and availability. During 1998/99 the HFEA will be reviewing all of its literature to ensure that it best meets the needs of patients and the general public.

THE HFEA ANNUAL CONFERENCE

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

The seventh HFEA Annual Conference was held in December 1997 and attended by almost three hundred delegates. Dr Ian Wilmut of the Roslin Institute discussed the implications of his team's cloning of Dolly the sheep, and Dr Ann Chandley and Professor Inge Liebaers discussed

22 HFE Act, section 8(c)

23 see Annex 8.

the scientific and other concerns with intra-cytoplasmic sperm injection (ICSI). There were also workshops on licensing and audit, multiple pregnancy and the policy on the number of embryos transferred, and the review of the Patients' Guide. The conference closed with a question and answer session with the HFEA's Chairman, Deputy Chairman and Chief Executive.

The 1998 Conference will take place in December, and the programme will include sessions on the assessment of 'welfare of the child', the licensing of new procedures, and the perspectives of various patients.

REGIONAL AND OTHER MEETINGS

The HFEA recognises the importance of maintaining a continual dialogue with all those involved or interested in the area of assisted reproduction. For example, in December 1997 the HFEA Chairman and Deputy Chairman met with representatives of various groups opposed to practices which the HFEA has a statutory duty to regulate, to discuss current areas of concern. We found this a useful occasion and would like to thank those bodies that took part.

Also in line with this policy the HFEA together with the BFS has organised regional meetings in Sheffield, Bristol and Birmingham. Future meetings are planned for Glasgow and Cambridge. These meetings are opportunities for all those involved in licensed infertility treatments – patients, clinicians, embryologists, nurses, counsellors and researchers – to discuss HFEA policy in an open forum with HFEA representatives.

In addition, HFEA representatives have had regular meetings with members of the British Fertility Society and the Royal College of Obstetricians and Gynaecologists. There is also ongoing contact with other organisations including the patient representative groups Child and Issue, the British Medical Association, the Health Education Authority, the Family Planning Association, the General Medical Council, Progress, DI Network, the British Infertility Counselling Association, the British Andrology Society, the Association of Clinical Embryologists and the Royal College of Nursing. The HFEA also works closely with the Department of Health on many areas of mutual concern.

Annex 1

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

CHAIRMAN
Ruth Deech
Principal
St Anne's College,
Oxford

DEPUTY CHAIRMAN
Jane Denton
Nursing Director,
The Multiple Births Foundation,
Queen Charlotte's & Chelsea Hospital, London

MEMBERS

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

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

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

Moira Coath
Solicitor
Non-executive Director of Dorset Healthcare NHS Trust

Liz Forgan
Broadcaster,
journalist, and media consultant

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

David Greggains
Director,
Gorham &
Partners Ltd

Professor Andrew Grubb
Professor of Medical Law,
University of Cardiff

Professor Martin Johnson
Professor of Reproductive Sciences,
University of Cambridge

Richard Jones
Legal Consultant

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

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

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

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

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

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

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

Julia Tugendhat
Family therapist

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

Annex 2

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

Standing Committees

Audit Committee

Joan Stringer (Chairman)
Gulam Bahadur
David Greggains
John Williams

Code of Practice Committee

Jane Denton (Chairman)
Gulam Bahadur
Ruth Chambers
Andrew Grubb
Anne McLaren
Michael Nazir-Ali
Allan Templeton

Communications Steering Group

Stuart Lewis (Chairman)
Moira Coath
Liz Forgan
Brian Lieberman
Joan Stringer
Anthony Thiselton

Ethics Committee

Michael Nazir-Ali (Chairman)
Liz Forgan
Christine Gosden
Andrew Grubb
Anthony Thiselton
Julia Tugendhat
John Williams

Information Committee

John Williams (Chairman)
David Barlow
Ruth Chambers
Stuart Lewis
Brian Lieberman
Allan Templeton
Julia Tugendhat

Co-opted members:

Clare Brown
Peter Donnelly
Angela Mays
Alison Murdoch
Tony Rutherford

Licensing and Fees Committee

Julia Tugendhat (Chairman)
David Barlow
Jane Denton
Christine Gosden
David Greggains
Martin Johnson
Richard Jones

Organisation and Finance Committee

Ruth Deech (Chairman)
Moira Coath
Jane Denton
David Greggains
Richard Jones
Joan Stringer

Working Group on New Developments in Reproductive Technology

Anne McLaren (Chairman)
Gulam Bahadur
David Barlow
Jane Denton
Christine Gosden
Martin Johnson
Richard Jones
Brian Lieberman
Allan Templeton
Observer: Dr Elaine Gadd

Ad Hoc Committees

Advisory Group on Safe Cryopreservation

Jane Denton (Chairman)

Co-opted members

Ian Cooke
Karin Dawson
Lynn Fraser
Stewart Irvine
David Pegg
Richard Tedder
Maureen Wood

HFEA/ACGT Working Group on Pre-Implantation Genetic Diagnosis

Allan Templeton (Chairman) (HFEA)
Liz Forgan (HFEA)
Christine Gosden (HFEA)
Stuart Lewis (HFEA)
Anne McLaren (HFEA)
Hillary Harris (ACGT)
Philip Webb (ACGT)

Working Group on Embryo Biopsy

Brian Lieberman (Chairman)

Co-opted members

Karin Dawson
Ian Findley
Joyce Harper
Alan McDermott

HGAC/HFEA Working Group on Cloning

Revd Dr John Polkinghorne (HGAC) (Chair)
Professor Christine Gosden (HFEA)
Dr Anne McLaren (HFEA)
Dr George Poste (HGAC)

Annex 3

EXECUTIVE STAFF

Main telephone no: 0171 377 5077

	Job Title	*Telephone Extension*
Suzanne McCarthy	Chief Executive	202
Senior Managers		
Mark Salmon	Policy and Finance Manager	208
Dr David Thorne	Licensing Manager	215
Allan Wright	Information Technology Manager	206
Administration		
Derek Hodge	Personnel and Resources 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	
Anne-Louise Crowther	Systems & Data Auditor	212
Sarah Quereshi	Systems & Data Auditor	223
Communications		
Barney Wyld	Director of Communications	205
Data		
Dr Richard Baranowski	Deputy Information Manager	228
Debra Farrell	Deputy Register Supervisor	231
Tina Kundu	IT Support and Research Assistant	209
Maureen Goodman	Data Officer	230
Patricia Honnor	Data Officer	220
Gaby Jeremiah	Data Officer	220
Sandy Lathleiff	Data Officer	230
Kerri Reardon	Data Administration Officer	231
Finance		
Gill Davidson	Finance Manager	204
Tony Smith	Accounts Manager	200
Licensing		
Anne-Louise Crowther	Inspector Co-ordinator	212
Kim Hayes	Inspector Co-ordinator	211
Dr Debbie Holland-Jaggers	Inspector Co-ordinator	221
Nan Hume	Inspector Co-ordinator	213
Sarah Quereshi	Inspector Co-ordinator	222
Alison Threlfall	Inspector Co-ordinator	223
Dr Mary Wall	Inspector Co-ordinator	214
Kerri Treston	Licence Administrator	216
Policy		
Danielle Marx	Policy Manager	207
Carol Perkins	Policy Manager	219
Dr Virginia Shires	Policy Manager	207

Annex 4

LIST OF LICENSED CLINICS
(as of 30 September 1998)

Avon

Royal United Hospital, Bath

Centre for Reproductive Medicine, University of Bristol

University of Bristol, St Michael's Hospital, Bristol

Southmead General Hospital, Bristol

Tower House Clinic, Bristol

University of Bristol IVF Service, The BUPA Hospital, Bristol

Berkshire

Belmore Park Health Centre, Reading

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

Cleveland Fertility Centre, Stokesley

Derbyshire

Derby City General Hospital

Devon

Royal Devon and Exeter Hospital, Exeter

Southwest Centre for Reproductive Medicine, Derriford Hospital, Plymouth

Dorset

Winterbourne Hospital, Dorchester

Durham

Bishop Auckland General Hospital

East Sussex

Assisted Conception Unit, The Esperance Private Hospital, Eastbourne

Essex

Brentwood Fertility Centre, The Essex Nuffield Hospital

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 District General Hospital

Queen Mary's Hospital, Sidcup

Leicestershire

Middle England Fertility Centre, BUPA Hospital, Leicester

Leicester Royal Infirmary

London (Central)

Assisted Reproduction and Gynaecology Centre, Welbeck Street

Bridge Fertility Centre, London Bridge Hospital

Chelsea & Westminster Hospital

Churchill Clinic

The Cromwell IVF and Fertility Centre

Dr Louis Hughes

Lister Hospital

London Gynaecology and Fertility Centre, Harley Street

London Womens' Clinic/ Hallam Medical Centre

The Portland Hospital

St Bartholomew's Hospital

Assisted Conception Unit, St Thomas' Hospital

Seymour Clinic, St Mary's Hospital

Assisted Conception Unit, University College Hospital

Reproductive Medicine Unit, University College Hospital

London (East)

Homerton Hospital

Multicare International Ltd, Harbour Exchange

Newham General Hospital

London (North)

London Female and Male Fertility Centre, Highgate Private Hospital

London (South)

King's College Hospital

Diana, Princess of Wales Centre for Reproductive Medicine, St Georges' Hospital, Tooting

London (West)

West Middlesex University Hospital

Wolfson Family Clinic, Hammersmith Hospital

Merseyside

Fazakerley Hospital, Liverpool

Liverpool Women's Hospital

Wirral Fertility Centre,

BUPA Murrayfield Hospital,

Northern Ireland

The Regional Fertility Centre, Royal Maternity Hospital, Belfast

Norfolk

Fertility Centre, BUPA Hospital, Norwich

Northamptonshire

Northamptonshire Fertility Service, Three Shires Hospital, Cliftonville

Nottinghamshire

Centres for Assisted Reproduction Ltd (CARE), Park Hospital, Arnold

Fertility Service, Nottingham City Hospital

NURTURE, University of Nottingham

Queen's Medical Centre, Nottingham

Oxfordshire

Oxford Fertility Unit, John Radcliffe Hospital, Oxford

Scotland-Grampian

Assisted Reproduction Unit, Aberdeen Maternity Hospital, Aberdeen

Scotland-Lothian

Royal Infirmary of Edinburgh

Western General Hospital Infertility Clinic, 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

Surrey

Fertility Treatment Centre, Shirley Oaks Hospital, Croyden

Woking Nuffield Hospital

Tyne and Wear

Royal Victoria Infirmary, Newcastle upon Tyne

The Cromwell IVF & Fertility Unit, Sunderland District General Hospital

Cromwell IVF & Fertility Centre, Washington Hospital

Centre for Assisted Reproduction, 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 Women's Hospital

BMI Priory Hospital, Birmingham

Wolverhampton Assisted Conception Unit, New Cross Hospital, Wolverhampton

Walsgrave Hospital, Coventry

Yorkshire (South)

Jessop Hospital for Women, Sheffield

Sheffield Fertility Centre

Yorkshire (West)

Clarendon Wing, Leeds General Infirmary

St James' University Hospital, Leeds

CLINICS WITH SPERM STORAGE LICENCES ONLY

North West Wales Fertility Centre, Gwynedd Hospital, Bangor

Cheltenham General Hospital

Royal Surrey County Hospital, Guildford

Bridge Centre Cryoservices, London

Andrology Unit, Hammersmith Hospital

Department of Semenology, Nottingham City Hospital

Singleton Hospital, Swansea

Yorkshire Regional Tissue Bank, Wakefield

Annex 5

LIST OF HFEA INSPECTORS
(as of 31 July 1998)

CLINICIANS

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

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

Dr 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 Obstetrician & Gynaecologist
Senior Lecturer, Royal Infirmary of Edinburgh NHS Trust

Dr John Mills
Consultant Obstetrician & Gynaecologist
Ninewells Hospital, Dundee

Dr Alison Murdoch
Consultant Obstetrician & Gynaecologist
Honorary Senior Lecturer
Head of Department of Reproductive Medicine, Royal Victoria Infirmary, Newcastle-upon-Tyne

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

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

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

Dr Elizabeth Pease
Clinical Assistant,
St Mary's Hospital, Manchester

Dr David Polson
Senior Registrar in Obstetrics & Gynaecology,
Salford Royal IVF & Fertility Centre

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

Mr Robert Sawers
Consultant Obstetrician & Gynaecologist
Programme Director, Birmingham & Midland Hospital for Women

Dr Francoise Shenfield
Reproductive Medicine Unit,
University College London Medical School

Mr Eric Simons
Medical Director,
Cromwell Hospital, London

Dr Alison Taylor
Senior Registrar
Lecturer, St Thomas' Hospital

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

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

Dr John Waterstone
Consultant Obstetrician and Gynaecologist, Bon Secours Hospital, Cork, Ireland

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 and Education,
University of Exeter

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

Dr John Clarke
Retired lecturer in Zoology
University of Oxford

Dr John Coutts
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.

Ms Ceinwen Gearon
IVF Laboratory Director
Lister Hospital, London

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

Professor Henry Leese
Scientist, Department of Biology,
University of York

Mr Terry Leonard
Senior Embryologist,
Northamptonshire Fertility Services

Dr Alan McDermott
Director, 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

Mr 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
Relate
Psychological Therapist and Fertility Counsellor at Royal Devon and Exeter Hospital

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

Ms Jennifer Clifford
Counsellor

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

Ms Marilyn Crawshaw
Social Worker

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

Mrs Heideh Hillier
IVF Nurse Manager,
Edinburgh Assisted Conception Unit

Ms Jennifer Hunt
Senior Infertility Counsellor,
Hammersmith Hospital, London

Ms Margaret Inglis
Counsellor,
Royal Free Hospital, London

Ms Janice Kerr
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, Oxford

Ms Jennifer Speirs
Director of Family Care,
Edinburgh

Annex 6

LIST OF RESEARCH PROJECTS
(as of 31 July 1998)

Centre for Genome Research, University of Edinburgh

Culture of multipotential human embryos

Glasgow Royal Infirmary

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

Centres for Assisted Reproduction Ltd (CARE), Park Hospital, Nottinghamshire

Diagnosis of the common aneuploidies in human preimplantation 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*

Study of human eggs matured *in vitro* and *in vivo*

The Hammersmith Hospital, London

Preimplantation 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

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

Newham General Hospital

Effect of angiotensin II on *in vitro* sperm capacitation and egg penetration in the golden hamster

NURTURE, University of Nottingham

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

Oxford Fertility Unit

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

Development of a model to study implantation in the human

Royal Infirmary of Edinburgh

Cell biology of human spermatozoa

Royal Victoria Infirmary, Newcastle upon Tyne

A study of mosaic chromosomal abnormalities in human blastocysts and their relationship to mosaicism in the late trimester

St Mary's Hospital, Manchester

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

St Thomas' Hospital, London

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

University College Hospital, London

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

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 (with St Mary's Hospital)

University Of York

Biochemistry of early human embryos

Walsgrave Hospital, Coventry

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

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

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

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

Annex 7

LIST OF PEER REVIEWERS
(As of 31 July 1998)

Professor John Aitken

MRC Special Appointment,
MRC Reproductive Biology Unit,
Edinburgh

Dr Gulam Bahadur

Clinical Biochemist
Head of Fertility Laboratories,
University College London

Medical School / University College,
London Hospital Trust

Professor David Barlow

Nuffield Professor of Obstetrics and Gynaecology, University of Oxford

Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital, Oxford

Professor Peter Braude

Chairman of UMDS Department of Obstetrics and Gynaecology,

Director of Fertility Services, Guy's and St Thomas', London

Dr Nigel A Brown

Reader, Head of Teratology,
St George's Hospital Medical School,
London

Professor Tim Chard

Professor of Obstetrics and Gynaecology,
St Bartholomew's Hospital Medical College, London

Dr J R T Coutts

Reader, Division of Biochemistry and Molecular Biology,
University of Glasgow

Professor Mark Curry

Professor of Human Reproduction,
University of Cambridge,

Dr Simon Fishel

Managing Director, CARE, Park Hospital, Arnold, Nottingham

Professor Stephen Franks

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

Professor Lynn Fraser

Professor of Reproductive Biology,
Kings College, London

Professor Christine Gosden

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

Professor Roger Gosden

Professor of Reproductive Biology,
University of Leeds

Dr Geraldine Hartshorne

Scientific Director, Walsgrave Hospital Assisted Conception Unit, Coventry

Principal Research Fellow,
Department of Biological Sciences,
University of Warwick

Dr Alan Handyside

Reader in Reproductive Genetics

Scientific Director, Assisted Conception Unit, UMDS Guy's and St Thomas', London

Mr Jonathan Hewitt

Consultant Gynaecologist,
Liverpool Womens Hospital

Professor Martin Johnson

Professor of Reproductive Sciences,
University of Cambridge

Dr M H Kaufman

Professor of Anatomy,
University of Edinburgh

Mr Charles Kingsland

Consultant in Obstetrics and Gynaecology,
Liverpool Women's Hospital

Professor G.E. Lamming

Department of Physiology and Environmental Science,
University of Nottingham

Professor Henry Leese

Scientist, Department of Biology,
University of York

Dr Brian Lieberman

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

Dr Alan McDermott

Director, Regional Cytogentics Centre, Southmead Hospital, Bristol

Dr Anne McLaren

Principal Research Associate,
Wellcome/CRC Institute, Cambridge

Professor Marilyn Monk

Head of Molecular Embryology Unit,
Institute of Child Health, London

Professor R Moor

Head of Development and Genetics,
Babraham Institute, Cambridge

Professor H D M Moore

Professor, Department of Molecular Biology and Biotechnology,
University of Sheffield

Dr David Pegg

Director, Medical Cryobiology Unit,
Biology Department, University of
York

Dr Karl Swann

Lecturer,
University College London

Professor Allan Templeton

Professor of Obstetrics and
Gynaecology,
University of Aberdeen

Reverend Professor Paul Watson

Professor of Reproductive
Cryobiology,
Royal Veterinary College, London

Professor Michael Whitaker

Head of Department of
Physiological Sciences,
University of Newcastle-upon-Tyne

Dr Maureen Wood

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

Professor David Whittingham

Professor of Embryology,
Department of Anatomy and
Developmental Biology,
St George's Hospital Medical School

Annex 8

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. All of the HFEA's literature is to be reviewed during 1998-9

Annual Reports: 1992-97

Clinics' data on DI and IVF treatments

(Comprehensive data on the outcomes for licensed treatments at each licensed centre, April 1996–March 1997)

List of all licensed clinics

List of sperm donor recruitment centres

List of egg donor centres

Code of Practice *(Fourth Edition)*

Information leaflets:

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

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

Website: http://www.hfea.gov.uk

Annex 9

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 which contain the genes.

Clinical pregnancy

Ultrasound evidence of a fetal heart.

Clinical pregnancy rate

This is calculated as a proportion of pregnancies with beating heart for every 100 treatment cycles commenced.

Cloning

The production of genetically identical (sharing the same nuclear gene set) individuals.

Clones

Organisms that are genetically identical (share the same nuclear gene set) to each other.

Congenital abnormalities

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

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.

Cytoplasm

The material between the nucleus and the cell surface.

Directions

The HFE Act allows the HFEA 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 of a woman with 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 1-1.5 mm 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

A reproductive cell such as a mature egg or a sperm

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 HFEA 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 28 days after the birth.

Perinatal death

The death of a baby either in the uterus after 24 weeks pregnancy (stillbirth) or within 28 days after the birth.

Preimplantation genetic diagnosis

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

Primitive streak

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

Spermatid

An immature sperm cell.

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 (e.g. ovulation induction or egg retrieval) are performed at a secondary centre (not necessarily HFEA licensed). The embryology and embryo transfer take 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.

c) A DI treatment cycle begins when the first insemination with donor sperm takes place.

Financial Report 1996/7

FOREWORD

BACKGROUND

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

The Authority is a Non-Departmental Public Body sponsored by the Department of Health.

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

Statutory Remit

The main statutory function of the Authority is to regulate, by means of a licensing system, centres undertaking infertility treatment involving the creation or use of embryos outside the body, the storage or donation of embryos or gametes or research involving human embryos.

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

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

PRINCIPAL ACTIVITIES

Licensing:

On 31 March 1997 there were a total of 123 licensed centres. During the year, 111 inspection visits were carried out and 30 Licence Committee meetings were convened to consider 279 items relating to the activities of the centres. A total of 148 licenses were issued during the year (73 IVF treatment, 38 DI treatment, 12 Storage and 25 research licenses).

The Authority's Systems and Data Auditor began a five year inspection process of all licensed clinics in October 1996. The programme has been established to ensure that centres and the Authority are complying with their statutory obligations.

Information:

The Authority collects data from all licensed centres about IVF and donor insemination treatments and their outcomes and about every donor. The Authority also currently publishes the outcome data for individual clinics in the form of a Patients' Guide.

In order to ensure the long term accuracy of the data, to maintain relevance of data collected in the light of new medical practice and to keep pace with the growing size of the register, the Authority continues to work on the redevelopment of its database programs.

Ethics and Policy:

During the year the Authority was involved in a number of high profile court cases. These related to the ending of the statutory storage period for human embryos created and stored before 1st August 1991, and the posthumous use of human sperm. These cases substantially increased the professional fees paid to its legal advisers by the Authority in comparison with previous years.

FINANCIAL REPORT

Overall Results

The operating surplus for the year amounted to £98,040.

Performance against key financial targets

1. Expenditure

The Authority must ensure that its cash expenditure remains within the budget set by the Department of Health. In the year 1996/7 the actual cash expenditure was £1,493,841 which was 99.5% of the allocated budget of £1,501,243. 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 ways of reducing costs are continually being considered and, wherever possible, introduced.

2. Licence Fees

In the year the Authority's financial objective was to raise 70% of its expenditure through licence fees. This level is also set for 1997/98. The proportion for the following years is currently being reviewed by the Department of Health and the Treasury.

The fee structure is made up of an initial and an additional fee. Each centre is required to pay an initial fee on application. 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 Authority's 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 amount raised in cash from licence fees in 1996/7 was £1,086,175 which was 72.7% of the cash expenditure. The Authority intends to review both the structure of fee collection and the level of fees when the new income targets for 1998/99 onwards have been issued in order to ensure that the Authority's financial targets are met.

3. Other Targets

The Authority is currently working with the Department of Health on the development of further performance measures.

Payment of Creditors

The Authority has adopted the Treasury's guidance on prompt payment and works to ensure that all invoices which are not in dispute are paid within 30 days. In 1996/7 the Authority paid 100% of non-disputed invoices within 30 days and 37% within 7 days.

Post Balance Sheet Events

There have been no post balance sheet events.

Charitable Donations

There have been no charitable donations.

Related Party Transactions

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

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

Equal Opportunities

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

Consultation with Employees

In the past year employees have been consulted regarding the Pay and Grading Review, which included an assessment of the Authority's Performance Appraisal system, and on matters of Health and Safety.

HFEA Membership

The Authority is made up of the Chairman, Deputy Chairman and nineteen members. Members who have served the Authority for some period of the year 1996/7 are listed in Annex A.

FUTURE DEVELOPMENTS

In addition to the recurring work involved in licensing, policy, information and communications, the Authority has placed the following issues on its agenda for the financial year 1997/98:

- The review of the new licensing system.
- The further development the licensing information management system.
- Further examination of the implementation programme for the Authority's policy on non-payment for donors.
- The continued development of the Authority's policy on pre-implantation genetic diagnosis.
- The continued development of the Authority's policy on cloning.
- The completion of work on the safe cryopreservation of sperm and embryos.
- Responding to the Department of Health reviews of the 1990's Act's requirement for written consent, and surrogacy.
- The ongoing development of its data register system. In undertaking this work programme the Authority will continue to strive for the highest possible standards while also giving close attention to the need to provide best value for money.

Signed: Suzanne McCarthy

Position: Chief Executive

Date: 6 November 1997

Annex A

Membership of the Human Fertilisation and Embryology Authority 1996/7

Ruth Deech (Chairman)
Lady Diana Brittan (Deputy Chairman)
Dr Gulam Bahadur
Professor Sam Berry
Dr Ruth Chambers
Mrs Jane Denton
Ms Liz Forgan
Professor Christine Gosden
Mr David Greggains
Mrs Joan Harbison
Professor Stephen Hillier
The Most Reverend Richard Holloway
Professor Martin Johnson
Mr Richard Jones
Ms Penelope Keith
Professor Stuart Lewis
Dr Brian Lieberman
Mrs Angela Mays
Dr Anne McLaren
Dr Jeanette Naish
Professor Rory Nicol
Dr Joan Stringer
Professor Allan Templeton
Professor the Reverend Canon Anthony Thistleton
Lady Julia Tugendhat
Mr John Williams

STATEMENT OF AUTHORITY'S AND CHIEF EXECUTIVE'S RESPONSIBILITIES

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

In preparing the accounts the Authority is required to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed, and disclose and explain any material departures in the financial statements;
- prepare the financial statements on the going concern basis, unless it is inappropriate to presume that the Authority will continue in operation.

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

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 47 to 54 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 50.

Respective responsibilities of the Authority, the Chief Executive and the Auditor

As described on page 46 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.

Basis of opinion

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

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

Opinion

In my opinion:

- the financial statements give a true and fair view of the state of affairs of the Human Fertilisation and Embryology Authority at 31 March 1997 and of the surplus, 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
19 November 1997
National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31 MARCH 1997

	Notes	£	1996/97 £	Restated* 1995/96 £
Gross Income				
- Government grants	2		**377,609**	329,130
- Income from licensing			**1,453,307**	1,004,158
- Income from other sources			**1,274**	1,177
			1,832,190	1,334,465
Transfer from reserves/deferred government grant	13		**43,485**	51,856
			1,875,675	1,386,321
Expenditure				
- Staff costs	3	**720,134**		586,358
- Depreciation	5	**43,485**		51,856
- Other operating charges	4	**1,014,016**		752,345
			1,777,635	1,390,559
Operating surplus/(deficit)	6		**98,040**	(4,238)
Notional interest - (capital charges)	9		**25,500**	18,500
Surplus/(deficit) on ordinary activities			**72,540**	(22,738)
Write back of notional interest			**25,500**	18,500
Surplus/(deficit) for the financial year			**98,040**	(4,238)
Appropriations	7		**–**	–
			98,040	(4,238)
Retained surplus/(deficit) brought forward			**44,589**	48,827
Retained surplus carried forward			**142,629**	44,589

• *1995-96 figures have been restated to take account of the write-back of Notional Interest*

STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES

	Notes	1996/97 £	Restated 1995/96 £
(Deficit)/Surplus for financial year		**98,040**	(4,238)
Revaluation of fixed assets	5	**(4,196)**	3,654
Total recognised gains/(losses) for the year		**93,844**	(584)

The notes on pages 50 to 54 form part of these accounts.

BALANCE SHEET AS AT 31 MARCH

	Notes	£	1996/97 £	Restated 1995/96 £
Assets Employed				
Fixed Assets				
- Tangible Assets	5		**112,683**	121,191
Current Assets				
- Debtors: amounts falling due within one year	8	540,165		243,597
Amounts falling due after one year		28,151		516
- Cash at bank and in hand		42,568		32,138
		610,884		276,251
Creditors				
Amounts falling due within one year	10	(250,069)		(74,848)
Net current assets			**360,815**	201,403
Total assets less current liabilities			**473,498**	322,594
Financed by Accruals and Deferred Income				
- Deferred government grant	13		**108,596**	112,908
Capital and Reserves				
- Income and Expenditure account	13		**142,629**	44,589
- Revaluation Reserve	13		**4,088**	8,284
- Notional Superannuation Costs	11		**218,185**	156,813
			473,498	322,594

The notes on pages 50 to 54 form part of these accounts

Suzanne McCarthy
Chief Executive
7 November 1997

CASH FLOW STATEMENT FOR THE YEAR ENDED 31 MARCH 1997

	Notes	£	1996/97 £	£	Restated 1995/96 £
Net cash inflow/(outflow) from operating activities	19		**10,430**		(9,583)
Capital expenditure					
- Purchase of tangible fixed assets	5	(39,173)		(33,769)	
- Net cash outflow from capital expenditure			**(39,173)**		(33,769)
Net cash outflow before financing			**(28,743)**		(43,352)
Financing					
- Receipts of Government Grants for fixed assets		14	**37,713**	21,898	
- Transfer from revenue grant	13	1,460		11,871	
- Net cash inflow from financing			**39,173**		33,769
Decrease in Cash and Cash Equivalents			**10,430**		(9,583)

The notes on pages 50 to 54 form part of these accounts.

NOTES TO THE ACCOUNT

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.

(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	1996/7 £	1995/96 £
Department of Health		
Class XI, Vote 2	**1,223,961**	1,101,762
Less:		
Licence fees retained, payable to the Department of Health	**(1,453,307)**	(1,004,158)
Add: miscellaneous income adjustment	**365,885***	-
Net grant funds returned to the Department of Health	-	-
	136,253	97,604
Scottish Office, Home and Health Dept., Class XIII, Vote 4,	**136,253**	136,740
Welsh Office Class XIV, Vote 4,	**68,127**	68,370
Department of Health and Social Services, Northern Ireland Class XV, Vote1	**38,150**	38,287
	379,069	341,001
Less Transfer for Deferred Government Grant Reserve (Note 13)	**(1,460)**	(11,871)
	377,609	329,130

** Accruals accounting adjustment to take account of changes in trade debtors and miscellaneous income. 1995-96 figures not adjusted.*

3. Staff Costs

	1996/7 £	1995/6 £
(a) Remuneration of Authority Members		
Fees paid to members including Chairman	**76,298**	67,716
Social Security Costs	**2,411**	1,815
Reversal of National Insurance Provision (Note 11)	-	-
	78,709	69,531

	1996/7 £	1995/6 £
(b) Salaries - HFEA Staff	**454,295**	334,226
Salaries - Seconded Staff	**58,604**	89,067
Social Security Costs	**43,178**	36,602
Superannuation Contributions	**72,565**	54,592
Agency Staff	**12,783**	2,340
	641,425	516,827

The Superannuation Contributions includes a notional charge of £61,372 for Authority employees (Note 12).

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

	1996/7 No.	1995/6 No.
Management	**5**	4
Administrative	**23**	22
	28	26

(d) The remuneration for the Chairman for the year was £8,785.

(e) The emoluments paid to the former chief executive in the year were £19,438.

The emoluments paid to the present chief executive in the year were £40,731.

Both chief executives were normal members of the Principal Civil Service Pension Scheme.

Two executive members of staff, ordinary members of the Human Fertilisation & Embryology Pension Scheme Principal Civil Service Pension Scheme, received remuneration between £40,000 and £50,000.

Three executive members of staff, all ordinary members of the Human Fertilisation & Embryology Pension Scheme Principal Civil Service Pension Scheme, received remuneration between £30,000 and £40,000.

No other executive members of staff received remuneration of more than £30,000.

4. Other Operating Charges

	1996/97 £	1995/96 £
Accommodation	**202,646**	214,115
Travel & Subsistence - Employees	**11,992**	4,350
Travel & Subsistence - Members	**43,904**	36,246
Travel & Subsistence - Inspectors	**49,200**	28,986
Attendance Fees - Inspectors	**24,675**	22,282
Professional & Administrative Fees	**290,950**	114,755
Audit Fees	**10,000**	10,000
Register of Information	**93,161**	56,196
Stationery & Printing	**92,481**	102,491
Photocopying Charges	**15,434**	19,757
Telephones & Postage	**35,131**	29,531
Communications	**2,998**	2,556
Training & Staff Development	**42,840**	28,368
Recruitment & Advertising	**22,360**	42,705
Conferences & Meeting Expenses	**21,319**	19,817
Library & Reading Materials	**8,539**	6,270
Sundry Office Equipment	**8,935**	12,523
Miscellaneous	**6,451**	1,397
Provision for Doubtful Debts	**31,000**	-
Total	**1,014,016**	**752,345**

5. Tangible Fixed Assets as at 31 March 1997

	Computer Equipment £	Office Equipment £	Furniture & Fittings £	Installations £	Totals £
Cost as at 1 April 1996	125,216	22,290	90,933	53,869	292,308
Additions	7,126	0	8,855	23,192	39,173
Disposals	0	0	0	0	0
Revaluation	(10,876)	(1,936)	1,621	959	(10,232)
As at 31 March 1997	**121,466**	**20,354**	**101,409**	**78,020**	**321,249**
Depreciation as at 1 April 1996	74,264	12,503	73,748	10,602	171,117
Charge for the year	22,510	4,625	9,553	6,797	43,485
Disposals	0	0	0	0	0
Revaluation	(6,451)	(1,086)	1,313	188	(6,036)
As at 31 March 1997	**90,323**	**16,042**	**84,614**	**17,587**	**208,566**
Net Book Value (NBV)					
At 31 March 1997	**31,143**	**4,312**	**16,795**	**60,433**	**112,683**
At 31 March 1996	50,952	9,787	17,185	43,267	121,191
Increase (Decrease) in NBV	(19,809)	(5,475)	(390)	17,166	(8,508)

6. Operating Surplus

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

	Licensing 1996/97 £	1995/96 £	Others 1996/97 £	1995/96 £	Total 1996/97 £	1995/96 £
Income						
Government grant	-	-	**377,609**	329,130	**377,609**	329,130
Licence fees	**1,453,307**	1,004,158	-	-	**1,453,307**	1,004,158
Other	-	-	**1,274**	1,177	**1,274**	1,177
Transfer from Reserves	**21,742**	25,928	**21,743**	25,928	**43,485**	51,856
Total	**1,475,049**	1,030,086	**400,626**	356,235	**1,875,675**	1,386,321
Expenditure						
Staff Costs	**(407,311)**	(242,645)	**(312,823)**	(343,713)	**(720,134)**	(586,358)
Depreciation	**(21,742)**	(25,928)	**(21,743)**	(25,928)	**(43,485)**	(51,856)
Other Charges	**(621,456)**	(402,747)	**(392,560)**	(349,598)	**(1,014,016)**	(752,345)
Total	**(1,050,509)**	(671,320)	**(727,126)**	(719,239)	**(1,777,635)**	(1,390,559)
Operating Surplus/(Deficit)	**424,540**	358,766	**(326,500)**	(363,004)	**98,040**	(4,238)

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 pensions transfer receipts payable to the consolidated fund via the Department of Health.

8. Debtors

	1996/97 £	1995/96 £
Debtors (Licence Fees)	**460,009**	123,877
Other Debtors	**7,937**	4,447
Pre-payments	**100,370**	115,789
	568,316	244,113

At 31 March1997, the Authority had debts of £28,151 that were over one year old. The Authority continues to pursue these disputed licence fee debts and is confident of clearing them in the coming year.
The Authority had a total of £7,854.59 outstanding for staff loans at 31 March 1997. No individual member of staff had more than £2,500 outstanding.

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 and Expenditure Account amounting to £25,500.

10. Creditors: Amounts falling due within one year

	1996/97 £	1995/96 £
Trade Creditors	**0**	0
Other Taxes and Social Security	**48,209**	41,725
Accruals	**201,860**	33,123
	250,069	74,848

11. Reserves

	Notional Superannuation £
Balance at 1.4.96	156,813
Increase in year	61,372
Balance at 31.3.96	218,185

12. Pension Arrangements

Seconded staff belong to the Principal Civil Service Pension Scheme. For 1996/97 contributions of £8,866 were made to the Paymaster General at rates determined from time to time by the Government Actuary and advised by the Treasury. For 1996/97 these rates were 11% and 17.5% for non-industrial staff. For its own employees, the Authority operates an analogous non-contributory scheme, to which the conditions of the Superannuation Acts 1965 and subsequent amendments apply. In 1996/97 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	112,908	44,589*	8,284
Revaluation of fixed assets			(4,196)
1996/97 capital grant	37,713		
Transfer from Revenue Grant	1,460		
Transfer to Income & Expenditure	(43,485)		
Surplus for the year	-	98,040	
Balance Carried Forward	**108,596**	**142,629**	**4,088**

** Income & Expenditure balance brought forward has been restated to take account of the write-back of notional interest charges*

14. Government Grants for Capital

	1996/97 £	1995/96 £
Department of Health		
Class XI, Vote 2, MVT26C (Note 13)	37,713	21,898
Transfer from Revenue Grant	1,460	11,871
	39,173	33,769

15. Capital Commitments

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

16. Contingent Liabilities

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

17. Material Losses

The Authority had no material losses in the year 1996/97.

18. Performance against key financial targets

The Authority has two key financial targets.

(a) The Authority must ensure that its cash expenditure remains within the budget set by the Department of Health. In the year 1996/7 our actual cash expenditure was £ 1,493,841 which was 99.5% of the allocated budget of £1,501,243.

(b) The Authority was also required to raise 70% of its cash expenditure from Licence Fees. The amount raised in cash from licence fees in 1996/7 was £1,086,175 which was 72.7% of the cash expenditure.

19. Notes to the Cash Flow Statement

	1996/97 £	Restated 1995/96 £
1. Reconciliation of operating deficit to net cash outflow from operating activities:		
Operating Surplus/(Deficit)	**98,040**	(4,238)
Depreciation Charges	**43,485**	51,856
Increase in Debtors	**(324,203)**	(42,497)
Increase in Creditors	**175,221**	(7,332)
Increase in Notional Superannuation Contributions	**61,372**	44,484
Transfer from Deferred Government Grant	**(43,485)**	(51,856)
Net Cash Inflow/ (Outflow) from Operating Activities	**10,430**	(9,583)
2. Reconciliation of Net Cash Flow to movement in Net Debt.		
Balance at 1 April 1996	**32,138**	41,721
Net cash Inflow	**10,430**	(9,583)
Balance at 31 March 1997	**42,568**	32,138

3. Analysis of Changes in Net Debt

	At 1/4/96	Cash Flow	At 31/3/97
Cash at Bank and in Hand	32,138	10,430	42,568

APPENDIX TO THE ACCOUNTS

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 31st March 1997 shall be as set out in the following paragraphs 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 requirements, 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

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

SCHEDULE

Foreword

1 The foreword shall include a statement that the account has 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 Account and Balance Sheet

4 The income and expenditure account and balance sheet shall follow the prescribed format shown in Annex C to "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 *Revised* shall be followed in preparation of the cash flow statement.

Statement of Total Recognised Gains and Losses

8 The recommendations of Financial Reporting Standard No. 3 shall be followed in the preparation of the and Losses 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 cost 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.

Financial Report 1997/8

FOREWORD

BACKGROUND

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

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

The HFEA's accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Determination issued by the Secretary of State for Health in May 1997 and amended by DAO 10/97 (reproduced as an appendix to these accounts).

Statutory Remit

One of the main statutory functions of the HFEA is to regulate, by means of a licensing system, centres undertaking infertility treatments involving the creation or use of human embryos outside the body, the storage or donation of embryos or gametes or research involving human embryos. The HFEA is also required to maintain a register of information about all licensed treatments performed in the United Kingdom. This contains information about those receiving treatment, donors of gametes and embryos and any children born as a result of such treatments. At the age of 18 (or 16 if wishing to marry), people may enquire as to whether information held on the register shows that they were born as a result of this treatment, and, if so, whether they are related to a prospective spouse.

In addition, the HFEA has other statutory responsibilities including:

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

PRINCIPAL ACTIVITIES

Licensing:

On 31 March 1998 there were a total of 114 licensed centres. During the year 103 inspection visits were carried out and 38 Licence Committee meetings were convened to consider 274 items relating to the activities of the centres. A total of 133 licences were issued during the year (110 Treatment and Storage Licences, 6 Storage and 17 research licences).

The year saw the start of a three year licensing programme of full and focused inspections.

The HFEA's Systems and Data Auditor began a five year inspection process of all licensed clinics in October 1996. The programme has been established to ensure that centres and the HFEA are complying with their statutory obligations.

Information:

The HFEA collects data from all licensed centres about IVF and donor insemination treatments and their outcomes and about every donor. The HFEA also published the outcome data for individual clinics in the form of a Patients' Guide.

In order to ensure the long term accuracy of the data, to maintain relevance of data collected in the light of new medical practice and to keep pace with the growing size of the register, the HFEA continues to work on the redevelopment of its database programs.

Policy:

During the year the HFEA began consulting on a number of high profile issues such as human cloning (with the Human Genetics Advisory Commission) and payment for gamete donors. In addition the HFEA completed its third revision of the Code of Practice.

FINANCIAL REPORT

Overall Results

The operating deficit for the year amounted to £164,942

Performance against key financial targets

1. Expenditure

The HFEA must ensure that its cash expenditure remains within the budget set by the Department of Health. In the year 1997/8 the actual cash expenditure was £1,481,206 which was 99.8% of the allocated budget of £1,483,900. The HFEA 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 ways of reducing costs are continually being considered and, wherever possible, introduced.

2. Licence Fees

During the three year period 1994/5-1997/8 the HFEA's financial objective was to raise 70% of its cash expenditure through collection of licence fees. Fee income has to be surrendered to the Consolidated Fund. The amount raised in cash from licence fees in 1997/98 was £1,592,780 which was 107.5% of the cash expenditure. The average amount raised from licence fees for the three year period was 83.6% of cash expenditure.

The HFEA's financial objective for the period 1998/99 to 2000/01 is to raise 70% of its cash expenditure through collection of licence fees.

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 HFEA's 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.

Payment of Creditors

The HFEA has adopted the Treasury's guidance on prompt payment and works to ensure that all invoices which are not in dispute are paid within 30 days. In 1997/8 the HFEA paid 100% of non-disputed invoices within 30 days.

Post Balance Sheet Events

There have been no post balance sheet events.

Charitable Donations

There have been no charitable donations.

Related Party Transactions

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

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

Equal Opportunities

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

Consultation with Employees

The HFEA's policy is to consult and involve staff on relevant matters such as health, safety and welfare. In October 1997 the HFEA held an executive team day, 'Working Together for Success', organised by a team of management consultants. This event was held to encourage staff to clarify and negotiate what is needed from each other to function effectively and to build capabilities as a team.

Organisational Development Study

During 1997/98 the HFEA was subject to an Organisational Development Study as part of the government wide comprehensive spending review. That study recommended, among other things, that work already in progress or planned in several main areas should continue, including the further development of a more risk based approach to inspections, the implementation of a new data register, a review of its literature and the development of performance measures.

Year 2000 Compliance

As is well known, many computer and digital storage systems express dates using only the last two digits of the year and will thus require modification or replacement to accommodate the year 2000 and beyond in order to avoid malfunctions and resulting widespread commercial disruption. This is a complex and pervasive issue. The operation of the HFEA depends not only on our own computer systems, but also to some degree on those of the clinics, our landlord and other suppliers. This could expose us to further risk in the event that there is a failure by other parties to remedy their own Year 2000 issues.

An Authority-wide programme, designed to address the impact of the Year 2000 on our business, has been commenced by the HFEA and is under way. Resources have been allocated and the Members receive reports on progress.

A significant risk analysis has been performed to determine the impact of the issue on all our activities. From this, prioritised action plans have been developed which are designed to address the key risks in advance of critical dates and without disruption to the underlying activities. Priority is given to those systems which could cause a significant financial or legal impact on the HFEA if they were to fail. The plan also includes, where relevant, a requirement for the testing of systems changes, involving the participation of users.

The risk analysis also considers the impact on our business of Year 2000 related failures by our significant suppliers (including computer bureaux) and the clinics. In appropriate cases we have initiated formal communication with these other parties.

Given the complexity of the problem, it is not possible for any organisation to guarantee that no Year 2000 problems will remain because at least some level of failure may still occur. However, the HFEA believes that it will achieve an acceptable state of readiness and will also provide resources to deal promptly with significant subsequent failures or issues that might arise.

Much of the cost of implementing the action plans will be subsumed into the recurring activities of the departments involved. A proportion of the programme has been completed in 1997-98 and most of the remainder is expected to be completed in 1998-99.

HFEA Membership

The HFEA full complement is a Chairman, Deputy Chairman and nineteen members. Members who have served the HFEA for some period of the year 1997/8 are listed in Annex A.

FUTURE DEVELOPMENTS

In addition to the recurring work involved in licensing, policy, information and communications, the HFEA has placed the following issues on its agenda for the financial year 1998/99.

- The general review of HFEA literature, in particular the Patients' Guide,including exploring alternative mechanisms for more cost effective distribution
- The development of a new system for the collection of licence fee income
- Register redevelopment within the development and implementation of the HFEA's overall IT strategy
- To continue the review of the licensing system, considering the further application of a risk based approach to the coverage of inspections; the staffing and

frequency of inspections and licence committees
- To analyse responses to HFEA's various consultations
- The development of performance measures

In undertaking this work programme the HFEA will continue to strive for the highest possible standards while also giving close attention to the need to provide best value for money.

Signed: Suzanne McCarthy
Position: Chief Executive
Date: 3 July 1998

Annex A

Membership of the Human Fertilisation and Embryology Authority 1997/8

Mrs Ruth Deech (Chairman)
Mrs Jane Denton (Deputy Chairman)
Lady Diana Brittan (Former Deputy Chairman)*
Dr Gulam Bahadur
Professor David Barlow
Professor Ruth Chambers
Ms Liz Forgan
Professor Christine Gosden
Mr David Greggains
Professor Andrew Grubb
The Most Reverend Richard Holloway*
Professor Martin Johnson
Mr Richard Jones
Professor Stuart Lewis
Dr Brian Lieberman
Mrs Angela Mays*
Dr Anne McLaren
Professor Rory Nicol*
Dr Joan Stringer
Professor Allan Templeton
Professor the Reverend Canon Anthony Thiselton
Lady Julia Tugendhat
Mr John Williams
*Retired in 1997

STATEMENT OF AUTHORITY'S AND CHIEF EXECUTIVE'S RESPONSIBILITIES

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

In preparing the accounts the Authority is required to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed, and disclose and explain any material departures in the financial statements;
- prepare the financial statements on the going concern basis, unless it is inappropriate to presume that the Authority will continue in operation.

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

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 61 to 69 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 64.

Respective responsibilities of the Authority, the Chief Executive and the Auditor

As described on page 59 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.

Basis of opinion

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

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements

are free from material misstatement, whether caused by error, or by fraud or other irregularity and that, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I have also evaluated the overall adequacy of the presentation of information in the financial statements.

Opinion

In my opinion:

- the financial statements give a true and fair view of the state of affairs of the Human Fertilisation and Embryology Authority at 31 March 1998 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
9 July 1998

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

INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31 MARCH 1998

	Notes	£	1997/98 £	£	*Restated 1996/97 £
Gross Income					
- Government grants	2		(160,424)		377,609
- Income from licensing			1,340,823		1,453,307
- Income from other sources			1,618		1,274
			1,182,017		1,832,190
Transfer from reserves/deferred government grant	13		38,540		43,485
			1,220,557		1,875,675
Expenditure					
- Staff costs	3	753,545		720,134	
- Depreciation & revaluation of computer equipment	5/21	40,831		47,910	
- Other operating charges	4	591,123		1,014,016	
			1,385,499		1,782,060
Operating (Deficit)/Surplus	6		(164,942)		93,615
- Notional Interest (capital charges)	9		(25,000)		(25,500)
(Deficit)/Surplus on ordinary activities			(189,942)		68,115
- Write back of notional interest			25,000		25,500
(Deficit)/Surplus for the financial year			(164,942)		93,615
Appropriations	7		-		-
			(164,942)		93,615
Retained (deficit)/surplus brought forward			135,894		42,279
Retained (deficit)/surplus carried forward			(29,048)		135,894

STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES FOR THE YEAR ENDED 31ST MARCH 1998

	Notes	1997/98 £	Restated 1996/97 £
(Deficit)/Surplus for financial year		(164,942)	93,615
Revaluation of fixed assets	5	145	229
Total recognised (losses)/gains for the year		(164,797)	93,844

The notes on pages 64 to 69 form part of these accounts

BALANCE SHEET AS AT 31 MARCH 1998

	Notes	£	1997/98 £	* Restated 1996/97 £
Assets Employed				
Fixed Assets				
- Tangible Assets	5/21		**112,421**	112,683
Current Assets				
- Debtors: Amounts falling due within one year	8	**320,949**		540,165
Amounts falling due after one year		**28,411**		28,151
- Cash at bank and in hand		**37,725**		42,568
		387,085		610,884
Creditors:				
Amounts falling due within one year	10	**(120,056)**		(250,069)
Net current assets			**267,029**	360,815
Total assets less current liabilities			**379,450**	473,498
Financed by Accruals and deferred income				
- Deferred government grant	13/21		**110,480**	108,596
Capital and Reserves				
- Income and expenditure account	13/21		**(29,048)**	135,894
- Revaluation Reserve	13		**10,968**	10,823
- Notional Superannuation Costs	11		**287,050**	218,185
			379,450	**473,498**

The notes to the accounts (pages 64 to 69) form part of these accounts

Suzanne McCarthy
Chief Executive
3 July 1998

CASH FLOW STATEMENT FOR THE YEAR ENDED 31 MARCH 1998

	Notes	£	1997/98 £	£	1996/97 £
Net cash (outflow)/inflow from operating activities	19		**(4,843)**		10,430
Capital Expenditure					
- Purchase of Tangible Fixed Assets	5	**(40,424)**		(39,173)	
- Net Cash Outflow from Capital Expenditure			**(40,424)**		(39,173)
Net Cash Outflow before financing			**(45,267)**		(28,743)
Financing					
- Receipts of Government Grants for fixed assets	14	**25,600**		37,713	
- Transfer from revenue grant	13	**14,824**		1,460	
Net cash inflow from financing			**40,424**		39,173
(Decrease)/Increase in Cash and Cash Equivalents			**(4,843)**		10,430

Note 20 forms part of the Cash Flow Statement.

NOTES TO THE ACCOUNT

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.

(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. In 1996/97 downward revaluations on IT assets were taken to the revaluation reserve but from 1997/98 the HFEA has changed policy and downward revaluations of computer equipment are treated as permanent diminutions and are charged to Income and Expenditure. (See Note 21).

(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	**1997/8 £**	1996/97 £
Department of Health		
Class XI, Vote 2	**1,213,000**	1,223,961
Less:		
Licence Fees retained, payable to the Department of Health	**(1,340,823)**	(1,453,307)
Add: Miscellaneous Income Adjustment	**(263,077)**	365,885
Net grant funds returned to the Department of Health	**0**	0
	(390,900)	136,539
Scottish Office, Home and Health Dept., Class XIII,Vote 4	**137,800**	136,253
Welsh Office, Class XIV, Vote 4,	**68,900**	68,127
Department of Health and Social Services, Northern Ireland . Class XV,Vote1	**38,600**	38,150
	(145,600)	379,069
Less Transfer for Deferred Government Grant Reserve (Note 13)	**(14,824)**	(1,460)
	(160,424)	377,609

3. Staff Costs

		1997/8 £	1996/7 £
(a)	Remuneration of Authority Members		
	Fees paid to members including Chairman	**63,829**	76,298
	Social Security Costs	**2,208**	2,411
	Reversal of National Insurance Provision (Note 11)	**0**	0
		66,037	78,709

		1997/8 £	1996/7 £
(b)	Salaries - HFEA Staff	**510,110**	454,295
	Salaries - Seconded Staff	**46,657**	58,604
	Social Security Costs	**51,365**	43,178
	Superannuation Contributions	**81,201**	72,565
	Agency Staff	**5,308**	12,783
	Vat Refund re prior year	**(7,133)**	
		687,508	641,425

(c) The Superannuation Contributions includes a notional charge of £68,865 for Authority employees (Note 12).
The average monthly number of staff employed, including secondees, during the year was as follows:

	1997/8 No.	1996/7 No.
Management	**5**	5
Administrative	**24**	23
	29	28

(d) The remuneration for the Chairman for the year was £8,785.

(e) The emoluments paid to the present Chief Executive in the year were £54,710.

The Chief Executive is a normal member of the Principal Civil Service Pension Scheme.

Four executive members of staff, all ordinary members of the Human Fertilisation & Embryology Staff Pension Scheme, received remuneration between £30,000 and £40,000.

No other executive members of staff received remuneration of more than £30,000.

4. Other Operating Charges

	1997/98 £	1996/97 £
Operating Lease Payments		
Land and Buildings	**110,339**	102,333
Other Leases	**13,274**	9,294
Accommodation	**125,420**	100,313
Travel & Subsistence - Employees	**12,154**	11,992
Travel & Subsistence - Members	**44,770**	43,904
Travel & Subsistence - Inspectors	**29,976**	49,200
Attendance Fees - Inspectors	**22,784**	24,675
Professional & Administrative Fees	**23,657**	290,950
Audit Fees	**13,000** *	10,000
Register of Information	**(3,762)**	93,161
Stationery & Printing	**78,718**	92,481
Photocopying Charges	**4,669**	6,140
Telephones & Postage	**37,305**	35,131
Communications	**131**	2,998
Training & Staff Development	**17,011**	42,840
Recruitment & Advertising	**36,477**	22,360
Conferences & Meeting Expenses	**15,037**	21,319
Library & Reading Materials	**9,405**	8,539
Sundry Office Equipment	**11,276**	8,935
Miscellaneous	**9,489**	6,451
Provision for Doubtful Debts	**(20,007)**	31,000
Total	**591,123**	1,014,016

* *includes £1000 not provided for in 1996/7*

5. Tangible Fixed Assets as at 31 March 1998

	Computer Equipment £	Office Equipment £	Furniture & Fittings £	Installations £	Totals £
Cost as at 1 April 1997	121,466	20,354	101,409	78,020	321,249
Additions	22,634	1,818	2,327	13,645	40,424
Disposals	-	-	-	-	-
Revaluation	(8,830)	(1,480)	578	445	(9,287)
As at 31 March 1998	**135,270**	**20,692**	**104,314**	**92,110**	**352,386**
Depreciation as at 1 April 1997	90,323	16,042	84,614	17,587	208,566
Charge for the year	18,331	2,973	8,954	8,282	38,540
Disposals	-	-	-	-	-
Revaluation	(6,539)	(1,167)	472	93	(7,141)
As at 31 March 1998	**102,115**	**17,848**	**94,040**	**25,962**	**239,965**
Net Book Value (NBV)					
At 31 March 1998	**33,155**	**2,844**	**10,274**	**66,148**	**112,421**
At 31 March 1997	31,143	4,312	16,795	60,433	112,683
Increase (Decrease) in NBV	2,012	(1,468)	(6,521)	5,715	(262)

NOTES TO THE ACCOUNT

6. Operating (Deficit)/Surplus

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

	Licensing		Others		Total	
	1997/98 £	Restated 1996/97 £	**1997/98** £	Restated 1996/97 £	**1997/98** £	Restated 1996/97 £
Income						
Government grant	-	-	**(160,424)**	377,609	**(160,424)**	377,609
Licence fees	**1,340,823**	1,453,307	-	-	**1,340,823**	1,453,307
Other	-	-	1,618	**1,274**	1,618	**1,274**
Transfer from reserves	**19,270**	21,742	**19,270**	21,743	**38,540**	43,485
Total	**1,360,093**	1,475,049	**(139,536)**	400,626	**1,220,557**	1,875,675
Expenditure						
Staff Costs	**(432,634)**	(407,311)	**(320,911)**	(312,823)	**(753,545)**	(720,134)
Depreciation & revaluation of computer equipment	**(20,415)**	(23,954)	**(20,416)**	(23,956)	**(40,831)**	(47,910)
Other charges	**(361,964)**	(621,456)	**(229,159)**	(392,560)	**(591,123)**	(1,014,016)
Total	**(815,013)**	(1,052,721)	**(570,486)**	(729,339)	**(1,385,499)**	(1,782,060)
Operating (Deficit)/Surplus	**545,080**	422,328	**(710,022)**	(328,713)	**(164,942)**	93,615

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 pensions transfer receipts payable to the consolidated fund via the Department of Health.

8. Debtors

	1997/98 £	1996/97 £
Debtors (Licence Fees)	**76,946**	460,009
Other Debtors	**12,191**	7,937
Pre-payments & Accrued Income	**260,223**	100,370
	349,360	568,316

At 31 March 1998, the Authority had debts of £28,411 that were over one year old. The Authority continues to pursue these disputed licence fee debts and is confident of clearing them in the coming year. Debtors are shown net of a provision of £10,965 for a debt which may be irrecoverable .
The Authority had a total of £12,191 outstanding for staff loans at 31 March 1998. No individual member of staff had more than £2,500 outstanding.

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 and Expenditure Account amounting to £25,000.

10. Creditors: Amounts falling due within one year

	1997/98 £	1996/97 £
Trade Creditors	**0**	0
Other Taxes and Social Security	**59,799**	48,209
Accruals	**60,257**	201,860
	120,056	250,069

11. Reserves

	Notional Superannuation £
Balance at 1.4.97	218,185
Increase in year	68,865
Balance at 31.3.98	**287,050**

12. Pension Arrangements

Seconded staff belong to the Principal Civil Service Pension Scheme. For 1997/98 contributions of £8,096 were made to the Paymaster General at rates determined from time to time by the Government Actuary and advised by the Treasury. For 1997/98 these rates were 11% and 17.5% for non-industrial staff. For its own employees, the Authority operates an analogous non-contributory scheme, to which the conditions of the Superannuation Acts 1965 and subsequent amendments apply. In 1997/98 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 at 1 April 1997 as previously reported	108,596	142,629	4,088
Prior Year Adjustment (Note 21)	-	(6,735)	6,735
Balance brought forward at 1 April 1997 as restated	108,596	135,894	10,823
Movements in Year:			
Revaluation of fixed assets			145
1997/98 capital grant	25,600		
Transfer from Revenue Grant	14,824		
Transfer to Income & Expenditure	(38,540)		
(Deficit) for the year	-	(184,804)	
Balance Carried Forward	**110,480**	**(48,910)**	**10,968**

14. Government Grants for Capital

	1997/98 £	1996/97 £
Department of Health		
Class XI, Vote 2, MVT26C (Note 13)	**25,600**	37,713
Transfer from Revenue Grant	**14,824**	1,460
	40,424	39,173

15. Financial Commitments

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

	1997/98 £	1996/97 £
Land and Buildings		
Leases which expire within 1 year		105,339
Leases which expire within 2 to 5 years	**110,450**	
Other Leases		
Leases which expire within 2 to 5 years	**12,259**	12,259

16. Capital Commitments

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

17. Contingent Liabilities

A claim by one supplier, vigorously disputed by the HFEA, has not been settled. Until resolved, it is not possible to determine the HFEA's liability in this regard, if any.

18. Material Losses

The HFEA had no material losses in the year 1997/98.

19. Performance against key financial targets

The HFEA has two key financial targets .

(a) The HFEA must ensure that its cash expenditure remains within the budget set by the Department of Health. In the year 1997/8 our actual cash expenditure was £1,481,206 which was 99.8% of the allocated budget of £1,483,900.

(b) The HFEA was also required to raise 70% of its cash expenditure from Licence Fees. The amount raised in cash from licence fees in 1997/8 was £1,592,780 which was 107.5% of the cash expenditure.

20. Notes to the Cash Flow Statement

	1997/98 £	Restated 1996/97 £
1. Reconciliation of operating deficit to net cash outflow from operating activities:		
Operating (Deficit)/Surplus	(164,942)	93,615
Depreciation Charges	40,831	47,910
Decrease in Debtors	218,956	(324,203)
Decrease in Creditors	(130,013)	175,221
Increase in Notional Superannuation Contributions	68,865	61,372
Transfer from Deferred Government Grant	(38,540)	(43,485)
Net Cash (Outflow)/Inflow from Operating Activities	(4,843)	10,430
2. Reconciliation of Net Cash Flow to movement in Net Debt.		
Balance at 1 April 1997	42,568	32,138
Net cash (Outflow)/Inflow	(4,843)	10,430
Balance at 31 March 1998	37,725	42,568

3. Analysis of Changes in Net Debt

	At 1/4/97	Cash Flows	At 31/3/98
Cash at Bank and in Hand	42,568	(4,843)	**37,725**

21. Prior Year Adjustment

The accounting policy on the treatment of losses on revaluation of IT equipment has been changed in 1997.98. These losses are now regarded as permanent diminutions in value and, whereas in previous years the loss has been charged to the Revaluation Reserve, from 1997/98 the loss is charged to the Income and Expenditure Account. Comparative figures for 1996/97 have been restated to reflect this change in policy. The results are summarised below:

	As previously reported in 1996/97 £	Adjustment £	As restated in 1997/98 £
Income and Expenditure Account			
Depreciation and revaluation of computer equipment	43,485	4,425	47,910
Retained surplus brought forward	44,589	(2,310)	42,279
Statement of Total Recognised Gains and Losses			
Surplus for financial year	98,040	(4,425)	93,615
Revaluation of fixed assets	(4,196)	4,425	229
Balance sheet			
Income and Expenditure Account	142,629	(6,735)	135,894
Revaluation Reserve	4,088	6,735	10,823

APPENDIX TO THE ACCOUNTS

Accounts Determination

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

Direction given by the Secretary of State

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

Form of Accounts

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

a. a foreword;

b. an income and expenditure account;

c. a balance sheet;

d. a cash flow statement; and

e. a statement of total recognised gains and losses;

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

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

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

a. generally accepted accounting practice in the United Kingdom (UK GAAP);

b. the disclosure and accounting requirements contained in 'The Fees and Charges Guide' (in particular those relating to the need for appropriate segmental information for services or forms of service provided) and in other guidance which the Treasury or the Secretary of State may issue from time to time in respect of accounts which are required to give a true and fair view;

c. the accounting and disclosure requirements given in '*Government Accounting*' and in '*Executive NDPBs: Annual Reports and Accounts*' guidance, as amended or augmented from time to time: insofar as these are appropriate to the Authority and are in force for the financial year for which the statement of accounts is to be prepared.

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

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

a) fixed assets at their value to the business by reference to current costs; and

b) stocks valued at the lower of net current replacement cost (or historical cost if this is not materially different) and net realisable value.

7 This accounts determination supersedes that dated 26 April 1996 and shall be reproduced as an appendix to the accounts.

Date: 6 May 1997

Signed by the authority of the Secretary of State for Health

P. Kendall

Branch Head (RMF-EAC Division)
Department of Health

SCHEDULE 1

Application of the Accounting and Disclosure requirements of the Companies Act and Accounting Standards

Companies Act

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

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

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

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

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

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

Accounting standards

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

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

SCHEDULE 2

Additional Disclosure Requirements

1 The foreword shall, inter alia:

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

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

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

a. include details for the accounting policies adopted;

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

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

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