



*Human
Fertilisation
and
Embryology
Authority*

EIGHTH

ANNUAL REPORT & ACCOUNTS

1999

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All information contained was correct as of 31 August 1999.

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Chairman's Letter

In the last decade several issues have arisen to challenge society's view of what is 'normal' or 'acceptable' in human reproduction. These issues have been difficult for society to accommodate, and have presented serious challenges to conventional ideas. The HFEA has, however, been able to assure both public and legislators that fertility clinics and centres conducting research are acting properly and that there are adequate controls in place.

The aims of the HFEA are to regulate licensed clinics in a rigorous but sensitive way; to protect patients who may be vulnerable to exploitation, whether intended or inadvertent; to enable this sensitive area of science and medicine to progress in a responsible way; and to reassure the public that possible excesses are guarded against. The HFEA balances the desire for scientific progress with the need to protect patients and future offspring. No other field of medicine in the UK is regulated as strictly as IVF and embryo research – and no other country in the world regulates these fields as closely as the UK. This year, both areas have seen rapid developments.

After discussion and consultation lasting several years, the HFEA decided to continue to allow the payment of up to £15 for egg and sperm donors. It had become increasingly clear that the issue of payment could not be considered as an issue of principle in isolation from others, and that the continued provision of safe donor treatments in the UK would be seriously undermined by the removal of payments.

We also decided that it would not be right to ban paid egg sharing, which can be beneficial to both sharer and receiver. We were influenced by the argument that egg sharers are not motivated by money, but by the desire for a baby. It is clear, however, that such schemes need to be closely controlled and regulated, and we are actively preparing specific guidelines.

We are continuing the development of the licensing system, moving towards three year licences for established centres. We are also working towards the redevelopment of our data register system. As part of that process we plan to introduce a process for the direct electronic transfer of treatment data from clinics. We aim to publish detailed, non-identifying data sets of treatments and their outcomes during 2000, possibly on the HFEA website.

A key role of the HFEA is to provide information to current and prospective patients finding their way through the maze of infertility



clinics and treatments, and who face a bewildering wall of technical terms, statistical probabilities, and often worrying financial decisions. This year we have fundamentally revised our *Patients' Guide to DI and IVF Clinics*, which includes detailed, impartial information about all licensed clinics, the treatments they offer and their success rates.

In late 1998 the HFEA and the Human Genetics Advisory Commission (HGAC) published a report to Ministers on human cloning. In the report the HFEA repeated its policy that it would not license the use of nuclear replacement for the purpose of reproductive cloning. The Government had also explicitly ruled this out. The HGAC and the HFEA recommended that these safeguards should be recognised as being wholly adequate to forbid human reproductive cloning in the UK. However, we suggested that the Government might wish to consider the possibility of introducing legislation that would explicitly ban human reproductive cloning regardless of the technique used so that this ban would not depend upon the decision of a statutory body (the HFEA), but would itself be enshrined in statute. We also recommended that the Secretary of State for Health should consider specifying in regulations two further purposes for which the HFEA might issue licences for research, so that potential benefits can clearly be explored: firstly, the development of methods of therapy for mitochondrial disease; and, secondly, the development of therapeutic treatments for diseased or damaged tissues or organs. We also recommended that the issues be re-examined in five years' time in the light of developments and public attitudes towards them. In June of this year the Government announced the creation of a high-level advisory group to consider in more detail the scientific implications of the use of the cloning techniques in embryo research. The HFEA welcomed this move.

One must, of course, respect the views of those who believe it is wrong to create embryos outside the body for either treatment or research. Yet we believe that for many years now, a clear majority of both the public and politicians has supported such work, which has enabled many thousands of couples to have children previously denied them. The embryo is the first step to the creation of a human being, and always deserves respect and protection. Both we and the professionals in this field are well aware that we are operating at the outer limits of technology in a field uniquely intimate as well as scientific. In probing the depths of human reproductive biology, decisions and discoveries raise ever more questions. After 30 years of public awareness of embryo research there is more moral and ethical discussion than ever before and a new profession of bio-ethics has emerged. For that reason, and in the light of new

research and treatment that springs from embryo creation, close regulation will continue to be necessary for the foreseeable future.

I am extremely grateful to 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: Ruth Chambers, Liz Forgan, David Greggains, Martin Johnson, Richard Jones and Anthony Thiselton. I am sure that their successors will carry on their fine work.

A handwritten signature in black ink, reading "Ruth Deech". The signature is written in a cursive style with a large initial 'R' and 'D'.

Ruth Deech

Chairman

The Human Fertilisation and Embryology Authority

1

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 unease about the potential future of human embryo research and infertility treatments, and a widespread desire for statutory regulation of this highly sensitive area. The recommendation for such a body had come from the 1984 report of the Committee of Inquiry into Human Fertilisation and Embryology (the 'Warnock' report).

In 1996 the HFEA was the subject of a Quinquennial Review¹. 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 ROLE

The HFEA's other statutory functions are:

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

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

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.

**THE HFEA'S
MEMBERSHIP AND
ITS EXECUTIVE**

HFEA Members are appointed by UK Health Ministers in accordance with guidance from the Commissioner for Public Appointments (Nolan guidelines). The Members determine the HFEA's policies and scrutinise treatment and research licence applications. In order that a perspective can be maintained which is independent of the medical-scientific view, the HFE Act requires that the Chairman, Deputy Chairman and at least half of the HFEA's Membership are neither doctors or scientists involved in human embryo research or providing infertility treatment.

Members are not appointed as representatives of different groups, but bring to the HFEA a broad range of expertise: medical; scientific; social; legal; managerial; religious and philosophical. Some Members have personal experience of infertility problems. A list of Members' can be found at page 4.

The HFEA's Executive² are responsible for implementing the HFEA's policy and licensing decisions and conducting the HFEA's day-to-day activities.

**PERFORMANCE
INDICATORS**

As a means of better assessing the standard of its performance in various areas, the HFEA has this year introduced a set of performance indicators. We will be monitoring, with the Department of Health, the levels of performance reached.

The initial set of agreed indicators are:

- PI 1 – Percentage of licence applications dealt with within target timescale
- PI 2 – Percentage of requests for HFEA publications responded to within three days
- PI 3 – Data entry unit costs per DI/IVF treatment
- PI 4 – HFEA performance against Government financial targets including:
 - Percentage of creditors paid within 30 days
 - Percentage of debts recovered within 60 days

Additional indicators may be introduced in the future, and will form part of the Ministerial Accountability Review.

² A list of Executive Staff is at Annex 1.

The HFEA is committed to carrying out its duties as economically as possible. The HFEA has endeavoured to reduce costs by using new suppliers to provide goods and services, obtaining increased discounts and using resources more efficiently. In particular, savings have been made on publication costs, telephone services, stationery purchases, insurance, IT training and on the cost of special events. The HFEA will continue to seek to identify where further savings can be made.

EFFICIENCY SAVINGS

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 from the HFEA.

**THE CODE OF
PRACTICE ON
ENFORCEMENT**

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY³



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



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

MEMBERS



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



Professor Andrew Grubb
Professor of Medical
Law, University of
Cardiff



Sara Nathan
Freelance journalist,
previously Editor of
Channel 4 News



Dr Gulam Bahadur
Clinical Biochemist,
Head of Fertility
Laboratories,
Reproductive Medicine
Laboratories, Royal Free
and University College
Medical School/UCLH
Trust, London



Professor Henry Leese
Professor of Biology,
University of York



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



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



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



Sharmila Nebhrajani
Head of Corporate
Planning, BBC



Dr Brian Lieberman
Medical Director,
Regional IVF and DI
Unit, St Mary's Hospital,
Manchester
Director & Consultant
Gynaecologist,
Manchester Fertility
Service



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



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



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



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



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



Dr Sadia Muhammed
General Practitioner,
Priory Medical Group,
York



Julia Tugendhat
Psychotherapist



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

³ A list of members' declarable interests is at Annex 6.

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

Standing Committees

Audit Committee

Joan Stringer (Chairman)
Gulam Bahadur
Sharmila Nebhrajani
John Williams

Code of Practice Committee

Jane Denton (Chairman)
Gulam Bahadur
Andrew Grubb
Anne McLaren
Sadia Muhammed
Allan Templeton

Communications Steering Group

Stuart Lewis (Chairman)
Moirra Coath
Brian Lieberman
Sadia Muhammed
Sara Nathan
Joan Stringer

Ethics Committee

Michael Nazir-Ali (Chairman)
Brenda Almond
Christine Gosden
Andrew Grubb
Henry Leese
Julia Tugendhat
John Williams

Information Committee

John Williams (Chairman)
David Barlow
Stuart Lewis
Brian Lieberman
Sara Nathan
Allan Templeton
Julia Tugendhat

Co-opted members:

Clare Brown (National Infertility
Awareness Campaign)
Karin Dawson (Association of Clinical
Embryologists)
Richard Fleming (British Fertility
Society)
Alison Murdoch (British Fertility
Society)
Angela Mays

Licensing and Fees Committee

Julia Tugendhat (Chairman)
Brenda Almond
David Barlow
Jane Denton
Christine Gosden
Henry Leese

Organisation and Finance Committee

Ruth Deech (Chairman)
Moirra Coath
Jane Denton
Sara Nathan
Sharmila Nebhrajani
Joan Stringer

Working Group on New Developments in Reproductive Technology

Anne McLaren (Chairman)
Gulam Bahadur
David Barlow
Jane Denton
Christine Gosden
Henry Leese
Brian Lieberman
Sara Nathan
Allan Templeton

Observer:

Dr Elaine Gadd
(Department of Health)

Ad Hoc Committees

Advisory Group on Safe Cryopreservation

Jane Denton (Chairman)
Co-opted members
Ian Cooke (British Fertility Society)
Karin Dawson (Association of Clinical
Embryologists)
Lynn Fraser
Stewart Irvine (British Andrology
Society)
David Pegg
Richard Tedder
Maureen Wood

HFEA/ACGT Working Group on Pre-Implantation Genetic Diagnosis

Allan Templeton (Chairman)
Christine Gosden
Stuart Lewis
Anne McLaren
Hillary Harris (Advisory Commission
on Genetic Testing)
Philip Webb (Advisory Commission on
Genetic Testing)

Working Group on Embryo Biopsy

Brian Lieberman (Chairman)
Co-opted members
Karin Dawson
Ian Findley
Joyce Harper
Alan McDermott

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

2

*Licensing and Audit of Licensed Clinics***INTRODUCTION**

Every clinic in the UK which offers IVF or DI treatment, the storage of gametes (sperm or eggs) or embryos or which carries out human embryo research is required by law to be licensed by the HFEA. Not only does the licensing process ensure that proper standards are maintained, but it also assists in informing the HFEA about current and developing practices. As such it is a useful mechanism for gathering and disseminating information and thereby helps to raise standards of practice. As of 31 August 1999 there were 118 clinics licensed to carry out various activities as shown in Table 1⁴.

Table 1***HFEA licensed clinics***

IVF and DI	75
IVF only	0
DI only	32
Storage of sperm only	8
Research licences only	3
Total	118

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 whether a licence should be granted, suspended or revoked. If a licence is granted, centre-specific conditions may be attached.

Licensed clinics are inspected annually. In 1997 the HFEA modified 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. In recognition that a large percentage of centres have been licensed by the HFEA for many years and understand the legislative requirements, in June 1999 we announced that centres licensed for at least three years would normally be granted three year licences. Annual inspections would continue, with inspection by a full team always preceding licence renewal. Teams for interim inspections

⁴ A list of licensed clinics is at Annex 2.

would be identified by Licence Committees on a systematic basis according to the nature of the centre.

The HFEA currently employs 65 part-time inspectors⁵ who assist the HFEA in inspecting clinics. At full inspections the inspection team will normally consist of a clinician, a scientist, a person with a background in another field, such as counselling, as well as a member of the HFEA's Executive staff. The chairman of the team is usually an HFEA Member. Where a focussed inspection is scheduled a Licence Committee will determine the particular focus as well as the composition of the inspection team.

Information on alleged or apparent breaches of the HFE Act or the Code of Practice comes to the HFEA from a wide range of sources including HFEA inspections, information from patients, centre staff, analysis of the HFEA's 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 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. The audit programme also provides assurance for the National Audit Office regarding the collection of licence fee income. All licensed clinics will be audited during the course of the programme. Feedback is given after every audit including a formal audit report to which the clinic concerned may respond. The report is then considered by a Licence Committee which will direct any follow up action. Approximately 60 audits will have been carried out by October 1999.

BREACHES AND ENFORCEMENT

THE AUDIT PROGRAMME OF LICENSED CLINICS' DATA

⁵ A list of HFEA Inspectors is at Annex 3.

3

*The Code of Practice***INTRODUCTION**

The HFE Act⁶ 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.

'WELFARE OF THE CHILD'

In particular, the Code of Practice provides guidance on the assessment of the welfare of the child. In passing the HFE Act Parliament decided that no category of women should be excluded from consideration for 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*"⁷.

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

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

6 Human Fertilisation and Embryology Act 1990, section 25.

7 HFE Act, section 13(5).

During 1999 the Code of Practice Committee prepared two leaflets on the welfare of the child for use by clinics. The first, produced with the co-operation of the Royal College of General Practitioners, provides information for GPs and explains their role in the welfare of the child assessment process. The second, designed for patients, provides a full explanation of the process and covers issues of consent, confidentiality and the reasons why treatment may be refused.

The Code is reviewed regularly and updated in the light of technical advances and to deal with issues that emerge from the licensing process. Revisions of the Code must be approved by the Secretary of State⁸ 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 on request.

Work has started on the Code's fifth edition and this includes a thorough reconsideration of the Code's structure. Specific issues identified for consideration include guidance on expenses payments to donors and guidelines for egg-sharing arrangements.

Egg sharing is an arrangement whereby a woman may receive free or subsidised IVF treatment in return for donating her surplus eggs. The HFEA decided to allow egg sharing to continue, but only on condition that strict guidelines were prepared to protect all those involved in such arrangements. The HFEA was persuaded that, if properly regulated and monitored, the practice could in some cases be beneficial to participants. These guidelines are now being drafted with the assistance of representatives of the BFS and the RCOG. They will centre on the importance of information provision, counselling and consent.

FIFTH EDITION OF THE CODE

GUIDANCE ON EGG-SHARING

⁸ HFE Act, section 26(4).

4

Collecting and Providing Data

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

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

**DEVELOPMENT
OF THE HFEA'S
DATA REGISTER**

The HFEA register began operating in 1991 and contains details of licensed treatments and patient characteristics for the whole of the UK. It is the largest database of its kind in the world. During April 1998 to March 1999 details of 40,165 IVF and 9,625 DI treatment forms were added to the register.

In 1998 the HFEA adopted a strategy for replacing the original register system that had remained largely unchanged since its introduction. The first phase, a series of consultations with interested parties about the overall plans, began in June 1998. In mid 1999 the HFEA began to introduce the new software to deal with treatments carried out from April 1999 onwards.

In conjunction with this the HFEA will be introducing a system for the secure electronic transfer of treatment data from clinics. It is hoped that testing will shortly begin before the end of 1999 with a view to phasing out paper based input from all but the smallest licensed centres within five years.

In addition the HFEA has reviewed the provisions for archiving records, and has introduced new methods and procedures for managing this. It is intended that a system will be put in place for publishing detailed, non-identifying data sets of treatments and their outcomes during 2000. It is hoped that these data can be made available on the HFEA's website.

The following data tables and graphs present data collected for treatment cycles that were carried out during the period 1 April 1997 to 31 March 1998. 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 following information was reported to us by clinics during the period 1 April 1997 to 31 March 1998 26,685 patients received IVF treatment. There were a total of 34,638 cycles started, including frozen embryo replacements, of which 29,014 reached embryo transfer. There were 6,864 clinical pregnancies (19.8% of treatments started) which led to 5,687 live birth events (16.4% of treatments started). The number of clinical pregnancies where no outcomes or incomplete information was received was 161 or 2.3% of all pregnancies reported. The annual difference between the clinical pregnancy rate and the live birth rate remains within the range 3.3%–4.0%.

The number of cycles involving micromanipulation continues to increase markedly showing a 40% increase on last year's figure. The increased use and success of micromanipulation (figure 4.1) has been behind the rise in the total IVF live birth rate seen since 93/94 (table 4.4), although this appears now to have levelled off. Success with micromanipulation seems higher than with IVF, although this may not be the case when corrected for female factors (figures 4.1 and 4.2)

Analysis of the tables shows:

- Live birth rates for IVF and micromanipulation both decrease steadily after women pass the age of 30 (figure 4.2)
- IVF frozen embryo transfer cycles (table 4.11) have significantly lower pregnancy and live birth rates than those involving fresh embryos (table 4.13)

The incidence of multiple births (and attendant risk to maternal and infant health) as a result of IVF and micromanipulation remains high (table 4.1 – see also tables 4.6–4.10). For example, table 4.6 shows that 47% of individual babies born from all types of IVF come from a multiple pregnancy (3,488 out of 7,397) This figure has remained virtually unchanged during the period 1994 to 1998⁹. The stillbirth and neonatal death rate for a triplet pregnancy with one or more of the babies dying is 74.2 per 1000 birth events (7.4%) compared to 10.5 per 1000 (1%) for singleton pregnancies.

IVF DATA

Multiple Births and Two and Three Embryo Transfer

9 HFEA Annual Reports 1996–1999.

Table 4.9 shows that reducing the number of embryos transferred in the majority of cases¹⁰, reduces the risk of a multiple birth (particularly of triplets – see table 4.10) without reducing the chance of giving birth to at least one child.

Encouragingly, the number of embryo transfers where the maximum of three embryos were replaced has fallen steadily from 68.6% in 1995/6 to 58.6% in 1997/98¹¹. Conversely, the number of transfers where only two embryos were replaced has risen from 30.9% to 41.0% during the same period.

DONOR INSEMINATION DATA

During the period 1 April 1997 to 31 March 1998, 4,905 patients received treatment involving DI or GIFT using donated gametes. Table 4.18 shows that 12,753 cycles were started which led to 1,485 clinical pregnancies (11.6%) and 1,229 live births (9.6). The number of clinical pregnancies for which no outcome or incomplete information was submitted totalled 68 or 4.6% of all pregnancies reported.

- Up to the 1996/7 reporting period the live birth rate for DI has steadily increased, but has not changed since then (table 4.18).
- The number of DI cycles carried out annually has dropped by 50% since the 1992/3 reporting period (from 25,623 to 12,753) (table 4.18).
- Live birth rates for DI decrease with age, and increasingly so after the age of 35 (table 4.21).

¹⁰ Where more than four embryos have been created.

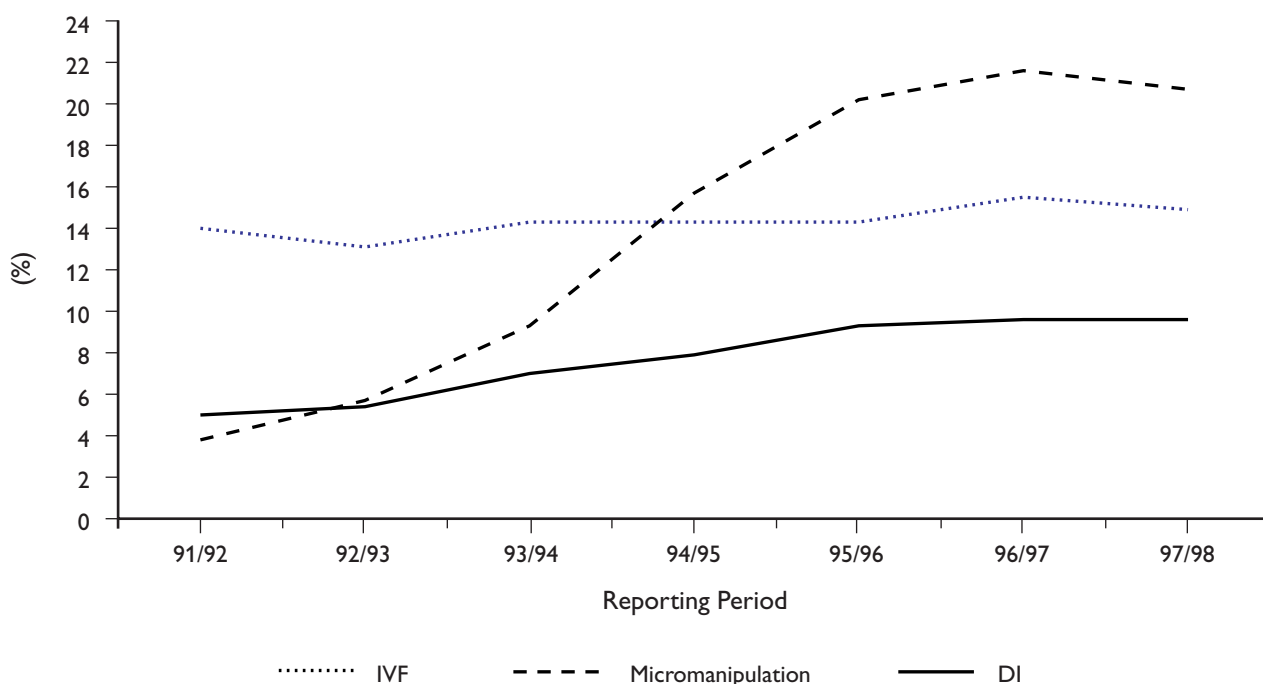
¹¹ Where more than four embryos have been create. HFEA Annual Reports 1997–1999.

Table 4.1 Live birth and multiple birth rates for IVF, micromanipulation and DI, 1991–1998

Reporting period	IVF ¹			MICROMANIPULATION ²			DI ³		
	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 ⁴	10434	14.0	27.3	80	3.8	33.0	16299	5.0	7.3
92/93	19309	13.1	28.1	244	5.7	35.7	25623	5.4	6.7
93/94	21726	14.3	27.6	798	9.3	25.7	23869	7.0	8.3
94/95	24193	14.3	27.7	1685	15.7	26.4	20604	7.9	7.2
95/96	25781	14.3	29.6	4651	20.2	28.9	16874	9.3	8.3
96/97	26865	15.5	26.8	6652	21.6	29.1	14333	9.6	6.5
97/98	24889	14.9	27.3	9295	20.7	27.4	12753	9.6	7.0

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

Figure 4.1 Live birth rates per Treatment Cycle for Licensed Treatments 1991–1998



Notes

1. Micromanipulation data include ICSI treatments.
2. The 'IVF' line does not include micromanipulation data.

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

	Boys		Girls		Total
DI	634	(48.0%)	687	(52.0%)	1321
IVF	3736	(50.5%)	3661	(49.5%)	7397

Table 4.3 Mean clinical pregnancy and live birth rates for female causes of infertility

<i>(%s are of number of treatment cycles)</i>				
Factor	Number of cycles	% of all cycles	Clinical pregnancy rate (%)	Live birth rate (%)
Tubal Disease	11254	32.5	18.2	14.9
Endometriosis	3005	8.7	20.2	16.3
Unexplained	16414	47.4	20.3	17.2
Other	7116	20.5	21.0	16.8

**Table 4.4 IVF clinical pregnancy and live birth rates:
1/8/1991–31/3/1998**

(including micromanipulation treatments but excluding frozen embryo replacements)

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

1. Data for eight months only.

Table 4.5 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	1002	1587	2489	3507	4046	3874	3007	2207	1027	451	196	23393
Live Birth Rate	17.3	14.7	16.5	18.8	17.6	14.8	12.7	9.6	5.8	2.0	0.5	14.6

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	504	763	1167	1584	1730	1433	1070	686	317	147	35	9436
Live Birth Rate	23.8	25.8	23.4	23.4	22.1	21.5	15.4	9.9	5.7	4.8	0	20.2

Note: There were 285 micromanipulation cycles using donated eggs resulting in 71 live birth events.

All tables exclude treatments using donated embryos.

Figure 4.2

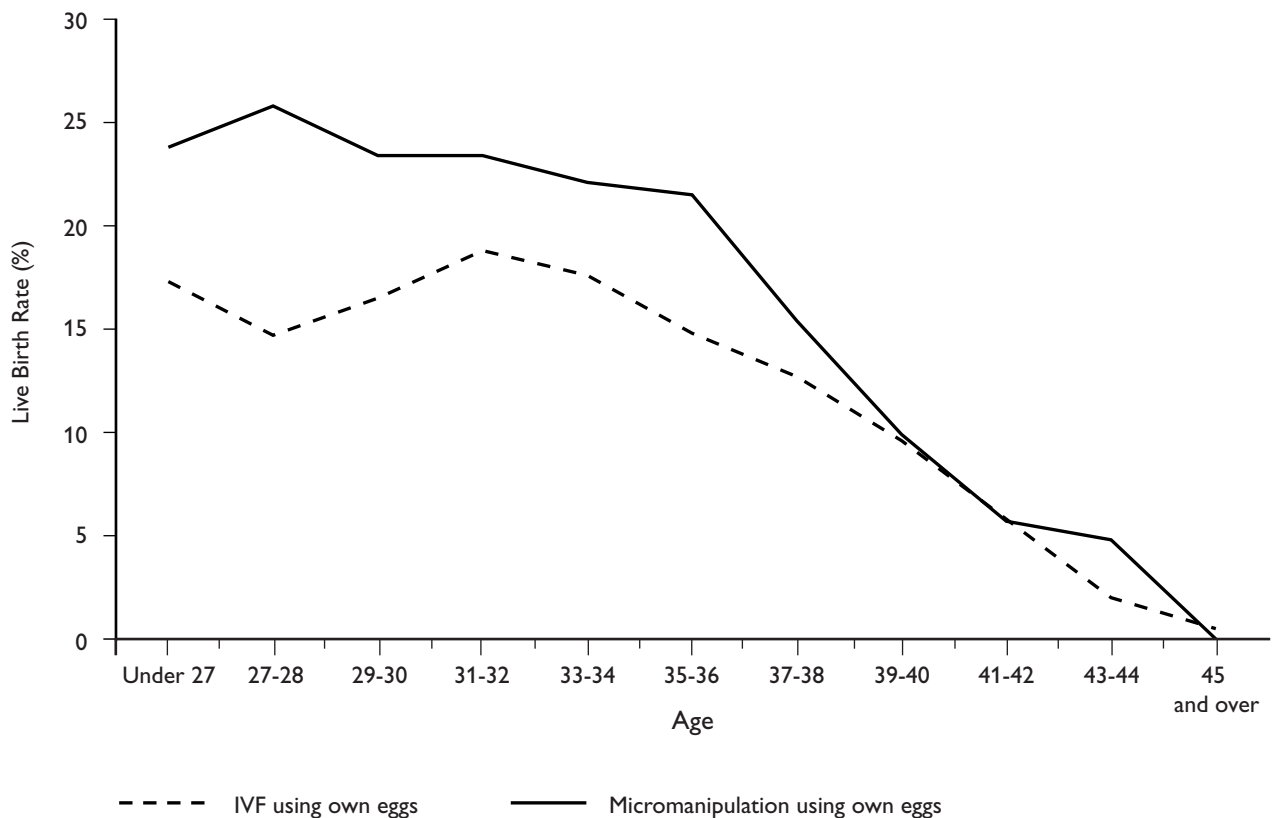


Table 4.6 Single and Multiple Clinical Pregnancy Outcomes after IVF or Frozen Embryo Transfers

	Clinical Pregnancies	Live Births	Miscarriages	Terminations	Ectopics	Unknown Outcomes	Babies Born	Still Birth and Neonatal Deaths (per thousand birth events)
Singleton	4746	3902	602	30	109	66	3909	10.5
Twin	1647	1526	237	8	9	24	2831	41.3
Triplet	283	256	73	32	1	5	651	74.2
Quads	3	2	-	-	-	-	6	500.0
Totals	6679	5686	912	71	119	95	7397	21.8

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 161 clinical pregnancies reported for which no outcome form was received.

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

Embryos transferred	No of cycles	Number of clinical pregnancies			Clinical Pregnancy rate (% of treatment cycles)	Multiple Clinical Pregnancy (% of clinical pregnancies)
		Singleton	Twin	Triplet or greater		
One	2846	253	5	-	9.1	1.9
Two	11984	2083	656	11	22.9	24.3
Three	13742	2347	974	271	26.1	34.7
Total	28572	4683	1635	282	23.1	29.0

Notes:

The total number of clinical pregnancies is less than the total given in other tables because there were 161 clinical pregnancies reported for which no outcome form was received.

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

	No of cycles	Number of live births			Live birth rate (% of treatment cycles)	Multiple birth rate (% of live birth events)	Stillbirths and neonatal deaths per 1000 birth events
		Singleton	Twin	Triplet or greater			
One	2846	209	2	-	7.4	1.0	14.2
Two	11984	1894	527	5	19.9	22.3	19.7
Three	13742	2028	848	156	22.1	33.1	24.1
Total	28572	4086	1377	161	19.7	27.3	21.9

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

Number of embryos transferred	Number of cycles	Live birth rate (% of number of cycles)	Multiple birth rate (% of number of live births)
2	5435	26.0	24.9
3	7760	25.7	34.3

There were 58 cycles where 1 embryo was transferred.

Table 4.10 IVF live birth and multiple birth rates by age and number of embryos transferred

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	244	71	(29.1%)	21	(29.6%)	-	-
25-29	2247	627	(27.9%)	228	(36.4%)	30	(4.8%)
30-34	5660	1627	(28.7%)	534	(32.8%)	54	(3.3%)
35-39	4120	965	(23.4%)	237	(24.6%)	29	(3.0%)
40-44	927	123	(13.3%)	16	(13.0%)	1	(0.8%)
45+	49	7	(14.3%)	3	(42.9%)	1	(14.3%)
Total	13247	3420	(25.8%)	1039	(30.4%)	115	(3.4%)

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 treatment cycle (twins, triplets and quads)	Number of triplets and quads	Triplet and quad birth rate per treatment cycle
<25	148	39	(26.4%)	15	(38.5%)	-	-
25-29	1203	327	(27.2%)	93	(28.4%)	-	-
30-34	2615	730	(27.9%)	198	(27.1%)	2	(0.3%)
35-39	1339	302	(22.6%)	45	(14.9%)	1	(0.3%)
40-44	123	16	(13.0%)	1	(6.3%)	-	-
45+	4	1	(25.0%)	1	(100.0%)	-	-
Total	5432	1415	(26.0%)	353	(24.9%)	3	(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 treatment cycle (twins, triplets and quads)	Number of triplets and quads	Triplet and quad birth rate per treatment cycle
<25	95	32	(33.7%)	6	(18.8%)	-	-
25-29	1038	299	(28.8%)	135	(45.2%)	30	(10.0%)
30-34	3020	893	(29.6%)	336	(37.6%)	52	(5.8%)
35-39	2757	658	(23.9%)	191	(29.0%)	28	(4.3%)
40-44	802	107	(13.3%)	15	(14.0%)	1	(0.9%)
45+	45	6	(13.3%)	2	(33.3%)	1	(16.7%)
Total	7757	1995	(25.7%)	685	(34.3%)	112	(5.6%)

Table 4.11 IVF Clinical Pregnancy and Live Birth Rates (Frozen embryo replacements)

(All percentages are of number of treatment cycles)

	<i>Patients</i>	<i>Treatment Cycles</i>	<i>Embryo Transfers</i>	<i>Clinical Pregs</i>	<i>Live Births</i>	<i>Babies Born</i>
Own Gametes	4364	5103	4533 (88.8%)	691 (13.5%)	531 (10.4%)	638
Donated Sperm	334	375	336 (89.6%)	68 (18.1%)	52 (13.9%)	69
Donated Eggs	370	430	375 (87.2%)	68 (15.8%)	49 (11.4%)	66
Donated Embryos	146	180	176 (97.8%)	40 (22.2%)	35 (19.4%)	47
Totals	5214	6088	5420 (89.0%)	867 (14.2%)	667 (11.0%)	820

Table 4.12 Treatments using micromanipulation

(including ICSI)

Clinics	56
Patients	8254
Number of cycles *	9749
Number of embryo transfers	9295
Clinical pregnancies	2248
Clinical pregnancy rate (%)	23.1
Total live births	1919
Live birth rate (%)	19.7
Miscarriages	302
Terminations	30
Ectopics	27
Unknown	31
Babies born	2491
Stillbirths and neonatal deaths (per thousand birth events)	15.6

* The number of cycles excludes those which were abandoned prior to egg collection. The data includes the results from 454 frozen embryo transfers.

Table 4.13 Results of stimulated IVF and fresh embryo transfer cycles

(All percentages are of number of treatment cycles)

	<i>Patients</i>	<i>Treatment Cycles</i>	<i>Embryo Transfers</i>	<i>Clinical Pregnancies</i>	<i>Live Births</i>	<i>Babies Born</i>
Own Gametes	21798	26086	21428 (82.1%)	5345 (20.5%)	4481 (17.2%)	5833
Donated Sperm	1030	1196	1060 (88.6%)	314 (26.3%)	266 (22.2%)	366
Totals	22828	27282	22488 (82.4%)	5659 (20.7%)	4747 (17.4%)	6199

Table 4.14 Results of unstimulated IVF and fresh embryo transfer cycles

(All percentages are of number of treatment cycles)

	<i>Patients</i>	<i>Treatment Cycles</i>	<i>Embryo Transfers</i>	<i>Clinical pregnancies</i>	<i>Live Births</i>	<i>Babies Born</i>
Own Gametes	72	77	20 (26.0%)	3 (3.9%)	2 (2.6%)	2
Donated Sperm	6	6	3 (50.0%)	-	-	-
Totals	78	83	23 (27.7%)	3 (3.6%)	2 (2.4%)	2

Table 4.15 Results of IVF using donated eggs or donated embryos

(All percentages are of number of treatment cycles)

	<i>Patients</i>	<i>Treatment Cycles</i>	<i>Embryo Transfers</i>	<i>Clinical pregnancies</i>	<i>Live Births</i>	<i>Babies Born</i>
Donated Eggs	980	1059	966 (91.2%)	300 (28.3%)	243 (22.9%)	338
Donated Embs	114	126	117 (92.9%)	35 (27.8%)	28 (22.2%)	39
Totals	1094	1185	1083 (91.4%)	335 (28.3%)	271 (22.9%)	377

Table 4.16 Clinical IVF pregnancy and live birth rates with fresh embryo transfer**a) Stimulated IVF**

	Number of treatment cycles	Pregnancy rate %			Live birth rate		
		Per treatment cycle	Per egg collection	Per embryo transfer	Per treatment cycle	Per egg collection	Per embryo transfer
Own Gametes	26086	20.5	22.4	24.9	17.2	18.8	20.9
Donated Sperm	1196	26.3	26.8	29.6	22.2	22.7	25.1
All	27282	20.7	22.7	25.2	17.4	19.0	21.1

b) Unstimulated IVF

	Number of treatment cycles	Pregnancy rate %			Live birth rate		
		Per treatment cycle	Per egg collection	Per embryo transfer	Per treatment cycle	Per egg collection	Per embryo transfer
Own Gametes	77	3.9	9.1	15.0	2.6	6.1	10.0
Donated Sperm	6	-	-	-	-	-	-
All	83	3.7	8.3	13.0	2.4	5.6	8.7

c) Cycles using donated eggs or donated embryos

	Number of treatment cycles	Pregnancy rate %			Live birth rate		
		Per treatment cycle	Per egg collection	Per embryo transfer	Per treatment cycle	Per egg collection	Per embryo transfer
Donated Eggs	1059	28.3	n/a	31.1	22.9	n/a	25.2
Donated Embryos	126	27.8	n/a	29.9	22.2	n/a	23.9
All	1185	28.3	n/a	30.9	22.9	n/a	25.0

Table 4.17 Developmental defects and syndromes

	<i>Total</i>	<i>Fresh IVF</i>	<i>Frozen IVF</i>	<i>DI</i>	<i>Micro- manipulation</i>
Chromosomal syndromes					
Downs' Syndrome	5	2	1		2
Other chromosomal abnormalities	3			1	2
Congenital abnormalities					
Cleft lip	0				
Cleft palate	4	1	1	0	1
Cleft lip with cleft palate	2	2			
Tracheo-oesophageal fistula, oesophageal atresia and stenosis	5	2	1	1	1
Atresia and Stenosis of the large intestine, rectum and anal canal	7	2		1	4
Anomalies of the alimentary system	8	5		2	1
Cardiac murmurs	6	2		2	2
Ventricular septal defect	6	3	1	1	1
Other congenital cardiac anomalies	8	4		1	3
Other anomalies of the cardiac septa	2		1		1
Patent Ductus	2	1			1
Anomalies of the cardiovascular system	4	1			3
Hypospadias, Epispadias	3	1		1	1
Anomalies of the male external genitalia	2	1			1
Renal anomalies	10	1	1	1	7
Polydactyly or syndactyly	8	4	1	2	1
Reduction deformities of the limbs	4	2	1	1	
Talipes	9	2	1	3	3
Congenital dislocation of the hip	3	1		1	1
Other anomalies of the limbs or limb girdle	1				1
Anomalies of the nose, face, neck and skull	3	2			1
Anomalies of the abdominal wall	4	1		1	2
Ear anomalies	3	2	1		
Spina bifida	1				1
Exomphalos	2	1		1	
Anomalies of the tongue, branchial cleft and auricular sinus	2	1			1
Total number of children born	114	44	10	19	41
As a percentage of total number of babies born as a result of each type of licensed treatment	1.3	1.1	1.2	1.4	1.6

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

Table 4.18 DI clinical pregnancy & live birth rates per treatment cycles 1/8/91–31/3/98

(Data includes GIFT using donor gametes and Intra Uterine insemination)

(Percentages are of number of treatment cycles)

Reporting period	Number of treatment cycles	Clinical pregnancy rate per treatment cycle (%)	Live birth rate per treatment cycle (%)
01/08/91 to 31/03/92	16299	6.6	5.0
01/04/92 to 31/03/93	25623	6.9	5.4
01/04/93 to 31/03/94	23869	8.6	7.0
01/04/94 to 31/03/95	20604	9.7	7.9
01/04/95 to 31/03/96	16874	11.2	9.3
01/04/96 to 31/03/97	14333	11.6	9.6
01/04/97 to 31/03/98	12753	11.6	9.6

Table 4.19 Donor Insemination Data

<i>Stimulated DI</i>		<i>Unstimulated DI</i>	
Number of Centres	101	Number of Centres	94
Number of Patients	2567	Number of Patients	2975
Number of Treatment Cycles	5552	Number of Treatment Cycles	7201
Total Clinical Pregnancies	672	Total Clinical Pregnancies	813
Clinical Pregnancy Rate per Cycle	12.1%	Clinical Pregnancy Rate per Cycle	11.3%
Total Miscarriages	73	Total Miscarriages	80
Total Terminations	11	Total Terminations	7
Total Ectopics	6	Total Ectopics	2
Total Live Births	537	Total Live Births	692
Live Birth Rate per Cycle	9.7%	Live Birth Rate per Cycle	9.6%
Total stillbirths and neonatal deaths	7	Total stillbirths and neonatal deaths	10

Table 4.20 Single and multiple clinical pregnancy outcome

a) Stimulated DI

	<i>Clinical pregnancies</i>	<i>Live births</i>	<i>Miscarriages</i>	<i>Terminations</i>	<i>Ectopics</i>	<i>Unknown outcomes</i>	<i>Babies born</i>	<i>Stillbirths and neonatal deaths (per thousand birth events)</i>
Singleton	535	457	62	3	6	3	457	8.8
Twin	73	67	7	-	-	1	130	29.9
Triplet	11	10	3	4	-	0	23	100.0 (1 out of 10)
Quad	2	2	-	2	-	0	4	-
Quin	2	1	1	2	-	0	2	-
Totals	623	537	73	11	6	4	616	13.0

b) Unstimulated DI

	<i>Clinical pregnancies</i>	<i>Live births</i>	<i>Miscarriages</i>	<i>Terminations</i>	<i>Ectopics</i>	<i>Unknown outcomes</i>	<i>Babies born</i>	<i>Stillbirths and neonatal deaths (per thousand birth events)</i>
Singleton	781	679	79	7	2	4	679	14.7
Twin	12	12	1	-	-	-	23	-
Triplet	1	1	-	-	-	-	3	-
Totals	794	692	80	7	2	4	705	14.5

Table 4.21 DI live birth rate by woman's age

	<i>Under 25</i>	<i>25-29</i>	<i>30-34</i>	<i>35-39</i>	<i>40-44</i>	<i>45 and over</i>
Number of cycles	479	2879	4916	3428	986	54
Live Birth Rate per cycle	12.1	11.0	11.0	8.0	4.1	1.9

Research is vital for the advancement of clinical medicine. Early knowledge of human embryology was based entirely on the physical description of embryos at different stages of development and comparison with processes in other species, mainly the mouse. The first successful *in vitro* fertilisation of mouse ova was achieved in 1958 and was followed ten years later with the successful fertilisation of human eggs *in vitro* and in 1970 with the cleavage of fertilised human eggs. With the ability to freeze and store embryos, the possibilities for research have risen significantly in the past few years.

BACKGROUND

Any research project that involves the creation, keeping or use of human embryos outside the body must be licensed by the HFEA¹². 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:

HFEA REMIT

- 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.¹³

The HFEA must be fully satisfied that the use of human embryos is essential for the purpose of the research before it grants a licence. Human 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;

¹² A list of HFEA licensed research projects is at Annex 4.

¹³ HF&E Act Schedule 2, para 3(2).

- 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

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. 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.

All applications for research licences are submitted for peer review¹⁴. Peer reviewers comment on a number of issues including the works originality and the justification for it. Their recommendations are submitted to a Licence Committee which will decide whether a research licence should be granted. The HFEA must be fully satisfied that the use of human embryos is essential for the purpose of the research before it grants a licence.

In coming to their decisions 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.

The HFEA requires reports on the progress of licensed research projects and may discuss these during inspections. Centres must submit a provisional report to the HFEA of the results and conclusions drawn from the research project within three months of its end. A final report of results, conclusions and references to any publications arising from the research project must be made to the HFEA as soon as reasonably practicable.

CURRENT SITUATION

As of 31 August 1999 the HFEA had received 124 applications for research licences since 1991. Of these, 102 were granted, although 12 of these were subsequently refused at renewal. Research has been completed in 63 licensed projects.

¹⁴ The HFEA's panel of peer reviewers is at Annex 5.

At 31 August 1999 there were 27 licensed research projects ongoing. A list of these is at Annex 4. The projects can be classified into the following areas of research (some are classified under more than one ‘purpose’):

- To promote advances in the treatment of infertility (10);
- To develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation (4);
- To promote advances in the treatment of infertility and to increase knowledge about the causes of miscarriages (4);
- To promote advances in the treatment of infertility and to develop more effective techniques of contraception (1);
- To promote advances in the treatment of infertility and to increase knowledge about the causes of congenital disease (1);
- To increase knowledge about the causes of congenital disease and to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation (2);
- To promote advances in the treatment of infertility, to increase knowledge about the causes of miscarriages and to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation (3); and
- To promote advances in the treatment of infertility, to increase knowledge about the causes of congenital disease and to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation (2).

As can be seen from the above, the main objective of the majority of the projects currently licensed by the HFEA is to promote advances in the treatment of infertility. This has been reflected in significant improvements in IVF procedures and pregnancy rates over the last 10 years.¹⁵

¹⁵ The live birth rate for IVF in 1986 was 8.6%, according to data collected by the OPCS on behalf of the Voluntary Licensing Authority. The live birth rate for treatments in 1997/8 was 16.4%.

6

Policy update and issues for the coming year

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

PAYMENTS TO SPERM AND EGG DONORS

In 1998 the HFEA conducted a consultation exercise on the subject of payments to donors. In considering this, the HFEA stressed its commitment to altruistic donation and its belief that the donation of sperm or eggs to create new life should be a gift, freely and voluntarily given. Nevertheless, we became increasingly aware that the issue of payment could not be considered as an issue of principle in isolation from others. It became clear that the continued provision of donor treatments in the UK would be seriously undermined by the removal of payments.

The HFEA was also mindful of an emerging international trade in gametes and of the increased use of the Internet to advertise donors from abroad. The HFEA considered that the supply of safe, screened sperm through licensed centres in UK clinics was preferable to the potential risks to patients that might be involved in obtaining samples from donors recruited abroad. It was also clear that the HFEA could not regulate payments made to donors in other countries.

As a result, the HFEA decided to allow the current payment of £15 per donation, plus reasonable expenses incurred as a direct result of making the donation, to continue. In addition, it decided that guidelines for the payment of expenses to donors and for the regulation of egg-sharing schemes should be drawn up for inclusion in the next edition of the Code of Practice.

CLONING

In January 1998 a consultation document on cloning was jointly produced by the HFEA and the Human Genetics Advisory Commission (HGAC). Over 1,000 copies of the document were issued and it was also accessed from the HGAC's website. Nearly 200 responses were received – about 40% from individual members of the public and the rest from a wide range of constituencies, including professional bodies, religious organisations and lay groups, many of whom had organised their own discussion groups or otherwise canvassed views.

The ensuing report to Ministers, *Cloning issues in reproduction, science and medicine*, was published in December 1998. The consultation process had demonstrated widespread support for the views initially expressed by the HFEA and the HGAC that human ‘reproductive cloning’ (i.e. the deliberate creation of a cloned human being) should not take place. The HFEA had already made it clear that it would not issue a licence for any project that had reproductive cloning as its aim. The HGAC/HFEA report observed that current statutory safeguards are wholly adequate to forbid human reproductive cloning, but suggested that the Government may wish to consider the possibility of legislation explicitly banning reproductive cloning regardless of the technique used, as a clear public statement on reproductive cloning in the UK.

The report also drew a distinction between reproductive cloning and *in vitro* work using cell nucleus replacement technology with a therapeutic aim. It concluded that the latter may hold promise for the treatment of serious illnesses, and recommended keeping the door open to these potential benefits. Specifically, the report recommended to the Secretary of State that consideration should be given to specifying in Regulations two further categories for which HFEA-licensed embryo research may take place, being:

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

The report also recommended that the situation should be re-examined in five years.

In June 1999 the Government announced the creation of a high-level advisory group to consider in more detail the scientific implications of the use of the cloning technique in embryo research. The HFEA welcomed this move.

PGD is a technique used to detect whether an embryo created *in vitro* is carrying a genetic defect that will give rise to a serious inherited genetic disorder. It can also be used to determine the sex of an embryo where a family is at risk of passing on a serious sex-linked disorder, such as Duchenne’s Muscular Dystrophy.

Four centres are licensed by the HFEA to carry out PGD with one further centre licensed only to carry out the embryo biopsy procedure only. Six 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

PREIMPLANTATION GENETIC DIAGNOSIS (PGD)

different conditions increases and the techniques involved continue to develop.

The HFEA established a joint working group with the Advisory Committee on Genetic Testing (ACGT) and is preparing a public consultation document on the issues surrounding the use of PGD. It is expected that this will be published in autumn 1999. The joint working group also developed an interim inspection and licensing framework for PGD that includes the development of training and assessment criteria for the evaluation of practitioners carrying out the embryo biopsy part of the procedure. This licensing framework is expected to be developed further in the light of responses received to the consultation document.

CRYOPRESERVATION OF SPERM AND EMBRYOS

A consultation paper on this subject was issued in June 1998 and sent to licensed centres, relevant experts and professional organisations. The document discussed the issues around the safe cryopreservation of sperm and embryos following a reported incident of cross contamination of hepatitis B in liquid nitrogen storage vessels containing bone marrow. The HFEA concluded that the potential risks, while very low, had to be taken seriously. The consultation document included a review of the safety issues and recommended a series of new guidelines for inclusion in the next edition of the Code of Practice.

Responses to the consultation document are currently being considered and the Working Group on Safe Cryopreservation has been reconvened to prepare a draft report to the HFEA.

STORAGE OF TESTICULAR AND OVARIAN TISSUE

During 1998 the HFEA published its policy of the storage of testicular and ovarian tissue. Essentially, any tissue containing viable gametes must not be stored except under a licence from the HFEA. In 1999 the RCOG set up a Working Group, on which the HFEA is represented, to develop best practice guidelines on the storage and handling of such tissue.

ONCOLOGY PATIENTS – REVIEW OF GUIDELINES

The HFEA is currently reviewing its guidelines which relate to the long term storage of gametes (and embryos) for patients about to undergo chemotherapy, radiotherapy or surgery which is likely to adversely affect their fertility and is consulting centres on this issue.

WORKING GROUP ON NEW DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY (WGNDRT)

The HFEA's Working Group on New Developments in Reproductive Technology (WGNDRT) advises the Authority on the progress and safety of, and the training standards for, new clinical and scientific techniques. When considering novel applications the WGNDRT always places great emphasis on evidence of the safety and efficacy of the procedure. Additionally, once new procedures have been licensed, the WGNDRT

has an ongoing role in keeping the results under review. For example, the WGNDRRT has regularly examined information provided by licensed centres and in published literature regarding such techniques as ICSI, PGD and laser assisted hatching.

The WGNDRRT has identified a number of factors that it takes into account when examining the licensing of a new technique. These include:

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

The technique of assisted hatching has been used for a number of years. This procedure involves making a small hole in the shell (zona pellucida) of the embryo *in vitro*. The aim of the procedure is to assist in the hatching of the embryo and therefore to increase the chance of the embryo implanting in the uterus. Historically mechanical or chemical means have been used to make the hole. Recently the WGNDRRT was asked to consider the use of assisted hatching by laser in embryos used for treatment. After consideration of the evidence the WGNDRRT agreed to recommend that laser assisted hatching could be used in treatment. The first licence for laser assisted hatching was granted in August 1998.

Some researchers have proposed that the transfer of cytoplasm from a ‘normal’ egg into the egg from a patient whose embryos had previously developed poorly could correct such development in certain cases. This procedure is called cytoplasmic transfer or donation, and has as its aim the restoration of normal growth and development of the subsequent embryo. Having considered the evidence the WGNDRRT felt that a strong case could not be made for the biological basis of cytoplasmic transfer, and that there was a lack of animal and human research and clinical data in this field. Whilst the HFEA would encourage applications for research into this procedure, we believe that, at this time, it would be premature to license its use in treatment.

Certain research studies have suggested a possible link between the use of superovulatory drugs to stimulate the ovaries and an increased risk of certain types of cancer. In 1998 the WGNDRRT considered the latest published literature and concluded that there was no convincing evidence for such an association. The WGNDRRT will continue to

Licensing of Novel Applications

Laser Assisted Hatching

Use of Cytoplasmic Donation in Treatment

Fertility Drugs and Cancer

monitor the situation. Patients concerned should be encouraged to discuss this with their doctor.

**Guidance for Centres
Regarding the Use of
Blastocyst Transfer in
Treatment**

The WGNDRT has recognised that the practice of embryo transfer at the blastocyst stage has become widespread. Work on cattle and sheep shows that prolonged embryo culture followed by blastocyst transfer can, in some cases, give rise to neonatal problems, notably increased birth-weight and fetal abnormalities. There is no evidence so far of similar changes following the transfer of human blastocysts. Nevertheless the WGNDRT felt that centres should pay particular attention to the outcome of this new form of treatment and caution patients accordingly in their patient information.

Communications

7

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.”¹⁶ In fulfilling this function the HFEA offers a comprehensive range of information for current or prospective patients, donors and the general public (listed at the end of this chapter). We receive, on average, 150 requests per week for our publications. About twice a year the HFEA circulates a newsletter, *HFEA Update*, to licensed clinics and interested bodies, informing them of recent policy decisions and discussing areas of concern.

The HFEA works closely with journalists and media researchers and supplies speakers for national and international conferences and for press, radio and television interviews. In addition, HFEA Members and staff have written articles for mainstream, specialist and patient publications. This year the HFEA’s website (www.hfea.gov.uk) was expanded to include the Patients’ Guide, the Annual Report and the Code of Practice, as well as recent press releases and summary minutes of HFEA meetings.

Since 1995 the HFEA has produced an annual *Patients’ Guide to DI and IVF Clinics*. This is designed to be a comprehensive guide to people seeking, or considering, treatments licensed by the HFEA.

During 1998–9 the HFEA has been fundamentally reassessing all aspects of the Guide. The presentation of individual patient data has changed this year to more readily reflect the different patient mixes in respect to age.

We are committed to producing clinic data that is both fair to clinics and informative and understandable for patients.

INTRODUCTION

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

¹⁶ HFE Act 1990, section 8(c).

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 1998 Conference included sessions on the assessment of the 'welfare of the child', the licensing of new procedures and the perspectives of various patients on licensed treatments. The 1999 Conference will include sessions on embryo transfer, the licensing system and HFEA inspections, the HFEA data register, egg sharing and meeting patients' needs.

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. In line with this policy the HFEA has this year organised regional meetings in Glasgow, Cambridge and London. A meeting in York is planned for spring 2000. These meetings are opportunities for all those involved in licensed infertility treatments – patients, clinicians, embryologists, nurses, counsellors and researchers – to discuss HFEA policy 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 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.

INFORMATION AVAILABLE TO THE PUBLIC

The HFEA provides information which is available to prospective patients, interested organisations and the general public. Those requiring any of the following publications should contact the HFEA.

Annual Reports: 1992–97

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

The 1999 Patients' Guide to DI and IVF Clinics

Pack includes:

- The Patients' Guide to Infertility and IVF
- The Patients' Guide to IVF Clinics
- The Patient's Guide to DI Clinics

List of all licensed clinics

List of sperm donor recruitment centres

List of egg donor centres

Code of Practice (*Fourth Edition*)

Information leaflets:

- Egg Donation
- Sperm and Egg Donors and the Law
- HFEA: Who we are and what we do

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

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

Annex 1

EXECUTIVE STAFF

Main telephone no: 0171 377 5077



Suzanne McCarthy
Chief Executive

<i>Member of Staff</i>	<i>Job Title</i>	<i>Telephone Extension</i>
Suzanne McCarthy	Chief Executive	0171-539-3303
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Mark Salmon	on secondment	
Dr David Thorne	Licensing Manager	0171-539-3316
Allan Wright	IT Manager	0171-539-3307
Office Administration		
Julie Jones	Administration Officer/ PA to Suzanne McCarthy	0171-539-3303
Tony Burkett	Administration Officer	0171-539-3319
Dilpa Patel	Administration Assistant	0171-539-3318
Audit		
Anne-Louise Crowther	Systems & Data Auditor	0171-539-3313
Sarah Qureshi	Systems & Data Auditor	0171-539-3323
Communications		
James Yeandel	Director of Communications	0171-539-3306
Data		
Dr Richard Baranowski	Deputy Information Manager	0171-539-3329
Debra Farrell	Deputy Register Supervisor	0171-539-3327
Tina Kundu	IT Support and Research Assistant	0171-539-3310
Maureen Goodman	Data Officer	0171-539-3331
Patricia Honnor	Data Officer	0171-539-3321
Gaby Jeremiah	Data Officer	0171-539-3321
Sandy Lathleiff	Data Officer	0171-539-3331
Nick Best	Data Officer	0171-539-3332
Sally Payne	Data Administrator	0171-539-3332
Finance		
Gill Davidson	Finance Manager	0171-539-3305
Tony Smith	Accounts Manager	0171-539-3302
Licensing		
Nan Hume	Licensing Business Administrator/ Inspector Co-ordinator	0171-539-3314
Dr Joanne Rippington	Inspector Co-ordinator	0171-539-3325
Anne-Louise Crowther	Inspector Co-ordinator	0171-539-3313
Kim Hayes	Inspector Co-ordinator	0171-539-3312
Dr Debbie Holland-Jaggers	Inspector Co-ordinator	0171-539-3322
Sarah Qureshi	Inspector Co-ordinator	0171-539-3323
Alison Threlfall	Inspector Co-ordinator	0171-539-3324
Dr Mary Wall	Inspector Co-ordinator	0171-539-3315
Kerri Treston	Licence Administrator	0171-539-3317
Jacy Emmett	Licence Administrative Assistant	0171-539-3326
Policy		
Danielle Marx	Policy Manager	0171-539-3308
Virginia Shires	Policy Manager	0171-539-3311

Annex 2

LIST OF LICENSED CLINICS

(as of 31 August 1999)

Avon

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

Berkshire

Berkshire Fertility Centre, Reading
BUPA Dunedin Hospital, Reading

Buckinghamshire

BMI Chiltern Hospital, Great
Missenden
Thames Valley Nuffield Hospital

Cambridgeshire

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

Cleveland

Cleveland Fertility Centre, Stokesley
Hartlepool General Hospital
South Cleveland Hospital,
Middlesbrough

Derbyshire

Derby City General Hospital

Devon

Derriford Hospital, Plymouth
Royal Devon and Exeter Hospital,
Exeter

Dorset

Winterbourne Hospital, Dorchester

Durham

Bishop Auckland General Hospital

East Sussex

Esperance Private Hospital, Eastbourne

Essex

Brentwood Fertility Centre
Essex Fertility Centre, Buckhurst Hill
North East London Fertility Services,
Ilford
The BUPA Roding Hospital, Ilford

Greater Manchester

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

Hampshire

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

Hertfordshire

Watford General Hospital

Humberside

Princess Royal Hospital, Hull

Kent

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

Leicestershire

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

London (Central)

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

London (East)

Homerton Hospital
Multicare International, Harbour
Exchange
Newham General Hospital

London (North)

London Female and Male Fertility
Centre, Highgate Private Hospital

London (South)

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

London (West)

West Middlesex University Hospital
Wolfson Family Clinic, Hammersmith
Hospital

Merseyside

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

Northern Ireland

Royal Maternity Hospital, Belfast

Norfolk

BUPA Hospital, Norwich

Northamptonshire

BMI Three Shires Hospital, Cliftonville

Nottinghamshire

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

Oxfordshire

John Radcliffe Maternity Hospital,
 Oxford
 Scotland-Grampian
 University of Aberdeen

Scotland-Lothian

Royal Infirmary of Edinburgh
 Western General Hospital, Edinburgh

Scotland-Orkney

Balfour Hospital, Orkney

Scotland-Strathclyde

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

Scotland-Tayside

Ninewells Hospital and Medical School,
 Dundee

Shropshire

Shropshire and Mid-Wales Fertility
 Centre, Royal Shrewsbury Hospital

Staffordshire

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

Surrey

Shirley Oaks Hospital, Croydon
 Woking Nuffield Hospital

Tyne and Wear

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

Wales (South Glamorgan)

BUPA Hospital Cardiff
 University Hospital of Wales, Cardiff

Wales (West Glamorgan)

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

West Midlands

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

Yorkshire (South)

Jessop Hospital for Women, Sheffield
 Sheffield Fertility Centre

Yorkshire (West)

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

**CLINICS WITH SPERM
 STORAGE LICENCES
 ONLY**

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

Annex 3

LIST OF HFEA INSPECTORS (as of 31 August 1999)

CLINICIANS

Mr Masoud Afnan

Consultant Obstetrician & Gynaecologist,
Honorary Senior Lecturer
Director of ACU, Birmingham
Maternity Hospital

Professor Peter Braude

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

Mr Peter Brinsden

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

Mr Chris Chandler

Clinical Director, Consultant
Obstetrician and Gynaecologist,
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 ICSM Campus, London

Dr Mark Hamilton

Consultant Obstetrician & Gynaecologist
Clinical Senior Lecturer, University of Aberdeen

Mr Richard Kennedy

Consultant Obstetrician & Gynaecologist,
Walsgrave Hospital,
Coventry

Mr Charles Kingsland

Consultant Obstetrician & Gynaecologist
Honorary Lecturer
The Women's Hospital Liverpool

Dr Martin Lees

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

Dr John Mills

Consultant Obstetrician & Gynaecologist
Ninewells Hospital, Dundee

Dr Alison Murdoch

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

Mr Roger Neuberg

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

Mr Julian Pampiglione

Consultant Obstetrician & Gynaecologist,
The Royal Bournemouth Hospital

Mr John Parsons

Senior Lecturer
Honorary Consultant, King's College Hospital, London

Dr Elizabeth Pease

Consultant,
St Mary's Hospital, Manchester

Dr David Polson

Consultant in Obstetrics & Gynaecology,
Salford Royal IVF & Fertility Centre

Mr Anthony Rutherford

Consultant Obstetrician & Gynaecologist,
The Leeds Teaching Hospitals NHS Trust

Mr Robert Sawers

Consultant Obstetrician & Gynaecologist
Programme Director, BMI Priory Hospital, Birmingham

Dr Francoise Shenfield

Clinical Lecturer,
Reproductive Medicine Unit,
University College London Medical School

Mr Eric Simons

Medical Director,
Cromwell Hospital, London

Dr Alison Taylor

Consultant
Lecturer, St Thomas' Hospital, London

Mr Peter Wardle

Consultant & Senior Lecturer in Obstetrics and Gynaecology,
Southmead Hospital, Bristol

Dr John Waterstone

Consultant Obstetrician & 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

Scientific Director,
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

Retired Reader in Reproductive
Endocrinology

Ms Karin Dawson

Consultant Embryologist,
Hammersmith Hospital, London

Dr Simon Fishel

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

Dr Richard Fleming

Scientist, Glasgow Royal Infirmary

Professor Tom Fleming

Cell Sciences Division, School of
Biological Sciences,
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

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University Department of Obstetrics &
Gynaecology,
Glasgow Royal Infirmary

Dr John Keith

Senior Scientist
Edinburgh Assisted Conception Unit

Mr Terry Leonard

Co-Director,
ISIS Fertility Centre, Colchester

Dr Alan McDermott

Director, Regional Cytogenetics Centre
Southmead Hospital, Bristol

Dr Dave Morroll

Senior Clinical Embryologist
NURTURE, Nottingham

Ms Barbara Ray

Principal Embryologist,
University of Bristol, BUPA Hospital,
Bristol

Dr John Robinson

Scientific Director,
Hull IVF Unit

Professor Mary Seller

Professor of Development Genetics,
Medical & Molecular Genetics, Guy's
Hospital, London

Dr Arasaratnam Srikantharajah

Research Embryologist,
University of Aberdeen

Mr Stephen Troup

Scientific Director,
Liverpool Women's Hospital

Reverend Professor Paul Watson

Professor of Reproductive Cryobiology,
Royal Veterinary College, London

Dr Maureen Wood

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

SOCIAL AND ETHICAL INSPECTORS

Mrs Sarah Biggs

Member of Kings Fund Committee on
Counselling, London

Mrs Linda Breeze

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

Dr Elizabeth Bryan

Medical Consultant, 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

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Ms Margaret Inglis

Counsellor,
Royal Free Hospital, London

Ms Janice Kerr

Services Manager, Clinical Nurse
Specialist (Infertility),
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Dr Jim Monach

Lecturer,
SCHARR, University of Sheffield

Ms Kathryn Parkinson

Unit Manager of IVF & OPD
BMI Portland Hospital, London

Mrs Roz Shaw-Smith

Counselling Psychologist,
John Radcliffe Hospital, Oxford

Ms Jennifer Speirs

Freelance Infertility Counsellor and
Social Work Consultant
Edinburgh

Annex 4

LIST OF RESEARCH PROJECTS

(as of 31 August 1999)

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) at the Park Hospital, Nottinghamshire

Assessment of human spermatid chromosomes after injection into hamster oocytes

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

Liverpool Women's Hospital

Biopsy practice of three pronucleate 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

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

Metabolism of human embryos as an index of quality

University of Manchester

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

University of York

Biochemistry of early human embryos

Walsgrave Hospital, Coventry

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

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

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

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

Randomised controlled clinical trial of blastocyst vs. cleaving embryo transfer

Sheffield Fertility Centre

An investigation of embryonic-endometrial dialogue during the peri-implantation period *in vitro*

Annex 5

LIST OF PEER REVIEWERS

(As of 31 August 1999)

Dr Gulam Bahadur

Clinical Biochemist
Head of Fertility Laboratories,
University College London
Medical School / University College,
London Hospital Trust

Mr Adam Balen

Consultant Obstetrician and
Gynaecologist and Sub-specialist in
Reproductive Medicine,
Leeds General Infirmary

Professor David Barlow

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

Dr Siladitya Bhattacharya

Lecturer in Obstetrics and Gynaecology
University of Aberdeen

Dr Virginia Bolton

Senior Lecturer,
King's Assisted Conception Unit

Professor Peter Braude

Chairman of UMDS Department of
Obstetrics and Gynaecology,
Director of Fertility Services, Guy's and
St Thomas', London

Professor Nigel A Brown

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

Professor Iain Cameron

Head of Department, Department of
Obstetrics and Gynaecology,
University of Southampton

Dr John Carroll

Department of Anatomy &
Developmental Biology,
University College, London

Professor Tim Chard

Department of Reproductive
Physiology,
St Bartholomew's Hospital Medical
College, London

Dr J R T Coutts

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

Professor Mark Curry

Senior Lecturer in Equine Science,
Department of Agriculture and
Horticulture,
De Montford University

Ms Karin Dawson

Consultant Embryologist
Hammersmith Hospital, London

Professor Joy Delhanty

Professor of Human Genetics,
University College, London

Dr Simon Fishel

Managing Director, CARE at the Park
Hospital, Arnold, Nottingham

Dr Richard Fleming

Department of Obstetrics and
Gynaecology
Glasgow Royal Infirmary

Professor Stephen Franks

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

Professor Lynn Fraser

Professor of Reproductive Biology,
Kings College, London

Dr Rafet Gazvani

Lecturer in Obstetrics &
Gynaecology
University of Aberdeen

Professor Christine Gosden

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

Professor Roger Gosden

Professor of Reproductive Biology,
University of Leeds

Dr Mark Hamilton

Clinical Science Lecturer, Department
of Obstetrics and Gynaecology,
University of Aberdeen

Dr Joyce Harper

University College London

Dr Geraldine Hartshorne

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

Professor Alan Handyside

School of Biochemistry and Molecular
Biology,
University of Leeds

Mr Jonathan Hewitt

Consultant Obstetrician and
Gynaecologist, Chairman of Medical
Committee, Liverpool Womens
Hospital

Dr Mark Johnson

Senior Lecturer,
Chelsea & Westminster Hospital

Professor Martin Johnson

Professor of Reproductive Sciences,
University of Cambridge

Professor M H Kaufman

Professor of Anatomy,
University of Edinburgh

Dr Sue Kimber

Senior Lecturer,
University of Manchester

Mr Charles Kingsland

Consultant in Obstetrics and
Gynaecology,
Liverpool Women's Hospital

Professor G.E. Lamming

Department of Physiology and
Environmental Science
University of Nottingham

Professor Henry Leese

Department of Biology,
University of York

Dr Brian Lieberman

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

Dr Alan McDermott

Director, Regional Cytogenetics Centre,
Southmead Hospital, Bristol

Dr Anne McLaren

Principal Research Associate,
Wellcome/CRC Institute, Cambridge

Professor Alan McNeilly

Deputy Director and Senior Scientist,
MRC Reproductive Biology Unit,
Edinburgh

Dr Tony Michael

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

Professor Marilyn Monk

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

Professor R Moor

Babraham Institute, Cambridge

Professor H D M Moore

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

Professor David Pegg

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

Dr Ian Sargent

John Radcliffe Hospital, Oxford

Professor Allan Templeton

Professor of Obstetrics and
Gynaecology,
University of Aberdeen

Reverend Professor Paul Watson

Professor of Reproductive Cryobiology,
Royal Veterinary College, London

Professor Robert Webb

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

Dr Maureen Wood

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

Professor Michael Whitaker

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

Professor David Whittingham

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

Annex 6

LIST OF MEMBERS' INTERESTS

Ruth Deech

Principal, St Anne's College, Oxford

- Shares in Glaxo (through a PEP) and Oxford Glycobiology
- Member – United Oxford & Cambridge Club; Royal Society of Arts
- St Anne's College has shares in London International GP, Glaxo, Smithkline Beecham, Zeneca GP, Nyomed Amersham
- Rolls Royce – Supports engineering at St Anne's College
- Linnells Solicitors (Dr John Deech, Partner)

Jane Denton

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

- Editorial Board Member Human Fertility
- The MBF receives grants from The Gatsby Charitable Foundation, Smiths Charity, Department of Health (Section 64)
- RCOG Infertility Guidelines Development Group Member

Brenda Almond

Professor of Moral and Social Philosophy, University of Hull

Gulam Bahadur

Clinical Biochemist, Head of Fertility Laboratories, Reproductive Medicine Laboratories, Royal Free and University College Medical School/UCLH Trust, London

- Member medical advisory panel - Hodgkins & Lymphoma Association (Charity); McMillan Cancer Fund, BACUP cancer link (charity)
- Intermittent lecturing, publishing and organising conference for various organisations

- Participant UK Multi-Centre study of occupational and environmental exposure to chemicals and male infertility

David Barlow

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

- Consultancy with Pharmaceutical Industry: Novo-Nordisk, Zeneca
- Intermittent publishing/lecturing for various organisations
- Intermittent involvement with advisory committees and expert reports for pharmaceutical industry: Novo-Nordisk; Zeneca; Proctor & Gamble; Ely Lilly; Pharmacia Upjohn; MHR
- Board or Council positions on public organisations (unpaid): RCOG; National Osteoporosis Society; British Menopause Society; National Endometriosis Society; Pennell Initiative
- Membership of research grant awarding bodies (no personal gain): Wellbeing (chairman); South East Region NHS R&D committee
- Department receives research grants from many sources (no personal gain): The Wellcome Trust; Action Research; WellBeing; MRC; EU, OXAGEN, NHS R&D Programme; Schering; Searle; Serono; Organon; Zeneca; Wyeth; Jansen-Cilag; Pharmacia-Leiras

Moira Coath

Solicitor
Administrator, Simon Coath, Legal Training Consultancy

- Non-Executive Director, Dorset Healthcare NHS Trust
- Mental Health Act Manager
- Previously Chair of "Child", the National Infertility Support Network

Christine Gosden

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

- Honorary Consultant, Liverpool Women's Hospital, NHS Trust
- Intermittent writing/publishing: Oxford University Press, Blackwells, Churchill Livingstone, Wiley Saunders, Times Higher Education Supplement, Washington Post
- Commissions for filming/ interviews/articles, CBS, Channel 4
- Holder of research grants; Wellbeing, North West Cancer Research Fund, Roy Castle International Foundation for lung cancer research, NHS NW R & D Research Funding, Humanitas, UK Department for International Development, US State Department
- Fees received for lectures on cancer, fetal medicine, human rights, genocide
- Small personal shareholdings; Abbey National, Scottish Power

Andrew Grubb

Professor of Medical Law, University of Cardiff

- Various author and editorial royalties from academic publishers

Henry Leese

Professor of Biology, University of York

- Director and shareholder in Cellutions Ltd, a company that will develop embryo culture media (part funded by a grant from DTI)
- Research grants from the following: European Commission, MAFF, Milk Development Council, Medical Research Council (no personal gain)
- Editor in Chief, *Human Fertility*
- Committee Member: British Fertility Society
- Small personal shareholdings: Natwest, Zeneca
- Wife is at National Primary Care R&D Centre funded by the Department of Health

Stuart Lewis

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

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

Brian Lieberman

Medical Director, Regional IVF and DI Unit, St Mary's Hospital, Manchester
Director & Consultant Gynaecologist, Manchester Fertility Service

- Consultant Gynaecologist, C.M.H.C.T (NHS)
- Editorial Board, Medicine Group
- Research Associate, Organon
- Occasional lectures, Serono
- Medical advice re. clinical trials, IBSA
- Senior Lecturer, Department of Obstetrics & Gynaecology, University of Manchester
- External Examiner in Obstetrics & Gynaecology, University of London

Anne McLaren

Principal Research Associate, Wellcome CRC Institute, Cambridge

- Society for the Study of Fertility (Member and Trustee)
- British Fertility Society (Honorary Member and Trustee)
- Genetical Society (Member)
- Progress Educational Trust (Member)
- British Society for Development Biology (Member)
- European Society for Human Reproduction & Embryology (Member)
- European Developmental Biology Organisation (President)
- International Society of Differentiation (President)
- Royal Society (Fellow)
- Royal College of Obstetrics & Gynaecology (Fellow)
- Novartis Foundation (Trustee)
- National History Museum (Trustee)
- Nuffield Council of Bioethics (Member)
- Government Panel on Sustainable Development (Member)
- Wellcome Trust Population Panel (Member)
- Project Grant Holder from Wellcome Trust (including post-retirement stipend)
- Oxford International Biomedical Centre (Trustee)
- Shares: Smithkline & Beecham; Shell; Unilever

Sadia Muhammed

General Practitioner, Priory Medical Group, York

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

Sara Nathan

Freelance journalist, previously Editor of Channel 4 News

- Freelance journalism for 'The Scotsman', BBC2 and other publications and broadcasters
- Shareholdings in Williams, Rio Tinto, Shell, Imperial Chemical, Cookson Group, Diageo, Glaxo Wellcome
- Council Member, Jewish Museum
- Member of Radio Authority
- Lay Member, Professional Conduct Committee of the Bar Council
- Consultancy Project for DfID on Slovak TV News

Michael Nazir-Ali

Lord Bishop of Rochester

- Director, Diocesan Board of Finance
- President, Diocesan Board of Education
- Harper Collins; SPCK; Paternoster; Publishers of books
- Fellow, St Edmund Hall, Oxford University
- Endowed lectureships; University of Cambridge; University of Oxford; Queen's; Belfast; Wycliffe College, Toronto; St John's, Auckland, NZ
- Visiting Professor, Faculty of Humanities, University of Greenwich
- Chairman of Council, Trinity College, Bristol

Sharmila Nebhrajani

Head of Corporate Planning, BBC

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

Joan Stringer

Principal and Vice Patron, Queen Margaret University College, Edinburgh

- Commissioner for Scotland, Equal Opportunities Commission
- Member, Secretary of State's Consultative Steering Group and Financial Issues Advisory Group on the Scottish Parliament
- Chair, Northern Ireland Equality Commission Working Group, 1998-99
- Commissioner, Scottish Election Commission
- Vice-Convenor, Committee of Scottish Higher Education Principals
- Member, Scottish Council for Postgraduate Medical and Dental Education

Allan Templeton

Professor of Obstetrics & Gynaecology and Head of Department, University of Aberdeen

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

Julia Tugendhat

Psychotherapist in Private Practice
Vice President: British Association of Counselling

- Shares in Norwich Union; Abbey National; Diageo; PLC; MEP; BT; Babcock Int; Selfridges; Sears; Merit Zero dividend prefs

John Williams

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

- Training and consultancy, Local Government in England & Wales