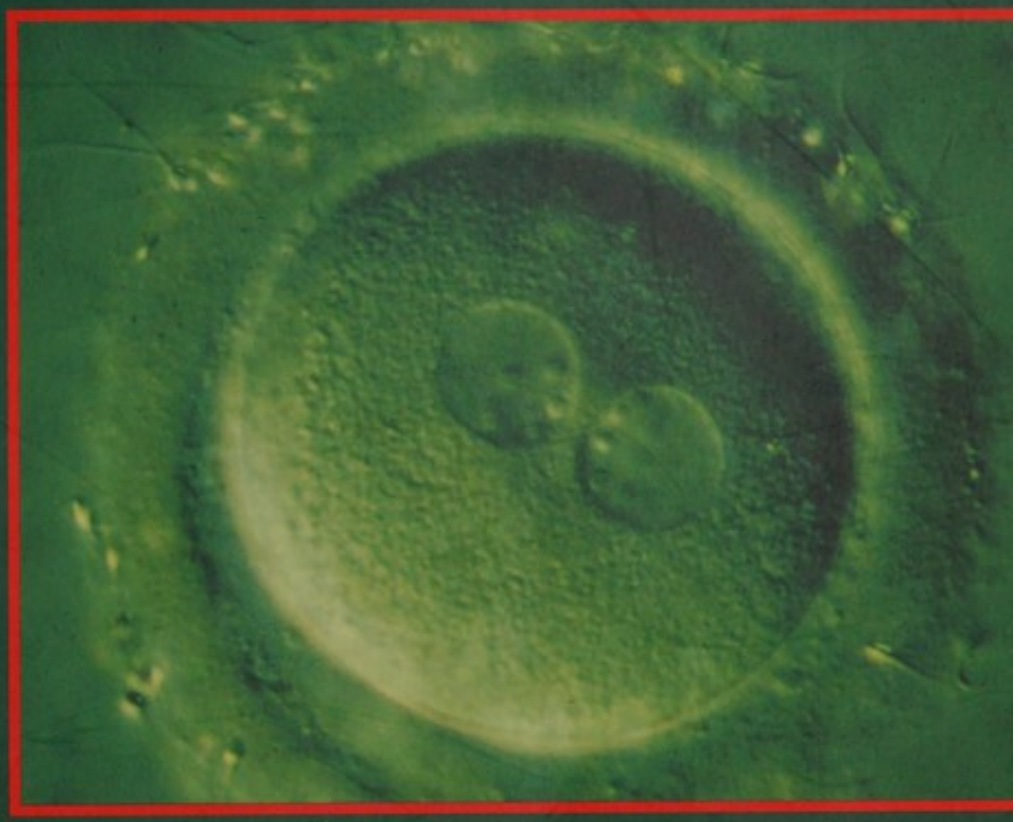
Annual report : 1993 ann. rep. / Human Fertilisation & Embryology Authority.

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY



SECOND ANNUAL REPORT

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HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Human Fertilisation & Embryology Authority
Paxton House, 30 Artillery Lane, London E1 7LS

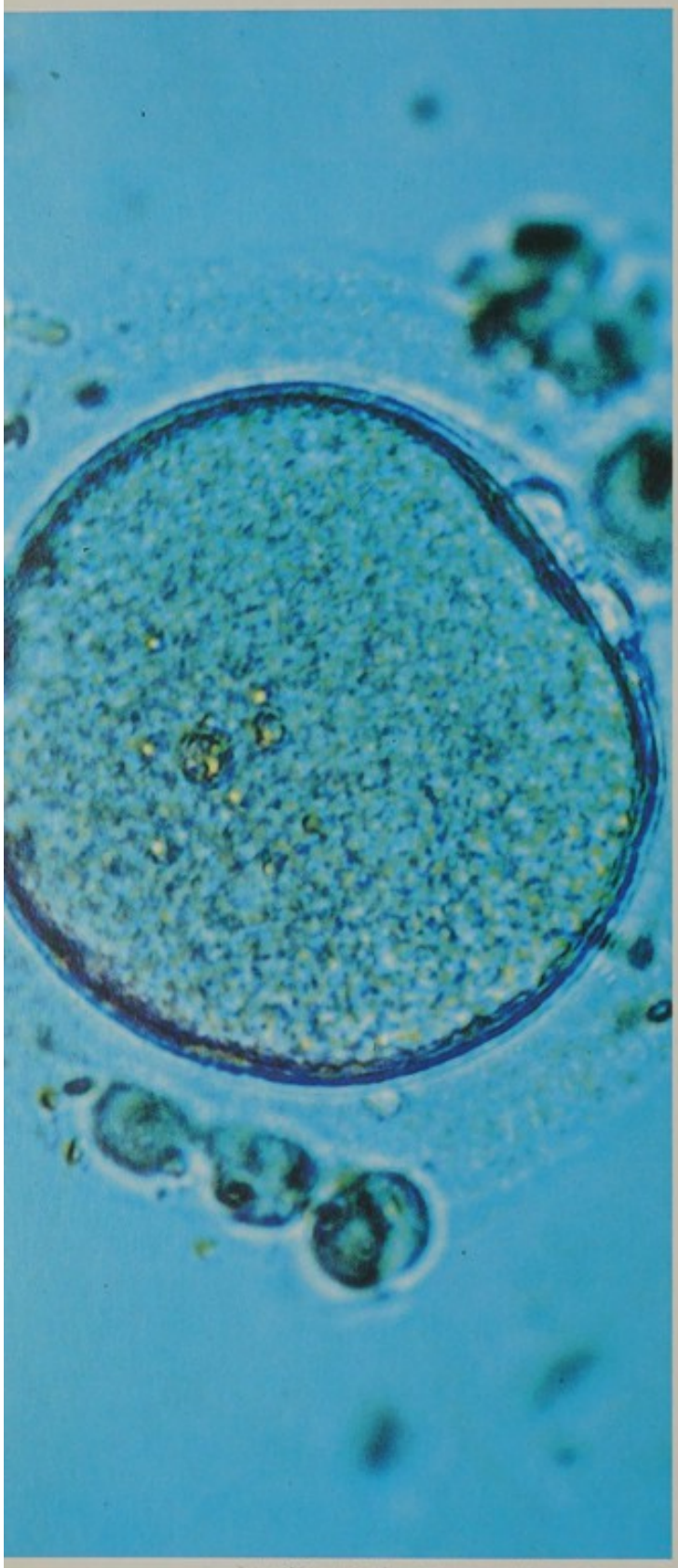
This report covers the year beginning 1 November 1991
with a forward look for the year beginning 1 November 1992

PUBLISHED JULY 1993

C O N T

E N T S

FOREWORD



Unfertilised egg

One of the major events in the last year was the passage of the Human Fertilisation and Embryology (Disclosure of Information) Act 1992. The Authority, with the help of centres, had made a strong and successful case to Ministers calling for changes to the law which eased the excessive restrictions on centres concerning the disclosure of identifying information about patients or donors to **anyone** not covered by a licence. The new Act retains the principle that patients should have control over the dissemination of identifying information relating to them but it allows for disclosure in very limited circumstances, usually with the patient's consent.

These changes are reflected in new guidelines in the Authority's revised Code of Practice which was issued in July. The revised Code also incorporates policy decisions on issues which arose during the first year of licensing. We stated at the outset that our Code of Practice was not set in stone but that it would evolve as new developments occurred and in the light of experience in licensing centres. That process will continue in the future.

LICENSING

The main focus of our second year of operations has been the practical aspects of inspections and licensing. The critical objective before us was to complete the whole process of licensing **all** existing centres by 31 July 1992. This date marked the end of the transitional period allowed for under the Act. If we had failed to meet this deadline for any particular licence application, the centre would have had to close. It is a tribute to the tremendous efforts and commitment of our members, our inspectors and our staff that all 121 centres were properly inspected and 147 licences were issued within the deadline.

Managing the programme of licensing is not a one-off activity. It is an annual series of events which will recur as long as the Human Fertilisation and Embryology Act 1990 remains on the statute books. However, we are a relatively new body and we must seek refinements over the years. Accordingly, having completed the first full year of licensing, we reviewed our procedures and took account of the lessons learnt. We will continue to look for improvements. We are determined to keep ourselves up-to-date and informed

about relevant developments. Our aim is to ensure that new practices are properly monitored and controlled whilst ensuring that there are no unnecessary delays to the introduction of improved services.

SOCIAL AND ETHICAL ISSUES

As well as regulating particular infertility treatment services and embryo research, we have sought throughout the year to anticipate future possibilities which raise important social and ethical issues in infertility treatment and embryo research. Over the past year, we have addressed two such issues which we believe merit careful public debate: sex selection and the use of donated ovarian tissue.

In January this year, we published a public consultation document on sex selection. Almost 2,000 copies of the document have been sent, on request, to interested bodies and individuals. The consultation period ended on 1 June and we are considering the responses. Our decisions or recommendations will be made known in the early Autumn.

A second public consultation document on the use of fetal and other donated ovarian tissue will be published later this year. This is another highly contentious issue which deserves full and informed debate. We intend to distribute the document widely. We believe that it is important, on those issues which have far-reaching implications for society as a whole, that our policies are informed by the broadest range of opinion and commentary.

INFORMATION

It is not just on difficult issues that we need good information. We require accurate data from centres so as to fulfil another of our main statutory responsibilities: maintaining a register of information about treatments, donors and treatment outcomes. We receive several hundred forms every week containing this information. We recognise that it is no easy task for centres for whom the completion of these forms is only one of several administrative tasks required by the Authority. Providing consistent and correct information, particularly on treatment outcomes, remains a considerable problem for some centres. It is one we will seek to resolve by working with the centres over the coming year.

The Authority does not just collect information for monitoring purposes. It has a responsibility to give people the information that they would find useful and helpful. We have now published five information leaflets for the public about treatment, donation and the role of the Authority and are considering others. We have also produced two videos for people about to undergo licensed infertility treatment. The videos are a remarkable achievement because they draw on the experiences of real people who voluntarily gave their time to help others to understand the emotional and financial commitments that can be involved in licensed fertility treatment. I am grateful to each one of them for their contribution.

The Authority will provide further information for those involved in treatment and will continuously seek ways of obtaining feedback from them about their needs.

CONCLUSION

Our second year has provided a quite different experience from the first but it has been no less demanding. We are now more experienced and have a clearer understanding of our responsibilities. But people's expectations of the Authority are growing and we must take care to meet these expectations where it is reasonable to do so. We continue to have two over-riding priorities. These are that the interests of all those involved are recognised by properly informed and thorough analysis of the issues and that people seeking treatment and donors should receive the highest possible standards of service.

We could not have accomplished the work in the past year without the constructive contributions of all the members of the Authority. Nor could the Authority's policies have been implemented so ably and effectively without the unstinting and high calibre support provided by the staff, led by our Chief Executive, Flora Goldhill. I wish to thank all members and staff for their efforts, the results of which are described in this Annual Report.

Colin M. Campbell

Colin M Campbell
Chairman

1. LICENSING

Fertilised egg (zygote)

When the Authority took up its licensing powers on 1 August 1991, there was a transitional period of one year in which a centre could continue operating until the outcome of its licence application was known. This meant that the Authority was committed to inspecting and licensing all centres by 31 July 1992. In total, there were 121 centres to visit and 152 treatment, storage and research licence applications to consider by that date.

Once an application has been received, the process is as follows:

i. a site visit by a team of inspectors;
ii. consideration of the application and inspection report by a licence committee;
iii. notification of the outcome to the applicant.

If the applicant is not content with the decision, representations may be made to the committee before the decision takes effect. This may be followed by an appeal to the full Authority and finally, on a point of law, an applicant may appeal to the High Court.

One of the most important aspects of the whole inspection and licensing process is to promote and sustain good practice and, in doing so, to ensure a consistent approach. At the beginning, the Authority established a number of procedures to ensure that these objectives are met and regularly reviewed.

1.1 Inspections

All centres were inspected between November 1991 and July 1992. In most cases the inspection team consisted of a clinician, a scientist and an inspector with skills in nursing, counselling or a background relevant to the Authority's work. In addition, the member of the Authority's Executive with responsibility for liaison with that centre took part in the inspection.

These teams found that in a good number of centres the quality of practice was notably high. Clearly the standards that had been set in the Authority's Code of Practice were realistic and could be achieved. In many clinics these standards reflected existing practice. However, there was considerable variation in standards of practice across centres as a whole. In some centres progress was being made to meet the requirements of the Code of Practice and this was encouraging, but in others it seemed that considerable pressure would be needed to improve the

standards to an acceptable level. In a very small number of centres, it was evident that they would not be able, for a variety of reasons, to achieve the standards set out in the Code within a reasonable period of time. The way in which the Authority dealt with these findings is set out in the following paragraphs.

After an inspection, a report is submitted to a licence committee. The committee's decision to issue or refuse a licence takes account of the recommendations of the inspection teams.

1.2 Licence Committees

Licence committees consist of five members of the Authority, with a quorum of three. All of the original licence applications had been considered and the outcome decided by licence committees by mid-July 1992. This meant that licences could be in force by the end of that month.

In considering licence applications and the standards to be met, licence committees must be guided by the Act and the Code of Practice. Where new or major issues arise, such as home insemination, licence committees have taken policy advice from the Authority. Guidance has then been given as an addition to the Code of Practice which, following consultation, has been revised accordingly.

To ensure that the Authority maintained a consistent approach to licensing, a strategy was developed for assessing and monitoring standards in centres based on the following:

(i) As well as the standard conditions attached to all licences, additional conditions are attached to licences on occasions where the inspection team or the licence committee discovers a breach (or breaches) of the Act or of the Code of Practice. Centres may be given a certain amount of time to comply with conditions of licence or, alternatively, compliance may be assessed at the next full inspection. Licence conditions have been used, when appropriate, as a means of applying pressure on centres to conform quickly in areas where there have been observed deficiencies in their practice. In this first year, it has been only those centres where this approach was not thought to be sufficient to achieve the required result which have been refused treatment licences. Monitoring of conditions is also carried out by the inspector coordinators who act as the point of contact between the Authority and the centre.

(ii) Licences are issued for a specific period of time with twelve months being the standard duration. A number of fifteen month licences were issued in the first year in order to spread the expiry dates more evenly throughout the year. Centres which have particularly stringent (or numerous) conditions attached to their licence have normally been given short-term licences so that the concerns of a licence committee can be reassessed at further inspections. The licence committee judges what is a reasonable length of time within which the centre should be expected to meet the conditions before a decision is made on the duration of the licence.

The following table shows the length of time for which treatment licences were issued in the first year of licensing.

Length of licence issued (months)

	Three	Six	Twelve	Fifteen
No. of Centres	4	3	81	19

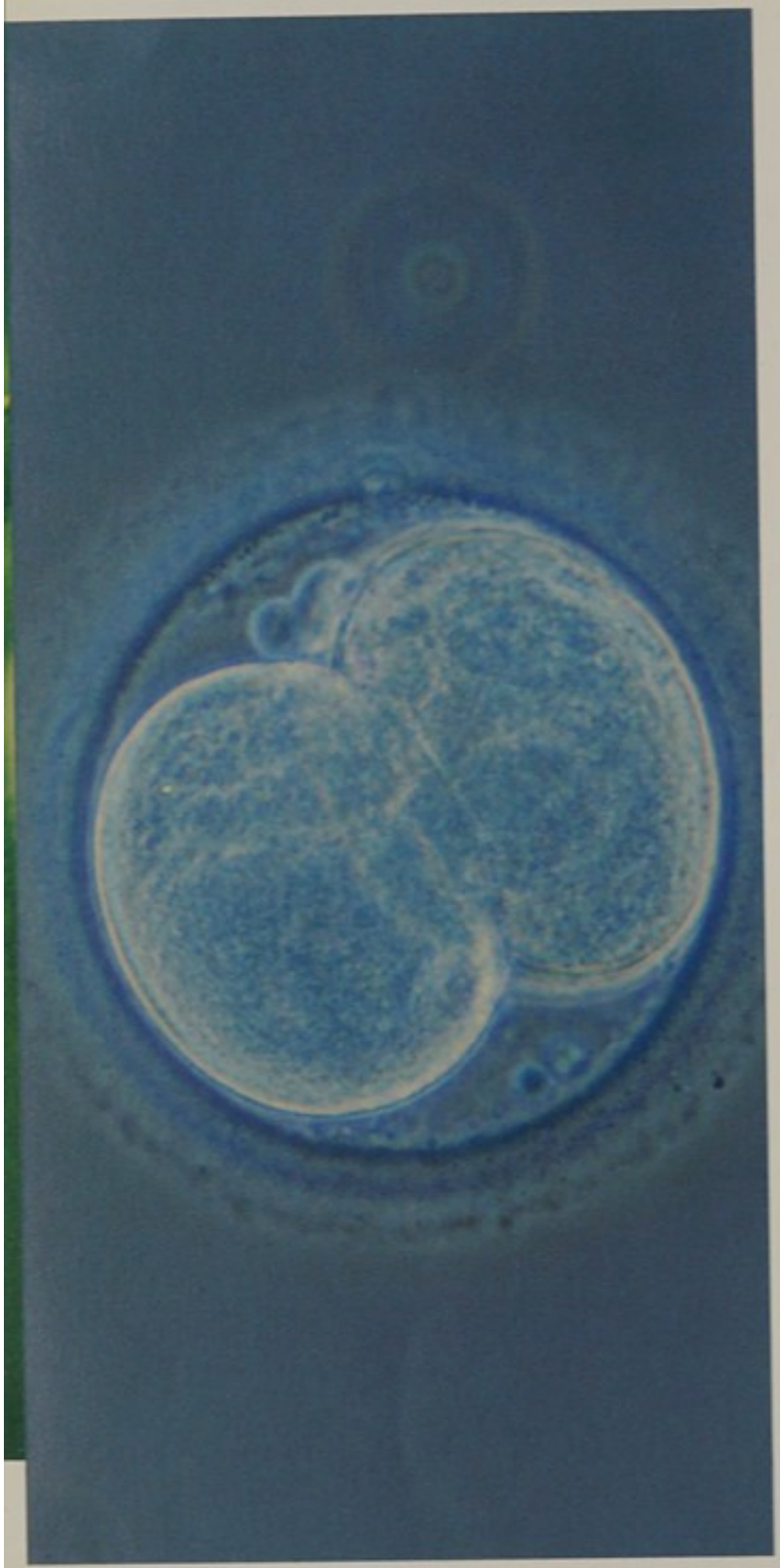
(iii) Licence committees may ask that a letter be sent to a centre which includes specific recommendations. Generally a recommendation is practical advice, based on the Authority's experience of good practice.

The Authority has reviewed all of the conditions and recommendations attached to licences issued in the first year. Not only has this demonstrated a good degree of consistency in the decision-making process, but it has also led to standardisation in the wording of some of the more common conditions and recommendations.

(iv) Centres are commended for particularly high standards of practice and their procedures and methods may be used by the Authority to help other centres obtain equally high standards. Communication between centres is encouraged.

1.3 Licences Issued and Refused

The Authority currently licenses 107 treatment centres of which 65 are for IVF and 37 for donor insemination only. A total of 32 research and 8 storage only licences have been issued. Lists of currently licensed centres and research projects are set out at Annexes 3 and 4. Five licence applications have been refused, including 2 research applications.



2 cell embryo - 32 hours

Where treatment licences have been refused the reasons for the refusal have been given to the applicants. Generally these have been cases where the centres failed in significant ways to meet the standards required by the Act and Code of Practice, and where it appeared to the licence committee that the centre would be unable to meet the required standard within a reasonable period of time.

Licence conditions have related to aspects of the Code of Practice. However, given the emphasis placed on certain issues in the Act and the Code of Practice, it is not surprising that many of the conditions relate to counselling, confidentiality and security, the welfare of the child and information for patients. These are all new statutory obligations which some centres are considering for the first time. It is reasonable therefore for the Authority to recognise that in some centres it may take a little time to develop adequate procedures.

1.4 Appeals

Appeals against licence committee decisions may be made to the full Authority. If the appellant is unhappy with the outcome of an appeal and believes there are grounds, on a point of law, a further appeal may be lodged with the High Court. The Authority has, so far, heard one appeal against a licence committee's decision to refuse a treatment licence application. This was an application for an IVF licence in a centre which offered GIFT as a treatment and the centre wished to use IVF as a diagnostic means of establishing the likelihood of fertilisation in vivo.
The Authority took the view that the quality of embryology support needed to make this procedure worthwhile in these circumstances was as great as that demanded in an IVF treatment centre and that it should therefore only be used in centres which had the expertise to offer IVF treatment. In this particular case the centre was unable to meet that standard and the resulting appeal did not succeed. The principle that emerged from this has subsequently been included in the Authority's revised Code of Practice.

1.5 Breaches of the Code of Practice

Licence committees have also considered cases where centres are in breach of Code of Practice guidelines. Most notably there have been some cases where centres have transferred to a woman four embryos during a single treatment cycle. The limit stated in the Code of Practice is three. In each case the centres concerned had done this on only a single occasion which was shortly after the Code of Practice took effect on 1 August 1991. Each of the centres

concerned provided the licence committee with a report of how the breach had occurred. They also gave assurances that this was the only occasion on which four embryos had been transferred, and that their policies were to limit the number to three in all cases. Having seen the centres' reports, the licence committees asked the Chief Executive to write to the centres concerned informing them of the seriousness with which the Authority viewed the breach and warning them of the possible consequences of any further breach of this limit. This might include suspension or revocation of licences.

1.6 Review of Procedures

While much of the licensing procedure is set out in statute, the corresponding administrative arrangements are entirely at the discretion of the Authority. The Authority is aware that it is important to ensure that the right information is available to centres, to inspectors and to licence committees.

The Licensing and Fees Committee has therefore examined the inspection and licensing procedures in the light of experience from the first year. The views of centres and of inspectors have been taken into account in this review process.

The Authority's first year of licensing has been very successful. In order to maintain consistency, licence conditions will, in future, be standardised as far as possible to show how they relate to particular parts of the Code of Practice. Information gained from experience of licensing will continue to be used to develop and improve the licensing process.

The manual for centres is being updated to take account of recent amendments to the Code of Practice, and to other procedures and guidance.

1.7 The Inspection Process

For some centres the inspection process was an entirely new experience and was somewhat daunting. Over the last year inspections lasted between two hours and a full day depending on the size of the centre, the applications made and the services offered. The aim has been to ensure that the centre is adhering to the Act and the Code of Practice, that the staff are properly qualified and that the facilities are of an appropriately high standard.

During the inspection the team meets the "Person Responsible", whose duty it is to ensure that the centre complies with the requirements of the Act and the Code of Practice. The team also meets the medical and scientific staff, nurses, counsellors and staff in charge of record-keeping. Each is questioned about the procedures at the clinic and about their particular role. In addition questions are asked and investigations made in the following areas:

Staff

The inspectors ensure that all staff have appropriate qualifications and experience.

Facilities

The visiting team inspects the facilities used during treatment and research. Particular consideration is given to ensuring that the facilities and laboratory conditions are of a sufficiently high standard and that attention has been given to overall security as well as to monitoring clinical, counselling and laboratory practice.

Assessing Clients

Centres are required, by law, to take account of the welfare of any child who may be born or affected by the treatment. Questions are asked about what medical and social investigations are performed before treatment begins and the criteria used in deciding whether to treat and which treatment is most appropriate.

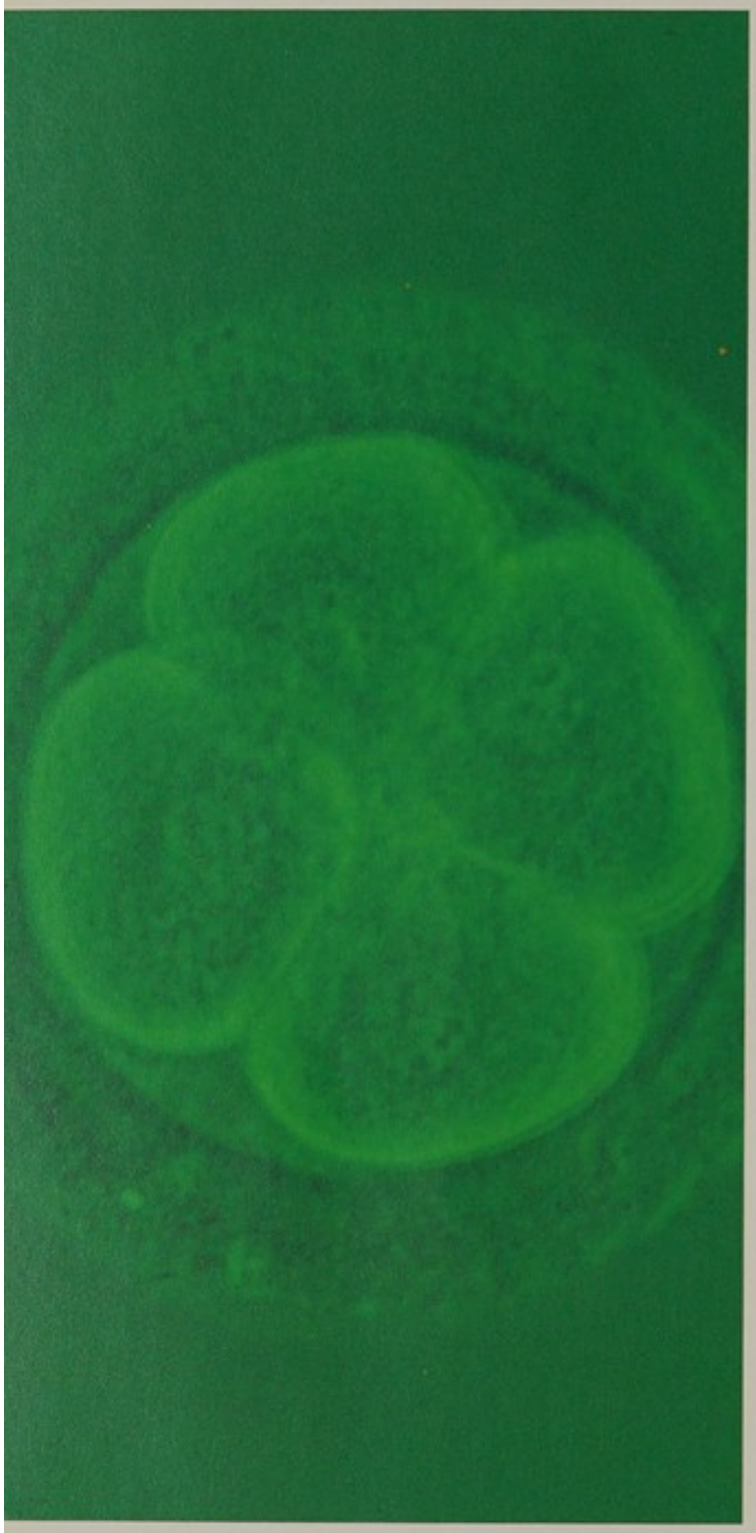
Donors

Centres using donated eggs, sperm or embryos are asked about their procedures for the recruitment and counselling of donors and the screening performed before donated material is used. The team also ensures that there are suitable procedures for limiting the number of children born from a single donor.

Information and Consent

Centres are required, by law, to provide information to those considering treatment. Any written information given to patients before, during or after treatment is assessed by the inspection team to ensure that it is accurate, comprehensive and easily understood. In particular, it should not be misleading, any success rates quoted should be accurate for that particular centre and all charges should be clearly set out with no hidden costs. The consent forms are also reviewed.

Diana Brittan, Deputy Chairman



4 cell embryo - 48 hours

Counselling

All centres are required, by law, to offer counselling to those considering or undergoing treatment and to potential donors. On inspection visits consideration is given to when, where and how the offer of counselling is made.

Handling, Use, Storage and Disposal of Gametes and Embryos

By speaking to staff and inspecting the facilities, a judgement is made on the standard of service offered and the centre's adherence to the guidelines on good practice set out in the Code of Practice.

Records

Particular attention is given to the precautions taken for the security of patient and donor records and the system of record keeping.

Research

In those centres undertaking licensed research, the inspection team meets the chairman or a member of the local research ethics committee and the staff involved in the research. The reasons for undertaking the research, its aims, the justification for the use of human embryos and the ethics committee's deliberations are all discussed.

Other

Centres are required to have a formal complaints procedure and questions about the number, nature and outcome of any complaints are asked during the inspection visit. Enquiries are also made about any other issues which may be of interest to the HFEA.

Flora Goldhill, Chief Executive, and Hugh Whittall, Deputy Chief Executive

2. INCOME AND EXPENDITURE

The Human Fertilisation and Embryology Act makes it a requirement for all centres seeking a licence from the HFEA to contribute towards the Authority's costs by paying licence fees. The amount of these fees will vary over time depending on the Authority's budget and the proportion of income to be derived from this source.

2.1 HFEA Budget

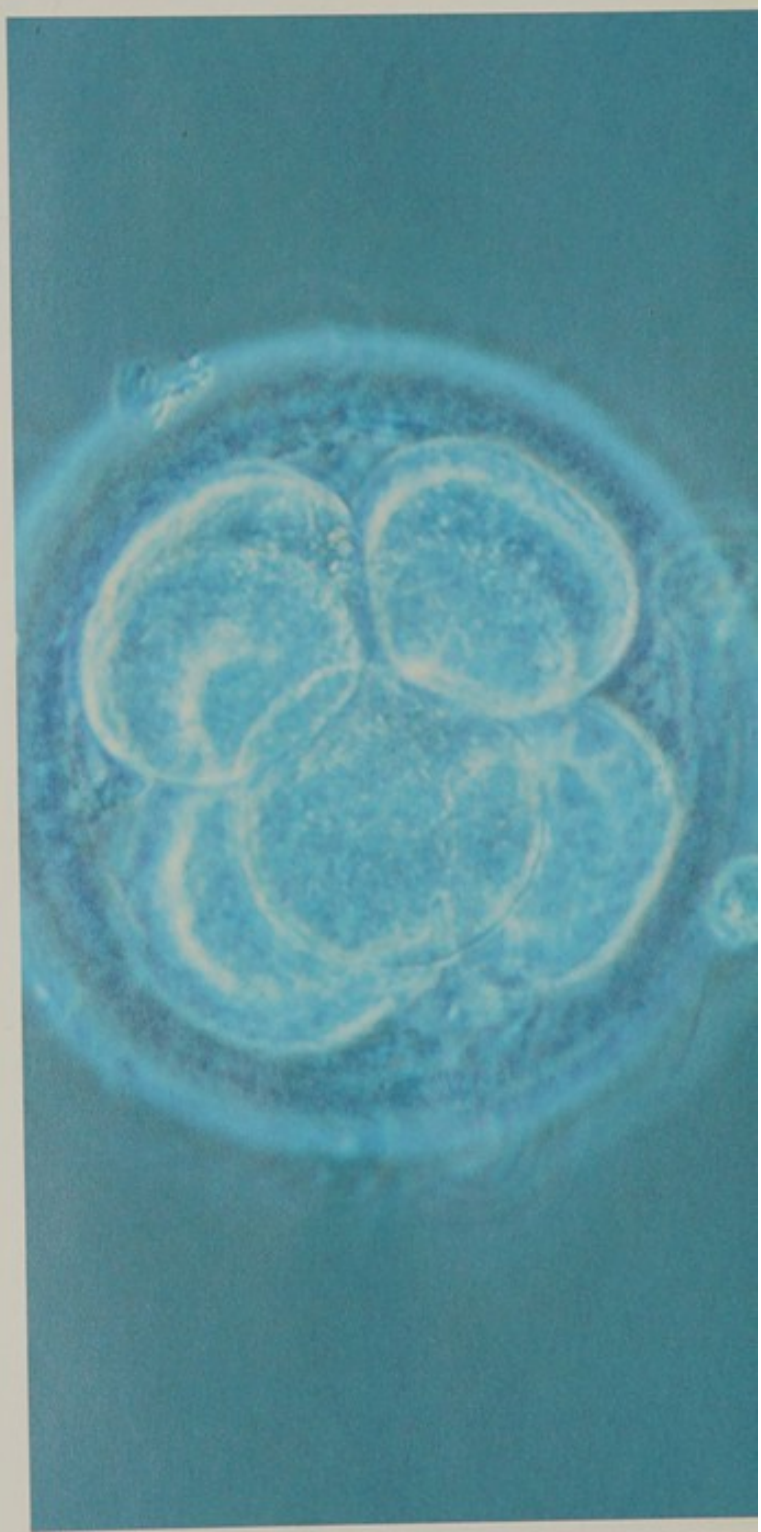
The Authority's budget for the financial year 1992/93 was set at £1.38 million. The members and staff of the Authority are constantly aware of the costs of offering and receiving treatment and have therefore made every effort to minimise its administrative costs so that the fees are kept to a minimum. This has been done in a number of ways and the Authority has been able to make substantial savings on its budget. All expenditure is carefully checked to ensure that it is justified, necessary and provides good value for money. A summary of the Authority's accounts for the 1991/92 financial year is presented at Annex 7.

2.2 Licence Fees

After considerable negotiation with the Department of Health and Treasury the percentage of income to be derived from licence fees was initially set at 50%. This was based on the premise that half of the Authority's costs are attributable to its licensing function. The remainder was to be provided from central funds. An independent survey of HFEA expenditure has subsequently confirmed this split between the Authority's licensing activities and policy and information related issues. We do not expect any change in the proportion of costs spent on each activity over the next few years.

The fee structure is made up of an initial and an additional fee. Each centre is required to pay an initial fee on application. This is currently set at £250 for a treatment licence and £100 for a storage only licence or for a licence for a research project. The additional fee, which is payable upon acceptance of the terms and conditions of a treatment licence, is calculated on the number of treatment cycles carried out in the previous year. The rates are currently £30 for each IVF cycle and £7 for each cycle of donor insemination. As the number of cycles completed in any year will vary and long term trends have yet to be established, the task of raising exactly 50% of expenditure from fees in order to achieve our financial target is very difficult. For this reason there will be some variation from year to year on the percentage of expenditure raised.

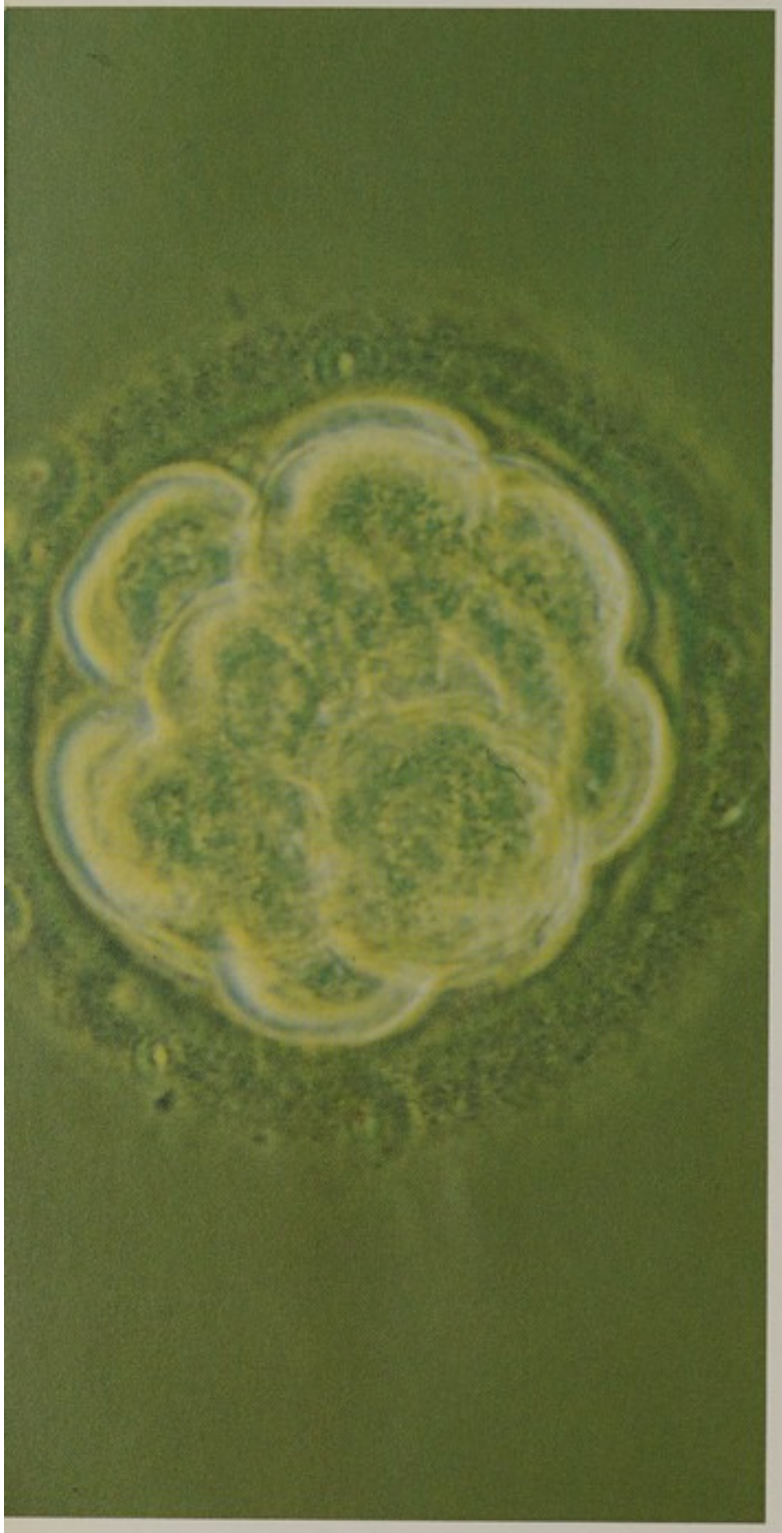
At the time of writing the HFEA is again in negotiation with the Department of Health and Treasury. Our aim is to keep the percentage of income to be derived from fees at its present level and to amend the fee structure to take account of this. The Authority is conscious of the fact that many centres will pass these costs directly to the patient and are under financial constraints themselves.



8 cell embryo - 60 hours

Therefore they need to be informed in advance about the level of fees in order that they may budget effectively. The Authority will seek to give centres as much notice as possible about any changes in the level of fees and will continue to review the effects of these fees on both the centres and their patients.

3. CODE OF PRACTICE



16 cell embryo - 4 days

After extensive consultation which included professional bodies, clinicians and patients, the HFEA produced its first Code of Practice in July 1991. It was always intended that this Code would be regularly reviewed to take account of developments in both professional practice and public opinion.

3.1 Human Fertilisation and Embryology (Disclosure of Information) Act 1992

The confidentiality provisions of the Human Fertilisation and Embryology Act 1990 were identified early on as a matter for concern. The provisions were in some cases too restrictive and it was feared that patient care was being jeopardised. The Authority collected information from centres about the practical difficulties encountered due to the restrictions and concluded that an amendment to the Act was required. In November 1991 the Authority sought the help of the Minister for Health in obtaining an amendment to the Act. On 16 July 1992, the Human Fertilisation and Embryology (Disclosure of Information) Act became law. This relaxes some of the restrictions on liaison between different doctors involved in patient care and between lawyers and their clients. At the same time it maintains the safeguards which give the patients control over who has access to their personal information. The sections of the Code of Practice dealing with confidentiality of patient records have been extensively revised to take this new Act into account.

HFEA meeting

3.2 Revision of the Code of Practice

A year after the introduction of the first Code of Practice, the need for some revision was obvious. The experience of licensing in this first year brought a number of issues to the Authority's attention which were not covered by the guidance in the Code of Practice. These related to such issues as surrogacy, "diagnostic IVF", home insemination, "transport IVF" and donors producing sperm at home. Proposed revisions to the Code were detailed in a consultation document which was widely distributed in October 1992. The proposals were generally well received and the revised Code of Practice was published in July 1993.

3.3 Survey of Semen Donors

Another matter related to policy set out in the Code of Practice is the supply of semen donors. The Authority has a duty to monitor the provision of treatment services generally. Centres have provided the Authority with conflicting anecdotal evidence about the supply of donors and the effect that the Act and the policies of the HFEA may have had upon it. In order to find out more accurately the position on availability of sperm donors in the UK, the Authority commissioned a survey of centres involved with recruiting donors. The survey, carried out by the Clinical and Health Psychology Research Centre at the City University, also canvassed the views of existing donors and of men who had never considered donating in an attempt to discover the motivation of donors and what measures might encourage more donors to come forward. Preliminary results should be available in the summer of 1993.

Blastocyst - 5 days

4. COMMUNICATION WITH PATIENTS

The Authority believes it is important to establish a dialogue with users of licensed centres and has considered appropriate ways of obtaining feedback from patients about the service and treatment they have received. It is also keen to ensure that potential patients have sufficient accurate information about the services available, the various treatment options and the Authority's role in regulating clinics. A set of information leaflets and information videos for IVF and donor insemination patients have therefore been produced. These are intended to supplement the information provided by centres and to raise awareness amongst patients of the kinds of questions they might find it useful to ask.

4.1 HFEA Information Leaflets

The Authority considers it vitally important that, before embarking on any licensed treatment, patients are fully informed about the procedures used and the implications of the treatment in a way that they readily understand. Potential donors should also be fully informed about the implications of donation and about how the law affects them. As a step towards achieving this, the Authority has issued a series of information leaflets.

A leaflet, *Sperm and Egg Donors and the Law*, has been published to reassure those donating sperm or eggs that their identities remain protected under the Act. This had been highlighted as an area of concern by centres.

Leaflets have also been published on egg donation and IVF treatment. These are intended to give potential donors and patients an idea of what to expect when they attend a clinic. A fourth leaflet, *Treatment Clinic: Questions to Ask* has been designed to help people seeking treatment to ask useful questions so they can make comparisons of the services and costs at different clinics. A further leaflet has been prepared about the role of the HFEA. The leaflets are available through centres and on request from the Authority.

In the coming year it is proposed to prepare a leaflet for men wishing to store their own sperm for medical reasons, explaining the need for legal consent to storage under the Act.

HFEA information leaflets and videos

4.2 HFEA Information Videos

A further step towards helping patients to gain a better understanding of the treatment they are considering was the production of information videos about IVF and donor insemination. The videos are directed at prospective patients. They are for viewing in their own homes, at the stage when they are considering, or are about to start, treatment. They are intended to give patients an idea of what to expect when they start the treatment and to give information in a balanced and clear manner. It is hoped that those who have seen the videos will be encouraged to ask the centre further questions about their own treatment; they are not intended to, and cannot, give detailed information. The videos outline the basic features of licensed treatments, highlighting counselling and the availability of support before, during and after the course of treatment.

Tenders for the making of the video were received from seven production companies, and one was appointed in January 1993. Questionnaires about the proposed video were sent to all licensed treatment centres who were also asked to give a copy of the questionnaire to at least five of their patients undergoing treatment. Responses to these questionnaires were used to develop the specification of the video. A user panel was also set up to view and comment on the initial and final edits. The video was completed in May 1993.

Copies of the videos have been sent to each licensed centre. These can then be given to patients on a take home and return basis. Copies of the videos are also available for educational purposes only from the HFEA.

4.3 Feedback from Patients

Further attention is being given to the most appropriate ways of receiving feedback from patients. Some letters from patients are received at the Authority. These are mainly patients who wish to complain about the service or treatment they have received at a particular centre. Most grievances can be dealt with under the complaints procedure at the centre, but where this has not proved satisfactory, the details are sent to the Authority. It is not possible for the Authority to investigate individual cases on behalf of the patient, but all such complaints are carefully assessed and may be addressed in a general way at the inspection and taken into account when deciding on the licence renewal of the centre concerned.

5. SOCIAL AND ETHICAL ISSUES

During the past year the Authority has considered a number of important social and ethical issues including the use of fetal ovarian tissue, sex selection, surrogacy, and cloning.

5.1 Research using Fetal Tissue

The use of fetal tissue in the treatment of disease is permitted under the guidelines of the Polkinghorne Report (Review of the Guidance on the Research Use of Fetuses and Fetal Material (CM 762) HMSO London 1989). The use of fetal germ line cells such as ovarian tissue raises ethical issues of a different kind. Fetal ovaries contain many thousands of potentially viable eggs which researchers may wish to try to mature in vitro. The HFEA has no authority to regulate research on ovarian cells. However, because ultimately the purpose of maturing the cells could be to provide eggs for transfer to a woman in licensed fertility treatment, the HFEA has a strong interest in the matter. The Authority has decided to produce a consultation document in order to encourage public debate and assess public opinion on the matter before reaching any conclusions. This document will be published later in the year.

5.2 Sex Selection

Advances in pre-implantation diagnosis now make it possible to determine the sex of an embryo before it is transferred to a woman. Embryos of a particular sex can be selected and replaced to ensure that only children of that sex are born. Similarly, it is claimed that it is possible to separate sperm bearing X or Y chromosomes so as to produce female or male offspring following artificial insemination.

Sex selection consultation document

Pre-implantation diagnosis is permitted in cases of sex-linked diseases to ensure that the particular sex at risk from the disease can be avoided. There is the potential for the use of these techniques for couples who would simply prefer to have a child of one sex or the other. A wide-ranging public debate on the use of these techniques for both medical and social reasons has begun.

After considering these developments, their implications for society and the ethical issues involved, the Authority decided that a wide consultation of public and professional opinion was needed before it came to conclusions which would affect its licensing policy and the Code of Practice. A consultation document was therefore published in January 1993 to encourage public debate on the issues. The consultation period ended on 1 June and the responses are now being analysed. Ministers have asked to be advised of the outcome of the consultation.

5.3 Surrogacy

The Human Fertilisation and Embryology Act 1990 makes surrogacy arrangements unenforcable by law. The activity is not illegal although it is illegal for commercial surrogacy agencies to make the arrangements. Using IVF techniques and embryo transfer, "full" surrogacy arrangements are now possible whereby the carrying mother is not the genetic mother of the child. The embryo transferred to the surrogate mother may be derived from the eggs and sperm of the eventual social parents. Such a case may arise where the genetic mother is able to produce eggs but unable to carry the child to full term.

In considering the ethical issues surrounding surrogacy the Authority benefited from the full examination given to this matter by the British Medical Association and the Surrogacy Report (BMA Annual Report of Council 1989-90) it issued in 1990. In particular, the Authority was concerned that surrogate pregnancies might be initiated for social or convenience reasons on the part of the genetic parents. The Authority decided that it would be unethical to permit licensed fertility treatment to initiate a surrogate pregnancy where the commissioning mother herself was able to carry a baby. Guidelines have therefore been included in the Code of Practice. These state that the use of assisted conception techniques in surrogacy arrangements should only be considered in cases where it is physically impossible or medically undesirable for the commissioning mother to carry a baby to full term.

5.4 Cloning

Although the cloning of human embryos by nuclear replacement (ie.replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person or embryo) is forbidden by the Act, cloning by means of splitting embryos is not covered by the legislation. If research proved that this technique produced viable embryos it might, in the future, offer advantages by increasing the number of embryos available to a woman for transfer and therefore improving her chance of pregnancy. The embryos would however be genetically identical. The Authority is currently considering the social and ethical implications of this technique.

6. RESEARCH

Under the Human Fertilisation and Embryology Act 1990 the Authority can issue a research licence authorising the creation of an embryo in vitro or the keeping or using of embryos for the purposes of a research project. A licence may be issued for a research project only if the work appears to be necessary or desirable for one of the five purposes given below:

(i) Promoting advances in the treatment of infertility;

(ii) Increasing knowledge about the causes of congenital disease;

(iii) Increasing knowledge about the causes of miscarriages;

(iv) Developing more effective techniques of contraception; or

(v) Developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

At the time of writing 34 research applications have been considered by the Authority and, of these, two have been rejected. One research application was refused on the grounds that the aims of the research were not consistent with the purposes for which embryo research may be licensed as set out above; the other was refused because the objectives of the project were not sufficiently clear.

Of the research licences granted thirteen of the projects aim to advance the treatment of infertility, one is developing more effective techniques of contraception, and 4 cover work on the development of techniques for pre-implantation diagnosis. Thirteen projects come under more than one of the headings specified in the Act. Finally there is one research licence issued under that section of the Act which allows mixing human sperm with the egg of a hamster to develop more effective techniques for determining the fertility or normality of sperm.

The Authority will continue to give detailed consideration to research issues and is actively considering the way in which more information about these issues can be made available.

7. DATA COLLECTION

The Authority is required to collect data for the treatment it licenses in order to give information to children born as a result of licensed treatment and to enable the provision of IVF and donor insemination to be monitored and evaluated. The Authority is notified of every treatment cycle of IVF and donor insemination initiated in the United Kingdom. Data for IVF were previously collected by the Office of Population Censuses and Surveys (OPCS) on behalf of the Interim Licensing Authority (ILA), which regulated IVF on a voluntary basis until 31 July 1991.

The HFEA's remit covers donor insemination and IVF treatment but not GIFT (Gamete Intra-fallopian Transfer) treatment, unless donated sperm or eggs are used. Prior to 1 August 1991, there was no comprehensive collection of donor insemination data.

7.1 Presentation of Success Rates

For many years there have been calls for the success rates of individual centres to be publicised so that patients are able to take account of these in choosing a centre. So far, it has not been possible to do this since the ILA had given an assurance to centres that their individual data would not be divulged.

The submission of data to the HFEA register of information is a legal requirement and so centres are required to provide accurate data. The Authority has collected and analysed 5 months' data, from August - December 1991. It will not be until the Authority's third annual report is issued that the HFEA will be able to produce its first full year of data from the register. There are arguments for and against publishing individual centre's success rates. Each of these arguments needs to be considered in detail before a decision is reached about publication. The Authority will be discussing this issue over the coming months and will reach a decision by the early part of 1994 on how the relevant information should be presented.

Colin Campbell, Chairman, and Diana Brittan, Deputy Chairman

7.2 The Register of Information

Development and installation of the computer system for the register of information was completed in mid May 1992. Access to the data has been restricted to a small number of the Authority's Executive and the register itself has several levels of security. It is located in a secure room with a sophisticated alarm system to protect the data.

Initially the quality of the data received was variable with approximately 50% of all forms having to be returned to centres for correction or completion. As the ILA did not collect donor insemination data, the completion of treatment forms was a new experience for DI centres. Since the identification of one person at each centre with overall responsibility for the provision of treatment data, the lines of communication between the centres and the Authority have been strengthened and the quality of the data returns has improved considerably.

7.3 Treatment Data 1991

The HFEA's computer database and the information collected differ slightly from those used by OPCS and it is not easy to produce a composite analysis of the data for the whole of 1991. The HFEA data from 1 August 1991 to 31 December 1991 are included in the tables which follow and the data for the earlier seven months of the year collected by OPCS are contained at the end of this section. Except where stated, the following paragraphs comment on the data collected by the HFEA. ILA figures, given in square brackets, relate to the period January to July 1991 and are given for comparison. Data for GIFT collected by the ILA for the period 1 January to 31 July are presented at Annex 6. The HFEA would like to thank Dr Joan Morris of the Wolfson Institute of Preventative Medicine for her assistance with the analysis of the statistics.

7.4 IVF Data 1 August - 31 December 1991

Following previous practice, the centres providing IVF treatment have been grouped into three categories: those performing more than 400 IVF treatment cycles per year (large centres), those performing 100-400 treatment cycles (medium centres) and those performing fewer than 100 cycles (small centres). Since the period covered was only five months, extrapolations about the number of treatment cycles have been made to classify centres in this way. By 31 December 1991, there were 67 centres performing IVF treatment. This represents an increase of 3 in the number of centres providing services over 1990. However, the growth of IVF treatment has led to there now being 14 large centres and 30 medium centres (as compared to 8 and 21 respectively in 1990) with a consequential reduction in the number of small centres (35 in 1990) providing services.

Table 1a IVF Data 1991 - TREATMENT

	PATIENTS	TREATMENT CYCLES	EGG COLLECTIONS	EMBRYO TRANSFERS
Large centres (14)	3382	3689	2720	2828
Medium centres (30)	2367	2488	2054	1907
Small centres (23)	446	476	361	343
TOTALS (67)	**6195**	**6653**	**5135**	**5078**

Table 1b IVF Data 1991 - OUTCOME

	PREGNANCIES	LIVE BIRTHS	MISCARRIAGES	ECTOPICS	PERINATAL DEATHS
Large centres (14)	739	546	132	13	10
Medium centres (30)	432	332	71	10	9
Small centres (23)	56	39	13	6	1
TOTALS (67)	**1227**	**917**	**216**	**29**	**20**

Table 1a and 1b shows the total number of IVF cycles and their outcome. From August to December 1991, there were 6,653 treatment cycles. When those recorded by OPCS for the earlier part of the year are included, the total number of treatment cycles is 13,156. This shows a 13.6% increase over the 1990 figure (11,583) and indicates the continued increase in the provision of IVF treatment. There were 161 outcome forms not included in the data (8.6% of all pregnancies). Fifty one of these were pregnancies where no resulting outcome form was sent to the HFEA.
One hundred and ten outcome forms were received where the information was incomplete and provided no meaningful information about the outcome of the pregnancy. The number of pregnancy outcomes which we have not been able to record is greater for DI treatment than IVF. This could be due to the fact that many people wish to keep DI treatment secret and centres find it difficult to keep in touch with DI patients.

The IVF pregnancy and live birth rates per treatment cycle are given in Table 2. Table 3 gives the pregnancy and live birth rates for 1985-1990 (collected by OPCS). There is a statistically significant increase for the last five months of 1991 compared with 1990 from 17.3% to 18.4% for the pregnancy rate (Chi-squared test, P = 0.052) and 12.5% to 13.8% for the live birth rate (Chi-squared test, P = 0.011). [The ILA data for the preceding seven months were 14.7% and 10.6% respectively.]

As in previous years the perinatal mortality rate (16.3/1000 pregnancies) significantly exceeds that of the general population for England and Wales (1991 8.1/1000) (Chi-squared test, P = 0.001). This may be a reflection of the greater incidence of multiple pregnancies following IVF treatment (Table 6). [ILA: 17.7/1000 pregnancies.]

Table 2a and 2b shows the mean pregnancy and live birth rate by size of centres. As in previous years, the large centres generally appear to have a higher average success rate, but there is a wide variation of success rates. For example, the live birth rate in medium centres is between 1.9% and 28.8% per patient treated or 2.1% and 32.7% per embryo transfer performed [ILA: 0.0% to 27.6% per embryo transfer]. However, it is important to recognise that several factors combine to produce the success rates for individual centres such as the age of patients and the type of problems treated. Average success rates for individual centres may not therefore be directly comparable.

Table 2a IVF Mean Pregnancy Rate 1991 · PREGNANCY RATES %

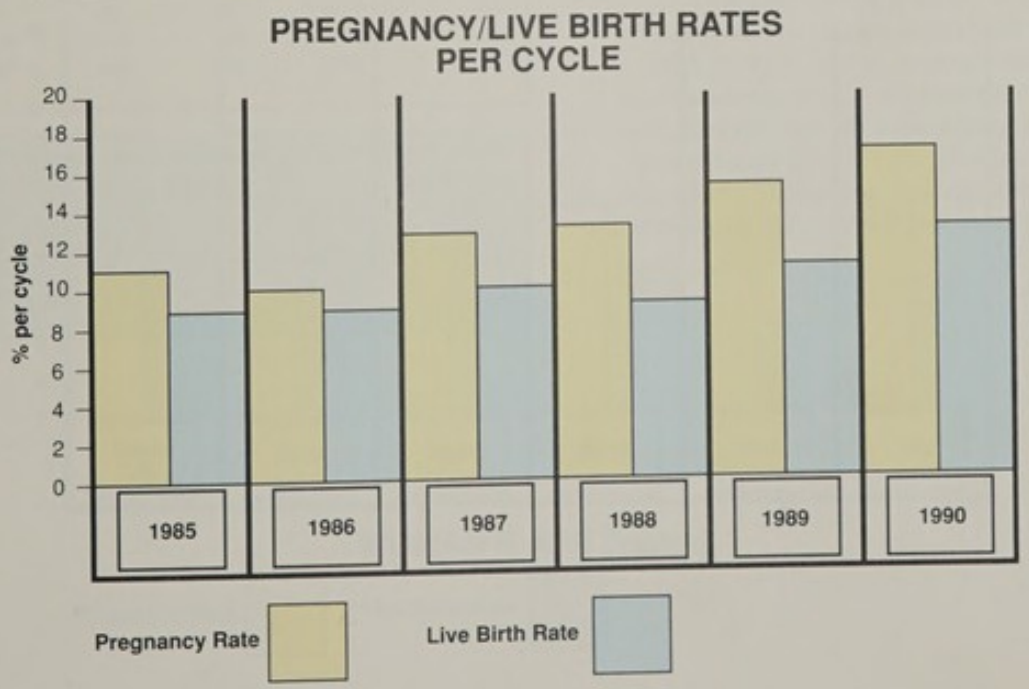
	PER TREATMENT CYCLE	RANGE	PER EGG COLLECTION	RANGE	PER TRANSFER	RANGE	PER PATIENT	RANGE
Large centres	20.0	14.7 - 25.6	27.2	16.6 - 54.8	26.1	19.5 - 34.4	21.9	16.0 - 29.6
Medium centres	17.4	5.2 - 33.3	21.0	6.1 - 45.0	22.7	6.4 - 37.3	18.3	5.6 - 36.5
Small centres	11.8	2.8 - 50.0	15.5	4.2 - 50.0	16.3	4.8 - 50.0	12.6	2.9 - 50.0
Overall	18.4		23.9		24.2		19.8	

Table 2b IVF Mean Live Birth Rate 1991 · LIVE BIRTH RATES %

	PER TREATMENT CYCLE	RANGE	PER EGG COLLECTION	RANGE	PER TRANSFER	RANGE	PER PATIENT	RANGE
Large centres	14.8	10.5 - 21.8	20.1	13.3 - 40.3	19.3	13.0 - 29.0	16.1	11.6 - 22.3
Medium centres	13.3	1.7 - 26.3	16.2	2.0 - 31.7	17.4	2.1 - 32.7	14.0	1.9 - 28.8
Small centres	8.2	2.6 - 33.3	10.8	3.7 - 33.3	11.4	2.8 - 40.0	8.7	2.6 - 33.3
Overall	13.8		17.9		18.1		14.8	

Table 3 IVF Pregnancy and Live Birth Rates per Treatment Cycle 1985-1990 %

ALL CENTRES	1985	1986	1987	1988	1989	1990
Pregnancy Rate %	11.2	9.9	12.5	12.9	15.4	17.3
Live Birth Rate %	8.6	8.6	10.1	9.1	11.1	12.5



Multiple Pregnancy Rate

The overall multiple pregnancy rate for IVF was 29.1% [ILA: 26.5%]. This was significantly higher than the figure for 1990 given in the HFEA's first Annual Report of 25.5% (Chi-squared test, P = 0.030).

The increase in multiple pregnancy rate may indicate improvements in IVF practice producing better quality embryos. Though no more than three embryos are now transferred (as required by the HFEA Code of Practice), better quality embryos may be more likely to grow to term. However, there is considerable concern about the physical, emotional and financial stresses associated with multiple births. The issue of multiple births is therefore one which the Authority will continue to monitor carefully. It is interesting to note that there were no quads or higher order multiple pregnancies reported.

Table 4 Multiple Pregnancies with IVF 1991

PREGNANCY	RATE %
Singleton	70.9
Twin	24.5
Triplet	4.6
Quad or more	0.0
Overall Multiple Pregnancies	29.1

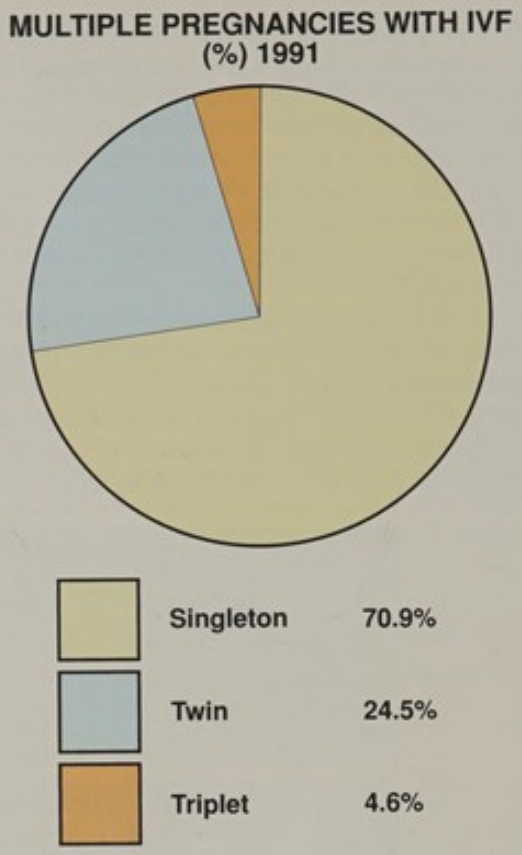


Table 5 shows the number of embryos transferred in each of the 5,078 embryo transfers performed. The majority of the transfers, 60.4%, involved the transfer of three embryos [ILA: 60.3% involved the transfer of three or more embryos]. When three embryos were transferred (as seen in Table 6) the pregnancy rate overall was 27% which is similar to the figure of 27.1% in 1990. The multiple pregnancy rate for 1991 is 32% amongst those who conceived, an increase since the last reporting year which showed the rate to be 28.1% (Chi-squared test, P = 0.056). [ILA: the pregnancy rate was 20.1% for three or more embryos transferred and the multiple pregnancy rate 30.4%.]

Table 5 Multiple Pregnancy and Embryo Transfer 1991

EMBRYOS TRANSFERRED	NO OF TRANSFERS	SINGLETON	TWIN	TRIPLET	QUAD
One	673	57	1	0	0
Two	1338	220	78	0	0
Three	3067	562	211	54	0
TOTAL	**5078**	**839**	**290**	**54**	**0**

Table 6 IVF Pregnancy and Multiple Pregnancy Rates per Embryo Transfer 1991

NO OF EMBRYOS TRANSFERRED	PREGNANCY RATE %	MULTIPLE PREGNANCY RATE%
One	8.6	1.7
Two	22.3	26.2
Three	27.0	32.0

IVF Success Rates by Woman's Age and Indications for Treatment

Table 7 shows the pregnancy rate and live birth rate by woman's age divided into six different groups. As in previous years, younger patients were more likely to become pregnant in a single treatment cycle than older patients (Chi-squared test for trend: $P < 0.001$). The data in this report also indicate the success rate of patients receiving treatment with donor eggs. Pregnancy rates and live birth rates were significantly higher for women over 35 where donor eggs were used as opposed to their own eggs ($P < 0.001$ for pregnancy rates and live birth rates).

Table 8 shows average success rates according to indications for treatment. The total number of cycles shown in the table exceeds that of 6,653, the number actually performed, because, in some cases, there was more than one indication for treatment. The success rates for male factors include cycles in which donated sperm was used. The figures are very similar to those for 1990.

Table 7 IVF Success Rates by Woman's Age 1991

	UNDER 25	25 -29	30 - 34	35 - 39	40 - 44	45+
No of cycles	102	1143	2585	2136	628	59
No. of cycles using donated eggs	2	20	26	33	48	23
No. of cycles using own eggs	100	1123	2559	2103	580	36
PREGNANCY RATES %						
Per cycle	19.6	21.5	20.9	16.2	10.8	15.3
Per cycle using donated eggs	100	15.0	11.5	36.4	35.4	30.4
Per cycle using own eggs	18.0	21.6	20.9	15.8	8.8	5.6
No. of transfers	63	858	2009	1624	480	44
Per transfer	32.3	28.7	26.8	21.2	14.2	20.9
LIVE BIRTH RATES %						
Per cycle using donated eggs	50.0	10.0	3.8	15.2	25.0	21.7
Per cycle using own eggs	10.0	16.7	16.7	11.2	5.0	2.8
Per transfer	17.5	22.1	21.3	14.8	8.5	13.6

Table 8 Success Rates by Indications for Treatment 1991

	NO OF CYCLES	PER CYCLE	PER TRANSFER
	PREGNANCY RATES%		
Tubal	3441	18.2	22.2
Endometriosis	692	20.8	26.9
Male factors	2105	17.8	23.8
Unexplained	2252	17.4	25.2
Cervical factors	111	17.1	21.1
Ovarian and other	709	22.0	29.9
	LIVE BIRTH RATES %		
Tubal	3441	13.0	15.9
Endometriosis	692	15.8	20.3
Male factors	2105	13.2	17.7
Unexplained	2252	13.5	19.5
Cervical factors	111	14.4	17.8
Ovarian and other	709	16.6	22.6

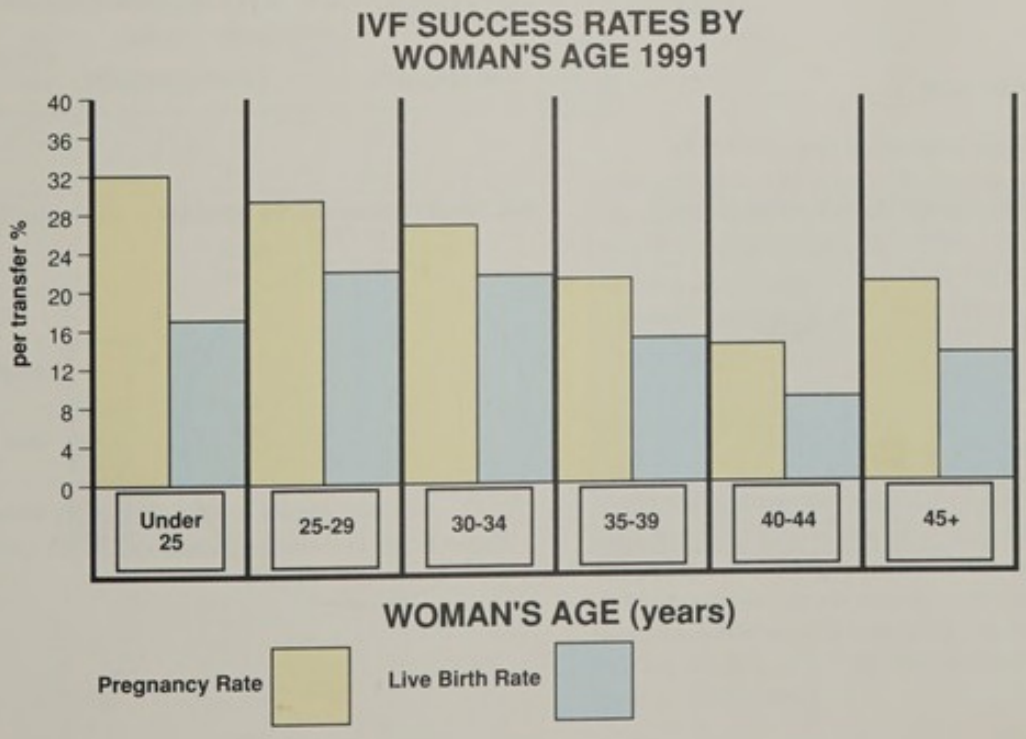


Table 9 shows the underlying trend that the pregnancy rate decreased with the increasing number of previous attempts (Chi-squared test for trend, $P < 0.001$). In patients who had only one, two, three or four IVF cycles the pregnancy rates ranged between 17.3% and 20.8% per treatment cycle. The live birth rates also decreased as the number of previous attempts increased (Chi-squared test for trend, $P < 0.001$), ranging from 12.9%-15.1% per treatment cycle for under four attempts.

Table 9 IVF Success Rates by Number of Previous Attempts

	0	1	2	3	4	5	6-9	10+
Number of cycles	2908	1685	914	476	264	124	208	74
PREGNANCY RATES %								
Per treatment cycle	20.0	17.3	18.3	20.8	9.8	19.4	14.4	10.8
Per transfer	26.9	22.3	23.8	25.1	12.3	25.3	19.0	14.5
LIVE BIRTH RATES %								
Per treatment cycle	15.1	12.9	14.0	14.7	8.0	13.7	9.6	4.1
Per transfer	20.4	16.7	18.3	17.8	10.0	17.9	12.7	5.5

7.5 Donor Insemination Data 1 August - 31 December 1991

For the first time, data on donor insemination are presented. Such comprehensive data have not previously been collected. The period covered is 1 August 1991, when the HFEA began collecting such information, to 31 December 1991. Following experience gained from publishing DI data this year, changes may be made to the format and display of the tables for next year. It is difficult to make an analysis of the data without previous data with which to compare.

Table 1a and 1b shows that there were 85 centres offering this treatment by 31 December 1991 and 9,262 treatment cycles were performed in the 5 month period for 4,260 patients.

Table 1a DI Data 1991 - TREATMENT

	PATIENTS	TREATMENT CYCLES
Centres (85)	4260	9262

Table 1b DI Data 1991 - OUTCOME

	PREGNANCIES	LIVE BIRTHS	MISCARRIAGES	ECTOPICS	PERINATAL DEATHS
Centres (85)	645	458	89	6	6

The pregnancy and live birth rates are contained in Table 2a and 2b which shows a pregnancy rate of 7% per treatment cycle, with a live birth rate of 4.9% per treatment cycle.

Table 2a DI Mean Pregnancy Rates 1991

	PER TREATMENT CYCLE	RANGE	PER PATIENT	RANGE
Pregnancy Rate %	7.0	2.0 - 100	15.1	4.2 - 100

Table 2b DI Mean Live Birth Rates 1991

	PER TREATMENT CYCLE	RANGE	PER PATIENT	RANGE
Live Birth Rate %	4.9	1.3 - 50.0	10.8	2.9 - 50.0

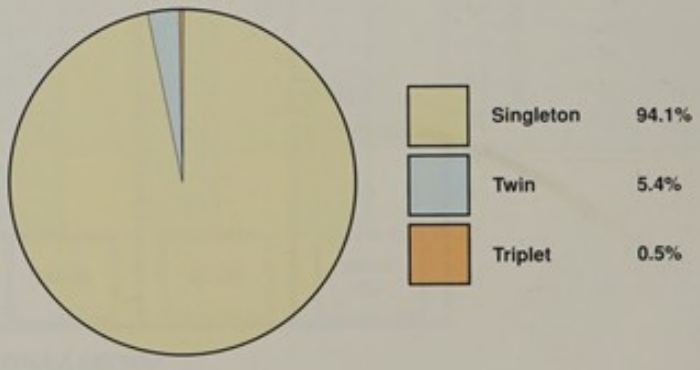
Multiple Pregnancy Rate

The overall multiple pregnancy rate at 5.9% is significantly lower than that of 29.1% for IVF (Chi-squared test, $P < 0.001$), although still significantly higher than that of the population at large which is approximately 1.5%. (The margin of error is 1.9%).

Table 3 Multiple Pregnancies with DI 1991

PREGNANCY	RATE %	NO. OF PREGNANCIES
Singleton	94.1	545
Twin	5.4	31
Triplet	0.5	3
Quad or more	0.0	0
Overall Multiple Pregnancies	5.9	34

MULTIPLE PREGNANCIES WITH DI (%) 1991



DI Success Rates by Woman's Age and Indications for Treatment

As in IVF, there is an indication that younger women were more successfully treated with DI than older women (Table 4 Chi-squared test for trend for both pregnancy rate and live birth rate, $P < 0.001$). However, most of the women treated are in the age range of 25-39 and there was no significant difference between the pregnancy rates per cycle according to the age of women treated across this age range (Chi-squared test for trend, $P = 0.1466$). The trend for live birth rates decreased significantly with the increase in age in this age group ($P = 0.007$).

Table 4 DI Success Rates by Woman's Age 1991

	UNDER 25	25 - 29	30 - 34	35 - 39	40 - 44	45+
No. of cycles	361	2548	3778	2057	501	17
		PREGNANCY RATES %				
Per cycle	10.2	7.6	7.1	6.5	2.6	5.9
		LIVE BIRTH RATES %				
Per cycle	7.5	5.7	5.3	3.9	1.2	0.0

Table 5 DI Success Rate by Indications for Treatment 1991

	NO. OF CYCLES	PER CYCLE
Pregnancy Rates %		
Male factors	8743	7.1
Female factors	496	9.3
Unexplained	41	14.6
Live Birth Rates %		
Male factors	8743	5.1
Female factors	496	6.0
Unexplained	41	9.8

As would be expected, Table 5 shows that the primary indication for donor insemination treatment was a male factor.

Table 6 DI Success Rates by Number of Previous Attempts

	0	1	2	3	4	5	6-9	10+
Number of cycles	1573	1341	1046	796	652	518	1535	1801
			PREGNANCY RATES %					
Per treatment cycle	8.4	6.9	7.4	7.2	6.9	8.3	5.6	6.2
			LIVE BIRTH RATES %					
Per treatment cycle	5.1	5.2	5.8	5.4	5.7	5.8	3.8	4.3

Table 6 shows pregnancy rates decrease with increasing number of previous attempts (Chi-squared test for trend, $P = 0.007$). The live birth rate per treatment cycle showed a much weaker trend with increasing number of previous attempts (Chi-squared test for trend, $P = 0.055$). The live birth rate is 5.4% for under 5 attempts and 4.1% for over 5 attempts.

7.6 IVF Data 1 January - 31 July 1991 (Collected by OPCS)

OPCS
Table 1a IVF Data 1991 - TREATMENT

	PATIENTS	TREATMENT CYCLES	EGG COLLECTIONS	PRE-EMBRYO TRANSFERS
Large centres (4)	2077	2308	1913	1594
Medium centres (15)	2645	2915	2617	2194
Small centres (50)	1218	1280	1109	881
TOTALS (69)	**5940**	**6503**	**5639**	**4669**

OPCS
Table 1b IVF Data 1991 - OUTCOME

	PREGNANCIES	LIVE BIRTHS	MISCARRIAGES	ECTOPICS	PERINATAL DEATHS
Large centres (4)	390	278	60	22	5
Medium centres (15)	451	333	87	7	11
Small centres (50)	118	76	26	6	1
TOTALS (69)	**959**	**687**	**173**	**35**	**17**

OPCS
Table 2a IVF Mean Pregnancy Rates 1991 %

	PER TREATMENT CYCLE	RANGE	PER EGG COLLECTION	RANGE	PER TRANSFER	RANGE
Large centres	16.9	13.3 - 27.1	20.4	14.3 - 33.2	24.5	18.4 - 37.1
Medium centres	15.5	0.0 - 29.5	17.2	0.0 - 29.7	20.6	0.0 - 31.7
Small centres	9.2	0.0 - 100.0	10.6	0.0 - 100.0	13.4	0.0 -100.0
Overall	14.7		17.0		20.5	

OPCS
Table 2b IVF Live Birth Rates 1991 %

	PER TREATMENT CYCLE	RANGE	PER EGG COLLECTION	RANGE	PER TRANSFER	RANGE
Large centres	12.0	8.8 - 18.9	14.5	10.2 - 23.2	17.4	12.8 - 25.9
Medium centres	11.4	0.0 - 20.7	12.7	0.0 - 24.2	15.2	0.0 - 27.6
Small centres	5.9	0.0 - 24.5	6.9	0.0 - 30.0	8.6	0.0 - 33.3
Overall	10.6		12.2		14.7	

OPCS
Table 3 IVF Pregnancy and Live Birth Rates Per Treatment Cycle 1985 - 90 %

ALL CENTRES	1985	1986	1987	1988	1989	1990
Pregnancy rate	11.2	9.9	12.5	12.9	15.4	17.3
Live birth rate	8.6	8.6	10.1	9.1	11.1	12.5

OPCS
Table 4 Multiple Pregnancies with IVF 1991

PREGNANCY	RATE
Singleton	73.5
Twin	24.0
Triplet	2.4
Quad or more	0.1
Overall Multiple Pregnancies	26.5

OPCS
Table 5 Multiple Pregnancy and Embryo Transfer 1991

EMBRYOS TRANSFERRED	NO OF TRANSFERS	SINGLETON	TWIN	TRIPLET	QUAD
One	588	44	3	0	0
Two	1265	215	59	1	0
Three	2667	373	143	19	1
Four	146	20	7	1	0
Five or more	3	0	1	0	0
TOTAL	**4669**	**652**	**213**	**21**	**1**

OPCS
Table 6 IVF Pregnancy and Multiple Pregnancy pre Embryo Transfer 1991

NUMBER OF EMBRYOS TRANSFERRED	PREGNANCY RATE %	MULTIPLE PREGNANCY RATE %
One	8.0	6.4
Two	21.7	21.8
Three	20.1	30.4
Four	19.2	28.6
Five or more	33.3	100.0

OPCS

Table 7a IVF Pregnancy Rates by Woman's Age 1991

	CYCLES	UNDER 25	25 -29	30 - 34	35 - 39	40 - 44	45+
				PER TREATMENT CYCLE %			
Large centres	2308	23.7	18.9	19.6	15.0	9.5	0.0
Medium centres	2915	14.6	17.1	16.2	14.5	13.7	5.6
Small centres	1280	4.2	12.0	10.1	7.8	4.7	0.0
CYCLE TOTAL	6503	103	1100	2624	2003	619	30
RATES TOTAL		15.5	16.5	16.1	13.5	10.5	3.3
				PER EGG COLLECTION %			
Large centres	1913	25.7	20.5	21.9	17.5	12.4	0.0
Medium centres	2617	15.4	17.8	17.7	16.2	15.4	7.7
Small centres	1109	5.0	13.8	11.1	8.9	5.7	0.0
CYCLE TOTAL	5639	94	988	2317	1702	494	22
RATES TOTAL		17.0	17.8	17.7	15.4	12.6	4.5
				PER EMBRYO TRANSFER %			
Large centres	1594	32.1	26.5	27.3	22.3	15.2	0.0
Medium centres	2194	17.6	21.7	21.0	18.7	18.8	8.3
Small centres	881	5.6	14.9	13.7	11.1	7.7	0.0
CYCLE TOTAL	4669	80	821	1914	1412	407	17
RATES TOTAL		20.0	21.7	21.7	18.7	15.7	5.9

OPCS

Table 8a IVF Pregnancy Rates by Indications for Treatment 1991

	CYCLES	TUBAL	ENDOMETRIOSIS	MALE FACTORS	UNEXPLAINED	CERVICAL FACTORS	OVARIAN AND OTHER
				PER TREATMENT CYCLE %			
Large centres	2308	18.1	18.0	13.8	18.2	25.0	16.6
Medium centres	2915	16.3	18.3	13.9	15.5	20.0	13.4
Small centres	1280	8.3	7.7	10.1	8.8	0.0	16.9
CYCLE TOTAL	6503	3434	679	1708	1333	102	820
RATES TOTAL		15.1	16.2	13.2	14.8	18.6	15.5
				PER EGG COLLECTION %			
Large centres	1913	20.8	19.2	14.9	21.5	30.0	18.9
Medium centres	2617	17.7	19.8	15.2	17.4	21.3	13.7
Small centres	1109	9.4	8.2	11.6	10.7	0.0	19.0
CYCLE TOTAL	5639	3011	607	1476	1143	89	679
RATES TOTAL		16.8	17.3	14.5	17.1	21.3	16.9
				PER EMBRYO TRANSFER %			
Large centres	1594	24.6	25.3	21.5	27.0	47.4	27.4
Medium centres	2194	19.7	21.6	20.2	21.5	27.8	18.5
Small centres	881	10.7	9.9	15.6	13.2	0.0	25.9
CYCLE TOTAL	4669	2634	537	1095	890	63	529
RATES TOTAL		19.4	20.5	20.1	21.3	30.2	23.6

OPCS

Table 7b IVF Live Birth Rates by Woman's Age 1991

	CYCLES	UNDER 25	25 -29	30 - 34	35 - 39	40 - 44	45+
				PER TREATMENT CYCLE %			
Large centres	2308	18.4	14.5	13.7	10.8	5.4	0.0
Medium centres	2915	9.8	13.0	13.0	10.0	7.7	5.6
Small centres	1280	0.0	8.0	7.5	3.5	2.8	0.0
RATES TOTAL		10.7	12.4	12.1	9.2	6.0	3.3
				PER EGG COLLECTION %			
Large centres	1913	20.0	16.1	15.5	12.3	6.7	0.0
Medium centres	2617	10.3	13.8	14.2	11.1	8.8	7.7
Small centres	1109	0.0	9.2	8.2	4.1	3.4	0.0
RATES TOTAL		11.7	13.6	13.4	10.3	7.1	4.5
				PER EMBRYO TRANSFER %			
Large centres	1594	25.0	20.4	19.2	16.1	8.6	0.0
Medium centres	2194	11.8	16.9	16.9	12.8	10.5	8.3
Small centres	881	0.0	9.6	10.5	4.4	4.6	0.0
RATES TOTAL		13.8	16.3	16.4	12.6	8.8	5.9

4 treatment records with age not stated

OPCS

Table 8b IVF Live Birth Rates by Indications for Treatment 1991

	CYCLES	TUBAL	ENDOMETRIOSIS	MALE FACTORS	UNEXPLAINED	CERVICAL FACTORS	OVARIAN AND OTHER
				PER TREATMENT CYCLE %			
Large centres	2308	12.5	12.6	10.5	14.2	19.4	11.3
Medium centres	2915	11.5	15.0	11.0	12.4	16.0	8.4
Small centres	1280	5.5	5.4	6.5	6.0	0.0	7.7
RATES TOTAL		10.5	12.4	10.1	11.5	14.7	9.6
				PER EGG COLLECTION %			
Large centres	1913	14.5	13.7	11.5	16.5	23.3	12.5
Medium centres	2617	12.5	16.2	12.2	13.9	17.0	8.8
Small centres	1109	6.2	5.7	7.5	7.3	0.0	8.6
RATES TOTAL		11.7	13.3	11.1	13.2	16.9	10.5
				PER EMBRYO TRANSFER %			
Large centres	1594	17.1	17.7	16.3	21.0	36.8	18.6
Medium centres	2194	13.9	17.6	16.0	17.4	22.2	11.8
Small centres	881	7.1	6.9	9.1	8.6	0.0	11.1
RATES TOTAL		13.5	15.6	15.2	16.6	23.8	14.7

8. RECENT DEVELOPMENTS IN INFERTILITY TREATMENT

Infertility treatment is a rapidly moving field with new techniques and changes of existing techniques frequently developing. Some of the recent developments in the field are set out below.

8.1 Male Factor Infertility and Micromanipulation

By 1 August 1992 seven research applications had been licensed to investigate various techniques of micromanipulation. This research was aimed at enabling those couples where the male partner has a low sperm count or poor quality sperm to use the partner's sperm rather than donated sperm. The objective of many of these techniques is to bypass the zona pellucida (protein shell) which surrounds the egg, as this frequently prevents sperm which have poor motility or morphology from penetrating and fertilising the egg. Some of the new developments are noted below:

Zona Drilling (ZD)

This involves the partial opening of the zona pellucida by "drilling" with culture media of acid pH, followed by insemination with prepared sperm(Diagram 1).

Partial Zona Dissection (PZD)

This involves a small hole being made in the zona pellucida by inserting a small glass needle into it. This eases the passage for the sperm although they must still swim into the hole and therefore show some forward progression(Diagram 2).

Sub Zonal Insemination (SUZI)

This technique involves a small number of sperm being drawn up into a sharp microinjection pipette which is passed through the zona pellucida. The sperm are injected into the perivitelline space of the oocyte (between the egg and its surrounding membrane) (Diagram 3).

Intra Cytoplasmic Sperm Injection (ICSI)

This technique, which is similar to SUZI in some respects, is aimed at patients who have severely impaired sperm and in whom IVF and perhaps some of the above techniques have already failed. The technique involves the injection of sperm directly into the ooplasm (the inner cellular structure) of the egg. Pregnancies as a result of this technique have been reported from some European centres and the treatment is now available in a small number of centres in the UK (Diagram 4).

Micro Epididymal Sperm Aspiration (MESA)

One cause of male infertility is an absence of sperm in the semen due to a blockage or absence of the duct system. Such patients can have an operation, under general anaesthetic, to collect their sperm directly from the collection ducts behind the testicle (known as the epididymis). This technique does not, in itself, require a licence under the Act, although it may be used in conjunction with one of the techniques above or with standard IVF.

Zona Drilling

Diagram 1

Partial Zona Dissection (PZD)

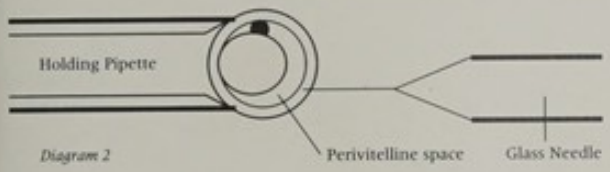


Diagram 2

Sub Zonal Insemination (SUZI)

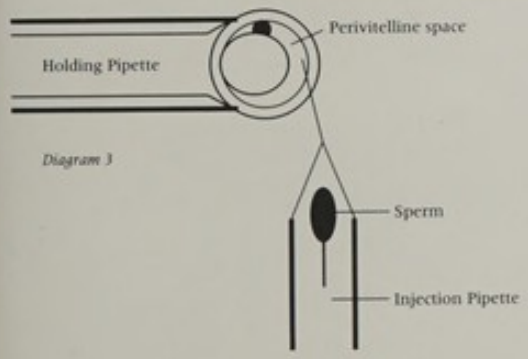


Diagram 3

Intra Cyloplasmic Sperm Injection (ICSI)

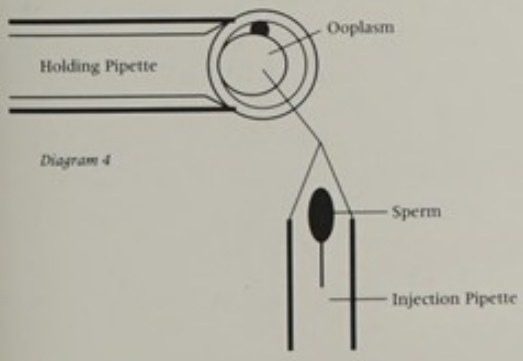


Diagram 4

Diagrams not to scale

The table below illustrates the number of centres currently involved in licensed research and/or clinical treatment using these treatment methods:

Technique	Research	Clinical treatment
ZD	0	3
PZD	2	8
SUZI	3	10
ICSI	1	2
MESA*	0	4

(used in conjunction with licensed treatment)*

It is important to note that the success rates for these techniques are very low and centres should make this clear at the outset. A survey presented at the International Symposium on Pre-implantation Genetics and Assisted Fertilisation, in Brussels in February 1992, estimated that approximately sixty per cent of patients receiving such treatments will reach the stage of embryo transfer. Only 7 per cent of those patients will then go on to establish a pregnancy. Around 25 per cent of these pregnancies will miscarry.

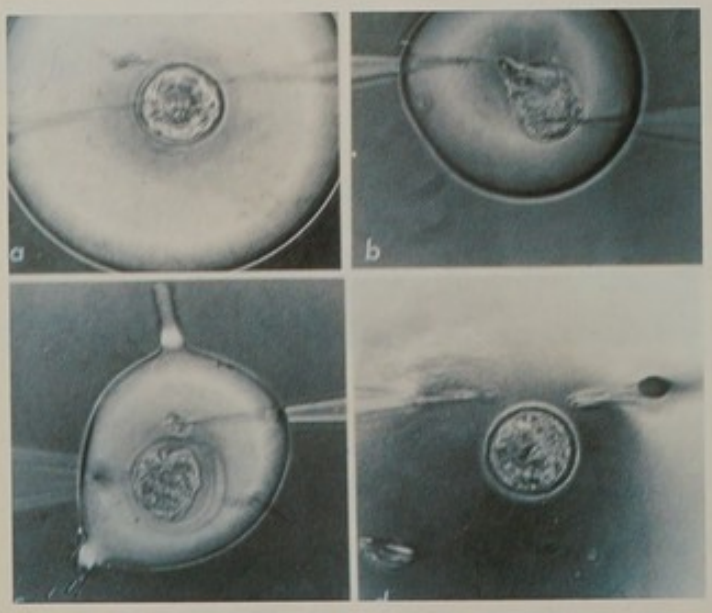
8.2 Pre-implantation Diagnosis

Current methods of prenatal diagnosis involve chorion villus sampling (testing of the developing placenta at 10-12 weeks) or amniocentesis (testing of the fluid surrounding the fetus at 14-17 weeks). In vitro fertilisation and subsequent diagnosis before the embryo is implanted could allow only those embryos which are unaffected to be transferred to the uterus. This avoids the risk of terminating the pregnancy if the fetus is found to be affected.

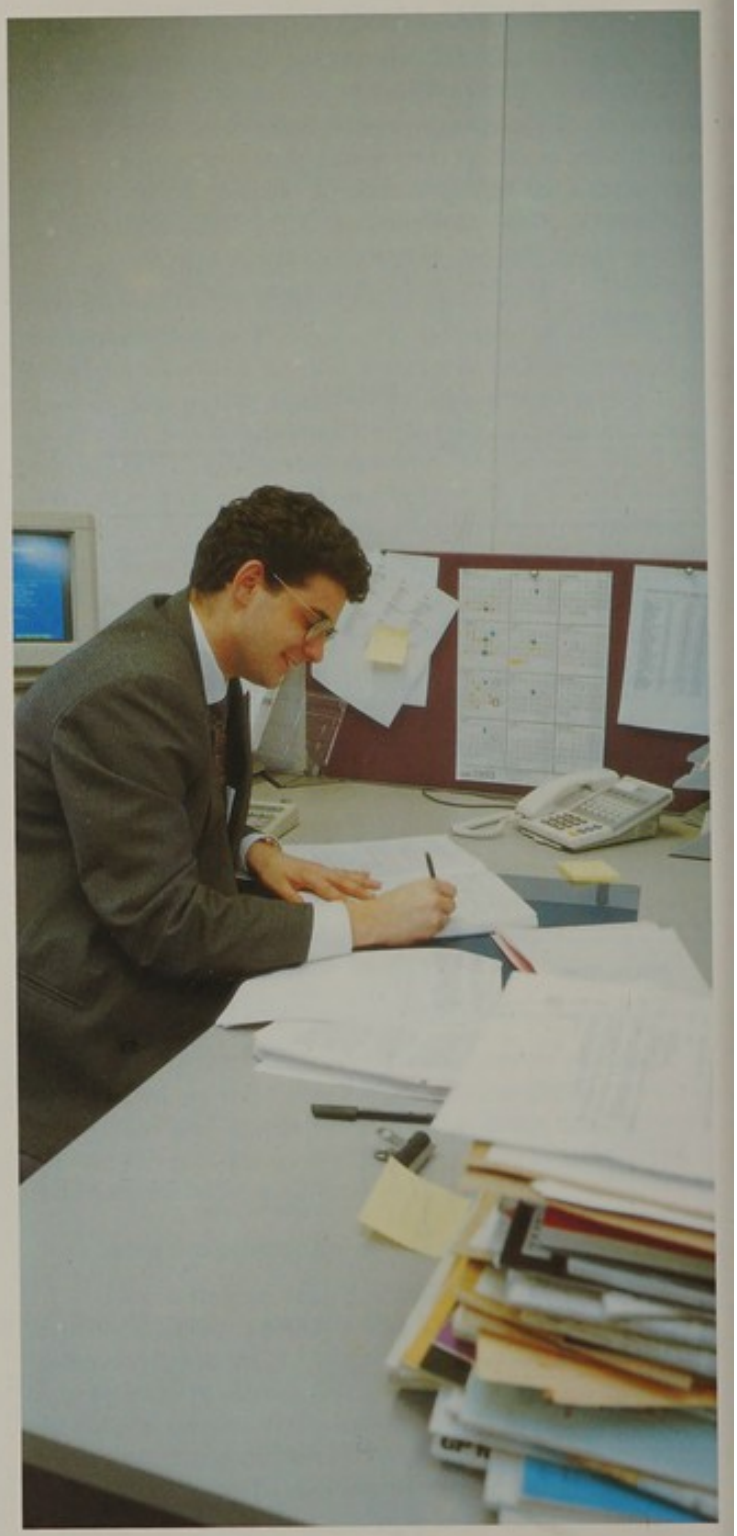
In simple terms pre-implantation diagnosis involves IVF techniques to recover eggs from a woman which are then fertilised with her partner's sperm. After a few days, embryos in the cleavage stage undergo a biopsy and one or two cells are removed for DNA analysis. It is possible at the present time to determine the sex of the child and thus avoid genetic diseases which affect only boys or girls. Research is also being carried out towards identifying whether or not a particular embryo is affected, unaffected or a carrier of the disease for which the parents are carriers. These techniques are at a very early stage of development. At present only one clinical licence exists for the use of pre-implantation diagnosis for the prevention of sex-linked genetic diseases.

The HFEA have approved four research licences for studies into pre-implantation diagnosis. Areas of research involve diseases such as sickle cell anaemia, haemophilia and cystic fibrosis as well as studies comparing the genetic make-up of biopsied cells with the embryos themselves to determine the accuracy of the techniques.

To give an idea of the potential for these techniques, there are approximately 200 X-linked genetic disorders and 3500 dominant single gene defects which cause death or severe disability. In addition chromosome disorders may account for 2% of fetal deaths and about 35% of human embryos which do not establish a viable pregnancy because they have a severe genetic abnormality.



Embryo biopsy for pre-implantation diagnosis



Mark Salmon, HFEA Executive

9. THE AUTHORITY'S EXECUTIVE

On 2 May 1992 the Authority's Executive moved into new offices close to Liverpool Street Station in London. This was done to reduce the cost of accommodation, to provide more secure premises and to obtain more suitable office space. Paxton House provides twenty-four hour manned security cover and there is a sophisticated alarm system in the Authority's premises.

9.1 Staffing Levels

The Authority currently employs fifteen full-time and two part-time members of staff. The Executive is split into four separate teams:

Licensing (seven staff)
Information (four staff)
Policy (three staff)
Finance, Personnel and Administration (two staff).

The Chief Executive is involved in all areas of the Authority's work. Some staff were employed on short-term contracts during the year, to provide extra support during particularly busy periods or for particular projects. A review of the current staffing level of the Executive is being undertaken to ensure that the number and expertise of staff is appropriate in relation to the work required.

HFEA Executive

10. ISSUES FOR THE COMING YEAR

In addition to the recurring work involved in licensing, policy and information, there are certain issues which the Authority has placed on the agenda for discussion in the next twelve months.

Treatment for Post-menopausal Women

Although the HFEA Code of Practice recommends an age limit of 35 for egg donors, no limit is recommended for women receiving eggs and/or treatment. With recent advances in fertility treatment it is now possible for a post-menopausal woman to become pregnant and carry a baby, using donated eggs. Treating older women presents potential ethical and social difficulties relating to both mother and child. The Authority will be addressing the issue to determine whether specific guidance should be given in the Code of Practice.

Payments to Gamete Donors

The Act prohibits the payment of money or other benefits for gametes (eggs or sperm) except where allowed by the Authority. When the Authority first took up its powers, directions were issued to limit the value of money or other benefits which may be given to donors. This was in order to maintain existing practice during the transitional period but the intention, in the longer term, was that payment should eventually be phased out. The Authority will need to review the ethical issues surrounding this matter and assess the possible effects of phasing out payment to donors.

Supply of Semen Donors

When the results of the survey of semen donors are available, the Authority will need to decide whether any policy changes are required.

HFEA meeting

Public Consultation on the Use of Fetal Ovarian Tissue

A consultation document on research involving fetal ovarian tissue has been prepared. This will be distributed for consultation as widely as possible and the replies analysed. As a result of this consultation the Authority will decide what, if any, action it needs to take.

Information for Patients and Potential Patients

The Authority will need to consider what further information should be made available to patients and potential patients. The arguments in favour and against publicising individual centres' success rates will be addressed and consultation on how to proceed is likely.

The Provision of GIFT

An assessment of the provision of GIFT services will be undertaken during the year. This study has been postponed partly due to pressure of other work and partly because another organisation was undertaking a study of all infertility services in the National Health Service, including GIFT. The results of this study will be taken into account when the Authority is preparing its own survey.

Transport IVF

A small number of centres are now involved with transport IVF whereby preparation for treatment and egg collection are carried out at a satellite unit and the gametes are transported to a licensed centre for fertilisation and embryo replacement. In these circumstances the satellite unit does not require a licence under the Act. The Authority is very keen to ensure that patients receiving this form of treatment receive the same quality of care as those who receive all their treatment in a licensed centre. Work is therefore underway to develop a system to control standards in the satellite units within the existing framework of licensing. This system will be formalised in the coming months and guidance will be issued.

Training for Counsellors

A conference was held in February 1993 for representatives from counselling organisations and others with an interest in infertility. As a result of this conference, members of the different organisations have set up a working group, with HFEA representation, to discuss the training needs of counsellors.

Storage of Sperm and Embryos.

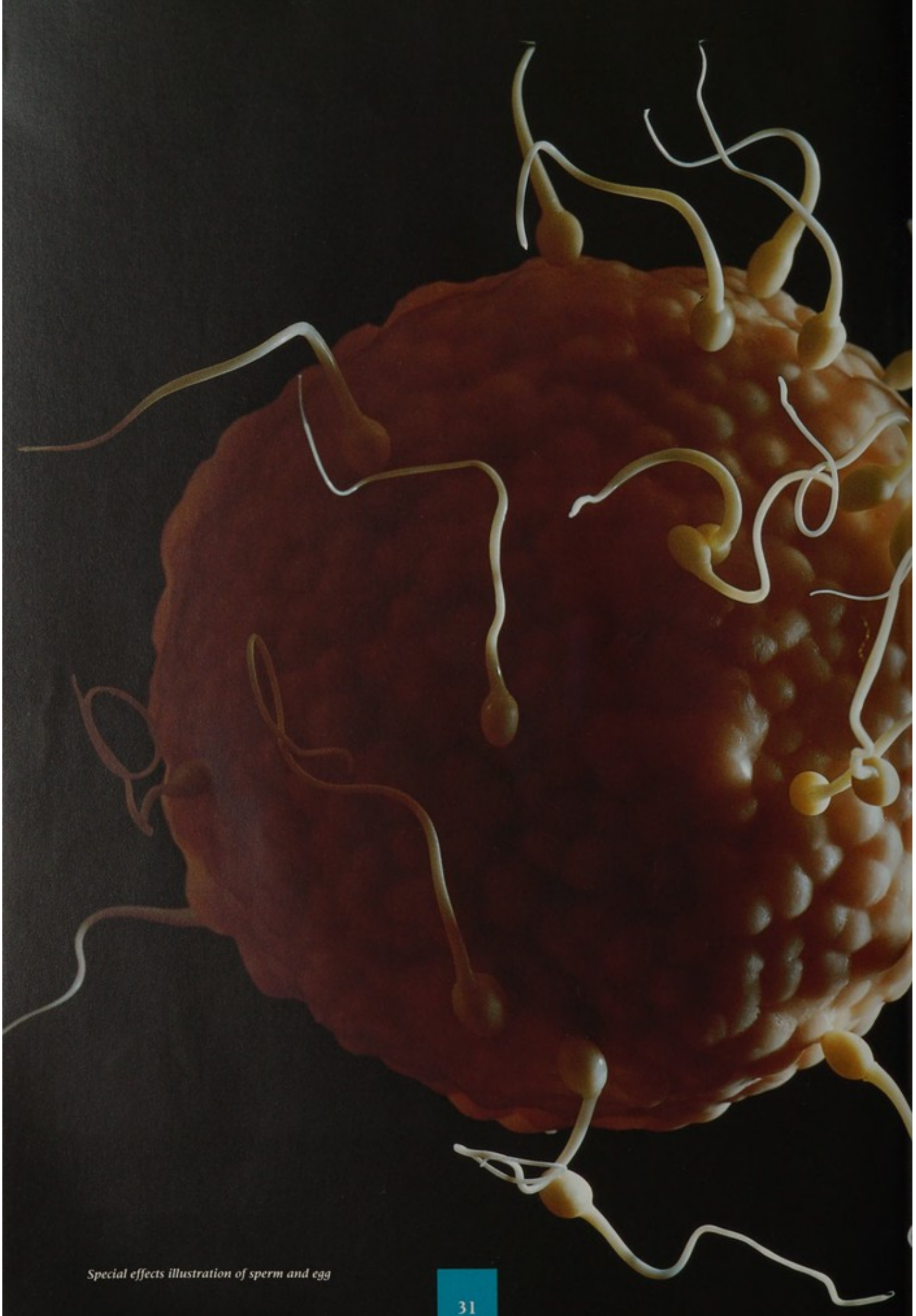
It is now nearly two years since the Authority took up its responsibilities under the Act and there are a number of issues which need to be addressed with regard to the storage of sperm and embryos. The Act sets a limit of five years on the storage of embryos except in circumstances set out in regulations. The Authority will need to consider whether there is a case to be made for regulations.

Some centres now have a considerable number of cases where embryos were stored before 1 August 1991 and attempts to contact the providers of the gametes have been unsuccessful. The centres need advice on the fate of these embryos once the statutory storage period is reached. Similarly, centres have a number of sperm samples in long-term storage for patients who wished to store their sperm prior to commencing radio- or chemotherapy. In many cases the centres have lost contact with these patients and are now seeking advice on how to cope with an ever increasing demand for storage. The Authority will be addressing these issues in order to provide guidance to centres.

Contact with other Ethics Committees

The Authority will seek to establish stronger relationships with other bioethical organisations in the UK and abroad, to increase the Authority's knowledge of other organisations with a view to informing the discussions of the Authority and its committees.

Flora Goldhill, Chief Executive



Special effects illustration of sperm and egg

ANNEXES

1. Members of the Human Fertilisation and Embryology Authority

Chairman **Professor Colin Campbell**
Vice-Chancellor of Nottingham University.

Deputy Chairman **Diana Brittan**
Member of the Equal Opportunities Commission; Magistrate, City of London; Chairman, Community Industry.

Members: **Professor Robert Berry**
Professor of Genetics, University College, London.

Professor Ian Cooke
Professor of Obstetrics & Gynaecology, University of Sheffield Jessop Hospital for Women.

Professor Antony Cox
Professor of Child & Adolescent Psychiatry, United Medical & Dental Schools of Guy's & St Thomas's Hospitals.

Jane Denton
Nursing Research Fellow, Multiple Births Foundation, Queen Charlottes & Chelsea Hospital, London.

Liz Forgan
Managing Director, BBC Radio.

Joan Harbison
Senior Lecturer in Education, Stranmillis College, Belfast.

Dr Stephen Hillier
Director, Reproductive Endocrinology Laboratory, University of Edinburgh Centre for Reproductive Biology.

Professor Brenda Hoggett
Law Commissioner; Recorder of the Crown Court; Visiting Professor of Law, King's College, London.

The Most Rev Richard Holloway
Bishop of Edinburgh.

Penelope Keith
Actress.

Angela Mays
Management Consultant.

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

Dr Jeannette Naish
General Practitioner; Senior Lecturer, General Practice & Primary Care, Colleges of St Bartholomew's & London Hospitals, University of London.

Rabbi Julia Neuberger
Chairman, Camden & Islington Community Health Services NHS Trust.

Professor Robert Shaw
Professor of Obstetrics & Gynaecology, University of Wales College of Medicine, Cardiff.

David Shilson
Senior Official, Bank of England.

Professor Robert Snowden
Professor of Family Studies, Exeter University.

Christine Walby
Director of Social Services, Staffordshire.

Professor David Whittingham
Professor of Experimental Embryology, University of London; Director of Medical Research Council Experimental Embryology & Teratology Unit.

ANNEXES

2. Members of HFEA Committees

LICENSING AND FEES COMMITTEE
Diana Brittan *(Chairman)*
Jane Denton
Stephen Hillier
Richard Holloway
Angela Mays
Julia Neuberger
Robert Shaw
David Shilson
Christine Walby
David Whittingham

CODE OF PRACTICE COMMITTEE
Brenda Hoggett *(Chairman)*
Robert Berry
Ian Cooke
Antony Cox
Liz Forgan
Joan Harbison
Penelope Keith
Anne McLaren
Jeannette Naish
Robert Snowden

INFORMATION COMMITTEE
Antony Cox *(Chairman)*
Robert Berry
Diana Brittan
Angela Mays
David Whittingham
David Birch *(Co-opted member from Office of Population Censuses and Surveys)*

ORGANISATION AND FINANCE COMMITTEE
Colin Campbell *(Chairman)*
Diana Brittan
Robert Berry
David Shilson

COMMITTEE ON SOCIAL AND ETHICAL ISSUES
(CORE MEMBERSHIP)
Liz Forgan *(Chairman)*
Colin Campbell
Joan Harbison
Stephen Hillier
Richard Holloway
Christine Walby

3. List of Centres Licensed by the HFEA for Treatment and Research

	IVF	DI	Research
AVON			
St Michael's Hospital, Bristol	•	•	•
University of Bristol IVF Service	•	•	-
Southmead General Hospital,Bristol	•	•	-
Tower House Clinic, Bristol	-	•	-
BUCKINGHAMSHIRE			
The AMI Chiltern Hospital, Great Missenden	•	•	-
CAMBRIDGESHIRE			
Bourn Hall Clinic, Cambridge	•	•	-
The Rosie Maternity Hospital, Cambridge	-	•	-
CLEVELAND			
Hartlepool General Hospital	•	•	-
South Cleveland Hospital, Middlesbrough	•	•	-
Cleveland Fertility Centre, Great Broughton	-	•	-
Nuffield Cleveland Hospital, Stockport	•	•	-
DEVON			
Royal Devon & Exeter Hospital	-	•	-
Nuffield Hospital, Plymouth	-	•	-
DORSET			
The Winterbourne Hospital, Dorchester	-	•	-
ESSEX			
Holly House Hospital, Buckhurst Hill	•	•	-
BUPA Roding Hospital, Ilford	•	•	-
HAMPSHIRE			
BUPA Chalybeate Hospital, Southampton	•	•	-
Princess Anne Hospital, Southampton	•	•	-
HERTFORDSHIRE			
Queen Elizabeth II Hospital, Welwyn Garden City	-	•	-
HUMBERSIDE			
Princess Royal Hospital, Hull	•	•	-
KENT			
The Maidstone District General Hospital	-	•	-
Chelsfield Park Hospital, Orpington	•	•	-
Queen Mary's Hospital, Sidcup	-	•	-
LANCASHIRE			
Manchester Fertility Services Ltd, BUPA Manchester	•	•	-
Withington Hospital, Manchester	•	•	•
Regional IVF & DI Unit, St Mary's Hospital, Manchester	•	•	•
Hope Hospital, Salford	•	-	-
Billinge Hospital, Nr Wigan	-	•	-
LEICESTERSHIRE			
Leicester Royal Infirmary	•	•	-
BUPA Hospital, Leicester	•	•	-

	IVF	DI	Research
MERSEYSIDE			
Fazakerley Hospital, Liverpool	•	•	-
Royal Liverpool University Hospital	•	•	•
The Women's Hospital, Liverpool	•	•	-
The Rodney Fertility Clinic, Liverpool	-	•	-
BUPA Murrayfield Hospital, Thingwall	•	•	-
MIDDLESEX			
West Middlesex University Hospital, Isleworth	-	•	-
MIDLANDS (WEST)			
Birmingham Maternity Hospital, Edgbaston	-	•	-
AMI Priory Hospital, Birmingham	•	•	-
Infertility Advisory Centre, Birmingham	•	•	-
Midland Fertility Services, Aldridge	•	•	-
SAI Medical Centre, Walsall	-	•	-
NORFOLK			
BUPA Hospital, Norwich	•	•	-
NORTHAMPTON			
Three Shires Hospital, Cliftonville	-	•	-
NOTTINGHAMSHIRE			
AMI Park Hospital, Arnold	•	•	•
Nurture, University of Nottingham	•	•	-
Nottingham City Hospital	-	•	-
OXFORDSHIRE			
John Radcliffe Maternity Hospital, Oxford	•	-	•
Churchill Hospital Andrology Unit, Oxford	-	•	-
Zoology Department, University of Oxford	-	-	•
SUSSEX (EAST)			
Esperance Private Hospital, Eastbourne	•	•	-
STAFFORDSHIRE			
North Staffordshire Maternity Hospital	•	•	-
TYNE AND WEAR			
Royal Victoria Infirmary, Newcastle	•	-	•
Lindon Clinic, Newcastle General Hospital	-	•	-
Sunderland District General Hospital	-	•	-
Cromwell IVF & Fertility Centre, Washington Hospital	•	•	-
WARWICKSHIRE			
The Walsgrave Hospital, Coventry	•	•	•
University of Warwick	-	-	•
YORKSHIRE (SOUTH)			
Doncaster Fertility Services	-	•	-
Sheffield Fertility Centre	•	•	-
Jessop Hospital for Women, Sheffield	-	•	-
YORKSHIRE (WEST)			
St. James's University Hospital Trust, Leeds	•	•	-
Clarendon Wing, General Infirmary, Leeds	•	•	-
Allerton Medicare plc, Leeds	•	•	-
LONDON (CENTRAL)			
St Bartholomew's Hospital	•	•	•
Bridge Fertility Centre, London Bridge Hospital	•	•	-
St Thomas's Hospital	•	-	•
The Churchill Clinic	•	•	-
The Lister Hospital	•	•	-
Guy's Hospital	•	•	-
Cromwell Hospital	•	•	-
St George's Hospital	•	•	-
Dr L Hughes, Harley Street	-	•	-
Infertility Advisory Centre	•	•	-
Dr G B Carruthers, Wimpole Street	-	•	-
AMI Portland Hospital	•	•	-
Middlesex Hospital	-	•	-
Hallam Medical Centre (4 centres)	•	•	-
London Fertility & Gynaecology Centre (2 centres)	•	•	•
Dr M Katz, Harley Street	-	•	-
Pregnancy Advisory Service	-	•	-
University College Hospital	•	•	-
The London Welbeck Hospital	•	•	-
LONDON (EAST)			
Rowan Clinic, Royal London Hospital	-	•	-
The London Independent Hospital	-	•	-
Newham General Hospital	•	-	-
LONDON (SOUTH)			
King's College Hospital	•	•	•
LONDON (WEST)			
The Royal Masonic Hospital	•	•	-
Hammersmith Hospital	•	•	•
Queen Charlotte's & Chelsea Hospital	-	•	-
NORTHERN IRELAND			
Royal Victoria Hospital, Belfast	•	•	-
SCOTLAND			
Aberdeen Maternity Hospital	•	•	-
Monklands District General Hospital, Airdrie	-	•	-
Ninewells Hospital, Dundee	•	•	•
Dept of Reproductive Biology, University of Edinburgh	•	•	•
Western General Hospital, Edinburgh	-	•	-
Glasgow Royal Maternity Hospital	-	•	-
Glasgow Nuffield Hospital	•	•	-
Ross Hall AMI Hospital, Glasgow	-	•	-
Royal Infirmary Hospital, Glasgow	•	-	-
Raigmore Hospital, Inverness	-	•	-
Balfour Hospital, Orkney	-	•	-
WALES			
University Hospital of Wales, Cardiff	•	•	-
Neath General Hospital	-	•	-
Singleton Hospital, Swansea	-	•	-

CENTRE PROVIDING HAMSTER EGG PENETRATION TEST ONLY

London Andrology Centre

CENTRES PROVIDING STORAGE FACILITIES ONLY

St David's Hospital, Bangor
Danum Lodge, Doncaster
Blackdown Nursing Home, Leamington Spa
Walm Lane Clinic, London
Department of Clinical Biochemistry, Newcastle General Hospital
Semenology Department, Nottingham City Hospital
Watford General Hospital
Bridge Fertility Centre Donor Bank

ANNEXES

4. List of Current Research Projects

King's College Hospital, London
Pre-implantation stage diagnosis of sickle cell anaemia and haemophilia A in the human embryo

King's College Hospital, London
A study of the growth requirements of cell lines derived from parts of the human blastocyst

King's College Hospital, London
The definition of optimal culture conditions for the culture of human pre-implantation embryos in vitro

King's College Hospital, London
The identification of criteria of human pre-implantation embryo viability

Royal Liverpool University Hospital
Measurement of intracellular metabolites at fertilisation

Royal Liverpool University Hospital
Immunobiological investigations into human fertilisation and implantation

Royal Liverpool University Hospital
The definition of optimal culture conditions for human pre-implantation embryo development in vitro

St. Thomas's Hospital, London
The development of a contraceptive vaccine

St Thomas's Hospital, London
Methods for evaluating normality of pre-implantation development

St Thomas's Hospital, London
Studies of methods for the cryopreservation of human oocytes

John Radcliffe Maternity Hospital, Oxford
Transplantation antigen expression on human pre-implantation embryos

John Radcliffe Maternity Hospital, Oxford
Biopsy of human embryos for the pre-implantation diagnosis of genetic disease

John Radcliffe Maternity Hospital, Oxford
The use of growth factors to improve human embryo culture for in vitro fertilisation

John Radcliffe Maternity Hospital, Oxford
Assisted hatching of human IVF embryos

John Radcliffe Maternity Hospital, Oxford
Partial zona dissection (PZD) and sub-zonal insemination for the alleviation of male infertility

University of Edinburgh
A study of the mechanism of trisomy formation in man

University of Edinburgh
Development of techniques and establishing a protocol for the microinsemination, by injection, of spermatozoa, into the perivitelline space of human oocytes

Park Hospital, Nottingham
In vitro studies of human oocytes after microinjection of spermatozoa

University of Oxford
Growth and characterisation in vitro of cells derived from the early human conceptus

Ninewells Hospital, Dundee
Growth of the human pre-implantation embryo in vitro. Assessment of functional normality using endocrine markers.

Withington Hospital, Manchester
In vitro development and implantation of normal human embryos and comparison with uni- or poly- pronucleate embryos

Royal Victoria Infirmary, Newcastle
Evaluation of 3 different types of culture for embryos

St Michael's Hospital, Bristol
Effects of substances and procedures on the ability of human spermatozoa to penetrate zona free hamster eggs

Hammersmith Hospital, London
To measure the activity of metabolic enzymes in spare human pre-implantation embryos

Hammersmith Hospital, London
To measure the activity of enzymes implicated in genetic disorders

Hammersmith Hospital, London
Sperm oocyte interaction and fertilisation failure

Hammersmith Hospital, London
Pre-implantation genetic diagnosis parallel studies

St Mary's Hospital, Manchester
Development of sub-zonal insemination: a technique to micro inject sperm into oocytes as a treatment for male infertility

London Fertility & Gynaecology Centre
Micromanipulation of human gametes in the treatment of male factor infertility: comparison of partial zona dissection and sub-zonal insemination

Walsgrave Hospital, Coventry
The use of cocultures in human in vitro fertilisation

Warwick University
The use of cocultures in human in vitro fertilisation

St Bartholomew's Hospital, London
The release of lymphokines by the human embryo

5. List of HFEA Inspectors

Professor John Aitken
Scientist, MRC Reproductive Biology Unit, Edinburgh

Margaret Auld
Formerly Chief Nursing Officer, Scottish Home & Health Department and Vice-President, Royal College of Midwives

Dr Linda Baggott
Lecturer in Biology, Exeter University

Dr Sarah Ball
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ANNEXES

6. GIFT Data 1 January - 31 July 1991
(Collected by OPCS)

OPCS
GIFT Data 1991 - TREATMENT

	PATIENTS	TREATMENT CYCLES	EGG COLLECTIONS	GAMETE REPLACEMENTS
IVF centres (64)	933	993	902	816
Non-IVF centres (35)	100	101	99	92
TOTAL	**1033**	**1094**	**1001**	**908**

OPCS
GIFT Data 1991 - OUTCOME

	PREGNANCIES	PREGNANCY/ PATIENTS TREATED %	PREGNANCY/ TREATMENT CYCLE %	MISCARRIAGES	ECTOPICS	LIVE BIRTHS	LIVE BIRTHS/ TREATMENT CYCLE %	STILL BIRTHS	NEONATAL DEATHS
IVF centres (64)	162	17.4	16.3	41	1	112	11.3	0	3
Non -IVF centres (35)	16	16.0	15.8	4	0	12	11.9	0	0
TOTAL	**178**	**17.2**	**16.3**	**45**	**1**	**124**	**11.3**	**0**	**3**

OPCS
Multiple Pregnancy and Gamete Transfer - GIFT Pregnancies

EGG TRANSFERRED	NO OF TRANSFERS	SINGLETON	TWIN	TRIPLET	QUAD	QUIN
One	27	1	0	0	0	0
Two	126	21	3	1	0	0
Three	537	80	19	4	0	0
Four	213	17	8	2	1	0
Five or more	5	2	0	0	0	0

OPCS
Pregnancy and Multiple Pregnancy Rates Per Gamete Transfer

EGGS TRANSFERRED	PREGNANCY RATE %	MULTIPLE PREGNANCY RATE %
One	3.7	0.0
Two	19.8	16.0
Three	19.2	22.3
Four	13.1	39.3
Five or more	40.0	0.0

OPCS
Multiple Pregnancy Rates for GIFT

PREGNANCY	RATES %
Singleton	76.1
Twin	18.9
Triplet	4.4
Quad	0.6
Quin	0.0
Overall Multiple Pregnancy Rate	23.9

ANNEXES

7. Summary of HFEA Accounts 1991/92

RECEIPTS AND PAYMENTS ACCOUNTS FOR THE PERIOD ENDED 31st MARCH 1992

	1991-92 £	1990-91 £
Receipts		
HMG Advances received	749,070	113,144
Operating Receipts (Fees)	70,549	-
	819,619	113,144
Payments		
Staff Costs	247,465	53,870
Other Operating Payments	563,520	55,370
	810,985	109,240
Surplus (Deficit) from operations	8,634	3,904
Other Receipts/Payments (Net)	977	-
Surplus (Deficit) for the financial year	9,611	3,904
Appropriations	-	-
Excess of receipts over payments for the financial year	9,611	3,904

	1991-92 £	1990-91 £
Other Operating Payments		
Accommodation	199,626	-
Travel & Subsistence - Inspectors	46,464	-
Travel & Subsistence - HFEA Members	41,850	11,213
HFEA Staff Travel & Subsistence	3,994	630
Attendance Fees - Inspectors	41,281	-
Attendance Fees - HFEA Members	41,489	13,786
Professional & Administrative Fees	56,006	-
Register of Information	35,616	-
Sundry Office Equipment	16,841	9,487
Stationery & Printing	28,520	6,028
Telephones & Postage	14,313	2,353
Training & Staff Development	17,757	-
Recruitment & Advertising	9,431	11,037
Conferences & Meeting Expenses	4,263	287
Library & Reading Materials	3,858	65
Miscellaneous Expenditure	2,211	484
	563,520	55,370

8. Information available from the HFEA

HFEA Information Leaflets

- The role of the HFEA
- Sperm and Egg Donors and the Law
- Egg Donation
- In Vitro Fertilisation (IVF)
- Treatment Clinic: Questions to Ask

All free of charge.

HFEA Videos

- IVF: The Next Step?
- DI: The Next Step?

Available for use by patients and for educational purposes only. A small charge will be made per copy.

HFEA Documents

- List of Licensed Centres
- Code of Practice
- Annual Reports

All free of charge.

- Manual for centres

£15.00 per copy.

Other Documents

- Important information for semen donors (Produced by the Royal College of Obstetricians & Gynaecologists)

Free of charge.

Acknowledgments

Page

Front cover and page 5	*Fertilised egg*	*Dr Phillip Matson*
Foreword	*Unfertilised egg*	*Dr Simon Fishel*
7	*2 cell embryo*	*Professor Peter Braude*
9	*4 cell "*	" " "
10	*8 cell "*	" " "
11	*16 cell "*	" " "
12	*Blastocyst*	" " "
26	*Diagrams of ZD, PZD, SUZI*	*Dr Ian Findlay*
27	*Embryo Biopsy*	*Professor Audrey Muggleton-Harris*
31	*Special effects illustration of sperm and egg*	*Art Director: Bob Schuchman* / *Photo Library: Phototake NTC*