



HFEA ANNUAL REPORT 2006/7

Supplement to HFEA Annual Report Accounts 2006/7

**Presented to Parliament pursuant to
section 7(3) of the Human
Fertilisation and Embryology Act
1990**

CHIEF EXECUTIVE'S FOREWORD

During 2006/07, the Human Fertilisation and Embryology Authority (HFEA) endeavoured to do more than simply fulfil our statutory responsibilities. In line with the principles of the Better Regulation Taskforce, we want to help clinics to provide safe care of high quality, as well as providing support and protection to patients and the public. We believe we have achieved this. The outcomes of our programme of work are set out in the following pages.

Our aim is to continue to improve the way that we regulate treatment and research. To this end, we have introduced risk-based inspections in order to direct the focus of our effort towards high risk and poorly performing centres. Our inspections have become more streamlined and we have continued to reduce the amount of paperwork required for inspections. We have developed assessment procedures for Persons Responsible for research centres. This year, for the first time, we published a thematic report on the performance of clinics. We are working closely with the professional organisations from the sector and our licensed centres panel to help determine what improvements are necessary, and where.

Patients' interests are at the heart of the HFEA's work. This year, we have published a new *HFEA Guide to Infertility* magazine which has attracted praise from patients. We have also produced our interactive guide to clinics to help enable patients to obtain comprehensive information about treatments. We launched the new look HFEA website last year, specifically based on the feedback we have had from patients. The website also offers a service of downloadable patient factsheets to make access to information quicker and simpler than ever before. We have been able to provide guidance to patients on issues such as going abroad for treatment and reproductive immunology.

Our online patients' panel – Fertility Views – has provided us with useful feedback on HFEA policies as well as raising important matters of concern to patients. At a clinic level, we have introduced a new patient questionnaire to allow us to survey patients' experiences. What patients tell us about a clinic plays an essential role in our inspections. In addition, we meet regularly with key representatives from UK patient organisations to help us to keep abreast of current views and to strengthen our commitment to understanding the needs of patients during what can be a very traumatic time for them. Building on our role in protecting and communicating with patients, we gave a keynote speech to the National Infertility Day conference in June 2006, where we addressed issues such as multiple births and donor shortages, and publicised the HFEA's role in inspecting clinics.

Another achievement during the year has been to improve on the use of evidence in determining our policies. Our policy work has been characterised by working closely with stakeholders and the public. We are conscious that we operate in an environment where sensitive and controversial issues arise. It is important, in light of disparate and often conflicting views, that we air the issues and help to secure and maintain a consensus for moving forward. During the year, we published a policy review on the use of Pre-implantation Genetic Diagnosis (PGD) for lower penetrance cancer conditions and a policy review on witnessing procedures in the laboratory. We launched a policy consultation on 'Eggs for Research' and planned two more consultations; one on multiple births and embryo transfer and the other on the use of hybrids and chimeras in research.

We now face new challenges. We will continue to be heavily involved in the ongoing implementation of the European Tissue and Cells Directive which came into force on 5 July 2007. This Directive applies to all In Vitro Fertilisation and Donor Insemination centres, as well as services new to regulation. We will also continue to take the lead on working with other regulators and practitioners through the European Assisted Conception Consortium.

In the coming year, we will also be working to prepare for amendments made to the Human Fertilisation and Embryology Act 1990.

Our achievements this year have been underpinned by good resource management, and we have achieved the financial and staffing reductions required by the Department of Health's Arm's Length Body Review targets.

Finally, I would like to place on record my particular gratitude for the hard work and commitment of our Authority Members and HFEA staff. Their involvement and determination to improve the regulation of treatments and embryo research has been crucial to our success.



Alan Doran
Interim Chief Executive

Who we are

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7th November 1990 and began operating on 1st August 1991. The HFEA was created by the Human Fertilisation and Embryology Act 1990 to license and regulate human embryo research and specified forms of infertility treatment. The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health.

What we do

The Human Fertilisation and Embryology Act 1990 (HFE Act) provides for the regulation of centres offering assisted conception involving the manipulation of sperm, eggs or embryos outside the human body (e.g. In Vitro Fertilisation –IVF, Donor Insemination - DI), the storage of sperm, eggs or embryos and research involving human embryos. The HFEA aims to safeguard the interests of patients, children, the wider public and future generations.

Our statutory responsibilities are to:

- License and monitor clinics carrying out IVF and DI
- Regulate storage of eggs, sperm and embryos
- Provide information and data about the services, treatments and techniques that clinics provide
- Keep a register of treatments to enable people born as a result of IVF or DI to obtain information about their origins
- License embryo research to ensure science can progress in a responsible way
- Advise government on all aspects of assisted reproductive technology
- Produce a Code of Practice to help clinics comply with the requirements of the HFE Act
- Publicise the services the HFEA provides

Performance during the year 2006/7

The HFEA continues to operate in a fast moving, complex and ethically challenging area of science and clinical practice. There is a very high level of public interest in our activities.

There are disparate and often conflicting views about the issues we address. We recognise the importance of engaging well with a range of stakeholders and with the fertility sector itself. Ensuring safety for patients, embryos and children born as a result of Assisted Reproductive Technologies (ART) is paramount, as is maintaining public confidence in fertility treatment and embryo research.

The HFEA has led the establishment of the European Assisted Conception Consortium (EACC) to bring about closer international links between ART Regulation and service providers. This has left us well placed to deliver the requirements of the EU Tissue and Cells Directive (EUTCD) bringing Intra Uterine Insemination (IUI)/Gamete Intra Fallopian Transfer (GIFT) Centres into regulation within the first two quarters of the 2007/08 business year. The HFEA's remit has changed accordingly with the implementation of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 from the 5th July 2007.

We are responsive to the external drivers of increasing cost effectiveness and are ensuring that our regulatory processes demonstrate risk-based and proportionate regulation.

Ministerial Performance Targets for 2006/07

- Prepare for implementation of the requirements of the EU Tissue and Cells Directive in April 2007, including practice standards for clinics as part of a revised code of practice and proposals for a fee structure
- Continue to develop arrangements for joint working with the Human Tissue Authority (HTA), in preparation for the establishment of RATE
- Continue the rigorous approach to inspection and regulation, including the implementation of a risk-based approach to the centre regulation.
- Establish an effective working relationship with the Department's new ALB Business Support Unit, in addition to maintaining a good working relationship with the Department's sponsor team, dealing promptly with requests for information on finance and staffing issues.

Some Highlights of 2006/7*

- Handled in excess of 152 requests under the Freedom of Information Act (FOI)
- Held an Annual Conference for stakeholders, media and the public
- Held three Licensed Centres' Panel meetings to engage and consult with the sector
- Consulted regularly with 750 patients on the Fertility Views on-line panel
- Processed 408 import/export directions (compared to 60 in 2004/05 and 175 in 2005/06 – a 680% increase in two years)
- Answered 24,926 patient enquiries by telephone/email, an increase of 8,926 from 2005/06
- Twenty Centre Audits were undertaken as part of the Operational Audit Program 2006/07 to apply and demonstrate control over the HFEA's income from fees for licensed treatments. A sample of 1,535 treatments (both IVF and DI) were reviewed.

** Figures refer to the business year 1st April 2006 – 31st March 2007*

Meeting Key Challenges

During the past year, the HFEA has delivered on the key objectives in the 2006/07 Business Plan, and commenced delivery on the 2007/08 Business Plan. Below are selected achievements under each objective, and additional activities undertaken. This text relates to the period April 2006 to the end of August 2007¹.

Provide proportionate, more cost-effective, targeted and risk-based regulation, to be seen as a model regulator

- Delivered annual programme of regulation, inspection and licensing activity, including completion of all 143 statutory inspections in the 2006/07 business year
- Introduced risk-based inspections, directing attention to high risk poorly performing centres
- Introduced new streamlined inspection processes to decrease the overall length of time from start to finish of inspections
- Further streamlining of the licensing process for research and treatment through the introduction of risk-based inspection, using a revised risk assessment tool, and ensuring that Person Responsible (PR) assessments were carried out and feedback obtained from PRs after inspections.
- Carried out major investigation into a clinic and managed extensive regulatory proceedings arising from this
- Introduced new standardised inspection documentation
- Reduced the information burden on clinics, with an 80% reduction in the volume of paperwork required (prior to the introduction of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007)
- Improved performance in timeliness of inspection reports, improving the number of reports available to the centre within 28 days of the inspection from 73% to 96% during the 2006/07 business year
- Improved the format and content of inspection reports, incorporating patient feedback

¹ All figures quoted are for the business year 1st April 2006 – 31st March 2007, unless stated otherwise.

- Issued improved consent forms to centres
- Dealt with 137 patient complaints about centres and clinics
- Developed a distance learning and assessment pack for Persons Responsible
- Developed and implemented a new assessment procedure for Persons Responsible in research centres.
- Developed policy review on witnessing procedures in the laboratory, and an implementation plan for the sector.
- Produced a thematic overview report on the performance of clinics
- Collated a national picture of the sector through inspectors' reports, complaints and incidents, and prepared a thematic review summarising the findings of research inspections.
- Licensing activity included continued prompt and efficient processing of licence applications and renewals, including those for Preimplantation Genetic Diagnosis (PGD) and import/export of gametes.

Drive forward the implementation of the EUTCD and lead the European Committee in addressing this

- Prepared for the implementation of the EUTCD to all IVF and donor insemination centres and services new to regulation
- Consulted with the sector on EUTCD standards
- Provided advice to the Department of Health on the development of the draft regulations and on practical implementation
- Developed licensing and inspection procedures and agreed a fee strategy for the clinics
- Provided guidance and information to IUI/GIFT centres and currently licensed IVF clinics, to support them in achieving compliance and explain the impact on the sector
- Engaged with professional bodies and other organisations including the HTA, the EACC, and the European Society for Human Reproduction and

Embryology (ESHRA), collaborating to inform the European Commission and ensure requirements were achievable and proportionate

- Provided training for external advisers and inspectors
- IUI and IVF clinics, newly regulated under the EU Tissues and Cells Directive, were successfully integrated into regulatory activity on 5 July 2007.

Provide reliable information and advice to donor-conceived adults and donors

- Developed and launched a new-look website with a specific section for donor issues
- Responded to 149 'opening the register' requests and developed a process for handling applications, following the ending of anonymity for new donors in April 2005.
- Continued to improve the accuracy of register data and successfully completed the Historic Audit Project, to compare key information held on the HFEA Register with the corresponding Centre records, and thereby improve the accuracy of the data held
- Conducted review of imports of sperm from the United States
- Continued to manage an increasing number of requests made under the Freedom of Information Act 2000, responding to all of these within the required timescales.

Empower patients and inform patients of future choices

- Published a new HFEA Guide to Infertility magazine and an interactive guide to clinics for patients
- Launched a consultation on the "Eggs for Research" policy review
- Surveyed patients through the online "Fertility Views" patients panel
- Included patient questionnaires as part of inspecting clinics

- Developed proposal for consultation on multiple births and single embryo transfer
- Published Licence Committee reports on the HFEA website
- Produced and launched new downloadable web-based patient information sheets
- Launched and publicised the new HFEA website to patients and the public
- Held bi-annual meetings with patient and donor organisations
- Published two updates of the Find-A-Clinic facility on the web site
- Published a Long-Term Data Analysis for 1991-2006.

Strengthen relationships with key stakeholders by better engagement

- Promoted joint working with Healthcare Commission and other regulators (for example, through carrying out joint inspections with the Healthcare Commission)
- Continued to maintain formal links with the key professional organisations and bodies including the British Fertility Society, Royal College of Obstetricians and Gynaecologists, the Association of Clinical Embryologists, the Royal College of Nursing's Fertility Nurses Group, the British Infertility Counselling Association and the Project Group on Assisted Reproduction
- Undertook horizon scanning on new scientific developments, including consulting international experts
- Held open Authority meetings in London and Belfast
- Held various conferences including a Primary Care event for GPs, nurses, pharmacists and Primary Care Trusts
- Involvement at key conferences including British Fertility Society, BMI Healthcare, Infertility Network UK and ACeBabes National Infertility Day
- Organised and consulted Licensed Centres' Panel

- Published HFEA Update quarterly to improve communication of HFEA activities to the sector
- Participated in the European Union project on regulation (known as EUSTITE: European Union Standards and Training in the Inspection of Tissue Establishments)
- Consulted widely with a range of stakeholders on key policy issues including multiple births and the use of hybrids and chimeras in research
- Provided training and ongoing direct support to Clinics in the introduction and use of electronic data interchange (EDI) to improve the accuracy of data submitted
- Worked with the International Society for Stem Cell Research on current and future research developments
- Worked with clinics to validate the data to be used in the Interactive Guide
- Held meetings with Patient Organisations, and gained patients' views through the Fertility Views on-line panel.

Develop public understanding and confidence in research on assisted conception and stem cell research

- Commissioned an expert report into multiple births and options for single embryo transfer
- Carried out horizon scanning for new scientific developments in fertility science and new technologies
- Published a policy review on the use of Preimplantation Genetic Diagnosis for lower penetrance cancer conditions
- Developed a policy review on the use of hybrids in research
- Undertook widespread public dialogue on the use of hybrids and chimera in research, with support from Sciencewise.
- Promoted the UK's role in the regulation of research internationally through speeches by the Chair and Chief Executive at key international conferences

- Provided advice and support to the Department of Health on the Review of the Human Fertilisation and Embryology Act
- Continued to publish lay summaries of the outcomes of research licence applications, and research inspection reports, on the HFEA website
- Produced a thematic review of research projects licensed by HFEA, including information about the types of research carried out and a summary of the results.
- Completed and published a review of policy on the use of eggs in research.
- Undertook annual horizon scanning to identify priority areas of scientific embryology research and practice to focus on for 2007-2008 and beyond
- Published a report summarising the horizon scanning issues identified, prioritised and considered in 2005 and 2006
- Provided support and advice to the European Assisted Conception Consortium, successful influencing EU policy.

Develop close working relationships with the Human Tissue Authority (HTA) to create integral working wherever possible in readiness for the transition to the Regulatory Authority for Tissue and Embryos

- Provided the HTA back office functions – finance service commenced in July 2006; Human Resources and Legal support provided throughout the year
- Provided ongoing support via Service Level Agreements (SLAs) for Legal, Human Resources and Finance functions
- Began joint working on RATE planning, via project groups on regulation, communications, and operations, finance and human relations. (These groups were subsequently discontinued when the plans for RATE were dropped in October 2007.)

Develop the 7th edition Code of Practice, incorporating professionally agreed standards to meet requirements of the EUTCD and Better Regulation Taskforce objectives

- Consulted upon and issued revised Code of Practice for clinics, including an online interactive version to increase accessibility
- Introduced a new format to provide clearer guide to legal requirements and guidance
- Commenced work in preparation for the Review of the 1990 Human Fertilisation and Embryology Act, providing advice and starting to plan ahead for changes to be implemented in the 2008-2009 business year and beyond. This included contributing to the work of the Joint Parliamentary Scrutiny Committee on the draft Bill
- In accordance with the Government's Better Regulation agenda, developed a model process for conducting impact assessments (including the assessment of potential equalities impacts for all new major activities and projects), and for costing the implications of simplification plans.

Maintain robust financial and staff management and corporate governance to increase efficiency and reduce costs

- Continued to ensure sound budgeting, compliance, invoicing and accounting, complying with all relevant accounting standards
- Ensured compliance with taxation and other regulations
- Introduced automated billing element of Electronic Data Interchange (EDI) across all centres, improving information on income
- Continued progress towards ALB efficiency standards for back office functions
- Full Annual Report produced and laid in Parliament prior to the Summer Recess
- Full costings exercise carried out to support improved awareness of resource implications of projects/initiatives
- All purchasing decisions followed appropriate tendering procedures, to ensure that good value was obtained in procurement

- Achieved break-even position for the financial year
- Completed all Department of Health Arms Length Body returns in accordance with set deadlines
- Carried out financial modelling of resource requirements for the EUTCD
- Supported managers to improve the personal development process for staff
- Developed and implemented a behavioural competency framework linked to Performance Development Planning (PDP) and recruitment processes
- Continued to ensure effective performance management through annual staff Performance and Development Plans (PDPs) and 6 month reviews of progress against objectives
- Organisational training priorities were agreed to ensure staff and Members are in possession of the right skills and knowledge to enable them to deliver the organisation's business.
- Monitored key Human Resources metrics were monitored to enable proactive and well informed staff management, including sickness absence rates, recruitment, staff turnover and reasons for leaving
- Developed equality and diversity strategy
- Built consideration of diversity issues into planning through the introduction of an Equalities Impact Screening and Assessment tool, applied to all new major projects and activities
- Provided training in diversity issues to staff and Authority members
- Published an annual progress report on the disability aspects of the HFEA equality scheme, and achieved ✓✓ disability symbol status
- Ensured compliance with Age Discrimination legislation
- Introduced a Diversity Update for the sector, to enable diversity issues and best practice to be shared, including information for Clinics about equalities legislation and its implications
- Made links with media targeted at minority audiences, for example to increase the representation of ethnic minorities in the Fertility Views panel membership

- Further developed existing risk management procedures to increase awareness and anticipation of risk at operational level
- Ongoing support for the Authority's procedures and its processes for corporate governance included a review of the Authority's business management and decision-making framework, and implementation of a new Committee structure
- Continued to ensure our office environment was appropriate to support staff in the effective delivery of business.

Longer term goals

The current business year, 2007/08, is a particularly demanding year. As well as delivering the annual Business Plan, the HFEA needs to support the review of the Human Fertilisation and Embryology Act. This will require a high level of commitment from staff.

Since the original publication of our Corporate Plan for 2004-2009, we have regularly reviewed and updated our corporate goals to take into account new legislation and other events with a key impact on our role and therefore our strategy. Next year we will be reviewing the 5 year corporate plan.

The main strategic objectives in the coming year's business plan (for 2008-2009) are:

- A. Continuously improve the effectiveness of regulation, information to support patient choice, and the policy framework.
- B. Plan for the implementation of the new HFE Act in keeping with the Government's intentions by: reviewing and updating the Code of Practice; redesigning the functions of the HFEA; and updating our processes and procedures to keep them compliant with contemporary requirements.
- C. Raise the quality of the information we make available to each of our stakeholders, including patients, the public, clinics, donors and donor-conceived offspring.
- D. Ensure that the Authority is able to offer Government and the public the best guidance on existing and new fertility treatments through evidence-based decision making, monitoring existing research, and horizon scanning for scientific developments.

Performance Indicators – Achievements from 1st April 2006 to 31st August 2007

| | Target 2006/07 | Achieved 2006/7 | Target 2007/08 | Achieved Apr-Aug 2007 |
|--|----------------------------|---|---------------------------|-----------------------------------|
| A. Regulation | | | | |
| No. of random unannounced inspections carried out in the year | 4 | 7 | 4 | 3 |
| Reports resulting from inspection of treatment centres available to centre within 28 working days of the inspection date | 90% | 96% | 90% | 88% |
| Reports resulting from research inspections available to centre within 28 working days | 90% | 96% | 90% | 88.5% |
| New licence applications processed within 4 months of receipt | 90% | 100% | 90% | 91.5% |
| Research licence applications processed within 3 months of receipt of complete application & peer review | 100% | 100% | 100% | 100% |
| Reduction in items of information required from clinics | A further reduction of 10% | Achieved. Paperwork for inspections reduced to approximately one fifth of previous level. | Further 10% reduction | Achieved |
| B. Communication and Information | | | | |
| Patient/public enquiries replied to within 3 working days | 95% | 92.22% | 95% | 66.47%* |
| Number of 'page views' of 'For Patients' section of website | - | - | 5% increase | 52.5% increase (since March 2007) |
| Number of 'page views' of 'Find a Clinic' function on website | - | - | 5% increase | 0.95% decrease (since March 2007) |
| Number of Authority meetings held in public during the year | 3 | 3 | 3 | 2 |
| Number of stakeholder events | 8 | 8 | 8 | 24 |
| Freedom of information requests dealt within 20 working days | 100% | 98.67% | 100% | 100% |

| | | | | |
|--|--|-----------|----------------------------|---|
| Publication of finalised Licence Committee decisions on the website | 80% within 14 working days of finalised decision | 90.6% | 90% within 20 working days | 55%** |
| C. Corporate | | | | |
| Invoices paid within 30 days | 95% | 93% | 95% | 95.5% |
| Debts collected within 60 days | 85% | 83% | 85% | 81.5% |
| Monthly billings of clinics achieved in three weeks | 100% | 98% | 95% | 97% |
| D. Diversity | | | | |
| Initial EIA screening completed for all major new policies or projects | - | - | 95% | Not yet known |
| Full EIA completed for all major policies or projects identified as requiring additional assessment | - | - | 95% | Not yet known |
| Develop self assessment and pre-inspection questionnaires, and train clinics to understand their use | - | - | 75% (of clinics) | Not yet known |
| E. ALB Targets | | | | |
| Reduce revenue costs | £1.93m grant aid | On target | £2.109m grant aid | On target |
| Reduce staff full-time equivalents to 82.1 by March 2007 and then maintain this reduction | 82.1 | On target | 82.1 | 80.1 (provided 4 maternity leaves are discounted) |
| Assess the option to utilise a shared service provider for back-office functions | Finance function to be shared with HTA | Achieved | - | - |

* This indicator has been adversely affected by staff turnover and resulting staff shortages, coupled with a marked increase in the volume of enquiries being handled since January 2007.

** This indicator was adversely affected in quarter 1 by staff illness, additional work associated with the introduction of the EUTCD, and further additional administration associated with centres causing concern. In quarter 2 this indicator was improving.

Sources of data used in calculating performance indicators

- A: Inspection and Regulation – data held within the regulation department, monitored by the Authority throughout the year
- B: Communications and Information – records of telephone and email patient/public enquiries held at the HFEA
- C: Corporate – performance indicators generated from HFEA accounting records
- D: ALB Targets – personnel data and periodic management accounts submitted to the ALB Review Team and the Department of Health.

Business Plan Objectives for 2006/07

Key objective 1:

Provide proportionate, cost effective, targeted and risk based regulation to be seen as a model regulator and achieve ALB targets

Key objective 2:

Drive forward the implementation of the European Tissue and Cells Directive and lead the European Committee in addressing this

Key objective 3:

Provide reliable information and advice to donor conceived adults, donors and parents of donor conceived offspring

Key objective 4:

Empower patients and inform them for future choices

Key objective 5:

Strengthen the relationships of the HFEA with key stakeholders by better engagement

Key objective 6:

Contribute to maintenance of public understanding and confidence in research on assisted conception and stem cell research

Key objective 7:

Develop close working relationships with the Human Tissue Authority (HTA), to create integral working wherever possible and move forward towards the establishment of RATE)

Key objective 8:

Maintain robust financial/staff management and corporate governance to increase efficiency and reduce costs

Business Plan Objectives for 2007/08

The key objectives for 2007/08 are:

Key objective 1:

Ensuring patient safety through effective, proportionate, risk-based regulation, and implementing the requirements of the EUTCD to IVF and donor insemination clinics and services new to regulation.

Key objective 2:

Work with the HTA to promote further joint working, in the interests of more streamlined regulation and support services. *(Revised October 2007.)*

Key objective 3:

Promote public understanding of and confidence in research on assisted conception and embryos through proportionate effective regulation and transparent policy making.

Key objective 4:

Develop policies and methods to support effective regulation, ensuring evaluation and amendment as appropriate.

Key objective 5:

Improve the range of reliable, meaningful information and advice to patients, donors, offspring and the public on the performance of services regulated.

Key objective 6:

Maintain robust corporate governance, financial and staff management to increase cost effectiveness.

Key objective 7:

Implement the HFEA's Diversity Strategy and ensure diversity is addressed in all our functions.

Key objective 8:

Ensure that the organisation recruits and retains staff with the right skills and knowledge to achieve its objectives, through a robust organisational development strategy, focused on successful change management.

List of Authority Members as at September 2007

Ms Shirley Harrison (**Chair**)

Mr Hossam Abdalla

Professor David Archard

Professor Christopher Barratt

Ms Clare Brown

Ms Anna Carragher

Ms Sally Cheshire

Mrs Rebekah Dundas

Mrs Ruth Fasht OBE

Professor Neva Haites OBE

Lord Richard Harries of Pentregarth

Ms Jennifer Hunt

Professor Emily Jackson

Dr Maybeth Jamieson

Professor Bill Ledger

Ms Sharmila Nebhrajani

Mr Roger Neuberg

Dr Sue Price