

Human Fertilisation and Embryology Authority

Corporate Plan 2004-2009

2004-2009

Introduction by the Chair

The nature of the Human Fertilisation and Embryology Authority's remit and work dictates that we remain an ever evolving organisation. We operate within a context of rapid scientific and technological advance and ethical and social debate of considerable complexity and sensitivity. In this environment it is essential that the HFEA is efficient, focussed and responsive. I am pleased therefore to present our Corporate Plan, which outlines the aims and objectives we have for the coming five years.

The Corporate Plan focuses on our core functions: regulation, policy development, and communication with patients and the public. This Plan has been developed with the help of organisations, experts and individuals who have professional and personal interests in the HFEA's work and the services and research that we regulate. The Plan reflects the HFEA's desire to contribute to the provision of services that will help to develop families. It also reflects our intention to be a modern and forward thinking organisation, satisfying the needs and expectations of our stakeholders.

I would like to thank everyone who has been involved in the development of this Corporate Plan, and I commend it to all our staff, members and collaborators to use as a guide and measure of the HFEA's development and performance.



Suzi Leather

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1. Introduction

1.1 This is the HFEA's second Corporate Plan, which sets out the vision and strategic objectives for the five years 2004-2009. This Corporate Plan has been agreed with our sponsoring department, the Department of Health, and informed by the views of key professional and patient groups. The Plan will be an important cornerstone in the process of holding the HFEA accountable in carrying out its statutory responsibilities.

1.2 Within a relatively short period of time we have consulted key patient and provider groups, and other agencies with an interest in *in vitro* fertilisation (IVF) and its regulation. We will continue to involve these groups in the monitoring and development of the HFEA's work as the Corporate Plan unfolds over the next five years.

1.3 The Plan identifies seven strategic goals:

- Strengthening our regulatory role
- Being an open organisation, through excellent communications and working in partnership with stakeholders
- Working closely with other regulators and with international agencies
- Strengthening the process of policy development
- Developing an information base which meets the needs of offspring, stakeholders, and the wider regulation and public health functions
- Supporting the development of research in assisted conception, and its application
- Developing an organisation which will fulfil these goals, supported by strong corporate governance

These themes and priorities will inform each annual business plan.

2. Purpose and functions of the HFEA

2.1 The HFEA was established in August 1991, under the 1990 Human Fertilisation and Embryology Act (the HFE Act), as an executive, non-departmental public body; and was the first statutory body of its kind in the world. Its purpose is to assure patients and the wider public that research and treatment undertaken in the field of assisted reproduction is conducted to the highest standards, and within a robust ethical framework.

2.2 The Authority's Members are appointed by the Secretary of State for Health, and its key responsibility is the licensing and monitoring of clinics and centres carrying out *in vitro* fertilisation, donor insemination, and human embryo research. The HFEA is a UK-wide agency, and the functions of the HFE Act are reserved to the UK Government. However, in carrying out its work, the Authority will take account of the different arrangements in the devolved administrations in Scotland, Wales and Northern Ireland, which affect the delivery of assisted conception.

2.3 The HFEA's principal statutory functions are to:

- License and monitor clinics carrying out *in vitro* fertilisation and donor insemination
- License and monitor centres undertaking human embryo research
- Regulate the storage of gametes (eggs and sperm) and embryos.

2.4 The Authority's other statutory tasks are to:

- Produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities
- Maintain a formal register of information about donors, treatments and children born as a result of those treatments
- Publicise the HFEA's role and provide relevant advice and information to patients, donors and clinics
- Review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act and, where appropriate, advise the Secretary of State for Health on developments in these fields.

2.5 The second Quinquennial Review (QQR) of the HFEA, carried out in 2000, concluded that there was a continuing need for an independent body to carry out the functions described above. The report said that the need for the HFEA was "even more relevant and important than when it was established".¹ The continuing debates around new developments, such as Human Leukocyte Antigen (HLA) tissue typing and human embryonic stem cell research, demonstrate that the HFEA still has a significant role in maintaining public confidence in these services, and that this is likely to be so for the life of this Corporate Plan.

¹ Second Quinquennial Review of the Human Fertilisation & Embryology Authority. Report to Health Minister, October 2000.

3. Principles and values

- 3.1** The HFEA is committed to working within the seven principles of public life, which are the baseline for all public bodies (see Annex A). Within these principles, the Authority's overriding concern is safeguarding the public interest, and most particularly, the children created through the new technologies. The welfare of the child is at the centre of the work of the HFEA.
- 3.2** Ethical concerns are at the heart of the Authority's work, operating as it does in a field, which generates very strong and diverse views. In order to maintain the confidence of the public, the HFEA will demonstrate that it understands, and works within, very clear ethical principles.
- 3.3** To this end, the HFEA has adopted a number of core values:
- Integrity and honesty
 - Impartiality and independence
 - Openness in decision making
 - Being rigorous, consistent and fair
 - Working collaboratively
 - Promoting safe, effective and ethical practices in clinical service and science
 - Being timely
 - Seeking, sharing and learning
- 3.4** The importance of these values was highlighted during the consultation about the future of the HFEA, held in the summer of 2002. The evidence given to the Independent Steering Group which led the consultation, illustrated real concern amongst many people about the ability of the HFEA to listen to outside views, and our commitment to working with others.²
- 3.5** One of the Authority's primary aims over the five years of this Corporate Plan is to demonstrate that we have heard these concerns. We intend to uphold the values set out above, and show the Authority's real commitment to openness and working in partnership with relevant groups and agencies.

² Improving the performance of the HFEA. Independent Steering Group Recommendation to the HFEA, September 2002

4. The changing context

- 4.1** In the first decade after the passage of the HFE Act, the HFEA established a strong national and international reputation as a regulator of assisted reproductive technology (ART). It played a prominent role in leading and informing public debate about increasingly complex, and sometimes controversial, scientific and ethical issues. Since 1991, however, the environment in which the HFEA works has changed significantly.
- 4.2** Scientific and clinical developments, changes in public expectations and Government policies are making increasing and complex demands on the Authority. There have been significant increases in the numbers of people seeking information and receiving treatment, as well as major changes in the treatment and research activities regulated by the HFEA. In order to meet these challenges, the Authority has a duty to continuously modernise both how it works, and how it communicates with the public and key interests.

Scientific and Clinical Change

- 4.3** Over the last 10 years, biological science and technological advances have led to important development in genetics and to the transfer of techniques from animals to humans. Micromanipulation techniques, such as Intra Cytoplasmic Sperm Injection (ICSI), Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS) and PGD with Human Leukocyte Antigen (HLA) tissue typing, have greatly extended the scope of assisted reproduction and the numbers of people that it can help.
- 4.4** We cannot predict all the new developments the HFEA will need to address, but we do not anticipate any lessening of the pace of change. The use of reproductive technologies to assist in the treatment of serious disease, through techniques such as PGD, seems likely to increase.
- 4.5** These techniques do have implications for the children born, and for society as a whole. Strategic policy development, and the monitoring of these and other areas are essential if the HFEA is to be able to fulfil its statutory role. The HFEA recognises the importance of keeping abreast of these changes and communicating to the public what the potential implications may be.
- 4.6** In the early years of the Authority's work, regulation of human embryo research did not attract the same level of attention as assisted conception, but this has changed with the emergence of embryonic stem cell research. Human embryonic stem (hES) cells may have the potential to treat a wide range of diseases by virtue of their ability to differentiate and develop into a range of cell types. The Government's policy of allowing regulated research into human embryonic stem cells, including those created via cell nuclear replacement (CNR), has brought with it an expansion of the Authority's regulatory functions.
- 4.7** The importance of the HFEA's role was confirmed by the report of the House of Lords Select Committee on Stem Cell Research, which described the Authority as "the lynchpin" of regulation for stem cell research.³ The potential scientific and commercial requirements of stem cell research,⁴ and the increased professional and public scrutiny involved, will place increased demands on the Authority in terms of both activity and the complexity of the issues to be addressed.

^{3,4} Report of the House of Lords Select Committee on Stem Cell Research, HMSO February 2002.

Ethical and Social Issues

- 4.8** That something can be done does not always mean that it should be done, and scientific and technological advances can create difficult ethical choices and public concern. This is particularly so in the field of assisted conception, where the boundaries of ethical concern are possibly pushed further than in any other area of health care. There is less stigma attached to assisted conception than in 1991, as is demonstrated by the increasing number of people seeking treatment. Also public attitudes to the provision of assisted reproductive technology (ART) for people beyond the traditional family – single women and same sex couples – have shifted significantly.
- 4.9** There are now different issues confronting the public and hence the HFEA. Recently, concern has been focussed on whether families should be able to avoid genetic diseases; whether couples should be able to choose characteristics such as the sex of a future child; the possibility that IVF (and ICSI) brings with it an increased risk to the long-term welfare of children born as a result of ART. Possible changes in the law on donor anonymity are also likely to raise ethical issues which the Authority must address.
- 4.10** The importance of the continued regulation of research using human embryos has been emphasised with emergence of embryonic stem cell research. Although the HFEA is not a research organisation, continued public confidence and the need to provide patients with information upon which they can make fully informed choices depends on the Authority providing strong regulation. This was clearly articulated in the House of Lords Report. The Authority has a leading role in encouraging awareness and debate about research and treatment involving human embryos, and must be seen to consult widely and to communicate the outcomes of its consultations effectively.

The Regulatory Environment

- 4.11** The general demand for greater and more open regulation of public services has grown in recent years. There is increased parliamentary and public interest in how public services are managed, their standards and accountability. This shift in public expectations is particularly evident in the health care field. In response to the increased public concern, a number of agencies, including the National Patient Safety Agency (NPSA), the Commission for Health Improvement (CHI), the National Care Standards Commission (NCSC) and the Commission for Patient and Public Involvement in Health (CPPIH) have been established. (In addition the new Commission for Health Audit & Inspection (CHAI) will be established in 2004.) These developments have major implications for the work of the HFEA.
- 4.12** The HFEA has been largely successful in ensuring that the public has confidence in its regulation of fertility treatments and research. However, the increasing number of major media stories about assisted reproduction and related technologies, alongside high profile cases concerning mistakes in clinics has caused public concern. There have also been challenges to the HFE Act and the Authority's decisions, through judicial review and due legal process. The key to creating greater confidence amongst all stakeholders, is the demonstrable fairness and robustness of the regulatory process.

The HFEA Modernisation Agenda

- 4.13** The past two years have been a period of re-appraisal for the HFEA. The second Quinquennial Review (QQR), carried out in 2000, highlighted the need for modernisation of key aspects of the Authority's operations, to take account of the changing environment discussed above. This conclusion was confirmed by subsequent reviews of the regulatory and information management systems, commissioned by the HFEA. The Authority also needed to respond to the more recent requirements of wider government policy on improving governance in the public sector.
- 4.14** There has been increased interest in the work of the HFEA amongst parliamentarians. Two important reports from the House of Commons Select Committee on Science & Technology,⁵ and the House of Lords Select Committee on Stem Cell Research, already mentioned, recommended improvements in the Authority's regulation of research and its communication with the public. Other developments which may have a significant impact on the configuration of fertility services, and hence the work of the HFEA, are the guidelines from the National Institute for Clinical Excellence (NICE) on IVF in the NHS and the European Union Tissue Directive.
- 4.15** The HFEA has responded positively to the need for change, and the last two years have seen significant progress in the modernisation process, as is illustrated by the Business Plans for 2002-4. This has been supported by the Department of Health, who recognised the need for a major increase in the Authority's budget, financed both from increased funding from government and higher fees from clinics.
- 4.16** The first 12 years of the life of the HFEA have seen rapid change affecting all aspects of our work. There is no indication that the pace of change will lessen, if anything it may well increase. To inform the Corporate Plan, Authority Members and senior staff undertook a scenario planning exercise. This gave the Authority an opportunity to speculate more freely about the long term developments and uncertainties likely to affect and influence events around reproductive health and related research over the next five to 10 years.
- 4.17** What emerged was a framework of ideas around two axis (Annex B):
- The extent of freedom allowed to scientific and clinical advances, particularly around biotechnology and genetics
 - The political/economic context in which this might operate, varying from individual, market-driven arrangements, to highly regulated, collective provision of services
- 4.18** From this, a number of potential scenarios were developed, ranging from a situation of market-driven freedom, where those who could afford treatment could obtain whatever science could offer; to highly controlled and regulated provision, with a very conservative moral framework, dictating what research and treatment was permitted.
- 4.19** The political and ethical climate in the UK, and the attitude of the public at large and the key interest groups, does not suggest that the more extreme scenarios are likely. It was concluded that scientific and clinical developments in IVF and human embryo research will most probably continue to receive support, underpinned by a framework of strong regulation.
- 4.20** This is the assumption underpinning the Corporate Plan. It carries forward the changes already begun, but also looks forward to the next set of challenges facing the HFEA.

⁵ Developments in Human Genetics and Embryology, House of Commons Science and Technology Committee, Fourth Report of Session 2001-2, HMSO July 2002.

5. Corporate goals

5.1 From both internal and external reviews and discussions we have had, a number of consistent themes have emerged, and there is broad agreement about where the Authority should concentrate its efforts. These are expressed below as seven corporate goals, which will set the direction for the HFEA over the next five years.

5.2 Strengthening our regulatory role.

- Delivering a systematic, open and timely inspection process, based on risk assessment by March 2005.
- Ensuring risk reduction and safety are at the heart of regulation (ongoing).
- Revising the Code of Practice and related guidelines regularly, setting out clear, evidence-based standards (ongoing).
- Developing mechanisms for incorporation of patients' views and experience in the inspection process by December 2004.
- Implementing by December 2004 an efficient and open process for licensing and inspection of research projects, based on the highest standards of scientific scrutiny, and taking account of the recommendations of the Better Regulation Task Force.
- Publishing inspection reports and licence committee decisions by April 2004.
- Having clear and effective performance indicators for clinics, agreed with patients by April 2005.
- Monitoring assisted conception provision, particularly in relation to outcomes and patient safety (ongoing).
- Supporting clinics to achieve improved practice, through clinical governance and processes for learning from mistakes (ongoing).
- Supporting clinics to improve laboratory standards, compatible with future European Union Directives (ongoing- dependent on timing of the EU Directive).

5.3 Being an open organisation, through excellent communications and partnership with stakeholders.

- Ensuring patients and providers understand the role of the HFEA, the need for regulation, and the support it can provide by May 2005.
- Developing a strong role as an efficient provider of high quality information and guidance on fertility issues for patients and public (ongoing).
- Delivering timely and effective communications in response to issues raised by the media, parliament and public (ongoing with specific Performance Indicators by January 2004).
- Consulting stakeholders comprehensively on regulation and policy decisions, and giving explanations of decisions (ongoing).

5.4 Working closely with other regulators and international agencies.

- Setting in place by May 2004 Memoranda of Understanding with other regulatory agencies (including new CHAI), which support the specialist role of the HFEA.
- Developing by December 2004 collaborative working arrangements with other organisations (e.g., integrated inspection teams, mutual delegation of functions).
- Collaborating with the Department of Health to develop relationships and influence within relevant EU organisations (ongoing).
- Developing a leading role in working with regulatory agencies and relevant bodies in other countries across the world (ongoing).

5.5 Strengthening the process of policy development.

- Anticipating emerging scientific, clinical and ethical issues, and developing robust policies (ongoing).
- Establishing comprehensive and effective networks of scientific and other advisors to support and inform the policy process by December 2004.
- Maintaining a regular review of all policies, reporting on a yearly basis.

- Advising government on the implications for current legislation of new developments in assisted conception and related research (ongoing).
- Ensuring close collaboration with other relevant policy agencies, such as the Human Genetics Commission (ongoing).

5.6 Developing an information base which meets the needs of offspring and stakeholders, and the wider regulation and public health functions.

- Achieving by April 2007 a fully operational, reliable modern database, enabling the HFEA to meet its statutory responsibilities.
- Developing a data set by December 2004 which meets the needs of key stakeholders, and facilitates research into, and understanding of, assisted conception.
- Supporting patients with clear and accurate information about treatment services and outcomes by December 2004.
- Ensuring the HFEA is prepared for provision of information to offspring in 2008/9 by December 2007.
- Ensuring the HFEA is able to respond to any future changes in the law relating to donor anonymity (ongoing).
- Completing an historic audit by December 2007, ensuring optimal accuracy and accessibility of data.
- Establishing by March 2005 electronic exchange of data systems with clinics, to maximise efficiency and reduce bureaucracy.

5.7 Supporting the development of research in assisted conception, and its application.

- Working with other agencies to support research into the safety and outcomes of assisted conception techniques (ongoing).
- Supporting the development of new IVF techniques being licensed as part of clinical trials (ongoing).
- Encouraging and supporting studies, which evaluate new techniques in assisted conception (ongoing).
- Reviewing by March 2004 the position of assisted conception techniques currently outside existing legislation, and advising government as necessary.

5.8 Developing an organisation, which will fulfil these goals, supported by strong corporate governance.

- Ensuring value for money can be demonstrated in all systems and processes (ongoing, with yearly reporting from April 2005).
- Ensuring by May 2004 a corporate governance framework which meets the highest standards of best practice.
- Ensuring HFEA has the skills and experience required to fulfil the corporate goals (ongoing).
- Having in place a strong HR framework by December 2004, to support the continuing change in the organisation.
- Ensuring a positive culture, which promotes integrated team working across the organisation, both executive and non-executive (ongoing).
- Having in place by March 2004 appropriate legal expertise, to ensure the whole organisation can keep abreast of legal developments.
- Introducing a transparent, comprehensible and cost-effective fee structure for regulation by December 2005, including regulation of research.
- Agreeing the level and purpose of central government funding by December 2004.
- Exploring possible new sources of funding by December 2005 (e.g., fees for international advice & consultancy).
- Ensuring by December 2004 patients and other stakeholders understand what the HFEA provides in return for the fees.

6. Performance monitoring

- 6.1** Each year, the annual Business Plan will include measurable milestones, which demonstrate the Authority's progress in meeting specific targets within its corporate goals. These will be published, and will be an important element in the process of accountability to government and our wider public. More generally, the HFEA will be seen to be succeeding if it maintains and enhances its reputation as a regulator; and its policy and licensing decisions are understood and supported by the majority of public, patients and providers.

7. Financial perspective

- 7.1** The Authority derives its income from two sources: licence fees levied on centres, as provided for in section 16 of the HFE Act; and an annual grant-in-aid from the Department of Health, on behalf of the four UK administrations. The past two years have seen significant changes in the financial profile of the HFEA, with major increases in both sources of income to support the process of change the Authority has begun. The HFEA budget at 2003/4 is £5.2 million. Additional resources will be made available by the Department of Health for development of the HFEA database.
- 7.2** Over the next five years, the overall aim will be to consolidate the changed financial base, ensuring that we demonstrate to government, patients and clinics the added-value delivered by the increased resources the Authority is now receiving.

Annex A

The seven principles of public life

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations which might influence them in the performance of their official duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

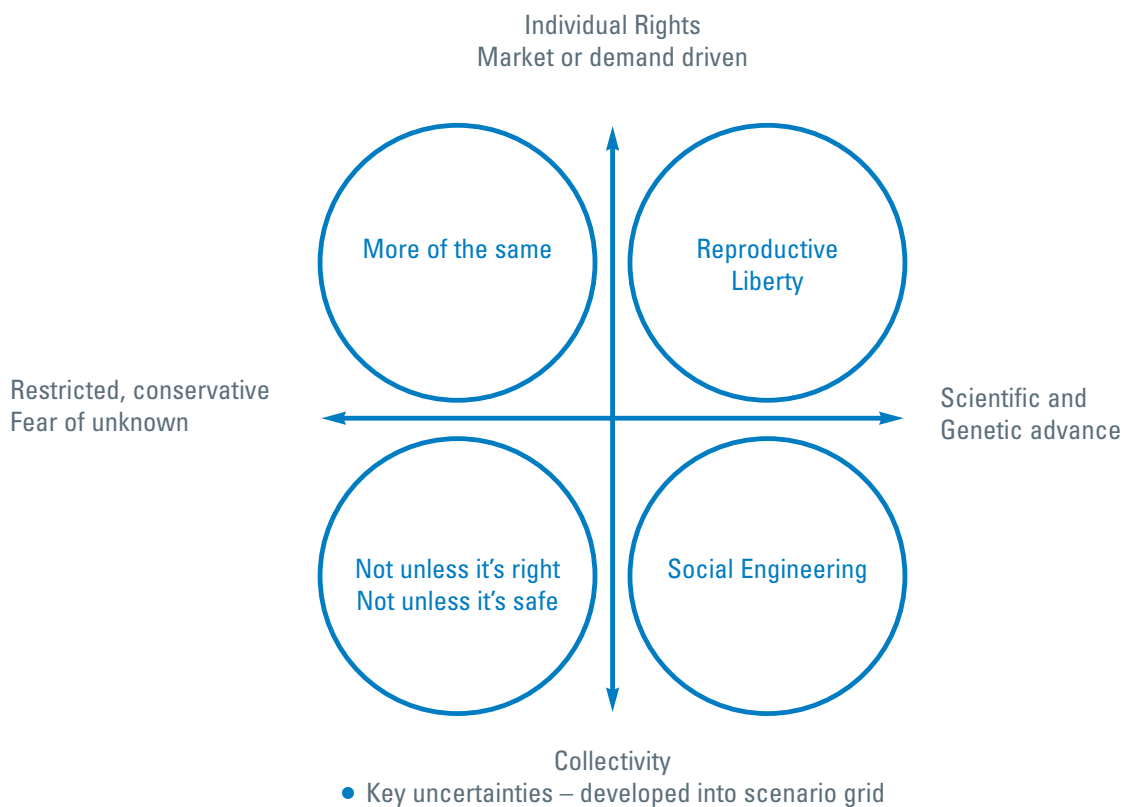
Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

Leadership

Holders of public office should promote and support these principles by leadership and example.

Annex B



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