2011
2012

Business Plan

Human Fertilisation & Embryology Authority

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Contents

HFEA Purpose, Principles and Statutory Functions

The Future Regulatory Landscape

The review of Arm's Length Bodies conducted by central Government in 2010 has determined that the HFEA's functions will continue to be delivered, but that the organisation itself will be abolished within the lifespan of the current Parliament. At the time of writing, the details are still evolving. However, until other arrangements are in place, the HFEA remains an independent arms length body responsible for the delivery of the functions set out below.

Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to, centres. We provide authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.

Principles

We treat people and their information with sensitivity, respect and confidentiality

We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector[1]

We consult widely - listening to and learning from those with an interest in what we do

We keep abreast of scientific and clinical advances

We exercise our functions consistently, proportionately, openly and fairly.

Functions

In November 2008, the Human Fertilisation and Embryology Bill received Royal Assent. The majority of the resulting Act subsequently came into force in October 2009.

The HFEA is required to have regard to two primary sets of legislation:

- The Human Fertilisation and Embryology Act 1990 (as amended) – in this business plan we refer to this as "the 1990 Act (as amended)"; and
- The Human Fertilisation and Embryology Act 2008 ("the 2008 Act").

Primarily, the 2008 Act is amending legislation. It extensively amends the provisions of the 1990 Act, which continues to form the main framework governing the duties and responsibilities of the HFEA. However, the 2008 Act also contains new provisions which were not originally in, and have not been inserted into, the 1990 Act. In particular, these include provisions relating to legal parenthood.

The 1990 Act (as amended) gives the HFEA a number of statutory functions:

[1] 'The sector' refers to the assisted reproduction/fertility sector and all the treatment clinics, storage centres and research establishments within it.

- To keep a formal register of information about donors, treatments and children born as a result of those treatments
- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment
- To license and inspect establishments undertaking human embryo research
- To license and inspect the storage of gametes (eggs and sperm) and embryos
- To maintain a formal register of licences granted
- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities
- To maintain a register of certain serious adverse events or reactions (this relates to certain specific activities, which are set out in the amended Act)
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures
- To respond to any request from a competent authority in another European Economic Area state to carry out an inspection relating to a serious adverse event or reaction, and to take any appropriate control measures
- To collaborate with the competent authorities of other European Economic Area states.

In addition to these specific statutory functions, the legislation also gave the HFEA some more general functions, including:

- Publicising the HFEA's role and providing relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients
- Promoting compliance with the requirements of the 1990 Act (as amended), the 2008 Act and the Code of Practice
- Maintaining a statement of the general principles that should be followed by the HFEA when conducting its functions, and by others when carrying out licensed activities
- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed
- Carrying out its functions effectively, efficiently and economically
- Reviewing information about:
    - Human embryos and developments in research involving human embryos
    - The provision of treatment services and activities governed by the 1990 Act (as amended)
- Advising the Secretary of State for Health on developments in the above fields, upon request.

Looking Back on 2010/11

Meeting Key Challenges

Embedding the New Regulatory and Licensing Framework

Regulatory Framework

Following legislative change and process development, the HFEA implemented a new compliance cycle and inspection approach on 1 April 2010. This included the basic framework for a new risk tool and a pre-inspection Self-Assessment Questionnaire (SAQ). Throughout the 2010/11 business year, further work was done to develop and embed the new tools and processes, and to ensure that the new compliance cycle and inspection and audit processes were operating effectively.

Work included refinement and full implementation of the risk tool, development of a new research SAQ, and further development of the online applications system. Operational audit staff were trained in inspection methodology to further integrate this work.

A two year inspection cycle was achieved, as planned. Centres are now issued with licences for up to four years.

A review was commenced of the Compliance and Enforcement Policy and adverse incident reporting. This project will be completed in 2011/12.

Joint Working and Relationships with Other Agencies

The HFEA continued to maintain good working relationships with regulators and other agencies to ensure that investigations and inspections could be carried out jointly when possible, in keeping with the Concordat (a voluntary agreement between organisations that regulate, audit, inspect or review elements of health and healthcare in England). We also continued to participate in the European Union Standards and Training in the Inspection of Tissue Establishments (EUSTITE) project on Europe-wide inspection standards, and attended biannual meetings of the Competent Authorities in Brussels.

Arising from the Government's review of Arm's Length Bodies, the HFEA has initiated a programme of activities aimed at broadening and deepening existing relations and working with the Care Quality Commission (CQC). This is reciprocated by the CQC and has led to the HFEA moving into the same London premises as the CQC in summer 2011. In addition both ALBs will assess sharing services and co-ordinating other activities.

Licensing Framework

New licensing processes were introduced in October 2009, and these continued to be monitored throughout 2010/11. An external evaluation of new Executive Licensing Panel (ELP) and licensing processes was completed in March 2011, reviewing consistency of decision-making and adherence to Regulations and protocols.

In conjunction with the ongoing review of the compliance and enforcement policy, a review was commenced of the list of licensable activities, to ensure conformity with the HFEA Act 1990 (as amended) and the EUTCD. This will conclude in 2011/12.

Evaluation

The review of the compliance and enforcement policy, commenced in 2010/11, will enable the HFEA to evaluate the first year of operation of the new compliance cycle under the new regulatory framework.

Improving the HFEA's Information Provision to the Public and Patients

Published Information

Following a year in which the HFEA website and Choose a Fertility Clinic function were relaunched, the HFEA concolidated this work in 2010/11 by maintaining and improving the ways in which the HFEA communicates with patients and clinics (while ensuring compliance with central Government rules on communications which were introduced early in the business year). The HFEA continued to maintain its website and published key reports such as the Annual Report, horizon scanning report and revised Guide to Infertility.

The publication of Committee and Authority papers on the HFEA website was expanded and improved, increasing transparency and ease of access to key information. The HFEA also began to review the new requirements of the Equality Act 2010, to ensure that the HFEA's website and publications are compliant.

Information Access

Our staff continued to fulfil the numerous requests made to the HFEA under various information access regimes, including Freedom of Information requests and Parliamentary Questions.

In addition, new Regulations on the disclosure of information for research purposes were implemented, and an Authority Oversight Committee and staff Register Research Panel were established to deal with requests from researchers for information.

The newly established voluntary contact sibling register for genetic siblings (Donor Sibling Link) also began operation during the year.

Corporate Efficiencies and Improved Governance

Governance Framework

An annual review of Committee governance arrangements was commenced, following the establishment of a new structure in 2009/10. The annual review and amendment process for the Standing Orders and the Authority's publication policy for Committee papers and minutes was also completed. An annual report on licensing was presented to the Authority.

One litigation claim was made against the Authority in the 2010/11 business year. In addition, the Authority assisted the police in a successful criminal prosecution for the unlawful procurement of gametes over the internet.

Following some preparatory steps in the previous year, a major project was conducted to improve the HFEA's records and information management, and to ensure good information governance. This will help the organisation to ensure that documents and other records are well-managed, accurately filed, accessible and not held in duplicate.

An internal review was also started of the delivery of the previous year's 'Programme 2010' project. The review will focus on programme management, quality assurance of efficacy of processes, value for money and delivery of benefits.

Delivery Framework

Work was completed on the introduction of a Quality Management System (QMS) for the Compliance Directorate. The QMS approach will also be adopted by the licensing team in 2011/12.

Throughout the year, we continued to improve organisational efficiency by relating workforce considerations to operational requirements, putting in place training and development as needed by our workforce. This included continued participation in the collaborative Talent Management Consortium of ALBs, ('the Hubbub') and other joint learning and development activities.

The Authority also began to consider its duties under the Equality Act 2010. Training was arranged for both Authority members and staff, and an Authority Champion was appointed to steer future monitoring and work.

Policy Developments

Policy Reviews and Development

A review of donation policies is in progress, addressing a range of discrete issues surrounding embryo, egg and sperm donation. The review will be completed in the coming year, and will ensure that the HFEA's policies on donation are evidence based, workable and in line with wider social attitudes.

There was continued monitoring throughout the year of the progress and effectiveness of the Authority's policy to reduce the incidence of multiple births. This included the ongoing monitoring of outcomes following the setting of a year two upper limit for multiple births.

A project on the regulation of PGD (preimplantation genetic diagnosis) applications was established, for completion in 2011/12. The project will review how decisions are made by the HFEA about PGD licence applications in order to achieve safe, evidence based practice.

The HFEA's unique identification system (HFEA ID) was extended to all patients and people born as a result of treatment. This enables each individual to be uniquely identified, regardless of centres used.

Initial scoping work was completed to inform consideration in the second half of 2011/12 of the HFEA's data collection and use. Consideration will be given to whether the data collection burden could perhaps be lightened without compromising data quality and use.

Evidence-Based Decision-Making

The Authority continued to consider scientific and ethical matters through its Scientific and Clinical Advances Advisory Committee (SCAAC) and Ethics and Law Advisory Committee (ELAC). An annual scientific horizon scanning exercise, involving an external panel of experts, was carried out to help the HFEA to identify and anticipate emerging research and treatments. This work assists each year in planning for future policy development and licensing needs and supports evidence-based decision-making by the Authority. ELAC conducted a similar annual horizon scanning exercise on upcoming legal and ethical issues.

Communication and Dialogue

Joint working, dialogue and ongoing contact with key professional stakeholders and patient groups was maintained throughout the year. These include the British Fertility Society, the Infertility Network, the Donor Conception Network, the National Gamete Donation Trust, the RCN Fertility Nurses Group, the Human Genetics Commission, the British Infertility Counselling Association and the Project Group on Assisted Reproduction. The HFEA's own

Licensed Centres Panel met three times during the year. The HFEA has continued to consult and engage widely with the public during the development and implementation of new policies, to increase public understanding of the HFEA's work and current issues in fertility treatment and research. The HFEA also conducted a polling exercise on public attitudes towards the HFEA and various social and ethical issues, following on from an earlier 2005 poll.

Facts and Figures:

The following facts and figures give a wider picture of the type and volume of HFEA work.

Number of:	2009/10	2010/11
Active clinics and research establishments	138	134[1]
Clinics and research establishments inspected	83	79
Licences inspected	97	85
New licence applications processed and presented to a Licence Committee	6	2
Licence renewals processed and presented to a Licence Committee/Executive Licensing Panel	52	32
Applications for Preimplantation Genetic Diagnosis (PGD) with Human Leukocyte Antigen (HLA) processed and presented to a Licence Committee/Executive Licensing Panel	25	3
New PGD applications processed and presented to a Licence Committee	52	46
Incident reports from centres processed	494	564
Alerts issued	2	1
Complaints about centres processed	45	14[2]
Licensed Centres Panel meetings held	3	3
Meetings with Patient Organisations held	2	2
'Fertility: Have Your Say' surveys conducted	-	1
Public and stakeholder consultation meetings	30	36
Freedom of Information (FOI) requests dealt with	133	119
Environmental Information Regulations (EIR) requests dealt with	0	0
Opening the Register requests received	90	142
Opening the Register requests closed	91	149
Information for researchers requests received	-	2
Donor Sibling Link applications processed	-	3
Visits to the Anonymous Register download page	-	759
Enquiries responded to under the Data Protection Act	4	1
Parliamentary Questions responded to	144	163
Authority meetings held (including 3 open to the public)	7	7
Phone enquiries from patients and the general public	4,781	3,025
Email enquiries from patients and the general public	6,073	2,026
Visits to the HFEA website	558,780	662,147
Most popular/viewed page on the HFEA website	-	Choose a Fertility Clinic

[1] 7 centres voluntarily revoked their licences during the 2009/10 inspection year and 3 new centre licences were granted during the same period.

[2] The decrease in formal centre complaints is as a result of better resolution at centre level and the provision of informal advice and response to enquiries by the HFEA.

Looking Forward to 2011/12

The review of Arm's Length Bodies conducted by central Government in 2010 is set to bring about a number of changes over the next few years. However, for the time being the HFEA remains an independent arm's lenth body, responsible for the ongoing regulation of treatment using eggs and sperm, and of treatment and research involving human embryos. Our business objectives for the year include further improvements to our regulatory systems.

The review of Arm's Length Bodies has proposed that the HFEA will be abolished within the lifespan of the current Parliament, and its functions transferred to other bodies. The intention is to transfer most existing HFEA functions to the Care Quality Commission (CQC). It is possible that the regulation of embryo research may pass to a new research regulator (the Academy of Medical Sciences in its recent review concluded only that this would be a decision for the Government). It is also possible that the management of some or all of the HFEA's register information collected from centres could be transferred to the Health and Social Care Information Centre (HSCIC). However, the scope and nature of the information that might be transferred have not yet been defined; and the HSCIC currently collects data only from the NHS, and not from private clinics, which form the bulk of the HFEA's regulatory sector. The HSCIC also only collects data from the NHS in England, whereas the HFEA's remit is UK wide. It is not yet apparent, therefore, which of these potential future scenarios will come to pass, and in what form, although it is likely that there will be more clarity about this by the end of the 2011/12 business year or shortly thereafter.

The Government's Business Support Services Transition (BSST) Programme is ongoing at present, with a view to a move towards shared services in the interests of efficiency savings. The HFEA will continue to participate in preparatory work to shape the way in which support services might be delivered in the future. We recognise that this will have an impact on current HFEA posts and staff, and on our corporate ways of working, from 2011/12 onwards.

The HFEA is considering how best to achieve closer future integration with the CQC, the Human Tissue Authority (HTA) and others, and this will be assisted by a move, achieved in summer 2011, to new premises in the same building as the CQC. It is currently too early to quantify the potential savings and set these out in detail, but the move will certainly yield significant rent savings for the HFEA. Regular discussions with CQC (in particular) and other organisations have commenced, in order to begin the process of establishing, over time, new working arrangements which will enhance delivery for the organisations involved while making the requisite savings.

In addition to managing a period of significant change, the HFEA must continue to deliver all of its statutory functions, and it will need to do so within a shrinking resource envelope. For the time being, therefore, it is important for the HFEA to be able to retain sufficient dedicated and expert capability.

In light of the major changes envisaged over the next three years, the HFEA will also need to ensure it is prepared to transfer its functions smoothly to other bodies, if and when the time comes, without impairing delivery and performance during the transition.

The HFEA's core business of regulating and licensing clinics will continue to be maintained during the change period. in 2011/12 the HFEA needs to continue to embed and improve the new systems and processes that were introduced in 2009/10 and 2010/11 in order to implement the HFE Act 1990 (as amended) and the HFE Act 2008. We will also need to continue to address new and emerging treatment and research developments which may have policy and regulatory implications for the sector.

As ever, it will be important for the HFEA, in common with all public sector organisations, to continue to demonstrate real cost benefits and value for money in the outcomes it delivers and the resources it uses to deliver them. New public sector spending controls were introduced by the Treasury and the Department of Health[1] in 2010. Like all public bodies, the HFEA needs to work within the constraints imposed by central Government, which may change from time to time. This Business Plan shows how the HFEA is responsibly managing its limited resources within the current rules, and ensuring all the requirements are met. As the finance section shows, the HFEA is continuing to make efficiencies and lower its recurring running costs. This will continue to be the general direction of travel over the next three years.

The HFEA's business objectives for 2011/12 will be:

1. **Delivery of core functions and regulatory improvements**
   To continue to deliver core regulatory and information provision activities, underpinned by evidence-based policies, clear guidance and improved systems and tools.

2. **Increasing the effectiveness of regulation for centres**
   To seek to improve centres' compliance and the efficiency of HFEA regulation, and to make best use of the data we collect from centres.

3. **Managing change and preparing for the future**
   To ensure that the HFEA's workforce, offices, systems and information resources are ready for the planned future integration of functions into other bodies.

[1] HM Treasury, letter dated 27 April 2010, *Review of Civil Service Expense Policies*; Department of Health, letter dated 28 May 2010, *HFEA revised budget 2010-11 and implementing efficiencies to support £6bn savings*; Department of Health, two letters dated 14 June 2010, *Efficiency measures in 2010-11* and *Implementing controls relating to the communications freeze.*

Business Objectives for 2011/12

In 2011/12 the HFEA has agreed the following activities and deliverables under each objective.

Objective 1: Delivery of core functions and regulatory improvements

To continue to deliver core regulatory and information provision activities, underpinned by evidence-based policies, clear guidance and improved systems and tools.

Regulation and information provision

The HFEA will continue to deliver inspection and licensing activities, and to deal with incidents and complaints about centres, under the framework of the new compliance cycle introduced in 2010. We will continue to respond to requests for access to information we hold, under various access and transparency regimes.

Evidence-based policies

A new policy on donation will be developed and implemented, and the multiple births policy will continue to be tracked and updated so as to achieve a continued reduction in the incidence of multiple births resulting from treatment. The HFEA will continue to provide policy advice and guidance, and the Code of Practice will be updated.

Improved systems and tools

A review of the Compliance and Enforcement Policy, started in 2010, will be completed. The risk tool and will be further refined, and the centres database (Epicentre) project will be completed.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Regulation and Information	To maintain the compliance cycle of inspection and audit processes, and to continue licensing clinics.	Deliver full programme of inspection and licensing.	Centres are appropriately monitored and issued with licences for up to 4 years.	Throughout year
		Fully embed risk tool and Self-Assessment Questionnaire (SAQ) into compliance cycle, and refine as needed.	Outputs of risk tool work with inspection information to inform licensing decisions.	April 2011 - March 2012
		Monitor and respond to incidents at and complaints about centres.	Incidents and complaints result in learning and adjustments to procedures where necessary.	Throughout year
	To facilitate access to information under various regimes.	'Opening the Register' requests continue to be met in a timely and sensitive manner and within required time limits.	20 working days, excluding time for counselling.	Throughout year
		Information provision in relation to Freedom of Information Act (FOI), Data Protection Act (DPA), Environmental Information Regulations (EIR), Parliamentary Questions, and Information for Researchers.	FOI Requests – 20 working days; DPA requests – 40 calendar days; EIR requests – 20 working days; Parliamentary Questions – varying deadlines, set by the Department of Health on a case-by-case basis; Information for Researchers – within 90 calendar days of payment.	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Evidence-based policies	To develop and implement evidence-based policies that take into account social attitudes and the views of stakeholders.	Develop new donation policies and implement, following consultation and Authority approval.	Policies which facilitate adequate, effective and safe services for donors, recipients and people born as a result of donation.	July and October 2011 (Authority decisions); and onwards
		Embed multiple births policy and continue long-term implementation.	Achieve a continued reduction in the incidence of multiple births resulting from treatment. Multiple births licence condition.	April 2011 – March 2012 October 2011
	To continue to provide the sector with appropriate policy advice and guidance.	Update the Code of Practice to reflect latest policy and legislative developments.	Up to date Code of Practice guidance, new Directions, and new patient and public information as relevant.	October 2011
		Support and inform evidence-based decision-making by the Authority through scientific, social and ethical horizon scanning.	Emerging research and treatments considered and anticipated. Ethical and legal issues considered and anticipated. Future licensing and policy decisions informed by work.	Throughout year
Systems and tools	To complete the review of the Compliance and Enforcement Policy started in 2010	Review the compliance and enforcement policy, with associated refinements to interconnected systems, including the risk tool and the list of licensable conditions; and completion of the new centres database (Epicentre) and associated workflows.	Up to date compliance and enforcement policy incorporating an improved incident risk grading matrix. Tools in place to support implementation of the revised policy.	October 2011 March 2012

Objective 2: Increasing the effectiveness of regulation for centres

To seek to improve centres' compliance and the efficiency of HFEA regulation, and to make best use of the data we collect from centres.

Improving compliance and regulatory efficiency

The HFEA will aim to improve sector performance by identifying areas of non-compliance and considering how to address these. In addition, we will open a dialogue with centres about how we might work towards more efficient regulation. We will also add further enhancements to the clinic portal and continue to maintain the EDI (electronic data interchange) system.

Making best use of data

We will be reflecting on the data we collect from clinics, and how this is used, in the second half of the business year. This work will include consideration of whether there are any ways of lightening data collection burdens without compromising data quality and use. We also plan to improve our networking with researchers and establish a dialogue about the research undertaken using data held by the HFEA.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Compliance and regulatory efficiency	To continue to drive improvements in overall sector performance.	Identify common areas of non-compliance and consider how these could be improved.	Improved sector performance.	March 2012
	To work towards more efficient regulation without compromising its effectiveness.	Open a dialogue with centres about measures the HFEA could take to regulate more efficiently without decreasing the quality of regulation or weakening the reputation of the sector.	Dialogue established. Ideas considered by Authority.	March 2012
		Add further enhancements to the clinic portal and continue to maintain the EDI (electronic data interchange) system.	Electronic information maximised to assist centres in managing their administrative workload and getting access to performance information more readily.	March 2012
Making best use of data	To ensure that the HFEA and others can make the best use of data collected.	Consideration of data collection and use exploring whether the data collection burden can be lightened without compromising data quality and use.	Clarity about what is collected and for what purpose.	March 2012
		Enhance dialogue with researchers about the research undertaken using data held by the HFEA.	Good quality research using HFEA data goes ahead and enables the monitoring of the safety and efficacy of assisted reproduction techniques.	March 2012
		Continue to work with centres to promote best practice in seeking consent from patients for the use of data in research.	Increase consent rates so as to ensure that future research opportunities are not compromised.	March 2012

Objective 3: Managing change and preparing for the future

To ensure that the HFEA's workforce, offices, systems and information resources are ready for the planned future integration of functions into other bodies.

Workforce and capacity management

Workforce management will be critical during the coming change process, and the HFEA will need to manage its human resources and corporate knowledge against the backdrop of the various centrally imposed restrictions (particularly that on recruitment). It will be necessary to keep capacity and organisational priorities under constant review as resources decrease, to maintain good staff engagement, and to ensure that staff are equipped for both change and ongoing delivery. Careful project management will enable us to work within our resource envelope.

Organisational preparedness

The HFEA will need to prepare for future dispersal and integration of its functions into other bodies. In order to ensure organisational readiness, further work will be done on our records management and quality management systems. In addition the HFEA has moved (in August 2011, shortly before publication of this business plan) to new premises in the same building as the Care Quality Commission (CQC), one of the bodies our functions are expected to transfer to in due course. Co-location will enable both organisations to begin to develop shared services and make efficiency savings. In addition to planning this transition, the HFEA will work to establish collaborative relationships and joint working with other organisations, and consider how to ensure compliance with the Equality Act 2010.

Data returns and transparency

The HFEA will continue to supply data to central Government in response to requests for returns following on from the ALB Review, and to publish required transparency information on the HFEA website and elsewhere. We will also continue to balance the need for transparency and accountability against data security considerations.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Worforce and capacity management	To ensure that the HFEA retains a workforce capable of delivering its business plan within the allocated resource envelope.	Management of human resources and corporate knowledge against the backdrop of the various centrally imposed restrictions (particularly on recruitment) so as to ensure that staff are equipped for both the change process and ongoing delivery.	Organisational capability to deliver core work is maintained. Training/skills gaps met and staff development needs met. Organisational knowledge retained. Staff feel equipped and prepared for both the change process and delivery of ongoing work.	Throughout year
		Continued participation in the collaborative Talent Management Consortium of ALBs.	Improved development opportunities for HFEA staff. Assessment programme in place to evaluate progress.	April 2011 – March 2012
		Management of Authority capacity and workload (since the Authority's membership is expected to reduce over the next 3 business years).	Capacity to make critical licensing and policy decisions retained.	March 2012
		Continual review of business plan priorities and capacity, and use of project management and risk management processes and controls.	Risks to capacity and/or capability recognised early. Decisions about prioritisation made in a proactive rather than reactive way, giving better control over outcomes.	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Organisational preparedness	To begin to prepare the HFEA's systems and information for the future transfer of functions into other bodies.	Complete records management project started in 2010, and consider quality management system improvements.	Organisational preparedness for transition. Decrease in volume of hard-copy papers and ability to avoid storing documents unnecessarily. Greater search efficiency when documents are required. Important processes recorded in the form of Standard Operating Procedures (SOPs).	March 2012
	To facilitate future opportunities for shared services by co-locating with the Care Quality Commission (CQC) or another organisation; and to explore opportunities provided by Government / Department initiatives to aggregate and standardise shared services	Plan and implement an office move.	Accommodation cost savings. Opportunities for shared services, efficiency savings and obtaining better value for money.	August 2011
		Ensure ongoing communication and engagement with our staff, and ensure that they are prepared to cope with the coming changes.	Communications strategy regarding the move. All-staff conference. Staff Forum engagement and HR workshops about the move and other changes.	August 2011 and beyond
		Establish collaborative relationships and joint working with other organisations, and participate in Department of Health transition working groups for various business support services initiatives.	Increased opportunities for shared services, efficiency savings and obtaining better value for money.	Ongoing work
	To ensure the HFEA is compliant with Equality Act 2010.	To consider and implement actions to ensure compliance with the Equality Act 2010.	Compliance with the requirements of the Equality Act 2010.	April 2011 onwards

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Data returns	To ensure that the HFEA supplies required data in response to a range of central Government requests for returns.	Respond to all requests for data returns further to the ALB Review and other central Government requirements.	Deadlines for returns met. Returns completed fully and accurately.	Throughout year
		Balance transparency requirements with data security considerations.	Material is not disclosed inappropriately (for instance information that could identify an individual patient or member of the public).	Throughout year
		Publish required transparency and other information (on website and data.gov.uk).	Government requirements met.	Throughout year

Corporate Enablers and Resources

Delivery Framework

In addition to the objectives set out above, it is important to acknowledge the underlying core strategies, activities and functions that will enable the HFEA to deliver this business plan and the ongoing change management work over the next few years.

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the successful delivery of any business plan. The HFEA has in place a number of corporate functions and strategies which underpin and are essential to its day-to-day activities. These include a Knowledge and Information Management Strategy, a Sustainability Action Plan, a Human Resources Strategy and a Corporate Governance Framework.

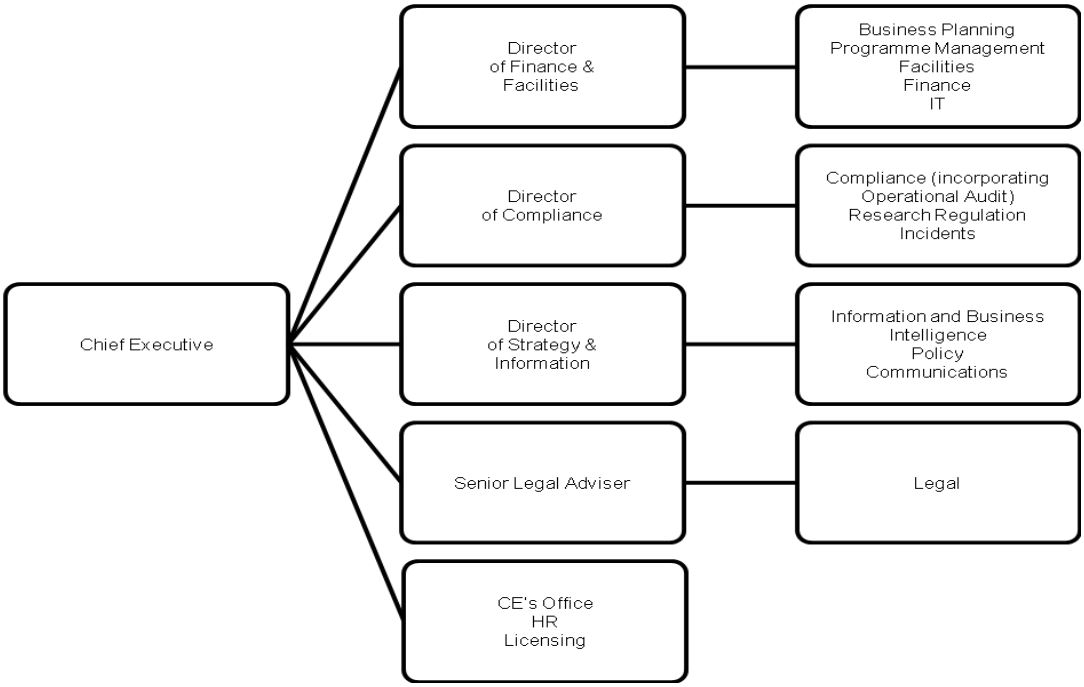
Planning and Development

Over the coming year, we will continue to instil best practice into our business processes and develop our people. This will be especially important during the coming period of change, so that we can retain the knowledge and skills of our staff, manage within resource constraints, and be flexible when we experience staff turnover or encounter capacity issues.

We have been enhancing the role of our internal Programme Board and Programme Management Office to help us manage projects more efficiently and effectively, and this will continue to be important in 2011/12. We will also further develop our people, for example by collaboration with others in learning activities and leadership development.

In 2009/10, the HFEA completed a change programme called Programme 2010. This led the organisation through the changes that were needed in order to improve internal governance and establish the right structure and processes to deliver an effective regulatory system under the 1990 Act (as amended). The resulting changes, new processes and policies have since become part of the organisation's infrastructure and ways of working. We will continue to build on this work in 2011/12, with a focus on the new period of change and transition.

The following diagram shows the HFEA's current staffing structure:



Financial Context

The HFEA will need to remain responsive to economic and political drivers by increasing its organisational efficiency and cost-effectiveness while managing change. Overall, the recurring cost of the organisation will continue to fall in 2011/12.

The HFEA will continue to maintain sound financial governance and business planning processes. We will continue to drive out inefficiencies and introduce quality processes and to develop collaborative relationships with other bodies (notably the CQC) to improve economies of scale. This should enable the HFEA to use its limited resources more effectively whilst maintaining delivery of key statutory functions.

Equality Act 2010

The Authority has begun a review process in order to ensure that the HFEA is compliant with the requirements of the Equality Act 2010. A staff working group has drawn together information to inform the review, and the Authority has appointed a member as an Equality Champion. We will continue to ensure, throughout the year, that the HFEA fulfils the requirements of the Equality Act.

Establishment and Resources

The new legislation that came into effect in 2009/10 brought with it increased duties for the HFEA. The HFEA's workforce strategy needs to reflect this. However, the financial pressures across the whole public sector mean that all organisations are under pressure to cut costs significantly. The HFEA is considering what this will mean for its workforce strategy during the current period of change and transition.

Currently, the organisation is carrying a number of vacancies, all of which will continue into the 2011/12 business year. During the next three business years, we recognise that the HFEA's size will need to decrease further, most likely by between 15 and 30 more posts. If the reduction is at the lower end of this estimate, it may be possible to achieve this without making redundancies; if, on the other hand, the reduction is of a higher order, a small number of redundancies will be necessary in the 2012/13 and 2013/14 business years. No redundancy provision has been made in the 2011/12 business year, since arrangements with CQC and other organisations for future shared services (potentially affecting staff posts) will be contingent on ongoing discussions following on from our change of premises in August.

We will continue to build on the shared services discussions that have been initiated with the CQC, and to seek out opportunities for our staff so that, where possible, suitable alternative employment can be arranged. We have begun, with the CQC, to explore potential synergies and opportunities for the organisations to work more closely, where this would be of mutual benefit. This also represents an opportunity to develop our people in a more coherent and broader way, so that we have a more flexible and efficient human resource set at our disposal.

Human Resources (HR)

The HFEA will continue to maintain sound HR processes during the change period, including recruitment and retention practices to retain a high quality workforce within agreed budgets and Government rules. The HFEA's management training and key skills programmes will be continued and where necessary expanded, so as to equip our remaining staff with the core - and new - skills they will need in order to maintain the organisation's workload and cope with the coming changes, as well as providing the organisation with greater flexibility in the deployment of staff. The training and development we provide to staff will be procured in accordance with new Government requirements to ensure value for money, using Buying Solutions as appropriate.

Together with the other Arm's Length Bodies and the Department of Health, we have actively developed a Talent Management network to nurture and manage talent across the sector and provide personal development and career planning for managers and future leaders. We will continue to participate in 2011/12.

A review of all HR policies was completed in 2010/11. Management and reporting procedures have also been improved. All staff pay is determined in line with HM Treasury annual guidance.

Information Technology (IT)

The HFEA has an IT project pipeline plan that underpins the developing Knowledge and Information Management Strategy and an Information Asset Register identifying our key IT systems and their owners. Our IT systems ensure the HFEA complies with the data management requirements of legislation, including the HFE Act 1990 (as amended) and support the significant databases we hold.

The HFEA's databases are held on highly secure servers within the premises. Owing to the requirements of Section 33 of the HFE Act 1990 (as amended), patient-identifying data can only be viewed by officers of the HFEA. The move to the same premises as the CQC has necessarily entailed sharing an appropriately cooled 'communications room' on-site to house the HFEA's servers. Appropriate security measures have been put in place so as to ensure that Section 33 data is appropriately protected at all times. For similar reasons it is not presently possible to outsource or share certain other IT functions (such as desktop support), since staff performing this function are inevitably in a position to see documents containing patient information, and must therefore be HFEA employees.

It is possible that the management of some or all of the HFEA's register information, collected from centres, could be transferred to the Health and Social Care Information Centre (HSCIC) in the future. The scope and nature of the information that might be transferred has not yet been defined, and there are a number of known practical difficulties with this plan. The HSCIC currently collect data only from England (whereas the HFEA regulates centres UK wide). The HSCIC also collects data only from the NHS, not from private clinics, which form the bulk of the HFEA's regulatory sector. This may mean that different data would have to be held by different organisations, making it more difficult to manage and use. Taking on responsibility for parts of the HFEA's data is therefore not currently in the HSCIC's strategy. In addition, the proposed separation of the regulatory function from the information that informs it would present challenges for the HFEA in terms of effective regulatory functioning. However, our staff are in discussion with the HSCIC to identify all of the potential issues, and the HFEA has contributed to a major HSCIC information return request about data held. Following this, in 2011/12, the HSCIC will consider whether it will be viable for them to take on any of the HFEA's data.

Business Continuity

The HFEA has a business continuity plan in place, and this is regularly updated. This includes consideration of arrangements for continuing to operate business critical functions in the event of an emergency or significant staff sickness and has undergone a recent overhaul to reflect organisational changes.

Estates Strategy

The HFEA has an estates strategy in place, and responds as required to property data benchmarking exercises carried out by the Office of Government Commerce. The move to the same premises as the Care Quality Commission (CQC) will enable the HFEA to save on accommodation costs, use the existing estate of CQC more efficiently and, within a short period, enable a net reduction in public sector occupancy of private sector London property.

For the HFEA, this move has meant a considerable reduction in office space from over 1100 square metres to around 550 square metres and this has significantly reduced the space per work-station. However, the effect of this is to take the average HFEA work-station from well above the current benchmark down to the future benchmark, with corresponding effects on costs per square metre. The HFEA prepared and developed (with the CQC) the necessary project plans, and a business case was approved by the Department of Health and the Cabinet Office.

Sustainable Development

Our landlord until August 2011, the Insolvency Service, enabled the HFEA to recycle paper, plastic and glass bottles, cans, drinks cups, batteries and toner cartridges. Similar facilities are available in our new premises. All capable printers are pre-set to print on both sides of the paper and in black-and-white. Our IT equipment is reused as far as possible, is switched off when the offices are not in use and surplus equipment is either sold or donated.

The Insolvency Service building had water taps operated by motion detectors to prevent water wastage, and all plants in the building were planted in peat free material and in 100% recycled pots. Nevertheless, the DEC showed a rating of G, which poorly reflected the efforts made by both building and HFEA staff to be more sustainable, but did indicate some serious building infrastructure shortcomings. These included the uncertain performance of a large photovoltaic array on the atrium roof, building windows and floor level heating and cooling equipment. The HFEA continued throughout its time in these offices to work constructively with the landlord on BUG (Bloomsbury Users Group), initiated in 2009/10, to assess what could be done. At the time of our move to new premises, there were suggestions that it would be necessary to invest large amounts in the building to fix some of the major issues. This is therefore an additional cost that the HFEA will now avoid.

Assurance Framework

The HFEA will continue to manage its assurance framework and organisational infrastructure, through sound planning, resource and risk management, and the continuous maintenance of premises and our IT infrastructure.

The HFEA has robust information security arrangements in place, in accordance with Cabinet Office Security Policy Framework requirements. These include a Security Policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards. All staff completed mandatory training on information security in 2010/11, and any new starter completes this on their first day of employment, before starting work.

The HFEA also operates a clear desk policy, and has on-site shredders and confidential material disposal arrangements in place.

The overall resource position for the 2011/12 business year is set out in the following financial section.

Financial Picture

Overview

The Authority will face a number of income and costs management challenges during the financial year 2011/12, as the impact of the current ALB review accelerates whilst the Authority continues to meet operational demands during recruitment and procurement constraints.

The budget shows an operationally break even position with a decrease in grant in aid that goes well beyond the initial proposal from the Department of Health, and reflects the reduction in treatment fees of 28% that will take effect from 1 October 2011. Some important project work is included in budgeted costs.

The budget also includes a 'windfall surplus' of £0.35m that arose due to a clinic reporting a large number of chargeable treatments from previous years (and which is under regulatory scrutiny as a result). Discussions on deploying this, together with the historic accidental accumulated surplus, will begin with the Department during the second half of the year.

Overall, including the co-location with the CQC in summer 2011, the HFEA has developed an outline plan to reduce its financial 'footprint' by at least 30% over a three to four year period, regardless of the functional changes aired in the ALB review.

Costs in a significant number of areas have reduced materially from financial year 2010/11, reflecting both our continuing drive for efficiencies and the reality of Government imposed restrictions on public sector expenditure. The total number of staff posts has fallen by 13.5, representing over 12% of the 2010/11 complement.

Income Assumptions

Grant in aid for the year has been reduced by 33% overall from 2010/11, well beyond first year ALB review targets. Requirements for capital grant in aid have been reduced by 48%, reflecting efficiencies in procurement and extended utilisation of existing fixed assets.

Income from licensed centres generated this financial year has been estimated at £5m and incorporates a 28% reduction in treatment fees from 1 October 2011. This was approved in August by both HM Treasury and the Department of Health and reflects not only HFEA efficiencies and capable responses to Government spending restrictions, but also continuous improvements and investments in core information and regulatory processes and systems. The total number of treatments undertaken by centres continues to grow each year, recently by well above the 3% long-term trend, despite current economic uncertainties.

Income from licence applications and EUTCD licence fees together are estimated at £0.13m, a fall from 2010/11 due to fewer renewals arising as the new compliance cycle takes effect.

Cost Assumptions

It has been assumed that current procurement and recruitment restrictions will continue in force for the year with some possibly being eased and the HFEA requesting exemptions where justified.

The HFEA reduced its workforce by 13.5 posts during financial year 2010/11 through natural wastage and increased efficiencies. The impact of further staff turnover will therefore need to be assessed closely to ensure that operations can continue successfully.

The budget assumes that no litigation entailing material costs will arise in the year. Should this position change, further financial resources may be required.

It has also been assumed that the major projects commenced in 2010/11, chiefly the development of the clinics database (Epicentre); the complete overhaul and rationalisation of records management; the development of an enhanced comprehensive risk based assessment tool; the development of a new quality management system; and the external evaluation of the Executive Licensing Panel will all be substantially completed by 31 March 2012. The budget allows some resourcing to fully complete these, notably Epicentre, and funding for some further projects that have recently been identified.

Authority and Committee Costs

Authority members are now remunerated on a fixed salary basis, consistent with other comparable ALBs within the health regulatory sector. Changes in costs in this area are related to more effective use of lower cost travel options and increased video-conferencing to avoid the need for longer-distance travel.

Capital Costs

There are no major capital projects expected in 2011/12 (excluding transition costs.) Estimated capital costs are lower than budgeted for 2010/11, due to a review establishing that replacement of existing office and IT equipment can be undertaken over a longer period.

ALB Transitional Costs

Negotiations with the HFEA's landlords in respect of the early termination of the occupation of the Bloomsbury Street office have proceeded amicably. Agreement has been reached on vacancy periods, mitigated by temporary occupation of the HFEA's former office space by another ALB, and an outline estimate of dilapidations. Both are within the provisions made in the 2010/11 financial accounts.

The move to the same premises as the CQC in summer 2011 was highly successful, notwithstanding issues arising from the move of the HFEA IT equipment. The HFEA is in discussions with the relevant contractors to resolve these issues, which included some breakages. Initial estimates of the office cost savings accruing to the HFEA are considerable.

All Authority staff transferred to the new offices and will remain in post for the whole financial year. Accordingly, no redundancy costs have been estimated, although as the impact of the colocation and the drive to shared services manifest, this may need to be reviewed.

Budget Summary

2011/12 Budget		
Item	**£m**	
Costs:		
Salaries (78 posts; 74 F.T.E.)	3.95	
Training and other staff costs	0.15	
Travel and subsistence	0.14	
Recruitment, maternity, long term sickness	0.12	
Total staff costs:		**4.36**
Printing and telephones	0.06	
Offices	0.57	
Service charges	0.26	
Publications, events, web and media	0.23	
Total office costs:		**1.12**
Legal fees	0.27	
Audit fees etc.	0.12	
Total non-staff legal and governance costs:		**0.39**
Members	0.30	
Total Members costs:		**0.30**
Total revenue costs 'base':		**6.17**
Capital 'base':		
IT hardware/software	0.03	
Furniture/office	0.03	
Total capital costs:		**0.06**
Total operating costs 2011/12:		**6.23**
Non-recurring project & ALB transition investment costs:		**0.40**
Total Costs for year:		**6.63**
Income:		
Clinic fees	5.00	
EUTCD fees	0.10	
Licences	0.03	
Grant in aid revenue	1.44	
Grant in aid capital	0.06	
Total operating income generated 2011/12:		**6.63**
Treatment fees "windfall" – refer to *Financial Picture* page 24		**0.35**
Total Income for year:		**6.98**

Performance Indicators

Performance against last year's targets is shown in the table below:

Performance Results in 2010/11:	Target	Outcome
A. Compliance		
No. of unannounced inspections carried out this year	4	2[1]
Reports resulting from initial applications and renewal inspections of clinics and research establishments available to clinics within 28 working days of the inspection date.	90%	94%
New treatment and research licence applications processed within four months of receipt of all necessary documentation and confirmation that the premises are ready for use.	90%	50%[2]
B. Communication and Information		
Responses made to requests for contribution to Parliamentary Questions within the deadlines set by the Department of Health	100%	100%
Number of Authority meetings held in public during the year.	3	3
Written enquiries from patients and the public responded to within 3 working days.	95%	100%
Increase in visits to the HFEA website compared to 2009/10	10% increase	18% increase
Increase in visits to Choose a Fertility Clinic function on the HFEA website compared to 2009/10	10% increase	26% increase
Publication of finalised Licence Committee/Executive Licence Panel decisions on the HFEA Website within 20 working days	90%	68%[3]
Freedom of Information (FOI) requests dealt with within 20 working days	100%	99%
Opening the Register requests dealt with within 20 working days (excluding counseling time for the person making the request)	100%	99%
C. Corporate		
Invoices paid within 30 days	95%	99%
Debts collected within 60 days	85%	92%
Monthly billings of clinics achieved in three weeks	95%	100%
Achieve revenue cost targets	£2.4 million Grant-in-Aid	£2.1 million drawn

[1] Unannounced inspections were deprioritised to ensure that there were enough staff to complete the risk based assessment tool project.
[2] One of the two new licence applications was unable to achieve the key performance indicator (KPI) as the monthly Licence Committee meeting took place 4 days after this period.
[3] The process for publication of licence committee and ELP minutes changed during August 2010. This involved development of the tool used to upload the minutes to the website. This resulted in a backlog accumulated in August and September, which was then addressed between October and November. This has affected the percentage overall, but for each of the other, unaffected 8 months of the financial year, performance was 100%.

Following a thorough review of our performance scorecard in early 2011, new key performance indicator targets for the coming business year have been set as follows:

Performance Indicators:	Target 2011/12
A. Compliance	
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	60 working days or less
Percentage of PGD applications processed within 4 months (88 working days).	90%
B. Communication and Information	
Opening the Register requests responded to within 20 working days.	100%
Requests for contributions to Parliamentary Questions answered within Department of Health deadlines.	100%
C. Corporate	
Staff sickness absence rate (%) per month.	Under 3.5%
Cash & Bank Balance.	To move towards DH recommended limit of £750k
Percentage of invoices paid within 30 calendar days.	95%
Debts collected within 60 calendar days.	85%