

Human Fertilisation and Embryology Authority

Business Plan 2006-2007

2006-2007



CONTEXT

The HFEA continues to operate in a fast moving, complex and ethically challenging area of science, with a very high level of public interest in its activities. It has proved itself to be an organisation that is able to continually adapt to changing expectations.

Policies developed take into account the disparate and often conflicting views of the public. The organisation recognises the importance of engaging well with a range of stakeholders and with the fertility sector itself. The key aim of the HFEA is to maintain confidence in fertility treatment and embryo research and ensure safety for patients, embryos and children born as a result of Assisted Reproductive Technology (ART).

The HFEA leads the establishment of European Assisted Conception Consortium (EACC) to bring about closer international links between ART regulation and service providers in anticipation of the EU Tissues and Cells Directive. The Directive will extend the HFEA's remit to include the regulation of clinics carrying out IUI. It will reinforce the need to focus on a quality system approach for clinics.

During 2006, as the government conducts its review of the regulation of infertility treatment and embryo research, the need to ensure that the patient's voice is heard is more important than ever. The HFEA has a prominent role in this.

The organisation has demonstrated how well it has adapted to changing expectations over the years and is now taking a rigorous approach to the requirements of the ALB Review, specifically implementing more targeted, proportionate and risk-based regulation.

THE ROLE OF THE HFEA

Purpose:

- 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.

Principal Statutory Functions:

- 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.

The HFEA's other Statutory Tasks:

- 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.

Some Achievements during 2005:

Patient and public involvement

- Handled approximately 15,000 calls from the public.
- Published new style Guide to Infertility and Directory of Clinics, also available as a web-based interactive guide.
- Handled 50 patient complaints and issued UK-wide report to clinics on the key issues for patients highlighted by such comments.
- Recruited 750 patients to the Fertility Views online panel.
- Analysed 1500 questionnaires giving patient views on the centres treating them.

Regulating Research

- Effectively managed complex applications for research on embryos.
- Held the third Annual Research Conference.
- Developed a new process for horizon scanning for scientific developments, involving an international expert panel.
- Made available lay summaries of research licence applications granted including how/why decisions have been taken.
- Extended pool of peer reviewers internationally to capture further expertise to handle the increasing complexity of research applications.

The Model Regulator

- Implemented a risk-based tool for inspections which ensures that centres performing well against the Code will receive less intervention in 2006/07.
- Recommended to Licence Committees that well established centres with a good history of compliance have their licences extended from 3 to 5 years at next renewal (increased proportionate regulation).
- Reduced the amount of paperwork required from centres to support the inspection process by making better use of data held on HFEA IT systems. Development of a web-based application which will enable more information to be submitted electronically.
- Streamlined decision making and administration of PGD applications.
- Carried out all statutory inspections within timescale and to budget.
- Set up a Licensed Centres Panel representing the IVF sector to seek views on how the inspection process could be improved and used all feedback to inform improvements in our process and methods.

Policy Review and Advice

- Produced detailed recommendations to the Department of Health on the review of future legislative requirements to ensure the effective regulation of ART.
- Provided evidence to the House of Commons Science and Technology Select Committee Inquiry into Human Reproductive Technologies and the Law.
- Helped set up and chair EACC to support implementation of the EU Tissues and Cells Directive in ART across Europe.
- Conducted major consultations on sperm, egg and embryo donation (SEED) and The Welfare of the Child.
- Launched the Choices and Boundaries Review on PGD and late onset cancer.
- Launched the review of multiple births with an international multi disciplinary group to assess the implications in the United Kingdom.
- Developed a project to understand the variation in success rates at centres and how reporting could be improved.

Improving Efficiency / Effectiveness

- Commenced the roll-out of the Electronic Data Interchange (EDI).
- Completed the Historic Audit Project (HAP) to verify critical information held within the Register. By 31 March the project had achieved an audit outcome of 95.2% of all forms required to be checked, 96.4% of all live birth outcomes and 90% of donor registrations.
- Commenced sharing of services (HR) and Legal with the Human Tissue Authority (HTA).

Corporate Goals 2005-2009

- Strengthening the regulatory role and ensuring that regulation is proportionate and risk-based.
- Being an open organisation through excellent communications and partnership with stakeholders.
- Working closely with other regulators and international agencies.
- Strengthening the role and 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 that will fulfill these goals, supported by strong corporate governance.

Ministerial Performance Targets

- Preparation for and implementation of the requirements of the EU Tissues and Cells Directive in April 2007, including practice standards, as part of a revised code of practice for clinics, 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 the Regulatory Authority for Tissue and Embryos (RATE).
- Continue the rigorous approach to inspection and regulation, including the implementation of the risk-based approach to centre regulation.
- Establish an effective working relationship with the Department's new ALB Business Support Unit, as well as the sponsor branch, dealing promptly with requests for information on finance and staffing issues.

Key Objectives for 2006/07

- Provide proportionate, more cost effective, targeted and risk-based regulation, to be seen as a model regulator, and achieve all ALB targets.
- Drive forward the implementation of the European Union Tissues and Cells Directive and chair the European Committee in addressing this.
- Provide reliable information and advice to donor-conceived adults, donors and parents of donor-conceived offspring.
- Empower patients and inform them for future choices.
- Strengthen relationships with key stakeholders by better engagement.
- Develop public understanding and confidence in research on assisted conception and embryo research.
- Develop close working relationships with the Human Tissue Authority (HTA), to create integral working wherever possible in readiness for the transition to RATE.
- Develop the 7th edition Code of Practice incorporating professionally agreed standards to meet the requirements of the EU Tissues and Cells Directive and Better Regulation Taskforce objectives.
- Maintain robust financial, staff management and corporate governance to increase efficiency and reduce costs.

Key objective 1: Provide proportionate, cost effective, targeted and risk-based regulation to be seen as a model regulator and achieve ALB targets.

- Implement risk-based inspections and audits, proportionately redirecting attention from low risk to high risk, poorly performing centres.
- Process and evaluate applications for PGD, import / export of gametes, new and variations to licences promptly and efficiently.
- Continue to streamline licensing process to reduce costs of regulating the sector
- Fully implement development of in-house inspectorate to promote consistency and even-handed regulation.
- Work closely with Healthcare Commission, MHRA, NPSA and other regulators to reduce overlap and duplication of regulation and promote best practice in licensed centres.
- Develop further guidance for clinics to incorporate EUTCD standards.
- Implement, monitor and evaluate policy decisions on SEED and Welfare of the Child.
- Manage complaints and incidents investigation and produce Alerts to improve practice and promote patient safety.
- Modify the Code of Practice to improve its effectiveness as a regulatory tool and to reduce regulatory burdens on centres.

Outcomes/Success Measures:

- *Be recognised as a model regulator, being used as an example of good practice when establishing a regulator (the regulation framework used by other organisations)*
- *Be seen as a source of advice and support for professionals and the public (the number of requests for information/advice increases)*
- *The rollout of the new streamlined inspection process from April 2006 is effective and viewed by the sector as being proportionate and transparent. The streamlined process demonstrates a 20% efficiency saving. (Survey of Licensed Centres Panel in January 2007 demonstrates satisfaction with new regulatory processes)*
- *The new risk-based targeted inspection programme has been effective in diverting resources to centres in most need of improvement against the Code of Practice*
- *Professional understanding/benefit of Incident Alert system seen to be effective by an increase in the number of incidents reported and a reduction in the severity of incidents*
- *Fewer number of licence committees, reflected by regulation being more proportionate (number of committees reducing by 20% during 2006/7)*
- *A reduced number of interim inspections*

Outputs/Activities:

- *Despatch 90% of Inspection reports to centres within 28 days of inspection*
- *Commence incident investigations within 30 days of notification*
- *Complete new premises visits post licence within 6 months*
- *Carry out PR assessments within 4 weeks of receiving a completed application*
- *Apply the risk matrix to all portfolio centres on a six monthly basis*
- *Ensure one additional visit to each high/medium risk centre*
- *Respond to all enquiries from centres within 3 working days*
- *Carry out at least 4 joint inspections with the Health Care Commission (HCC)*
- *Increase joint working with other regulators in the production of alerts*
- *Publish alerts*

Inspections activity:

- *21 interim (treatment/storage)*
- *20 renewal (treatment/storage)*
- *14 research renewals*
- *15 research interim*
- *4 research only*

Key Dates/milestones:

- *Inspectors receive training on new in-house inspectorate regime – April*
- *Revised inspection report with patient feedback incorporated – June*
- *New consent forms issued to centres – June*
- *New standardised inspection documentation in place by June (including Self Assessment)*
- *Inspector external adviser training in place for implementation of policy decisions on SEED and Welfare of the Child by June*
- *Report on joint inspection process with Health Care Commission (HCC) by September*
- *Pilot EUTCD inspections (3) October-December*

Key objective 2: Drive forward the implementation of the European Tissues and Cells Directive and lead the European Committee in addressing this.

- Develop policy on implementation of the EU Tissues and Cells Directive (EUTCD) and provide advice to the Department of Health.
- Develop licensing and inspection procedures and a fee strategy to implement the EUTCD.
- Provide guidance and information to IUI / GIFT centres and currently licensed IVF clinics to support them in preparing to meet standards.

Outcomes/Success Measures:

- *The European Tissues Directive is transposed into UK law in a way that is workable for UK clinics*
- *Timely and clear advice given to the Department of Health*
- *The HFEA meets its legal obligations as a competent authority by bringing over 100 IUI/GIFT clinics into regulation to meet the requirements of the Directive*
- *The licensing and inspection procedures are clear and transparent and the fee strategy considered proportionate by the Sector*

Outputs/Activities:

- *Develop policy on implementation of the EU Tissues and Cells Directive (EUTCD) and provide advice to the Department of Health*
- *Develop licensing and inspection procedures and a fee strategy to implement the EUTCD*
- *Carry out a public consultation exercise on the fee strategy (July-September)*
- *Set up a stakeholder panel for IUI centres*
- *Provide guidance and information to IUI/GIFT centres and currently licensed IVF clinics to support them with compliance and explain the impact on the sector*
- *Engage with professional bodies*
- *Establish contact with sperm sorting clinics and any other new stakeholders*
- *Provide training for external advisers and inspectors*
- *Communicate the fees and licensing structure to the sector and clinics*
- *Continued close working with the professional bodies around the Standards and possible changes to Standards based on outcome of consultation on the Code of Practice*
- *Hold three Regional Workshops for IUI centres in London, Bristol and Manchester to inform the sector*
- *Issue new licences / vary current IVF licences to meet EUTCD requirements (January-March)*

Key Dates:

- *June/July – Fee strategy and EUTCD implementation plan approved by OFC and the Authority*
- *June-September - Consultation on draft regulations, consultation on fee strategy*
- *September-December – Preparatory work for issue of new licenses, regional workshops*
- *January 07 – Regulations come into force*
- *January-March 07 – New licences issued*
- *Current IVF centres have new licences (31 March 2007)*
- *IUI / Gift clinics all licensed by 7 April 2007*

Key objective 3: Provide reliable information and advice to donor-conceived adults, donors and parents of donor-conceived offspring.

- Respond to 'opening the register' requests in a timely and sensitive manner and develop a process for post-anonymity applications.
- Quality assure accuracy of register data.
- Implement reviewed guidance on ensuring donor limits are met.
- Close the historic audit of treatment records project (HAP).

Outputs/Activities/ Key dates:

Quarter 1, April – June 2006

Accuracy of register data (to be completed by September):

- Comprehensive review of validation engine / validation rules
- Develop process to drive up quality of data input from centres
- Provide support to centres on the use of EDI
- By June: develop a plan to work with centres that are not meeting HFEA standards in terms of data quality

Donor limits:

- Register capture data, provide reports and centre questions
- Advise clinics on the safety and efficacy of bar coding and RFID technologies and review associated witnessing requirements
- June/July - consideration by SCAG, Regulation Committee and the Authority of advice to clinics and new witnessing protocols
- July / August - issue of advice to clinics

Quarter 2, July – September 2006

Accuracy of register data (to be completed by September):

- Comprehensive review of validation engine / validation rules
- Develop process to drive up quality of data input from centres
- Provide support to centres on the use of EDI

Key objective 4: Empower patients and inform them for future choices.

- Use views of patients, public and clinics to improve provision of information through publishing inspection reports and the Patients' Guide to Infertility.
- Promote greater patient involvement in inspection.
- Produce thematic reports on centres' performance.
- Review multiple births and develop appropriate policies on embryo transfer.
- Improve patients' access to good information, through new patient web-based briefings and better marketing of HFEA's role.
- Learn more about patient needs through consultation, research and the Patients Panel.
- Review how data on success rates is used to inform patient choice.
- Relaunch the HFEA website to widen the range of information made publicly available.

Outcomes/Success Measures:

- Continued transparency and public/patient engagement
- More meaningful presentation of success rate data for patients and clinics from 2007
- Develop web-based briefings, improving accessibility of information to patients
- Develop better understanding of patients' needs and satisfaction with HFEA through consultation, research and the Patients Panel
- Use thematic reports

Outputs/Activities:

- *Proposal for consultation document on multiple births and single embryo transfer*
- *Report delivered on presentation of success rates data by NPEU (National Perinatal Epidemiology Unit, Oxford)*
- *Finalised Licence Committee reports published on website within 15 working days*
- *Produce and launch new downloadable web-based patient information sheets*
- *Publication of inspection reports and thematic review*
- *Fertility Views surveys*
- *Launch and marketing of the new website to patients and the public*
- *Develop new patient questionnaire for use in inspection*
- *Hold bi-annual meetings with all patient organisations*

Key Dates:

- *Website launch – June*
- *Publication and launch of ‘Choices & Boundaries’ report – by end May*
- *National statistical data available on website – July*
- *7th Edition of Code of Practice consultation launched by September*
- *Launch consultation on proposal to reduce multiple births – November 06–February 07*
- *Launch and marketing activity for the HFEA Guide to Infertility*
- *Roll out new patient questionnaire – October-December*

Key objective 5: Strengthen the relationships of the HFEA with key stakeholders by better engagement.

- Promote the HFEA’s inspection role to increase confidence for patients and the sector.
- Ensure GPs and commissioning bodies have reliable information on performance, availability and capacity of licensed clinics.
- Actively consult licensed centres and other stakeholders through Licensed Centres Panel, BFS, RCOG and other professional organisations.
- Increase transparency through improved range of corporate events and annual publications.
- Provide advice and information to the Department of Health, particularly to inform the review of the HFE Act.

Outcomes/Success Measures:

- *Active consultation with licensed centres and other stakeholders through the Licensed Centres Panel, BFS, RCOG and other professional organisations*
- *Improved range of corporate events and annual publications to increase transparency*
- *Effective and timely advice / information to the Department of Health particularly to inform the review of the HFE Act*
- *Greater understanding / awareness of HFEA activities / objectives*
- *Positive feedback from parliamentarians after briefing sessions*
- *Better understanding of HFEA’s role by parliamentarians and opinion-formers*

Outputs/Activities:

- *Quicker response rate to DH requests for advice*
- *Open Authority meeting London*
- *Authority meeting in Belfast*
- *Marketing of HFEA Guide*
- *Primary Care event and other professional conferences*
- *BFS PR training (October-January 07)*
- *Licensed Centres Panel (September-December & January-March)*
- *Quarterly publication of HFEA update*

- *Production of HFEA Annual Report (July) & Annual Review (November)*
- *Preparation for Parliamentary briefing*
- *Implement stakeholder relationship strategy across the organisation*

Key Dates:

- *HFEA annual report completed for publication by June*
- *Review of the Act consultation (October-December)*
- *Annual review completed for publication by November*

Key objective 6: Contribute to maintenance of public understanding and confidence in research on assisted conception and stem cell research.

- Scan scientific horizon for new developments in fertility science and assess new technologies.
- Carry out rigorous, informed regulation of research through improved business processes.
- Develop assessment procedure for Persons Responsible (PRs) of research centres.
- Work with the Department of Health and Central Office Research Ethics Committees (COREC) to review regulatory interface.
- Publish lay versions of research applications and licensing decisions.

Outcomes/Success Measures:

- *Better preparation for responses to new scientific developments and licensing decisions*
- *Renewed understanding of the processes around the reporting of adverse incidents relating to research*
- *Incorporate research centres into unannounced inspection programme*
- *Better understanding of the HFEA's role in research regulation*

Outputs/Activities and key dates:

- *Policy positions agreed by SCAG and ELC by June*
- *Implement new processes for research regulation (April-June)*
- *Annual meeting of expert panel - June*
- *Identification of horizon scanning priorities for 07/08 by December*
- *Research Person Responsible (PR) Assessment in place (October-December)*
- *Relevant speeches by Chair of HFEA at key conferences on research regulation*
- *International networking*

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).

- Share knowledge on piloting self-assessment.
- Develop joint business planning/risk management approaches.
- Adopt consistent approaches to implementation of the EUTCD.
- Share back-office and other functions as appropriate particularly to ensure a cost effective transition to RATE.
- Develop shared regulatory methods, wherever possible.

Outcomes/Success Measures:

- *Joint working and planning is in place, wherever possible, between the HFEA and HTA and systems and processes are integrated to ensure the smooth transition to RATE*

Outputs/Activities and key dates:

- *Joint working wherever possible to share skills / resources*
- *Further work on shared systems/processes to ensure smooth transition to RATE*
- *Joint planning on implementation of the EUTCD/ sharing knowledge on piloting self assessment*
- *Work towards sharing finance function by mid year*

Key objective 8: Develop 7th edition Code of Practice, incorporating professionally-agreed standards to meet requirements of EU Tissues Directive and Better Regulation objectives, i.e. improve effectiveness as a regulatory tool and reduce regulatory burden on centres.

Outcomes/Success Measures:

- *European Tissues Directive fully transposed into UK law*
- *New Code format provides clearer guide to legal requirements and guidance*

Outputs/Activities:

- *7th edition of Code, incorporating standards, issues to come into force by 6 April 2007*

Key Dates:

- *Draft standards published by April*
- *Pre-consultation on the Code of Practice (COP) agreed by the Authority by July*
- *Launch public consultation on COP – September*
- *Public consultation – October / November*
- *Code signed off by the Authority – February*
- *Code published and brought into force – April*

Key objective 9: Maintain robust financial/staff management and corporate governance to increase efficiency and reduce costs.

- Develop and support IT systems to raise productivity and increase access to information both at the HFEA and at centres.
- Complete the staff training and development programme, and align it to the organisation's objectives.
- Develop internal communications and management capability to lead and develop people effectively.
- Maintain sound financial processes including budgetary control and improve cost awareness.
- Review income sources and financial strategy including overall fee strategy
- Use and develop costing models.
- Maintain a high standard of office facilities gaining best value through effective procurement.
- Develop a relationship management system to improve effectiveness of handling customers' and stakeholders' expectations.
- Close the Electronic Data Interchange (EDI) project.

FINANCE / HR / IT – SUPPORT FUNCTIONS

FINANCE
<p>Outcomes/success measures:</p> <ul style="list-style-type: none"> • Provide effective and efficient support services, meeting all ALB targets and ensuring delivery of key objectives within the Business Plan
<p>Outputs/Activities:</p> <ul style="list-style-type: none"> • Produce management accounting activity and projects • Prepare and deliver financial plans and in year financial reports to budget holders, Senior Management Team, Authority Members and the Department of Health • Ensure the organisation achieves a break even position on its budget and remains within ALB guidelines in terms of finance and HR establishment • Hold monthly meetings with budget holders • Ensure the smooth transition of the activity costing model within the organisation, including training for budget holders to enable accurate resource forecasts • Provide assistance and on-going support to budget holders • Complete DH/ALB returns in accordance with set deadlines • Continue to pay 95% of invoices within 30 days • Financial modelling of the resource requirements under the EU Tissues and Cells Directive regulations • Ensure taxation compliance and regulations, specifically in respect of VAT, corporation tax and PAYE issues
<p>Key Dates:</p> <ul style="list-style-type: none"> • Implement the revised strategic risk register format • Deliver the Audit Plan by 31 March • Implement all audit recommendations to timescales • Produce Annual Report and Accounts, complying with Accounting Standards and produce draft set of accounts by end June • Progress towards shared financial services with the HTA; develop the finance team with the aim of establishing an integrated accounts function.
HUMAN RESOURCES
<p>Outcomes/success measures:</p> <ul style="list-style-type: none"> • Deliver an effective HR function to both the HFEA and HTA
<p>Outputs/Activities:</p> <ul style="list-style-type: none"> • Support managers to develop the personal development process • Identify core training needs analysis • Implement the organisational development strategy to ensure the organisation improves its performance and effectiveness • Develop a behavioural competency framework for the HFEA and HTA and link to PDP and recruitment process • Review and evaluate systems for implementing 360° feedback • Support staff involvement within the business through active engagement with the Staff Forum • Develop and embed equality and diversity issues within the organisation • Ensure managers understand compliance with Age Discrimination legislation • Review pay and reward strategies • Support managers with any workforce requirements associated with the closure of the HAP project • Provide a comprehensive HR service to the HTA which matches the agreed Service Level Agreement
<p>Key Dates:</p> <ul style="list-style-type: none"> • Deliver refresher PDP training - April • PDP process completed by 31 May • Implement pay award (August)

INFORMATION TECHNOLOGY

Outcomes / success measures:

Register Project

- Improved accuracy in the reporting of Register information from centres
- Improved accuracy and speed in reporting of information from the Register
- Reduced resource overheads through remote software updates
- Increased data accessibility through development of "Query Builder"

Regulation

- HFEA resources focused on data interpretation rather than process and validation
- Reduction of conflicting data and a 'self-service' update facility for centres thus delivering more reliable and timely information

Resources

- Encourage self management and greater individual ownership of development process
- Have an effective and efficient feedback tool which promotes better management and staff development and will support the evidence base of the implementation of the competency framework and PDP process

Finance Requirements

- Redeployment of current resources used on manual billing system
- Increased accuracy in the billing process.

Information Technology

- Improve business processes by increased efficiency, greater tracking, control and monitoring

Outputs / Activities / Key Dates:

Register Project

- Review, check and validation processes complete by the second quarter 06/07
- Complete the rollout of EDI by end of September 06
- Merge the HAP cleansed data back into the Register by July
- Create a single reference number for every individual in the Register by end of September
- Release a new version of the EDI application which will increase the system's functionality by end of September
- Provide a reporting tool to enable users to create their own queries and run reports by April 07

Regulation

- Ensure that centres have the ability to apply online for licenses by October 06

Resources

- Review the PDP process by April 07 with a view to using online forms

Information Governance

- Establish Customer Relationship Management system (CRM) that will store all related contact information on an individual or a centre in one place by July
- Link the CRM system with Centrepede (the central repository for all centres' based information) by August

Finance Requirements

- Full implementation of automated billing by September 06 using information extracted from the Register to create invoices to centres.

Communication and Policy

- Content Management System (CMS) implemented by June
- Guide to Infertility requirements – January 07-March 07
- Intranet review and development by July
- Interactive Code of Practice by December

Information Technology

- Implement organisational workflow by April 07

High Level Risks for the Organisation

Description of the risk	Controls in place to mitigate the risk
<p>Being insufficiently prepared / resourced to implement the requirements of the European Tissues and Cells Directive to bring over 100 IUI/GIFT clinics into regulation to ensure compliance with the legislation.</p>	<p>On-going dialogue with The Department of Health (DH) on regulations to implement the Directive and transitional provisions.</p> <p>Working in collaboration with the professional bodies to inform the Commission's negotiations to ensure requirements are achievable and proportionate.</p> <p>Proposing changes to the IT infrastructure to accommodate new requirements and forward planning within Regulation to manage the increased workload.</p> <p>Developing a fee strategy for the EUTCD.</p>
<p>Not effectively closing two major complex projects: The Historic Audit Project (HAP) and the Electronic Document Interchange (EDI) in the first quarter of the financial year by running over budget.</p>	<p>A limited amount of rescheduling resources from 2005/6 to 2006/7 during the first quarter of the financial year to close the projects effectively.</p>
<p>Being unable to deliver a more challenging business plan within the context of reduced resources and tighter funding levels as a result of the Arms Length Body Review (ALB), which increases the risk of not delivering fully on 2006/7 key objectives.</p>	<p>Close monitoring of progress against objectives on a monthly basis will avoid the potential for mission creep.</p> <p>A new decision making process to enable more systematic prioritisation of new work, which complies with the principles of The Better Regulation Taskforce of the 'one in, one out' approach to new regulatory activities.</p> <p>A new way of managing the business through Programme Boards (which enables joint working between directorates on achieving objectives).</p>
<p>Uncertainty generated over the future of the organisation by the review of the HFE Act and the Government's wider review of regulation, which will cause problems in recruiting, retaining and replacing key personnel. This situation is likely to be more problematic moving closer to the formation of RATE, especially if the transition absorbs considerable resources.</p>	<p>Working closely with the Department of Health (DH) on the Review of the Act, providing guidance and support as required.</p> <p>Membership of DH Steering Group to share knowledge and understanding on the move towards RATE.</p> <p>Internal communications strategy being developed to keep staff better informed and alleviate uncertainty about the future. A Staff Forum has been established to address issues of highest staff concern.</p>
<p>A major incident occurring at one of the centres which could divert significant staff resources from delivery of key objectives.</p>	<p>Centres are required to have adverse incident procedures/quality management systems in place and the new Self Assessment process should encourage greater incident awareness within centres.</p> <p>Using the inspection risk matrix will make it easier to divert internal resources if a significant incident should occur.</p>

Improving Efficiency / Effectiveness

The organisation adheres to the principles of The Better Regulation Taskforce and requirements of the ALB review by being able to demonstrate efficiencies to provide more targeted, proportionate and risk-based regulation. Some examples of current and achieved activities are: -

- Reducing the reliance on external specialist advisors by developing an in-house inspectorate team, which will improve consistency and impartiality.
- Devolving responsibility for approval of new techniques wherever possible to Persons Responsible in centres; examples are approving ICSI practitioners and PGD.
- Adopting a new approach to risk management by risk assessing all objectives within the Business Plan.
- Piloting a risk-based tool to identify clinics in high/medium/low risk categories to enable low risk clinics to have greater autonomy and to concentrate inspector time on clinics which require greatest improvement against the Code of Practice.
- Merging operational audit with the regulation inspection team to demonstrate a more seamless approach to the inspection process and reduce the number of interactions with Centres by the HFEA.
- Developing a self assessment tool for Centres and PRs in response to feedback from the Licence Centres Panel for greater autonomy.
- Developing web-based communication for patients.
- Piloting joint inspections with the Health Care Commission (HCC) to identify areas of duplication and streamline both inspection processes, according to concordat principles.
- Significantly reducing the burden of regulation on centres by streamlining the inspection process and analysing existing data to profile performance enabling a reduction in information requests prior to inspection.
- Providing greater analysis of data held on HFEA core I.T. systems (the Centres database and Register) to support a more rigorous and proportionate inspection regime.
- Developing a costing mechanism to be able to demonstrate the true cost of projects/ initiatives during 2006/7.

The Financial Picture

HFEA BUDGET 2006/7 Commentary

1. Overview

- The Budget shows break-even for 2006/7, following a review of income and taking the latest position on fees and treatment volumes.
- HAP and EDI were completed by 31 March 2006 as planned, apart from a small amount of work, for which a cost provision of £94k has been included.
- The headcount reduction of 100 posts was achieved by March 2006, largely by the planned staff reduction due to termination of fixed term contracts.
- In the second half of the year, there is a requirement to process over 100 applications from IUI / GIFT centres for a conditional licence under the EU Tissues and Cells Directive and to pilot and put in place an inspection regime to commence from April 2007.
- Costs of £100k are assumed with a similar level of extra fee income from these previously unregulated centres. A public consultation on fee levels is planned for summer 2006. There remains a risk that the demand for support will outstrip resources as new clinics to be regulated under the EUTCD may require significant support to achieve compliance.

2. Income Assumptions

- Fee increase of 1.5% is assumed.
- DH operating grant rises from £1.2 million to £1.8 million. This rise restores the cut of £0.2 million and adds allowances for inflation, additional pension costs, and European Tissues Directive Work.
- Treatment cycles rise in volume on those forecast for 2005/6, returning to previous levels of growth. Fee income rises from £4.0 million to £4.4million.
- If the fee increase is not approved or volumes are less than expected, it will be necessary to reduce costs by reviewing the level of support.

3. Authority/Committee costs

Costs are budgeted to reduce slightly next year as Regulation and Corporate Governance plan fewer Licence Committees and Regulation Committee meetings. Also reduced room hire is budgeted, as pressure on meeting rooms will be reduced with the ending of HAP and EDI projects.

4. Regulation and Corporate Planning

Costs are changed to reflect the increase in workload arising from the EUTCD. The reduced budget for external advisors has been offset by increased internal staff costs as the changeover to an in-house inspection team is completed. Efficiency savings will allow for some of the additional work for EUTCD to be absorbed as licensing activity doubles in the last quarter.

5. Information Management

Gross costs are budgeted to reduce by half from £1,238k to £622k. This follows substantial downsizing of the Register and Operational Audit staff levels. However, it is more than offset by a loss of £1,015k of recharge of costs from this area to the Register project. Remaining staff will be switching their work from Historic Data clean-up to ongoing support of clinics, particularly in their first year of EDI, and improvements to accuracy and presentation of information from the Register.

£	<u>2005/06</u>	<u>2006/07</u>
Gross Cost	1,238,000	622,418
Re-charge Register Project	<u>1,015,000</u>	_____
Net Cost	223,000	622,418

6. Communications and Policy

Communications and Policy is budgeted to reduce costs by £195k (15% reduction). This is mainly due to a move towards use of the web for communications and more targeted communications activities, along with a reduced number of Policy reviews and a more streamlined Policy-making process.

7. Resources and Corporate Development

Gross costs have been reduced from £2,497k to £1,986k with the downsizing of all central support units. However, this is more than offset by the loss of £1,200k of recharges to the Register project. The full cost of office premises and services will now be borne by HFEA operations. IT staff (reduced in number) will switch onto supporting EDI and undertaking development to improve productivity and data accuracy and availability in all departments.

£	<u>2005/06</u>	<u>2006/07</u>
Gross Cost	2,497,000	1,986,734
Re-charge Register Project	<u>1,200,000</u>	_____
Net Cost	1,297,000	1,986,734

8. Legal Fees

The budget assumes payment from CORE is received which reduces the net cost of legal fees.

9. Outlook for 2007/8

Income and costs in 2007/8 are expected to be in line with 2006/7, with the following exceptions:

- DH grant-in-aid will rise by £56k as communicated to the HFEA by DH.
- Legal costs will rise by a similar amount due to the non re-occurrence of the CORE payment.

Efficiencies will be found to offset cost inflation, and the result will be break-even. EU Tissues and Cells Directive work will expand further, with additional costs and further fees charged, but it is too early to scope this work and predict likely fees or costs.

Budget Summary				
	Revised Forecast			
	2005-06	2005-06	2006-07	2007-08
	Budget	Forecast	Budget	Budget see note 9 above
	£	£	£	£
Summary HFEA				
Operational Activity				
Income	5,300,500	5,482,000	6,348,000	6,404,000
REVENUE COSTS				
Chief Executive's Office	405,747	422,000	451,411	451,410
Staff Costs - Other	456,273	327,000	323,273	323,273
Authority / Committee Costs	255,000	257,000	250,686	250,686
Regulation & Corporate Planning	1,209,425	1,253,500	1,352,860	1,352,860
Information Management (Registry)	140,885	223,000	622,418	622,418
Communications and Policy	1,155,205	1,259,500	1,064,119	1,064,119
Resources and Corporate Devt.	1,222,590	1,297,000	1,986,734	1,986,734
Legal Fees	194,500	100,000	66,500	122,500
Professional Fees	145,000	256,000	145,000	145,000
Total Revenue Costs	5,184,625	5,395,000	6,263,000	6,319,000
CAPITAL COSTS	115,875	87,000	85,000	85,000
Total Costs	5,300,500	5,482,000	6,348,000	6,404,000
NET Operational Activities	0	0	0	0

Workforce Planning

Department	2006-7 WTE
Communications & Policy	17.5
IT / Information Management	19
Human Resources	2
Regulation (including Business Planning)	23.3
Audit	3
Facilities	3
Finance	5
Chief Executive / Outer office	6.35
HAP	0
TOTAL	79.1

Performance Indicators

A. Inspection and Regulation	Achieved 2004/05	Target 2005/06	Achieved 2005/06	Target 2006/07
No. of random unannounced inspections carried out in the year	4	4	7	4
Reports resulting from inspection of treatment centres available to centre within 20 working days of the inspection date	72%	90%	73%	90% (PI is now 28 days)
Reports resulting from research inspections available to centre within 4 weeks	N/A	90%	90%	90%
Alerts issued within 21 working days	N/A	90%	3 alerts issued	No longer a PI
New licence applications processed within 4 months of receipt	None received	90%	90%	90%
Research licence applications processed within 3 months of receipt of complete application & peer review	69%	90%	100%	100%
Reduction in items of information required from clinics during the inspection process	N/A	20%	Achieved	A further reduction of 10%
B. Communication and Information				
Patient/public enquiries replied to within 3 working days	90%	95%	90%	95%
Number of Authority meetings held in public during the year	3	3	3	3
Number of stakeholder events	10	7	8	8
Freedom of information requests dealt within 20 working days	N/A	100%	100%	100%
Publication of finalised Licence Committee decisions on the website (new PI)				80% within 14 working days of finalised decision
C. Corporate				
Invoices paid within 30 days		85%	83%	85%
Debts collected within 60 days		95%	93%	95%
Monthly billings of clinics achieved in three weeks		100%	100%	100%
D. ALB Targets				
Reduce revenue costs to £8.4m		On target	On target	On target
Reduce headcount to 79.1 (by March 07)			On target	79.1
Assess shared services potential for back-office study of finance	Achieved	N/A	Complete*	Finance function to be shared with HTA

*(HR function not viable for shared service)

HR strategic and operational/payroll functions shared with the HTA