

Human Fertilisation and Embryology Authority

Business Plan 2007-2008

2007-2008



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. The organisation is continually in the media spotlight and needs to be responsive to changes in the external environment.

Policies developed take into account the disparate and often conflicting views of the public. We recognise the importance of engaging well with a range of stakeholders and with the fertility sector itself. Maintaining public confidence in fertility treatment and embryo research is paramount as is ensuring safety for patients, embryos and children born as a result of Assisted Reproductive Technologies (ART).

The HFEA has led the establishment of the European Assisted Conception Consortium (EACC) to bring about closer international links between ART Regulation and service providers. This has left us well placed to deliver the requirements of the EU Tissue and Cells Directive (EUTCD) bringing Intra Uterine Insemination (IUI)/Gamete Intra Fallopian Transfer (GIFT) Centres into regulation within the first quarter of the business year.

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

2007/08 will be a particularly demanding year as there will be a requirement to deliver the business plan in addition to supporting the Review of the Act and, within that, working towards the establishment of the Regulatory Authority for Tissues and Embryos (RATE). This will require a high level of commitment from staff.

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.
- Implement the requirements of the EUTCD to In Vitro Fertilisation (IVF) clinics and to IUI, GIFT and other services new to regulation.

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 Human Fertilisation and Embryology (HFE) Act 1990 and, where appropriate, advise the Secretary of State for Health on developments in these fields.

Some Achievements During 2006/07

During the past year, the HFEA has worked hard to fulfil its statutory obligations and to drive improvements. Some examples are:-

Patient and Public Involvement

- Surveyed patients through our online “Fertility Views” patients panel.
- Published HFEA Guide to Infertility and interactive guide to Clinics.
- Developed and launched new-look website.
- Held two meetings with Patient Organisations.
- Improved format and presentation of inspection reports.
- Included patient questionnaires as part of inspecting clinics.
- Produced thematic report on outcomes from inspection.

Regulating Research

- Published lay summaries of outcomes of research licence applications.
- Developed new assessment procedure for Research Persons Responsible.
- Undertook horizon scanning on new scientific developments, including consulting international experts.
- Launched consultation on “Eggs for Research” policy review.

The Model Regulator

- Introduced risk based inspection.
- Completed all statutory inspections.
- Improved performance in timeliness of inspection reports.
- Promoted joint working with Healthcare Commission and other regulators.
- Developed distance learning and assessment pack for PRs.
- Prepared for the implementation of the EU Tissue Directive to all IVF and donor insemination centres and services new to regulation.
- Investigated 224 incidents and issued 3 alerts.
- Reduced information burden on clinics.

Policy Review and Advice

- Consulted on EUTCD standards.
- Consulted upon and produced revised Code of Practice including online version.
- Commissioned expert report into multiple births and options for single embryo transfer.
- Developed policy review on witnessing in the laboratory.

Improving Efficiency / Effectiveness

- Introduced automated billing element of Electronic Data Interchange (EDI) across all centres.
- Continued progress towards Arm's Length Bodies (ALB) efficiency standards.
- Full Annual Report produced and laid in Parliament prior to the Summer Recess.
- Provided the Human Tissue Authority (HTA) back office functions – finance service commenced in July 2006; Human Resources and Legal support provided throughout the year.
- Full costings exercise carried out to support improved awareness of resource implications of projects/initiatives.

Corporate Goals – 2004-2009

Since publication of our Corporate Plan for 2004-2009, we have regularly reviewed and updated our corporate goals to take into account new legislation and other events with a key impact on our role and therefore our strategy. The following are our current corporate goals, which will remain in place until 2009 or until RATE is created.

- Reducing the cost and burden of regulation and ensuring that it is proportionate, targeted and risk-based (new goal).
- Preparing the organisation for transition to the Regulatory Authority for Tissue and Embryos (RATE), and for regulating against the changing demands of new legislation (new goal).
- Being an open organisation, through excellent communications and working in partnership with stakeholders.
- Working closely with other regulators and with international agencies.
- Strengthening the process of policy development.
- Developing an information base which meets the needs of offspring, stakeholders, and the wider regulation and public health functions.
- Supporting the development of research in assisted conception, and its application.
- Developing an organisation, which will fulfil these goals, supported by strong corporate governance.

Ministerial Performance Targets 2006/2007

- Prepare for implementation of the requirements of the EU Tissues and Cells Directive in April 2007, including practice standards for clinics as part of a revised code of practice and proposals for a fee structure.
- Continue to develop arrangements for joint working with the Human Tissue Authority (HTA), in preparation for the establishment of 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, in addition to maintaining a good working relationship with the Department's sponsor team, dealing promptly with requests for information on finance and staffing issues.

Key Objectives for 2007/08

1. Ensuring patient safety through effective, proportionate, risk-based regulation, and implementing the requirements of the EUTCD to IVF and donor insemination clinics and services new to regulation.
2. Support the Department of Health to establish RATE, working closely with the HTA and maintaining strong relationships with stakeholders to ensure a smooth transition.
3. Promote public understanding of and confidence in research on assisted conception and embryos through proportionate effective regulation and transparent policy making.
4. Develop policies and methods to support effective regulation, ensuring evaluation and amendment as appropriate.
5. Improve the range of reliable, meaningful information and advice available to patients, donors, offspring and the public on the performance of services regulated.
6. Maintain robust corporate governance, financial and staff management to increase cost effectiveness.
7. Implement the HFEA's Diversity Strategy and ensure diversity is addressed in all our functions.
8. Ensure that the organisation recruits and retains staff with the right skills and knowledge to achieve its objectives, through a robust organisational development strategy, focused on successful change management.

Key objective 1: Ensuring patient safety through effective, proportionate, risk-based regulation, and implementing the requirements of the EUTCD to IVF and donor insemination clinics and services new to regulation.

- Work closely with other regulators to reduce overlap and duplication of regulation and promote best practice in inspection, and specifically to work towards future government policies on simplified IVF regulation.
- Continue to review and refine regulatory processes which ensure that regulatory activity meets statutory requirements.
- Participate in European Commission project to enable consistency of regulation across EU.
- Promptly and efficiently process and evaluate applications for Pre-implantation Genetic Diagnosis (PGD) and import/export of gametes, and variations to licences.
- Manage complaints and incidents investigations and produce Alerts to improve practice, systems and processes to promote patient safety.
- Integrate into regulatory activity the IUI/GIFT and IVF Centres, to ensure smooth implementation of the EUTCD.
- Report on national picture through thematic reviews.

Selected Activities:

- *Ensure that PR assessments contribute to regulatory activity effectively.*
- *Obtain feedback from PRs after inspections.*
- *Continue joint inspection and close working with the Healthcare Commission throughout the period of consolidation.*
- *Refine the streamlined licensing process rolled out in 2006 to reduce the costs of regulating the sector.*
- *Revise and strengthen the risk tool.*
- *Integrate into regulatory activity the IUI/GIFT and IVF Centres (planned to be licensed by 5 July 2007).*
- *Continue to process applications and licences promptly and efficiently.*
- *Participate in European Union project on regulation (EUSTITE – European Union Standards and Training in the Inspection of Tissue Establishments).*
- *Increase joint working with other regulators in the production of alerts.*
- *Complete implementation of electronic incident reporting.*
- *Continue to encourage professional organisations to increase training provision for centres in risk management associated with human factors.*
- *Continue with thematic reviews.*
- *Applications for PGD and the import/export of gametes normally to be dealt with in 3-4 weeks, and variations to licences within 3 months (including some PGD applications in certain circumstances).*
- *Gathering data on national picture through inspectors' reports, complaints and incidents.*
- *Produce national report for the public.*

Outcomes:

- *Be recognised as a model regulator; being used as an example of good practice when a regulator is established; the HFEA regulation framework is used by other relevant organisations.*
- *Be seen as a source of advice and support for professionals and the public, and ensure high levels of satisfaction.*
- *The new risk-based targeted inspection programme continues to be effective in diverting resources to centres most in need of improvement, resulting in specific improvements at those centres.*
- *Professional understanding/benefit of Incident Alert System seen to be effective (increase in the number of incidents reported and a reduction in the severity of incidents).*
- *The organisation meets its legal obligations as a competent Authority by bringing IUI/GIFT clinics into regulation to meet the requirements of the EUTCD and ensuring all existing clinics comply with requirements.*

Key objective 2: Support the Department of Health to establish RATE, working closely with the HTA and maintaining strong relationships with stakeholders to ensure a smooth transition.

- Provide policy advice/support for the Department of Health in the development of RATE.
- Consult with Ministers and inform parliamentarians of HFEA issues and progress towards RATE.
- Work jointly with HTA wherever possible to share skills and resources, and to develop joint thinking on key issues.
- Provide capacity and skills to the designated RATE project teams.
- Maintaining support and interaction with key professional stakeholders from the sector and patient organisations, during a time of change and transition.
- Begin work (when appropriate) associated with the review of the HFE Act 1990 and associated parliamentary process.

Selected Activities:

- *Develop and implement RATE communications strategy.*
- *Further work on shared systems/processes to ensure smooth transition to RATE.*
- *Prepare for consultation with Ministers, Parliamentary briefings and informal briefings.*
- *Ensure continued engagement and stakeholder satisfaction through Licensed Centres Panel, British Fertility Society (BFS), Royal College of Obstetricians and Gynaecology (RCOG), Association of Clinical Embryologists (ACE), the Royal College of Nursing's Fertility Nurses Group and other professional organisations.*
- *Forge good relations with patients' organisations and use Fertility Views on line panel to gain patient views.*
- *Develop a shared approach with HTA to the change management process.*
- *Develop a joint understanding with HTA to risk based regulation.*
- *Together with the HTA formulate a shared approach to the Equality and Diversity agenda.*
- *Provide comprehensive support services to the HTA which match the agreed Service Level Agreements.*
- *Participate in RATE project board meetings.*
- *Clear action plan for progress to RATE through joint working adhered to (all strategies in place by April 2007).*
- *Commence work associated with the review of the 1990 Act (this will possibly begin in January 2008).*

Outcomes:

- *Better understanding of HFEA's role and the transition to RATE by parliamentarians and opinion formers with positive feedback.*
- *Increased transparency with stakeholders on RATE and HFEA issues through improved range of corporate communications.*
- *Joint working and planning, wherever possible, between the HFEA and HTA, and systems and processes are integrated to ensure the smooth transition to RATE.*
- *A robust internal communications strategy, ensuring RATE messages are conveyed quickly and consistently and generate positive feedback from staff.*
- *HFEA retains the key skills and talents it needs to ensure business continuity in a time of change.*
- *Development of shared regulatory methods, including risk based approach to inspection.*

Key objective 3: Promote public understanding of and confidence in research on assisted conception and embryos through proportionate effective regulation and transparent policy making.

- Scan the scientific horizon for new developments in fertility science research, and assess new technologies.
- Work with the Department of Health (DH) and Central Office Research Ethics Committees (COREC) to streamline procedures for research applications.
- Continue to publish lay versions of research applications and licensing decisions.
- Produce thematic report giving an overview of the research projects licensed by HFEA.
- Continue to publish outcomes of policy reviews and consultation, including those on the use of eggs for research and the use of hybrids and chimera in research.
- Ongoing regulation of research including reporting of adverse incidents.

Selected Activities:

- *Identify horizon scanning priorities for 2007/2008.*
- *Work with the International Society for Stem Cell Research (ISSCR).*
- *Continue engaging with DH and COREC with the aim of sharing best practice and streamlining regulation.*
- *Continue to publish research inspection reports on the HFEA website.*
- *Produce thematic review of licensed research projects, including types of research carried out and a summary of results.*
- *Complete the policy review on the use of eggs for research.*
- *Produce public report on policy on the use of hybrids and chimera in research.*
- *Implement the PR procedure for research centres and review its effectiveness.*

Outcomes:

- *Members are kept informed of scientific developments which will inform licensing decisions.*
- *HFEA plays a major role internationally in the debate on the regulation of research, and in spreading best practice.*
- *Public are confident in regulation of research and have greater understanding of compliance issues.*
- *Continued updates of research information published on the website.*
- *Public are confident in the policies on procurement of eggs for research and the use of hybrids and chimera in research, and the sector has clear guidelines.*
- *Improved sectoral learning from adverse incidents, and improved PR procedures.*

Key objective 4: Develop policies and methods to support effective regulation, ensuring evaluation and amendment as appropriate.

- Develop process for evaluation of key policies.
- Publish and implement new Code of Practice.
- Develop and implement Multiple Births and Single Embryo Transfer policy.
- Develop and implement revised policy on witnessing in the laboratory.
- Consult on and develop policy on the use of hybrids and chimera in research.
- Continue to review and revise standards and guidance as needed.

Selected Activities:

- *Develop a model process for evaluating the effectiveness of policies which have been developed (Regulatory Impact Assessment) (RIA), including costing the implications of the simplification plans.*
- *Evaluate policy decisions on SEED and Welfare of the Child.*
- *Provide support/advice for the European Assisted Conception Consortium (EACC).*
- *Maintain and make changes to the interactive Code of Practice to improve its effectiveness as a regulatory tool (7th edition to come into force 5 July 2007).*
- *Approve policy proposals on multiple births and single embryo transfer (SET) by end of November 2007.*
- *Implement new policy on witnessing in laboratories, by 5 July 2007.*
- *Consultation to gain increased understanding of public and scientific opinion on the use of hybrids and chimera in research.*
- *Ensure all new policies have an Equality Impact Assessment (EIA).*
- *Review the effectiveness and safety of embryo screening.*
- *Continue post-inspection questionnaires to gauge satisfaction with process.*

Outcomes:

- *Policies developed 'add value' to the sector and guidance is transparent and proportionate to improve the regulatory interface.*
- *Public and sector are well consulted and informed on developing policies.*
- *Witnessing processes are strengthened.*

Key objective 5: Improve the range of reliable, meaningful information and advice to patients, donors, offspring and the public on the performance of services regulated.

- Improve patients' access to good information, through new patient web-based briefings, the interactive guide to clinics, inspection reports and increased publicising of HFEA's role.
- Improve responsiveness and quality of replies to patient enquiries.
- Supply prompt, up to date outcome data for inspection reports.
- Continue to respond to register requests in a timely and sensitive manner and ensure that data held is accurate.

Selected Activities:

- *Communication campaign for patients on understanding single embryo transfer policy (autumn/winter 2007).*
- *Provide validated Interactive Guide data.*
- *Fertility Views Panel surveys (2-3 times per year) and feedback to the panel.*
- *Twice yearly meetings with Patient Organisations.*
- *Ensure that the process to drive up the quality of data input from centres is working effectively.*
- *Continue to provide on-going support to centres on issues relating to EDI.*
- *Ensure that validation rules are working effectively.*
- *Deal with requests for medical files when centres have been closed.*
- *Maintain and make changes to the format of the Code of Practice.*
- *Ongoing training and support for staff to handle difficult patient enquiries.*
- *Analyse the variation in outcome data, and review its presentation for patients / public (to February 2008 Authority meeting).*
- *Review and develop the processes for responding to Opening The Register requests and continue to deal with ongoing requests to comply with the Act.*

Outcomes:

- *More user friendly, understandable and meaningful presentation of different types of outcome data of relevance to patients and the public.*
- *Patients Panel and Patients Organisations satisfied with HFEA's role.*
- *Improved accuracy in the reporting of Register information from centres.*
- *Annual Report produced and laid in Parliament before summer 2007 recess.*
- *Low rate of complaints regarding HFEA responses to patient enquiries.*
- *Improved accuracy and speed in reporting of information (reduce the average delay for submissions from 2 months to 5 working days).*

Key objective 6: Maintain robust corporate governance, financial and staff management to increase cost effectiveness.

- Maintain sound financial and business planning processes including budgetary control, and improve cost awareness.
- Maintain a high standard of office facilities gaining best value through effective procurement.
- Maintain sound HR processes including recruitment and retention practices to maintain a high quality workforce within ALB agreed establishment and within efficiency benchmarks.
- Improve business processes by more automation of routine functions across the organisation.
- Ensure corporate governance arrangements remain robust and effective particularly in the lead up to the RATE transition.

Selected Activities:

- *Continue prompt and accurate production and use of monthly management accounts.*
- *Continue to pay 95% of invoices within 30 days.*
- *Ensure taxation compliance specifically in respect of VAT, corporation tax and PAYE issues.*
- *Develop the functionality of the new fixed asset register.*
- *Develop financial capabilities and understanding within all departments.*
- *Implement process to ensure seamless business, financial and workforce planning.*
- *Cost simplification measures and provide figures to the Better Regulation and Simplification Branch of the Department of Health within timeline.*
- *Meet targets set by NAO and Treasury to achieve faster production of Annual Report & Accounts, complying with accounting standards; produce a draft set of accounts by end of May 2007.*
- *Complete DH/ALB returns in accordance with set deadlines.*
- *Develop procedures to ensure speedier completion of audit recommendations.*
- *All purchasing decisions to follow appropriate tendering procedures.*
- *Make full use of Office of Government Commerce (OGC) and ALB networks to ensure good value in procurement practices.*
- *Produce and monitor HR metrics including recruitment, turnover, absence rates and analysis of leavers.*
- *Further improvement of automated processes to reduce time spent by all teams on routine tasks.*
- *Provide support in the development of and compliance with the Authority's procedures and processes for Corporate Governance.*

Outcomes:

- *The organisation achieves a break even position on its budget and remains within ALB guidelines in terms of finance and HR establishment.*
- *Development of integrated business planning and risk management approaches.*
- *Costing models continue to be used and developed.*
- *Cost effective support services are provided, meeting all ALB targets and ensuring delivery of Business Plan objectives.*
- *Staff satisfaction with information about HFEA and understanding of development of RATE.*
- *Improved time-saving in performance of routine functions.*
- *Response to all data requests from the Better Regulation and Simplification Branch for further work on the simplification plan.*

Key Objective 7: Implement the HFEA's Diversity Strategy and ensure diversity is addressed in all our functions.

- Ensure that diversity is addressed throughout all our business functions.
- HFEA actively promotes diversity issues within the sector and helps to spread best practice.

Selected Activities:

- *Ensure future business planning includes diversity issues.*
- *Develop Equalities and Diversity Impact Assessments for all policy reviews and major projects.*
- *Incorporate diversity requirements into HFEA employment policies and practices*
- *Progress reports to the Organisation and Finance Committee (OFC) in March 2007 and March 2008; annual statement on implementation progress March 2008.*
- *Develop a communication programme with the sector and patients to address diversity issues and share best practice.*
- *Develop links with media targeted at minority audiences.*
- *Build diversity considerations explicitly into HFEA inspections, and our communications.*

Outcomes:

- *Diversity Strategy published and promoted.*
- *Staff and members are fully aware of diversity issues in their work and can address these.*
- *Diversity is embedded in the organisation's planning and work.*
- *Good progress made against diversity targets.*
- *Our policy-making process includes equality impact assessments.*
- *Inspectors address diversity issues, and Persons Responsible are assessed on diversity requirements.*
- *Our communications deal with diversity issues and we engage well with minority groups.*

Key objective 8: Ensure that the organisation recruits and retains staff with the right skills and knowledge to achieve its objectives, through a robust organisational development strategy, focused on successful change management.

- Proactive performance management to maximise the effectiveness of the organisation and value staff commitment and contribution.
- Full implementation of the competency framework, ensuring appropriate skills are effectively used and assessed in all roles.
- Delivering targeted training and development opportunities.
- Develop and implement a strategy for improved internal communications, during a period of significant change.

Selected Activities:

- *Ensuring the performance management processes are effectively and appropriately implemented.*
- *Embed use of competencies in the recruitment and performance management processes.*
- *Develop a culture of positive championing of diversity issues.*
- *Ensure training and development plans are targeted and within budget to support the achievement of the business plan and future requirements.*
- *Continue to encourage staff involvement within the business through active engagement with the staff forum.*
- *Further intranet development to improve accessibility for staff and promote knowledge sharing.*
- *Roll out improved internal communications strategy.*
- *Celebration of continued achievement.*
- *Continue to ensure office environment supports staff in delivering effective business.*

Outcomes:

- *Managers feel supported by the Organisational Development strategy, which provides them with an effective tool to increase their managerial skills and the motivation of staff.*
- *Managers and team leaders are effective leaders during times of significant change.*
- *Office environment contributes to well-being of staff, and complies with all Health & Safety Regulations.*
- *HFEA has the right staff with the right skills to deliver the Business Plan objectives.*
- *Positive status about disabled people achieved in August 2007.*
- *Staff training and development supports HFEA's future needs.*
- *Staff feel valued, involved and informed, and actively engage in business decisions and changes.*

High Level Risks for the Organisation

Description of the risk	Controls in place to mitigate the risk
<p>RATE Insufficient resource allocation to prepare sufficiently for the move towards RATE which will impact on the delivery of other business plan objectives.</p> <p>Key risks include:</p> <ul style="list-style-type: none"> • Staff turnover due to uncertainty over future organisation. • A location outside of the London area, with resultant loss of staff / knowledge. • Insufficient transitional costs. • Lack of effective joint working between HFEA & HTA on initiatives/activities which could mean RATE being a high cost regulator from its inception. • Lack of effective communication strategy to support the transition towards RATE. 	<p>Draft Bill announced in Queen's speech, so longer preparation time, which should ensure better preparation/planning.</p> <p>Location consultants appointed in 2006/07 to look at the possible options around location. Early decisions requested from DH.</p> <p>HFEA has identified likely RATE transition costs as part of the ALB requirements.</p> <p>DH RATE Steering Group in place with members of HFEA and HTA to work on joint planning.</p> <p>Transitional monies allocated by DH to the 2006/7 Business Plan, specifically for improving internal communications.</p> <p>RATE is regular topic on agenda for SMT meetings/Heads of Service and Staff Forum to ensure consistent messages are given/opportunity for discussion about issues of concern.</p>
<p>EUTCD The fee strategy is not sufficient to cover the resources required to implement the Directive effectively. The prediction of the likely numbers is incorrect which will mean that the organisation exceeds budget.</p> <p>The 'unknown' factor about the level of understanding within the sector and the types of enquiries that the organisation is likely to receive within the first quarter of the business year.</p>	<p>Considerable involvement/engagement with the Sector.</p> <p>Detailed planning and preparation.</p> <p>Staff recruited and trained.</p> <p>Full public consultation exercise carried out on fee proposals.</p> <p>Systems and process in place for inspection and reporting.</p>
<p>ALB and other Government Requirements On-going requirements of the Government's ALB Review, the DH's simplification plan and the Better Regulation Taskforce objectives absorb considerable staff resources in producing data required to timescales.</p>	<p>Identified project lead for the simplification process.</p> <p>Previous returns have been produced to timescale.</p>
<p>Joint working Providing a joint HR/finance/legal function for the HTA causing difficulty in meeting HFEA objectives as resources spread so thin that slight variations in requirements within the Service Level Agreements (SLAs) causes pressure on delivery of HFEA objectives.</p>	<p>Service Level Agreements in place and tested at the year end to show how demand has matched original specification.</p> <p>Greater joint working on similar initiatives which demonstrates greater cost effectiveness.</p>
<p>A major incident A major incident or prolonged enforcement action occurs at one of the centres which diverts time and resources away from delivery of other objectives.</p>	<p>Preparedness is the main control. Effective damage limitation and response systems are in place.</p>
<p>General contingency planning Large-scale high-impact events could put the functionality of the whole organisation at risk (events such as major building damage, loss of IT, police or civil emergencies, transport infrastructure collapse, epidemics, etc).</p>	<p>HFEA has an up to date business continuity plan. This provides us with contingency plans for ensuring that, within reason, business can be continued and staff communicated with in the event of any disaster.</p>

The Financial Picture

HFEA BUDGET 2007/8 Commentary

1. Overview

- The Budget shows break-even for 2007/08, following a review of income and taking the latest position on fees and treatment volumes.
- We will receive an amount of £450k funding ringfenced for transitional costs in the lead up to RATE.
- The HFEA remains on target as regards the headcount reduction required by the Arms Length Body Review team.
- The EUTCD comes into force on 5 July 2007 and the budget for 2007/08 assumes estimated income of £160k and includes costings for a full inspection team and all the associated support functions.

2. Income Assumptions

- Fee income from IVF and donor insemination clinics is assumed to remain approximately constant at approximately £4.3 million.
- DH operating grant rises marginally from a budget of £1.93 million in 2006/07 to £1.98 million in 2007/08. An amount of £212k brokerage has been requested, which reduces the grant in aid payable in 06/07 and increases that in 07/08. The amount relates to work on Multiple Births and EUTCD which will be undertaken in 07/08.
- An amount of £25k grant in aid above budgeted amount was paid in 06/07 to support early work towards RATE.
- Fee income raised from IUI and GIFT clinics to be regulated under the EUTCD increases from £100K to £160K as clinics are charged an annual fee for the financial year.
- The budget for other income increases from £30k in 06/07 to £120k in 07/08 which includes a full year of provision of support services to HTA.

3. Authority/Committee costs

- Costs remain broadly constant, although there is a marginal rise in 2007/08 as the number of Licensed Committees increases to deal with licences for the IUI & GIFT clinics regulated under the EUTCD.

4. Regulation and Corporate Planning

- Costs increase in 2007/08 to reflect the additional regulation staff required to regulate the IUI and GIFT centres which are to be licensed under the EUTCD.

5. Communications and Policy

- The budgeted expenditure in Communications and Policy reflects a number of major and publicly sensitive policy reviews to be undertaken in 2007/08 which will need to be communicated effectively. These include in

particular the development and implementation of the Multiple Births and Single Embryo Transfer Policy and the Authority policy on Hybrids.

6. Resources and Corporate Development

- There has been a reduction in salary costs within resources and corporate development, and the staffing structure has been revised. These savings have been offset by an increase in the rent and rates charges on accommodation. The rent increase is effective in November 2007, but these are only applied every five years.

7. Information Management

- Gross costs are budgeted to reduce as the HAP and EDI finalisation phases have been completed in 2006/07.

8. Legal Fees

- The figures for legal costs for 2006/07 were stated net of payment from Comment on Reproductive Ethics (CORE).
- Gross legal costs for 2007/08 are forecast to remain stable.

9. Capital Costs

- Capital expenditure is set at £87k in 2007/08 and £90k in 2008/09 to support renewal requirements.

10. Transitional Costs

- Transitional costs for 2007/08 have been calculated on the basis of costs that would be incurred by the HFEA as a result of the planned formation of RATE.
- They assume that RATE will not be fully operational until April 2009 and that there would not be relocation outside of London until that point.
- The figures also assume that there will be no relocation costs in the financial year 2007/08 and further no co-location costs. If it were decided that HFEA and HTA should be co-located in the financial year 2007/08, any costs of fit-out of the building, including any IT re-cabling and building works, would have to be assessed and an additional bid for transitional cost funding would have to be made for this workstream.
- The transitional cost calculations therefore do not include any capital costs that would be associated with relocation or co-location of HFEA with HTA, if that were decided to be appropriate in the financial year 2007/08.
- At this point, it is not possible to accurately assess the likely transitional costs for 2008/09 onwards, as this would be dependent on the location of RATE.

11. 2008/09

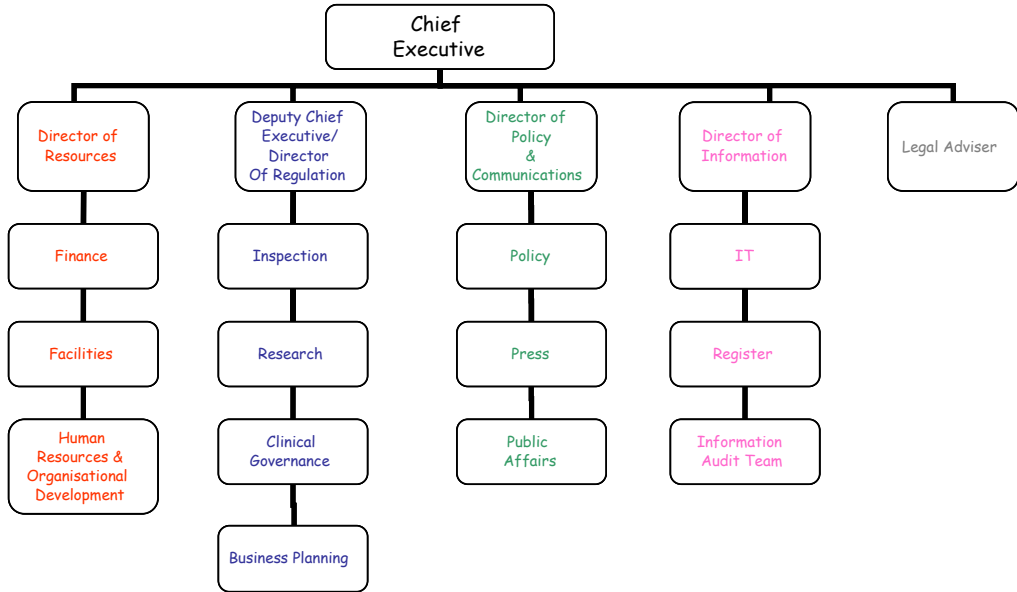
- The figures for 2008/09 are based on broadly stable fee income. It is assumed that inflationary cost pressures will be offset by efficiency savings. Staff reductions are assumed across the board.

Budget Summary

	2006-07 Budget £'000 (restated)	2006-07 Forecast £'000 (Month 7) (Return)	2007-08 Budget £'000	2008-09 Budget £'000
Summary HFEA				
Operational Activity				
Income	6,348	6,373	6,806	6,599
REVENUE COSTS				
Chief Executive's Office	451	478	517	534
Staff Costs - Other	323	295	323	323
Authority / Committee Costs	251	246	255	258
Regulation & Corporate Planning	1,316	1,322	1,392	1,386
Communications & Policy	1,064	1,102	1,298	1,133
Resources & Corporate Development	1,345	1,365	1,409	1,451
Information Management	1,301	1,269	1,196	1,157
Legal Fees	67	66	123	105
Professional Fees	145	145	206	162
Total Revenue Costs	<u>6,263</u>	<u>6,288</u>	<u>6,719</u>	<u>6,509</u>
Transitional Costs			450	
Total costs including transitional costs	6,263	6,288	7,169	6,509
Less Transitional Funding Requested			450	
Net Revenue & Transitional Costs	6,263	6,288	6,719	6,509
CAPITAL COSTS				
Total Costs	6,348	6,373	6,806	6,599
NET Operational Activities	-	-	-	-

* Costs for IT Department are now included under the Information Management Directorate.

HFEA Executive Structure



Workforce Planning

	06-07 WTE	07-08 WTE	07-08 Headcount
Communications & Policy	17.5	17.6	18
IT / Information Management	19	18.5	19
Human Resources	2	2	2
Regulation (inc Business Planning)	23.3	26.5	27
Audit	3	3	3
Facilities	3	3	3
Finance	5	5	5
Chief Executive / Outer Office	6.35	6.5	7
Total	79.1	82.1	84

The 07/08 figures include 3 additional posts that were agreed to cover regulation of the EUTCD.

**3 Year Indicative Plan
ALBs Funding Targets 2007/08 to 2009/10**

	REVENUE FUNDING	Indicative 2007/08	Indicative 2008/09	Indicative 2009/10
		£000	£000	£000
	Revenue Grant in Aid:			
1	Baseline Allocation	1897	1955	2014
2	Brokerage required from 2006/07	212	0	0
3	Total Revenue Grant in Aid and Cash	2109	1955	2014
	Depreciation	204	204	204
	Cost of Capital	46	46	46
4	Capital Charges	250	250	250
5	Total DH Target Funding	2359	2205	2264

6	Transitional Cost Requirements	450	not yet known	not yet known
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	CAPITAL FUNDING	Indicative 2007/08	Indicative 2008/09	Indicative 2009/10
		Capital £000	Capital £000	Capital £000
7	Total Capital Grant in Aid and Cash (Baseline Allocation)	87	90	92

	SAVINGS (Cumulative)	Savings	Savings	Savings
		£000	£000	£000
8	Total Cash releasing Savings/target	2726	2726	2726

		wte posts	wte posts	wte posts
9	Headcount Savings Targets at 31 March	82	82	82

Notes:

- 1 The starting point for the baseline allocation is the business plans provided by ALBs in Jan 2006. These figures may have changed following ALB Programme Team review.
- 2 This is the brokerage that you may require in 2007/08
- 3 Revenue Cash Limit for 2007/08
- 4 Capital Charges are non-cash items but are part of the overall ALB sector for target purposes.
- 5 The total resource provided by the DH against which savings will be targeted.
- 6 Transition cost requirements associated with the programme
- 7 The starting point for the baseline allocation is the business plans provided by ALBs in Jan 2006. These figures may have changed following ALB Programme Team review.
- 8 Total cumulative Cash Savings made against 2005/06 funding levels
These are the headcount savings/targets based on ALB business plans adjusted for the ALB Programme
- 9 Targets

Performance Indicators

	Achieved 2005/06	Target 2006/07	Achieved 2006/07	Target 2007/08
A. Regulation				
No. of random unannounced inspections carried out in the year	7	4	7	4
Reports resulting from inspection of treatment centres available to centre within 28 working days of the inspection date	73%	90%	96%	90%
Reports resulting from research inspections available to centre within 28 working days	90%	90%	96%	90%
New licence applications processed within 4 months of receipt	90%	90%	100%	90%
Research licence applications processed within 3 months of receipt of complete application & peer review	100%	100%	100%	100%
Reduction in items of information required from clinics	Achieved	A further reduction of 10%	Achieved. Paperwork for inspections reduced to approximately one fifth of previous level.	Further 10% reduction
B. Communication and Information				
Patient/public enquiries replied to within 3 working days	90%	95%	92.22%	95%
Number of 'page views' of 'For Patients' section of website	-	-	-	5% increase
Number of 'page views' of 'Find a Clinic' function on website	-	-	-	5% increase
Number of Authority meetings held in public during the year	3	3	3	3
Number of stakeholder events	8	8	8	8
Freedom of information requests dealt within 20 working days	100%	100%	98.67%	100%
Publication of finalised Licence Committee decisions on the website	-	80% within 14 working days of finalised decision	90.6%	90% within 20 working days
C. Corporate				
Invoices paid within 30 days	93%	95%	94%	95%
Debts collected within 60 days	83%	85%	89%	85%
Monthly billings of clinics achieved in three weeks	100%	100%	98%	95%
D. Diversity				
Initial EIA screening completed for all major new policies or projects	-	-	-	95%
Full EIA completed for all major policies or projects identified as requiring additional assessment	-	-	-	95%
Develop self assessment and pre-inspection questionnaires, and train clinics to understand their use	-	-	-	75% (of clinics)
E. ALB Targets				
Reduce revenue costs	On target	£1.93m grant aid	On target	£2.109m grant aid
Reduce full-time equivalents to 82.1 by March 2007 and then maintain this reduction	On target	82.1	On target	82.1
Assess shared services potential for back-office study of finance	Complete*	Finance function to be shared with HTA	Achieved	-
Note: Qualitative service reviews are also carried out to assess the effectiveness of inspection, and user satisfaction with the website. These will continue in the business year 2007-2008.				

* (HR function not viable for shared service)
HR strategic and operational/payroll functions shared with the HTA