HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Human Fertilisation & Embryology Authority

Business Plan 2014-2015

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Preface

The HFEA in 2014-2015

It is over 30 years since the birth of the world's first 'test tube' baby, Louise Brown. And it is over 20 years since the establishment of the world's first regulator of assisted reproduction and research involving human embryos, the Human Fertilisation and Embryology Authority (HFEA).

Since then, the science of assisted reproduction has moved on quickly and society's views have changed too. As the regulator we need to constantly review our policies and priorities to ensure that they remain effective in ensuring the safety of patients and that the public have the confidence that this still controversial area of medicine is appropriately overseen and the law upheld.

The wider health and social care system has not stood still over this time either. There are now several regulators of different aspects of healthcare and we need to ensure that the HFEA works well within this wider system. We are the UK regulator, and so we need to work with the NHS in the four nations, and with the private sector. We are also part of the wider family of Department of Health Arm's Length Bodies (ALBs), and need to ensure that we work collaboratively and in common purpose with the Department's overall aims and priorities, as these apply to our work.

Today, the quality of the care people receive in hospitals is rightly uppermost in everyone's minds. And patients' views matter more than ever in improving the quality of those services. In many ways, IVF patients are just like other patients: they need good information and easy access to high quality care. But, despite the fact that IVF has become a routine medical treatment, it remains complex in other ways. Most patients have to pay for their treatment, increasing their appetite for accurate information about treatments and clinics. And when the treatment involves donated eggs and sperm, patients – and donors – need easy access to information and support for themselves and their families.

At the same time, all organisations in the public sector must control their costs and demonstrate that they are using their resources responsibly and to good effect, giving value for money.

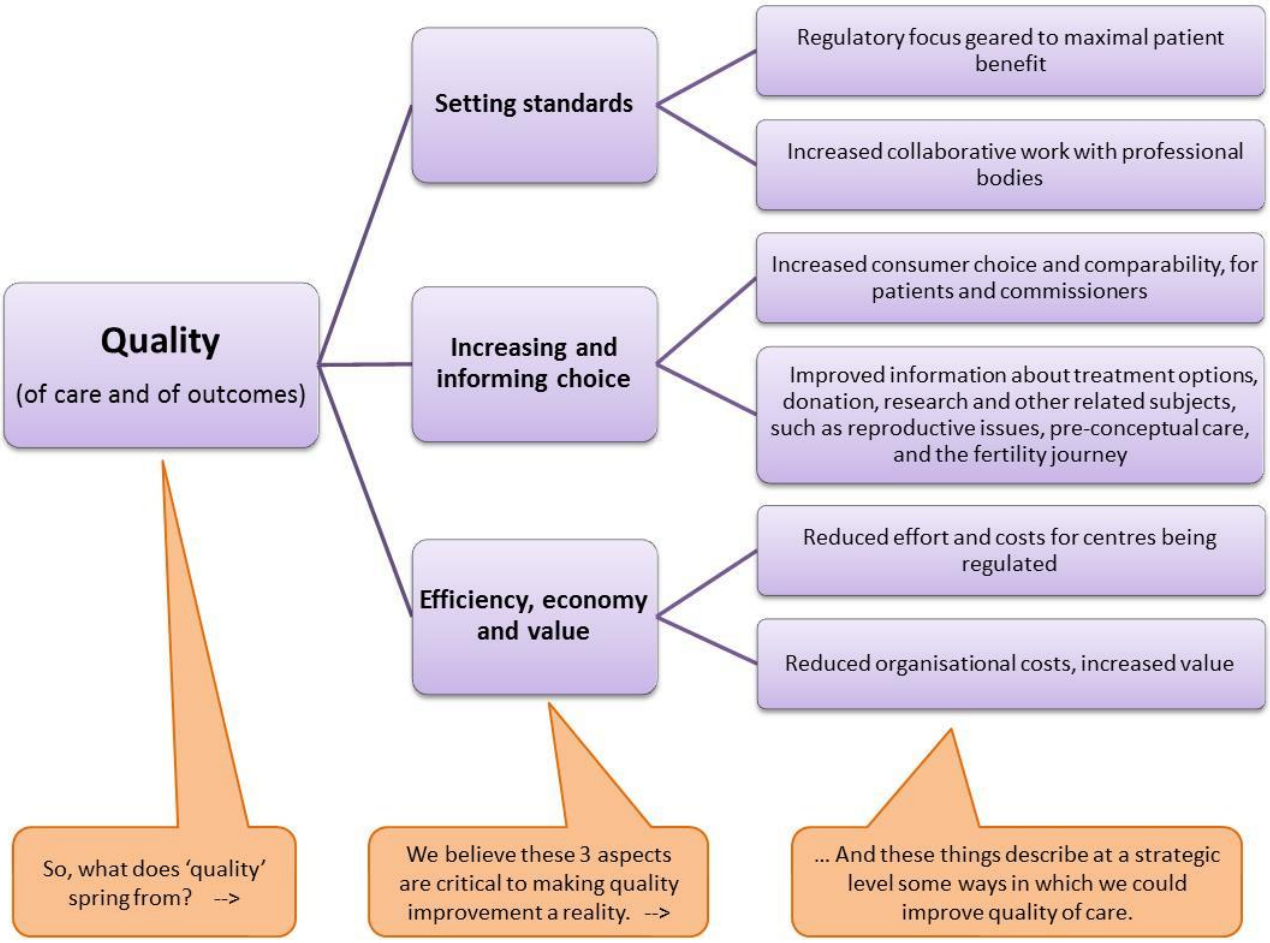
We need to respond to all of these developments if we are to remain relevant and effective. To this end, we are currently developing a new strategy for the next three years. It will set out what we want to achieve, what impact we want to have and what our priorities are.

What delivers good quality care?

We believe that, as the regulator, we can improve the quality of care in three different, but linked ways:

- Setting standards in clinics and checking compliance with them through inspection
- Playing a public education role by providing information about treatments and services, so that patients are able to choose better quality care
- Reducing costs for clinics so that they can focus more of their time on providing care.

This model is illustrated in the following diagram.



We have always aimed for the highest levels of quality in the services we provide, and we will continue to do so. We do not believe that seeking good value means we should compromise in setting high quality standards for ourselves in the information we provide (for example, through our website), the way we develop our policies, and our approach to regulation.

For instance, following the final report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Report) in February 2013, we considered the findings and detailed recommendations and how best to apply them to our work and improve the quality of our regulatory activities. As a result of this, we began to phase in unannounced and short notice inspections from 2012 onwards, and this approach to inspection is now fully in place.

Our ultimate aim is to improve the quality of patients' experience of treatment, and of other stakeholders' experience of providing information to and obtaining information from the HFEA.

Information for Quality Programme

In 2013/14 the HFEA started work on two large-scale capital projects, focused on improving the underlying structure of our Register and updating our website and other digital communications. These are major pieces of work which will continue throughout the 2014/15 business year. Their aim is to ensure that both our Register

and our communications infrastructure are fit for purpose for a modern and efficient regulator.

Efficiencies and driving down costs

We continue to drive down costs, as we have done for the past several years, proactively managing the organisation against the tight expenditure environment in place for all public sector organisations.

In January 2013, in keeping with the latest research on board size and effectiveness, we reduced the size of our Authority by one third. We made corresponding changes to our licensing procedures and decision-making arrangements, including a new Committee structure and new decision trees for our Committees to use when considering licensing matters.

We have maintained our previously established 'shared services' arrangements with the CQC (with whom we share a building) on facilities management, office accommodation, occupational health, some elements of learning and development, and recruitment. Following an upgrade of our financial accounting system, to ensure that we are prepared for future collaborative working with other ALBs, we have reduced our Finance team staffing and now share a single Head of Finance with the HTA. From March 2014, we have also shared a single Director of Finance and Resources. This arrangement will lead to appreciable savings, over time.

Working with Other Arm's Length Bodies (ALBs)

We continue to develop closer working relationships with other health ALBs, particularly the Health Research Authority (HRA), the Human Tissue Authority (HTA), the Care Quality Commission (CQC) and the Medicines and Healthcare Products Regulatory Agency (MHRA). We are working collaboratively to ensure that arrangements for regulation of the sector are effective and that any overlap between our own regulatory duties and others' is removed. For instance, certain surgical procedures (egg collection for example) bring some clinics within the remit of CQC registration. Following work with the CQC to resolve this overlap, from October 2013 clinics did not need to be independently registered with the CQC and are no longer inspected by them.

The HFEA also remains committed to the principles of the Voluntary Sector Compact and works with the voluntary sector in a number of ways. For example, the HFEA has worked for some years with other organisations to reduce the prevalence of multiple births in the fertilty sector[1], and routinely opens developments to its policies and processes to a wide range of inputs and influences, including voluntary organisations.

[1] See http://www.oneatatime.org.uk/229.htm

McCracken Review

In January 2013, the Government decided that the HFEA should be retained as an independent expert regulator. At the same time, the Parliamentary Under Secretary of State for Public Health and the Minister for the Cabinet Office tasked Justin McCracken to conduct an independent review of the HFEA and the HTA, to see whether efficiencies could be identified in the way in which both bodies carry out their respective functions.

The Government accepted all of the recommendations of the McCracken review in July 2013, and the Authority agreed an action plan in September. Progress on meeting the McCracken recommendations is set out later in this Business Plan.

Looking to the Future

This business plan continues to build on the work commenced in 2013/14. Our objectives for the coming year remain broadly the same, focusing on:

- Supporting the sector to provide high quality, safe care with the best possible outcomes for patients
- Improving the effectiveness and transparency of the information we hold, collect and provide
- Seeking further efficiencies and ensuring the organisation and its staff are equipped to deliver associated changes.

HFEA Purpose, Principles and Statutory Functions

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 in our sector[1]. We provide authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. We set policy in relation to 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
- 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.[2]

Functions

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").

The 2008 Act is primarily 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:

- 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

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

[2] This section is being reviewed as part of HFEA Strategy development in 2014.

- To ensure, where a licensed clinic makes use of an external service which does not hold an HFEA licence, that there is a third party agreement in place which is in accordance with any licence conditions imposed by the Authority, for the purpose of securing compliance with the requirements of technical Directives under which the third party procures, tests or processes gametes and/or embryos on behalf of the Licence Holder, or supplies to them goods or services which may affect the quality or safety of gametes and/or embryos
- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities
- To keep a formal register of information about donors, treatments and children born as a result of those treatments
- To maintain a formal register of licences granted
- 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 (EEA) 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 EEA states.

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

- 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
- Publicising the HFEA's role and providing relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients
- 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.

The HFEA also functions as one of the two UK competent authorities for the European Union Tissues and Cells Directive (EUTCD). This Directive regulates the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

Looking Back on 2013/14

Meeting Key Challenges – Delivery of the 2013/14 Business Plan:

Compliance activity supported by effective policies

"To continue to deliver our statutory regulatory functions, underpinned by policies that equip the organisation to regulate effectively and support the sector to provide high quality, safe care with the best possible outcomes."

Statutory Regulatory Functions

In 2013/14 the HFEA performed its core functions well and we strove to further improve the quality of our regulatory work, by adopting a notably more patient-focused stance.

We undertook a substantial programme of inspection and licensing activities, monitoring the performance of centres, and dealing with incidents and complaints about centres.

Our focus on the quality of care that patients receive in clinics, and the way in which clinics and the HFEA respond to incidents and complaints about care, was important, in keeping with our consideration of the first recommendation in the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Report).

On inspection, we enhanced scrutiny of the quality and safety of patient care, and continued the programme of unannounced inspections, commenced in 2012/13. We continued to monitor centre risks through the HFEA's risk based assessment tool - providing timely information for both HFEA and centres, by highlighting areas of concern and opportunities for improvement.

In keeping with the recommendations of the independent review of the HFEA and the HTA by Justin McCracken, we concluded and fully implemented our work to remove regulatory overlap with the CQC in relation to 'surgical procedures.' (The full set of McCracken recommendations and the work in progress to meet them is detailed later in this Business Plan.)

Monitoring of sector performance in relation to the multiple births target maximum rate continued, further reducing the negative outcomes for patients and children born as a result of fertility treatment. During the year, the Authority also took the decision to remove the associated licence condition (known as T123) from all licences, in the face of legal challenge and its associated cost. The policy itself remains in place, and continues to exert a positive downward pressure on multiple birth rates. Clinics mostly continue to work very hard to meet the increasingly tough requirements on the minimisation of multiple births.

We ensured that our governance tools and the documentation that underpins licensing and other decisions continued to be in place and effective, under new governance arrangements that were introduced in April 2013. We also completed a review of PGD conditions and ensured that the published PGD list was up to date and reflected current scientific and medical knowledge.

In our role as the UK's Competent Authority for assisted reproductive technologies (ART) in the European Union, we attended two meetings of the European Competent Authorities, and ensured that our obligations as the competent authority were discharged.

Policy Development

We supported the ongoing work of our Ethics and Standards Committee and the Scientific and Clinical Advances Advisory Committee, along with the annual horizon scanning process which helps us to remain responsive to emerging scientific developments in fertility treatment and related research.

We also continued to ensure that the Code of Practice, containing guidance for clinics, was up to date and supportive of our regulatory work with the sector.

We provided secretariat and financial support to the National Donation Strategy Group, established to help to tackle barriers to egg and sperm donation in the UK. Now operating under the campaign name Lifecycle, the group's aim is to develop and promote more effective approaches to raising awareness of donation and improving the care of donors in the UK. The group has started to disseminate information, through attendance at fertility shows and through a range of leaflets[1] for different audiences within donation.

Dialogue with stakeholders

Joint working, dialogue and ongoing contact with key professional stakeholders and patient organisations continued to be central to our work throughout the year. Organisations we worked with included the Association of Clinical Embryologists, the British Fertility Society, the British Infertility Counselling Association, the Donor Conception Network, Infertility Network UK, the National Gamete Donation Trust and the Royal College of Nursing Fertility Nurses Group. The HFEA's own Licensed Centres Panel met three times during the year and the Authority had two meetings with the Association of Fertility Patient Organisations and three with our professional bodies stakeholder group, including one focused on the early development of our new strategy, which will be published during 2014.

We also established the Information for Quality Advisory Group which oversees our Information for Quality Programme (see below for more information about this).

We also continued to communicate current regulatory and policy news and information to the sector through our website, and through our monthly Clinic Focus newsletter.

Effective and transparent information

"To improve the effectiveness of the information we hold and collect, by reviewing our forms, validation rules and verification procedures, enhancing the clinic portal, reviewing the Choose a Fertility Clinic function, and increasing the transparency of publishable information."

[1] Available online at www.hfea.gov.uk/8350.html

Register Information and Intelligence

In 2013/14, we began work on a significant, two-year, Information for Quality (IfQ) programme to modernise how we collect and use information that forms the 'Register' of treatments. This major capital expenditure programme is designed to improve and modernise our underlying technology and our approach to Register data collection. We are reviewing the type and amount of information collected, exploring the way that data is submitted to simplify it, reviewing the regime for data validation and correction, and reviewing Choose a Fertility Clinic (CAFC).

Our intention in doing this work is to minimise the amount of time clinics spend on satisfying regulatory requirements at the expense of patient care. We want to ensure that necessary information is collected as efficiently as possible, and that the effort involved in ensuring data is of the right quality is proportionate as well as effective. Our emerging new strategy will also place central strategic importance on quality for the benefit of patients (and other stakeholder groups), and this programme of work will support the new strategy.

Crucially, while the IfQ programme will focus on changing and improving our ways of working with data, we have still continued the important work of maintaining the Register of treatments and outcomes and supporting clinics in reporting the current data-set in compliance with the law and by Directions. It is vital for patients, donors and donor-conceived people that Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions, and through validation and verification of Register entries.

Transparency

The HFEA receives and responds to a large number of different types of requests for data each year. We respond to requests for access to information we hold under various access and transparency regimes, and we publish required data regularly through data.gov.uk.

We also produce several publications describing and analysing statistical and other information from our Register, which is of interest to researchers and others.

'Opening the Register' requests continued to be met in a sensitive manner and within required time limits. We also responded to significant numbers of requests for information in relation to the Freedom of Information Act (FOI), the Data Protection Act (DPA), Parliamentary Questions, and the Information for Researchers regime.

This year, we redesigned and re-launched our Clinic Focus publication which provides regular information updates about HFEA work to clinics. Most of our planned work on developing the HFEA website will take place in the coming business year, as part of our two year IfQ Programme. This will enable us to redevelop our communications with external stakeholders to enhance patient feedback, improve transparency, and develop a more interactive dialogue with audiences. We will be redeveloping the HFEA website to make better use of feedback mechanisms, video and integration with social media platforms.

Responding to Government information requests

We responded to all requests for data returns and other central Government requirements, completing all returns fully and accurately within deadlines. All regular and ad hoc Government information provision requirements were met.

We also continued to publish required transparency information on the HFEA website and elsewhere. In so doing, we must always carefully balance transparency and accountability requirements against both general Cabinet Office and specific HFE Act data security considerations.

Managing change and seeking further efficiencies

"To ensure the organisation and its staff are equipped to deliver, and to continue to seek efficiencies through 'shared services' work and partnership working with other ALBs."

Equipping the Organisation

We continued to seek out efficiencies and savings, while maintaining a capability to deliver our core work. Our new people strategy will run alongside our agreed strategy and, in the course of the next few months, this will detail how we will ensure the organisation remains appropriately resourced and equipped, and can retain our staff capacity and capability needed for the future.

We participated throughout in Department of Health shared service developments, progressed further collaborative working with other regulators and the devolved nations, and continued our existing service level agreements with the CQC. Following considerable savings made in the previous two years, we further reduced our organisational size and continued to drive down our overall costs.

We also began to respond to the McCracken review of efficiency savings at the HFEA and the HTA. Further work on the McCracken recommendations is detailed later in this Business Plan.

Shared Services and Efficiencies

During the final quarter of 2013/14, after thorough preparation, the HFEA and HTA appointed a shared Director of Finance and Resources. A plan has been prepared to manage the transition and organisational changes to ensure continuity in both organisations. This process will be completed in the 2014/15 business year.

In addition there was further progress in the following areas:

Finance

An accounting system upgrade was completed that enabled a reduction in Finance headcount. Finance now has 2 whole time equivalent (wte) staff (down from 3.8), while sharing a Head of Finance with the HTA. Although the proposed move to the Independent Shared Service Centre 1 (ISSC1) will no longer take place, following a decision by the Department of Health in March 2014, the HFEA is prepared for any future collaborative working opportunities that may emerge over time.

Internal Audit

The HFEA internal audit service is provided under a Service Level Agreement (SLA) with the Department of Health Group Internal Audit Service, which provides similar services to an increasing number of other ALBs in the health family. A new co-sourcing contract was let for three years to Price Waterhouse Coopers (PWC) beginning in April 2013 and the first year's plan is in progress.

Human Resources

The SLA with the CQC for recruitment, some learning and development and occupational health services continued, with other activities sourced directly using the Government's central procurement service Crown Commercial Services (CCS). The HFEA retains the necessary strategic HR capability, and also provides ad hoc advice and support to the HTA free of charge.

Payroll

The HFEA's payroll arrangements have been outsourced for many years. The HFEA will consider whether there is any future benefit in using the same interface as the HTA for submitting information to the payroll provider, Frontier.

Facilities

The SLA with CQC for the provision of office and other services at Finsbury Tower was in place throughout the year. Having saved over £370,000 per annum by moving, the HFEA then benefitted during 2013/14 from a reduction in rates of 80% backdated to the date of our move. Consideration has begun of the SLA break clause in August 2016, aligned with that for CQC with the building owner. The last Facilities team post was relinquished during the year.

Procurement

In response to Government restrictions and increased mandating of procurement into CCS, the HFEA has either eliminated or reduced the need for services or moved major items of expenditure to CCS, including travel, communications, IT purchasing, office supplies, some of our staff training, agency and short-term hires and conference room bookings.

Legal Services

The HFEA migrated early in the 2013/14 business year to the new NHS Litigation Authority legal services frameworks. Three of the existing HFEA providers were appointed as preferred suppliers in August and two more firms were added as approved suppliers in January 2014. This provides more choice and flexibility and cheaper rates overall than the previous arrangements, which nonetheless had worked well for a number of years.

In general, the HFEA has continued to focus on the critical issue of workforce and capacity management throughout the ongoing changes, ensuring that sufficient human resources and organisational knowledge are retained, within the rules of the various centrally imposed restrictions.

We continued our participation in the collaborative 'Hubbub' Leadership Development Programme in a consortium of ALBs, in order to provide improved development opportunities for HFEA staff.

Our staff were kept fully informed on developments following the McCracken review.

We reduced the size of our Authority from 19 to 12 members from 1 April 2013, remodelling our governance arrangements to ensure that the capacity to make critical licensing and policy decisions was retained. These arrangements were successfully reviewed in the Autumn of 2013.

Partnership working with other ALBs

This year again saw a particular emphasis on working in partnership with other relevant ALBs. In addition to the various examples of joint working and shared services already referred to above, we worked extensively with the Health Research Authority to streamline the regulation and governance of research using human embryos or human admixed embryos, and the use of HFEA Register data in research. This will ensure good continuity of service now that the HRA has taken over the former function of the National Information Governance Board for Health and Social Care (NIGB) to provide an opinion as to whether the use of Register data in research is justified. The HFEA will in due course become a full partner in the Integrated Research Application Service (IRAS) so as to ensure that only one single ethics approval needs to be sought for each research application.

Facts and Figures:

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

Number of:	2012/13	2013/14
Active clinics and research establishments	132	131
Clinics and research establishments inspected	82	80
Licences inspected	89	89
New licence applications processed and presented to Licence Committee	3	10
Licence renewals processed and presented to Licence Committee/Executive Licensing Panel	38	40
Applications for Human Leukocyte Antigen (HLA) testing processed and presented to Licence Committee/Executive Licensing Panel	10	9
New PGD applications processed and presented to Statutory Approvals Committee	49	37
Incident reports from clinics processed	499	506
Alerts issued	0	1
Complaints about clinics received	2	9
Licensed Centres Panel meetings held	3	3
Meetings with patient organisations held	2	2
Public and stakeholder meetings	21	24
Freedom of Information (FOI) requests dealt with	69	82
Environmental Information Regulations (EIR) requests dealt with	0	0
Opening the Register requests closed within 20 working days	193	215
Information for researchers requests received	3	1
Donor Sibling Link applications processed	11	24
Visits to the Anonymised Register download page	776	779
Enquiries responded to under the Data Protection Act (DPA)	2	3
Parliamentary Questions (PQ) responded to	63	80
Authority meetings held (including two open to the public)	6	9
Unique visits to the HFEA website	643,731	979,078
Most popular/viewed page on the HFEA website	IVF - What is in vitro fertilisation (IVF) and how does it work?	IUI - What is intrauterine insemination (IUI) and how does it work?

Looking Forward to 2014/15

The HFEA's business objectives for 2014/15 are essentially a continuation of the previous year's objectives, in recognition of the fact that the organisation is part-way through a major two year programme of capital improvements (Information for Quality), and that organisational change initiatives started in 2013/14 will also continue for the duration of the next business year.

1. Ensuring high quality safe care for patients

To support the sector to provide high quality, safe care with the best possible outcomes, through policies and services that address the needs of patients, donors and donor-conceived people while also ensuring the effective delivery of statutory regulatory functions.

2. Increasing and informing choice

To improve the effectiveness of the information we hold, collect and provide, by reviewing our forms, validation rules and verification procedures, reviewing the Choose a Fertility Clinic function, and increasing the transparency of publishable information.

3. Managing change and providing best value

To ensure the organisation and its staff are equipped to deliver, while continuing to seek efficiencies and increase the value we offer as a public body.

These objectives are designed to ensure that the HFEA continues to regulate the sector to a continuing high level of quality, in the interests of patients, donors, donor-conceived people and our other stakeholders. The HFEA must also manage itself effectively as a responsible public body. We must ensure that our statutory duties are met, and are met well, for the ultimate benefit of both patients and the sector we regulate. We must also continue to be a reflective and open organisation that constantly seeks both improvements and efficiencies.

Building on previous work to ensure that we are an efficient and modern regulator, we will continue to review our own performance and effectiveness, and to decrease costs where we can.

Our new three year strategy, which will be published in mid 2014, will set out how we aim to drive up quality through the ways in which we set standards, provide information to inform choice, and deliver efficiency, economy and value.

This business plan will be revised later in the year, to better reflect the contents of the strategy, once it is published.

Business Objectives for 2014/15

For 2014/15, the HFEA has agreed the following activities and deliverables under each objective.

Objective 1: Ensuring high quality safe care for patients

To support the sector to provide high quality, safe care with the best possible outcomes, through policies and services that address the needs of patients, donors and donor-conceived people while also ensuring the effective delivery of statutory regulatory functions.

Statutory regulatory functions

We will continue to deliver our core inspection and licensing activities, to monitor the performance of centres, and to deal with incidents and complaints about centres, under the framework of the compliance cycle. Our focus on the quality of care that patients receive in clinics, and the way in which clinics and the HFEA respond to incidents and complaints about care, will be important aspects this year in keeping with our consideration of the first recommendation in the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Report). There will be ongoing monitoring of sector performance against the multiple births target maximum rate of 10% introduced in October 2012, so as to encourage a reduction in the associated risks for patients and children born as a result of fertility treatment.

Policies that support effective regulation and best possible outcomes

We will support the work of our Ethics and Standards Committee and the Scientific and Clinical Advances Advisory Committee, along with the annual horizon scanning process which helps us to remain responsive to emerging scientific developments in fertility treatment and related research. We will continue to maintain and, where necessary, update the Code of Practice containing guidance for clinics. We will also undertake various pieces of in-year policy development work, as required, to ensure that our policies are up to date and support our regulatory work with the sector. In particular we will undertake a range of work on donation and on storage consent.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Statutory regulatory functions	To maintain the compliance cycle of inspection and audit processes, and to continue licensing clinics.	Delivery of full programme of inspection and licensing, increasingly focusing on quality and safety of care.	Centres are appropriately inspected and monitored against published performance indicators, and issued with licences for up to 4 years. Assurance for the public and other stakeholders. Continued programme of unannounced inspections, commenced in 2012/13. Effective management and automation, through Epicentre, of administrative processes.	Throughout year
		Monitoring centre risks through the HFEA's risk based assessment tool.	Outputs from the risk tool continue to provide management information for both HFEA and centres, highlighting areas of concern and opportunities for improvement. Analysis of general clinic performance indicators and clinic responses to self assessment questionnaire (SAQ). Close to real-time monitoring of: treatment outcomes; multiple birth rates; completeness, accuracy and timeliness of register	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
			submissions; and payment of invoices and fees.	
		Maintenance of Compliance Directorate Quality Management System (QMS).	Processes remain standardised and consistent. Process improvements identified, documented and implemented when needed.	Throughout year
	To ensure that governance tools and documentation underpinning licensing and other decisions are in place and effective.	Ensuring that tools and procedures used by Licence Committees, the Executive Licensing Panel and other Authority Committees continue to be fit for purpose under new governance arrangements introduced in April 2013.	Documentation (e.g. decision trees and indicative sanctions guidance) continues to be up-to-date and effective.	Throughout year
	To maintain the HFEA's role as the UK's Competent Authority for assisted reproductive technologies (ART) in the European Union.	Attendance at meetings of the European Competent Authorities.	HFEA attends 2 meetings per year. Up-to-date intelligence gained about European perspective.	Twice per year
		Involvement in projects about the regulation of ART in Europe.	The HFEA contributes, as and when appropriate, to European projects, and ensures that its obligations as the competent authority are discharged.	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	That the multiple births maximum target rate of 10% is met.	Continual monitoring through the Risk Based Assessment Tool (RBAT). Workshops with the sector to reinforce and reinvigorate policy objectives.	Continued reduction in multiple birth rates. Monitoring and analysis of multiple birth rates and associated data (such as pregnancy success rates). Reports to the Authority, centres, and the Multiple Births Stakeholder Group. Continued clarity in the sector about the policy and its aims.	Throughout year September 2014 – March 2015
Effective policies	To ensure that patient views are better incorporated into the HFEA's work.	Through Corporate Strategy development and other means, to explore how the patient voice can be enhanced in all of the HFEA's work.	Increased understanding to enhance the HFEA's 'Information for Quality' Programme of work (see next objective). Increase in patient views about centres received by the HFEA (for example, to inform inspections). Patients consistently a central reference point in all relevant HFEA activities.	March 2015

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	To implement access to support services for applicants to the Register.	Ensuring counselling support is provided for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor conceived applicants receiving donor identifying information. Ensuring mediation services are in place for when donors and donor conceived people meet. Incorporating points raised at the stakeholder meeting held in June 2013.	Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people. OTR applicants will feel more supported and will be prepared to deal with the information they receive from the HFEA.	March 2015
	To continue to evaluate areas of regulatory concern, so as to identify levers for improving performance.	To identify and implement whatever actions are needed in each case.	Improvements in clinic compliance, resulting from HFEA evaluation and ensuing actions.	March 2015
	To continue to provide the sector with appropriate policy advice and guidance.	Update the Code of Practice to reflect latest policy and legislative developments.	New edition of Code of Practice.	October 2014
	To maintain an overview of emerging developments and the advisory mechanisms to support decision-making.	Support and inform evidence-based decision-making by the Authority through scientific, social and ethical horizon scanning and the maintenance of the Scientific and Clinical Advances Advisory Committee (SCAAC) and the Ethics and Standards Committee.	Emerging research and treatments considered and anticipated. Ethical and legal issues considered and anticipated. Future licensing and policy decisions informed by work.	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	To continue to support and inform the work of the National Donation Strategy Group established to help to tackle barriers to egg and sperm donation in the UK.	Establish Lifecycle website to provide information for donors and recipients about donation and treatment options. Continue to provide secretariat and financial support to the Group and generally to facilitate its work, including the 'Lifecycle' campaign.	Effective approaches developed to raising awareness of donation and improving the care of donors and donor-conceived people in the UK.	Throughout year
	To complete a scientific review of safety and efficacy of mitochondria replacement, as requested by Ministers.	To undertake a scientific review. Subsequent policy and licensing advice relating to draft regulations, upon request.	Report provided to Ministers as requested.	May 2014 Not yet known
	To conduct a review of issues with the current storage consent regime and consider future actions.	Information gathering about current practice in clinics with respect to the various types of storage consent. Supporting clinics to improve knowledge and understanding of storage consent issues.	The HFEA gains an understanding of current practice in clinics and the amount of variation in this. Clinics' understanding of storage consent issues and forms is improved, reducing their vulnerability to legal risks. Patients and donors have a better experience of being asked for storage consent, and feel fully informed. The HFEA is in a position to identify any future work that may be needed on the wider consent regime in future business years.	September 2014 March 2015 March 2015

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	To review import/export requirements and imported donor gamete compensation.	To undertake a project to review HFEA policy and its implementation. (This project, however, cannot start until a pending EU Directive on import has been finalised.)	Improved clarity for clinics, patients and donors. Improved internal clarity and refreshed procedures for HFEA Committees.	After EU Directive finalised (timescale not yet known)

Objective 2: Increasing and informing choice

To improve the effectiveness of the information we hold, collect and provide, by reviewing our forms, validation rules and verification procedures, reviewing the Choose a Fertility Clinic function, and increasing the transparency of publishable information.

Improving the effectiveness of the information we hold, collect and provide

We will modernise the HFEA's Register function and information collection processes, through a major capital expenditure programme of project work known as Information for Quality. This has been designed to review and simplify register forms submitted by clinics, reduce the amount of information collected, review the regime for data validation and correction, and review the verification processes for data published on the Choose a Fertility Clinic (CAFC) web page. Our intention in doing this work is to minimise the amount of time clinics spend on satisfying regulatory requirements at the expense of patient care. A set of business intelligence reports will be developed, to enable us to identify examples of good practice and inform the sector and others about these, thus supporting and motivating service quality improvements.

Increased transparency

We will continue to respond to requests for access to information we hold, under various access and transparency regimes, and to publish required data through data.gov.uk. We will produce a number of publications describing and analysing statistical and other information from our Register, which is of interest to researchers and others.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
‚Information we hold collect and provide	To modernise the HFEA's Register function and processes, through a major programme of project work (Information for Quality: modernising how we collect, use and publish information), involving stakeholders as appropriate.	Project to review and simplify register forms, and to articulate why remaining register fields are collected from centres.	Reduction in the data the HFEA collects about standard IVF/ICSI cycles. Corresponding reduction in data collection and submission workload for centre staff. Simplification of register forms. Amendment of all interdependent systems and forms. Increased understanding in the sector of why remaining data is collected.	March 2015
		Project to determine the scope for recalibrating the current data validation and correction regime. Development of a data quality assurance framework and data validation model.	More focused validation regime within an agreed assurance framework. Effort and impact involved in validation are proportionate.	March 2015

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
		Project to review the verification processes for and the content of the clinic outcome pages on Choose a Fertility Clinic (CAFC).	Reduced workload associated with production of CAFC pages (for both clinic and HFEA staff). Improved timeliness of data provided to prospective patients. Changes made without reducing usefulness or accuracy of published data.	March 2015
	To identify and articulate what quality means in the IVF sector, and what the characteristics are of centres that demonstrably deliver quality, so as to support and motivate service quality improvements.	Project to create this intelligence through the development of a set of business intelligence reports to identify trends, inform and support centres, and provide information on quality to stakeholders.	Increased business intelligence about success factors and quality indicators. Information for the sector, supporting clinics to improve their success rates. Better informed commissioning, through provision of information to NICE and to those commissioning fertility services.	March 2015

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	To maintain the Register of treatments and outcomes and to support clinics in reporting the data required by the law and Directions[1].	Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions, and through validation and verification of Register entries.	High quality data available to develop patient information, and to support risk-based regulation and evidence-based policy-making.	Throughout year
Increased transparency	To facilitate access to information under various regimes.	'Opening the Register' requests continue to be met in a 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), and Parliamentary Questions.	FOI Requests – 20 working days; DPA requests – 40 calendar days; Parliamentary Questions – varying deadlines, set by the Department of Health on a case-by-case basis	Throughout year
		Information provision for researchers requesting access to Register data.	Information for researchers provided within 90 calendar days of payment.	Throughout year

[1] Directions are issued to clinics by the HFEA and require licence holders to submit particular information.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	To continue to publish the information we hold, for the benefit of patients, researchers and other stakeholders.	Provision on the HFEA website of regularly updated 'Choose a Fertility Clinic' (CaFC) information, with a particular focus on assisting patient choice.	6 monthly verification and publication schedule to maintain provision of up-to-date information.	Throughout year
		To continue to publish statistical reports.	'Fertility Treatment in 2012' report presenting information about patients, treatments and results from 2011-2012; and 'Fertility Treatment in 2013' report covering 2012-2013. Statistical report on donation and donor conception.	March 2014 November 2014 May 2014
	As part of the Information for Quality programme, to redevelop our communications with external stakeholders to enhance patient feedback, improve transparency, and develop a more interactive dialogue with audiences.	To redevelop the HFEA website to make better use of feedback mechanisms, video and integration with social media platforms. To enhance patient feedback via the website and through inspection, exploring the potential for using other data sources.	Completion of redesigned HFEA website.	March 2015

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
	To continue to supply required data in response to a range of central Government requests for returns, and to respond to Department of Health requests.	Respond to all requests for data returns 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

Objective 3: Managing change and providing best value

To ensure the organisation and its staff are equipped to deliver, while continuing to seek efficiencies and increase the value we offer as a public body.

Efficiencies and savings

We will continue our efforts to seek out as many efficiencies and savings as we can. This will include further collaborative working, and a continuation of service level agreements with other ALBs. Following considerable savings made in the previous four years, we will continue to seek efficiencies and drive down our costs, while also ensuring we maintain the level of resources and the types of skills needed to deliver our programme of work. We will also continue to respond to the McCracken review of potential efficiency savings at the HFEA and the Human Tissue Authority (HTA), which reported to Government in 2013. The Authority agreed an action plan in response the McCracken Report's recommendations in September 2013, and this is included in full below.

Partnership working with other ALBs

This year will continue to see a particular emphasis on working in partnership with other relevant ALBs. This will include continued working with the Health Research Authority (HRA) to ensure that the regulation and governance of research using human embryos or human admixed embryos remains as streamlined as possible. We will also continue to work with the HTA and the Care Quality Commission (CQC) to ensure that our regulatory processes are neatly aligned and do not result in duplication of effort for centres, or for either regulator.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Efficiencies and savings	To continue to seek opportunities for shared services and efficiency savings with the Human Tissue Authority (HTA), the Care Quality Commission (CQC) or other organisations.	More developments in the area of shared Finance staffing provision arrangement with the HTA.	Ensuring the HFEA's financial and HR systems and processes are as efficient as possible.	March 2015 and beyond
		Continue with the Service Level Agreement (SLA) with the CQC for certain HR services, and use Civil Service Learning as a key learning and development provider.	SLAs in place, monitored and managed. HR support for recruitment, some learning and development and occupational health in place. Strategic HR function retained by the HFEA. Quantifiable ongoing efficiencies made by HFEA.	Throughout year
		Continue to receive support services from the CQC, via the existing SLA.	Facilities services fulfilled; SLA in place, monitored and managed. Working relationship facilitates a range of other initiatives, e.g. the HR and Facilities SLAs, and the ad hoc arrangement with the HTA for strategic HR advice and guidance, referred to earlier in this Business Plan.	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Collaborative working with other ALBs	To continue to explore opportunities for strategic alignments and co-ordinated working with other relevant bodies.	Embedding new inspection methodologies and information sharing procedures that have been introduced as result of collaborative working with CQC. Continuing to develop joint working procedures and to embed information sharing agreements with HTA.	Effective regulatory oversight of clinics in England after their deregistration with CQC. Reduction in regulatory overlap between CQC and HFEA. Joint inspection of facilities licensed to do stem cell research that are also regulated by the HTA, to minimise regulatory overlap. Development of a culture of information sharing that ensures that all relevant regulatory partners are aware of concerns about providers and that actions in relation to concerns are co-ordinated and proportionate.	Throughout year (ongoing work)

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
		Working with the HRA to ensure continuity of service now that the HRA has taken over the former function of the National Information Governance Board for Health and Social Care (NIGB) to provide an opinion as to whether the use of Register data in research is justified.	Continuity of service for Register research decisions safeguarded. Researchers make one single application and obtain one single ethics approval. Memorandum of Understanding in place to ensure the HFEA and the HRA have an agreed, integrated approach in place. IT systems maintained so that the HFEA can receive research applications from the IRAS system.	Throughout year
		Working with the HRA, HTA, MHRA and other relevant bodies to ensure that the regulation of stem cell therapies, from research to development to clinical application, is streamlined (for example as a 'one stop shop') and has clarity.	The HFEA ensures that the regulatory landscape is as good as possible. Effective and sensitive regulation is ensured.	Throughout year
		Continued discussions with regulatory bodies in the devolved nations.	Joint working protocols and MoUs where appropriate. Increased understanding between organisations about what information should be shared and in what	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
			circumstances. Alignment of organisational processes and standard operating procedures (SOPs).	
		Working with the Medicines and Healthcare Products Regulatory Agency (MHRA) and UKAS (the UK Accreditation Service, which is the body that accredits laboratories that provide services to HFEA licensed facilities) to establish effective working relationships and, where relevant, information sharing agreements.	Greater co-operation and sharing of skills and knowledge between bodies, for the benefit of patients and the regulated.	Throughout year

McCracken Review - Action Plan

In addition, in September 2013 the Authority agreed an action plan in response to the recommendations in the McCracken Review of the HFEA and the HTA. Much of this work will be completed before the start of the 2014/15 business year, but it is recorded here in its entirety, for completeness:

Heading	Theme	Recommendation	HFEA Actions	Timescale
McCracken Review	**Shared services.** *(Links to Objective 3 above.)*	**Recommendation 2:** The support services of the two bodies (the HFEA and HTA) should be combined and managed by a single Director of Finance and Resources supporting both Chief Executives. This will facilitate the achievement of significant further efficiency savings, estimated at £2.8M over 10 years.	In 2013, the HFEA and HTA reached agreement on the scope of the support services to be shared (including: finance, procurement, audit, business continuity planning, facilities). A new shared Director of Finance and Resources took up post in March 2014.	Delivered March 2014
	Stakeholder engagement. *(Links to Objective 2 above.)*	**Recommendation 4:** In order to improve transparency, both the HFEA and the HTA should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings.	A stakeholder survey was commissioned in February 2014 to understand better perceptions of the HFEA, its work, and to gather views about possible improvements. The findings of the survey will then inform a stakeholder engagement plan which will be presented to the Authority later in 2014. The stakeholder survey will be rerun in Autumn 2014 to assess progress.	May and October 2014

Heading	Theme	Recommendation	HFEA Actions	Timescale
		Recommendation 13: The HFEA should review its approach to engagement with its stakeholders and should publish an action plan within 6 months. In 12-18 months' time the HFEA should undertake a structured and anonymous stakeholder attitude and satisfaction survey, and publish the results and associated action plan.	See recommendation 4 above.	See above.
		Recommendation 5: Both the HFEA and the HTA should establish and operate a (permanent) fees review group to improve accountability and facilitate dialogue with licence fee payers.	The fees review group will be established. Preparations have been made, and the group will be set up during 2014.	August 2014
	Better use of Information. *(Links to Objective 2 above.)*	**Recommendation 6:** To reduce unnecessary regulatory burden the HFEA should proceed without delay with its planned fundamental review of information requirements, using the BFS/ACE paper as the basis for discussion, and adopting for the project an inclusive approach similar to that used successfully in the "One at a Time" project. The HFEA should publish the Project Initiation	A work programme entitled 'Information for Quality: modernising how we collect, use and publish information' was set out in a scoping paper in August 2013. The Programme is being overseen by an Advisory Group, chaired by Alan Thornhill (Authority member), drawing on a wide range of stakeholder expertise. The group was established in	March 2015

Heading	Theme	Recommendation	HFEA Actions	Timescale
		Document for this work by July 2013 and then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1M.	October 2013 and progress has been reported to each Authority meeting since. The group has established expert sub-groups to advise on project details. Programme to be completed by end of 2014-15 business year.	
		Recommendation 7: On completion of the review of information requirements the HFEA should establish inclusive projects (a) to review whether further use could be made of the information in its statutory Register to promote public understanding and facilitate more research into issues pertaining to ART; and (b) to identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART.	For (a), the recommendation assumes completion of Recommendation 6 before beginning work. Progress is possible on (b), meanwhile. HFEA staff met a range of external stakeholders in June 2013 to discuss, amongst other donation issues, information and support for people seeking information from the Register. With widespread support from the stakeholders present, it was agreed that a project to scope out the possible models for support be started. Options presented to the Authority in March 2014.	After the work above has completed (2015/16) Project initiation work commencing

Heading	Theme	Recommendation	HFEA Actions	Timescale
	Working with other regulators. *(Links to Objectives 1 and 3 above.)*	**Recommendation 8:** In order to improve the approval process for research projects involving gametes and embryos the HFEA should commit to participating fully in the new IRAS system from its launch in 2014 (and to cooperating fully with the other bodies involved), and should make adequate resources available now to prepare for it.	Discussions with the HRA were already well advanced. An agreement was reached in November 2013 with the HRA that the HFEA will participate in the new IRAaS system when it launches.	Completed in November 2013
		Recommendation 11: The HFEA should clarify to all concerned how it cooperates with the MHRA to achieve effective joint working on matters falling within the latter's regulatory oversight but which take place within premises regulated by the HFEA.	An information sharing agreement between the HFEA and the MHRA has been agreed. It covers: • The exchange of information on medical devices used in ART • MHRA Field Safety Notices and other information sent to users by the manufacturer • HFEA Grade A incidents which involve medical devices. MHRA/HFEA collaboration has already resulted in CE Marking Guidance being issues to licensed clinics.	Completed in October 2013

Heading	Theme	Recommendation	HFEA Actions	Timescale
		Recommendation 12: The HFEA should implement their agreement with the CQC, which was approved by the HFEA during my review, to eliminate duplication of regulatory activity between them.	The HFEA / CQC agreement on this came into effect on 1 October 2013.	Completed in October 2013
	Regulatory focus. *(Links primarily with the HFEA's new Corporate Strategy, which is in development for 2014/15; and also with Objective 1 above).*	**Recommendation 10:** The HFEA should conduct a review of the balance of its regulatory focus to ensure that it reflects the relative risks of the different activities that it oversees. Its approach should reflect the relative maturity of the sector it regulates now, the need to ensure appropriate oversight of technical developments in the field of ART, the need to ensure that appropriate standards of practice are implemented consistently throughout the sector, and the continuing need for a high degree of public assurance regarding the sensitive activities that it oversees. This should not lead to any overall increase in regulatory activity or cost, but a rebalancing of activity.	The new HFEA Strategy will address directly the issues of regulatory focus. Consultation on aspects of the strategy was issued online on 10 February 2014. The finalised Strategy is expected to be in place by mid 2014.	By June 2014

Corporate Enablers and Resources

Introduction

In addition to the objectives set out in the previous section, it is important to acknowledge the underlying core strategies, activities and functions without which the HFEA would be unable to deliver this Business Plan and the ongoing change management work over the coming year.

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 an HR framework, business continuity plan and corporate governance tools. It is important for the HFEA to be able to maintain its governance structure, to ensure high standards of records management, to conduct its corporate business and workforce planning in an organised and rational way, to produce an Annual Report and other required documents to sufficient quality, to respond to information requests from central Government, and to manage organisational risks and performance.

Similarly, it is critical to the smooth functioning of the organisation that we maintain our relationships with stakeholders, ensure our website is up-to-date and accessible, meet our responsibilities under the Equality Act 2010, manage our internal communications systems and messages and continue to respond to media and public enquiries. We must also ensure that we perform necessary maintenance of the Register of treatments and other critical systems. Many of these areas must be maintained while also being the focus of particular project or developmental work throughout the period covered by this Business Plan.

In general, the HFEA is continuing to work collaboratively with the HTA, the HRA, the CQC and other ALBs, further building on positive relationships established in previous years. We continue to work across the Department of Health ALB family to explore potential synergies and opportunities for our organisations to work more closely, where this would be of mutual benefit.

Organisation Design and Development

Having made some small changes to our organisational structure in 2013/14 we will ensure that any further changes reflect the needs of our new three year Strategy. Similarly, our new People Strategy will also align with the overall Strategy in order to attract, retain and develop a high quality and flexible workforce, that will help ensure the HFEA achieves its strategic aims, within agreed budgets and Government rules.

This approach will enable us to ensure we deliver all the activities in this business plan, and to ensure that the changes we are making in response to the McCracken recommendations are implemented well. We will also further develop our people, for example through collaboration with others in learning and development activities.

Our internal Programme Board and Programme Management Office (PMO) help us to manage projects more efficiently and effectively, and this will continue to be important in 2014/15. Our two year capital expenditure programme, Information for Quality (IfQ) is served by its own programme structure, which sits alongside the

HFEA's overall programme management arrangements, with project assurance provided by the establishment PMO.

At the end of 2012 we reduced the size of our Authority from 19 members down to 12 members. A smaller board size is now widely recognised to be more effective. Achieving this reduction at the HFEA required a change programme to manage the transition to different governance and decision-making mechanisms. The revised arrangements are working well and will be subject to regular review.

Internal Audit

The HFEA will continue to be part of the Department of Health Group Assurance framework and to work with the newly appointed co-sourcing provider on completing the internal audit plan for 2013/14 and preparing and delivering the plan for 2014/15. It is possible costs may come down over the next few years as the framework helps drive systemic risk out and improves levels of assurance for the Group.

Financial Management

Overall, the recurring cost of the organisation continued to fall in 2013/14. In that year we received Grant-in-aid from the Department of Health at a reduced level of £1.3m, which included programme support for our fee discount for elective Single Embryo Transfer of £0.3m. Our total estimated revenue costs for the 2013/14 financial year are £5.4m (compared to a revenue budget of £6.1m in 2012/13). An additional allocation of an initial £0.7m for a Capital Expenditure programme (Information for Quality) was agreed, for work which began in 2013/14. This work will continue throughout 2014/15, and is funded from the HFEA's own resources. A further, similar amount for the planned website development aspects of this programme is expected to be agreed around the start of 2014/15.

The HFEA has continued, and will continue, to maintain sound financial governance and business planning processes. We will continue to seek further efficiencies and introduce quality processes and to continue to develop collaborative relationships and shared services with other bodies to improve economies of scale. The critical aspect is the continued capacity of the HFEA to maintain delivery of its functions as set out in law.

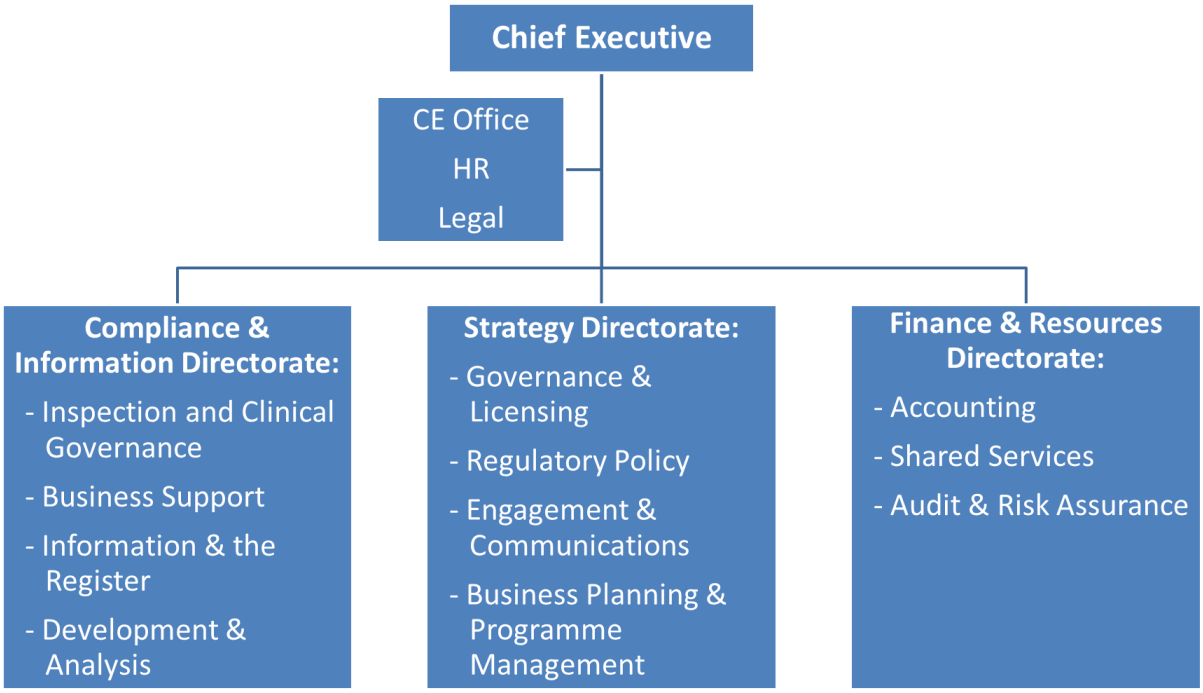
We have automated our billing process in 2012/13, introducing an upgraded accounts system in 2013/14 and extending its features to allow non-finance users and budget managers to carry out online transactions for procurement and expenses. This has almost eliminated duplicate data entry, reduced paperwork considerably and improved the accuracy of many transactions. For an investment of about £40,000, the recurring annual savings will be about £80,000.

Establishment and Resources

The HFEA has gradually reduced its staff complement over the past several years, from 86 in 2010/11 down to 69 by the end of the 2013/14 financial year, by continuing to make efficiencies and to share services, where feasible.

As mentioned earlier, we have now established a shared staff model with the HTA in relation to finance and resources. The following diagram shows the HFEA's current organisational structure.

HFEA Organisational Structure:



Equality Act 2010

The HFEA remains compliant with the requirements of the Equality Act 2010. There is an Equality Champion on the Authority. We will collectively continue to ensure, throughout the year, that the HFEA fulfils its obligations under the Equality Act.

Human Resources (HR)

Over the coming year our new People Strategy will enhance our already sound HR practices, and we will make adjustments and improvements to procedures and processes where it is evident that these would enhance our ability to meet our strategic objectives.

Our new Strategy will also provide for a greater emphasis on organisational development activities, including performance review and personal and key skills development.

The HFEA's learning and development activities will be continued (as far as possible, given procurement restrictions) so as to equip our staff with the skills they need. Services will be procured in accordance with continuing Government requirements to ensure value for money, using Civil Service Learning, other ALB or CQC provision or the Crown Commercial Service (CCS) as appropriate.

Together with the other ALBs, during 2014/15 we will continue to participate in a Talent Management Consortium across the sector which aims to provide cost effective leadership development programmes and other development opportunities.

All staff pay is determined in line with HM Treasury annual guidance. The HFEA adheres to the formal pay remit when it is announced.

The HFEA will continue to comply with data requests and publication of data arising from the Government's transparency agenda.

Required HR Benchmarking Information:

In common with other ALBs, the HFEA is required to maintain a record of the following standard benchmarking data:

Very Senior Manager (VSM) to staff complement ratio	1:19
Number of staff earning more than £142,500 now and any planned change during the next planning period	0
HR staff to employee ratio	1:45
Training budget as a percentage of pay bill	2.0%
Projected reductions in non payroll staff	No non payroll staff[1]

Through our performance management scorecard, we track standard HR operational metrics, such as sickness absence and staff turnover. This scorecard is reviewed regularly by the Corporate Management Group (CMG), and is also considered at regular Department of Health Update meetings.

Our sickness absence target is no more than 3% staff sickness absence rate per month, and this figure is rarely exceeded. The public sector sickness absence rate average is 8 days lost per person per year. This translates to a public sector sickness absence rate of 3.5% (IRS Survey 2011).

Our staff turnover is closely monitored. Our performance indicator target for this is to achieve less than 16% establishment turnover for the year (this is the public sector average). The current figure is worked out on a rolling basis each month. Planned reductions (e.g. redundancies to reduce our staffing complement) are excluded from our turnover figures. Typically, our month-by-month turnover figure varies between 10% and 20%. We also record any variations in our overall headcount in each month (rather than specifically recording recruitment figures, since in such a small organisation, recruitment is typically at a very low level, and sometimes at a zero level).

[1] Delivery of the Information for Quality (IfQ) Programme (capital expenditure) will include the appropriate use of some non-payroll staff for additional resource and flexibility. The business case for this work has been agreed with the Department of Health. There will be no net increase to our establishment headcount, although there may be instances where non-payroll backfill is necessary so that an existing establishment staff member can deliver aspects of the capital programme of IfQ work.

Information Technology (IT)

The HFEA has an IT project pipeline plan 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.

HFEA databases are held on highly secure servers within the premises. The move to the same premises as the CQC necessarily entailed sharing a communications room on-site to house the servers. Security measures are in place so as to ensure that Section 33A patient-identifying data is appropriately protected.

The HFEA is investigating the possibility of leveraging the services provided by both the G-Cloud and IMS3 Shared Service, to reduce ICT costs and complexity. We will continue to monitor opportunities arising from these.

Data Security and Data Transparency

The HFEA is fully compliant with Cabinet Office rules regarding data security and with its own legislative requirements regarding confidentiality of information under the HFE Act.

The robust information security arrangements the HFEA has in place, in line with Cabinet Office Security Policy Framework requirements, include a Security Policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards. All staff complete the annual mandatory training on information security, and new starters complete 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 organisation also regularly publishes all required spending data openly, in the required file format, via data.gov.uk. Committee and Authority papers, and a wealth of other information, are routinely published on the HFEA's public website.

Assurance Framework

The new Framework Agreement agreed with the Department in early 2014 sets out the critical elements of the relationship between itself and the Department, and other ALBs where relevant. As an ALB, the HFEA will continue to manage its assurance and risk management independently and report this to the Authority. The HFEA recognises that, on rare occasions, its risks or assurance may have a significant impact or interest within the Department and understands the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

Business Continuity

The HFEA has further developed its business continuity plan, which is regularly updated and periodically tested. The HFEA worked with the Emergency Planning College in 2013 to appraise alignment against the relevant standards. The disaster recovery site is now operational. The HFEA has an inter-dependency with the CQC with regards to building-related and system matters. The HFEA is participating in the

Department work to improve consistency and to pool resources so that the Department and the ALBs have a proportionate level of business continuity.

Estates Strategy

The HFEA office strategy remains to be a tenant or co-tenant of a larger Department of Health organisation. The current office space of 525 square metres has been recently rezoned to better align with the new organisation, improve flexibility ('hot' desks) and enable better use of space (with smaller desks). It is not possible to meet the benchmark of space per full time (equivalent) employee of 8 m^2 or below, for permanent staff but the HFEA will need to accommodate a series of short-term workers during the capital programme that has started.

The HFEA and the CQC will continue to work together on health and safety services in Finsbury Tower. The HFEA has adopted the CQC's online system for individual workplace assessment, and meets with the CQC lead on fire evacuation procedures and fire warden liaison.

There is a lease break for CQC in May 2016 for Finsbury Tower. The HFEA tenancy could end then or in August 2015, if sufficient notice is given. Early consideration of office requirements and any essential or desirable co-locations or other features will need to begin in 2014/15.

Sustainable Development

The HFEA recycles paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges. We have two multi-function devices (for secure printing, scanning and photocopying) that are pre-set to print on both sides of the paper and in black-and-white. Our IT equipment is re-used and working lives extended where possible, and is switched off when not in use. Surplus equipment is either sold or donated. The proportion of staff enabled to work from home has increased, allowing reduced travel impacts, where feasible. The HFEA does not procure energy or other items with significant environmental impacts.

Procurement

The HFEA is fully cognisant of Department of Health and Cabinet Office efficiency controls, and follows these. Where it is the purchaser, the HFEA procures the 9 mandated procurement categories from Government or other public sector frameworks: Energy (N/A), Office Solutions, Travel, Fleet (N/A), Professional Services, eEnablement, Property (N/A), ICT, Advertising and Media, Print and Print Management and Learning and Development. In addition, Legal Services and conference and events bookings became so frameworked in 2013/14.

The HFEA is aware of the green agenda in relation to procurement. However, the HFEA almost never sets its own contract terms or does purchasing directly and is dependent on CCS and other framework holders for integrating sustainability features in their contract letting.

Nearly all of the HFEA's procurement is done through CCS. So, as far as we are able, we aim to meet the Government target of 18% of procurement spend going to SMEs but we are dependent (as with sustainability) on CCS ensuring that SME

suppliers are present on the relevant frameworks in the first place. Where the HFEA has a choice of supplier, our criteria do include both sustainability and SME usage.

The HFEA is too small to have a procurement pipeline. In April 2014, the HFEA reviewed its contract for Multi-Function Device printers (MFDs). There are only two such printers in the HFEA offices, so this was an extremely small transaction. The only potential procurement of significance in the coming year will relate to the capital programme of work, Information for Quality, for which a business case has been accepted by the Department of Health. Full planning of this programme is under way using CCS frameworks. There is no significant non-pay spend that is not via CCS, CQC or DH frameworks or contracts – the one notable exception is the hire of QCs for legal actions. Frameworks therefore account for around £1.4m of the annual procurement budget of about £1.5m (including office rent, rates, travel, IT and audit costs). The HFEA also has no significant spend on contingent labour or consultancy services.

The overall resource position for the 2014/15 financial year is set out in the next section.

Financial Picture 2014/15

Overview

The HFEA has been successfully making efficiencies and reducing Grant-in-aid and headcount, whilst maintaining or increasing output, for several years.

The table overleaf displays the overall budget profiles for the last few years, showing a significant downward trend, with total costs down by over a quarter since 2010/11. The total turnover for 2014/15 shows little change from 2013/14 as existing changes are unlikely to have a major impact on short-term headcount or costs. However, current work – particularly the Information for Quality (IfQ) programme – may have an impact on headcount and costs beyond 2015/16. There is also a potential office move in 2016. These and the uncertain relationship between Grant-in-aid and fee income make indicative 2016/17 figures unrealistic at this time.

The headline recurring budget is £5.1m for 2014/15, with an expected IfQ budget of £1.2m from our own resources. Approval for the second stage of the IfQ project (due to start in September 2014) is being sought. This will permit the necessary redevelopment of our website and the digital services we can offer the public, patients and clinics.

Income Assumptions

The vast majority of fee income arises from individual IVF treatments in regulated clinics. In aggregate, these are intended to cover the costs of managing licences, inspection and regulatory activities and associated statutory information flows. In recent years, the numbers of treatments have increased by 6% per year, on average. This enabled the HFEA, in October 2011, to cut its treatment fees by 28% to reflect that its costs were spread over a much higher number of treatments. The growth in treatment numbers then stalled, leading to setting a 2013/14 budget with no increase over the actual for 2012/13. Growth in treatment numbers has now resumed, although it remains volatile month by month.

If growth continues, a treatment fee reduction may be considered when the Fees Review Group, recommended by the McCracken Review, meets later in 2014. This and further fee changes are heavily interdependent with the level of Grant-in-aid.

Routine licensing is a small element of income.

The remainder (i.e. other than fees) comes from the Department in the form of Grant-in-aid. There are three elements to this:

1. Revenue, administration – costs support for the corporate parts of the HFEA which support, or are deemed to support, the Department and Government, for example in answering Parliamentary Questions
2. Revenue, programme – the eSET fee discount is designed to provide a small incentive in support of the policy of avoiding unnecessary multiple births. The Department support for funding this discount is to disappear by 2015/16
3. Capital, administration – a small budget for replacing routine ICT equipment (£30k).

Cost Assumptions

The core assumptions are that there will be no further significant savings in:

- People, at least until the IfQ programme is complete and the People Strategy which will support the new three year HFEA Strategy begins to be implemented
- Offices, at least until a plan is developed and realised in response to the lease break for the current building.

Reductions and efficiencies will continue to be sought in other costs, but these are likely to be small in scale. For example, using the new NHSLA legal services framework ought to result in the need for a smaller budget due to lower rates, provided our need for legal support stays the same or decreases. Using framework suppliers and collaborating with other ALBs for training has enabled us to maintain training but at lower cost.

Year	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16
Headcount	79 (86 at start)	73	71	69	67	67
Non-payroll staff	3	2	0	0*	0*	0*
Total £m Programme Admin.	8.0	6.6	6.1	5.4* 4.3 1.1	5.1* 4.2 0.9	*(To be confirmed)*
Grant-in-aid £m Programme Admin.	2.4	0.7[#]	1.3	1.3 0.2 1.1	0.9 0.0 0.9	*(Not yet known)*
Plus £m IfQ	N/A	N/A	N/A	0.3	1.2	*(Subject to a business case)*

* This excludes the annual budgets and short-term hires for Information for Quality (IfQ) Programme, so as to present a clearer year-on-year recurring view.

[#] An unusal year when the Department withdrew £0.7m of budgeted Grant-in-aid.

Grant-in-aid included eSET fee discount support peaking at £0.3m in 2013/14 and then ceasing (the HFEA will fund the future discount).

Authority and Committee Costs

Since the Authority now numbers 12 (down from 19 in 2012/13), direct fees have reduced in total but this is partly offset by more frequent meetings, so higher travel costs per person, and increased involvement for advisors or staff. The overall effect is a small reduction.

Budget Summary

2014/15 Budget	
Item	£m
Costs:	
Salaries (Headcount by year end of 67)	3.4
Training and other staff costs	0.1
Travel and subsistence	0.1
Recruitment, maternity, long term sickness	0.1
Total staff costs:	**3.7**
Printing and telephones	0.2
Offices	0.2
Service charges	0.1
Publications, events, web and media	0.2
Total office costs:	**0.7**
Legal fees	0.3
Audit fees etc.	0.1
Total non-staff legal and governance costs:	**0.4**
Members	0.3
Total member costs:	**0.3**
Total revenue costs:	**5.1**
Capital:	
IfQ	1.2
Total capital costs:	**1.2**
Total operating costs 2013/14:	**6.3**
Total costs for year:	**6.3**
Income:	
Clinic fees	4.0
EUTCD fees	0.1
Licences	0.1
Grant in aid revenue	0.9
Grant in aid revenue eSET	0.0
Grant in aid capital	0.0
Use of Reserves	1.2
Total income for year:	**6.3**

Performance Indicators

Performance Indicators:	Target 2013/14	Performance 2013/14
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.	70 working days or less	68 working days
Percentage of PGD applications processed within 4 months (88 working days).	90%	97%
B. Communication and Information		
Opening the Register requests responded to within 20 working days.	100%	100%
Requests for contributions to Parliamentary Questions answered within Department of Health deadlines.	100%	100%
C. Corporate		
Staff sickness absence rate (%) per month.	Under 3.0%	1.3%
Cash & Bank Balance.	To continue to move further towards DH recommended limit of £750k	£2,800k
Percentage of invoices paid within 30 calendar days.	95%	92%[1]
Debts collected within 60 calendar days.	85%	88%

Performance targets for 2014/15 will be set once the HFEA's new three year strategy has been agreed, in mid 2014. Meanwhile, we continue as always to record and monitor a wide range of performance information (including all of the above indicators) on a monthly basis.

[1] Due to accounting systems changes and the Finance team restructure 45 invoices were paid beyond the 30 day target.