HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Human Fertilisation & Embryology Authority

Business plan 2015-2016

Contents

Our role and strategic aims

Who we are

The HFEA is the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

Our vision for 2014–2017 is:

High quality care for everyone affected by assisted reproduction

High quality care means…	safe, ethical and effective care and treatment support for patients, donors and donor-conceived people excellent service and information from the HFEA.
Everyone affected means…	patients and parents all those conceived through assisted reproduction donor-conceived people egg and sperm donors clinic staff.
Assisted reproduction means…	standard fertility treatments genetic testing and new treatments innovations in research.

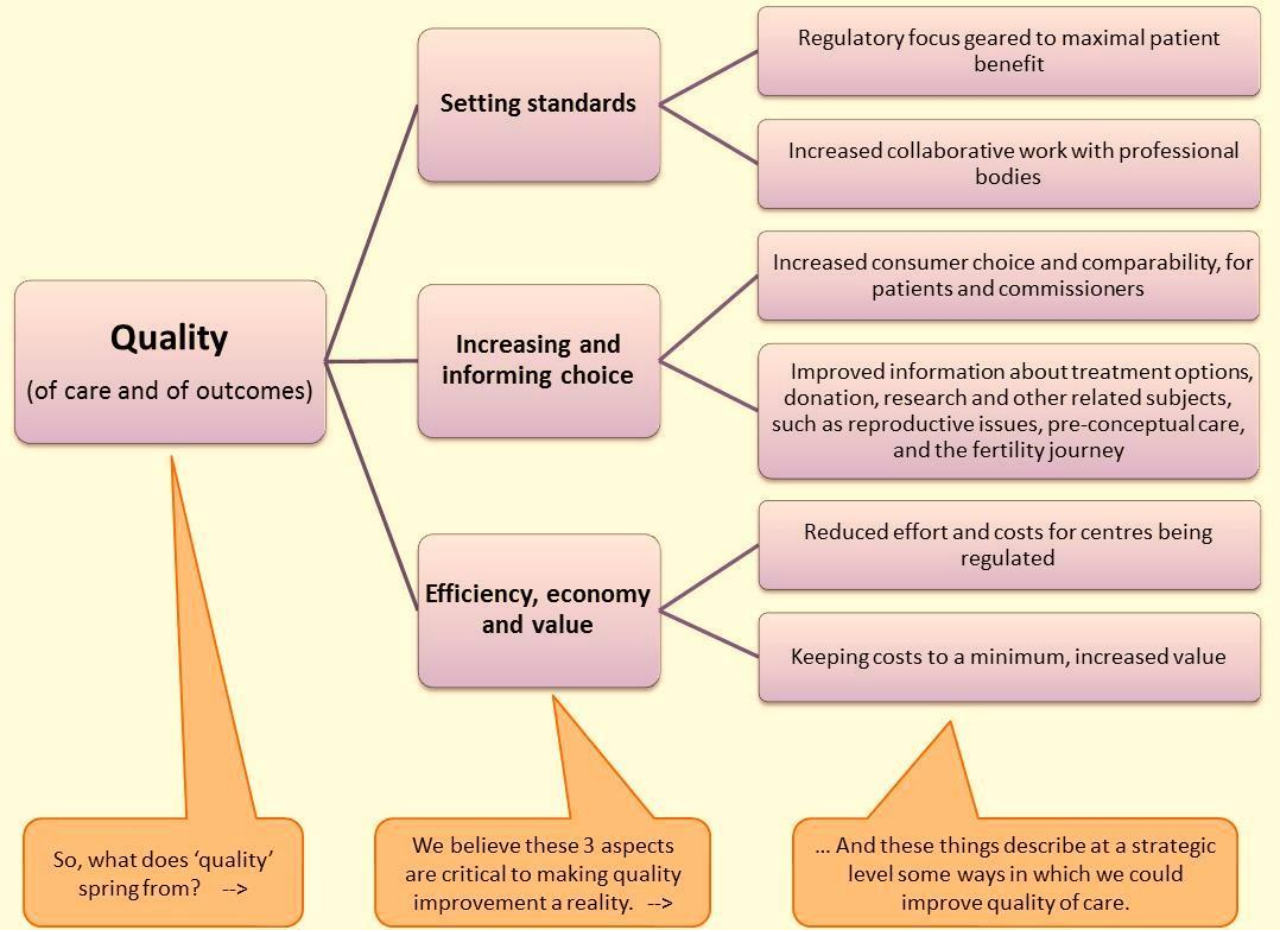
This business plan sets out how we will work towards this vision in 2015/16.

What can we do to achieve high quality care?

We believe that, as the regulator, there are three different means through which we can improve the quality of care:

- 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.

The following diagram illustrates this.



HFEA strategy 2014–2017

Our strategy for 2014–2017, published in July 2014, sets out our vision and how we will achieve it by utilising the quality channels available to us, as described above.

We have set out five strategic objectives that will collectively deliver the vision:

Strategic objectives	Setting standards	
	We will improve the quality and safety of care through our regulatory activities.	By… • Making the patient experience integral to the way in which we assess clinics' performance. • Seeking patients' views, and understanding their perspective, as part of the way we work. • Publishing more HFEA data to drive improvements in clinic performance. • Acknowledging that treatment is often unsuccessful. • Working with professional groups to improve treatment success rates.
	We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception and their wider families.	By… • Providing information about donor conception directly to patients and donors through the Lifecycle campaign. • Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider. • Ensuring that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation. • Collecting and publishing information regarding donor egg and sperm availability in the UK, and addressing impacts for patients (for example, by providing more information about the implications of treatment abroad).

Strategic objectives		
	Increasing and informing choice	
	We will use the data in the HFEA Register of Treatments to improve outcomes and research.	By… • Improving the presentation of clinic comparison information on Choose a Fertility Clinic (CafC). • Working with NHS commissioning bodies to ensure that they commission the best services using available data.
	We will ensure that patients have access to high quality meaningful information.	By… • Improving HFEA information about treatments available, scientific research, embryo and stem cell research and other fertility subjects, including reproductive issues, pre-conceptual care. • Working with clinics and scientific experts to publish information about new treatments. • Enhancing CaFC by including user experience scores. • Ensuring that clinics prepare and support patients and donors through the information they give them. • Collaborating with professional stakeholders to put patients in touch with better information and the right sort of care when they first realise they may have a fertility issue.
	Efficiency, economy and value	
	We will ensure the HFEA remains demonstrably good value for the public, the sector and Government.	By… • Ensuring we are easy to deal with and that we offer a professional and cost-effective service in all that we do. • Modifying our ways of working to ensure we are responsive, agile, innovative and effective in achieving our strategic and statutory goals. • Improving the methods used to submit and verify Register data.

In order to implement the above strategic objectives, we are planning to carry out a number of activities and projects, which are set out later in this business plan.

How we work

Our strategy also sets out our ways of working, which are as follows:

- We will make the quality of care experienced by patients, donors and donor-conceived people our central priority and the primary consideration in our decision making.
- We will consult and collaborate widely – listening to, and learning from, those with an interest in what we do.
- We will communicate more with stakeholders before making decisions and explain those decisions more clearly.
- We will take the time to implement decisions with appropriate stakeholder involvement, piloting new initiatives when appropriate.
- We will keep abreast of scientific and clinical innovations and actively consider what these might mean for the future quality of care.
- We will be a more agile and flexible organisation, changing course if needed in order to be responsive (both to stakeholders and to new priorities).
- We will continue to exercise our statutory functions consistently, proportionately, openly and fairly.
- We will observe the highest standards of integrity and professionalism in putting into effect the law as it governs the fertility sector.
- We will continue to treat people and their information with sensitivity, respect and confidentiality.

Our legislation and functions

The following information is provided to give a complete picture of our purpose and core functions, which are defined in law by the following two acts of Parliament:

- The Human Fertilisation and Embryology Act 1990 (as amended) – generally referred to as 'the 1990 Act'; 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 our duties and responsibilities. However, the 2008 act also contained new provisions which were not included in the 1990 act. In particular, these include provisions relating to legal parenthood.

The 1990 act (as amended) gives us 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.
- 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 gives us 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 we should follow when conducting our 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 our 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.

We also function 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.

Our work in 2014/15

What we did in 2014/15:

Delivery of the 2014/15 business plan:

Ensuring high quality, safe care for patients

Objective:

"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."

Improving the quality and safety of care through our regulatory activities

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, were important aspects this year in keeping with our strategic vision and our consideration of the first recommendation in the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis report).

We continued to deliver our core inspection and licensing activities, to monitor the performance of clinics, and to deal with incidents and complaints about clinics, under the framework of the compliance cycle. There was ongoing monitoring of sector performance against the multiple births target maximum rate of 10% introduced in October 2012, to reduce the associated risks for patients and children born as a result of fertility treatment. We published a report on clinical incidents that had taken place between 2010 and 2012, and began a dialogue with the sector about how best to learn from incidents and adverse events.

We supported the Parliamentary decision-making process in relation to treatment using new mitochondrial donation techniques, in various ways. We completed a third scientific review of the safety and efficacy of mitochondrial replacement, and a subsequent update. We gave extensive policy and licensing advice in relation to draft regulations, in response to ministerial requests. In February 2015, Parliament voted in favour of allowing mitochondrial donation in UK law for the first time anywhere in the world. As a result, towards the end of the business year we began work on the required application processing and licensing procedures so that we will be ready to implement the new legislation when it comes into effect (from 29 October 2015).

Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families

We continued to support the Lifecycle campaign in producing a range of information about donor conception. We also began a pilot exercise to improve access to support services for applicants to the Register.

The provision of timely access to information from the Register for those who are entitled to it continued to be important. We began to explore, through consultation and collaboration, what we (or others) could do to collect and publish more information about the availability of donor egg and sperm (gametes) in the UK. We also worked with clinics on the storage consent regime and continued with our work to reduce multiple birth rates. We ran sector workshops on both of these issues.

Increasing and informing choice

Objective:

"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."

Using data in the register to improve outcomes and research

We began detailed planning and consultation focused on modernising our Register function and information collection processes, through a major programme of work known as Information for Quality (IfQ). This work, which will continue throughout 2015/16, 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 CaFC web page. Our intention in doing this work is to minimise the amount of time clinics have to spend on satisfying regulatory requirements at the expense of patient care.

We have continued to provide regularly updated CaFC information on our website, and alongside this, we began a process (initially through a consultation completed in 2014) to identify how CaFC could be made easier to use to improve consumer choice.

We also continued to respond to researchers' requests for access to data in our Register of Treatments and Outcomes.

Ensuring patients have access to high quality information

We began to explore how patients' views could help to enhance our work. Over time, we plan to develop more ways of ensuring we can more effectively engage with, and provide information to, patients as an integral part of our ways of working.

We established a major review of our website, under the IfQ programme. This will be completed in 2015/16. We also continued to produce a number of publications, describing and analysing statistical and other information from our Register.

Managing change and providing best value

Objective:

"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."

HFEA is good value for the public, the sector and Government

We continued to seek out savings and efficiencies where possible to offer the best possible value to the public and patients, the clinics we regulate, and our Government sponsors.

Planning, and consultation for, the IfQ programme has enabled us to set out a detailed business case and implementation plan for how we will modernise our Register function and processes, improving the way we collect, use and publish information. This work (which comprises a set of projects) will ultimately offer increased efficiency both within the HFEA and at clinics.

While that work progressed, we also continued to maintain all of the internal systems, tools and processes that assist our regulatory efficiency and quality. We continued to respond to requests for access to information we hold, under various access and transparency regimes, and to publish required data through the data.gov.uk Government website.

We worked collaboratively and continued our use of service level agreements, with other ALBs and regulators. Following considerable savings made in the previous four years, we continued to maintain a focus on efficiency, while still ensuring we maintained the level of resources and the types of skills needed to deliver our work. We completed our implementation of the recommendations in the 2013 McCracken review, through continued shared services arrangements with the Human Tissue Authority (HTA), Care Quality Commission (CQC) and others and through setting in place a mechanism for increasing accountability and transparency in respect of the fees we charge clinics.

Delivering our strategy in 2015/16

Our strategic vision for the three years from August 2014 to 2017 is:

High quality care for everyone affected by assisted reproduction.

We aim to achieve this vision through delivering the following strategic objectives:

1. We will improve the quality and safety of care through our regulatory activities.
2. We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.
3. We will use the data in the HFEA Register of Treatments to improve outcomes and research.
4. We will ensure that patients have access to high quality meaningful information.
5. We will ensure we remain demonstrably good value for the public, the sector and Government.

These objectives are designed to ensure that we deliver our vision and continue to regulate clinics to a high level of quality, in the interests of patients, donors, donor-conceived people and our other stakeholders. We must manage ourselves effectively as a responsible public body, whilst ensuring that our statutory duties are met, and are met well, for the ultimate benefit of patients and the clinics we regulate.

We must also continue to be a reflective and open organisation that constantly seeks 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.

The activities and projects set out over the next few pages describe how we will meet these strategic objectives in 2015/16.

Activities in 2015/16

Activities	Methods and channels	Benefits and outcomes	Timescale
Setting standards			
Strategic objective 1: improving the quality and safety of care through our regulatory activities			
Delivering the full compliance cycle to maintain standards for patients.	Inspection, audit and licensing activities.	Clinics are appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. Continued programme of unannounced inspections. Assurance of standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites).	Throughout year
	Reviewing the inspection regime.	Consideration of the impact and effectiveness of our regulatory work and identification of further quality improvements that we could make. Report provided to the Authority.	September 2015

Activities	Methods and channels	Benefits and outcomes	Timescale
Identifying and implementing ways of improving the quality and safety of care.	Increased focus on quality and safety of care in inspection activities – in particular through focusing on properly informed consent, infection control, medicines management and using approved medical equipment.	Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics. Tracking of non-compliances in these areas, in order to measure impact. Clinics' understanding of, and adherence to, correct consent procedures and their understanding of the importance of getting this right, is improved. Patients and donors therefore have a better experience of being asked for consent, and feel fully informed. If an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust. Clinics have reduced vulnerability to expensive adverse legal and reputational risks.	Throughout year
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Increased focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include focused work with individual clinics, as necessary, to assist them in improving.	Publication of report on clinical incidents 2014. Sector provided with useful information about learning points from incidents and adverse events. Learning that can be used to inform future inspections. Patients' negative experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse event.	November 2015 March 2016
Making the patient experience integral to the way in which we assess clinics' performance.	Obtaining more patient feedback before and during inspections, eg, by improving the patient feedback form and further developing our channels for obtaining patient feedback.	Patient experiences made more explicit in inspection reports to licensing committees. Patient experience informs licensing outcomes.	March 2016
Seeking patients' views, and understanding their perspective, as part of the way we work.	Identifying, through user feedback, the quality factors that are the most relevant for patients, implementing these (eg, through the revised presentation of Choose a Fertility Clinic, CaFC, to be delivered in 2015/16 through the Information for Quality (IfQ) programme); and subsequently evaluating the impact.	Clearer understanding of the range of things that different patients want, and what 'quality' means to them. Ability for us to reflect on what this means for our own future work and for clinics and to use our data to drive up standards in clinics. Evaluation-led improvements.	March 2016 2016/17

Activities	Methods and channels	Benefits and outcomes	Timescale
Identifying the best ways to optimise success rates and developing a common improvement agenda.	Maximising the chances of success for patients by: • continuing to address with clinics any performance alerts in relation to success rates • continuing to review emerging procedures and publish evidence, working with regulatory partners to ensure there are no inappropriate barriers to the introduction of innovative (safe) new techniques • improving the presentation of our data about success rates on CaFC (through the IfQ programme).	Improved success rates (over time). Clinics are not disincentivised from treating patients who have an intrinsically lower chance of success because of age or other factors. Improved value for money for patients. Patients can more easily optimise their own chances of success through their choice of clinic. New and emerging techniques are reviewed and evidence published. Barriers to innovatory new techniques are removed. Identification of areas of clinical practice that would benefit from a renewed focus.	March 2016
Publishing more HFEA data to drive improvements in clinic performance.	Following on from the current Information for Quality (IfQ) programme, publishing a wider range of performance data on our website.	Increased transparency to empower and inform patients. Increased visibility for clinics of sector-wide data so that they can assess their own performance against it. Encouragement of best value and treatment outcomes for patients.	Next business year (2016/17)

Activities	Methods and channels	Benefits and outcomes	Timescale
Acknowledging that treatment is often unsuccessful.	Exploring with professional stakeholders (such as the British Fertility Society (BFS), the Association of Clinical Embryologists (ACE), infertility Network UK (INUK), and the Professional Bodies Group) how we, and clinics, could better address this issue.	Better support where treatment is unsuccessful. Prospective patients enter treatment with a realistic understanding that they may not have a baby, even if they undertake many cycles. More information on our website for prospective patients and signposting for patients who have experienced unsuccessful treatment. Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	March 2016 and next business year (2016/17)
Reviewing and advising on issues relating to mitochondrial replacement.	Implementation of agreed statutory changes (further to Parliamentary decisions).	Statutory changes introduced by Parliament are implemented clearly and robustly, with clear information for patients and clinics.	Oct 2015 (and ongoing core work in 2016/17)
Maintaining our role as the UK's competent authority for ART in the European Union.	Attendance at competent authority events and implementation of associated EU decisions.	We attend two meetings per year. Up-to-date intelligence gained about European perspective, helping to inform UK approach to patient safety and care. Free movement of gametes and embryos enabled within the UK and standards upheld in the UK that are consistent with the rest of the EU.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 2: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.			
Providing information about donor conception directly to patients and donors.	Facilitating and supporting the ongoing work of the Lifecycle Campaign.	Potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. As a result they feel better informed and supported with respect to the legal aspects and obligations of donation. All involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them.	March 2016
Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation.	Continued promotion of the Lifecycle information leaflets and the pack about donor information produced in 2014/15 for clinics.	Improved clarity of role and performance for clinics in relation to donation and associated information guardianship. Improved experience for donors, donor-conceived people seeking information and patients and their families.	March 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
Collecting and publishing information regarding donor egg and sperm availability in the UK and addressing impacts for patients (for example, by providing more information about the implications of treatment abroad).	Following consultation as part of the IfQ programme in 2014/15, exploring with stakeholders and professional organisations how best to collect and use UK data on the availability of donated eggs and sperm.	More complete and accurate data about donor gamete availability around the UK. Patients, clinics and others have more information at their disposal. Fewer people who would prefer to have their treatment in the UK feel they have to go abroad for treatment.	March 2016
Improving the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register.	Implementing access to support services for applicants to the Register. A three-year piloting period will commence in early 2015/16.	Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information. Mediation services are in place for when donors and donor-conceived people meet. Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people. OTR applicants feel more supported and will be prepared to deal with the information they receive from us.	Piloting from early 2015/16 through to end of 2017/18.

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	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
Implementing new EU requirements relating to the import and coding of donor eggs and sperm.	Completion of projects started in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells.	Improved clarity for clinics, patients and donors. Improved internal clarity and updated procedures for our decision-making committees. Compliance with new EU directives. Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.	Next business year – October 2016
Increasing and informing choice			
Strategic objective 3: using the data in the HFEA Register of Treatments to improve outcomes and research			
Publishing and supplying the information we hold, for the benefit of stakeholders.	Regularly updating CaFC information to assist patient choice.	Six monthly verification and publication schedule in place, maintaining provision of up-to-date and accurate information.	Throughout year
	Through the IfQ programme, improving the presentation of clinic comparison information on CaFC.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Increased consumer choice and clinic comparability.	March 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
	Producing a guide for NHS commissioning bodies to ensure that they commission the best services using available data.	Commissioning decisions that are more effective for patients. An HFEA guide to assist CCGs in making commissioning decisions.	March 2016
	Deepening our relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC) and being an active member of the National Information Board (NIB).	We contribute to the objectives of the wider health system, with respect to information management. Learning from best practice and sharing expertise, so that we can make use of each other's strengths and knowledge in data management, systems integrity and security.	March 2016
	Information provision for researchers requesting access to Register data.	Information for researchers provided within 90 calendar days of approval. Register information used to best effect, to promote understanding and facilitate good research, and ultimately patient benefit.	Throughout year
Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data.	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

Activities	Methods and channels	Benefits and outcomes	Timescale
Publishing reports on the information we hold for the benefit of stakeholders.	Continued publication of inspection reports and a review of their structure and presentation.	Inspection reports continue to be published via CaFC and are made as useful as possible for patients.	Throughout year
	To continue to publish statistical and other reports.	‘Fertility treatment in 2014’ report covering 2013–2014. - Provides patients, clinic staff and others with up-to-date, high quality information about a range of topics. - Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work. - Report carries ‘official statistics’ status.	November 2015
		Statistical report on multiple births. - Provides up-to-date, high quality information on progress in reducing the incidence of multiple births following ART.	June 2015

Activities	Methods and channels	Benefits and outcomes	Timescale
		Report on incidents and alerts. - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients. - Provides the sector with the most up-to-date information.	November 2015
Strategic objective 4: ensuring patients have access to high quality meaningful information			
Improved HFEA information about treatments available, scientific research, embryo and stem cell research and other fertility subjects.	Through the IfQ programme, redeveloping the content of our website to provide an expanded range of educative and scientific information about current treatments and fertility issues.	Increased information for patients and others. Information is accessible, engaging and meaningful. Patients better informed and better placed to deal with treatment issues and decisions. Patients feel safe and know they can expect certain standards in clinics. Prospective patients have clearer information and signposting. Patients more aware of the potential risks of new/different treatments as well as the possible benefits.	March 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
Enhancing the patient voice in all of our work, including information provision.	Seeking patients' views and information needs (to be taken forward based on the outcomes of the IfQ consultation in 2014/15) and making better use via the new website of feedback mechanisms, video and integration with social media platforms.	Patient views and needs are better incorporated into our work and the information we provide. There are increased feedback opportunities for patients via the website and easier interaction with us.	March 2016 (becoming ongoing core work thereafter)
Working with clinics and scientific experts to publish information about new treatments.	Establishing mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts.	Increased public understanding of emerging new science and future treatment possibilities. Patients better informed and better placed to deal with treatment issues and decisions when emerging new treatments begin to be offered by clinics and better placed to judge the merits of any media speculation about potential new treatments.	March 2016 (becoming ongoing core work thereafter)
Enhancing Choose a Fertility Clinic (CaFC) by including user experience scores.	Develop a methodology for incorporating user experience scores as part of the IfQ programme work on the redevelopment of the website and the future presentation of CaFC.	Patients feel better informed and can take into account other patients' experiences to help them decide on a clinic.	March 2016 (becoming ongoing core work thereafter)

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring that clinics prepare and support patients and donors through the information they give them.	Ensuring that clinics are giving accurate and sufficient information in their websites, publications and other materials given to patients.	Patients and donors can have confidence in the information clinics give them and are in a better position to compare and choose between clinics. Through asking patients directly (eg, on inspection) and conducting desk-based research, we are able to provide factual feedback to clinics and encourage best practice.	March 2016
Collaborating with professional stakeholders to put patients in touch with better information and the right sort of care when they first realise they may have a fertility issue.	Putting patients in touch with the best advice at the earliest possible stage, through collaborating with stakeholders, ensuring that our website contains good signposting information, continuing to respond to new enquiries from prospective patients seeking initial information and exploring whether there is any merit in working with GPs in their role as commissioners to improve early advice and referrals.	Patients consistently get good early advice and appropriate referral, regardless of the fertility knowledge of their particular GP.	March 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
Demonstrating efficiency, economy and value			
Strategic objective 5: ensuring the HFEA remains demonstrably good value for the public, the sector and Government			
Ensuring the HFEA is easy to deal with and offers a professional and cost-effective service in all that it does.	Using our strategy to prioritise our activities and manage our limited resources to best effect.	Resources are deployed in the interests of high quality care for everyone affected by assisted reproduction. Speedier service to patients when they interact directly with us. Achieving measurable 'added value' and internal efficiency.	Throughout year
	Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.	Accountability and transparency in respect of the fees we charge clinics.	Throughout year
	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained.	Throughout year
	Facilitating access to information under various regimes and fulfilling Government requests.	Legal and Parliamentary requirements continue to be met.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to seek opportunities for sharing services with the Human Tissue Authority (HTA), the Care Quality Commission (CQC) or other organisations: • Maximising benefit of finance resources shared with HTA. • Continuing with service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as a key learning and development provider. • Continuing to receive support services from the CQC (or other landlord when there is a change of office premises), via an SLA.	We continue to operate in as efficient a way as possible, extracting maximum value from shared support arrangements.	Throughout year
	Ensuring internally provided support services run smoothly and are efficient.	Our infrastructure is effective and supports the delivery of the strategic vision. Central systems, processes and tools are efficiently run, giving good value and service.	Throughout year
	Moving to new office premises, alongside other arms length bodies (ALBs).	Best use made of Crown Estate property. Further shared services and efficiencies realised from proximity of other similar organisations.	Date tbc – most likely in early 2016/17

Activities	Methods and channels	Benefits and outcomes	Timescale
Modifying our ways of working to ensure the organisation is responsive, agile, innovative and effective in achieving its strategic and statutory goals.	Building our staff capacity and skills and maintaining a high quality workforce in keeping with our people strategy.	Our people strategy is delivered, and this in turn ensures delivery of the overall strategy for 2014–2017. We are professional, capable, easy to deal with, agile and responsive, as well as effective.	March 2016 and ongoing
	Ensuring internal compliance processes and systems are up to date and effective.	Regulatory efficiency and quality is maintained and improved.	Throughout year
	Maintaining an overview of emerging scientific, clinical and legal developments.	Evidence-based decision-making continues to be supported.	Throughout year
Improving the methods used to submit and verify register data.	Modernising our Register function and processes, through the IfQ programme, which includes: • Developing and maintaining a Data Dictionary. • Redeveloping Data Submissions and associated processes. • Redeveloping the clinic portal. • Reviewing verification processes for clinic outcomes on Choose a Fertility Clinic (CaFC).	Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality. Reduction in unnecessary effort by clinics submitting the data.	March 2016

Measuring our performance:

Facts and figures:

The following facts and figures give a wider picture of the type and volume of our work between 1 April 2014 and 31 March 2015.

Number of:	2013/14	2014/15
Active clinics and research establishments	131	127
Clinics and research establishments inspected	87	61
Licences inspected	93	62
New licence applications processed and presented to the Licence Committee	10	6
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	40	35
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	9	9
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	37	44
Incident reports from clinics processed	506	453
Alerts issued	1	0
Formal complaints about clinics	11	9
Opening the Register requests closed within 20 working days	215	260
Donor Sibling Link applications processed	24	23
Licensed Centres Panel meetings held	3	2
Meetings with patient organisations held	2	1
Public and stakeholder meetings	24	48
Freedom of Information (FOI) requests dealt with	82	105
Environmental Information Regulations (EIR) requests dealt with	0	0
Enquiries responded to under the Data Protection Act (DPA)	3	0
Parliamentary questions (PQs) responded to	80	136
Information for researchers requests received	1	0
Visits to the anonymised Register download page	779	462
Unique visits to our website	979,078	1,337,484
Most popular/viewed page on our website	IUI - What is intrauterine insemination (IUI)	IUI - What is intrauterine insemination (IUI)

2014/018958

Required HR benchmarking information:

In common with other ALBs, we are 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	1.4%
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 eight 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 (eg, the redundancies to reduce our staffing complement between 2010 and 2013) have historically been 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).

In the second half of the 2014/15 financial year we experienced an increase in our turnover figures, which will continue to be monitored closely in 2015/16.

[1] Delivery of the Information for Quality (IfQ) programme will include the appropriate use of some non-payroll staff for additional resource and flexibility. The business case for this work is close to approval at the time of publication. There will be no 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 programme of IfQ work.

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Key performance indicators

In March 2015, we revised our in-house strategic performance report so as to enable us to keep track of our performance, with a particular focus on monitoring strategic delivery. This document is presented in summary form at every Authority meeting, and the associated papers are published regularly on our website.

The table below shows our performance in 2014/15 for a small sample of these indicators. We will continue to track the same indicators, and more, throughout 2015/16.

Performance indicator	Target for 2014/15	Performance
Setting standards		
Average number of critical/major recommendations at clinics in inspection reports that were considered by ELP/LC.	This indicator is for monitoring purposes and does not have an associated target. In 2015/16 we plan to focus on the timeliness with which inspection recommendations are met after non-compliances are identified.	21 critical 166 major (from 63 inspections during the year)
Percentage of Opening the Register requests responded to within 20 working days.	100% of complete OTR requests to be responded to within 20 working days (excluding counselling time).	100% (260 requests)
Increasing and informing choice		
Percentage of finalised Licence Committee, SAC, representations hearing and ELP decisions published on HFEA website within five working days of Chair sign-off.	100% published within five working days of Chair sign-off.	99.3% (195 items published, of which 194 were published within the target)
Number of emailed public enquiries successfully responded to.	No target, since the nature, volume and complexity of enquiries received varies widely.	1,306
Efficiency, economy and value		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	Less than or equal to 70 working days.	Average for year = 67.7 working days Range: 54-93 working days
Cash and bank balance.	To move closer to minimum £1,520k cash reserves.	Year start = £2,900k Year end = £2,038k

Financial picture:

We receive funding from two main sources: the majority from clinics and the balance from our sponsors, the Department of Health, as grant-in-aid.

The vast majority of fee income arises from individual IVF treatments in regulated clinics. In aggregate, together with licence fees, these cover the costs of evaluating licence applications, making licensing decisions and issuing licences, managing licences, site visit inspections, managing statutory information flows and providing advice and guidance to licensed establishments.

Treatment fee income has varied over time. A steady increase in the number of treatments enabled us, in October 2011, to cut its treatment fees by 28% to reflect that its costs were spread over a much higher number of treatments. In 2012, a discount was introduced for elective single embryo transfer. Subsequent treatment cycles using eggs from the first collection where elective single embryo transfer had previously occurred did not attract a treatment fee. Small growth in treatment numbers continues, but treatment income is now falling due to the elective single embryo transfer discount.

Our grant-in-aid funding from the Department of Health has reduced by over 50% since 2010.

Since 2010, our expenditure has decreased by over 40%. We place great importance on ensuring that our finances are managed efficiently, effectively and in a way which minimises risk. Staff numbers have decreased by 15% since 2010 and we have a small Authority of 12 members. We have also made significant efficiencies in office costs and by using framework suppliers and collaborating with other ALBs.

The high level budget for 2015/16 is shown below.

Income	**£000s**
Department of Health funding	1,120
Treatment and licence fees	4,120
Other income	6
Total income	5,246
Expenditure	**£000s**
Operating costs, of which	
Staff costs	3,845
Other operating costs	1,339
Total operating costs	5,184
Capital charges	62
Total revenue expenditure	5,246

We expect to spend up to £100,000 refreshing our IT equipment in advance of our office move, and have asked the Department of Health for capital funding to do so.

In addition the HFEA is spending the reserves that have accumulated in previous years from treatment fees on the Information for Quality programme and support services to applicants to the Register. In 2015/16, IfQ spend is expected to be £1.1million and support services will consume around £50,000 over a three year pilot period.

Other required information:

Introduction

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the successful delivery of any strategy or business plan. It is also important that we remain compliant with Government rules that apply across the whole family of arms length bodies (ALBs).

The HFEA's governance structure includes corporate governance tools, an HR framework and policies, and a business continuity plan. These enable us to manage our work effectively and meet external and internal requirements such as information requests, compliance with the Equality Act 2010, the production and laying in Parliament of our annual report, and the management of organisational risks and performance.

The information below is provided to explain those aspects of our organisation that are structural or which help us to meet particular Department of Health or cross-Government requirements.

Organisational structure and establishment

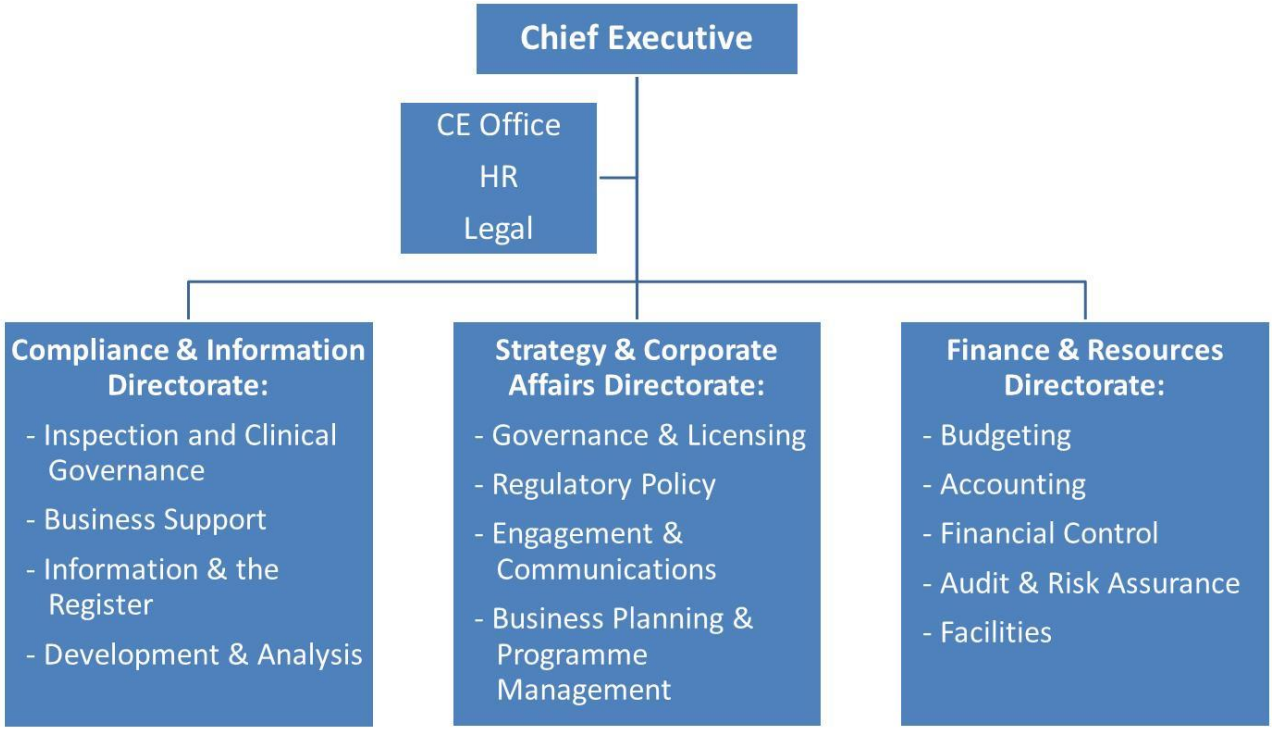
Over the past few years the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement has reduced from 86 in 2010/11 down to 67 by the end of the 2014/15 financial year. We have put in place shared services arrangements with other bodies, where feasible. For example, we share part of our finance and resources team staffing with the HTA, our facilities management service is provided by the CQC (since we occupy the same premises) and we have a shared services agreement with CQC for recruitment. We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. Our people strategy, to be published in 2015, sets out how we will ensure we retain the capability and capacity to deliver our overall strategy for 2014–2017.

Our learning and development activities continue to equip our staff with the skills they need. Services are procured in accordance with continuing Government requirements to ensure value for money, using Civil Service Learning, and their associated suppliers, or other ALB provision, as appropriate.

Together with other ALBs, we continue to participate in a talent management consortium 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. We adhere to the formal pay remit when it is announced.

The following diagram shows our current organisational structure.



In 2012/13 we also significantly reduced the size of our Authority, from 19 members down to 12 members, making a further ongoing cost saving. The revised governance arrangements are working well and will continue to be subject to regular review.

Financial management systems

We continue to maintain sound financial governance and business planning processes. We will continue to manage our processes efficiently and to continue to develop and deepen our various collaborative relationships and shared services with other bodies, which provide increased value as well as some economies of scale.

Internal audit

We continue to be part of the Department of Health group assurance framework and to work with the co-sourcing provider on delivering the annual internal audit plan for each year. The programme of internal audits has been streamlined to meet the HFEA's needs and to make best use of the group audit arrangement, which helps to improve the overall levels of assurance for the group.

Assurance framework

A framework agreement agreed with the Department of Health in early 2014 sets out the critical elements of the relationship between the HFEA 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 of Health and understands the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

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.

Whistleblowing policy

We value staff who raise concerns over potential wrongdoing and are committed to ensuring that staff have access to, and a clear understanding of, public interest disclosure (whistleblowing). Our policy was updated in late 2014 and will be reviewed each year to ensure that the details are up to date and reflect latest legislation and guidance. Should any individual raise a concern through this route, we are committed to ensuring that their confidentiality is appropriately protected and that they will not suffer any detriment as a result of whistleblowing.

Transparency requirements

We will continue to comply with the various data requests and requirements for the publication of data on our own website and on data.gov.uk, arising from the transparency agenda that was first introduced in 2010. We regularly publish all required spending data openly, in the required file format, via data.gov.uk.

All of our Authority meetings are held in public and the papers and audio recordings are published on our website. Committee papers and a wealth of other information are also routinely published on our website.

Information technology (IT) and data security

The HFEA maintains an information asset register identifying our key IT systems and their owners. Our IT systems ensure we comply with the data management requirements of legislation, including the HFE Act 1990 (as amended) and support the significant databases we hold.

HFEA databases are currently 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 remains fully compliant with Cabinet Office rules regarding data security and with its own legislative requirements regarding confidentiality of information under the HFE Act 1990 (as amended).

Since we are likely to move offices during the course of the coming year, we have developed, in March 2015, an IT strategy for the future. This includes making new

secure arrangements for our servers, while adhering to any applicable central Government requirements at the time.

The robust information security arrangements the HFEA has in place, in line with the information governance toolkit, 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.

We also operate a clear desk policy and have on-site shredders and confidential material disposal arrangements in place.

Business continuity

We have further developed our business continuity plan in 2014/15. The plan is regularly updated and periodically tested. There is an operational disaster recovery site available if needed.

We currently have an interdependency with the CQC with regards to building-related and system matters. If our office move goes ahead at the end of the 2015/16 financial year, as anticipated, business continuity will be considered afresh in collaboration with other relevant ALBs.

Estates strategy

The HFEA has no estate. Our office strategy remains to be a tenant or co-tenant of a larger Department of Health organisation.

Our current office space of 525 square metres includes flexible hot desking and we rezoned the office in 2013/14 to enable better use of space (with smaller desks).

Our tenancy with the CQC will end when the CQC moves from Finsbury Tower in 2016. Until the resulting office move takes place, the HFEA and the CQC will continue to work together on health and safety services. We have adopted the CQC's online system for individual workplace assessment and meet with the CQC lead on fire evacuation procedures and fire warden liaison. Similarly, new, arrangements will be put in place as appropriate in our new premises.

Sustainable development

We recycle 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. A proportion of our staff are able to work from home, allowing reduced travel impacts.

We do not procure energy or other items with significant environmental impacts.

Procurement

The HFEA complies with all relevant Department of Health and Cabinet Office efficiency controls. Where we are the purchaser, we procure the 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, learning and development, legal services and conference and events bookings. These frameworks were first established in 2011.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchases directly and are dependent on CCS and other framework holders for integrating sustainability features in their contract letting.

Nearly all of our procurement is done through CCS. So, as far as we are able, we aim to meet the public sector procurement 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 we have a choice of supplier, our criteria do include both sustainability and SME usage.

We are too small to have a procurement pipeline. The only procurement of significance in 2015/16 relates to the IfQ programme, which has been subject to specific business cases agreed by the Department of Health and the Government Digital Service through robust mechanisms. All related procurement has been conducted using CCS frameworks and with close CCS oversight. Apart from IfQ, which will be subject to its own departmental approvals, there will be no procurements over £100,000 in 2015/16.

There is no significant non-pay spend that is not via CCS, CQC or Department of Health frameworks or contracts.

We remain committed to the principles of the voluntary sector compact and work with the voluntary sector where applicable. For examplewe have worked for some years with other organisations to reduce the prevalence of multiple births in the fertilty sector[2] and we routinely open developments to our policies and processes to a wide range of inputs and influences, including voluntary organisations.

[2] See www.oneatatime.org.uk (NB this information will be moved to the HFEA's main website during the coming year – www.hfea.gov.uk)