Business plan 2016/17

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	11		
Paper number	HFEA (09/03/2016) 791		
Meeting date	9 March 2016		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to approve the Business Plan for 2016/17, subject to the addition of year end information, Department of Health (DH) confirmation of the budget, and final DH approval.		
Resource implications	In budget. Rated medium for risk, given limited resources and a challenging set of activities to deliver.		
Implementation date	Throughout 2016/17 business year.		
Communication(s)	Publication on HFEA website and Intranet.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Business plan for 2016/17		

1. Background

1.1. The Authority agreed a draft of the new business plan for 2016/17 at its November meeting. The content has now been developed further, and the business plan is at an advanced stage.

1.2. Following submission of our earlier draft in December 2016, our DH sponsors had only minor comments, and indicated that they were broadly content. We submitted a revised draft for their end of January deadline. Budget confirmation has been received.

1.3. The only change since that submission at the end of January is the addition of some activities to address new Government-wide better regulation initiatives, now that we have more information.

2. Remaining content

2.1. Some sections cannot be added until after the end of the business year on 31 March. This includes:

- the 'facts and figures' table relating to the previous business year
- confirmed budget for 2015/16
- standard HR benchmarking information
- the performance indicator section.

3. Review of activities

3.1. The Corporate Management Group (CMG) has reviewed the activities in the business plan so as to ensure that we can be confident of delivery within resources.

3.2. Service delivery plans are being refined, so that teams can manage their delivery of the business plan effectively across the year. At the March CMG meeting, we plan to share our service delivery plans and identify interdependent work, so make sure that the staff resources will be available to deliver the work when it is planned to take place (if not, the sequencing will be adjusted).

4. Recommendation

4.1. The Authority is asked to approve the business plan for 2016/17 for publication in April, subject to the later addition of the material mentioned in paragraph 2.1, confirmation of the budget, and formal permission to publish subsequently being received from DH in the usual way.

Human Fertilisation & Embryology Authority

Annex A

Business Plan

2016/17

www.hfea.gov.uk

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.

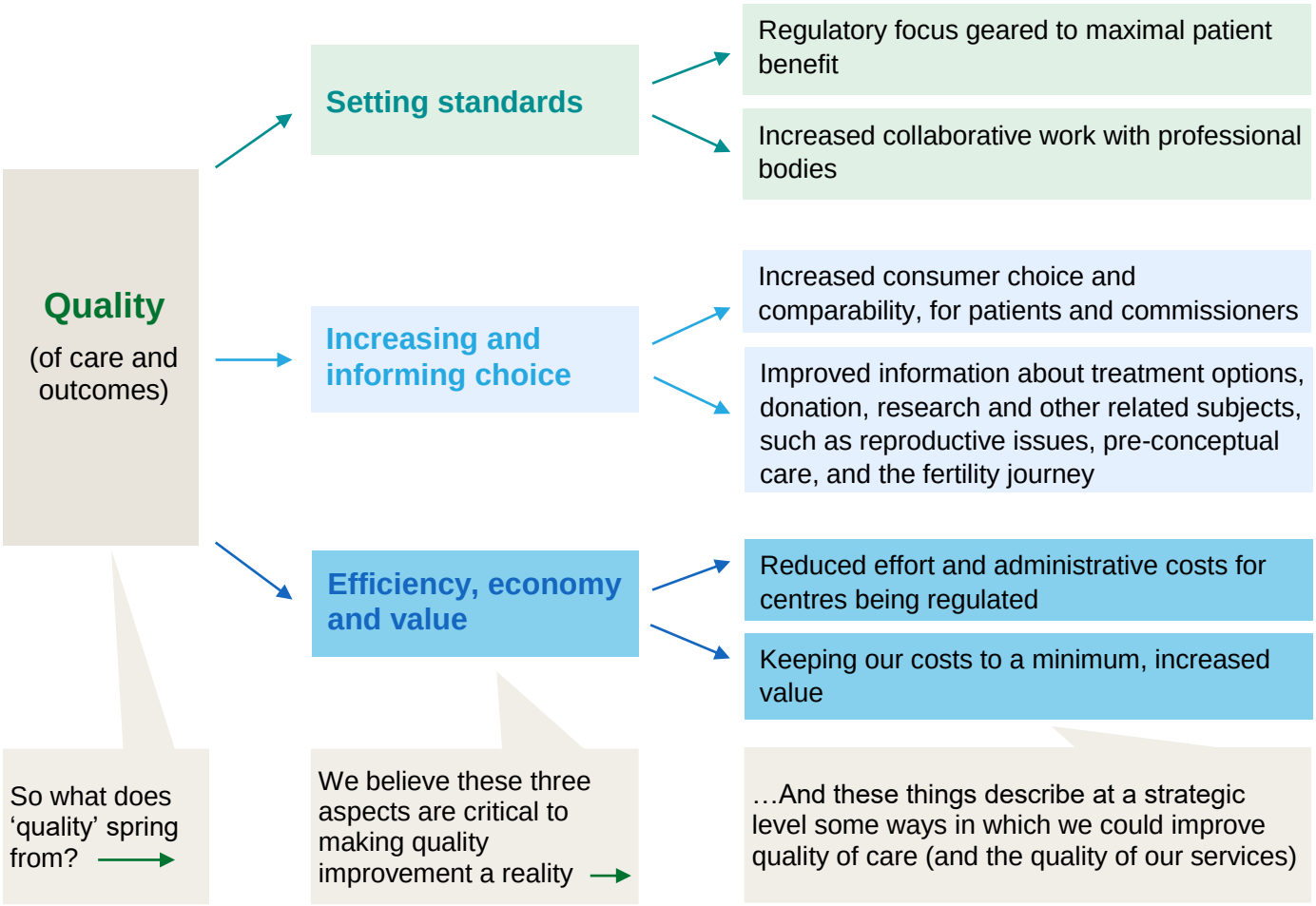
High quality care means…	• safe, ethical and effective care and treatment.
Everyone affected means…	• patients and parents • all those conceived through assisted reproduction • donor-conceived people • egg and sperm donors • clinic staff.
Assisted reproduction means…	• standard fertility treatments •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

This business plan sets out how we will work towards this vision in 2016/17.

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 administrative costs for clinics so that they can focus more of their time on providing care.



For the first time, there is now an agreed shared delivery plan for all arms length bodies and the Department of Health. This delivery plan gives high level clarity on objectives across the whole health system. Since we are a specialist body, not all of the Department's priorities are relevant to our work, but our activities fit well within them – most notably in relation to the objective of creating the the safest, highest quality healthcare services possible.

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).

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.

Strategic Objectives

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 will 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.

What we did in 2015/16

Setting standards

Improving the quality and safety of care through our regulatory activities

Delivering the full compliance cycle to maintain standards for patients:

As usual, we undertook our full range of inspection, audit and licensing activities. This ensured clinics were appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. We also continued our programme of unannounced inspections. Our compliance activities provide assurance on standards and safety for the public and our other stakeholders. We always aim to have a positive overall impact on the quality of care, on outcomes, safety and support, and on the information clinics provide to the HFEA and publish for patients (eg, on their websites).

We also intended to review our inspection regime during the year, but, in the event, the HFEA's triennial review was commissioned by the Department of Health during the business year, so we decided not to run another review at the same time. When our triennial review report is released, we will consider what actions we need to take, based on the report's recommendations, and consider whether another review would be good value or not.

Identifying and implementing ways of improving the quality and safety of care:

We increased our focus on quality and safety of care in our inspection activities – in particular through checking through inspection that properly informed consent, good infection control, medicines management and the use of approved medical equipment were all in place. Our aim is to improve compliance across the sector, improving quality and safety and increasing clinics' understanding of, and adherence to, the correct procedures and the reason these are important - particularly with regard to consent. If clinics are able to take consents correctly, then 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. This will provide greater certainty for patients at a time of stress, and reduced vulnerability for clinics in terms of expensive adverse legal and reputational risks.

We also continued to evaluate areas of regulatory concern and identify performance levers. Alongside this we increased our focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This included focused work with individual clinics who reported such events, to assist them in improving. We published our annual report on clinical incidents in 2014.

Legal parenthood

From 6 April 2009, women (and the partners of women treated with donor sperm, where the couple is neither married nor in a civil partnership), must give their consent in order for the partner to become the legal parent of any child born. Legal parenthood confers a lifelong connection between a parent and a child, and affects nationality, inheritance, financial responsibility and contact.

In 2015, following a number of consent failures in clinics, Sir James Munby, President of the Family Division of the High Court ruled on a cohort of legal parenthood cases that were brought before him for legal resolution.

In light of his judgment, the HFEA immediately put an additional range of actions in place. The HFEA had previously informed clinics about the legal parenthood consent requirements in various ways. The timeline of the HFEA's actions with respect to legal parenthood (before and after the cases emerged) is set out in full below.

- In 2009 (when the rules were introduced) – a Chair's letter was sent to all clinics, along with guidance; new consent forms were issued; and a series of workshops was held.
- Parenthood was then a specific theme of inspections from January 2010 to 2012.
- June 2013: Two separate cases of failure to take the correct consents in clinics emerged.
- August 2013: The HFEA sent out a Clinic Focus article emphasising the importance of robust consent procedures.
- September to December 2013: An audit was trialled to ensure professional engagement.

- February 2014: A Chief Executive's letter was sent to all clinics, requiring them to conduct a full audit; and announcing that all subsequent inspections would check up on the completeness of this audit process (a clinic responsibility).
- September 2014: A further Chief Executive's letter was sent, reporting on results. Findings indicated widespread poor practice. Several clinics at that stage were supporting patients to obtain the needed legal declaration.
- February 2015 to September 2015: Family Division consideration of eight cases took place.
- The HFEA confirmed to the sector that a legal 'declaration' was necessary in such cases, and that patients must be supported by clinics.
- We began a proactive follow-up process on the progress of all cases.
- The Person Responsible in each clinic was asked to confirm that they were satisfied that their parenthood consent audit had been robust.
- A further Clinic Focus article was published, signed by the Chair and Chief Executive, to ensure clinics were clear as to their responsibilities in seeking consent for parenthood correctly.
- Parenthood has been introduced once again as an inspection 'theme' in 2015/16 and beyond – so as to ensure understanding of this issue is embedded in all clinics. Each inspection report will set out how the clinic has performed in this area.
- A number of anomalies have occurred in a minority of clinics, and within those, the majority have one or two cases.
- As at January 2016, all clinics have engaged with us and have provided assurances about their current practices.
- Seven cases have been determined in court so far, with a further nine cases currently under consideration. Not all patients affected will choose to seek legal resolution.
- Since errors could always be made in clinics, there are limits to what can be found on inspection. However we will continue to send stronger signals about clinics' assurance of the quality of their own systems, and require more robust audits of clinics, so that we have better evidence of the quality of each clinic's compliance.
- In 2016, we will continue to follow up on individual cases and to focus on working closely with those clinics who have uncovered errors. Where appropriate, we will take further enforcement action.
- Legal parenthood consent has been added to our strategic risk register with the aim of closely monitoring and reducing the risk of any recurrence for patients, the concomitant risks for any clinics who make such consent-taking errors, and the HFEA itself.

There are a range of lessons learned from this episode, for both the HFEA and the clinics. These include:

- The need for thoughtful, careful and consultative implementation of new requirements. Change is tricky, and these errors have been made despite careful implementation in 2009.
- The importance of maintaining bespoke consent forms that protect patients' interests.
- That parenthood needs to remain an inspection 'theme' so as to embed understanding in clinics, with samples of records checked.
- That we must ensure that the chances of errors are reduced to a minimum, while recognising that some errors will always be made – there are limits on inspection and regulatory oversight.
- That clinics' assurance of the quality of their systems is important. We now require a robust audit – which we can check.
- That most clinics in most treatments get it right, and that the majority of patients are not facing any doubts about the parenthood status of their child.
- That the errors made in relation to these consents have been many and various, including missing names and signatures, dates inadvertently transposed, missing forms, or the use of self-invented 'in-house' forms produced by clinics, instead of using the HFEA's required form.

- That clinics that take consent well understand that this is not simply an administrative process. These forms confer legal status on family relationships and should therefore be completed with the greatest of care.

Our approach to this issue has been based on transparency and openness, with regular reporting to the Authority and to the Audit and Governance Committee. In working with clinics, we have sought assurances from all clinics, emphasising the PR's responsibility to ensure the robustness of their audits, and that all patients affected must be supported. We have received good cooperation from clinics.

Making the patient experience integral to the way in which we assess clinics' performance:

We increased the amount of patient feedback we obtain before and during inspections, and continued our work through the Information for Quality (IfQ) programme to increase this still further through our new website, in 2016. Patient experiences are now set out more explicitly in the inspection reports that are submitted to licensing committees, so that such experience informs licensing decisions.

Seeking patients' views, and understanding their perspective, as part of the way we work:

Our user research to underpin the IfQ programme enabled us to identify the quality factors that are the most relevant for patients. These findings are being implemented through the IfQ programme (eg, through the revised presentation of Choose a Fertility Clinic, or CaFC). We will subsequently evaluate the impact of this work and see if the approach needs to be refined.

Identifying the best ways to optimise success rates and developing a common improvement agenda:

We have continued to use every opportunity within our role as regulator to maximise the chances of success for patients. We address with clinics any performance alerts in relation to their success rates. We also review emerging procedures and publish any evidence available, working with regulatory partners to ensure there are no inappropriate barriers to the introduction of innovative (safe) new techniques. We have been working towards an improved presentation of our data about success rates on CaFC, through the IfQ programme. We hope this work will collectively lead to improved success rates, over time, and that this will be achieved without disincentivising clinics from treating patients who have an intrinsically lower chance of success because of age or other factors. We are aiming to ensure that patients can more easily optimise their own chances of success through their choice of clinic, and that they arrive in clinics feeling informed about new and emerging techniques and the treatment choices they may be offered. We also want to equip patients with a better and more realistic idea of their own chances of success.

In late 2015, we also updated the multiple births information for patients and professionals, to help minimise and reduce the occurrence of multiple births. This information also helps patients to make informed choices about their treatment options and the associated risks and benefits.

Publishing more HFEA data to drive improvements in clinic performance:

As a result of the IfQ programme, we will shortly be publishing a wider range of performance data on our website. Work on the programme has taken place throughout 2015/16, with a successful alpha stage between July and November 2015, and the beta stage (where products start to be built) commencing in December 2015 following required Government Digital Service approvals.

Publishing more data is an intrinsic aim of the IfQ programme, so as to increase transparency and inform and empower patients. This work will also increase visibility for clinics of sector-wide data, so that they can assess their own performance against it. Our aim is to encourage best value and the best possible treatment outcomes for patients.

Acknowledging that treatment is often unsuccessful:

We have started to explore with our professional stakeholders (including 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 for patients is needed when treatment has been unsuccessful. Prospective patients should also

enter treatment with a realistic understanding that they may not have a baby, even if they undertake many cycles.

More information and signposting for patients is being produced for our new website. We will do further work with professional stakeholders in the next business year to make clinics more aware of their responsibilities to patients beyond the immediate treatment setting.

Reviewing and advising on issues relating to mitochondrial donation:

This year we implemented a range of agreed statutory changes (further to Parliamentary decisions) to enable clinics to make applications to carry out mitochondrial donation in treatment, for the avoidance of serious mitochondrial disease.

The statutory changes introduced by Parliament were implemented clearly and robustly, with clear information for patients and clinics.

We now await the results of some externally-run safety and efficacy tests, before the first applications can be submitted to us. There will be a further scientific review once the tests have been completed and published.

Maintaining our role as the UK's competent authority for ART in the European Union:

We attend twice yearly competent authority events, and implement associated EU decisions as relevant. By participating, the HFEA gains up-to-date intelligence about European matters, and shapes European decisions so that they better reflect UK practices and perspectives. This year we have begun work on three projects to implement recent EU decisions on the import/export of gametes and on EU coding requirements. This work will continue until April 2017 (the implementation date for the EU Directives).

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:

Throughout the year, we continued to facilitate and support the ongoing work of the Lifecycle Campaign, established to find new ways of improving sperm and egg donation in the UK. We aim to ensure that potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. The Lifecycle leaflets explain all the issues, and have been made widely available. Our aim is to ensure that those affected by donor conception feel better informed and supported with respect to the legal aspects and obligations of donation. It is important that all involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them.

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:

By continuing to promote the Lifecycle information leaflets and the pack about donor information produced in 2014/15 for clinics, we have achieved improved clarity of role and performance for clinics in relation to donation and associated information guardianship. We have also improved the overall experience for donors, donor-conceived people seeking information and patients and their families.

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, we further explored with stakeholders and professional organisations how best to collect and use UK data on the availability of donated eggs and sperm. We will continue to

progress this work as we conclude the redevelopment of our website in 2016/17.

Improving the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register:

This year we began a three-year pilot providing support services for applicants to the Register. Counselling support is now 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 also in place for when donors and donor-conceived people meet. Basic mediation training and systems are in place for dealing with identity release to donors and donor-conceived people. Our aim is to ensure that OTR applicants feel more supported and are prepared to deal with the information they receive from us.

As before, we also continued to facilitate timely access to information from the Register for those who are entitled to it. Opening the Register requests continued to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling), throughout the year.

Implementing new EU requirements relating to the import and coding of donor eggs and sperm:

As mentioned above, we began work on three projects to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells. This work is due to complete by April 2017, and will give improved clarity for clinics, patients and donors. It will also provide improved internal clarity and updated procedures for our decision-making committees. The HFEA will then be compliant with the new EU directives when they come into force, and will have robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.

Increasing and informing choice

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:

We continued to regularly update CaFC information, so as to assist patient choice. This involves a six monthly verification and publication schedule, to maintain the provision of up-to-date and accurate information.

Through the IfQ programme, we are working on improving the presentation of clinic comparison information on CaFC. This work has been based on extensive user research, and the beta phase of work (the building phase) commenced in December 2015. The aim is for the published outcome data to be more useful and easier to understand and to set up positive incentives for improvements, as well as increased consumer choice and clinic comparability.

During the year, we also produced a guide for NHS commissioning bodies to help them to commission the best services for patients using available data. The draft guide for commissioners was road tested in 2015/16, first with our multiple births stakeholder group, and then with a sample of commissioners.

We continued to deepen 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). This helps us to contribute to the objectives of the wider health system, with respect to information management, and to learn from best practice in data management, systems integrity and security.

We continued our information provision for researchers requesting access to Register data, providing the requested information within 90 calendar days of approval. Our aim is to ensure that Register information is used to best effect, promoting understanding and facilitating good research, ultimately for patient benefit.

Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data:

Register data and forms continued to be processed and quality assured throughout the year, through liaison with clinics on errors and omissions and through validation and verification of Register entries. This ongoing process ensures that high quality data is available to develop patient information and to support risk-based regulation and evidence-based policy-making.

Publishing reports on the information we hold for the benefit of stakeholders:

We continued to publish statistical and other reports during the year. These included:

- The 'Fertility treatment in 2014' report covering 2013–2014. This report provides patients, clinic staff and others with up-to-date information about a range of topics, and carries 'official statistics' status.
- Statistical report on multiple births. This provides up-to-date information on progress in reducing the incidence of multiple births following ART.
- Report on incidents and alerts. This report contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. It also promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients.

In addition, we continued throughout the year to manage the ongoing work of the register research panel, which considers applications from researchers to use our register data for linkage studies, which result in publications about health outcomes and success rates.

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, we commenced the redevelopment of the content of our website to provide an expanded range of educative and scientific information about current treatments and fertility issues. This will lead to increased information for patients and others. The new website will ensure that our information is accessible, engaging and meaningful, so that patients are better informed and better placed to deal with treatment issues and decisions. Our aim is to ensure that patients feel safe and know they can expect certain standards in clinics, and that prospective patients have clearer information and signposting, and are more aware of the potential risks of new and different treatments as well as the possible benefits.

Enhancing the patient voice in all of our work, including information provision:

Following a consultation to inform the IfQ programme in 2014/15, we established patients' views and information needs which are fundamental to the redesign of our website. Over time, we will be able to make better use, via the new website, of feedback mechanisms, video and integration with social media platforms.

The new website will enable increased feedback opportunities for patients, and easier interaction with us.

Working with clinics and scientific experts to publish information about new treatments:

In redesigning the website, we have also begun to establish improved mechanisms for producing and publishing accessible information when new treatment options emerge, working in collaboration with clinics and experts where necessary (including the professional bodies we work with regularly, and whose input is essential to this process). This will enable us to increase public understanding of emerging new science and future treatment possibilities. It will also ensure patients are better informed and better placed to deal with treatment issues and decisions when such treatments begin

to be offered by clinics, and that they are better placed to judge the merits of any media speculation about new treatments.

Our ongoing annual scientific horizon scanning work also feeds into this, ensuring that early consideration is given to emerging scientific issues and developments.

Enhancing Choose a Fertility Clinic (CaFC) by including user experience scores:

We have developed a method for incorporating user experience scores, as part of the IfQ programme work on the redevelopment of the website. This will be introduced along with the newly redesigned Choose a Fertility Clinic (CaFC) functionality. This will enable patients to take into account other patients' experiences to help them decide on a clinic.

Ensuring that clinics prepare and support patients and donors through the information they give them:

We continued throughout the year to encourage clinics to provide accurate and sufficient information in their websites, publications and other materials given to patients. We do this so that 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 provided factual feedback to clinics and encouraged best practice, making recommendations for improvements whenever problems were found.

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:

We collaborated with professional stakeholders throughout the year to put patients in touch with the best advice at the earliest possible stage. We ensured that our current website contained good signposting information, and continued to respond to new enquiries from prospective patients seeking initial information. Our aim is to ensure that patients consistently get good early advice and appropriate referral, regardless of the fertility knowledge of their particular GP.

Efficiency, economy and value

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:

We achieved this through various means in 2015/16. We continued to use our strategy to help us to prioritise our activities and manage our limited resources to best effect. This is an ongoing process, ensuring that resources are deployed in the interests of high quality care for everyone affected by assisted reproduction (our vision for 2014-2017).

We continued our engagement arrangements with clinics on fees charged, established in 2014/15. This gives accountability and transparency in respect of the fees we charge clinics. Towards the end of the year, the Authority agreed the first change in fees for several years, which, following Department of Health and Treasury approval, will come into effect in April 2016, and will enable us to balance our budget.

We continued to maintain efficient and effective decision-making through our committees, ensuring governance tools underpinning licensing and other decisions were in place and effective.

The HFEA continued to receive a large number of requests for access to information, under various regimes, and we ensured legal and Parliamentary requirements were met.

We maintained our existing relationships and service level agreements (SLAs) with other ALBs, in the interests of efficiencies. These include sharing finance resources with the Human Tissue Authority (HTA), and SLAs for certain HR and facilities services.

These arrangements ensure our infrastructure is effective and supports the delivery of our strategic vision. Our central systems, processes and tools continued to be efficiently run, giving good value and service. At the start of the 2016/17 business year, the HFEA will move to new office premises, alongside another arm's length body (ALB). This move enables best use to the made of Crown Estate property, and is in keeping with the wider interests of government property strategy. Plans for

the move began in November 2015 and will continue until the move takes place in April 2016.

Modifying our ways of working to ensure the organisation is responsive, agile, innovative and effective in achieving its strategic and statutory goals:

We continued our focus on building our staff capacity and skills and maintaining a high quality workforce, in keeping with our people strategy, which supports the delivery of the overall HFEA strategy for 2014 to 2017.

We continued to ensure that our internal compliance processes and systems were up to date and effective, so that regulatory efficiency and quality was maintained and improved. We also maintained an overview of emerging scientific, clinical and legal developments, to ensure that evidence-based decision-making continued to be supported.

The HFEA also participates in the 'One Stop Shop' for life sciences, which was launched in 2014. This initiative brings together expertise from the HFEA, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA) to provide regulatory advice to those working in the life sciences industry. It was an outcome of the Government's Regenerative Medicine Expert Group and is a good example of constructive joint working between regulators, enabling businesses and other organisations in the life sciences industry to quickly and easily navigate the different regulators and allow them to access the right advice more quickly.

Improving the methods used to submit and verify register data:

We began the process of modernising our Register function and processes, through the IfQ programme. The work to date has been extensive, and continues into the next business year. We have developed a new data dictionary, which will be incorporated into the new Register structure and will then need to be maintained. We have begun to redevelop our data submissions processes and the clinic portal (used by clinics to view, and to provide us with, key information and licensing applications).

We have also started our review of the verification processes for clinic outcomes appearing on CaFC.

Our ultimate aim is to reduce transactional costs for clinics and increase user satisfaction, through achieving 'right first time' data quality, and reducing unnecessary effort by clinics in submitting the required data.

Delivering our strategy in 2016/17

Delivering the strategy

Our strategic vision for the three years from August 2014 to July 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 2016/17. During the year, we will also begin to shape our next strategy for the period 2017 to 2020.

Activities for 2016/17

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 and licensing cycle to maintain standards for patients.	Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities.	All clinics and research establishments in the sector are appropriately inspected and monitored against the requirements of the Act and 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
	Ensuring internal Compliance processes and systems support quality. This may include implementation of any recommendations for the inspection regime resulting from the HFEA's triennial review (reporting in 2016).	Consideration of the impact and effectiveness of our regulatory work and identification of further quality improvements that we could make.	September 2016
	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained. Decisions are evidenced and consistent.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Conducting an options appraisal for the future handling of representations and appeals processes.	To ensure that the HFEA's processes balance sound governance with cost effectiveness.	October 2016 onwards (into 2017/18 business year)
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines. Public confidence assured in the regulation of the new treatment of mitochondrial donation. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment.	Throughout year
Identifying and implementing ways of improving the quality and safety of care.	Continuing our relentless focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.	Improved compliance and a positive impact on the quality of care, outcomes and safety of patients. Clinics have reduced vulnerability to expensive adverse legal and reputational risks, and greater awareness of these risks. Tracking of non-compliances, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact (through our internal strategic performance monitoring mechanisms). Clinics' understanding of, and adherence to, correct consent procedures (including those associated with legal parenthood) and their understanding of the importance of getting this right, is improved. Patients and donors 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	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
		consents are more likely to be in place and are legally clear and robust.	
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	Improved levels of compliance. Inspection recommendations and advice or alerts targeting relevant issues, for maximum impact on quality of care, outcomes, and the safety of patients in clinics.	Throughout year
	Continued strong focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include a focus on incidents and clinics' learning culture during inspections, and publication of our annual review of clinical incidents.	Publication of report on clinical incidents 2015. Sector provided with useful information about learning points from incidents and adverse events. Learning gained, 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. Collaborative relationship established with the recently established NHS Improvement so as to consider wider lessons learned that may have relevance.	November 2016 March 2017
	Improved Register data quality, as a result of work done under the Information for Quality (IfQ) programme.	More 'right first time' data submission from clinics into the Register. Better service quality for Opening the Register (OTR) applicants. Fewer data submission and data accuracy related non-compliances found on inspection and audit.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	Working with commercial groups of clinics so as to improve quality and compliance on a group-wide basis, when relevant.	A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group. A benefit in one clinic is shared to others in the group without needing to wait for the next inspection date - for the ultimate benefit of patients. A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.	March 2017
	Collaborating with professional stakeholders (including the British Fertility Society, the BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.	More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options. Empowering patients, so they feel more equipped and are able to ask the right questions, regardless of the level of knowledge of their own particular GP about fertility issues and available treatments.	March 2017
Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.	Improving the chances of success as much as possible, by publishing a wider range of HFEA data on our website, to drive improvements in clinic performance. This information will be more useful and accessible, and will have a 'journey' focus, so as to better meet the needs of patients whose treatment is not successful. Ensuring the information we provide also enables patients to have realistic expectations (both of actual success rates and of what they should expect of clinics in the event that their treatment is unsuccessful). Continuing to publish the annual Fertility Trends report.	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. 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 specific signposting for patients who have experienced unsuccessful treatment.	March 2017 November 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
	Ensuring our messaging to clinics conveys the importance of handling the issue of unsuccessful treatment with sensitivity, including offering counselling. Continue to apply pressure on success rates and risk tool alerts related to these, through inspection reports and risk tool alerts.	Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	
Maintaining our role as the UK's competent authority for ART in the European Union.	Participation in competent authority events and implementation of associated EU decisions.	We attend and participate in 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.	June and December, annually. Throughout year
Reviewing our embryo research policies and regulation.	Reviewing the consent process in collaboration with the Health Research Authority (HRA), the sector and other stakeholders. Reviewing the Code of Practice guidance and relevant licence conditions. Review the end-to-end application and approval process. Research workshop to identify the barriers to research and innovation. Collaborative work with researchers, peer reviewers and Licence Committee to ensure a common understanding. Establishing clarity on what constitutes 'a single programme of research' within the bounds of the Act (which requires a separate	Review completed, in order that: No embryos are allowed to perish where the gamete providers would prefer them to be donated to research. The application and licensing process remains robust but does not impose unnecessary burdens. This outcome would also help to promote new research for the benefit of the sector, and support (or remove barriers to) innovation.	October 2016 – April 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	licence for every building) to inform a practical review of the licensing model.		
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.	Through the Lifecyle campaign (and through the IfQ work on Choose a Fertility Clinic, CaFC), we will continue to provide information about donation and gamete availability.	Lifecycle campaign leaflets continue to be available, giving a range of important information. 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. Improvements to CaFC delivered through the IfQ programme. Improved information about gamete availability.	Throughout year July 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.	Through the Lifecyle campaign (and through the IfQ work on CaFC), we will continue to provide information about donation.	Clarity of role and performance for clinics in relation to donation and associated information guardianship responsibilities. Improved experience for donors, donor-conceived people seeking information and patients and their families.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Continuing the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register.	Continuing to run the three year pilot of counselling support services for applicants to the Register.	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, throughout the pilot period. 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. Annual evaluation of the pilot provided to the Authority.	Piloting continues through to June 2018.
Implementing new EU requirements relating to the import and coding of donor eggs and sperm.	Completion of projects initiated 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 the new EU directives. Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.	April 2017 (the EU implementation date)

Activities	Methods and channels	Benefits and outcomes	Timescale
		Increasing and informing choice	
Strategic objective 3: using the data in the HFEA Register of Treatments to improve outcomes and research			
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 respond to information requests. Risk-based regulation and evidence-based policy-making are better supported.	Throughout year
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
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing useful insights for patients.	Throughout year
	Following the implementation of a revised CaFC (under development through the IfQ programme), continuing to develop and improve the presentation of clinic comparison information and user experience scores, guided by patient feedback.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Acquisition of ongoing feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	March 2017
	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

Activities	Methods and channels	Benefits and outcomes	Timescale
	Information provision for researchers requesting access to Register data.	Information for researchers is provided within 90 calendar days of approval. Register information is used to best effect, to promote understanding and facilitate good research, and ultimately patient benefit.	Throughout year
	Facilitating access to information under various regimes and fulfilling Government requests.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year
	To continue to publish statistical and other reports.	'Fertility treatment in 2015' report covering 2014–2015. - 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.	March 2017

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 2016
Maintaining our previously established collaborative information management relationships	Maintaining our good working 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 2017
Strategic objective 4: ensuring patients have access to high quality meaningful information			
Improved HFEA website information about treatments available, scientific research, embryo and stem cell research and other fertility subjects.	Continuing the development of new content for our website (redesigned in 2015/16) to provide an expanded range of educative and scientific information about current and future treatment options, the scientific evidence associated with these, and other fertility issues.	Increased information for patients and others, that is accessible, engaging and meaningful. Prospective patients have clearer information and signposting. Patients better informed and better placed to deal with treatment issues and decisions. Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments as well as the possible benefits.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. The horizon scanning panel meets once per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is improved by early identification of upcoming issues.	Throughout the year June/July Throughout the year
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.	More information about new treatments on our website. 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.	Throughout year
Enhancing the patient voice in all of our work, including information provision.	Further developing our communications with, and information provided to, patients so as to help them to make informed choices about fertility matters. Ensuring patient feedback is continuously incorporated into our core business, for example through user experience ratings of clinics.	Patient views and needs are better incorporated into our work and are reflected in the style and content of the information we provide. There are increased feedback opportunities for patients via the website, and easier interaction with us.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
Responding effectively to specific enquiries from individuals.	Continuing to respond to the many individual patient and public enquiries we receive each year.	Individual patients and members of the public are able to ask specific, sometimes complex, questions and receive a tailored and meaningful response. We remain responsive, and continue to be able to handle the range of one-off enquiries raised by individuals, providing a considered and informed response within a reasonable timescale. We are able to identify any trends and common themes in the enquiries we receive, informing the development of additional information which could be placed (for example) on our website.	Throughout year

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 service.	Completion of the work started in 2015/16 to modernise the HFEA's Register function and processes (EDI, data submission and verification, the Clinic Portal, and the data dictionary).	Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality. Reduction in unnecessary effort by clinics submitting the data.	October 2016
	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. Fees Group continues to be run effectively. Annual review of fees takes place.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is a good value organisation and makes best use of its limited resources.	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
	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
	Responding to the HFEA's triennial review report, as required.	Ensuring the organisation is soundly run, providing best possible value, and compliant with Government targets.	To be confirmed
	Building and maintaining our staff capacity and skills, in line with our people strategy.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need, through Civil Service Learning and other means.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Responding as appropriate to emerging new government rules on transparency and better regulation (the Enterprise Bill, the 'growth duty' and the Regulators' Code).	Complying with new better regulation requirements that may emerge from the current consultation exercise by: Consulting on an innovation plan (Spring 2016). Reporting in our Annual Report on the growth duty and compliance with the Regulators' Code . Complying with the Business Impact Target by identifying and reporting any 'in-scope activity' (a new ongoing duty). Note: Regarding the proposal to establish a Small Business Appeals Champion in every body, it was proposed by BIS in their February 2016 consultation that the HFEA should not be in scope for this requirement. Subject to the outcomes of that consultation no activity is expected in this area.	The HFEA responds consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties. Innovation plan consultation. Annual Report publication including additional required information. Compliance with the Business Impact Target for any activities that may be in scope.	Throughout year June 2016 July 2016 Throughout the year
Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations.	Continued participation in the collaborative 'one stop shop' for life sciences to provide regulatory advice to those working in the life sciences industry.	Continued constructive joint working between the HFEA, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA). Businesses and other organisations in the life sciences industry enabled to quickly and easily navigate the different regulators and allow them to access the right advice more quickly.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to share services and infrastructure with other organisations as practicable: 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 landlord of our office premises, via an SLA.	We continue to operate in as efficient a way as possible, extracting maximum value from shared support arrangements and seeking other opportunities.	Throughout year
	Moving to new office premises, alongside another arm's length body (ALB).	Best overall use made of Crown Estate property. Overall saving on accommodation achieved for the group of health ALBs as a whole, even if the HFEA's individual accommodation costs have to increase in order to enable this. Further shared services and efficiencies possible for and with other similar organisations in the health ALB family.	April 2016 onwards
	Continued collaborative and partnership working with other ALBs and health regulators UK wide, such as the CQC, MHRA, UKAS, HRA, GMC, NIB and the home nations, maintaining the close positive working relationships that have been developed over the past several years (particularly in response to the McCracken report, reviewing the HFEA and the HTA, which was published in 2013).	Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the best approach if any new areas of regulatory overlap should arise (as was done previously with the CQC, removing overlap in relation to the regulation of medicines management and surgical procedures in clinics).	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
		Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators.	

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 2015 and 31 March 2016. [DN: Data is added after year end, for obvious reasons]

Number of:	2014/15	2015/16
Active clinics and research establishments	127	
Clinics and research establishments inspected	61	
Licences inspected	62	
New licence applications processed and presented to the Licence Committee	6	
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	35	
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	9	
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	44	
Incident reports from clinics processed	453	
Alerts issued	0	
Formal complaints about clinics	9	
Opening the Register requests closed within 20 working days	260	
Donor Sibling Link applications processed	23	
Licensed Centres Panel meetings held	2	
Meetings with patient organisations held	1	
Public and stakeholder meetings	48	
Freedom of Information (FOI) requests dealt with	105	
Environmental Information Regulations (EIR) requests dealt with	0	
Enquiries responded to under the Data Protection Act (DPA)	0	
Parliamentary questions (PQs) responded to	136	
Information for researchers requests received	0	
Visits to the anonymised Register download page	462	
Unique visits to our website	1,337,484	
Most popular/viewed page on our website	IUI - What is intrauterine insemination (IUI)	

Required HR benchmarking information

In common with other ALBs, we are required to maintain a record of the following standard benchmarking data: [DN: Data is added after year end]

Very senior manager (VSM) to staff complement ratio	
Number of staff earning more than £142,500 now and any planned change during the next planning period	0
HR staff to employee ratio	Xx
Training budget as a percentage of pay bill	Xx
Projected reductions in non payroll staff	Xx

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 2015/16 for a small sample of these indicators. We will continue to track the same indicators, and more, throughout 2016/17. [DN: Data is added after year end]

Performance indicator	Target for 2015/16	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.	xx critical xxx major (from xx 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).	xxx% (xx no. of 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.	x% (x items published, of which x 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.	X,xxx
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 = xx.x working days Range: xx-xx working days
Cash and bank balance.	To move closer to minimum £1,520k cash reserves.	Year start = £2,038k Year end = £xxxxxk

Financial picture

Our finances and high level budget

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 regulation: 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 treatment fees by 28% to reflect that our 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. Treatment numbers have now levelled off and treatment income has fallen 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 also 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 an 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 2016/17 is shown below.

Income	£000s
Department of Health funding	938
Treatment and licence fees	4472
Other income	6
Total income	5416
Operating costs, of which	
Staff costs	4060
Other operating costs	1320
Total operating costs	
Capital charges	36
Total revenue expenditure	5416

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 2016/17, IfQ spend is expected to be £200k 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 arm's 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 in 2015/16. 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 currently occupy the same premises, although our office location will change, and new arrangements will be put in place, in early 2016/17). We also have a shared services agreement with CQC for recruitment, which will continue.

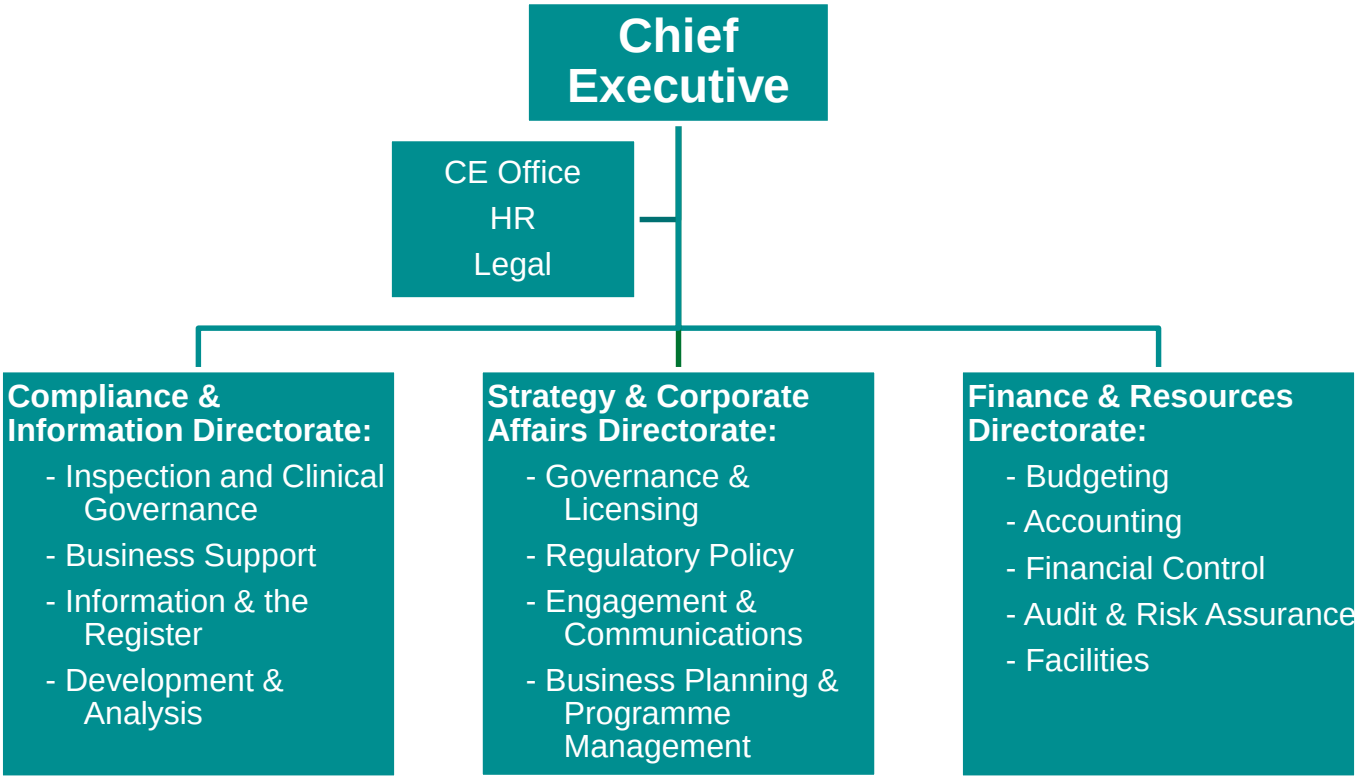
We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. Our people strategy, published in 2015, sets out how we will ensure we retain the capability and capacity to deliver our overall strategy for 2014–2017.

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.



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 with the Department of Health (in 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 is 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. While we occupy the same premises as the CQC, this necessarily entails 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 moving offices during the course of the coming year, we 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 reviewed our business continuity plan in 2015/16 to ensure it remains fit for purpose. 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. Following our office move early in the 2016/17 financial year, 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. In April 2016 we are moving into NICE's office space in Spring Gardens, taking up 269 square metres.

Our tenancy with the CQC will end in May 2016 when the CQC moves completely from the Finsbury Tower.

The HFEA will continue to work with CQC then NICE 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.

After our move, we will have a single multi-function device (for secure printing, scanning and photocopying), 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, and we expect this proportion to increase slightly following our move to smaller premises.

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 2016/17 will relate to the IfQ programme, which has been subject to specific business cases agreed by the

Department of Health and the Government Digital Service through various highly robust mechanisms. All related procurement in 2015/16 was conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2016/17.

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 example we have worked for some years with other organisations to reduce the prevalence of multiple births in the fertility sector and we routinely open developments to our policies and processes to a wide range of inputs and influences, including voluntary organisations.