Human Fertilisation & Embryology Authority

Business Plan

2017/18

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 2017-20 is:

High quality care for everyone affected by fertility treatment.

Patients, donors and donor-conceived people are at the heart of our strategy, and our work. We want them all to receive high quality care and support, at every stage in their journey through fertility services.

In setting our strategy, we considered people's needs at different points in their treatment journey.

Prospective patients (in particular) need to be able to find information to help them understand their options, know where to go for further advice and decide what steps to take next. People who have decided to have treatment (or to be a donor), and have contacted a clinic, need more detailed information to help them make decisions about treatment, and prepare for it. Patients and donors need good support during the treatment or donation process, and they need a deeper understanding of particular topics relating to their care. And people who have had treatment (whether it was successful or not), who have donated gametes, or who have been conceived through donation, need further information and emotional support at a later stage.

What can we do to achieve high quality care?

Our strategy for 2017-2020 focuses on three areas in order to meet these needs:

Safe, ethical, effective treatment

- High quality, safe care
- Effective evidence based treatment and treatment add ons that are well explained
- High quality research and responsible innovation

Consistent outcomes and support

- Access to treatment and donation
- The best possible treatment outcomes
- Value for money
- Support before, during and after treatment

Improving standards through intelligence

- Data and feedback used for improvement
- Targeted regulatory interventions
- Increased use of patient feedback
- A reshaped HFEA, to use our data well

This business plan sets out how we will work towards our vision in 2017/18.

Our legislation and functions

Our regulatory role and functions are set by two pieces of legislation:

- 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').

Under this legislation our main statutory functions are:

- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment.
- To license and inspect centres undertaking human embryo research.
- To license and inspect the storage of gametes (eggs and sperm) and embryos.
- To publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities.
- To keep a register of information about donors, treatments and children born as a result of those treatments.
- To keep a register of licences granted.
- To keep a register of certain serious adverse events or reactions.
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures.

In addition to these specific statutory functions, the legislation also gives us 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 our functions effectively, efficiently and economically.
- Publicising our role and providing relevant advice and information to donor-conceived people, 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 2016/17

Delivery of the 2016/17 business plan

Overview

In 2016/17 we formally completed our Information for Quality Programme, known as IfQ. This programme has given us the means to transform how we collect, analyse and publish information. It enabled us to complete our strategic delivery for 2014-2017, and equips us well for 2017-2020. The public, the sector and the HFEA itself will reap the benefits of a new and improved website with a better Choose a Fertility Clinic feature, both of which we expect to go live by the summer, and a clinic portal which has improved functionality and design, and which has already been launched.

Later in 2017, we will go on to introduce a new data submission system for clinics, which will increase the 'first time' accuracy of the data submitted to us, and decrease the effort required by clinics in submitting data to us for the Register of treatments. This will establish a more modern, effective and reliable technical underpinning for the Register, the clinic portal and the website.

Our activities for last year also included a particular regulatory focus on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites. In the second half of the year the Authority agreed to allow the new treatment of mitochondrial donation.

We reviewed our embryo research policies and regulation, and responded to various new Government agendas and reports, including our Triennial Review report (published in April 2017), and a range of new Government requirements on transparency, innovation and business impact.

We developed our next strategy, for 2017-2020, retaining our strong vision for high quality care for everyone affected by fertility treatment. We have the staff and the financial resources in place to complete this varied and challenging programme of work.

Setting standards

Improving the quality and safety of care through our regulatory activities

Delivering the full compliance and licensing cycle to maintain standards for patients

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 publish for their patients (eg, on their websites).

In 2016/17, we carried out our usual full range of inspection, audit and licensing activities. This ensured that 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 governance and licensing work during the year included handling applications for the licensing of preimplantation genetic diagnosis (PGD) and human leukocyte antigen (HLA) testing. This is a growing area of work, which needs to be processed effectively and efficiently so that decisions on whether to authorise such treatments are made, and communicated, in a proper and timely manner for the direct benefit of patients awaiting treatment. We have also recently received our first ever licensing application from a clinic that wishes to offer mitochondrial donation treatment.

Our triennial review action plan in response to the recommendations in the report has already been largely completed, and will conclude with the benefits realisation review for the IfQ programme, in the course of the coming year. We continually work to ensure that all our compliance processes encourage quality improvements. We want our regulatory work to have a positive impact and to be effective.

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

We continued to focus on the quality and safety of care in our inspection activities – in particular through identifying shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.

It is vital that clinics understand, and adhere to, correct consent procedures (including those associated with legal parenthood). Through our regulatory work, we emphasised the importance of getting this right, and helped clinics to improve their practices.

New guidance on consent will be published shortly after this business plan. This will include a new suite of forms for transgender people, which will help clinics to offer a high quality service to this small but growing group of patients.

Our multiple births policy, 'One at a Time', has been a real success. In 2008, 24% of all births from assisted reproduction were multiples. Today the average figure is 14%, with many clinics well under the 10% target. Success rates have remained steady and, most importantly, patient understanding of the risks of multiple births and the benefits of single embryo transfer has increased.

We published our latest report on clinical incidents in 2016. We encourage our clinics to have a learning culture, and to share learning throughout the sector so that all clinics are safer and errors are minimised. It is important that any negative patient experiences result in improvements, and that any recurrence is prevented. We developed a collaborative relationship with NHS Improvement, so as to consider wider lessons learned that may have relevance in the fertility sector.

As part of our IfQ programme, we worked with clinics throughout the year to improve the quality of our Register data. Building on that work, we will improve the data submission systems used by clinics so that less remedial work is needed in the future – data submitted will be 'right first time'. The end result will be a better quality service for Opening the Register (OTR) applicants, and fewer data submission and data accuracy related non-compliances found on inspection and audit. In the coming year we will also be in position to extract better value from the wealth of data we hold, and publish a wider range of information about trends and statistics.

Through our new website, shortly to go live, we are now publishing a wider range of reference material for patients, including better information and signposting for patients when they first realise they may have a fertility issue. We want to help patients to feel more equipped to ask the right questions about fertility issues and available treatments, regardless of the level of knowledge of their own particular GP.

Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.

Our new website contains more information about the chance of a birth following fertility treatment, so that patients have realistic expectations (both of actual success rates and of what they should expect of clinics in the event that their treatment is unsuccessful). We expect clinics to handle unsuccessful treatment with sensitivity, offering counselling and support as appropriate. This remains a priority in our new strategy.

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

As long as the UK remains in the EU we will continue to participate in competent authority events and the implementation of associated EU decisions. We participate in two meetings per year.

These meetings help us to gain up-to-date intelligence about the perspectives of other EU member states, helping to inform the UK approach to patient safety and care. As the competent authority, we continued to ensure that free movement of gametes and embryos was enabled within the UK and that standards upheld in the UK were consistent with those in the rest of the EU.

Reviewing our embryo research policies and regulation.

We reviewed the consent process for donating embryos for research, in collaboration with the

Health Research Authority (HRA), the sector and other stakeholders. We also reviewed the relevant Code of Practice guidance and licence conditions, the end-to-end application and approval process, and the associated paperwork.

As a result, we have made improvements to the application and licensing process, ensuring it remains robust but does not impose unnecessary burdens. We have also improved the forms used by peer reviewers to inform the Licence Committee's decisions about research project licences.

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

Better information was central to our IfQ programme, and remains a key benefit.

We have redesigned our website and Choose a Fertility Clinic (CaFC) tool, with a new headline measure of births per embryo transferred.

We provide up to date information about donation (via the new website) and have improved the information we provide about gamete availability (via CaFC). We want to equip potential donors, recipients and donor conceived people with clear, authoritative impartial information about a range of donor conception issues, so that they feel better informed and supported with respect to the legal aspects and obligations of donation.

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.

We published information about donation so that clinics, donors and patients could understand all of the issues and legalities associated with donation.

We also emphasised to clinics the importance of their role and performance in relation to donation and the associated information guardianship responsibilities.

Evaluating the provision and take-up to date of the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register

In July 2016, we evaluated the first full year of the three-year pilot of counselling support services for applicants to the Register[1]. Feedback so far has been positive.

Counselling support through the pilot 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 also in place for when donors and donor-conceived people meet. Our mediation training and systems assist us in managing the process of identity release to donors and donor-conceived people.

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

This year, we were due to complete a set 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. The aim is to achieve compliance with the new EU directives, improved clarity for clinics, patients and donors, and improved internal clarity and updated procedures for our decision-making committees. The projects will also ensure robust processes are in place to ensure the quality, safety and traceability of imported gametes and embryos.

A Department of Health consultation on the implementation of the directives was delayed following the EU referendum leading to Brexit, but

[1] Explanatory note: A donor conceived person aged 18 or above is entitled to access identifying information about their donor, provided the donor has asked for their right to anonymity to be removed.

is expected to be released shortly. The work will now be completed in 2017/18.

Increasing and informing choice

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

Throughout the development work of the IfQ programme, we have continued to ensure that Register data and forms are processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries. We are especially grateful to clinics for their cooperation and hard work during the latter part of the IfQ programme while we conducted a more extensive data verification exercise than usual to ensure that the new Register structure contains high quality, accurate data when we migrate from the old system.

Publishing and supplying the information we hold, for the benefit of stakeholders.

Our focus for much of the 2016/17 year, through IfQ, was to ensure our published outcome data is more useful and easier to understand and provides positive incentives for service improvements.

Our new CaFC gives users a much more rounded picture of quality. For the first time, patients are able to see at a glance not only the outcome statistics for a particular clinic, but also a rating based on the most recent inspection report and a patient experience rating.

The new edition of CaFC is subtly different from the beta (draft) version we issued for initial consultation in the summer of 2016. The consultation response was very strongly against our original proposal to aggregate all treatments and all ages in the headline measure – and the Authority therefore made a decision in November 2016 that the new headline births per embryo transferred measure should be based on stimulated IVF and ICSI involving women under 38 using their own fresh eggs. All the other data for patients that was available on the old CaFC continues to be available within the new CaFC.

While the new version was being developed, we continued to update the current CaFC periodically with the latest data and inspection reports, so as to assist patient choice and keep the information we provide as up-to-date and accurate as possible.

We will seek ongoing feedback to evaluate the effectiveness and usability of the new CaFC presentation, and to plan future improvements.

One of our most important legal duties is to facilitate timely access to information from the Register for those who are entitled to it, and we have continued to manage Opening the Register requests in a sensitive manner and within the required time limits (20 working days, excluding time for counselling), throughout the year.

We also provide information for researchers requesting access to Register data, within the required time limit (90 calendar days from approval). No such requests were received in the past year, but it remains important that the information in the Register is available in this way and can be used to best effect, to increase understanding and facilitate good research, and ultimately benefit patients. In our strategy for 2017-2020, we have placed a renewed emphasis on improving the evidence base for both embryo and data research.

We fulfilled a range of access to information requests under various regimes, including regular information publication under various legal and Parliamentary rules.

We published our annual report on clinical incidents and alerts. We encourage a culture of openness and information sharing, with clinic staff empowered to report mistakes and learn from each other. The purpose of our report is to increase transparency and maximise the opportunities for learning from incidents, so as to improve the quality and safety of care for patients.

Maintaining our previously established collaborative information management relationships

It is important for us to maintain the good working relationships we have established with the relevant

bodies, such as the Government Digital Service (GDS), NHS Digital (formerly the Health and Social Care information Centre) and the National Information Board (NIB). Through collaborative working, we contribute to the objectives of the wider health system, with respect to information management.

Our participation in joint work with such bodies facilitates learning from best practice and easier sharing of expertise, so that we can all make use of each other's strengths and knowledge in data management, systems integrity and security.

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

We expect to release the new HFEA website from the beta version to fully live in late spring 2017 (subject to a final GDS service assessment). The old site will then be switched off. The new site is aimed primarily at patients and donors and adopts a tone of voice and level of detail designed for that audience. It is simpler, more direct and – like our strategy – is organised round the patient's treatment journey.

It has been designed to be read on phones and tablets, since increasingly that is people's primary means of accessing information online. And it uses new ways of presenting information – with animations and videos, as well as the traditional text and documents.

The website now provides an expanded range of educative and scientific information about current and future treatment options, the scientific evidence associated with these, and other fertility issues. This includes clearer information for prospective patients, and some useful signposting to external sites and other information resources.

We conducted our annual horizon scanning exercise to ensure we identified possible new scientific developments, too. Our Scientific and Clinical Advances Advisory Committee (SCAAC) meets regularly to discuss issues identified through this exercise. This helps us to ensure that our future work, our policy developments and our website material are informed by experts and that we maintain an understanding of scientific issues and developments.

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

As part of our development work for the website, we established mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts, including SCAAC.

In providing more information about new treatments, our aim is to increase the public's understanding of emerging new science and future treatment possibilities. We believe this keeps patients better informed and leaves them better placed to make treatment decisions and to judge for themselves the merits or otherwise of any media speculation about potential new treatments.

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

In the course of IfQ, we greatly developed our communications with, and information provided to, patients, with the aim of making our information as patient-friendly and useful as possible, and to help them to make informed choices about fertility matters. Patient views and needs are now continuously incorporated into our core business, for example through user experience ratings of clinics.

Responding effectively to specific enquiries from individuals

We receive many individual patient and public enquiries each year. These are specific and sometimes complex, questions, and receive a tailored and meaningful response within a reasonable timescale.

Analysis of such enquiries also helps us to identify any trends and common themes, informing the

development of additional information which could usefully be placed on our website.

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 service

In 2017/18, we will complete the final part of the work started in 2015/16, through the IfQ programme, to modernise our Register function and processes (EDI, data submission and verification, the clinic portal, and the data dictionary). As well as a range of improvements for patients, this will ultimately result in reduced transactional costs for clinics and increased satisfaction for clinic users, whether they are submitting data to us or looking for the latest regulatory guidance.

In January 2017 we released the first stage of the new clinic portal, the primary means by which clinics interact with us between inspections. The portal reminds clinics about actions, offers searchable guidance and regulatory information, gives clinics clearer monitoring and performance information and allows them to apply for licence variations, through a simple online system.

The second stage of the clinic portal will follow later in 2017 and will greatly improve the data submission system. This will allow clinic staff to spend more time treating patients and less time filling in forms or verifying that the submitted data is correct. We have also been working positively with suppliers of patient records systems, used by approximately half of our clinics, so as to make the transition seamless.

The improvements will also allow our staff to spend less time checking data and chasing errors. Instead we will spend more energy on analysing the data we hold, providing clinics and patients with national level intelligence on a range of key issues.

We have also continued our engagement arrangements with clinics on fees charged. This provides both accountability and transparency in respect of the fees we charge clinics.

Ensuring the HFEA is a good value organisation and makes best use of its limited resources

We use our strategy as a mean of prioritising our activities and managing our limited resources to best effect.

We aim to provide a speedy service to patients whenever they contact us.

IfQ has provided us with an infrastructure that underpins the delivery of our strategic vision. At the start of the new business year, we have also put in place a new organisational structure to enable us to make full use of our data and improved information channels. A staff consultation on the changes took place at the end of the 2016/17 business year.

It is vital that we can maintain the staff capacity and capability needed to deliver our strategy and our core statutory duties. We ensure our staff have the skills and training they need to perform their roles effectively, and all our staff have access to Civil Service Learning to build their own development plans and enhance their competencies.

Responding as appropriate to emerging new government rules on transparency, innovation and better regulation (the Enterprise Bill, the 'growth duty' and the Regulators' Code)

In order to comply with new better regulation requirements, we consulted on an innovation plan in spring 2016. Encouraging responsible clinical innovation is at the heart of our new strategy for 2017-2020.

We report annually on compliance with the Regulators' Code, and in time, the new growth duty. In addition, during the year we ran a project to introduce the new business impact target, which requires regulators to submit a formal business impact assessment for all qualifying activities and projects.

Our statutory independent appeals mechanism means that we are exempt from the requirement to have a Small Business Appeals Champion.

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

Throughout the year, we participated in the collaborative 'one stop shop' for life sciences to provide regulatory advice to those working in the life sciences industry. This is continued joint work between ourselves, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA).

This year we worked with the MHRA to provide guidance on CE marking, and on the use of non-CE marked goods for mitochondrial donation techniques. We have attended meetings about their new guidance on medical devices and drug-device combination products. We also continue to work with them on related areas, such as medical devices alerts. We will continue to work with the MHRA, and others, to share intelligence and ensure joined up working.

We share services and infrastructure with other organisations as practicable, sharing a Finance Director and Head with the HTA, receiving services through service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as our key learning and development provider. We moved to shared premises with NICE in April 2016, helping both organisations to make best use of Crown Estate property, and receive facilities services from NICE.

We work collaboratively, and have various memoranda of understanding with various other ALBs and health regulators UK wide, such as the Care Quality Commission (CQC), the MHRA, the United Kingdom Accreditation Service (UKAS), the HRA, and the General Medical Council (GMC).

Throughout the year we were active members of the National Information Board (NIB) and maintained our good working relationships with regulators in the devolved nations of Scotland, Wales and Northern Ireland.

Delivering our strategy in 2017/18

Delivering the strategy

Our strategic vision for the three years from April 2017 to March 2020 is:

High quality care for everyone affected by fertility treatment.

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

In this area…	We will…
Safe, ethical, effective treatment	1. Ensure that all clinics provide consistently high quality and safe treatment
	Our aim: • patients know clinics provide a high quality, consistent, safe service
	2. Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment
	Our aim: • increase patients' understanding of the science and evidence base behind treatments and added extras known as add ons, and of their safety and effectiveness.
	3. Engender high quality research and responsible innovation in clinics
	Our aim: • improve the quality of treatment, by encouraging world class research and clinical trials.
Consistent outcomes and support	4. Improve access to treatment
	Our aim: • provide advice and information about access to treatment and improve access to donor conception treatment.
	5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients
	Our aims: • higher birth rates, without adverse outcomes. • patients and NHS commissioners receive good value fertility services • improve the emotional experience of care by clinics before, during and after treatment or donation
Improving standards through intelligence	6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.
	Our aims: • use our data and intelligence to drive quality improvements for patients. • targeted and responsive regulatory interventions in the interests of quality and consistency. • increase insight into patient experience in clinics and encourage good practice based on feedback. • work more smartly with our resources, and capitalise on recent systems improvements.

The activities set out over the next few pages describe how we will meet these strategic objectives in 2017/18.

There is also an agreed shared delivery plan for all arm's length bodies and the Department of Health. This delivery plan gives high level clarity on objectives that reach 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 safest, highest quality healthcare services possible. Linkages with specific objectives in the shared delivery plan are indicated in the activities section setting out our plan of work for 2017/18.

Activities for 2017/18

Having delivered the majority of our previous strategy (due to conclude in July 2017), we now have a new clinic portal, and we expect our new website to go fully live, from beta, before the summer. We are also preparing to migrate our Register of treatment information into a new database, and we are putting in place a new data submission system to collect treatment data in a more efficient and accurate way.

These developments enable us to collect and use our data, and to communicate with our audiences, more effectively and efficiently. We have also begun, in April 2017, to re-shape our organisation to ensure we have the skills and capacity in place to make full use of our new tools and the new possibilities they open up.

There are three main areas of focus in our strategy:

- safe, ethical, effective treatment
- consistent outcomes and support
- improving standards through intelligence.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2017/18, in the interests of high quality care for everyone affected by fertility treatment.

Aims	Methods and channels	Benefits and outcomes	Timescale
Safe, ethical, effective treatment			
Strategic objective 1: **Ensure that all clinics provide consistently high quality and safe treatment**			
Ensure that clinics are well regulated and provide a high quality, consistent service. Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities, with an increased emphasis on consistent standards across the sector, and between inspections. We will be clearer about what good performance looks like and will use our skills and our data to help clinics to be more compliant, more of the time.	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 consistent standards and safety for the public and other stakeholders. A clear Code of Practice and other guidance for clinics, that is regularly updated. Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites). Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances. Reduction in the number of clinic incidents, owing to learning from own and others' mistakes.	Throughout year October 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
	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 2016. 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 NHS Improvement to consider any wider lessons learned that may have relevance for the fertility sector.	November 2017 Throughout year
	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
	Conduct 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.	December 2017
	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 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

Aims	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 2: **Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment**			
Make use of our new website and other channels to increase patients' understanding of the science and evidence base behind treatments and added extras known as 'add ons', and of their safety and effectiveness. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.	Inclusion of up to date scientific content in our website so as to provide and maintain our expanded range of information about current and future treatment options and treatment add ons, and the scientific evidence base for these. Responding to new scientific developments and associated reporting, correcting myths and misunderstandings where necessary.	Patients and others turn first to the HFEA for up to date, clear unbiased information. Prospective patients have clear information on which to base decisions about treatment or add ons. Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments or add ons as well as the possible benefits.	Throughout year
	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 facilitated by early identification of upcoming issues.	Throughout year June/July 2017 Throughout year Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 3: **Engender high quality research and responsible innovation in clinics**			
Improving the overall quality of treatment, by encouraging world class data and embryo research and clinical trials. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 6: supporting research, innovation and growth.	Encourage an enquiring culture and responsible innovation in clinics. Explaining embryo and data research projects and their outcomes. Encouraging clinics to enable more patients to participate in data research, and to donate unused embryos for research. Publishing information about the availability of embryos donated for research purposes. Ensuring that clinics explain research consent adequately, record consent properly and then report consents accurately to the HFEA.	Clinics become more research-focused, leading to more scientific and clinical research in clinics, with new techniques properly tested. A larger, higher quality evidence base, leading to improved outcomes. Patients are aware of research they could take part in, and how it might benefit future patients. Patients can easily donate embryos to research and research centres have access to those donated embryos for their research projects. Higher rate of consent to research from patients. Improvement in consent-taking and reporting by clinics.	March 2018
	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 increase understanding and facilitate good research, and ultimately patient benefit.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Consistent outcomes and support			
Strategic objective 4: **Improve access to treatment**			
Providing advice and information about access to treatment, and improving access to donor conception treatment. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: Enabling people and communities to make decisions about their own health and care.	Publishing information and advice about accessing services, through various channels, including information for those considering going abroad for treatment on how they might access services in the UK.	People understand the possibilities and the hurdles, and can weigh up the options open to them (measured through patient surveys). People can easily find relevant information and signposting on our website, to inform their next steps.	March 2018
Improving access to donation, support for patients and donors and information about access to donor conception treatment. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: Enabling people and communities to make decisions about their own health and care.	Providing advice for patients about access to donor conception treatment, and encouraging better donation support for donors and patients, including those considering using unlicensed donor sperm services. Working with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm and eggs.	People understand the process, and are prepared for donation and treatment (measured through patient/donor surveys). Donors and patients are better supported by clinics. An increase in UK-based donation.	March 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 5: **Increase consistency in treatment standards, outcomes, value for money and support for donors and patients**			
Identifying and implementing ways of improving the quality and safety of care. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Continuing our focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, learning from incidents, 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 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 consents are more likely to be in place and are legally clear and robust.	Throughout year
	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.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	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 2018
	Working with commercial groups of clinics so as to improve quality, consistency 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 2018
	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 2018
Using our outcome data to improve the chances of successful treatment Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	With the aim of increasing birth rates while avoiding adverse outcomes, we will work with our professional stakeholders to define and establish the factors that lead to successful outcomes, and publish our findings. Continuing to publish the annual Fertility Trends report. Focusing on success rates through inspection reports and risk tool alerts.	Evidenced success factors, published on our website. More information published so that clinics can compare themselves more easily, based on different factors such as patient age. Fertility treatment in 2016 report published. Patients' chance of a live birth is maximised. Patients understand the risks of a multiple birth and the advantages of single embryo transfer.	March 2018 and further work in 2018/19 March 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving value for money, for both patients and NHS commissioners. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 9: Improving services through the use of digital technology, information and transparency.	Exploring how we can make use of externally generated benchmarking information, and our own outcome data, to assist NHS commissioners in securing fair prices and effective fertility services for patients. Eliciting more feedback from patients as to whether they paid what they expected to for fertility services.	Patients know the price of a treatment at a given clinic at the start of treatment, and pay what they expect. Patients question costs, and particular additional costs, more often. Less variation in the price of treatment. The NHS pays a consistent and fair price for fertility services.	March 2018
Improving the emotional experience of care before, during and after treatment or donation. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Improving the emotional experience of care in clinics, by defining and encouraging best practice in clinics, and focusing on support at inspection. Ensuring that best practice is applied to donors and donor conceived people as well as to patients.	Clinics acknowledge how emotionally difficult infertility and treatment can be, and act on this. An improvement in the experience of treatment, with minimal emotional harm. Properly taken consents. Regardless of treatment outcome, but especially if it was unsuccessful, patients know they should expect care and support from the clinic beyond their final treatment. More information on our website for prospective patients, and specific signposting for patients who have experienced unsuccessful treatment. Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	March 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Evaluating the provision and take-up to date of the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Evaluation of the second full year of the three year pilot of counselling support services for applicants to the Register[2].	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. Second annual evaluation of the pilot provided to the Authority.	Piloting continues through to June 2018. September 2017
Implementing new EU requirements relating to the import and coding of donor eggs and sperm. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	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. (This work continues from the 2016/17 business plan, pending the resolution of Brexit.)	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.	October 2017

[2] Explanatory note: A donor conceived person aged 18 or above is entitled to access identifying information about their donor, provided the donor has asked for their right to anonymity to be removed.

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving standards through intelligence			
Strategic objective 6: **Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce**			
Driving quality improvements in treatment standards and outcomes by using our data and regulatory intelligence. Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Publishing an information strategy on how we will analyse, publish and use our data. Re-shaping our organisation to equip us with enough analytical capability to extract more value from the data we hold.	An information strategy setting out our plans. Donors, parents and donor-conceived people understand where their information is stored, the responsibilities of the clinic and the HFEA, and their access rights. Patients have confidence in their clinic as a life-long information guardian with excellent data submission practices. Better outcomes from NHS cycles.	March 2018
Maintaining our role as the UK's competent authority for ART in the European Union[3]. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Participation in competent authority events and implementation of associated EU decisions.	We participate in two meetings per year. Up-to-date intelligence gained about the perspective of other EU member states, 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

[3] For as long as the UK remains in the EU.

Aims	Methods and channels	Benefits and outcomes	Timescale
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	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.	Throughout year
Responding effectively to specific enquiries from individuals. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.	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

Aims	Methods and channels	Benefits and outcomes	Timescale
Publishing and supplying the information we hold, for the benefit of stakeholders. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.	Regularly updating Choose a Fertility Clinic (CaFC) information to assist patient choice.	Regular 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 the revised CaFC, 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. Patient feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	Throughout year
	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
	Facilitating access to information under various statutory regimes and fulfilling Government requirements such as quarterly disclosure of information on procurement.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	To continue to publish statistical and other reports.	‘Fertility treatment in 2016’ report covering 2015–2016. - 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 2018
		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. - Increases 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 2017
Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data. Outcomes in this area of work will contribute to the Department of Health’s shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Applying the intelligence available to us from inspections, the sector, patient feedback, and analysis of our data to make more targeted and responsive interventions.	Ability to make earlier and more responsive regulatory interventions, without the need to wait for the next inspection point. Regulatory performance is more consistent across the inspection cycle.	March 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Gaining insight into the patient experience in clinics and encouraging good practice based on feedback. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.	Collecting more patient feedback through new routes, including our website and social media. Analysing and using this intelligence to inform our activities and our messaging to clinics, sharing the information with professional stakeholders.	Improvement in the quality of services and patient/donor support as a result of patient ratings and other feedback. Quantifiable increase in the amount and frequency of patient feedback available to the HFEA and our professional stakeholders. Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach.	March 2018
Ensuring the HFEA is a good value organisation and makes best use of its limited resources. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.	Working more smartly with our limited resources, capitalising on recent improvements in our information systems. This will entail re-shaping our capability and capacity profile, so as to make best use of our new website and Register.	Resources are deployed in the interests of high quality care for everyone affected by fertility treatment. Achieving measurable 'added value' and internal efficiency. Benefits of Information for Quality Programme realised.	Throughout year
	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
	Ensuring internally provided services are efficient.	Our infrastructure is effective and contributes to the delivery of the strategic vision. Central systems, processes and tools are efficiently run, giving good value and service.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is easy to deal with and offers a professional service. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.	Full release of the HFEA's improved Register function and processes (the completed EDI, data submission and verification system, the Clinic Portal, and the data dictionary).	Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality and reduction in unnecessary effort by clinics submitting the data.	October 2017
	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, and annual review of fees takes place.	Throughout year
Responding as appropriate to new government initiatives on transparency, innovation and better regulation (the Enterprise Bill, the 'growth duty' and the Regulators' Code). Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance, and objective 6: supporting research, innovation and growth.	Complying with better regulation requirements by: 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).	The HFEA responds in a manner consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties. HFEA innovation plan published March 2017. Innovation has been included in our strategy for 2017-2020. Annual Report publication including additional required information. Compliance with the Business Impact Target for any activities that may be in scope.	Throughout year March 2017 June 2017 Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
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. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 4: improving efficiency and productivity of the health and care system.	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
	Sharing 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 facilities 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 arrangements and seeking other opportunities.	Throughout year
	Collaborative and partnership working with other ALBs and health regulators UK wide, such as the CQC, MHRA, UKAS, HRA, GMC and the devolved nations, maintaining the close positive working relationships that have been developed over the past several years.	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). Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Maintaining our previously established collaborative information management relationships. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 4: improving efficiency and productivity of the health and care system.	Maintaining our good working relationships with relevant other information management bodies, such as the Government Digital Service (GDS), NHS Digital 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.	Throughout year

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 2016 and 31 March 2017.

Number of:	2015/16	2016/17
Active clinics and research establishments	132	132
Clinics and research establishments inspected	88	71
Licences inspected	91	72
New licence applications processed and presented to the Licence Committee/ Executive Licensing Panel	5	6
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	42	36
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	1	1
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	54	45
Incident reports from clinics processed	529	558
Alerts issued	0	0
Formal complaints about clinics	13	10
Opening the Register requests closed within 20 working days	275	255
Donor Sibling Link applications processed	17	38
Licensed Centres Panel meetings held	2	2
Meetings with patient organisations held	2	2
Public and stakeholder meetings	10	8
Freedom of Information (FOI) requests dealt with	99	82
Environmental Information Regulations (EIR) requests dealt with	0	0
Enquiries responded to under the Data Protection Act (DPA)	0	1
Parliamentary questions (PQs) responded to	68	55
Information for researchers requests received	1	0
Unique visits to our website	1,323,509	1,271,686
Most popular/viewed page on our website	IUI - What is intrauterine insemination (IUI) and how does it work?	Fertility treatment options – Surrogacy

Required HR benchmarking information

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

Executive senior manager (ESM) 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	1:47
Training budget as a percentage of pay bill	1.5%
Projected reductions in non payroll staff	Not applicable[4]

[4] Our normal quota of non payroll staff is zero. At present, we are completing a programme of project work (Information for Quality, IfQ), which has necessitated some use of non payroll staff for additional resource and flexibility – particularly where backfill has been needed so that existing establishment staff can deliver aspects of the programme. There are currently four such non payroll staff in place.

Key performance indicators

In 2017, we are revising 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 2016/17 for a small sample of these indicators, in the context of our outgoing strategy for 2014-2017.

Performance indicator	Target for 2016/17	Performance
Safe, ethical, effective treatment		
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.	18 critical 179 major (from 72 inspections during the year)
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: 65.2 working days Range: 45-113 working days
Consistent outcomes and support		
Number of emailed public enquiries successfully responded to.	No target, since the nature, volume and complexity of enquiries received varies widely.	2,690
Improving standards through intelligence		
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% (255 requests)
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.	95% (193 items published, of which 183 were published within the target)
Cash and bank balance.	To move closer to minimum £1,520k cash reserves.	Year start = £2,157k Year end = £2,353k

Financial picture

Our finances and high level budget

We receive funding from two main sources: the majority, around 80%, from clinics and the balance from our sponsors, the Department of Health, as grant-in-aid (GIA).

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 steadily increased in the last twelve months. We also removed our eSet (elective single embryo) discount in January 2016 and increased our treatment fee from £75 to £80.

Our grant-in-aid funding from the Department of Health has reduced by over 50% since 2010 and it will remain constant for the next three years. Over the years we have managed our expenditure to ensure we spend within budget where ever possible. We have also used our reserves to reduce the draw on GIA. In the years 2014/15 to 2016/17 we demonstrated this by use of our reserves to fund a significant programme (Information for Quality, IfQ).

The high level operating budget for 2017/18 is shown below.

Income	**£000s**
Department of Health funding	933
Treatment and licence fees	5005
Other income	6
Total income	5944
Operating costs, of which	
Staff costs	3643
Other operating costs	2141
Total operating costs	
Capital charges	160
Total revenue expenditure	5944

In addition to our operating expenditure we will be continuing to invest in our IT infrastructure through the completion of our improvements to our information systems and the general refresh of physical IT assets.

Our 2017/18 capital expenditure is therefore formed of two elements:

- a nominal (and usual) requirement for Capital GIA of £100k to provide for our routine technology refresh; and,
- a further £450k of Capital cover to complete the final phase of the IfQ programme – “Release 2”

Release 2 is the data submission portal through which clinics submit patient / treatment data to us and on which we rely to collect statistics and to invoice for our fees. With the two other pillars of our improvement

programme complete this is the final component and the one that will provide a significant improvement to our licensed establishments.

As in previous years we will fund the £450k investment in our improvement programme from reserves, so although we will require “capital cover” from our sponsor department of £550k we will only look to draw down £100k in terms of cash.

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, a people plan (currently being revised to reflect our new strategy and organisational structure) and HR 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.

Better regulation and innovation

The objective of the Business Impact Target (BIT) is to reduce unnecessary regulatory burdens on business and ensure that regulatory decisions are made in the light of high quality, robust evidence about the likely impact on business.

Reporting against the BIT became a statutory duty for the HFEA in 2016, when statutory regulators were brought into scope of the Small Business, Enterprise and Employment (SBEE) Act 2015. We must produce BIT assessments of all regulatory provisions that are in scope and obtain independent verification of the economic impact of these regulatory decisions by submitting assessments to the Regulatory Policy Committee. We must publish our assessments, which are used by the government to report on progress against its deregulation targets. On 3 March 2016 the Government announced its overall target is to save business £10 billion of regulatory costs from qualifying measures that come into force or cease to be in force during this Parliament. The Government also announced an interim target of £5 billion of savings in the first three years of this Parliament.

We established a project in 2016 to produce retrospective assessments for our initial reporting period 2015 – 2017. From 2017, this work will be handled as part of our usual processes. We plan to continue to work closely with our external stakeholders as well as the Department of Health Better Regulation Unit, the Better Regulation Executive (who have the responsibility for implementing the BIT framework) and the Regulatory Policy Committee to ensure that our assessments are fit for purpose. We will satisfy the statutory requirements that are relevant to us in a proportionate manner, that assists our continued implementation of effective regulation across the whole of the IVF sector, and our strategy objective of high quality care.

In 2016/17 we consulted on and then published an innovation plan, as part of a Government requirement. The aim of innovation plans is to ensure the UK regulatory framework is working effectively to encourage innovation and that regulators like us are using innovation to deliver our work more effectively and to reduce the burden on business. We are also focusing on responsible innovation in clinics as part of our strategy and business plan.

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 reduced from 86 in 2010/11 down to 67 in 2016/17. 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, and our facilities management service is provided by NICE (since we now occupy the same premises, having moved offices in early April 2016). We also have a shared services agreement with the Care Quality Commission (CQC) for recruitment.

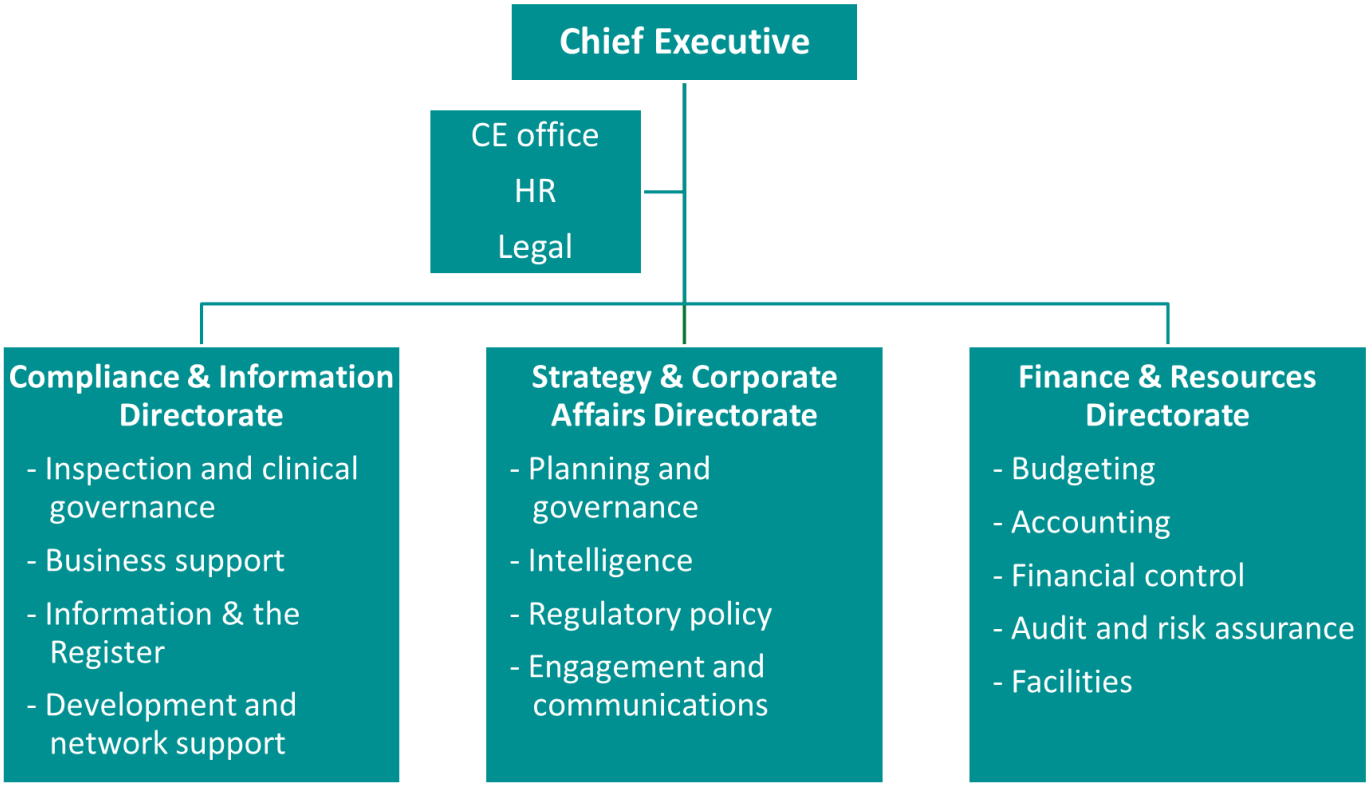
We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

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 manage our processes efficiently and 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 interdependency with the Department of Health or other ALBs 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 our 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 help us to manage the significant databases we hold.

HFEA databases are currently held on highly secure servers within the premises. While we occupy premises shared with another ALB, 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).

Our IT strategy includes secure arrangements for our servers, while adhering to all applicable central Government requirements. We have also moved, in the last year, into a cloud-based Office 365 arrangement for our desktop systems, which is more cost-effective and increases our resilience in the event of any business continuity issues with our physical premises.

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 2016/17 in light of our office move, 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.

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 moved into NICE's office space in Spring Gardens, taking up 269 square metres.

The HFEA works with NICE on health and safety and general facilities services. We have access to an online system for individual workplace assessment and meet with the NICE lead on fire evacuation procedures and fire warden liaison.

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), 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 this proportion has increased 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. These cover advertising, marketing and communications, IT, digital, professional services and learning and development. Business case approval from the Department is required in most cases.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchase 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 Department of Health target for public sector procurement of 23% 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 the previous year, 2016/17, was related to the IfQ programme, which was subject to specific business cases agreed by the Department of Health and the Government Digital Service through various highly robust mechanisms. All related procurement was conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2017/18. We provide the Department of Health with quarterly reporting on procurement.

There is no significant non-pay spend that is not via CCS, NICE 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 successfully 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.

10 Spring Gardens
London
SW1A 2BU
T 020 7291 8200
E enquiriesteam@hfea.gov.uk

www.hfea.gov.uk