Human Fertilisation & Embryology Authority

Annex A

Business plan

2018/19

www.hfea.gov.uk

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 2018/19.

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 2017/18

Delivery of the 2017/18 business plan

Overview

In the past year, we began to deliver our three year strategy for 2017-2020, with an emphasis on making full use of our clinic portal, website and data so as to improve quality for patients.

Our new clinic portal and website were launched in 2017, as part of our Information for Quality Programme. When the new Register and electronic data interchange systems are also fully complete, in autumn 2018, we will be even better equipped to collect and use our data in new and exciting ways.

Our aim, throughout our activities, has been to collect and use our data, and to communicate with our audiences, as effectively as possible. In order to capitalise fully on the advancements achieved through the Information for Quality Programme over the past three years, we restructured the HFEA's staffing, in April 2017, creating a new Intelligence team and re-shaping other functions. This reconfiguration will ensure we have the right skills and capacity in place to enable us to make full use of our new tools and to implement a newly agreed intelligence strategy in 2018/19 and beyond.

Following the restructuring, we involved our staff in the development of a people strategy setting out how we will attract and retain the skills and talent we need in order to deliver the Authority's strategic vision. Our people strategy describes our core values, which are:

- We care about our people
- We are expert and are knowledgeable about our business
- We are professional. We take pride in our work and act in an accountable way.

Our people strategy acknowledges that our success as an organisation depends on having skilled and motivated employees.

Safe, ethical, effective treatment

We carried out a full programme of clinic inspection, audit and licensing activities, increasing our emphasis on consistent standards and safety. We carried out additional inspections at a number of clinics after a Daily Mail investigation alleged poor practices in a number of clinics. We also began a conversation with the sector about clinic leadership, with the aim of putting in place new incentives to encourage and support excellent clinic leadership.

We maintained our strong focus on learning from incidents, adverse events and complaints from patients, and published our annual review of clinic incidents in November 2017.

Throughout the year, our licensing committees considered inspection reports and applications for preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) testing, and, for the first time, mitochondrial donation.

Our website includes a wide range of up to date scientific information, so as provide clear and unbiased information for patients about treatments or add ons. And our annual horizon scanning process helped to ensure that our policy developments and website material are informed by expert input and an understanding of current scientific issues and future developments.

We seek to encourage an enquiring culture and responsible innovation in clinics, and to improve the overall quality of treatment by engendering world class data and embryo research and clinical trials. Last year we completed two projects on research – one to ensure that clinics explain data research well to patients, and record consent accurately, and the other to promote and explain embryo research findings and improve the explanatory material available to patients about donating unused embryos for research purposes. We also continued to respond to requests from researchers for access to Register data for research purposes.

Consistent outcomes and support

We provided advice and information to patients about accessing treatment and donation, via our website. We also worked with professional stakeholders (such as the British Fertility Society, BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.

Through our inspection activities, we maintained our focus on quality and safety, focusing in particular on shortcomings in the taking and recording of consents, learning from incidents, medicines management, data submission, multiple birth rates, and the information clinics publish on their own websites. We also began to work with commercial groups of clinics, so as to improve quality, consistency and compliance on a group-wide basis, as relevant.

We have worked with NHS England on a piece of work led by them on price benchmarking, with the aim of assisting NHS commissioners in securing fair prices and effective fertility services for patients. This collaborative work will continue in 2018/19.

We began a project on the emotional experience of care before, during and after treatment, working with professional stakeholders to bring about improvement. Proposed changes will be incorporated into the next edition of the Code of Practice in 2018. We also evaluated the second year of a three year pilot of counselling support services for applicants to the Register.[1]

With the aim of improving the chances of successful treatment, we have been publishing more information in our annual Fertility Trends report, and focusing on success rates through inspection reports and risk tool alerts. In the coming year we plan to do further work on success rates.

At the end of the business year, we implemented new EU requirements relating to the import and coding of donor eggs and sperm. The introduction of new processes and certifications to ensure we are fully compliant will be in place by October 2018.

Improving standards through intelligence

In January 2018, the Authority approved a new information strategy, setting out how we will analyse, publish and use our data to improve the quality of the information we produce and, ultimately, to provide a sharper focus in our regulatory work. This followed on from the creation of a new Intelligence team in our organisational re-shaping in 2017. The information strategy sets out much of our strategic delivery in 2018/19.

We maintained our role as the UK's competent authority for ART in the European Union, participating in two meetings and implementing associated EU decisions such as the new requirements on certificating imports of eggs, sperm and embryos.

In addition to our programme of improvement work on the Register infrastructure, which will conclude this year, we maintained the Register of treatments and outcomes throughout the year, and worked with clinics to ensure accurate reporting of data. We also continued to publish the information we hold, and to respond to a range of enquiries from patients, clinics and central Government.

[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.

Delivering our strategy in 2018/19

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 2018/19.

We will start the year with a new set of tools and capabilities, and an intelligence strategy to enable us to capitalise on the work done through the Information for Quality Programme and the organisational restructuring we completed in 2017. We will be well positioned to begin to make better use of the data we hold – to assist clinics towards better performance, to make targeted regulatory interventions when this is merited, and to provide a range of improved information for patients and our other stakeholder audiences.

Our people strategy for 2018-2020 sits alongside our organisational strategy, and sets out how we will ensure that we have the capacity and capability to deliver our vision. We are proud of our people and the work we do, and we want to be recognised as an Employer of Choice. Through our approach to people management and organisational development, we aim to foster a culture of high performance and attract, develop, reward and retain highly skilled and innovative people. This will best serve our overall vision for high quality care and support for patients.

Although the HFEA is a specialist regulator, there are broad priorities that will be important across the health and care system and are relevant to us, and our programme of work is well aligned to these.

Activities for 2018/19

The focus of delivery in 2017/18 was to complete the programme of work known as Information for Quality, and to commence work on the aims set out in our strategy. There are three main areas of focus in the strategy:

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

Following the building of our new Register and electronic data submission system, we will now focus on making full use of the resulting tools and data to provide an enhanced range of information for patients and clinics on a range of topics, including access to treatment, treatment add ons, and success rates. We will also work with the sector to improve the leadership culture within clinics, encouraging them to be more responsive to patients' emotional needs, as well as their treatment.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2018/19, in the interests of high quality care for everyone affected by fertility treatment.

Activities for 2018/19

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.	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 'State of the Sector' report for 2016/2017, including information about clinical incidents. 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.	November 2018 Throughout year
	Proactively encouraging and supporting leadership in clinics, on inspection and through wider engagement with the sector and professional bodies.	Revised guidance in the Code of Practice setting clear expectations for clinics. Redesigned PR Entry Programme (PREP). Enhancements in the clinic portal and through other channels to encourage a quality-focused culture of learning and research throughout clinics. Improvements in standards and consistency over time, both between one inspection and the next, and between clinics – so that more clinics perform at the level of the best clinics.	October 2018 March 2019 March 2019 Throughout year
	Major revision of the Code of Practice.	Guidance for clinics is up to date and reflects latest scientific developments and policy decisions.	October 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensure that licensing decisions and other approvals are well governed.	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
	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
	Policy project to review the current list of PGD conditions and ensure that all listed conditions still meet the statutory tests regarding seriousness and significance.	The list of conditions will be up to date and reflect latest developments in treatment for genetic diseases.	September 2018
Strategic objective 2: **Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment**			
Make use of our 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.	Inclusion of up to date scientific content in our website so as to maintain our expanded range of information about current and future treatment options and treatment add ons, and the scientific evidence base for these.	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

Aims	Methods and channels	Benefits and outcomes	Timescale
	Guidance for clinics on what information they should publish on their own websites about the add on treatments they offer to patients.	Improved guidance in the Code of Practice. Information on clinics' websites is clear and transparent. Consensus statement with professionals setting out the appropriate way to introduce new techniques into treatment, through responsible innovation.	October 2018
	Refine the way we publish treatment information on our website, based on feedback from users.	Our information and site navigation better meets users' needs and preferences.	March 2019
	Responding to new scientific developments and associated reporting, correcting myths and misunderstandings where necessary.	Balance and accuracy provided when media coverage on scientific evidence is misleading or inaccurate.	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 2018 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.	Further work on embryo research, following the project in 2017/18 to produce better information about embryo research, streamline the application process and encourage collaboration between clinics and research centres. In 2019 we will carry out a review of embryo research, including the numbers of embryos donated, and whether the number of collaborations has increased.	Improvements in research information quality, applications and collaboration. To assess whether the decisions made at the June 2017 Authority meeting are having a positive impact.	September 2018 Spring 2019
	Focus on ensuring clinics explain research data consent adequately, record such consent properly, and report consents accurately to the HFEA.	The quality of research consent-taking, and the recording and reporting of consent, are improved. Higher rate of consent to research from patients.	March 2019
	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.	Publishing information and advice about accessing services, through various channels, and keeping this under review, taking into account user feedback. Providing 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 2019
	Collaborating with NHS Choices to put new patients in touch with better information about services when they first realise they may have a fertility issue.	New patients find relevant signposting and advice more easily. Quality and amount of information aimed specifically at new patients is increased. 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.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving access to donation, support for patients and donors and information about access to donor conception treatment.	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. Considering available data regarding 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.	March 2019
Strategic objective 5: **Increase consistency in treatment standards, outcomes, value for money and support for donors and patients**			
Using our outcome data to improve the chances of successful treatment	With the aim of increasing birth rates while avoiding adverse outcomes, we will analyse Register data on success rates, and work with our professional stakeholders to define and establish the factors that lead to successful outcomes, publishing our findings. Continuing to publish the annual fertility trends report. Using data more on inspection and in inspection reports.	More information published so that clinics can compare themselves more easily, based on different factors such as patient age. Fertility trends in 2017 report published. Patients' chance of a live birth is maximised. Redesigned inspection reports focusing more on outcomes.	March 2019 March 2019
	As part of the Code of Practice update for 2018, we will review the outcomes information on clinics' own websites, and provide revised guidance.	Revised guidance for clinics on the publication of outcomes data on their own websites. Clarity for the sector about how such data should be presented to prospective patients.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Identifying and implementing ways of improving the quality and safety of care.	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 and multiple birth rates. There will also be a greater focus on clinics' management of information responsibilities including meeting data submission and data security requirements, and ensuring information provided to patients generally and on clinics' websites is accurate and not misleading.	Improved compliance and a positive impact on the quality of care, outcomes and safety of patients. 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
	Improved Register data quality, as a result of work done previously 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 2019
	To further develop the inspection regime to be more efficient and effective in the regulation of groups of clinics.	A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
		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.	
Improving value for money, for both patients and NHS commissioners.	Make use of benchmarking information on price, working in collaboration with NHS England. 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 2019
Improving the emotional experience of care before, during and after treatment or donation.	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. (This will be implemented in the October 2018 Code of Practice update).	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. 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. Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Evaluating the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register.	Evaluation of the third and final year of the pilot of counselling support services for Register applicants, including an assessment of provision and take-up.	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 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- October 2018

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.	Developing our intelligence team and our analytical capability to extract more value from the data we hold, using the intelligence strategy developed in 2017/18.	Intelligence strategy delivery commenced. More outcome and other data published. Fertility Trends 2017 (for data up to 2016) published. Donor information report for 2013-2016 published. Egg freezing report published (data up to 2016). State of the Sector report published for 2017/18 Increased exposure of statistics and research using our new website.	Throughout year
Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data.	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 2019
	Reviewing our risk tool, to improve clinics' access to feedback about their own performance.	Risk tool brought up to date with latest benchmarks and available clinic data (entered through the HFEA's data submission system). More clinic data published for clinics' own use, using the clinic portal.	March 2019

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.	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
Publishing and supplying the information we hold, for the benefit of stakeholders.	Regularly updating Choose a Fertility Clinic (CaFC) information to assist patient choice.	Provide more up-to-date, and accurate, information to patients.	Throughout year
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing patients with an independent assessment of the quality of services offered by each clinic.	Throughout year
	Further develop and improve the presentation of clinic comparison information and user experience scores on CaFC, 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 trends’ report. - Provides the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes. - 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 2019
		‘State of the fertility sector’ report -2017-18 - Provides the public and the sector with the most up-to-date information about the performance of clinics. - 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.	November 2018

Aims	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
Maintaining our role as the UK's competent authority for ART in the European Union[2].	Gain intelligence through participation in competent authority events and implementation of associated EU decisions.	We participate in approximately 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.	Twice annually Throughout year
Gaining insight into the patient experience in clinics and encouraging good practice based on feedback.	Collecting more patient feedback through various channels, including our website and social media. Establish additional channels and methods for obtaining patient experience information. 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.	Throughout year

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

Aims	Methods and channels	Benefits and outcomes	Timescale
	Surveying stakeholders about our performance as a regulator.	Stakeholder input obtained to inform future developments and improvements.	March 2019
Ensuring the HFEA is a good value organisation and makes best use of its limited resources.	Working smartly with our limited resources, capitalising on improvements in our information systems and ensuring that our infrastructure and central systems are efficient and responsive.	Resources are deployed in the interests of high quality care for everyone affected by fertility treatment. Achieving measurable 'added value' and internal efficiency. 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. Updated staff intranet.	Throughout year
	Ensuring that we retain the staff we need in order to operate a good quality service, and implement our People Strategy for 2017-2020.	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
	Reviewing our internal records management and information governance arrangements.	HFEA's records management system updated and reviewed to ensure that records are securely held and that good practice is followed. Information governance arrangements comply with latest requirements and roles and responsbilities and are clearly set out for staff.	January 2019
	Use available data to understand the factors driving treatment activity and develop an income forecasting model to inform the future setting of treatment fees.	Model developed for use in future fee review exercises. Best value for money for patients.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is easy to deal with and offers a professional service.	Full realisation of the benefits of HFEA's improved Register function and processes (including the data submission system and the Clinic Portal).	System fully bedded in with Clinics and EPRS providers. Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality and reduction in unnecessary effort by clinics submitting the data.	October 2018
	Continuation of engagement arrangements with clinics on fees charged.	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 government requirements on transparency, better regulation and the new General Data Protection Regulation (from May 2018 onwards).	Ongoing compliance with government requirements, including: 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'. Complying with the new General Data Protection Regulation.	The HFEA responds to government requirements and new initiatives in a manner consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual Report publication including additional required information. Compliance with the Business Impact Target for any activities that may be in scope.	Throughout year June 2018 Throughout 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 regulatory advice service for regenerative medicine, to provide 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 can quickly and easily navigate the different regulators and allow them to access the right advice more quickly.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	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, NHS England, 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
Maintaining our previously established collaborative information management relationships.	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 2017/18

The following facts and figures give a wider picture of the type and volume of our work in the past year, between 1 April 2017 and 31 March 2018.

[Note: this material and updated KPIs will be added in early April, prior to publication.]

Number of:	2016/17	2017/18
Active clinics and research establishments	132	
Clinics and research establishments inspected	71	
Licences inspected	72	
New licence applications processed and presented to the Licence Committee/ Executive Licensing Panel	6	
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	36	
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	1	
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	45	
Incident reports from clinics processed	558	
Alerts issued	0	
Formal complaints about clinics	10	
Opening the Register requests closed within 20 working days	255	
Donor Sibling Link applications processed	38	
Licensed Centres Panel meetings held	2	
Meetings with patient organisations held	2	
Public and stakeholder meetings	8	
Freedom of Information (FOI) requests dealt with	82	
Environmental Information Regulations (EIR) requests dealt with	0	
Enquiries responded to under the Data Protection Act (DPA)	1	
Parliamentary questions (PQs) responded to	55	
Information for researchers requests received	0	
Unique visits to our website	1,271,686	
Most popular/viewed page on our website	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:

[Note: this material will be added in early April, prior to publication.]

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

Key performance indicators for 2018/19

[Note: This section will be added in early April, when year-end results are known, using a selection of the current metrics from the performance report that is regularly considered by the Authority.]

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 and Social Care, 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 consistently increased, primarily through increased treatment activity within the sector. We have just completed a piece of work to model, for the first time, the likely activity in future years. This is based on a combination of historic trend data and ONS population forecasts. Our lower confidence interval within the model suggests activity growth of c2% per annum through to 2020, as such we anticipate an increase of c£90k in income for 2018/19.

This modelling work is still in development and we will look to monitor how closely actual activity follows our projections.

Our grant-in-aid funding from the Department of Health and Social Care has reduced by over 50% since 2010 and we anticipate it will remain constant through to 2020 and the end of the current SR period. Over the years, we have managed our expenditure to ensure we spend within budget wherever possible. We have also used our reserves to reduce the draw on GIA and have demonstrated this by use of our reserves to fund our recent Information for Quality (IfQ) programme.

[DN: Budget information for 2018/19 will be added here following discussion at this Authority meeting]

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.

In 2016 when the requirement began, we produced retrospective assessments for our initial reporting period 2015 – 2017. This work is now 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.

Organisational structure and establishment

Since 2010/11, the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement is now 67 (compared to 86 in 2010/11). 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 occupy the same premises). We also have a shared services agreement with the Care Quality Commission (CQC) for recruitment.

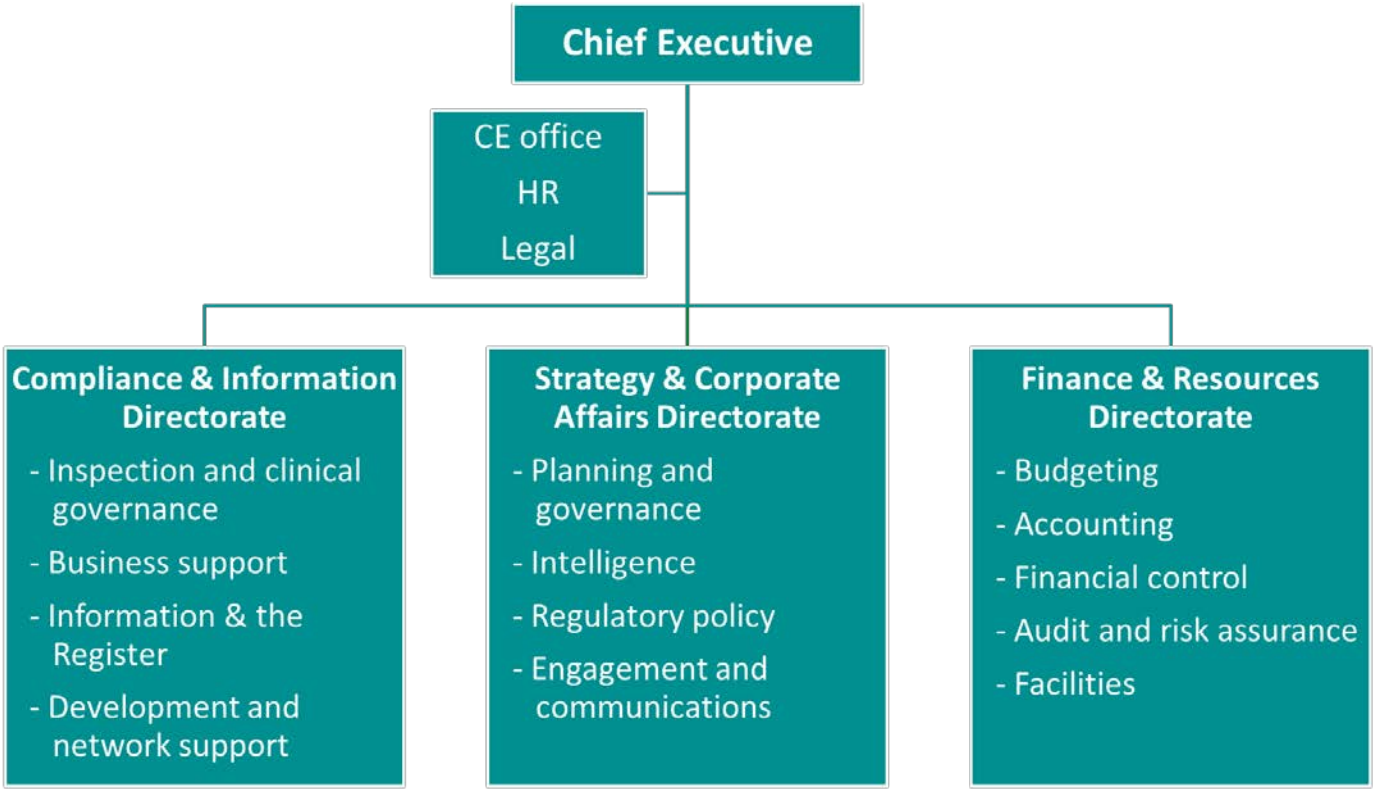
Having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

We have a people strategy, referenced earlier in this business plan, which sets out how we will ensure we attract and retain the capacity and skills we need in order to deliver our vision of high quality care for everyone affected by fertility treatment. 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.

In 2017/18 we revised our organisational structure so as to allow us to capitalise on the improvements to our information systems, achieved through our Information for Quality Programme. The current structure is illustrated below.



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 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 for systems and IT hardware. A programme of information security and cyber security training is conducted, and this is regularly reviewed.

We 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 2017/18, 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. 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 over the past two years, since we moved into 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. Any necessary procurement will be conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2018/19. 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.

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