



Human
Fertilisation &
Embryology
Authority

Business plan 2019/20

Contents

Our role and strategic aims	4
What we did in 2018/19	7
Delivery of the 2018/19 business plan	8
Measuring our performance	10
Delivering our strategy in 2019/20	13
Activities for 2019/20	15
Financial picture	36
Our finances and high-level budget	36
Other required information	38

Table of figures

Figure 1 - The three areas of strategic focus for the HFEA in 2017 to 2020	4
Figure 2 - Outline of what we delivered in 2018 to 2019	8
Figure 3 - Table outlining 2018 to 2019 performance data against the same data from 2017 to 2018	10
Figure 4 - Table outlining standard human resources benchmarking data	11
Figure 5 - Table indicating performance against key metrics from April 2018 to March 2019	11
Figure 6 - Outline of our strategic objectives and aims for 2017 to 2020	13
Figure 7 - Table outlining planned activities for 2019 to 2020	16
Figure 8 - HFEA high-level operating budget for 2019/2020	37

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.

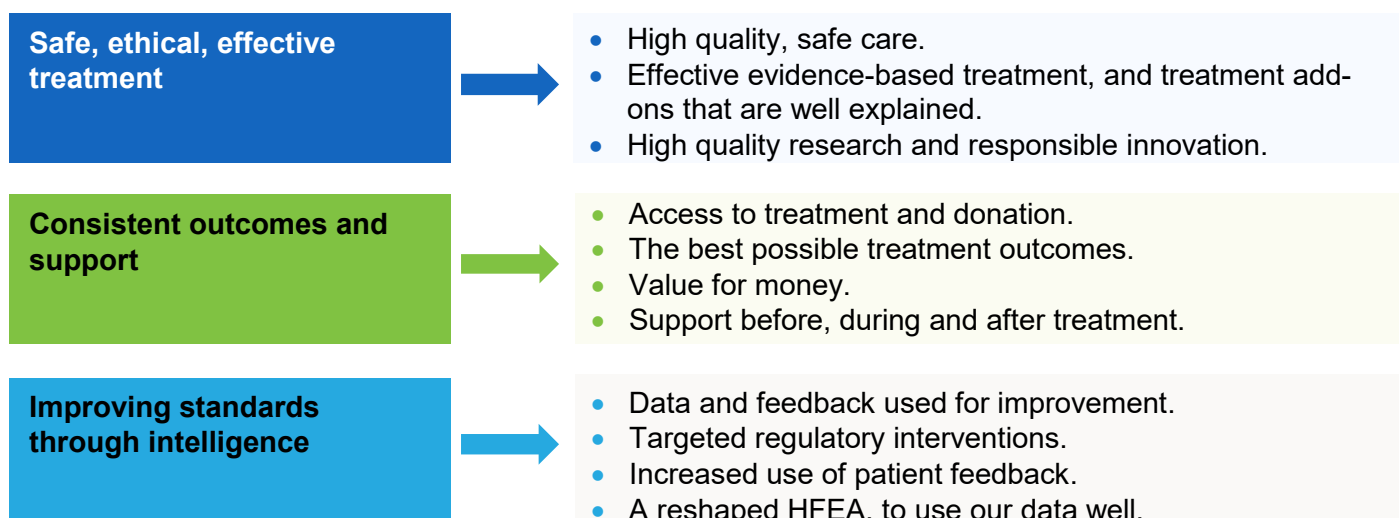
Prospective patients (in particular) need to be able to find information to help them understand their options, know where to go for further advice and decide what steps to take next. People who have decided to have treatment (or to be a donor), and have contacted a clinic, need more detailed information 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 sperm or eggs, 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:

Figure 1 - The three areas of strategic focus for the HFEA in 2017 to 2020



This business plan sets out how we will work towards our vision in 2019/20.

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
- license and inspect centres undertaking human embryo research
- license and inspect the storage of gametes (eggs and sperm) and embryos
- publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities
- keep a Register of information about donors, treatments and children born as a result of those treatments
- keep a register of licences granted
- keep a register of certain serious adverse events or reactions
- 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.

The Department has made statutory instruments under section 8 of the EU Withdrawal Act to introduce technical fixes required for legislation to be operable after the UK leaves the EU. They also transfer some functions that are currently carried out by the EU Commission to the Secretary of State for Health and Social Care. This will ensure that the current high standards of quality and safety for human reproductive tissues and cells are maintained after exit.

Once the UK has left the EU, the UK will be classified as a third country under the EU Directives. The relevant EU Directives allow for reproductive tissue and cell exchange between member states and third countries. This means that agreements can be put in place, if necessary, so the movement of reproductive tissues and cells between the UK and other countries can continue.

What we did in 2018/19

Overview

The past year represented the mid-point of our 2017-2020 strategy. We embedded a new set of capabilities including an intelligence strategy and a restructured workforce. We have begun to make better use of the data we hold to:

- assist clinics towards better performance, sharing more of their own performance data with them
- provide a range of improved information for patients and our other stakeholder audiences, such as the 2018 egg freezing, state of the sector and fertility trends reports.

In line with our vision of ensuring high quality care for everyone affected by fertility treatment, last year we undertook our first national fertility patient survey to gain valuable insight into the experiences of those going through fertility and donor treatments today. We have begun to bring this valuable intelligence to bear in our other work and it has shaped our plans for 2019/20.

We undertook major revisions and launched the 9th edition of our Code of Practice, which set out a new focus on clinic leadership and support for patients as fundamental for delivering high quality care. As part of our aim to proactively encourage and support leadership in clinics, we initiated a closer dialogue with centre PRs at leadership events in London and Manchester.

We want to be recognised as an 'employer of choice'. To ensure that we have the capacity and capability to deliver our vision, with our small staff complement of 68 people, we have implemented several aspects of our people plan for 2018-2020. We have reshaped our organisational culture and improved the offer to staff. We have invested in our internal systems, launching a new HR system and intranet, and we began to deliver a project to replace our document management system, with the aim of improving the effectiveness and efficiency of our internal communications, infrastructure and management.

Delivery of the 2018/19 business plan

Figure 2 - Outline of what we delivered in 2018 to 2019

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 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 our December 2018 State of the sector report.

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

Ethical treatment is that which is safe, effective, evidence-based and delivered to informed patients in a responsible way that is in their interest. Our website includes a wide range of up-to-date scientific information to provide clear and unbiased information for patients about treatments. We have a process in place for regularly assessing the efficacy of add-ons through a traffic light system. In 2018/19, none of the treatment add-ons we have assessed have been rated green. This means that we don't think any of these techniques should be used routinely.

We worked with a range of stakeholders to publish a consensus statement on the responsible use of treatment add-ons in fertility services, to provide guidance to the sector on best practice. Our annual horizon scanning process helped to ensure that our policy developments and website materials were 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. We continued to respond to requests from researchers for access to Register data for research purposes and reviewed the processes around our Register Research Panel to ensure that it remains fit for this purpose.

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. We also undertook various patient and public engagements, attending several fertility shows and events to provide clear, unbiased information.

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 to improve quality, consistency and compliance on a group-wide basis, as relevant.

We continued to work 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.

We continued to implement a project on the emotional experience of care before, during and after treatment, working with professional stakeholders to bring about improvement. This led to changes to the Code of Practice, the new 9th version of which launched in January 2019.

With the aim of improving the chances of successful treatment, we have published more information in our data reports and focused on success rates through inspection reports and risk tool alerts.

We introduced new processes and certifications to fully comply with European Union (EU) requirements relating to the import and coding of donor eggs and sperm.

Improving standards through intelligence

We delivered a number of aspects of our Intelligence strategy which was approved by the Authority in January 2018 and sets 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.

We maintained our role as the UK's competent authority for assisted reproductive technologies in the EU, participating in one meeting. We cooperated with the department to prepare for the UK's exit from the EU and began a project to consider the organisational and sector implications of this.

We continued to deliver our programme of improvement work on the Register infrastructure and maintained the Register of treatments and outcomes throughout the year, working 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.

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 2018 and 31 March 2019.

Figure 3 - Table outlining 2018 to 2019 performance data against the same data from 2017 to 2018

Type of work	2017/18	2018/19
Active clinics and research establishments	135	135
Clinics and research establishments inspected	87	84
Licences inspected	85	85
New licence applications processed and presented to the Licence Committee/Executive Licensing Panel	6	6
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	33	44
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	2	2
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	36	57
Incident reports from clinics processed	592	672
Alerts issued	0	0
Formal complaints about clinics	20	26
Opening the Register requests closed within 20 working days	238	327
Donor Sibling Link applications processed	33	41
Licensed Centres Panel meetings held	2	2
Meetings with patient organisations held	2	2
Public and stakeholder meetings	8	8
Freedom of Information (FOI) requests responded to	80	62
Environmental Information Regulations (EIR) requests responded to	0	0
Enquiries responded to under the Data Protection Act (DPA)	2	0
Parliamentary questions (PQs) responded to	44	117
Unique visits to our website	220,823	316,022

Type of work	2017/18	2018/19
Most popular/viewed page on our website	Clinic search	Clinic search

All centres are inspected at least every two years, but the volume of scheduled inspections has a natural variation from year to year due to the timing of licence expiry.

The increased number of incidents reported during 2018/19 reflects our culture of encouraging clinics to report, increasing openness and transparency. If we have concerns, or notice a pattern, we work with the clinic to identify what's going wrong, so improvements are implemented. Whenever there is a serious incident, we carry out an on-site inspection (these are additional to the number of licence inspections recorded above). A more in-depth analysis of the incidents received and any trends will be provided in the State of the sector report later in 2019.

Required HR benchmarking information

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

Figure 4 - Table outlining standard human resources 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	1:45
Training budget as a percentage of pay bill	1.5%
Projected reductions in non payroll staff	Not applicable

Key performance indicators

Figure 5 - Table indicating performance against key metrics from April 2018 to March 2019

Category	Performance indicator	Target for 2018/19	Performance
Engagement	Number of emailed public enquiries successfully responded to.	No target, since the nature, volume and complexity of enquiries received varies widely.	1,980
Licensing activities	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: 51 Range:38 - 69

Category	Performance indicator	Target for 2018/19	Performance
Information provision	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).	99% (327 of 329 requests)
Financial management	Cash and bank balance.	To move closer to minimum £1,520K cash reserves.	Year start: £3,227K Year end: £2,658K
People and capacity	Percentage turnover for the year.	5-15% turnover range.	28.4%

Delivering our strategy in 2019/20

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 will maintain this vision and our focus on maintaining high quality care after the UK leaves the EU.

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

Figure 6 - Outline of our strategic objectives and aims for 2017 to 2020

In this area...	We will...
Safe, ethical, effective treatment	<p>1. Ensure that all clinics provide consistently high quality and safe treatment.</p> <p>Our aim:</p> <ul style="list-style-type: none"> Patients know clinics provide a high quality, consistent, safe service.
	<p>2. Publish clear information so that patients understand treatments and treatment add-ons and feel prepared for treatment.</p> <p>Our aim:</p> <ul style="list-style-type: none"> Increase patients' understanding of the science and evidence base behind treatments and added extras known as add-ons, and of their safety and effectiveness.
	<p>3. Engender high quality research and responsible innovation in clinics.</p> <p>Our aim:</p> <ul style="list-style-type: none"> Improve the quality of treatment, by encouraging world class research and clinical trials.
Consistent outcomes and support	<p>4. Improve access to treatment.</p> <p>Our aim:</p> <ul style="list-style-type: none"> Provide advice and information about access to treatment and improve access to donor conception treatment.

In this area...	We will...
Consistent outcomes and support	<p>5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.</p> <p>Our aims:</p> <ul style="list-style-type: none"> • 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	<p>6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.</p> <p>Our aims:</p> <ul style="list-style-type: none"> • 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.

Our people plan sits alongside the organisational strategy and in the final year we will continue to work to attract and retain talented and capable staff to support the whole of our strategic delivery.

The activities set out over the next few pages describe how we will meet these strategic objectives in 2019/20.

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

Activities for 2019/20

The focus of delivery in 2018/19 was on making use of our restructured workforce, and new intelligence team capacity, to provide an enhanced range of information for patients and clinics on a range of topics.

The 2019/20 business plan represents the third and final year of our 2017-2020 strategy. As such, it includes all the remaining work we believe is needed in order to complete our strategy in 2020 and deliver our vision of high quality care for everyone affected by fertility treatment.

Our focus will be to embed changes and build on the work done in years one and two, while at the same time encouraging clinics to strive for excellence in leadership and patient support and provide the best possible outcomes for patients.

During the year, we will be composing our next strategy and will aim to publish this in the first few months of 2020.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2019/20, in the interests of high quality care for everyone affected by fertility treatment.

As the UK leaves the EU, the new context will require the HFEA to work with the Department of Health and Social Care (DHSC) and its arm's length bodies to manage any effects of EU Exit on the health and care system. The HFEA, as the UK regulator, will play a key role in maintaining the quality and safety of reproductive tissues and cells used in fertility treatments and research, and supporting licensed clinics to be ready for EU Exit.

Figure 7 - Table outlining planned activities for 2019 to 2020

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.			
<p>Ensure that clinics are well regulated and provide a high quality, consistent service.</p>	<p>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.</p> <p>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.</p>	<ul style="list-style-type: none"> • All clinics and research establishments in the sector are: <ul style="list-style-type: none"> • 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 publish (eg, on their websites) and provide to us. • 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. 	<p>Throughout year</p> <p>October 2019</p>

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 the publication of our annual review of clinical incidents.	<ul style="list-style-type: none"> • Publication of 'State of the sector' report for 2018/19, 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 events. 	November 2019 Throughout year
	Proactively encouraging and supporting leadership in clinics, on inspection and through wider engagement with the sector and professional bodies.	<ul style="list-style-type: none"> • 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. 	Throughout year
	Updates to the Code of Practice including further guidance on electronic consent.	<ul style="list-style-type: none"> • Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. 	October 2019
	Project to review HFEA consent forms and guidance around electronic consent.	<ul style="list-style-type: none"> • Consent forms remain fit for purpose and accessible and reflect GDPR requirements. 	October 2019
Ensure that licensing decisions and other approvals are well governed.	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	<ul style="list-style-type: none"> • Efficient and effective decision-making is maintained. • Decisions are evidenced, transparent and consistent. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	<ul style="list-style-type: none"> • Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines. • Public confidence assured in mitochondrial donation and PGD approvals. • 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
	Implementing recommendations from a review of our licensing function to ensure it remains fit for purpose.	<ul style="list-style-type: none"> • Quality improvements to processes and licensing 'products' and the resulting decision making. • Revisions to standing orders, particularly committee terms of reference and membership options. • Development of licensing reporting to Authority. 	March 2020

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Ensure that the HFEA and licensed clinics are ready for EU Exit, so that they continue to provide high quality and safe treatment after the UK leaves the EU.</p>	<p>Identify and mitigate EU Exit risks and issues, such as the continued supply of medicines, equipment and gas to licensed clinics.</p> <p>Gain assurance that clinics and suppliers have robust business continuity plans in place and continue to seek further engagement on any EU Exit risks and issues identified.</p> <p>Ensure there are mechanisms to report any EU Exit-related issues that may affect the quality and safety of the tissues and cells they use and ensure these issues are escalated to the Operational Response Centre at DHSC.</p> <p>Collaborate with the DHSC Operational Response Centre by providing information, advice and data on response.</p> <p>Update business continuity plans regularly, in line with the UK's future relationship with the EU.</p> <p>Ensure the appropriate governance and accountability structures are in place to monitor and assess the impacts of EU Exit.</p> <p>Assign senior responsible owners for key areas that will be impacted by EU Exit and ensure sufficient resources are allocated to these areas. Senior leaders and teams will continue to work closely with DHSC to support the health and care system after EU Exit.</p>	<ul style="list-style-type: none"> • HFEA, all clinics and suppliers have robust business continuity plans in place that factor in developments in the UK's future relationship with the EU and ensure services will be maintained during any EU Exit-related incidents. • All licensed establishments that exchange tissues and cells with EU organisations and need new agreements or amendments to existing arrangements to continue to do so, have completed this action. • High quality and safety standards are maintained. By maintaining alignment with the EU, this will allow reproductive tissues and cells to be transferred to and from the EU, thereby ensuring that people receiving fertility treatment in the UK can benefit. 	<p>Throughout year</p>

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.			
Maintain up-to-date information on our website to increase patients' understanding about the range of treatments available and what they entail as well as the science and evidence base behind treatments and added extras known as 'add-ons', and their safety and effectiveness.	<p>Inclusion of up-to-date scientific content on our website to maintain our expanded range of information about current and future treatment options and the scientific evidence base for these.</p> <p>In response to recommendations from SCAAC, we will review our information for patients on treatment add-ons to ensure it reflects the most up to date advice.</p> <p>SCAAC annual review of add-on treatments.</p>	<ul style="list-style-type: none"> • Patients and others turn to us first for up-to-date, clear unbiased information. Prospective patients have clear information on which to base decisions about treatment or add-ons. • Patients are easily able to locate accurate information about different treatments on our website • 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 – SCAAC add-on review in February 2020.
	Guidance for clinics on what information they should publish on their own websites about the add-on treatments they offer to patients.	<ul style="list-style-type: none"> • Information on clinics' websites is clear and transparent. 	Throughout year
	Undertake user testing of the website to allow us to further refine the way we publish treatment information.	<ul style="list-style-type: none"> • Our information and site navigation better meets users' needs and preferences. 	Throughout year
	Responding to new scientific developments and media reports.	<ul style="list-style-type: none"> • Balance and accuracy provided when media coverage on scientific evidence is misleading or inaccurate. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.</p>	<ul style="list-style-type: none"> • The Horizon Scanning Panel meets once per year. • The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times 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. 	<p>June 2019</p> <p>Throughout year</p> <p>Throughout year</p> <p>Throughout year</p>
Strategic objective 3: Engender high quality research and responsible innovation in clinics.			
<p>Improving the overall quality of treatment by encouraging world-class data and embryo research and clinical trials.</p>	<p>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.</p>	<ul style="list-style-type: none"> • To assess whether the decisions made at the June 2017 Authority meeting are having a positive impact. 	<p>Q1 2019-20</p>
	<p>We will undertake a project to explore ways to support research, including collaborating with research PRs, centres and other research stakeholders.</p>	<ul style="list-style-type: none"> • Support clinics and researchers in carrying out high quality research to drive up the quality of treatment and donation. 	<p>March 2020</p>
	<p>Information provision for researchers requesting access to Register data.</p>	<ul style="list-style-type: none"> • Information for researchers is provided within 90 calendar days of approval. 	<p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>Review of arrangements for information provision for researchers requesting access to Register data, including:</p> <ul style="list-style-type: none"> • how we engage and communicate with researchers using register data • a new data request process for researchers, including guidance and checklists • memoranda of understanding (MOUs) with external partners to ensure best use of resources. 	<ul style="list-style-type: none"> • Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. • More researchers can access and use our Register data. • Increased standardisation and clarity of processes. • Greater knowledge about the efficacy and safety of fertility treatment • More efficient use of time and resource. 	May 2019
<p>Ensure that appropriate guidance is issued to fertility clinics and patients to help them prepare for EU Exit.</p>	<p>Continue to send communications and guidance on EU Exit to licensed clinics to help them make appropriate arrangements. This guidance should assist licensed establishments with any amendments or new agreements necessary to continue to exchange tissues and cells with EU/EEA organisations.</p> <p>Disseminate communications to people using fertility services to inform them of EU Exit contingency plans.</p>	<ul style="list-style-type: none"> • Licensed clinics have robust business continuity plans in place. • People using fertility services feel prepared and reassured. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Consistent outcomes and support			
Strategic objective 4: Improve access to treatment.			
<p>Providing advice and information about access to treatment and donor conception treatment.</p>	<p>Publishing information and advice about accessing services through various channels and keeping this under review, taking into account user feedback.</p> <p>Providing information for those considering going abroad for treatment on how they might access services in the UK, including through seminars at fertility shows.</p>	<ul style="list-style-type: none"> • People understand the possibilities and the hurdles and can weigh up the options open to them. • People can easily find relevant information and signposting on our website to inform their next steps. 	<p>Throughout year</p>
	<p>Collaborating with the NHS website (NHS.UK) to put new patients in touch with better information about services when they first realise they may have a fertility issue.</p>	<ul style="list-style-type: none"> • New patients find relevant signposting and advice more easily. • 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. 	<p>Throughout year</p>
<p>Improving access to donation, support for patients and donors and information about access to donor conception treatment.</p>	<p>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.</p>	<ul style="list-style-type: none"> • People understand the process and are prepared for donation and treatment (measured through patient/donor surveys). • Donors and patients are better supported by clinics. And this includes emotional support, information provision and exploration of the short- and long-term implications of treatment or donation. • All patients and donors having the opportunity to explore the implications of treatment or donation. 	<p>March 2020</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	Working with clinics, sperm banks and voluntary organisations to consider what more could be done to improve the availability of donor sperm and eggs.	<ul style="list-style-type: none"> Better understanding of the factors affecting rates of donation in the UK and also the import or export of gametes overseas. Sharing good practice with the sector. 	March 2020
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, while avoiding adverse outcomes.	<p>We will analyse Register and other available data on success rates and work with our professional stakeholders to define and establish the factors that lead to successful outcomes, with a particular focus on service design, publishing our findings.</p> <p>Continuing to publish the annual Fertility trends report.</p> <p>Using data more on inspection and in inspection reports.</p> <p>The main health risk of fertility treatment is a multiple birth. We will continue to work with clinics to ensure their multiple births minimisation strategy is effective and progress is made towards reducing the rate of multiple births to the 10% target.</p>	<ul style="list-style-type: none"> Publication of information about success factors (particularly around service design). Patients are more aware of the factors which may affect their chances of success. Fertility trends in 2018 report published. Redesigned inspection reports focusing more on outcomes. Patients' chance of a live birth is maximised. Non compliances in relation to multiple birth rates continue to decline. Patients' risk of a multiple pregnancy is minimised. 	<p>March 2020</p> <p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Identifying and implementing ways of improving the quality and safety of care.</p>	<p>Continuing our focus on quality and safety of care in inspection activities, in particular through focusing on:</p> <ul style="list-style-type: none"> • the leadership of clinics in providing high quality care • a continued focus on the consent provided by patients and donors • the emotional support provided to patients • ensuring information provided to patients about their choices and care is clear, evidence-based and objective. <p>We will continue to evaluate areas of regulatory concern and identify performance levers.</p>	<ul style="list-style-type: none"> • Improved compliance and a positive impact on the quality of care, support, outcomes and safety of patients. • 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. • Feedback indicates that patients and partners feel cared for whatever the treatment outcome. • If an issue subsequently arises (such as the death of someone with sperm or eggs in storage), the correct consents are more likely to be in place and are legally clear and robust. 	<p>Throughout year</p>
	<p>Improved Register data quality, as a result of work done previously under the Information for Quality (IfQ) programme.</p> <p>There will 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.</p>	<ul style="list-style-type: none"> • New data quality strategy implemented to set out clear expectations to clinics about data quality. • Fewer data submission and data accuracy related non compliances and improved information assurance on inspection and audit. • More 'right first time' data submission from clinics into the Register. • Better service quality for Opening the Register (OTR) applicants. • Patients have confidence in the data and information on individual clinics' websites. 	<p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>To continue to develop the inspection regime to be more efficient and effective in the regulation of groups of clinics.</p>	<ul style="list-style-type: none"> • 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 us and the clinics involved. 	March 2020
	<p>Work to define quality criteria to recognise excellent patient care in clinics and allow patients to easily assess the quality of the care provided.</p> <p>Encouraging clinics to routinely include emotional support and access to counselling as part of a treatment cycle.</p>	<ul style="list-style-type: none"> • Patients have clearer expectations about the quality care that they should receive. • Patients receive excellent emotional support as an integral part of their treatment 	March 2020
<p>Improving value for money, for both patients and NHS commissioners.</p>	<p>Share benchmarking information with commissioners, working in collaboration with NHS England and others.</p> <p>Engage with stakeholders on commissioning guidance produced by us.</p> <p>Eliciting more feedback from patients as to whether they paid what they expected for fertility services.</p>	<ul style="list-style-type: none"> • 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 2020

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Improving the emotional experience of care before, during and after treatment or donation.</p>	<p>Building on our earlier work to improve the emotional experience of care in clinics by defining and encouraging best practice in clinics and focusing on support at inspection. Training webinars will be delivered to the sector, alongside face-to-face events.</p> <p>Ensuring that best practice is applied to donors and donor-conceived people as well as to patients.</p>	<ul style="list-style-type: none"> • 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. 	<p>October 2019</p>
<p>Implementation of new Donor Conceived Register service and, in addition, counselling services for OTR applicants.</p>	<p>New Donor Conceived Register and service launched.</p> <p>New counselling services in place.</p>	<ul style="list-style-type: none"> • 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. • Intermediary services are in place for when donors and donor-conceived people meet. • Intermediary training and systems in place for dealing with identity release to donors and donor-conceived people. • Performance management measures put in place for future management of the services. • OTR applicants feel more supported and prepared to deal with the information they receive from us. • Evaluation of the new services provided to the Authority. 	<p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	Undertaking early scoping to understand requirements for the organisation to effectively support donor conceived people born after the 2005 lifting of donor anonymity and their donors.	<ul style="list-style-type: none"> We are readier to prepare for these donor conceived people to access data from end of 2021 (non-identifying) and 2023 (full identifying information), plans for which will be implemented in the 2020-2023 strategy. 	March 2020
	Reviewing the impact of new technologies (such as direct to consumer DNA testing) on donor anonymity.	<ul style="list-style-type: none"> We have a clearer idea of the options available to the Authority and how these may affect the service provided to donors and donor conceived people in the future. 	March 2020
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.			
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.	<ul style="list-style-type: none"> 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 2020
	Reviewing our risk tool to improve clinics' access to feedback about their own performance.	<ul style="list-style-type: none"> Risk tool brought up to date with latest benchmarks and available clinic data (entered through our data submission system, PRISM). More clinic data published for clinics' own use using Clinic Portal. Provide data to clinics through PRISM to allow them to benchmark their performance against the sector 	March 2020

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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> Provide more up-to-date and accurate information to patients. 	Throughout year
	Continued publication of inspection reports on CaFC.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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 of clinic comparison information and to plan future improvements. 	Throughout year
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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, including the Fertility trends and State of the sector reports.	<ul style="list-style-type: none"> • Our Fertility trends report: <ul style="list-style-type: none"> • 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 • carries 'official statistics' status. • Our State of the sector report 2018-19: <ul style="list-style-type: none"> • 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. 	<p>March 2020</p> <hr/> <p>November 2019</p>

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.	<ul style="list-style-type: none"> 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 EU, for as long as the UK remains in the EU.	Gain intelligence through participation in competent authority events and implementation of associated EU decisions.	<ul style="list-style-type: none"> 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.	Analysing and using the intelligence gathered through various patient feedback channels to inform our activities and our messaging to clinics, sharing the information with professional stakeholders.	<ul style="list-style-type: none"> 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 us and our professional stakeholders. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>Reviewing our patient engagement channels and piloting a new patient forum to ensure we have access to feedback to inform our activities.</p>	<ul style="list-style-type: none"> • Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. 	
<p>Ensuring we are a good value organisation and that we make best use of our limited resources.</p>	<p>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, in line with a revised IT strategy.</p>	<ul style="list-style-type: none"> • 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. • We continue to move away from bespoke systems, standardising our approaches to ensure they are resilient. 	<p>Throughout year</p>
	<p>Ensuring that we retain the staff we need in order to operate a good quality service, and implement our People plan for 2017-2020.</p>	<ul style="list-style-type: none"> • 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. • Staff feel valued and motivated to deliver our strategic aims. 	<p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	Embed revised internal records management, information assurance and information governance arrangements.	<ul style="list-style-type: none"> • Completion of implementation of new document management system to ensure that records are securely held and that good practice is followed. • Good records management practice is embedded and maintained, including records retention and behaviours. • Information governance arrangements comply with latest requirements and roles and responsibilities and are clearly set out for staff. • Make best use of the Senior Inspector (Information) post, focussing on information assurance. 	March 2020
	Continue to engage on emerging international work.	<ul style="list-style-type: none"> • Take full advantage of expertise and seek opportunities to maximise the potential for exporting our expertise, raising standards overseas and raising revenue for the UK. 	March 2020
	Undertake a fee review informed by our income forecasting model.	<ul style="list-style-type: none"> • Best value for money for patients. 	March 2020
	Plan for move to new office premises in 2020.	<ul style="list-style-type: none"> • Make the best use of Crown Estate property, in keeping with the wider interests of Government property strategy. 	March 2020
	Develop our organisational strategy for 2020 – 2023.	<ul style="list-style-type: none"> • Focus our limited resources where we can have the most strategic impact and develop clear aims for the next three years. 	March 2020

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring we are easy to deal with and offer a professional service.	Full realisation of the benefits of our improved Register function and processes (including the data submission system and Clinic Portal), including ongoing engagement with and feedback from clinics.	<ul style="list-style-type: none"> • PRISM fully bedded in with clinics and Electronic Patient Record System (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. 	March 2020
	Continuation of engagement arrangements with clinics on fees charged.	<ul style="list-style-type: none"> • 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 general data protection regulation.	Ongoing compliance with government requirements, including:	<ul style="list-style-type: none"> • We respond to Government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. • Annual report published including required information. • Compliance with the business impact target for any activities that may be in scope. 	Throughout year
	Reporting in our annual report on the growth duty and compliance with the regulators' code.		June 2019
	Complying with the business impact target by identifying and reporting any 'in-scope activity'.		Throughout year
Complying with the general data protection regulation.			
Ensuring we're an effective collaborator and partner in the interests of the efficiency of the wider Department of Health and Social Care group of arm's length bodies (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.	<ul style="list-style-type: none"> • Continued constructive joint working between us and 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, allowing them to access the right advice more quickly. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>Sharing services and infrastructure with other organisations as practicable.</p> <p>Maximising the benefit of finance resources being shared with the HTA.</p> <p>Using Civil Service Learning as a key learning and development provider.</p> <p>Continuing to receive facilities services from the landlord of our office premises via an SLA.</p>	<ul style="list-style-type: none"> We continue to operate in as efficient a way as possible, extracting maximum value from shared arrangements and seeking other opportunities. 	Throughout year
	<p>Collaborative and partnership working with other ALBs and health regulators UK wide, such as the Care Quality Commission (CQC), NHS England, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom Accreditation Service (UKAS), Health Research Authority (HRA), General Medical Council (GMC) and the devolved nations, maintaining the close positive working relationships that have been developed over the past several years.</p>	<ul style="list-style-type: none"> 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
<p>Maintaining our previously established collaborative information management relationships.</p>	<p>Maintaining our good working relationships with other relevant information management bodies, such as the Government Digital Service (GDS), NHS Digital and being an active member of the National Information Board (NIB).</p>	<ul style="list-style-type: none"> 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

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 including:

- 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 maintain a model to predict the likely activity in future years. This is based on a combination of historic trend data and Office for National Statistics population forecasts. Our lower confidence interval within the model suggests activity growth of about 2% per annum through to 2020, however, we have taken the prudent approach and used an adjusted volume of IVF/DI treatments which represents 2% growth on our 2018/19 budget.

We monitor how closely actual activity follows our projections including a formal review of the model annually.

We have managed significant grant-in-aid funding reductions since 2010, however this planning round has seen further pressure from the increase in employer pension contributions which the DHSC has partly funded. We anticipate our core grant-in-aid will remain constant through to 2020.

Over the years, we have managed our expenditure to ensure we spend within our annual budget and expect to do so moving forward. We continue to maintain a cash reserve to ensure we can manage fluctuations in our monthly income and provide a buffer should we see a material deviation from our forecast income levels.

Figure 8 - HFEA high-level operating budget for 2019/2020

Income	£000s
Department of Health and Social Care funding	1,034
Non-cash income	504
Treatment and licence fees	5,374
Other income	146
Total income	7,058

Expenditure	
Operating costs, of which:	
Staff costs	4,322
Other operating costs	2,233
Total operating costs	6,555
Capital charges	503
Total revenue expenditure	7,058

Budgets for arm's length bodies (ALBs) have been set on an indicative basis because the DHSC Group financial plan for 19/20 is not yet finalised.

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

Our 2019/20 planned capital expenditure is £100k to provide for our routine technology refresh.

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).

Our governance structure includes corporate governance tools, a people plan (that we relaunched in 2018) 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 and Social Care 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 us 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 £10billion 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 £5billion 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 and Social Care 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, we have significantly reduced our staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement is now 68 (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).

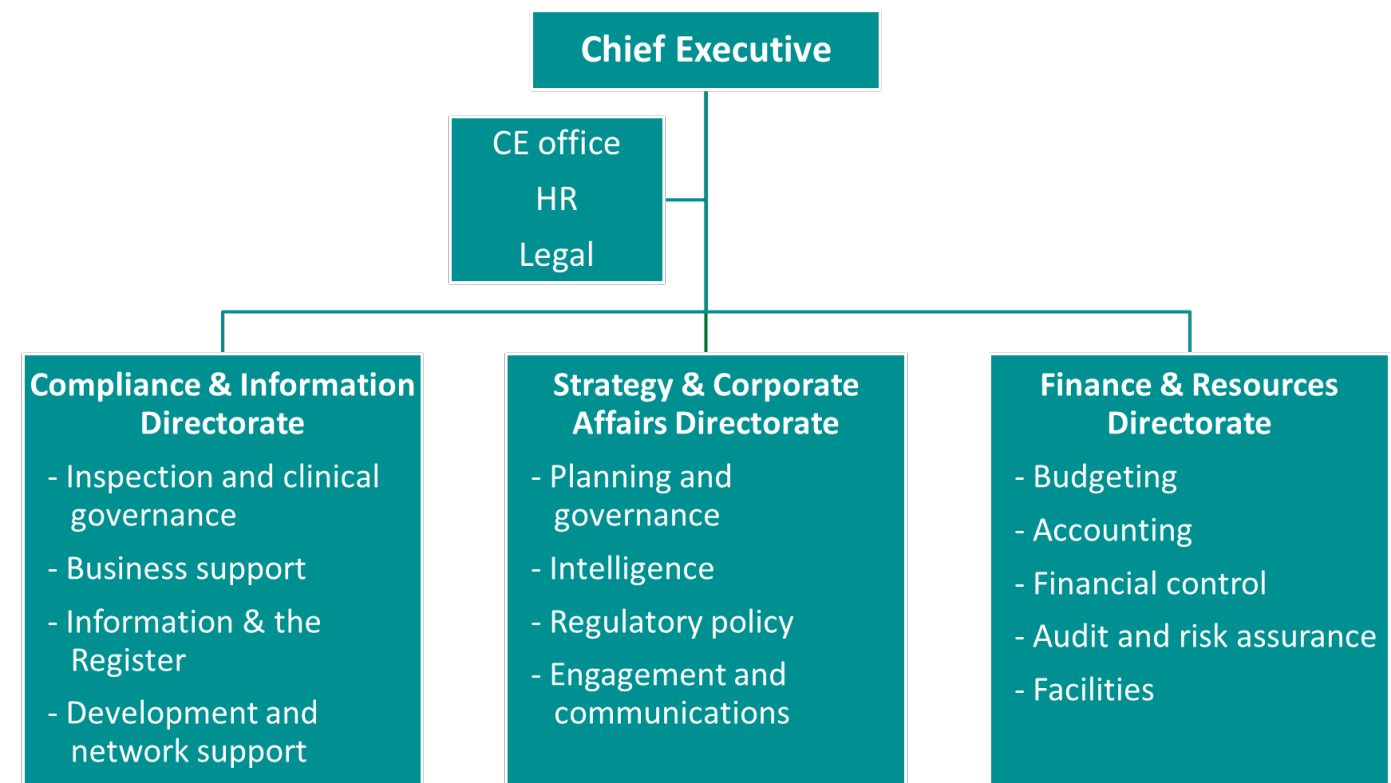
Having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

We have a people plan, 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.

Our current organisational 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 and Social Care 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 our 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 and Social Care (in 2014) sets out the critical elements of the relationship between us and the department and other ALBs where relevant. As an ALB, we will continue to manage our assurance and risk management independently and report this to the Authority. We recognise that, on rare occasions, our risks or assurance may have a significant impact or interdependency with the Department of Health and Social Care or other ALBs and understand the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

Equality Act 2010

We remain 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 we fulfil our 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

We maintain 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.

Our 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 to ensure that 'section 33A patient-identifying data' is appropriately protected.

We remain fully compliant with Cabinet Office rules regarding data security and with our 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 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 we have 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 confidential material disposal arrangements in place.

Business continuity

We reviewed our business continuity plan in 2018/19, 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

We have no estate. In April 2016 we moved into NICE's office space in Spring Gardens, taking up 269 square metres.

We work 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.

Looking ahead, our office strategy is to co-locate with other public bodies. To that end, we are planning to move in 2020.

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 three years since we moved into smaller premises.

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

Procurement

We comply with all relevant Department of Health and Social Care 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 Crown Commercial Service (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 and Social Care target for public sector procurement of 23% of procurement spend going to small and medium sized enterprises (SME) 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. We provide the Department of Health and Social Care with quarterly reporting on procurement.

There is no significant non-pay spend that is not via CCS, NICE or Department of Health and Social Care 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