Human Fertilisation & Embryology Authority

Business plan

Six-month plan October 2020 – March 2021

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 2020-2024 is:

Regulating for excellence: shaping the future of fertility care and treatment

We continue to put everyone who uses fertility services at the heart of everything we do - patients, partners, donors, donor-conceived people and surrogates. We want them all to receive excellent care, support and information.

Their experiences differ, based on their individual circumstances. Our strategic focus will be on providing the best, most effective care for everyone, recognising the diverse family structures in which treatment and donation take place. We want to ensure people can access the right information at the right time. As science and society advance, we will shape and respond to future changes, helping ensure that the translation from innovative treatment to everyday care is ethical and responsible.

As the regulator of fertility services and research involving human embryos, we aim to be effective and efficient, providing consistent oversight and advice to clinic staff and researchers.

What can we do to achieve excellent care, support and information?

Our strategy for 2020- 2024 focuses on three areas in order to meet these needs:

The best care

Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.

A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.

Improved recognition by clinics of partners' importance in the care process.

The right information

Accurate and useful information that is provided at the right time.

Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.

Access to relevant and impartial information for all – particularly about the evidence base, add-ons and treatment options.

Shaping the future

Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.

Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.

Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.

In March 2020 Covid-19 led to restrictions in the United Kingdom. As a result, the first six months of the 2020/2021 business year were spent ensuring that the risks that emerged were managed well and the fertility sector and patients were supported effectively. We suspended inspections for a six-month period, with alternative arrangements in place to ensure that statutory compliance and licensing arrangements could continue in the absence of physical clinic visits. Treatments were necessarily suspended under a new General Direction (0014) for a period of several weeks, in keeping with wider government policy. Clinics subsequently began to re-open in mid-May, when wider restrictions were somewhat eased. Although we were able to continue to work towards some of our strategic goals during this period, we did not publish an external business plan during this time, as we focused on ensuring that we effectively supported the sector and reprioritised our work.

This business plan sets out how we will work towards our vision in the second six months of 2020/2021.

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 UK's future relationships with the EU and the rest of the world

Following the UK's exit from the EU, the Human Fertilisation and Embryology Authority has continued to work closely with the Department of Health and Social Care (DHSC) and its arm's-length bodies to understand the opportunities available to the UK and our health and care system.

On the 31 December 2020 the transition period will end, and the UK will leave the EU single market and customs union. The UK will leave the transition period either with a Canada-style free trade agreement or the 2019 deal which will give us a trading relationship with the EU like Australia's. We continue to support the cross-organisational work on the UK's future relationships with the EU and the rest of the world to ensure that this includes consideration of the regulation of human reproductive tissues and cells.

We are working closely with DHSC to ensure preparations are in place for the end of the transition period and assess any implications this may have on the regulation of human reproductive tissues and cells. This includes working to implement the Withdrawal Agreement and Northern Ireland Protocol.

Following the end of the transition period, 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. We will work with DHSC to help to ensure 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.

We have responded to a drive by government (across healthcare and other industries) to maximise the potential for exporting our expertise, raising standards overseas and revenue for the UK. As such we have provided a service to various international partners, for example by providing assistance in establishing a regulatory regime in countries without one. In 2020/2021, we will continue to consider the opportunities available to us to build relationships internationally.

We will continue to update our business continuity plans in line with the UK's future relationships with the EU and the rest of the world and contribute to the post-transition planning and coordination work undertaken by DHSC.

Delivering our strategy in 2020/2021

The publication of our new strategy was delayed from April 2020 in light of the Covid-19 pandemic, and the Authority agreed we should publish it instead in the autumn, at the same time as this business plan. During the UK lockdown period, and beyond, our work has focused on the operational changes required to manage the effects of Covid-19 to ensure that patients, clinic staff and our inspectors are safe. The strategy itself has been extended by one year, to March 2024, to acknowledge the fact that so much of the current business year has been, and will continue to be, dominated by Covid-19 and its impact on fertility services. Our strategy remains clearly focused on achieving the very best care, ensuring the right information is available to people at the right time, and shaping the future.

Our strategic vision for the three and a half years from October 2020 to March 2024 is:

Regulating for excellence: shaping the future of fertility care and treatment

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

Table 1 - Outline of our strategic objectives and aims for 2020 to 2024

In this area…	We will…
The best care	1. Treatment that is effective, ethical and scientifically robust. Our aims: • To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes. • Clinics that are well led and see compliance and the provision of high quality care, including excellent support, as good business. • A transparent and accurate evidence base, to ensure that patients can make informed choices about their treatment. • More research and innovation to improve the evidence base and outcomes.
	2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Our aims: • Partners to be involved in care and treatment choices throughout the process. • Clinics to recognise that partner care is a core part of the service they provide.
The right information	3. Improved access to information at the earliest (pre-treatment) stage. Our aim: • Right-moment information provision from the outset for patients, partners, donors and surrogates.
	4. High quality information to support decision-making during and after treatment or donation.

	Our aim: • Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.
Shaping the future	5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Our aims: • Diverse fertility service users and professionals to have information that is up to date and relevant on developments such as genome research and editing, DNA tests and screening, home genetic testing and AI. • Clinics to assess innovative treatments (including add-ons), and to encourage responsible innovation that improves current practice.
	6. Preparing for future legislative and operational changes. Our aim: • To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.

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 2020/2021

This six-month business plan represents the first six-months of our 2020 - 2024 strategy which launches in October 2020.

Because of the work that was required during the first six months of the business year, to respond to the Covid-19 pandemic, our main focus for the remainder of the year will be on recovery, supporting the sector to re-establish normal services to patients and building a solid foundation for future strategic delivery.

A period of recovery has already started for our sector, and we plan to recommence inspections of licensed premises in November 2020. Careful plans have been put in place to manage this safely, minimising the duration of site visits.

We begin our new strategy looking firmly ahead, to the 30th anniversary of the HFEA in 2021, future developments in the fertility sector and an upcoming period of change for the organisation, as the government recruits several new Authority members, including a new Chair. During the UK's period of lockdown, we reviewed our intended plans, and have reprioritised some activities, and delayed others. But our overall vision remains the same – to regulate for excellence, and to shape the future of fertility care and treatment. Like all organisations, we will continue to work closely with the sector we regulate, and consider the best ways to achieve our aims while Covid-19 continues to be a factor in all our lives.

The activities set out over the next few pages will help us to deliver our strategic objectives in the remaining two quarters of 2020/2021, and beyond.

The best care

Our first aim is for effective and ethical care for everyone. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 2 - Strategic objective 1. Treatment that is effective, ethical and scientifically robust. Table outlining planned activities for October 2020 to March 2021

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Review of the compliance regime to ensure this remains robust and able to effectively assess care against target outcomes.	Review of: • compliance and enforcement policy • inspection priorities • our use of intelligence gained from inspections • information in reports • roll out and use of the revised PREP test. • Develop plans for quality improvements. • Readiness for next steps to ensure the HFEA's compliance regime is more aligned to strategic priorities	Throughout the year with further work falling into subsequent years.
Maintenance of Inspection Resumption Strategy and ongoing monitoring of Covid-19 risks and impacts on fertility sector and the HFEA. Clear actions and	Clear ongoing recovery plan and assistance for clinics as treatments recommence. Risk-based approach for the resumption of inspection activity. Clinics effectively respond to Covid-19 related risks. We effectively adapt and respond to any changes in Covid-19 circumstances, such as any local lockdowns, and also assist the sector to do so.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
communication as the situation develops.		
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes a revised approach to respond to Covid-19.	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. Assurance of consistent standards and safety for the public and other stakeholders. 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.	Throughout the year
A project to improve the provision of treatment add-ons and to encourage responsible supply of these by clinics. Including further development and publicising of patient information and traffic lights.	Responsible supply of add-ons by clinicians/clinics based on good evidence Add-ons offered: • with full information so patients can make informed decisions • only to specific groups where there is evidence of effectiveness and safety. • General agreement within the fertility sector around the direction of travel toward best practice around add-ons. Patients and clinics understand the risks associated with add-ons. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence	Throughout the year, with further work planned for subsequent years of strategy delivery.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Initiating a project to build on success rates work from 2019/2020.	We use our data to understand variations between clinics and collaboratively define best practices.	Autumn 2020
Effective handling of and communication about: • clinical incidents and adverse events, including publication of 2019/20 'State of the Sector' report and quarterly compliance reports • complaints about clinics	Continued strong focus on learning in dialogue with the sector. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to learning from own and others' mistakes. Learning gained, to inform future inspections. Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse events.	Throughout the year, with the state of the sector report published in Autumn 2020
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Ensure that licensing decisions and other approvals are well governed. Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually.	Throughout the year
Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. 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. Mitochondrial donation and PGD approvals taken in an accountable and transparent way.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing review of guidance for clinics to ensure this remains fit for purpose, including: • preparation of updates to the Code of Practice including further guidance on electronic and storage consent. • other clinic-facing resources such as patient support pathways.	Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. A clear Code of Practice and other guidance for clinics.	Throughout the year. Preparatory Code work this year with revised Code of Practice to be published in 2021.
Servicing the legal information needs of the HFEA including: • provision of legal advice to inform other HFEA work • management of team of external legal advisers to support effective licensing processes. • supporting the review of the Compliance and enforcement policy.	HFEA licensing decisions are sound and based on comprehensive legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Review of information provided on HFEA website about: • routine treatments for instance 'standard' IVF • typical prices for treatment • including testing of this information using the pilot patient forum.	We use our communications channels to make sure patients receive the right information at the right time. Information is reviewed on a cyclical basis to ensure that it is fit for purpose.	Throughout the year
Ensure that the HFEA and licensed clinics are ready for any changes as a result of the end of the EU exit transition period, so that they continue to provide high quality and safe treatment.	Identify and mitigate post-transition risks and issues, such as the continued supply of medicines, equipment and gas to licensed clinics.	Throughout the year
We review and update business continuity plans regularly, in line with the UK's future relationship with the EU.	Gain assurance that clinics and suppliers have robust business continuity plans in place and continue to seek further engagement on any risks and issues identified relating to the end of the transition period.	Throughout the year

Table 3 - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Table outlining planned activities for October 2020 to March 2021

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	**Benefits and outcomes**	**Timescale**
Nothing planned against this objective in year one, work to follow in years two and three.	None in year one.	Not applicable

The right information

Our second aim is to ensure that people can access the right information at the right time. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 4 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for October 2020 to March 2021

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	**Benefits and outcomes**	**Timescale**
Using social media and other channels, including the media, we will communicate relevant information to the wider general public and those who are not having fertility treatment.	We communicate via a range of channels and methods so people can access the right information at the right time for them. We will utilise our content strategy to position our information effectively. We will raise our profile and provide the general public, not just current fertility patients, with useful information.	Throughout the year

Table 5 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for October 2020 to March 2021.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing work to review our compliance with accessibility requirements.	Stakeholders' accessibility needs are considered so that they are able to access our information. HFEA services are available to everyone that needs them. We ensure that HFEA appropriately complies with government accessibility requirements and legal obligations. We maintain a clear accessibility statement for our website and Clinic Portal.	Throughout the year
Consideration of Clinic Portal and website updates (subject to budget) to: • increase stability • deliver additional functionality • enhance search functionality.	Our systems support continued information provision and improvements. Implementation of website improvements identified by users in 2019. The Clinic Portal remains useful and easy to use for clinic staff and meets their updated requirements.	Throughout the year
Update to the data available in Choose a Fertility Clinic (CaFC) and scoping work to consider and how clinic data will be published in future.	A project to integrate performance data from the new register into the CaFC website, to allow up to date CaFC data to be published. Patients have access to regularly updated data on clinic performance to inform their treatment decisions.	Throughout the year and into 2021/22

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Working with the Competition and Markets Authority (CMA) on their project on self-funded IVF and consumer law guidance.	We support the CMA to produce guidance so that clinics understand their obligations under consumer law in relation to self-funded treatment.	March 2021
Make use of patient feedback and our pilot patient forum to ensure that information is fit for purpose.	Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. We gain an insight into the patient experience in clinics and encourage good practice based on feedback.	Throughout the year
Engagement with researchers across the field of fertility research, particularly those using – or with potential uses for – HFEA Register data and those involved or interested in commencing research with human embryos.	Improved relations and communication with the fertility research community. Researchers have access to relevant and valuable data in our Register, to inform high quality research. We review the application process for researchers to use HFEA data, or human embryos. Anonymised Register dataset available for researchers. Promote quality research and collaboration using HFEA Register data and/or human embryos. More research and innovation to improve outcomes. We continue to be active members of the UK health data research alliance to encourage widespread and responsible access to data	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Maintain up to date and accurate information and advice on our public-facing website.	Patients see HFEA information as 'go to' impartial advice. People understand the possibilities and the difficulties of treatment 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.	Throughout the year
Responding to media reports.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wider range of issues	Throughout the year
Maintaining effective Opening the Register (OTR) and counselling services, including restarting services following the pause during Covid-19.	Opening the Register requests continue to be met in a sensitive manner and within agreed time limits. 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. OTR applicants feel more supported and prepared to deal with the information they receive from us.	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
We provide timely and appropriate responses to freedom of information (FOI), parliamentary question (PQ), and subject access requests.	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion. We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.	Throughout the year
To publish good quality statistical and other reports, including the Fertility Trends report.	We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes, trends and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment. We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
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.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Running the Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. 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 and efficient use of time and resource. Greater knowledge about the efficacy and safety of fertility treatment.	Throughout the year
Ongoing compliance with government information 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'.	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 the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Effective records management and information governance.	Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times. Information governance arrangements comply with latest requirements. Records management and information governance risks are managed effectively.	Throughout the year
Responding to external consultations and reviews including from the Department of Health and Social Care, other regulators and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector.	Throughout the year
Recruitment of new Authority and other committee members, in liaison with the Department of Health and Social Care.	HFEA governance and decision-making capabilities maintained. Effective induction to ensure new members are up to speed and able to carry out effective decision-making. Key knowledge is retained where possible, during a period of high member turnover.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Continued participation in the collaborative regulatory advice service for regenerative medicine, to provide advice to those working in the life sciences industry.	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. 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. Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators.	Throughout the year
Full realisation of the benefits of our improved Register function and processes, including early life support for the PRISM data submission system and ongoing engagement with and feedback from clinics.	PRISM fully bedded in with clinics and data being submitted into new register. Updates completed by third party system suppliers to their systems, and their updated systems deployed with data being submitted into the new register. Reduced transactional costs for clinics and increased user satisfaction. Stable system. Stable register. 'Right first time' data quality and reduction in effort by clinics submitting the data.	Throughout the year
Building and realising the benefits of a new Register Information Team Application (RITA), to enable us to query the new register and run reports.	Targeted support to improve data quality across the sector. Reports being provided and the ability to query the new register to internal HFEA teams' requirements to enable Register team and OTR team to provide an acceptable level of service.	By March 2021

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
	Ability for OTR team to provide statutory service and search across the new register. Ability for register team to provide support to clinics and provide cross-sector reporting. Ability for register team to improve their data quality focus, addressing patterns or trends of data quality issues across sector or within specific areas.	

Shaping the future

Our final aim is to embrace and engage with changes in the law, science and society. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 6 - Strategic objective 5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Table outlining planned activities for October 2020 to March 2021.

Objective 5 Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI) - methods and channels	**Benefits and outcomes**	**Timescale**
Activity to monitor the use of AI in fertility clinics and the wider sector.	We understand any developments and are responsive to these. We ensure that our regulatory regime is fit for purpose.	Throughout the year

Table 1 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for October 2020 to March 2021.

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
Respond to any requests for consultation on possible legislative changes as these	Early consideration of possible impacts of any changes on the sector and the HFEA. To ensure the HFEA and the sector are prepared for future changes in the fertility field.	As these occur

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
occur and consider how these will impact the HFEA.		
Project to scope future 'opening the Register' (OTR) demand and logistics.	To understand, through analysis, the likely future demand on the OTR service. To put the groundwork in place for a subsequent project to operationally prepare for a growth demand as donor-conceived people are eligible to make OTR requests from 2021 and 2023, ensuring that the OTR team can handle increasing demand.	By March 2021
HFEA Office relocation to Stratford.	Continue to implement a project to coordinate work for the HFEA to prepare for new accommodation in Stratford and engage with a wider DHSC project, managing the infrastructure and logistics of the move. HFEA have the space and facilities needed to operate effectively within the new office and for staff working remotely. HFEA successfully move in 2020 with minimal disruption to HFEA operations during the move.	Winter 2020
Ensuring that our working arrangements are suitable for maintaining appropriate Covid-19 safe working conditions.	We have reviewed our ways of working, including relevant policies. Our office-based staff is able to return to working in an office environment when it is safe to do so.	Throughout the year
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2024.	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 training and other means.	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
	We take into account equality and diversity in the design and implementation of our policies to ensure that these are fair and appropriate for all staff. Staff feel valued and motivated to deliver our strategic aims.	
Continue to engage on emerging international work (where possible given the impacts of Covid-19).	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.	Throughout the year
Scope a fee review informed by our income forecasting model.	Develop options for a fee review in 2021-22.	By March 2021
Planning for activities to mark the 30th anniversary of the HFEA.	We develop plans to mark this historic milestone, and take a forward view as to the future of the fertility sector.	Throughout the 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.

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

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.

Income

Table 8 - HFEA high-level income for 2020/2021

Income	Budget £000s	Forecast £000s (as at end July)
Department of Health and Social Care funding	1,338	3,438
Non-cash income	510	510
Treatment and licence fees	5,209	2,539
Other income	154	154
Total income	7,211	6,641

Expenditure

Table 9 – breakdown of HFEA operating costs

Operating costs	Budget £000s	Forecast £000s (as at end July)
Staff costs	4,791	4,675
Other operating costs	1,910	1,864
Total operating costs	6,701	6,539

Table 10 - HFEA high-level expenditure for 2020/2021

Overall expenditure	Budget £000s	Forecast £000s (as at end July)
Total operating costs	6,701	6,539
Capital charges	510	510
Total revenue expenditure	7,211	7,049

The Department of Health and Social Care have provided additional Grant in Aid funding of £2.4 million, increasing the overall figure to £3.438 million. Even so, we are still forecasting a shortfall which will be funded from our cash reserves.

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