Human Fertilisation & Embryology Authority

Business plan

April 2023 – March 2024

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.

During 2023 and early 2024 we will be developing our new strategy for 2025-2028. Our development process will include consultation with our stakeholders on a new vision and aims for the following three years.

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.

The Department of Health and Social Care's planning priorities for 2023/24 are reflected where relevant in our plans, and our strategy is well aligned to the Department's vision, which is to enable everyone to live more independent, healthier lives for longer.

In the wider health system, the aim is to fulfil this vision by supporting healthy behaviours, improving the UK's health and care system, and creating healthy environments. Our focus on the best care, the right information and shaping the future supports the Department's broad aims, within the specific context of fertility regulation and embryo research.

From 2020 and throughout 2021 and 2022, we focused on responding to changes due to Covid-19, adapting our inspection regime and our other planned strategic work accordingly. This will continue during 2023 and 2024 as we continue to ensure clinics are able to operate safely for patients and provide up to date information.

Over the past three years we also implemented a raft of changes in our regulatory and licensing regime, and in our guidance and information, in response to EU Exit. We will continue to respond to any further changes relating to EU Exit that may impact on the fertility sector or our own work.

The Government's levelling up agenda also includes health inequality reduction as a key priority. We will continue to advocate for equitable access to high quality fertility services and to provide information to help patients and their partners in their decision-making.

The Government has also published, in July 2022, and updated in August 2022, a 10-year Women's Health Strategy for England. This goes on to set out the approach to priority areas of women's health, including fertility.

The Government's ambition is to ensure women are supported through high-quality information and education to make informed decisions about their reproductive health and address the current geographical variation in access to NHS-funded fertility services. This aligns well with our own wish to see patients receive the best possible care and better information, and to see more equitable access to fertility treatment across the UK.

The HFEA will also continue to work with royal colleges and professional groups to consider how best to improve understanding among healthcare professionals about infertility, so that referrals to treatment services are quicker and easier for women.

This business plan sets out how we will work towards our vision in 2023-2024, the third and final full year of our current strategy.

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.

What we did in 2022-2023

Overview

In 2022-2023, we made good progress with our strategic aims, following the ongoing aftereffects of the pandemic. The below describes key work we undertook in 2022-2023 against our strategic aims.

Delivery of the 2022-2023 business plan

The best care

Following changes to our inspection methodology introduced during Covid, clinics were assessed using a hybrid approach involving a desk-based assessment (DBA) combined with an onsite visit to allow continued close regulatory oversight of the fertility sector. A risk-based approach was taken in prioritising inspections due this year with those deferred by the pandemic given priority.

Through our inspection activities, we have 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 introduced a revised Compliance and Enforcement Policy in 2021, setting out the approach we will take in dealing with non-compliance by licensed clinics and research centres. This provides a consistent ongoing basis for making regulatory decisions about clinics.

In October 2022, we also published our State of the Fertility Sector report, providing an overview of the UK fertility sector in 2021/22.

In April 2022 we published the National Patient Survey report which revealed that 72% of patients were satisfied with their care and that further clarity over effectiveness of treatment add-ons and costs was needed.

We continued our earlier work on treatment add-ons, to improve the way in which these are provided and to encourage responsible supply of add-ons by clinics. This project will conclude in the summer of 2023.

Although some of our planned work with researchers was delayed by earlier Covid restrictions, we maintained communication with the fertility research community and continued to be active members of the UK health data research alliance to encourage widespread and responsible access to data.

We also continued to work collaboratively where possible, maintaining our previously established relationships with other ALBs and health regulators e.g., to address issues that required joint working in an efficient and coordinated way, or to establish the best approach when new areas of regulatory overlap arise.

We engaged with patient groups, clinics, and other stakeholders to gain a greater understanding of the disparities in access, experience, and outcomes between ethnic groups, including those identified in our ‘Ethnic Diversity in Fertility Treatment 2018’ report (published March 2021). We continue to work through the actions identified in the March 2021 report, using the findings of the 2021 National patient survey and workshops with clinics to progress further activity in this area.

The right information

We provided advice and information to patients about accessing treatment and donation via our website and ensure that the information we provide about treatments remained up to date. We implemented some technical updates to our website to ensure that it continues to work smoothly.

We also extended our use of social media to Instagram and have continued to use LinkedIn, Facebook, and Twitter in order to increase our reach to patients, since one of our priorities is to position and promote our information so that people find what they need when they need it.

We continued with the implementation of our PRISM system, for clinics to submit data to the Register. We continue to onboard clinics, and this will be completed by the summer of 2023. We also began development work on our internal systems to restore connectivity with the new register after migrating our data across successfully. This work, once complete, will enable us to issue more regular updates to Choose a Fertility Clinic (CaFC), from the end of 2023 onwards.

We have commenced a new pilot in 2022 of our Patient Engagement Forum, recruiting members of the public to sign up to one or more of three newly created groups. Along with this, we have also continued with our Professional Stakeholder meetings These forums will continue to be utilised and reviewed in the summer of 2023.

We have put in place new governance structures to ensure that proposed changes to our register are properly evaluated. Our new Data review board will be active following the completion of the deployment of PRISM and the update to Choose a Fertility Clinic.

We also continued to engage with the Competition and Markets Authority and the Advertising Standards Authority, welcoming their new guidance and enforcement notice for fertility clinics in May 2021 and issuing a joint letter to clinics drawing the guidance to their attention.

We met the NHS Data Security and Protection Toolkit (DSPT) standards in 2022, and we are continuing to model our information governance and data protection and security practices around this. We have also implemented a new Information Governance Framework which sets out a strategic vision for improving data protection and security controls within the HFEA, and this is led by the Information Governance Steering Group established in 2023.

Shaping the future

We handled a significant number of Opening the Register requests, and following the pause to the service in 2021, we continue to look at the operational arrangements for this work to ensure that we are set up to deliver effectively when the law changes to donor anonymity are implemented in the autumn of 2023.

We continued to monitor areas of likely future developments, such as Artificial Intelligence (AI), which is a key consideration for our Scientific and clinical Advances Advisory Committee (SCAAC).

In September 2021, we welcomed the announcement that the Government planned to extend the storage limit for frozen eggs, sperm, and embryos, bringing the law in line with advances in science, changes in modern society and individuals' reproductive choices. This allowed patients more time to make important decisions about family planning. Following the commencement of this law in July 2022, we worked to ensure that the new rules are clear and that fertility clinics can both implement the changes effectively and give patients sufficient information so that they are fully informed about their options. The new Regulations have increased the statutory storage limits from the previous 10 years to a 10-year renewable storage period up to a maximum of 55 years. The transition period for this law ends in June 2024 after which all gametes in storage before 1 July 2022 must be stored with effective consent or be removed from storage.

During the year we also began early planning work to consider the way in which we authorise new processes proposed by clinics, and this work will be completed in 2023.

In March 2022, we welcomed several new members to the Authority, who joined the Authority in April and May 2022. We completed a programme of training and induction to ensure that those members who serve on our committees are well equipped to make governance and licensing decisions.

The Authority announced an increase in the IVF licence fee from 1 April 2022, the first such change since 2016. We will begin a review of our licence fee model in the 2023-24 business year.

We will also work with DHSC to support a programme of work to assess fertility provision across Integrated Care Boards, which have responsibility for commissioning fertility services, with a view to removing non-clinical access criteria, such as already having a child from a previous relationship, and standardising access across England in year two of implementation of the Women's Health Strategy.

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 2022 and 31 March 2023.

Table 1- Table outlining performance data against the same data from 2020 - 2023

Type of work	2020-2021	2021-2022	2022-2023
Active clinics and research establishments	134	133	137
Clinics and research establishments inspections delivered	77	105	132
New licence applications processed and presented to the Licence Committee/Executive Licensing Panel	1	4	4
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	41	52	49
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	1	1	0
New preimplantation genetic testing (PGT-M) applications processed and presented to Statutory Approvals Committee	32	52	45
New mitochondrial donation applications processed and presented to Statutory Approvals Committee	6	5	5
Incident reports from clinics processed (including near misses)	548 (69)	793 (121) **See note 1 below**	606 (89)
Alerts issued	1	4	10
Formal complaints about clinics	88	76	59
Opening the Register requests closed within 20 working days	54	76	**See note 2 below**
Donor Sibling Link applications processed	196 responses completed in total	110 responses completed in total	133 responses completed in total.
Licensed Centres Panel meetings held	61	110	2

Type of work	2020-2021	2021-2022	2022-2023
Formal roundtable meetings with patient organisations held	2	3	2
Professional and public stakeholder meetings (including Authority meetings either held in public or recorded and made public.)	4	1	7
Freedom of Information (FOI) requests responded to	8	8	50
Enquiries responded to under the Data Protection Act (DPA)	0	1	4
Parliamentary questions (PQs) responded to	6	0	16
Most popular/viewed page on our website	Homepage	Homepage	Fertility clinic search

Notes

Some of the data provided above is from the 'State of the Sector' reports published annually in the third quarter of the financial year. These have a more extensive data set and include additional details where appropriate.

Data provided in previous years' Business Plans has been amended so the data terms are consistent with the State of the Sector reports.

1. The increase in the number of incidents reported in 2021/2022 is a direct result of the requirement for all clinics to report all Covid 19 cases in staff and patients, and all hospital referrals during the pandemic.
2. We do not currently measure response times for OTR requests. In April 2020, due to Covid 19 impacting clinics' ability to respond to enquiries about records, we had to pause the OTR service. This led to pent up demand and very high levels of applications when the service reopened again in autumn 2020. In October 2020, the Authority agreed we should pause measuring our performance against a 20-working day target while we worked to clear the backlog of OTR applications. We have increased capacity in the team, and we have introduced new performance measures to track our progress in processing the outstanding backlog. As of the 2022/2023-year end, there were 698 OTR applications in the backlog. Alongside this, the rate of applications has also been steadily increasing over time. We typically now receive around 65 requests per month, compared to around 30 per month in 2019.

Required HR benchmarking information

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

Table 2- Table outlining standard human resources benchmarking data

Benchmarking area	2020-2021 data	2021-2022 data	2022-2023 data
Executive senior manager (ESM) to staff complement ratio	1:17	1:18	1:17
Number of staff earning more than £142,500 now and any planned change during the next planning period	1	1	1
HR staff to employee ratio	1:45	1:47	1:48
Training budget as a percentage of pay bill	1.5%	1.5%	1.5%
Projected reductions in non-payroll staff	Not applicable	Not applicable	Not applicable

Key performance indicators

Table 3 - Table indicating performance against key metrics from April 2022 to March 2023

Category	**Performance indicator**	**Target**	Performance in 2021-2022	**Performance in 2022-2023**
Engagement	Number of emailed public enquiries received.	No target, since the nature, volume and complexity of enquiries received varies widely.	1382	1273
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.	64 working days	64 working days
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).	N/A We have paused this indicator and are developing new measures alongside a project to review the OTR service, in light of increasing demand.	N/A We have paused this indicator and are developing new measures alongside a project to review the OTR service, in light of increasing demand.
Financial management	Cash and bank balance.	To move closer to minimum £1,520K cash reserves.	£3.69m	£3.37m
People and capacity	Percentage turnover for the year.	5-15% turnover range.	21.6%	18.7%

Activities for 2023-2024

This business plan represents the final year of delivery for our 2020-2024 strategy, which launched in October 2020. The effects of the Covid-19 pandemic continued to be felt within the sector and the HFEA itself throughout 2022/23, and this has had an impact on our strategic delivery. The Authority will be considering its next three-year strategy during the coming year and will review outstanding items from the current strategy when making decisions about new priorities.

In the first half of the business year, the HFEA's major resourcing priorities will be development work on the Opening the Register (OTR) service in anticipation of a marked increase in the numbers of applicants from the autumn onwards and implementing any recommendations that result from the public bodies review. We will then assess the resource available to further progress actions relating to the Government's Women's Health Strategy and future planned work on transparency and regulation. In addition to our statutory duties, our other main priorities for the year will be:

- Completion of a CoP update to incorporate storage limits changes made in July 2022
- PRISM, CaFC and Register team tools to enable us to fulfil our statutory functions
- Further work on ethnic disparities in fertility treatment – this is in line with the Governments Women's Health Strategy
- Maintaining our systems e.g., Clinic Portal, Epicentre to enable us to fulfil our statutory functions
- AI/genetics horizon scanning (maintaining a watching brief in this developing area)
- The impact of changes to the Northern Ireland Protocol (detail as yet unknown) and any consideration of changes to the EUTCD
- The conclusion and implementation of the work on authorised processes begun in 2022/23
- Input to NICE fertility guideline review
- Compliance with the DSPT toolkit
- Further work with our patient engagement forum
- The development of a new strategy for 2024-2027.

Our plans align well with the Department of Health and Social Care's planning priorities for the coming year. Through our activities we aim to support their overall vision of enabling everyone to live more independent, healthier lives for longer, through supporting healthy behaviours, improving our health and care system and creating healthy environments.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2023-2024.

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 4 - Strategic objective 1. Treatment that is effective, ethical and scientifically robust. Table outlining planned activities for April 2023 to March 2024

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes continuation of the revised approach developed in response to the Covid-19 pandemic.	All clinics and research establishments in the sector are: • appropriately inspected and monitored against the requirements of the Act and published performance indicators, and • if they meet the required standards issued with licences for up to five years. Clinics that are well led and see compliance and the provision of high-quality care, including excellent support, as good business. 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 (e.g., 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
Respond to any developments relating to Covid-19 and their impact on the fertility sector and the HFEA. Clear actions and communication.	Clear ongoing inspection plan and assistance for clinics in response to any new Covid-19 related situations and government guidance. We respond as required to the Covid-19 public inquiry.	Throughout the year
Collaborative and partnership working with other ALBs and health regulators UK wide as needed, to ensure streamlined regulation.	Joint working as and when required, including the provision of input into the current review of NICE fertility guidelines. Revised NICE guidelines are informed by HFEA input and data, such as on ethnic diversity and fertility treatment and family formations to ensure that health	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
	inequalities are addressed. NICE guidance updated to reflect current practice across the sector. Implementation of any changes into the inspection regime. Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. 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 most effective approach if any new areas of regulatory overlap should arise. We maintain clear and appropriate memoranda of understanding (MOUs) to ensure that we have clearly defined responsibilities and ways of working collaboratively with key regulators.	
Further work on ethnic disparities in fertility treatment, including an updated report on register data in this area, and a joint call to action/statement Autumn 2023.	Continue to address disparities in access, experience and outcomes identified in our 'Ethnic Diversity in Fertility Treatment 2018' report (published March 2021) and patient survey by issuing an updated report and a call to action. Continue to engage with stakeholders and to support the Government's objective of reducing health inequalities particularly among Black and ethnic minority groups.	Autumn 2023
Conclusion of work on changes to the ratings system on treatment add-ons.	Ethically and medically responsible supply of add-ons, only where these are safe and appropriate, by clinicians/clinics based on good evidence. Where add-ons are offered, this is: • with full information so patients can make informed decisions • only to specific groups where there is evidence of effectiveness and safety. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence. A refined presentation of the rating system and further consideration of the most appropriate forms of evidence to base it on.	Summer 2023

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Effective handling of and communication about: • clinical incidents and adverse events, including publication of a 2022-2023 'State of the Sector' report and quarterly compliance reports • complaints about clinics	Continued strong focus on learning in dialogue with the sector including engaging with clinic leaders. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to a proactive approach being taken 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 2023
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually ensuring improvements are made as required.	Throughout the year
Processing applications for the licensing of preimplantation genetic testing for monogenic gene defects (PGT-M) 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 PGT-M approvals taken in an accountable and transparent way.	Throughout the year
Ongoing review of guidance for clinics to ensure this remains fit for purpose, including: • delivery of any necessary updates to the Code of Practice (this year, in relation to storage limits changes in 2022) • issuing other clinic-facing communications, such as Clinic Focus,	Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. A clear Code of Practice as required by law and other guidance for clinics. An update incorporating updated guidance to clinics on the storage of gametes and embryos as a result of changes to storage limits introduced by the Health and Social Care Act 2022.	Throughout the year.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
on issues that require further clarification to the sector.		
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 any changes to the law.	HFEA licensing decisions are sound and supported by legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year
Maintain up to date information on the HFEA website about routine treatments, continuing our focus on clinics providing good support, and testing new information using the patient engagement forum.	We use our communications channels to make sure patients receive the right information at the right time to ensure our statutory duty to provide information is informed and effective. Information is reviewed on a cyclical basis to ensure that it is fit for purpose. New information added when needed. We use our social media channels to signpost people to the website information and if we include new information on the website, we promote this widely using our social media.	Throughout the year
Ongoing implementation and oversight of the changes being considered to the Northern Ireland Protocol and responding to any new developments that may arise.	We continue to work with the DHSC and others on any issues arising from the Northern Ireland Protocol. We will engage with any changes to the EUTCD and work with others on the implications of these.	Throughout the year

Table 5 - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Table outlining planned activities for April 2023 to March 2024

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	Benefits and outcomes	Timescale
No specific work in this area planned for this business year.		

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 6 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for April 2023 to March 2024

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

Table 7 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for April 2023 to March 2024.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Maintaining communication with our stakeholder groups, the patient engagement forum and our followers on social media.	The information we publish is informed by stakeholder needs and insights. We meet with our patient and professional stakeholder groups twice a year and engage with them on a range of issues. We will involve members of the patient engagement forum to gain feedback on our work to inform what we do. We maintain our social media channels to reflect the work we are doing and try to make these as interactive as possible to encourage feedback and discussion.	Throughout the year
Ensuring that patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant, impartial and accurate information.	We will ensure our website is up to date and reflects the latest information. 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
Position and promote information via our various channels.	Access to relevant and impartial information for patients, partners, professionals, surrogates, donors, donor-conceived people, and their families. Maximising the positive impact of the information we provide. We ensure we make an impact with our information by using a range of metrics to evaluate the impact of our digital and social channels and media work. We use our social media channels to drive people to our information both online and in the media. Promote information of relevance to the Government's Women's Health Strategy and work with the Women's Health Ambassador and others on this.	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**
Responding to media reports and requests.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wide range of issues.	Throughout the year
Scoping of future developmental work on regulatory transparency.	Scoping of potential future work to increase regulatory transparency. Consideration of how best to deliver this work in the most effective and efficient way possible.	Throughout the year
Ongoing work to ensure that we maintain our compliance with accessibility requirements and make changes as necessary.	Stakeholders' accessibility needs are considered so that they are able to access our information. We ensure that our website meets the Government accessibility guidelines and that HFEA staff produce accessible documents, especially those for the website.	Throughout the year
Work following the completion of the PRISM reporting system, to enable Choose a Fertility Clinic (CaFC) to be updated.	We ensure quality metrics and verification reports are in place. Clinics are able to fix validation errors. We ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions. New CaFC data published for the first time from the new system. Increased ability to analyse data and report from the Register.	Between September 2023 and June 2024
Continued support for the PRISM data submission system.	PRISM fully bedded in with clinics and data being submitted into the register. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime. 'Right first time' data quality and reduction in effort by clinics submitting the data.	July 2023 onwards
Further development work on the 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 July 2023

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.	
Maintaining an effective Opening the Register (OTR) service.	OTR requests continue to be met in a sensitive manner. The backlog of requests stemming from the clinic closure period during the pandemic and a subsequent increase in the ongoing number of requests is dealt with, and realistic timescales introduced.	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
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
Continue to engage with the requirements of the NHS Digital Data Security and Protection Toolkit.	We continue to maximise the quality of our submissions in the toolkit, in particular the areas of improvement previously highlighted. Maintain our oversight group, which combines best practice from other organisations and collects toolkit documentation on an ongoing basis to allow for faster, more complete submissions going forward.	June 2023 (annual process) 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 assure ourselves that we are practising good data security and personal information is handled correctly.	
To publish good quality statistical and other reports.	We provide the public, patients, clinic staff and others with up-to-date, high-quality information about treatments, 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
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	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. Promoting our Register data to ensure it is widely used in research. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	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**
Ongoing compliance with government information requirements.	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.	Throughout the year
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, calls for evidence and reviews including from the Department of Health and Social Care, other departments, regulators and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector.	Throughout the year

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 8 - 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 April 2023 to March 2024.

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
Maintain a watching brief over patient-facing AI and data-driven new technologies that are in or potentially approaching clinical use, via the Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning process and reviews. Ongoing horizon scanning on genetics policy issues.	We understand new developments and are responsive to these. We ensure that our regulatory regime and guidance is fit for purpose. Regular reports to SCAAC detailing issues raised used to inform our policy working and to be shared more widely as relevant. Our internal working group on AI meets regularly to monitor this. Regular horizon scanning information on genetics policy issues is considered by SCAAC and integrated into our other work as relevant (e.g., the work on the modernisation of the Act). Emerging new policy frameworks related to these areas are taken account of in our policy work. That responsible innovation is encouraged.	Throughout the year
To complete and implement a review of the methodology for authorising new processes for use in clinics.	Robust and up to date methodology for authorising new processes. Processes on the authorised processes list are clear and reflect up to date practices. Awareness among clinics of the requirements for introducing new processes.	July 2023

Table 9 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for April 2023 to March 2024.

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
To review responses to a targeted consultation on the HFE Act and complete proposals to government on changes we would like to see to the Act.	Any future review is informed by well-informed proposals based on engagement with our stakeholders. The Government is provided with useful proposals setting out the ways in which the Act could be developed.	Summer 2023
Respond to any requests for consultation on legislation or emerging proposals and consider how these might impact the HFEA.	We inform any work by DHSC on legislation relating to our functions. Early consideration of possible impacts of any planned changes on the sector and the HFEA.	As these arise
Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	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.	June 2023 Throughout year
Working to ensure the HFEA has prepared the 'Opening the Register' (OTR) service for future levels of demand.	The HFEA is operationally prepared for the existing and future growth in demand as more donor-conceived people become eligible to make OTR requests from 2023 onwards. Excellent OTR service maintained. Communication and engagement in place to ensure that the public, clinic staff, donors, donor conceived children and their families understand and are prepared for the changes.	Autumn 2023
Considering new arrangements for the provision of support services for OTR applicants.	Consideration of the future of support services for all OTR applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information.	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
	OTR applicants feel supported and prepared to deal with the information they receive from us.	
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. People strategy in place, setting out our vision for ensuring we strike the right balance of staff skills, 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. 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, by taking action on the results of our staff survey. We reflect our values and behaviours in all our work to ensure that quality and service improvement is part of our ongoing way or working.	Throughout the year
Maintaining the stability of our core IT systems.	Core systems including Epicentre and the Clinic Portal are maintained and upgraded as necessary in order to ensure business continuity.	Throughout the year
Supporting the DHSC-led public bodies review of the HFEA ('ALB review').	Responding and engaging with the ALB review team to provide best evidence of HFEA functions, effectiveness, and efficiency, addressing and implementing recommendations for HFEA action in the final ALB review report.	Report to be published in Sep 2023. Implementation throughout the year.
The first phase of a structural review of the HFEA's fee regime, informed by our income forecasting model.	We ensure that we meet the financial needs for effective regulation through a fair and transparent fee structure.	To commence by March 2024
The development of a new strategy for the HFEA from 2024 onwards.	We set a clear vision for the future, enabling us to plan for the next three-year period.	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 as part of the budgeting process.

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.

In April 2022 saw an increase in the fee charged for IVF treatment cycles from £80 to £85.

The increase to the licence fee, the first in 6 years, has enabled the HFEA to increase its headcount and invest further in information technology in support of our use of data.

Income

Table 10 - HFEA high-level income for 2023-2024

Income	Budget £000s
Department of Health and Social Care funding	1,038
Non-cash income	232
Treatment and licence fees	5,829
Other income	108
Total income	7,207

Expenditure

Table 9 – breakdown of HFEA operating costs for 2023-2024

Operating costs	Budget £000s
Staff costs	4,975
Other operating costs	2,232
Total operating costs	7,207

Table 11 - HFEA detailed Operating Budget 2023/24

Budgeted Income	**£000s**
Licence Fees	5,829
Interest received	35
Other income	73
Subtotal	**5,937**
DHSC Funding	
Grant in aid (includes pension funding	1,038
Ring-fenced RDEL	232
Total Income	**7,207**

Budgeted expenditure	**£000s**
Wages and salaries (including contingent labour)	5,093
Inspection costs	79
Other staff costs	102
Authority & Committee costs	235
IT and Development Costs	479
Other costs	185
Legal Costs	380
Accommodation	372
Projects	50
Non-cash	232
Total expenditure	**7,207**

Our licence fee income position has been based on an assumed 65,200 new IVF cycles that meet the criteria for the payment of a clinic licence fee. During the 2022/23 year, most of our clinics were slowing submitting their cycle data from 2021/22 and onwards. This resulted in clinics being billed based upon estimates. The impact of this means that we continue to use volumes from 2019/20 as a basis for setting our income budget.

As our income position is predicated on sector activity, we retain internal levers to limit expenditure should activity fall below our baseline. Responding to activity levels that might generate additional income proves more challenging, activity can vary dramatically month on month, and we would look to have at least a

quarter's data before considering additional activity – although we do have a pipeline of activity that could be accelerated, it is not always possible to complete these projects in the same financial year.

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 all arm's length bodies (ALBs).

Our governance structure includes corporate governance tools, a people strategy and HR policies, a risk strategy 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.

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 the best care.

Organisational structure and establishment

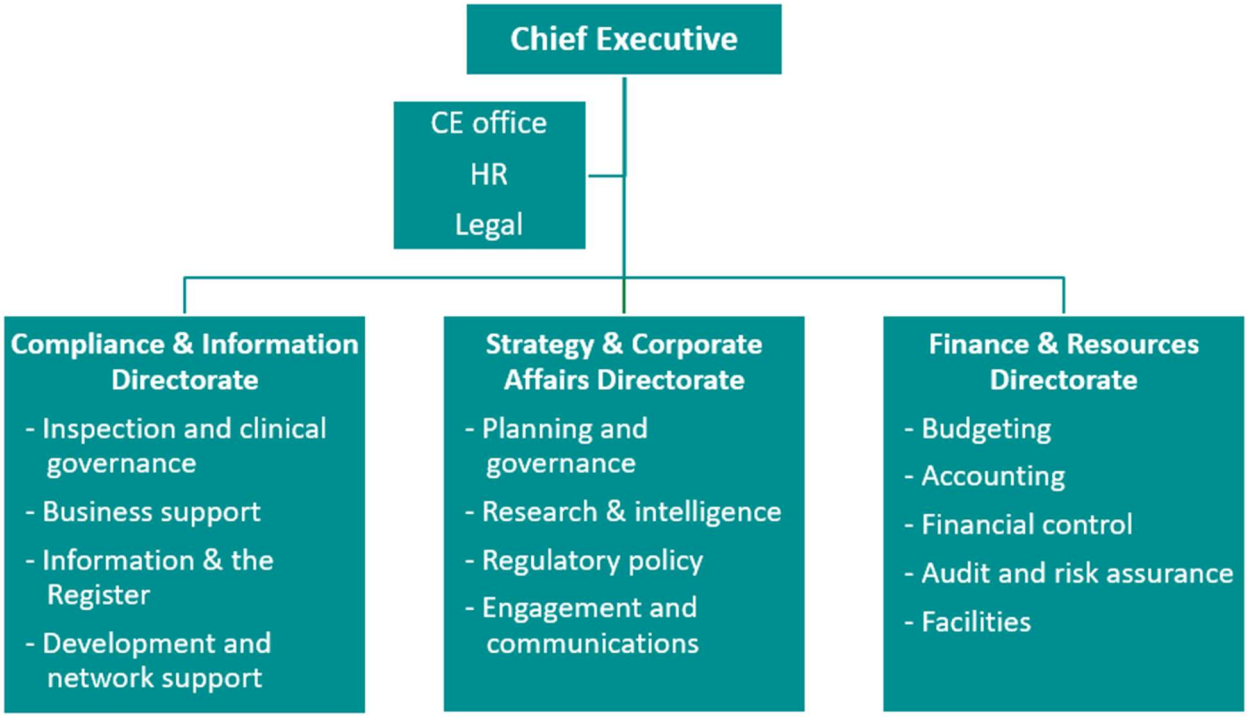
Our staff complement is 77 (from 1 April 2023). We have put in place shared services arrangements with other bodies where feasible. For example, we share part of our finance and resources team staffing with the Human Tissue Authority, and our facilities management service is shared with the five other Department of Health and Social Care ALBs with whom we occupy the same premises.

We need to ensure we retain the capability and capacity to deliver our overall strategy for 2020-2024.

We have a people strategy which sets out how we will ensure we attract and retain the capacity and skills we need in order to deliver our strategy. 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.

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 sets out the critical elements of the relationship between us and the department and other ALBs where relevant. A new framework agreement was approved in 2021. As an ALB, we will continue to operate 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. In accordance with the latest framework agreement, we will be working towards creating an over-arching corporate plan for the HFEA, to be in place when our new strategy is agreed (which will be in 2024).

Equality Act 2010

We remain compliant with the requirements of the Equality Act 2010. There is an equality champion within our Senior Management Team. 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, arising from the wider government transparency agenda. We regularly publish all required spending data openly, in the required file format.

All our Authority meetings are held in public (except in exceptional circumstances, such as during the early period of Covid-19) 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 Microsoft cloud. Security measures are in place to ensure that 'section 33A patient-identifying data' is appropriately protected. While we occupy premises shared with other ALBs, this necessarily entails sharing a communications room on-site to house a small number of 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 cloud and onsite servers, while adhering to all applicable central Government requirements. We have a cloud-based Microsoft 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 NHS Data Security and Protection toolkit (DSPT), 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. We completed the Data Security Protection Toolkit for the first time in 2021 and met the standards in 2022. We are working to improve our completion of this annual submission in 2023. We are modelling our approach to various aspects of our information management, data security and cyber security activities in keeping with the Toolkit. A programme of information security and cyber security training was conducted in 2022, and this is regularly reviewed.

We have a clear desk policy in place within our office along with confidential material disposal arrangements.

Business continuity

We review our business continuity plan regularly to ensure it remains fit for purpose. The plan is regularly updated and periodically tested. Our key IT functions are cloud-based, and throughout the Covid-19 pandemic, staff have been able to work from home for extended periods, as necessary. This remains the case for any future business continuity event or pandemic.

Estates strategy

We have no estate. Our office strategy is to co-locate with other public bodies. To that end, we moved office in 2020. Our site, 2 Redman Place in Stratford, brings together five DHSC ALBs under one roof, with some key services shared.

We work with other ALBs at 2 Redman Place on health and safety and general facilities services, which are provided centrally.

Sustainable development

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges. Our office at 2 Redman place also has sustainability features such as grey water harvesting for the toilets and blinds deployed automatically for energy efficiency.

Our multi-function devices (for secure printing, scanning, and photocopying) are 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. Staff are able to work from home for the majority of the time, allowing reduced travel impact.

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 33% 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 or Department of Health and Social Care frameworks or contracts.

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