Human Fertilisation & Embryology Authority

Business plan

April 2024 - March 2025

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 2020-2025 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 2024 we will be developing our new strategy for 2025-2028. Our development process will include engagement 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 **2020-2025** 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 Secretary of State for Health and Social Care's priorities for 2024-2025 are reflected where relevant in our plans, and our strategy is well aligned with 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 has continued 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 four 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 includes the reduction in geographical health inequality 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 published 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 Secretary of State's priorities also include improving outcomes for women (and in maternity care).

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 those who need them.

This business plan sets out how we will work towards our vision in 2024-2025, the additional 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 2023-2024

Overview

In 2023-2024, we made good progress with our strategic aims, following the ongoing aftereffects of the pandemic. The key work we undertook in 2023-2024 against our strategic aims is described below.

Delivery of the 2023-2024 business plan

The best care

Since 2020-2021, clinics have been assessed using a hybrid approach involving a desk-based assessment combined with an onsite visit to allow continued close regulatory oversight of the fertility sector. This approach is efficient, allowing the inspector to focus on specific areas of concern whilst reducing the time spent onsite. A risk-based approach was taken in prioritising inspections due this year with those deferred earlier 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.

Our Compliance and Enforcement Policy (revised in 2021) sets 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 September 2023, we published our State of the Fertility Sector report, providing an overview of the UK fertility sector in 2022-2023.

Our work on treatment add-ons led to the introduction of a revised ratings system with five categories to help patients make informed decisions, in October 2023. Patients can be offered add-ons with the claim that they will increase the success of their treatment but the evidence to support this for most fertility patients is often missing or not very reliable. The HFEA add-ons ratings will continue to help patients make better-informed decisions about their treatment.

The latest update to the Code of Practice came into effect from October 2023. The Code is our key guidance document, setting out the law and our guidance so that fertility clinics can continue to deliver safe treatment in line with legal requirements. The latest version includes updates related to the storage of gametes and embryos as a result of changes to storage limits introduced earlier, by the Health and Social Care Act 2022.

The ‘Ethnic diversity in fertility treatment 2021’ report was published in December 2023, looking at how use of fertility treatments and outcomes of fertility treatment differed by ethnic group. It found fertility treatment outcomes varied widely for Black, Asian and ethnic minority patients.

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.

The right information

We provided advice and information to patients about accessing treatment and donation via our website and ensured 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 use Instagram, LinkedIn, Facebook, and X (formerly 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 completed the implementation of our PRISM system, which enables clinics to submit data to the Register. We also continued development work on our internal systems to restore connectivity with the new Register after migrating our data across successfully. This work will enable us to issue more regular updates to Choose a Fertility Clinic (CaFC), from the end of 2024 onwards. Meanwhile we have commenced a data verification process with all clinics, in preparation for the first such CaFC update since the introduction of PRISM.

We have continued the pilot of our Patient Engagement Forum, recruiting patients to sign up to one or more of three newly created sub-groups. Along with this, we have also continued with our Professional and Patient Organisation Stakeholder meetings. The pilot patient forum was reviewed in summer 2023 and was judged to be a success.

We have put in place governance structures to ensure that changes to our Register are properly evaluated. A Data Review Board will be active following the completion of the first post-PRISM update to Choose a Fertility Clinic.

We concluded our development work on the Register Information Team Application (RITA), to enable us to query the new Register and run reports. A new case management system has been introduced to improve data security, accessibility and availability to meet the current and future demands of the Opening the Register (OTR) service.

Due to a change in the law, donors registered after 1st April 2005 were no longer allowed to be anonymous. The change enabled donor conceived individuals at the age of 18 to be provided with identifiable information about their donor. As 2023 saw the first donor conceived individuals turning 18 the HFEA launched the '#WhoIsMyDonor' campaign to raise awareness of donor conception and act as a fresh reminder for donors to update their information ahead of the first donor conceived people becoming eligible to apply. In January 2024, we launched a fertility data dashboard, thought to be the first of its kind in the world. The dashboard holds national UK fertility data from 1991 onwards. Users can customise data by age, IVF treatment and view success rates for a particular group or by UK nation and region. It also includes information on egg freezing and thawing.

We were classified as 'approaching standards' in the NHS Data Security and Protection Toolkit (DSPT) submission in 2022-2023. We are continuing to model our information governance and data protection and security practices around improvements so as to meet all the requirements of the toolkit. 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

Our law reform work, which commenced in 2022-2023, concluded with a report in November 2023 with recommendations under four key themes where we think legislative change is most needed: patient protection and safety, consent, donor anonymity and scientific developments. We will continue to work with ministers and our sponsors in the Department for Health and Social Care (DHSC) to achieve timely changes.

The demands of our OTR service remain high and we continue to look at the operational improvements for this work.

We continued to monitor areas of likely future medical and scientific developments, such as Artificial Intelligence (AI), through our Scientific and Clinical Advances Advisory Committee (SCAAC).

In 2022, legislation was passed extending 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 allows patients more time to make important decisions about family planning. Following the commencement of this law (in July 2022), we worked to ensure that fertility clinics could both implement the changes effectively and give patients sufficient information so that they are fully informed about their options. The new Regulations 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 and embryos in storage before 1 July 2022 must be stored with effective consent or be removed from storage. In the intervening two years we have updated all our clinics' licences to reflect the changes and updated our guidance and information.

During the year we continued our work to consider the way in which we authorise new and novel processes proposed by clinics, and this work will be completed in 2024.

We expect several new appointments to the Authority in the coming months to replace members who have finished their term of office. We completed a programme of training and induction to ensure that those members who serve on our committees are well equipped to make the governance and licensing decisions that are essential to our business as a regulator.

We will begin a review of our licence fee model in the 2024-25 business year.

The HFEA's Public Bodies Review

The independent review of the HFEA in November 2023 concluded that the HFEA should remain as an executive non-departmental public body and that the HFEA met all three Cabinet Office tests for continuing to exist – that we perform a technical function, that the function needs to be delivered with political impartiality; and that there is a need for the function to be delivered independently to establish the facts.

The report recognised that the HFEA performs important functions – it effectively regulates a discrete and specialised area of medical practice and scientific research, which can raise sensitive clinical, legal and ethical issues. The report made a number of recommendations, and the Department of Health and Social Care will continue to monitor the delivery of these into the new business year.

The HFEA's public body review report can be viewed online **here**.

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 2023 and 31 March 2024.

Table 1 – Table outlining performance data against the same data from 2021-2024

Type of work	2021-2022	2022-2023	2023-2024
Active clinics and research establishments	133	137	141
Clinics and research establishments inspections delivered	105	85	104
New licence applications processed and presented to the Licence Committee/ Executive Licensing Panel	4	4	6
Licence renewals processed and presented to the Licence Committee/ Executive Licensing Panel	52	49	38
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/ Executive Licensing Panel	1	0	1
New preimplantation genetic testing (PGT-M) applications processed and presented to Statutory Approvals Committee	52	45	49
New mitochondrial donation applications processed and presented to Statutory Approvals Committee	5	5	0
Incident reports from clinics processed (including near misses)	793 (121)	606 (89)	767 (62)
Alerts issued	4	10	16
Complaints about clinics	76	59	68
Opening the Register requests received	688	779	1290
Donor Sibling Link applications processed	110 responses completed in total	133 responses completed in total	96 responses completed in total
Licensed Centres Panel meetings held	110	2	2

Type of work	2021-2022	2022-2023	2023-2024
Meetings with patient organisations held	3	2	2
Professional stakeholder meetings	1	3	2
Freedom of Information (FOI) requests responded to	54	50	66
Enquiries responded to under the Data Protection Act (DPA)	1	4	4
Parliamentary questions (PQs) responded to	10	16	19
Most popular/ viewed page on our website	Homepage	Fertility clinic search	Fertility clinic search

Notes

Some of the data provided above is from an early draft of the 'State of the Sector' report published annually in the third quarter of the financial year. These reports have a more extensive, validated 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 published for those years.

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	2021-2022	2022-2023	2023-2024
Executive senior manager (ESM) to staff complement ratio	1:18	1:17	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	1:47	1:48	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 2023 to March 2024

Category	Performance indicator	Target	Performance in 2022-2023	Performance in 2023-2024
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	67 working days
PGT-M processing	PGT-M applications processed within 75 working days	100% completed within 75 working days	96%	100%
Financial management	Cash and bank balance.	To move closer to minimum £1,520K cash reserves.	£3.37m	£3.54m
People and capacity	Percentage turnover for the year.	5-15% turnover range.	18.7%	24%

Activities for 2024-2025

This business plan represents the additional year of delivery following the extension of our 2020-2024 strategy, which launched in October 2020 and was extended by one year in 2023. The Authority will be considering its next three-year strategy during the coming year and will review outstanding items from the current strategy, and its extension, when making decisions about new priorities.

In addition to our statutory duties, our other main priorities for the year will be:

- Developing further aspects of our law reform proposals published in 2023 to provide more detail, focusing on scientific developments and patient safety and protection in 2024-2025.
- Moving to a 'business as usual' model for our PRISM system.
- Prioritising work to actively look at the potential impact of AI on the fertility sector.
- Implementation of relevant statutory instruments as introduced by Government and any consideration of changes to the EUTCD.
- Issuing the third HFEA national patient survey and recruitment for new members of our patient engagement forum.
- Starting work relating to the HFEA fee review.
- Implementation of recommendations from the 2023 HFEA Public Bodies Review.
- Further development of dashboards to enable greater use of data within the HFEA to support compliance activities.
- Replacing Epicentre, our system to manage our statutory inspection and licensing function.
- The development of a new strategy for 2025-2028.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2024-2025.

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. Planned activities for April 2024 to March 2025.

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 (for example 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

Objective 1 Treatment that is effective, ethical, and scientifically robust – methods and channels	**Benefits and outcomes**	**Timescale**
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 ongoing provision of input into the current review of NICE fertility guidelines. Engagement with NHSE and devolved administrations as needed. 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.	Throughout the year
Highlighting inequalities found through our data reports. Follow up work to the ethnic disparities in fertility treatment report and Call to Action from December 2023, and publication of Family Formations updated data.	Continue to address disparities in access, experience, and outcomes by engaging with key stakeholdersas set out in the Call to Action. Updated report to be published on family formation in fertility treatment.	Throughout the year
Effective handling of and communication about: • clinical incidents and adverse events, including publication of a 2023-2024 ‘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 2024

Objective 1 Treatment that is effective, ethical, and scientifically robust – methods and channels	**Benefits and outcomes**	**Timescale**
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
Review of guidance for clinics to ensure this remains fit for purpose, including: • issuing other clinic-facing communications, such as Clinic Focus, on issues that require further clarification to the sector	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. Following legal clarification of near posthumous use, additional guidance may need to be issued to clinics.	Throughout the year.
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 and guidance.	HFEA licensing decisions are sound and supported by 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**
Maintaining 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. Following the launch of the HFEA 'dashboard' in December 2023, we will continue to develop them further. We will also commence work on 'Family Formations' in late spring/ early summer 2024.	Throughout the year
Ongoing implementation and oversight of the changes resulting from the updated EUTCD.	We will engage with any changes to the EUTCD and work with others on the implications of these.	Throughout the year
Implementation of relevant statutory instruments as introduced by Government.	Following the announcement in October 2023 of the IVF law change to the requirement for same-sex couples to pay for safety screening and where one or both partners have HIV but have an undetectable viral load to benefit couples with fertility issues; we will update our Code of Practice subject to parliamentary approval.	Throughout the year

Table 5 – Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Planned activities for April 2024 to March 2025

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 work planned under this objective for this 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. Planned activities for April 2024 to March 2025.

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. We aim to work with primary care organisations such as the Royal College of GPs and the RCN under the women's health strategy banner – with the aim of improving information for primary health care workers.	Throughout the year Summer 2024

Table 7 – Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Planned activities for April 2024 to March 2025.

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. We will ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions. New Choose a Fertility Clinic (CaFC) data will be published for the first time from data in the new PRISM system in late 2024, providing the most recent information on clinic performance for pregnancy outcomes and live birth rates. We ensure quality metrics and verification reports are in place for PRISM, and that clinics are able to fix validation errors. 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

Objective 4 High quality information to support decision-making during and after treatment or donation – methods and channels	**Benefits and outcomes**	**Timescale**
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
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
Continue to 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.	Throughout the year
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.	Throughout the year
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. New reports to ensure future CaFC data can be viewed and edited as needed. Ability for clinics to proactively assess their own data and make changes through-out the year.	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**
Maintaining an effective Opening the Register (OTR) service.	OTR requests continue to be met in a sensitive manner, following the expected increase from October 2023 onwards. Support and monitoring of the new IT system built in 2023. Reviewing the effectiveness of the system once it has been fully in use for at least six months.	Throughout the year
Provision of information for donors and people conceived from donor treatment.	Information and signposting is available for donor-conceived people and donors on the HFEA website. Information and advice is available for donor conceived people on making initial contact with their donor or a donor sibling.	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 ensure that our data is held securely and is protected in accordance with best industry practice.	We assure ourselves that we are practising good data security and personal information is handled correctly. Maintain our oversight group for the NHS Digital Data Security and Protection Toolkit (DSPT), combining best practice from other organisations and collecting toolkit documentation on an ongoing basis to allow for faster, more complete submissions going forward. We continue to maximise the quality of our DSPT submissions, in particular the areas for improvement previously highlighted.	Throughout the year June 2024 (annual process)

Objective 4 High quality information to support decision-making during and after treatment or donation – methods and channels	**Benefits and outcomes**	**Timescale**
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 through our dashboards and other data, which are accessible via our website. 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, including the use of the new dashboards. 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. HFEA keeps abreast of significant political changes and understands the impact on our work and key stakeholders.	Throughout the year
Conduct and publish the results from the third National Patient Survey to inform the work of the HFEA.	The HFEA will conduct its third National Patient Survey following the last previous one published in November 2021. The National Patient Survey, which explores the entire patient journey from accessing GP services, through to patients' most recent experience of treatment, aims to identify changes in the fertility landscape since the first survey in 2018. The survey will inform the work of the HFEA; helping it achieve its objective of providing high-quality care for everyone using the UK's fertility service.	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). Planned activities for April 2024 to March 2025.

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**
Project on patient-facing AI and data-driven new technologies that are in or potentially approaching clinical use. Continued oversight via the Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning process and reviews. Continued horizon scanning on genetics policy issues.	We understand new developments and are responsive to these, including monitoring developments in genetics and AI. 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

Table 9 – Strategic objective 6. Preparing for future legislative and operational changes. Planned activities for April 2024 to March 2025.

Objective 6 Preparing for future legislative and operational changes – methods and channels	Benefits and outcomes	Timescale
To press for legislative changes we would like to see to the Act.	Continue to pursue legislative change based on the proposals published in Autumn 2023.	Throughout the year
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.	Throughout the year
Running an 'Opening the Register' (OTR) service to meet increased levels of demand.	OTR requests continue to be met in a sensitive manner. New IT system built in 2023 in use and monitored for effectiveness. Communication and engagement in place to ensure that the public, clinic staff, donors, donor conceived children and their families understand the changes that have been made.	Throughout the year

Objective 6 Preparing for future legislative and operational changes – methods and channels	Benefits and outcomes	Timescale
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2025.	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.	Assess and evaluate the core systems to ensure plans are in place to have fit for purpose systems to ensure business continuity.	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. Following the recent public bodies review recommendation of a fees review, we will commence work on this from summer 2024.	Throughout the year Summer 2024
Implement recommendations from the public bodies review.	We will commence work to implement the other recommendations from the public bodies review. This includes working with the department on law reform work, shared service functions and support communications functions.	Throughout the year
The development of a new strategy for the HFEA from 2025 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

Our funding model is a mix of fees collected from the sector we regulate (for many years c.80% of our income) and Grant in Aid (GIA) (c.20%) from our sponsors, the Department of Health and Social Care. Following reform and efficiency measures which were brought into force during the 2023-2024 financial year, our GIA funding will be reduced to approximately 5% and this will require an increase in the licence fees charged to clinics from 1 April 2024.

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 levels of treatment 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.

Annually, we manage our expenditure to ensure we spend within our agreed budget and expect to continue to do so going 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.

The reduction in GIA funding from the Department of Health and Social Care, has meant that we have increased our fees charged for IVF treatment cycles from £85 to £100. The Reform and Efficiency programme undertaken by the DHSC encourages its ALBs who charge fees to reduce their reliance on GIA funding and cover a greater proportion of its costs through fee income.

The increase to the licence fee will enable the HFEA to meet the costs of delivering its statutory functions, including a significant programme of work which will benefit our regulatory processes and ultimately the clinics we licence.

Income

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

Income	Budget £000s
Department of Health and Social Care funding	846
Non-cash income	232
Treatment and licence fees	7,052
Other income	101
Total income	8,231

Expenditure

Table 11 – breakdown of HFEA operating costs for 2023-2024

Operating costs	Budget £000s
Staff costs	5,552
Other operating costs	2,679
Total operating costs	8,231

Table 12 – HFEA detailed Operating Budget 2024-2025

Budgeted Income	**£000s**
Licence Fees	7,052
Interest received	35
Other income	66
Subtotal	**7,153**
DHSC Funding	
Grant in aid (includes pension funding)	846
Ring-fenced RDEL	232
Total Income	**8,231**

Budgeted expenditure	**£000s**
Wages and salaries (including contingent labour)	5,552
Inspection costs	107
Other staff costs	112
Authority & Committee costs	49
IT and Development Costs	649
Other costs	221
Legal Costs	242
Accommodation	255
Projects	813
Non-cash	232
Total expenditure	**8,231**

Our licence fee income position has been based on an assumed 67,500 new IVF cycles that meet the criteria for the payment of a clinic licence fee, plus 6,650 DI cycles. During 2023-2024 all but 3 clinics were billed based upon their submission which has enabled us to make a reasonable estimate of activity levels across all clinics.

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, since 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 any such projects within 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

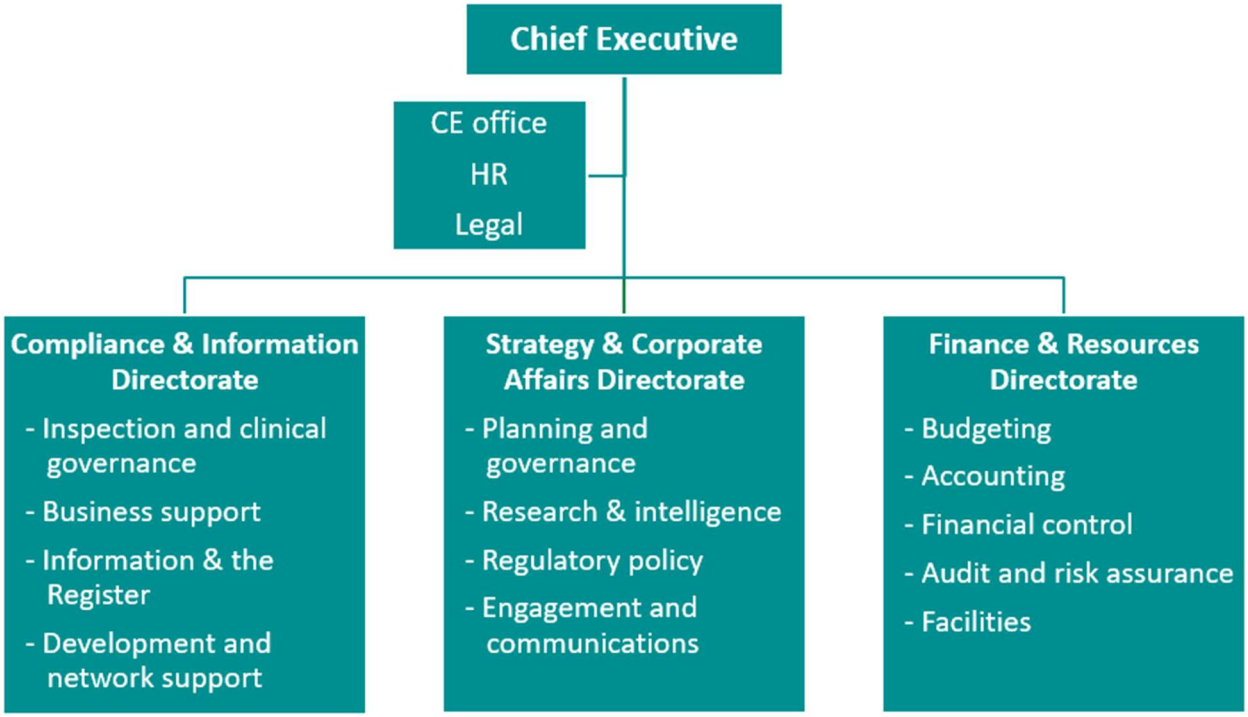
Our staff complement is 78 (from 1 April 2024). We have put in place shared services arrangements with other bodies where feasible. For example, we share part of our finance and resources team staffing with the Human Tissue Authority, and our facilities management service is shared with the five other 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 2020-2025.

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 2025).

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 were classified as 'approaching standards' for our 2022-2023 submission of the DSPT. We are continuing to model our information governance and data protection and security practices around improvements so as to meet the requirements of the toolkit, and we are working to improve our completion of this annual submission for 2023-2024. Staff complete annual training on information and cyber security through our training platform, Astute.

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 to ensure it remains fit for purpose. The plan is regularly updated and periodically tested. Our key IT functions are cloud-based, and since the Covid-19 pandemic, staff have been able to work from home for extended periods, as and when necessary. For many years some of our staff were home based across the UK. Since our office move to Stratford in 2020, the majority of our staff work from home up to four days per week, and a higher proportion are on working from home contracts. Our resilience remains strong 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 submit data to the Greening Government Commitments (GGCs) developed by DEFRA (Department for Environment, Food and Rural Affairs) on a quarterly basis and are aware of the new Taskforce for Climate Change Disclousres that requires organisations that meet the criteria to disclose their Governance, Strategy, Risk Management and Metrics and Targets. Currently we are exempt but still provide metrics where this data is available.

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 impact.

Procurement

We comply with all relevant Department of Health and Social Care and Cabinet Office efficiency controls. These cover advertising, marketing and communications, IT, digital, professional services and learning and development. Business case approval from the department is required in most cases.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchase directly and are dependent on Crown Commercial Service (CCS) and other framework holders for integrating sustainability features in their contract letting.

Nearly all of our procurement is done through CCS. So, as far as we are able, we aim to meet the Department of Health and Social Care target for public sector procurement of 23%[1] 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.

[1] The target was set to be achieved by March 2022 and no new target currently is available.

2 Redman Place

London

E20 1JQ

T 020 7291 8200

E enquiriesteam@hfea.gov.uk

www.hfea.gov.uk