



Human
Fertilisation &
Embryology
Authority

Business Plan

April 2026 – March 2027



Contents

| | |
|---|-----------|
| Our role and strategy | 3 |
| Our legislation and functions | 3 |
| Business Plan activities for 2026-27 | 5 |
| Key Performance Indicators | 9 |
| Financial picture | 11 |
| High-level budget for 2026-27 | 11 |

Our role and strategy

The HFEA is the UK's independent regulator of fertility treatment and research using human embryos. Our role includes setting standards for clinics, licensing and inspecting them, and providing free, clear, and impartial information for the public, particularly for people seeking treatment, donor-conceived people, and donors.

Our [Strategy for 2025-2028](#) outlines our vision, themes, and objectives as an organisation – high quality care for everyone affected by fertility treatment.

Our vision and aim is for a well-regulated fertility sector that is:

- trusted by patients and the wider public;
- supported by accessible information from the HFEA that helps patients make treatment choices; and,
- driving innovation across the bioscience sector, so treatment can flourish within an ethical framework.

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;
- license the testing of embryos for the avoidance of serious medical conditions;
- 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; and,
- investigate serious adverse events and serious adverse reactions, and take appropriate control measures.

In addition to these specific statutory functions, the legislation also grants 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);
 - and,
- advising the Secretary of State for Health and Social Care on developments in the above fields, upon request.

Business Plan activities for 2026-27

The 2026-27 Business Plan represents the second year of the HFEA's [strategy for 2025-28](#). Business Plan activities have been developed with a view to implementing the strategic aims and objectives over this three-year period.

Activities shown include 'business-as-usual' (BAU) activities for the HFEA, which use most of our resources, as well as activities that will take place in addition to BAU.

Activities are outlined against the seven strategic objectives in our three-year [strategy for 2025-28](#).

Should the Government decide to bring forward law reform proposals this year we will need to prioritise the proposed additional activities.

Regulating a changing environment

| Strategic objective | BAU activities | Additional activities |
|---|--|---|
| <p>Strategic objective 1 To effectively regulate a changing fertility sector</p> | <ul style="list-style-type: none"> Delivering the HFEA's licensing and appeals function, supporting the committees that make the decisions to grant licences to centres or authorise genetic testing. Ensuring quality and safety in clinics that offer licensed fertility treatments, including compliance with all regulatory requirements, through inspections at licensed centres every two years. Set standards for clinics through our Code of Practice, consent forms and associated guidance. | <ul style="list-style-type: none"> Completion of the Phoenix programme, to replace our inspection and licensing database (Epicentre) and our records management system with SharePoint. Review of HFEA licence fees. Support DHSC to recruit a new Chair and Authority Members to ensure a smooth transition following the conclusion of current Authority members' terms. Begin to look at how to build on our risk-based inspections and how our tools could be applied to a changing fertility sector. |

Strategic objective 2

To continue to increase the availability and benefit of our data for patients, clinics and researchers

- Maintaining the HFEA Choose a Fertility Clinic tool.
- Maintaining the HFEA Register.
- Our annual statistical release, *Fertility Trends*, and annual publication on our regulatory work: *The Fertility Sector*.
- Responding to research requests through the Register Research Panel.
- Responding to Freedom of Information requests, in line with statutory obligations.
- Advance our Data Security and Protection Improvement Plan in line with the National Cyber Security Centre's (NCSC) Cyber Assessment Framework (CAF), in order to strengthen cyber security and information governance.
- Post PRISM (Patient Register Information System) review of data collection, including development of a 5-Year PRISM roadmap, outlining key milestones and strategic priorities for system enhancement and patient data management.
- Develop plans for improving the use of data across the HFEA.
- Continue improvements to the HFEA website.
- Begin a review of presentation of data on the HFEA website including inspection and patient ratings.

Strategic objective 3

To ensure that the HFEA responds well to issues related to donation

- Responding to requests for information from donor-conceived people, their parents and donors through our Opening the Register (OTR) service.
- Consider a wider approach to donation-related issues, working with the fertility sector and others.

Strategic objective 4
To make a difference on issues that matter to patients

- Providing impartial, accurate information about IVF, clinics and other fertility treatments on our website, social media channels and through our patient enquiries team.
- Facilitating the HFEA Patient Engagement Forum to gather views and feedback from people with lived experience of fertility treatment to help shape our work and the information we produce.
- Review our Corporate Complaints Policy and Procedure, to ensure it is clear, accessible, and easy to follow for patients who wish to raise a concern or make a complaint to the HFEA.
- Potential recruitment for a new Patient Engagement Forum cohort.

Supporting scientific and medical innovation

| Strategic objective | BAU activities | Additional activities |
|--|---|---|
| <p>Strategic objective 5 To ensure the safe regulation of emerging new science and technology under a clear ethical framework</p> | <ul style="list-style-type: none"> • Consider advances in science and clinical practice which are relevant to the HFEA’s work through the Scientific and Clinical Advances Advisory Committee (SCAAC). | <ul style="list-style-type: none"> • Work on genetic testing guidance. |

Strategic objective 6

To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA

- Continue to monitor developments in the use of AI technologies across the fertility sector through our horizon scanning function and through SCAAC.
- Digital improvements and business efficiencies.

Strategic objective 7

To inform and advise Government in relation to new developments and their regulation

- Respond to Parliamentary Questions (PQs).
- Implement the new European Regulation on standards of quality and safety for substances of human origin intended for human application (the SoHO Regulation) for clinics in Northern Ireland.
- Engage and respond to any recommendations from the Women and Equalities Committee (WEC) inquiry into egg and embryo donation and freezing.

Key Performance Indicators

The HFEA uses Key Performance Indicators (KPIs) to measure our performance and track operational delivery.

Performance against KPIs is reviewed by:

- the Senior Management Team and Corporate Management Group at monthly meetings;
- the Authority at every bi-monthly meeting; and
- the Department of Health and Social Care (DHSC) at every quarterly accountability meeting.

Our KPIs for 2026-27 are listed below.

| Performance indicator | Description | Target |
|--|--|--|
| Inspections reports to Person Responsible (PR) | Reports completed and sent to PR within 25 working days | 100% reports sent to PR within 25 working days |
| Inspection reports to committee | Reports sent to relevant licensing committee within 65 working days | 100% reports sent to committee within 65 working days |
| End to end licensing | End to end licensing process within 80 working days | 100% reports completed within 80 working days |
| Pre-implantation genetic testing for monogenic disorders (PGT-M) processing efficiency | Average working days taken to process PGT-M items due in month. | Less than 60 working days taken to process PGT-M items |
| Pre-implantation tissue typing (PTT) processing efficiency | PTT processed within 30 working days | 100% items processed within 30 working days |
| Mitochondrial donation processing efficiency | Mito processed within 90 working days | 100% items processed within 90 working days |
| Licensing officer minuting | Average working days taken to minute decisions taken for those that were due to be signed in the month | Less than 5 working days |
| Executive Licensing Panel (ELP) minuting | Average working days taken to minute decisions taken for those that were due to be signed in the month | Less than 10 working days |
| Licence committee minuting | Average working days taken to minute decisions taken for those that were due to be signed in the month | Less than 15 working days |
| Statutory Approvals Committee (SAC) minuting | Average working days taken to minute decisions taken for those that were due to be signed in the month | Less than 20 working days |
| Opening the Register applications ('OTRs') closed in month | Number of OTRs closed within the reporting month | More than 156 OTRs closed within the reporting month |
| Opening the Register (OTR) waiting list reduction | Change of the OTRs waiting list within the reporting month | The waiting list reduction on more than 40 OTRs compared to previous month |
| Parliamentary Questions (PQs) efficiency | PQs processed within deadline set by DHSC | 100% items processed within the set deadline |

| Performance indicator | Description | Target |
|--|--|--|
| Freedom of Information request (FOIs) efficiency | FOIs processed within 20 working days | 100% items processed within 20 working days |
| Sickness rate | Staff sickness absence rate (incl. long-term sickness) | Less than 2.5% |
| Turnover rate | Average of turnover for year | Within target range of 5-15% |
| Debt over 60 days | The amount of debt older than 60 days | 25% or less of total debt older than 60 days |
| Debtor days | Average days debt remain outstanding | Less than 45 days |
| Prompt payments | % invoices paid within 10 days | More than 85% invoices paid within 10 days |

Financial picture

Our finances and high-level budget

We receive funding from two main sources: generally around 90% from clinic fees and the balance from our sponsors, the Department of Health and Social Care (DHSC), as grant-in-aid (GIA).

The majority of our clinic fee income is charged against individual IVF treatments in regulated clinics, with a smaller proportion charged against Direct Insemination (DI), as well as some charges for applications and licence renewals. GIA predominantly funds our Opening the Register Service, though DHSC also provides ad hoc investment funding, for example to support our current IT transformation programme.

In aggregate this income covers the cost of delivering our statutory duties, including:

- evaluating licence applications;
- making licensing decisions and issuing licences;
- site visit inspections;
- providing information about the fertility sector to patients and the public;
- providing advice and guidance to licensed establishments.

Our budget for 2026-27 covers the cost of regulating the fertility sector, including back-office and overhead costs. The 2026-27 budget includes an increase in our treatment fees (IVF from £100 to £115, donor insemination (DI) £40 to £45).

In 2026-27, we will undertake a review of our fee structure to better reflect the full cost of regulating around 130 clinics in both the public and private sectors.

Financial plan

Our expected revenue in 2026-27 from IVF/DI treatments fees and other charges to clinics, taking into account the fee increase mentioned above, is £8m. Our GIA funding from DHSC of over £1m includes admin funding of £0.7m, which generally covers the recurring cost of services that we do not charge for and programme funding of £0.4m, which is one-off funding to cover areas like projects and cyber security investments.

High-level budget for 2026-27

Income

Table 4 – HFEA high-level income for 2026-27

| Income | Budget £000s |
|--|--------------|
| Department of Health and Social Care funding | 1,066 |
| Non-cash income (unconfirmed) | 195 |
| Treatment and licence fees | 8,039 |
| Other income | 115 |
| Total income | 9,415 |

Expenditure

Table 5 – breakdown of HFEA operating costs for 2026-27

| Operating costs | Budget £000s |
|--------------------------------------|---------------------|
| Staff costs | 6,441 |
| Other operating costs | 2,318 |
| Project Costs | 461 |
| Non-cash (depreciation/amortisation) | 195 |
| Total operating costs | 9,415 |

Capital Expenditure

In addition to the revenue budget, we have received a capital allocation of £80k, which will be used to cover the cost of a refresh of our IT assets, specifically laptops, to ensure they are fit for purpose and meet the security standards that the HFEA maintains due to the sensitivity of the data it holds.

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