Human Fertilisation & Embryology Authority

Business plan

April 2022 – March 2023

Contents

Our role and strategic aims

Who we are

The HFEA is the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

Our vision for 2020-2024 is:

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

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

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

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

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

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

The best care

- Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.
- A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.
- Improved recognition by clinics of partners' importance in the care process.

The right information

- Accurate and useful information that is provided at the right time.
- Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.
- Access to relevant and impartial information for all – particularly about the evidence base, add-ons and treatment options.

Shaping the future

- Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.
- Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.
- Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.

The Department of Health and Social Care's planning priorities for 2022/23 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, we focused on responding to changes due to Covid-19, adapting our inspection regime and our other planned strategic work accordingly. In our work going forward we will continue to respond to Covid and any relevant Government guidance, ensure clinics are able to operate safely for patients, and provide up to date information.

Over the past two 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 December 2021, a vision for the Women's Health Strategy for England, and this includes a distinct focus on women's reproductive health needs, including fertility. The Government's ambition is to ensure women are empowered to make purposeful choices about their reproductive health and care, before, during and after pregnancy and pregnancy loss, with support from safe, high-quality health 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 Government's strategy on Women's Health will be published in 2022, and we look forward to working with Department colleagues on aspects related to fertility treatment.

We will also consider what more we can do, through work with royal colleges and professional bodies, to improve information and education about fertility for primary care healthcare professionals.

This business plan sets out how we will work towards our vision in 2022-2023, the second full year of our current three year 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 2021-2022

Overview

In 2021-2022, we made good progress with our strategic aims, against the ongoing backdrop of the pandemic. The below describes key work we undertook in 2021-2022 against our strategic aims.

Delivery of the 2021-2022 business plan

The best care

Following changes to our inspection methodology introduced during Covid, we have continued to make use of detailed desk-based assessments, to inform a risk-based approach for each inspection. On-site inspections still take place (since the resumption of inspections in November 2020), to address any areas where concerns remain, or which cannot be viewed remotely. In this way we have been able to deliver a full programme of inspection and licensing activity throughout the year.

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 November 2021, we also published our State of the Fertility Sector report, providing an overview of the UK fertility sector in 2020/21.

Our Code of Practice was updated in October 2021, to reflect various changes in legislation and other information. The main changes related to differences in guidance for clinics in Great Britain and Northern Ireland following EU Exit, counselling and patient support, information about consent, embryo testing and sex selection, EU Exit related information relating to donor recruitment, assessment and screening, surrogacy, and EU exit related information about importing and exporting gametes and embryos.

In February 2022 we also published our latest report on multiple birth statistics for treatments in 2019. This showed the long-term success of our campaigning on this issue – multiple birth rates have reduced from around 28% in the mid 1990s to 6% in 2019.

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. We have begun to further develop our traffic light system based on feedback and evidence.

Although some of our planned work with researchers was delayed by 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 eg, so as 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.

We completed our implementation of changes relating to EU Exit, ensuring that clinics were issued with new licences from 1 July 2021, at the end of the transition period. We also issued revised General Directions, import and export forms and other guidance to ensure the continuation of effective regulation across the UK.

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 so as to ensure that it continues to work smoothly.

We also extended our use of social media to Instagram 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 launched our new PRISM system, for clinics to submit data to the Register and work to onboard all clinics is being completed now. We also begun development work on our internal systems to restore connectivity with the new register after migrating our data successfully across. This work, once complete, will enable us to issue more regular updates to Choose a Fertility Clinic (CaFC), from the end of 2022 onwards.

During the year we also launched our new patient engagement forum for a trial period recruiting members of the public to take part. The forum will be utilised during the 2022 calendar year and reviewed later in this business year.

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 deployment of PRISM and the new 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.

Shaping the future

We handled a significant number of Opening the Register requests, following an earlier pause to the service, and have now begun to look at the operational arrangements for this work, to ensure that we are set up to deliver effectively into the future. This vital project will be ongoing into the new business year.

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 plans 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 will allow patients more time to make important decisions about family planning. Following the announcement, we will work 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, now approved by Parliament, will increase the statutory storage limits from the current 10 years to a 10 year renewable

storage period up to a maximum of 55 years. In January we issued a briefing providing information on the proposed amendment to the Health and Care Bill.

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 continued in 2022/23.

Towards the end of the business year we welcomed a number of new members to the Authority, who joined the Authority in April and May. We have established 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 recently 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 2022-23 business year.

We also completed our office move to new premises in Stratford, East London.

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 2021 and 31 March 2022.

Table 1- Table outlining performance data against the same data from 2019 - 2022

Type of work	2019-2020	2020-2021	2021-2022
Active clinics and research establishments	137	136	135
Clinics and research establishments inspections delivered	87	63 (By DBA/onsite/ virtual inspection, including licence extensions) – Most inspections not conducted between 1/04/2020 and 31/10/2020 owing to the Covid 19 pandemic.	120 **See note 1 below**
Licences inspected	96	58	105 **See note 2 below**
New licence applications processed and presented to the Licence Committee/Executive Licensing Panel	4	1	3
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	34	41	44
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	1	1	1
New preimplantation genetic testing (PGT-M) applications processed and presented to Statutory Approvals Committee	42	32	52
New mitochondrial donation applications processed and presented to Statutory Approvals Committee	4	6	5
Incident reports from clinics processed	663	1135 (of these, 576 were recorded as ‘not an incident’)	1487 (of these, 651 were recorded as ‘not an incident’) **See note 3 below**

Type of work	2019-2020	2020-2021	2021-2022
Alerts issued	2	1	4
Formal complaints about clinics	37	54	76 **See note 4 below**
Opening the Register requests closed within 20 working days	518	196 closed in total (10 within the 20wd target)	This target is not active at present, while we undertake work to deal with an increase in applications. **See note 5 below**
Donor Sibling Link applications processed	87	61	110 **See note 6 below**
Licensed Centres Panel meetings held	2	2	3
Formal roundtable meetings with patient organisations held	2	4 **See note 7 below**	1 **See note 7 below**
Professional and public stakeholder meetings (including Authority meetings either held in public or recorded and made public.)	7	8	8
Freedom of Information (FOI) requests responded to	39	56	58
Environmental Information Regulations (EIR) requests responded to	0	0	1
Enquiries responded to under the Data Protection Act (DPA)	0	6	0
Parliamentary questions (PQs) responded to	22	8	10
Most popular/viewed page on our website	Clinic search	Homepage	Homepage

Notes

1. Many of our statistics for the previous year, 2020-2021, were affected by restrictions relating to the Covid 19 pandemic. In 2021-2022 we were able to fully resume inspections, using a methodology consisting of both desk-based assessments and in-person inspections. In addition to the 120 inspections that were completed, we also extended the licences of 15 clinics by one year, and accepted two revocations of licences by clinics who were closing.
2. This number is lower than the total number of inspections, since some inspections are done in relation to other matters, such as incidents.
3. The increase in the number of incidents reported 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.
4. Of the 76 complaints received, 32 were classed as ‘not a formal complaint’. We are not certain why there has been an overall increase in complaints raised about clinics to the HFEA, but this may be due to the effects the pandemic has had on clinic staffing and working arrangements. We will continue to monitor this.

5. 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. This work is still in progress, and the high levels of applications have continued meanwhile. We have commenced a project to review the service and increase capacity, and we have introduced new performance measures to track our progress in processing the outstanding backlog. We have also taken on additional staff to help to process the backlog. Following a period of training, this is starting to make a real difference to our processing rates. At year end there were 408 OTR applications in the backlog. Our ability to process OTR applications has increased recently owing to the additional staff having been recruited and trained – the figure increased from 72 in February 2022 to 146 in March 2022. Alongside this, the rate of applications is also steadily increasing over time. We typically now receive around 60 requests per month, compared to around 30 per month in 2019.
6. The number of applications for Donor Sibling Link information is steadily increasing, due to increased awareness over time. We expect this trend to continue.
7. Owing to Covid, in 2020/21 we held more meetings with patient organisations so as to keep in touch with them about the impact of the pandemic. The meetings were held virtually. In 2021/22 we held one meeting (in November), since the spring meeting fell in the previous business year, and this year's spring meeting will be held in May 2022, after the commencement of the new business year.

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	2019-2020 data	2020-2021 data	2021-2022 data
Executive senior manager (ESM) to staff complement ratio	1:17	1:17	1:18
Number of staff earning more than £142,500 now and any planned change during the next planning period	0	1	1
HR staff to employee ratio	1:45	1:45	1:47
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 2020 to March 2022

Category	Performance indicator	Target	Performance in 2020-2021	Performance in 2021-2022
Engagement	Number of emailed public enquiries received.	No target, since the nature, volume and complexity of enquiries received varies widely.	1250	1415
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.	49 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 had to pause the service in April 2020 due to Covid-19 and did not measure against this KPI throughout the year.	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.	£3.29m	£3.69m
People and capacity	Percentage turnover for the year.	5-15% turnover range.	11.7%	21.6%

Activities for 2022-2023

This business plan represents the second full year of delivery for our 2020-2024 strategy, outlined above, which launched in October 2020.

2022-2023 follows on from a year that continued to be somewhat affected by the coronavirus pandemic, for patients, the sector and our staff. 2021 was also our anniversary year, marking thirty years since the HFEA was established. As such, we began to look forward to the future of fertility treatment and regulation, and will be doing more work on this in the coming year, together with our stakeholders.

The pandemic has been challenging for the sector, and for the HFEA. The ways in which we deliver our core work have changed, and in the same time period, our workload has grown in a number of areas.

We have had to closely examine our priorities and resources to ensure we focus on the highest value areas. We have permission to increase our fees in 2022 for the first time since 2016, which will go some way to alleviating staff pressures in key areas of our work. In the event of additional work arising during the year, we may need to alter the following plan to respond to that, and will consider this in light of our strategy.

Meanwhile, we consider our top priorities for 2022/23 to be:

- Continued delivery of our core statutory work – inspection, licensing and the provision of up to date guidance for clinics and information for patients and the wider public.
- Work following the launch, in 2021, of PRISM and the migration of data into our new register of treatments. This work is necessary to ensure that PRISM is fully operational for clinics, and that various internal systems that were linked to the old register, are now linked to the new register to restore full functionality.
- Linked to this, working towards a fresh publication of our CaFC data in 2022 to provide licensed clinics and patients with up to date information.
- Our Donor Information Service Development Project, which will help us to prepare for future, higher, levels of demand.
- Clearing the backlog of OTR requests that built up as a result of clinic closures during the first Covid lockdown, combined with increased volumes of requests.
- Continued work to present our ideas for modernisation of the HFE Act to ensure our legislation remains relevant for the treatment and care that patients receive today.
- Other work relating to more imminent legislative developments, such as changes to gamete and embryo storage limits to ensure licensed entities are prepared for these changes in a timely way.
- Completing the review of the treatment add-ons traffic lights and evidence base to ensure our information is as effective as it can be for patients.
- Reviewing our communication activities to ensure we are getting the most impact with the tools and resources we have to fulfil our statutory duties on information provision
- Engagement with NICE on their fertility guidelines review providing insight with our Register data and oversight of licensed fertility clinics.
- Meeting external legal requirements, for example responding to statutory information requests.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2022-2023.

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 2022 to March 2023

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 • 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 (eg, on their websites) and provide to us. Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances.	Throughout the year
Maintenance and adjustment as needed of our regulatory approach, and ongoing monitoring of Covid-19 risks and impacts 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. Risk-based approach to inspection activity. Clinics continue to effectively respond to Covid-19 related risks. We effectively adapt and respond to any changes in Covid-19 circumstances, such as any local lockdowns and new government guidance, and also assist the sector to do so.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Review of the Compliance and Enforcement Policy issued in 2021.	Ensuring the Compliance and Enforcement Policy remains fit for purpose and is being used in a correct and appropriate manner	December 2022
Responding as required to the public inquiry into the Covid-19 pandemic.	The HFEA meets its public duty to provide input as and when required.	Inquiry to commence in spring 2022
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 concluding work begun with the CQC in 2021/22 on streamlining regulation and clarifying responsiblities in relation licensed clinics, third party and satellite clinics. 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 best 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
Continue our engagement work to address disparities in access, experience and outcomes, including those identified in our 'Ethnic Diversity in Fertility Treatment 2018' report (published March 2021) and patient survey. Use this information to identify where we, as a regulator, can take action to address these inequalities and promote greater	Through our patient survey and discussions with patients, clinics, and other stakeholders (including through our Patient Engagement Group and stakeholder groups), we understand what disparities exist between ethnic groups in terms of patient experience, access to treatment and outcomes to continue to support the Government's objective of reducing health inequalities particularly among Black and ethnic groups HFEA website content is updated where needed to provide ethnicity minority patients with information about specific issues which may be relevant to them. We work with grassroots and other organisations to further understand cultural and religious beliefs that may impact on donor recruitment and help to overcome any barriers that may exist.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
equity across the fertility sector, for example by incorporating changes into the Code of Practice.	We review whether changes to our Code of Practice are needed relating to information provision for ethnic minority patients. Continue to implement the actions identified as a result of the report on Ethnic Diversity in Fertility Treatment in 2018.	March 2023
Providing input into the 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 inequalities are addressed. NICE guidance updated to reflect current practice across the sector.	Autumn 2022 onwards (multi-year review).
Development of the HFEA's information on treatment add-ons looking at the presentation on the website and exploring any expansion of the evidence base beyond Randomised Controlled Trials (RCTs).	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. Patients and clinics understand the risks associated with add-ons. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence. A refined presentation of the rating system and further consideration of the most appropriate forms of evidence to base it on.	March 2023
Better use of our register and information in data research using intelligence dashboards.	Development of internal resources and tools to enable our publications and responses to ad hoc enquires, FOIs and PQs. We'll also continue to work on our internal database to enhance the provision and usability of our data for researchers to make our data as accessible as possible.	Throughout the year
Effective handling of and communication about: • clinical incidents and adverse events, including publication of	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.	Throughout the year, with the state of the sector report

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
2020-2021 'State of the Sector' report and quarterly compliance reports • complaints about clinics	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.	published in Autumn 2021
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Ensure that licensing decisions and other approvals are well governed. Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually ensuring improvements are made as required.	Throughout the year
Processing applications for the licensing of preimplantation genetic testing for monogenic gene defects (PGT-M), human leukocyte antigen (HLA) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. Mitochondrial donation and 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 • issuing other clinic-facing communications, such as Clinic Focus, on issues that require further clarification to the sector. This will include a Code of Practice update project in 2023,	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 in 2022/23 or 2023/24 incorporating updated guidance to clinics on the storage of gametes and embryos as a result of changes to storage introduced in 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**
with the aim of publishing an updated Code in 2024.		
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 based on comprehensive 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 pilot 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 and tested on members of the patient forum. 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 that resulted from the end of the EU exit transition period, 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 2022 to March 2023

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 2022 to March 2023

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	Benefits and outcomes	Timescale
Utilising feedback from our 2021 Patient Survey, we will 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 obtained from the Patient Survey to improve the information provided to the public and to position our information effectively. 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 will publish a report on the findings of the Patient Survey.	Throughout the year Spring 2022

Table 7 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for April 2022 to March 2023.

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 start to 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
Utilising the feedback from our Patient survey in 2021, to ensure that patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.	We will use any insights from the patient survey to inform any changes or new information for our website.	Throughout the year
Evaluate the patient engagement forum after the pilot period.	We gain an insight into the patient experience in clinics and encourage good practice based on feedback. Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. We gain valuable insight into the experiences of those going through fertility and donor treatments, to inform our other work and the information that we publish.	December 2022-March 2023
Maintain up to date and accurate information and advice on our public-facing website.	Patients see HFEA information as ‘go to’ impartial advice. People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. People can easily find relevant information and signposting on our website to inform their next steps.	Throughout the year

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.	Throughout the year
Responding to media reports.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wide range of issues.	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 new PRISM reporting system, to enable Choose a Fertility Clinic (CaFC) to be updated.	We ensure quality metrics and verification reports are in place. A verification exercise can take place to assure the data in the new register for the first time. 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.	July 2022 June to October 2022 November 2022 Nov 2022
Continued support for the PRISM data submission system and ongoing engagement with clinics to ensure that their data can be submitted in a timely and accurate manner.	PRISM fully bedded in with clinics and data being submitted into the register. PRISM handover from contractors completed. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime.	May 2022 May to July 2022 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**
	'Right first time' data quality and reduction in effort by clinics submitting the data.	
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. 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.	By September 2022
Keep abreast of the impact of any Competition and Markets Authority (CMA) and Advertising Standards Authority (ASA) activities in our area.	Consider any changes to our guidance and other activities in response to any future changes by the CMA and ASA.	Throughout the year
To implement and embed the processes for a Data Review Board established in 2021/22	Data Review Board established. Clear methodology and process established for considering any future additions to the Register.	Throughout the year
Complete a review of our compliance against the NHS Digital Data Security and Protection Toolkit and submit a response to this.	We show significant progress on the quality of our submissions in the toolkit, in particular the areas of improvement highlighted by the auditors. Create a new oversight group that combines best practice from other organisations and collects toolkit documentation on an ongoing basis to allow for faster, more complete submissions going forward. We assure ourselves that we are practising good data security and personal information is handled correctly.	June 2022 (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**
Maintaining effective Opening the Register (OTR) and counselling services.	OTR requests continue to be met in a sensitive manner. The backlog of requests stemming from the clinic closure period during the pandemic is dealt with, and normal response timescales restored. Counselling support is offered for all OTR applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information. OTR applicants feel supported and prepared to deal with the information they receive from us.	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet.	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI), parliamentary question (PQ), and subject access requests.	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion. We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.	Throughout the year
To publish good quality statistical and other reports.	Preparing provisional reports on Covid treatment outcomes where fully validated Register data is not yet available from the new Register. 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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
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. More researchers can access and use our Register data. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	Throughout the year
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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
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
Induction of new Authority and other committee members.	HFEA governance and decision-making capabilities maintained. Effective induction to ensure new members are up to speed and able to carry out effective decision-making. Key knowledge is retained where possible, during a period of time when several Authority terms of office end and new members will join.	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 2022 to March 2023.

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**
Continued monitoring of 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 (eg 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 review 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.	October 2022-March 2023

Table 9 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for April 2022 to March 2023.

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
To produce proposals for modernisation of 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.	December 2022
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
Implementation of any legislative changes that occur, for example on storage limits.	Any legislative changes are successfully implemented as required. Following the amendment to the Health and Care Act on gamete and embryos storage we meet the required commencement date. New guidance and consent forms in place to reflect the new legislation, including guidance documents for clinic staff and inspectors and patient information, amended and new consent forms, and updates to the Code of Practice and General Directions. Guidance and communication with the sector throughout the transitionary period.	January 2022 onwards
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 2021 Throughout year
Delivery of a project to prepare 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.	March 2023

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Continuing to ensure that our working arrangements remain suitable following our office move in 2021.	We maintain appropriate ways of working, including relevant policies, taking full advantage of our modern, dynamic and collaborative facilities. Our People Strategy has highlighted key actions that will be put in place to help support staff welfare and wellbeing beyond the Covid-19. We will put initiatives in place to support positive mental health such as awareness sessions carried out by our mental health first aiders and greater promotion of our employee assistance and counselling programs.	Throughout the year
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2024.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. 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. Skills mapping to enable better oversight of organisational skills mix and deployment of resource. 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
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.	March 2023 (and further work in the next business 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 November 2021 the Authority agreed to proposals to increase the clinic licence fee per IVF cycle from £80 to £85, the increase to take effect from 1 April 2022. Approval was granted by Her Majesty's Treasury (HMT) and the Department for Health and Social Care (DHSC) in January 2022.

Following this approval, a Chair's letter (CH 22/01) was published on 1 March 2022 informing all licensed establishments of the changes to our licence fees and the date and process for implementation.

The agreed increase to the licence fee, the first in 6 years, will allow the HFEA to increase its headcount and invest further in information technology in support of our use of data. Areas that will see increased investment include

- Opening the Register team (OTR) – will fund a permanent increase in the team to 4 FTE, to meet both the increase in current demand and in preparation for further increases in demand from 2023, when we begin to receive the first requests for Donor information from those conceived using donor gametes after the removal of donor anonymity in 2005.
- Policy, Data & Intelligence – funding additional post within our data and policy teams to meet the increased demands internally and externally for our data and to support the introduction and development of legislative change.
- Compliance – temporary increase to the team will now be made permanent, increasing the capacity and resilience of our inspection and compliance function.
- Information technology – increase the size and capability of our in-house development team, to support and develop our new register and data submission system (PRISM).
- In addition to the developer support above there will be further funds available to support much needed upgrades to, or migration from, legacy technology tools and systems via third party and external providers.

Income

Table 10 - HFEA high-level income for 2022-2023

Income	Budget £000s
Department of Health and Social Care funding	1,198
Non-cash income	265
Treatment and licence fees	5,843
Other income	145
Total income	7,451

Expenditure

Table 9 – breakdown of HFEA operating costs for 2022-2023

Operating costs	Budget £000s
Staff costs	4,703
Other operating costs	2,748
Total operating costs	7,451

Table 11 - HFEA high-level expenditure for 2021-2022

Overall expenditure	Budget £000s
Total operating costs	7,186
Capital charges	265
Total revenue expenditure	7,451

The expenditure budget contains a number of assumptions around inflationary and demand pressures as well as providing for some difficult to predict areas of spend:

- The Wages and Salaries budget is based on a full establishment of 76 FTE and allows for a modest increase to staff salaries in this business year. The Cabinet Office has confirmed there will be no extension to the pay freeze in 2021, and has announced an increase to public sector pay in 2022 of 2%, with an additional 1% if certain tests are met.
- Other staff costs include Inspection travel costs, as well as staff wellbeing and training budgets, we anticipate a significant increase in this area compared to 2021/22 as more assessments will take place on clinic premises rather than remotely.
- IT Costs and development includes expenditure to fund the use of external providers and developers to enhance and upgrade systems, only expenditure relating to the development of a case management system for OTR requests has been committed at this time.
- Our legal budget provides for both normal operational expenditure, in support of committees, and a provision for emerging issues relating to policy, legislation or challenges to our regulatory position.

HFEA Operating Budget 2022/23

Budgeted Income	**£**	
Licence Fees - Activity	5,806,499	
Licence Fees - Renewal	16,125	
Licence Fees - Storage	900	
Licence Fees - Research	7,125	
EUTD Fees	11,500	
Interest Received	1,300	
Miscellaneouse Income	145,194	
DHSC Funding		
Grant in Aid	1,098,000	
Ring-fenced RDEL	265,058	
Pension funding	100,000	
		7,451,701

Budgeted expenditure		
Wages and salaries	4,703,431	
Other Staff costs	296,900	
Authority & Committee costs	230,749	
IT Costs & Development	989,410	
Legal Costs	215,000	
Other costs	350,168	
Accommodation	400,986	
Non-cash	265,057	
		7,451,701

Our licence fee income position has been based on an assumed 65,000 new IVF cycles that meet the criteria for the payment of a clinic licence fee. The impact of Covid 19 means that data relating to the 2020/21 and 2021/22 business years varies significantly compared to historic activity data in both volume and distribution, as such our budget is based on activity from the 2019/20 business year. A 1% variance against this estimate would result in a change to our income forecast of £55,000.

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 policy (currently under review) 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

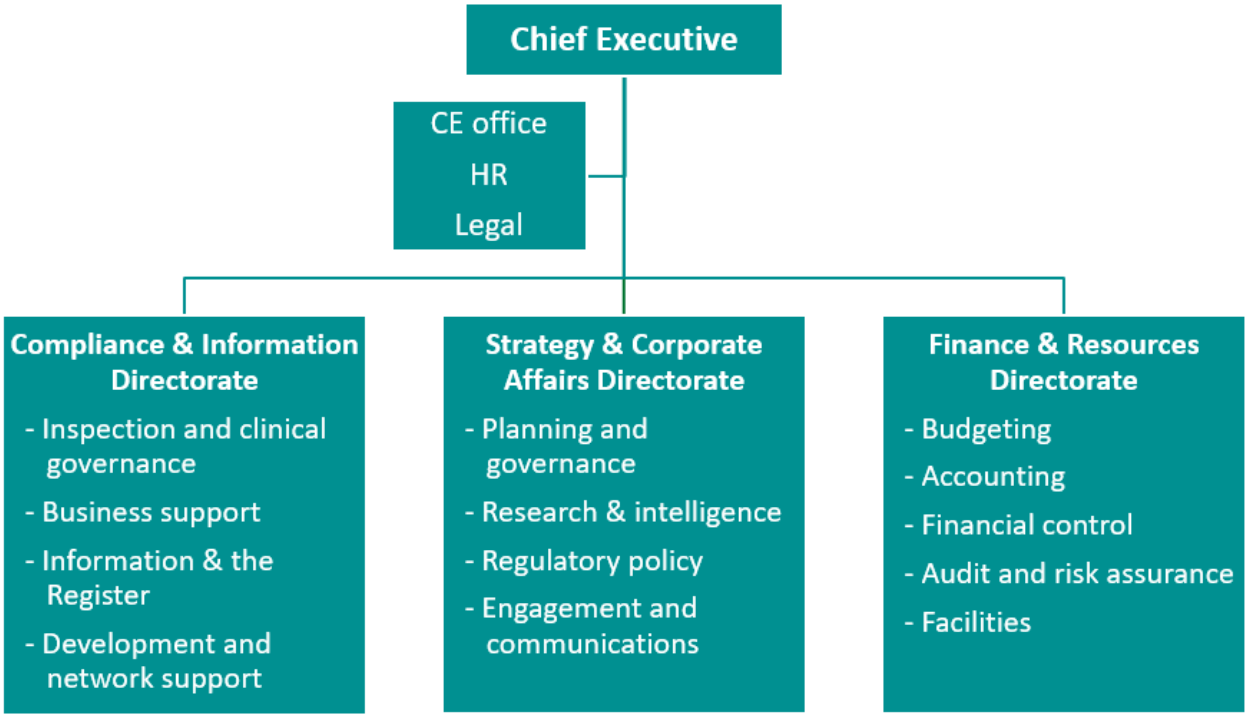
Our staff complement is 76 (from 1 April 2022). We have put in place shared services arrangements with other bodies where feasible. For example, we share part of our finance and resources team staffing with the Human Tissue Authority, and our facilities management service is shared with the four other Health 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 of 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 another ALB, 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 Office 365 arrangement for our desktop systems, which is more cost-effective and increases our resilience in the event of any business continuity issues with our physical premises.

The robust information security arrangements we have in place, in line with the 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 did not meet the required standard. We are working to improve our completion of this annual submission in 2022. We are now 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 is conducted, 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 multiple health 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 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 impacts.

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.

2 Redman Place

London

E20 1JQ

T 020 7291 8200

E enquiriesteam@hfea.gov.uk

www.hfea.gov.uk