Human Fertilisation & Embryology Authority

Business plan

April 2021 – March 2022

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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 priority outcomes for 2021-2022 are:

- Protect the public's health through the health and social care system's response to Covid-19
- Improve healthcare outcomes by providing high-quality and sustainable care at the right time in the right place and by improving infrastructure and transforming technology
- Improve healthcare outcomes through a well-supported workforce
- Improve, protect and level up the nation's health, including through reducing health disparities.
- Improve social care outcomes through an affordable, high quality and sustainable adult social care system

Given our specific remit, not all areas of these outcomes relate to the HFEA, however, we see our strong focus on The Best Care as directly supporting a number of the Department's aims. Our focus on the future will help us to ensure that we are also organisationally ready for any operational changes that are required, to make this a reality.

In 2020-2021, much of our focus was on responding to changes arising due to Covid-19, and consequently we rescheduled some of our planned strategic work and only published a six-month business plan for the second half of the year. This business plan sets out how we will work towards our vision in 2021-2022, the first full year of our 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.

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

Following the UK's exit from the EU, the Human Fertilisation and Embryology Authority has continued to work closely with the Department of Health and Social Care (DHSC) and its arm's-length bodies to understand the opportunities available to the UK and our health and care system. This includes supporting the cross-organisational work on the UK's future relationships with the EU and the rest of the world. We will work with the Department to contribute to delivering the future relationship with the European Union and implementing the Northern Ireland Protocol.

We have responded to a drive by Government (across healthcare and other industries) to maximise the potential for exporting our expertise, raising standards overseas and revenue for the UK. As such we have provided a service to various international partners, for example by providing assistance in establishing a regulatory regime in countries without one, though due to Covid-19 this has been limited in 2020-2021. In 2021-2022, we will continue to consider the opportunities available to us to build relationships internationally, including running an international horizon scanning meeting with our global partners.

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

What we did in 2019-2020 and 2020-2021

Overview

2019-2020 was the final year of our 2017-2020 strategy and the past year represented the first year of our new 2020-2024 strategy. When launching our last business plan, we were still responding to Covid-19 and so chose to instead review the last two years of delivery together now.

In 2019-2020, as well as delivering our usual range of statutory functions, such as regulating and licensing clinics, we completed some key work towards our vision of high-quality care for everyone affected by assisted reproduction and created a new strategy for 2020-2024, with input from our stakeholders. As 2020-2021 began, we responded to the Covid-19 pandemic, which meant that much of the year was spent ensuring that we and the sector were able to recover safely. For the first six-months of the year, we operated without a business plan, instead focussing on managing risk and responding to changes affecting the sector. However, across the year we did make some progress towards our strategic delivery, setting the foundation for future successes. Our new strategy for 2020-2024 was launched in October 2020.

The below describes key work we undertook in 2019-2020 and 2020-2021 against our strategic aims for each year.

Delivery of the 2019-2020 business plan

Safe, ethical, effective treatment

We completed our full programme of clinic inspection, audit and licensing activities, embedding and inspecting against leadership and support principles, until the restrictions from Covid-19 were imposed in mid-March 2020.

During the year up to mid-March, we also undertook several unplanned investigations in response to a range of events. Our inspection activity is summarised in our annual State of the Sector report which we published in October 2019 for 2018-2019 data and again in November 2020 for 2019-2020 data. A new quarterly incident report to the sector was introduced to aid learning in clinics.

We published an update to the 9th edition of our Code of Practice in December 2019, which focuses particularly on clinic leadership and patient support. We held our second PR event for clinic leaders in the Autumn of 2019 to set out our expectations. The new Code also included changes in relation to surrogacy, screening and professional guidelines. We separately released guidance on electronic consent and this will be reflected in a future edition of the Code.

The multiple birth rate has continued to fall and stands at 8% for 2018 data – this is below our 10% target and as the biggest single health risk to mothers and babies represents a real public health success. The multiple birth rate from IVF stood at 24% in 2008 when we first launched our campaign.

We implemented recommendations from a review of our licensing function, including making process improvements and an improved quality assurance system, to enhance the quality of licensing products and the resulting decision-making.

Consistent outcomes and support

We provided advice and information to patients about accessing treatment and donation via our website. We also worked with professional stakeholders (such as the British Fertility Society (BFS)) to put patients in touch with better information and services when they first realise they may have a fertility issue. We undertook various patient and public engagements, attending several fertility shows and events to provide clear, unbiased information.

Through our inspection activities, we 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 also began to work with commercial groups of clinics to improve quality, consistency and compliance on a group-wide basis, as relevant.

We continued to work with NHS England on a piece of work led by them on price benchmarking, with the aim of assisting NHS commissioners in securing fair prices and effective fertility services for patients.

We continued to implement a project on the emotional experience of care before, during and after treatment, working with professional stakeholders to bring about improvement. This led to changes to the Code of Practice.

With the aim of improving the chances of successful treatment, we have published more information in our data reports and focused on success rates through inspection reports and risk tool alerts.

We introduced new processes and certifications to fully comply with European Union (EU) requirements relating to the import and coding of donor eggs and sperm.

Improving standards through intelligence

We delivered a number of aspects of our Intelligence strategy which was approved by the Authority in January 2018 and sets out how we will analyse, publish and use our data to improve the quality of the information we produce and, ultimately, to provide a sharper focus in our regulatory work.

We maintained our role as the UK's competent authority for assisted reproductive technologies in the EU, participating in one meeting. We cooperated with the department to prepare for the UK's exit from the EU and began a project to consider the organisational and sector implications of this. This continued into 2020-2021.

We continued to deliver our programme of improvement work on the Register infrastructure and maintained the Register of treatments and outcomes throughout the year, working with clinics to ensure accurate reporting of data. We also continued to publish the information we hold, and to respond to a range of enquiries from patients, clinics and central Government.

Delivery of the 2020-2021 business plan

Our Covid-19 response

As mentioned above, the first six-months of the 2020-2021 business year were primarily about responding to Covid-19.

The Authority decided on 23 March 2020 that all licensed fertility clinics should close from 15 April. HFEA General Direction 0014 was issued setting out clinic requirements. Consideration of how clinics could reopen began in April and a revised GD0014 (v.2) was issued on 7 May. Clinics were able to apply to reopen from 11 May. Any clinic wishing to apply to reopen was required to complete an HFEA Covid-19 Treatment Commencement Self-assessment questionnaire which measures the robustness of their Treatment Commencement Strategy and assess their compliance with professional body guidance. A key element of the HFEA response throughout the pandemic has been the provision of clear, responsive guidance and information to both patients and clinics.

The fertility sector reopened quickly and was praised by Ministers at the time. The requirements of GD0014 (v.2) have proved to be adaptable and robust, allowing most clinics to continue to safely offer treatment, even during subsequent waves of the pandemic and various measures, including further local and national lockdowns.

HFEA inspections were paused when clinics were closed and only resumed in November. In the interim, a new inspection methodology was developed, which includes desk-based assessments, a risk-based approach and the use of virtual technology to assess clinic compliance in order to minimise on-site visits.

Throughout our Covid-19 response and since, we continued to undertake our core delivery and key regulatory functions including, licencing clinics, processing applications, launching data reports and engaging with stakeholders and communicating guidance. Following the launch of our strategy in October 2020, we prioritised progress in a few key strategic areas in the final six-months of the year:

The best care

We started a key strategic project on add-ons, following on from earlier work with the sector, with the aim to improve the provision of treatment add-ons and to encourage responsible supply of these by clinics.

We reviewed our Compliance and Enforcement policy, including a consultation with stakeholders, with the aim that this provides a consistent ongoing basis for making regulatory decisions about clinics.

The right information

A significant area of focus was around the patient information about add-on traffic lights. We completed a survey of patients and worked with partners from across the sector review and improve the information available, with the aim that all patients have the information needed to make informed decisions

In September 2020, we published a family formations report, which focused on IVF and DI statistics for heterosexual, female same-sex and single patients in the UK, identifying the changes that have taken place in the treatments used by different groups over the last ten years. And in March 2021 we published a report on ethnic diversity in fertility treatment, covering data from the same period.

We worked alongside the Competition and Markets Authority to support their project on self-funded IVF and consumer law guidance.

We undertook an update of the data on the Choose a Fertility Clinic (CaFC) pages on our website, to ensure that patients have access to up to date success rates information about clinics, to inform their choices.

We continued to develop our PRISM system, for clinics to submit data to the Register.

Shaping the future

We planned a series of blogs and events to mark the 30th anniversary of the HFEA, both to celebrate what has been achieved and also to begin a public conversation on the future, including developments in fertility treatment, wider scientific advancements and possible legislative change to support our role.

We handled a significant number of Opening the Register requests, following an earlier pause to the service, and began to look at the operational arrangements for this work, to ensure that we are set up to deliver effectively into the future.

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).

Towards the end of the year we welcomed several new members to the Authority and some of our other Committees and we began preparing to welcome a new Chair in 2021-2022.

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 2019 and 31 March 2021.

Table 1- Table outlining performance data against the same data from 2018 - 2021

Type of work	2018-2019	2019-2020	2020-2021
Active clinics and research establishments	135	137	136
Clinics and research establishments inspections delivered	84	87	63 (By DBA/onsite/ virtual inspection, including licence extensions) – Most inspections not conducted between 1/04/2020 and 31/10/2020 **See note 1 below table**
Licences inspected	85	96	58
New licence applications processed and presented to the Licence Committee/Executive Licensing Panel	6	4	1
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	44	34	41 (Including licences extended)
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	2	1	1
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	57	42	32
New mitochondrial donation applications processed and presented to Statutory Approvals Committee	9	4	6

Type of work	2018-2019	2019-2020	2020-2021
Incident reports from clinics processed	672	663	1135 (of these, 576 were recorded as 'not an incident') **See note 2 below table**
Alerts issued	0	2	1
Formal complaints about clinics	26	37	54
Opening the Register requests closed within 20 working days	327	518	196 closed in total (10 within the 20wd target) **See note 3 below table**
Donor Sibling Link applications processed	41	87	62
Licensed Centres Panel meetings held	2	2	2
Formal roundtable meetings with patient organisations held	2	2	4
Public and stakeholder meetings	8	7 **See note 4 below table**	8 **See note 4 below table**
Freedom of Information (FOI) requests responded to	62	39	56
Environmental Information Regulations (EIR) requests responded to	0	0	0
Enquiries responded to under the Data Protection Act (DPA)	0	0	6
Parliamentary questions (PQs) responded to	117	22	8
Unique visits to our website	316,022	401,302	504,652
Most popular/viewed page on our website	Clinic search	Clinic search	Homepage

Notes

1. All centres are usually inspected on-site at least every two years, but the volume of scheduled inspections has a natural variation from year to year due to the timing of licence expiry. In 2020-2021, in response to the Covid-19 pandemic, we undertook a revised inspection methodology; consequently, the number of licences inspected includes all those that were extended due to Covid, had virtual inspections and desk-based assessments (DBA) via a risk-based approach and some that were conducted on-site. In addition to the 63 inspections delivered through desk-based assessment, virtual inspection and licence extensions, the compliance team risk assessed 29 further centres (between April-October 2020 only). For those considered low risk, it was agreed that an interim inspection was not required or could be accomplished through an Executive Summary submitted to a licensing committee. For centres deemed higher risk interim inspections were re-scheduled and conducted at the earliest opportunity.

2. There were 1135 incident report forms processed. Of these 576 were recorded as ‘not an incident’. The reason for this large number of incidents recorded as ‘not an incident’ is that from May 2020, we asked centres to report via the HFEA incident reporting system any staff member or patient that tested positive for Covid-19. These Covid-19 reports were recorded as ‘not an incident’. In November 2020, we also asked centres to report through the HFEA incident reporting system all hospital referrals and admissions that are not covered in our definition of an incident. This was to assess the impact of any burden of continuing fertility treatments on the NHS. These reports were recorded as ‘not an incident’. Due to EU Exit, we are also asking clinics to report issues around vital supplies being held up at the border. These incidents are also recorded as ‘not an incident’. We have only received one such report.
3. 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 the autumn. 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.
4. Authority and stakeholder meetings in 2020 were affected by the need to respond to Covid-19. As a consequence, we held some of the meetings we would usually have held in public, privately (one of these – the March meeting - in 2019-2020; and four in 2020-2021). Therefore, these are not counted in our figure for public meetings. All of our stakeholder meetings were held virtually in 2020-2021.

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
Executive senior manager (ESM) to staff complement ratio	1:19	1:19
Number of staff earning more than £142,500 now and any planned change during the next planning period	0	1
HR staff to employee ratio	1:45	1:45
Training budget as a percentage of pay bill	1.5%	1.5%
Projected reductions in non-payroll staff	Not applicable	Not applicable

Key performance indicators

Table 3 - Table indicating performance against key metrics from April 2019 to March 2021

Category	Performance indicator	Target	Performance in 2019-2020	Performance in 2020-2021
Engagement	Number of emailed public enquiries received.	No target, since the nature, volume and complexity of enquiries received varies widely.	1406	1250
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.	62 working days	49 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).	98%	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.
Financial management	Cash and bank balance.	To move closer to minimum £1,520K cash reserves.	£2,463k (down from £2,658 in 2018-2019)	
People and capacity	Percentage turnover for the year.	5-15% turnover range.	12.2%	11.7%

Activities for 2021-2022

This business plan represents the first full year of our 2020-2024 strategy which launched in October 2020. This focuses on the best care, right information and shaping the future.

2021-2022 follows on from a year that was profoundly affected by the coronavirus pandemic, for patients, the sector and our staff. Having begun certain pieces of work in 2020-2021, this year will allow us to take our strategic activities further and to begin new strategic work. This is also our anniversary year, marking thirty years since the HFEA was established. As such, we will take the opportunity to look forward to the future of fertility treatment and regulation.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2021-2022.

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 2021 to March 2022

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Review of the compliance regime to ensure this remains robust and able to effectively assess care against target outcomes.	Review and development of: • inspection priorities • plans for quality improvements • our use of intelligence gained from inspections • inspection reports Roll out of • revised compliance and enforcement policy • the revised PREP test. Readiness for next steps to ensure the HFEA's compliance regime is more aligned to strategic priorities.	Throughout the year with further work falling into subsequent years.
Maintenance and adjustment as needed of our regulatory approach, and ongoing monitoring of Covid-19 risks and impacts on fertility sector and the HFEA. Clear actions and communication as the situation develops.	Clear ongoing recovery plan and assistance for clinics in response to the latest Covid-19 situations and government guidance. Risk-based approach to inspection activity. Clinics effectively respond to Covid-19 related risks. We effectively adapt and respond to any changes in Covid-19 circumstances, such as any local lockdowns and 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**
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes a revised approach to respond to Covid-19.	All clinics and research establishments in the sector are: • appropriately inspected and monitored against the requirements of the act and published performance indicators, and • issued with licences for up to 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
Collaborative and partnership working with other ALBs and health regulators UK wide, such as the Care Quality Comission (CQC), NHS England, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom Accreditation Service (UKAS), Health Research Authority (HRA), General Medical Council (GMC) and the devolved nations.	Joint working on regulatory innovation. 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. Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. Participation in cross-organisational working such as the regulatory advice service for regenerative medicine, as relevent. Learning from each other and acquiring best practice.	Throughout the year
Engagement with patients, clinics, and other stakeholders to gain a greater understanding of the	Through 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.	Throughout the year with further work

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
disparities in access, experience and outcomes between ethnic groups, including those identified in our 'Ethnic Diversity in Fertility Treatment 2018' report (published March 2021). Use this information to identify where we, as a regulator, can take action to address these inequalities and promote greater equity across the fertility sector.	HFEA website content is updated where needed to add information to provide ethnicity minority patients with information about specific issues which may be relevant to them. We enable better research on disparities across ethnic groups within the fertility sector by including more information on ethnicity in our regular data releases. 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. We review whether changes to our Code of Practice are needed relating to information provision for ethnic minority patients. We will explore the reasons why patients from some ethnic groups have higher multiple birth rates than White patients and consider this when reviewing our multiple births minimisation strategy. We share the data we have with GPs, highlighting for example that in some communities, access to fertility treatment is starting at a later age. We present the findings of this report to the Royal College of Obstetricians and Gynaecologists Race Equality Taskforce and invite their recommendations as to further actions we or others could take.	falling into subsequent years.
Continuation of a project to improve the provision of treatment add-ons and to encourage responsible supply of these by clinics. Including further development and publicising of patient information and traffic lights.	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. General agreement within the fertility sector around the direction of travel toward best practice around add-ons. Patients and clinics understand the risks associated with add-ons. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence	Summer 2021 with further work to be planned for subsequent years.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Scoping of a project to build on earlier success rates work.	We use our data to understand variations between clinics and collaboratively define best practices. We are prepared to deliver further targeted work in this area in 2022-2023.	Throughout the year
Engagement with researchers across the field of fertility research, particularly those using – or with potential uses for – HFEA Register data and those involved or interested in commencing research with human embryos.	Improved relations and communication with the fertility research community. Researchers have access to relevant and valuable data in our Register, to inform high quality research. We implement the 2017 review of the application process for researchers to use HFEA data, or human embryos. Promote quality research and collaboration using HFEA Register data and/or human embryos. More research and innovation to improve outcomes. We continue to be active members of the UK health data research alliance to encourage widespread and responsible access to data	Throughout the year
Scoping a review of guidance and implementation of the 10-family limit to consider what more can be done to provide clarity on this.	We monitor compliance with the guidance and understand any issues with this, to inform possible future work.	By March 2022
Effective handling of and communication about: • clinical incidents and adverse events, including publication of 2020-2021 '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 2021
Ensuring governance tools underpinning licensing and other	Ensure that licensing decisions and other approvals are well governed. Efficient and effective decision-making is maintained.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
decisions are in place and effective.	Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually.	
Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. Mitochondrial donation and PGD approvals taken in an accountable and transparent way.	Throughout the year
Ongoing review of guidance for clinics to ensure this remains fit for purpose, including: • delivery of an update to the Code of Practice • 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 and other guidance for clinics.	Throughout the year. Revised Code of Practice to be published in Autumn 2021.
Servicing the legal information needs of the HFEA including: • provision of legal advice to inform other HFEA work • management of team of external legal advisers to support effective licensing processes.	HFEA licensing decisions are sound and based on comprehensive legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
• supporting the review of the Compliance regime and Code of Practice		
Review of information provided on HFEA website about: • routine treatments for instance 'standard' IVF and associated costs • testing of new information using the patient engagement group.	We use our communications channels to make sure patients receive the right information at the right time. Information is reviewed on a cyclical basis to ensure that it is fit for purpose and new information added when needed.	Throughout the year
Implementing the changes that result from the end of the EU exit transition period, to ensure that the HFEA is able to function smoothly within new operating circumstances and licensed clinics can continue to provide high quality and safe treatment.	Identify and mitigate post-transition risks and issues, such as the continued supply of medicines, equipment and gas to licensed clinics. Implement changes to General Directions, licences, import and export forms and processes and any consequential organisational changes to ensure effective regulation across the UK.	Throughout the year New licences activated 1 July 2021.

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 2021 to March 2022

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

The right information

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

Table 6 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for April 2021 to March 2022

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

Table 7 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for April 2021 to March 2022.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Ongoing work to review our compliance with accessibility requirements and make changes as necessary.	Stakeholders' accessibility needs are considered so that they are able to access our information. HFEA services are available to everyone that needs them. We ensure that HFEA appropriately complies with government accessibility requirements and legal obligations. We maintain a clear accessibility statement for our website and Clinic Portal.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Clinic Portal and website updates to ensure ongoing stability and functionality for all users.	Our systems support continued information provision and improvements. Implementation of website improvements identified by users. The Clinic Portal remains useful and easy to use for clinic staff and meets their updated requirements.	Throughout the year
Continuation of scoping work to consider how clinic data will be published in future.	We identify actions to ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions.	Throughout the year
Improved Register data analysis tools to improve reporting and analysis	Realisation of a post-PRISM reporting database. Increased ability to analyse data and report from the Register.	Throughout the year
Follow on work from the Competition and Markets Authority (CMA) project on self-funded IVF and consumer law guidance. Including working with the Advertising Standards Authority (ASA).	We support the CMA to communicate and embed their guidance so that clinics understand their obligations under consumer law in relation to self-funded treatment. Consider any changes to our guidance and other activities in response to the CMA and ASA guidance.	April-Oct 2021
Data review board established	Clear methodology and process established for considering any future additions to the Register	First meeting Autumn 2021
Complete a review of our compliance against the NHS Digital Data Security and Protection Toolkit and submit a response to this.	We measure our performance against the National Data Guardian's ten data security standards. We assure ourselves that we are practising good data security and personal information is handled correctly.	Final Submission for 2020-2021 in June 2021. Review annually ongoing.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Make use of patient feedback and our patient engagement group to ensure that information is fit for purpose.	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.	Throughout the year
Maintain up to date and accurate information and advice on our public-facing website.	Patients see HFEA information as 'go to' impartial advice. People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. People can easily find relevant information and signposting on our website to inform their next steps.	Throughout the year
Responding to media reports.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wider range of issues.	Throughout the year
Maintaining effective Opening the Register (OTR) and counselling services.	Opening the Register requests continue to be met in a sensitive manner and within agreed time limits. Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information. OTR applicants feel more supported and prepared to deal with the information they receive from us.	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet.	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI),	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion.	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
parliamentary question (PQ), and subject access requests.	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.	
To publish good quality statistical and other reports, including the Fertility Trends report.	We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes, trends and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment. We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. High quality data available to develop patient information and respond to information requests.	Throughout the year
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Running the Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. More researchers can access and use our Register data. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing compliance with government information requirements.	We respond to government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual report published including required information.	Throughout the year
Effective records management and information governance.	Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times. Information governance arrangements comply with latest requirements. Records management and information governance risks are managed effectively.	Throughout the year
Responding to external consultations, calls for evidence and reviews including from the Department of Health and Social Care, other departments, regulators and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector.	Throughout the year
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 high member turnover.	Throughout the year
Launch of PRISM and the new Register. Early life support for the PRISM data submission system and ongoing engagement with and feedback from clinics.	PRISM fully bedded in with clinics and data being submitted into new register. Updates completed by third party system suppliers to their systems, and their updated systems deployed with data being submitted into the new register. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime. 'Right first time' data quality and reduction in effort by clinics submitting the data.	By October 2021, and ongoing use as BAU(PRISM

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
		launch will be in June 2021)
Launch, early life support and further development work on a new Register Information Team Application (RITA), to enable us to query the new register and run reports.	Targeted support to improve data quality across the sector. Reports being provided and the ability to query the new register to internal HFEA teams' requirements to enable Register team and OTR team to provide an acceptable level of service. 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 June 2021, and ongoing use as BAU

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 2021 to March 2022.

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**
Scoping piece on clarifying guidance to clinics about what to do when donors wish to make restrictions on their donation that could potentially disadvantage protected characteristic groups.	We take legal advice as required and are clear about legal and policy implications. We facilitate a discussion with the Authority about possible next steps.	Late 2021
Activity to monitor the use of AI and data-driven new technologies in fertility clinics and the wider sector.	We understand any developments and are responsive to these. We ensure that our regulatory regime is fit for purpose. We monitor AI and data-driven new technologies that are in or potentially approaching clinical use via SCAAC horizon scanning (AI is a priority topic, meaning there are scheduled reviews and discussions on the issue). We monitor patient-facing AI and data-driven new technologies by gathering together short regular reports detailing issues raised to inform policy working and share as relevant.	Throughout the year

Table 9 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for April 2021 to March 2022.

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Delivering activities to mark the 30th anniversary of the HFEA.	We mark this historic milestone, and take a forward view as to the future of the fertility sector, our legislation and our regulatory role. We will engage a wide audience to consider the next 30 years of fertlity treatment and facilitate expert discussion on ways to modernise our Act including on key issues such as anonymity, responsible innovation and modern regulatory powers.	Throughout 2021
Respond to any requests for consultation on possible legislative changes as these occur and consider how these will impact the HFEA.	Early consideration of possible impacts of any changes on the sector and the HFEA. To ensure the HFEA and the sector are prepared for future changes in the fertility field. We inform any work by DHSC on fertility sector regulation, participating and leading debates about the modernisation of our legislation.	As these occur
Scoping and implementation of any legislative changes that occur, for example on storage limits.	Any legislative changes are successfully implemented as required.	September 2021 onwards dependent upon external timeframes
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 scope future 'Opening the Register' (OTR) demand and logistics.	Scope and deliver a project to operationally prepare for a growth in demand as donor-conceived people are eligible to make OTR requests from 2021 and 2023, ensuring that the OTR team can handle increasing demand.	Early 2021-2022

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Optimisation of HFEA approach to office use following HFEA Office relocation to Stratford.	We consider ways of working changes resulting from the move and Covid-19 operational changes, to take full advantage of our more modern, dynamic and collaborative facilities and improve HFEA operational approaches. Any residual issues are resolved following the move to Stratford to ensure the smooth functioning of the new office. HFEA have the space and facilities needed to operate effectively within the new office and for staff working remotely.	Early 2021-2022
Continuing to ensure that our working arrangements are suitable for maintaining appropriate Covid-19 safe working conditions.	We maintain appropriate ways of working, including relevant policies. Our office-based staff are able to return to working in an office environment when it is safe to do so. Our People Strategy has highlighted key actions that will be put in place to help support staff welfare and wellbeing during and beyond 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

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Plan for a fee review informed by our income forecasting model.	We ensure that we meet the financial needs for regulation.	March 2022

Financial picture

Our finances and high-level budget.

We receive funding from two main sources: the majority, around 80%, from clinics and the balance from our sponsors, the Department of Health and Social Care, as grant-in-aid (GIA).

The vast majority of fee income arises from individual IVF treatments in regulated clinics. In aggregate, together with licence fees, these cover the costs of regulation including:

- evaluating licence applications
- making licensing decisions and issuing licences
- managing licences
- site visit inspections
- managing statutory information flows, and
- providing advice and guidance to licensed establishments.

We maintain a model to predict the likely activity in future years. This is based on a combination of historic trend data and Office for National Statistics population forecasts. We monitor how closely actual activity follows our projections including a formal review of the model annually.

Over the years, we have managed our expenditure to ensure we spend within our annual budget and expect to do so moving forward. We continue to maintain a cash reserve to ensure we can manage fluctuations in our monthly income and provide a buffer should we see a material deviation from our forecast income levels.

Income

Table 10 - HFEA high-level income for 2021-2022

Income	Budget £000s
Department of Health and Social Care funding	1,198
Non-cash income	516
Treatment and licence fees	5,188
Other income	147
Total income	7,049

Expenditure

Table 9 – breakdown of HFEA operating costs for 2021-2022

Operating costs	Budget £000s
Staff costs	4,601
Other operating costs	1,932
Total operating costs	6,533

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

Overall expenditure	Budget £000s
Total operating costs	6,533
Capital charges	516
Total revenue expenditure	7,049

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 the whole family of arm's length bodies (ALBs).

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

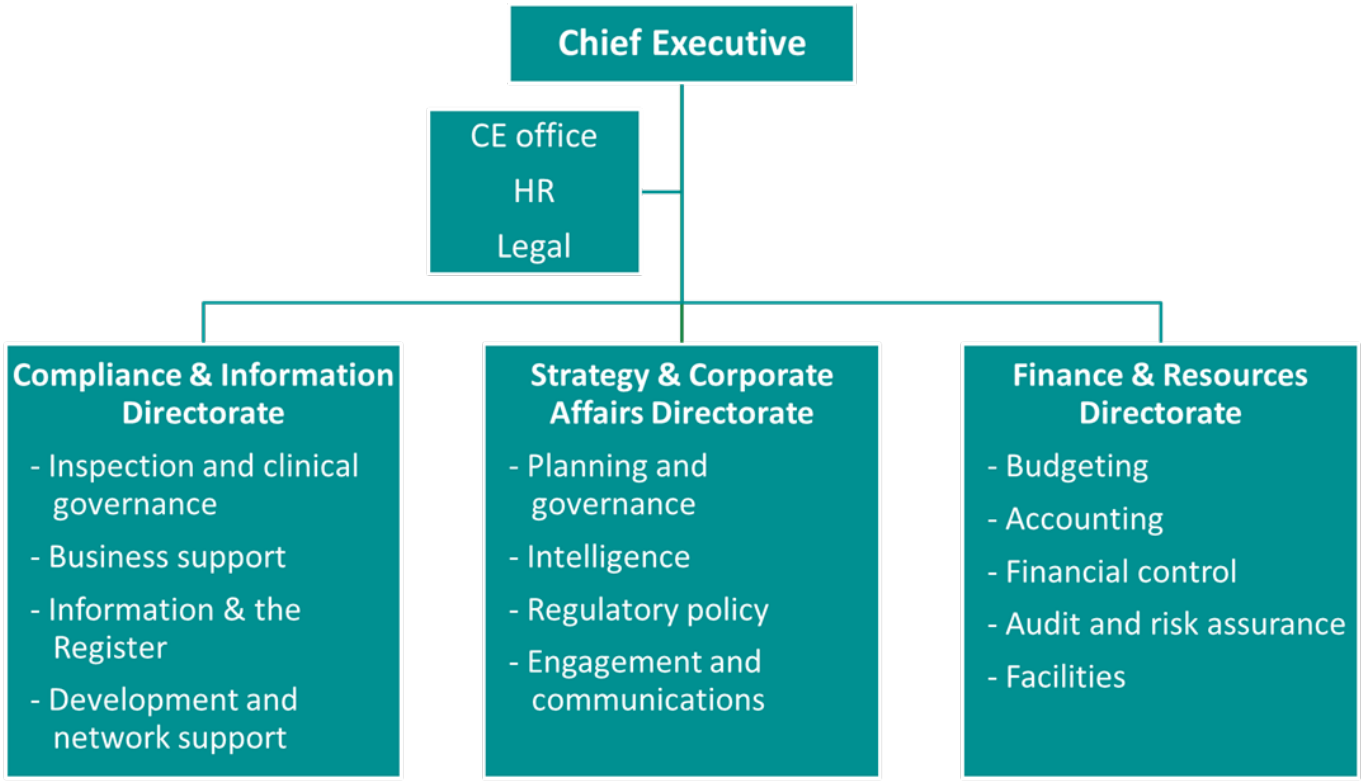
Our staff complement is now 68 (compared to 86 in 2010-2011). We have put in place shared services arrangements with other bodies where feasible. For example, we share part of our finance and resources team staffing with the Human Tissue Authority, and our facilities management service is shared with the four other Health ALBs with whom we occupy the same premises. We are seeking ways in which to work alongside these ALBs on talent management, to provide cost-effective leadership development programmes and other development opportunities.

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

We have a people strategy, referenced earlier in this business plan, 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. 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.

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 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 information governance toolkit, 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 will be completing the Data Security Protection Toolkit for the first time in 2021, which will further increase the security controls we have in place. 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 as was seen during the Covid-19 pandemic, staff are able to work from home for extended periods, if necessary, in the event of a business continuity event.

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 will work with other ALBs at 2 Redman Place on health and safety and general facilities services, which will be 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. A proportion of our staff are able to work from home, 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.

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