Human Fertilisation & Embryology Authority

Annual report and accounts 2021/22

HC 479

Human Fertilisation and Embryology Authority

Annual report and accounts 2021/22

For the period 1 April 2021 to 31 March 2022

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Chief Executive's foreword

Looking back at 2021-22 we have made good progress on our strategic aims, despite the continuing impact of Covid-19. The fertility sector was the first elective service to resume treatment in May 2020 and is perhaps closer to pre-pandemic levels of performance than any other service across the health sector.

I am pleased that we have been able to move forward on a number of initiatives, some informed by what we learnt during the pandemic, all of which will provide greater clarity and improved engagement with the providers we regulate and the patients they serve.

I am particularly pleased that we have been able to implement the learning from new ways of working under Covid restrictions in our revised inspection methodology. The new hybrid model uses both a desk-based approach and a focused on-site visit (as required by the Act) resulting in savings for both the HFEA and clinics. Early feedback suggests that clinics are supportive of this new model, and we think it provides a robust assessment method. Alongside we have introduced a revised Compliance and Enforcement Policy which provides the basis for a more consistent and transparent regulatory regime.

Fertility treatment is almost unique in healthcare in the UK in that the majority of patients have to self-fund their treatment. Hearing the voice of the patient is particularly important and that is why we have delivered on our commitment on getting more direct patient input into our work. We have rerun our National Patient Survey in 2021 which provides valuable information that will guide our core statutory activity and we have set up a new trial Patient Engagement Forum. In addition, we have continued to engage with the Competition and Markets Authority and the Advertising Standards Authority to ensure that we can collectively tackle the modern fertility market and improve the quality and reliability of information published by providers.

Other highlights from our statutory oversight include:

- We have updated our Code of Practice, General Directions and Licence Conditions to reflect changes in legislation and other information following EU exit;
- Dealt with a record number of requests for access to our Register from donor conceived people (what we term Opening the Register requests);
- Issued all licences for treatment and research on time;
- Received and responded to 76 formal complaints against clinics and almost 1500 incidents were reported to the HFEA.

Our work to publish high quality statistical and policy reports is a key component of our strategy. We have delivered a number of publications that have gained national coverage, including our State of Fertility Sector report in November 2021, our latest report on multiple births in February 2022 - which shows a continuation in the fall of multiple births to a national average of 6% (down from around 28% in the mid-1990s) - and our Ethnic Diversity in Fertility Treatment report, which made clear for the first time the stark differences in outcomes for some ethnic groups.

Our new data submission system launched during this business year. Deployment was in two phases: first to those clinics that use PRISM direct, and second to those clinics that interface with PRISM through their third-party electronic patient record systems (EPRS). The majority of our clinics have completed the transition with most expected to be migrated and up to date with statutory submissions by the end of Q1 2022/23. This will result in a saving to both the HFEA and clinics and should mean that, in time, patients have access to more up to date information to help them make more informed choices about their treatment options.

As we move forward in to 2022/23 our strategic vision (*'regulating for excellence: shaping the future of fertility care and treatment'*) will be underpinned by the continuation of the work above and the progress we make in embedding and benefitting from our new systems. There are also key changes to legislation and services that will have a significant impact on our resources over the coming year and into the medium term. This is why we sought approval for our first fee increase in 6 years, to meet the resource pressures that follow from the Board's strategic ambitions and to ensure we met our statutory responsibilities. Of particular note in the next 12 months:

- The complex rules around the storage of gametes and embryos have long been a source of contention and that complexity has led to clinics making errors, some of which require resolution in the courts. The decision by the Government to amend those rules is very welcome, although it has required an enormous amount of work for us to be ready for the law change on 1 July 2022.
- The decision by Parliament in 2005 to remove donor anonymity means that from autumn 2023 onwards, when the people born from donor treatment reach the age of 18, we can expect to see a significant increase in applications for identifying information held on our Register. This is not a new responsibility for us, but the change in the law will bring a new challenge of scale and the sensitivity of the information means that we will require new ways of working and new systems to manage caseloads

As ever we would be unable to achieve what we have this year, or be ready for the challenges 2022/23 will bring us, without the commitment of our dedicated Staff and Board. I would like to thank them all for the commitment, flexibility and sheer amount of work done in 2021/22. I am confident that we will keep the momentum we have gained through the coming year and move forward in delivering our ambitious strategy for patients and all stakeholders in the UK fertility sector.

Peter Thompson
Chief Executive
Accounting Officer

Performance Report

Overview

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.

Delivery in 2021/22

Overview

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

Delivery of the 2021-2022 business plan

The best care

Following changes to our inspection methodology introduced during Covid, we have continued to use a risk based regulatory approach combining on-site inspection (as required by the Act) and detailed desk-based assessments. 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 statistical report on multiple births 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 offered to patients 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 with other ALBs and health regulators, so as to address issues that require 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 ensured 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 began 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)[1], from around 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 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 to ensure that licensed clinics follow consumer protection law and advertise in clear and fair manner. We welcomed their new guidance and enforcement notice for fertility clinics in May 2021 and issued a joint letter to clinics drawing the guidance to their attention.

Shaping the future

We handled a significant number of Opening the Register[2] requests, following an earlier pause to the service, and have now begun a review of the operational arrangements for this work, to ensure that we are set up to deliver effectively into the future when the removal of anonymity takes effect in late 2023. 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 planned to extend the storage limit for frozen eggs, sperm, and embryos, bringing the law in line with advances in science, changes in modern society and individuals' reproductive choices. This will allow patients more time to make important decisions about family planning. In January 2022 we issued a briefing on the proposed amendment to the

[1] Choose a Facility Clinic (CaFC) is the tool that publishes comparable information about all fertility clinics in the UK.

[2] Opening the Register (OTR) is applications by donor-conceived individuals, donors and parents for Register information.

Health and Care Bill, and we worked hard 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 came into force on 1 July 2022 and 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.

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 continue in 2022/23.

At the end of the business year we welcomed seven new members to the Authority. 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.

Risks as at 31 March 2022

The main risks we face that, should they occur, would have the greatest material effect on the functioning of the HFEA as a whole are set out below.

By considering such risks, we can assess the continuing viability of our strategy and business plan against changes in circumstance and make adjustments when necessary. This does not mean we expect the risks to materialise – instead, it indicates that these are areas of risk of which we need to be aware and to consider our response to in order to perform our role effectively.

Further information on our approach to managing strategic risks and our assessment can be found in the governance statement.

Risk	Key risks and issues
Regulatory framework	This is the risk that our regulatory framework in which we operate is overtaken by developments and becomes not fit for purpose. As a regulator, we are by nature removed from the care and developments being offered in clinics and must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research are safe and ethical. The result of not having an effective regulatory framework could be significant. The worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way.

Information provision	There is a risk that the HFEA becomes an ineffective information provider, jeopardising our ability to improve quality of care and make the right information available to people. Information provision is a key part of our statutory duties and is fundamental to us being able to regulate effectively. We provide information to the public, patients, partners, donors, the donor conceived, their families and clinics alike. If we are not seen as relevant then we risk our information not being used, which in turn may affect the quality of care, outcomes, and options available to those involved in treatment.
Positioning and influencing	There is a risk that we do not position ourselves effectively and so cannot influence and regulate optimally for current and future needs. This risk is about us being able to influence effectively to achieve our strategic aims. If we do not ensure we are well placed to do this, we may not be involved in key debates and developments, and our strategic impact may be limited.
Financial viability	There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims. The in-year income position remains uncertain as actual activity data has not been available since August 2021 when clinics began the move to the HFEA's new reporting system, PRISM. Invoices have been raised and issued to clinics based on historic activity in previous years and a full reconciliation will be undertaken once clinics have entered backlog data and are submitting data in line with HFEA requirements.
Capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps threatening delivery of the strategy or our statutory work. This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity. There are also links with organisational change (such as hybrid working or the advent of PRISM), and risk elements that were formerly captured under a separate risk, OM1, which has now been discontinued, have been added to this risk accordingly.
Cyber security	There is a risk that the HFEA is subject to a cyber-attack, resulting in data or sensitive information being compromised, or IT services being unavailable. Cyber-attacks and threats are inherently likely. Our approach to handling these risks effectively includes ensuring we: • have an accurate awareness of our exposure to cyber risk • have the right capability and resource to handle it • undertake independent review and testing • are effectively prepared for a cyber security incident • have external connections in place to learn from others. We continue to assess and review the level of national cyber security risk and act as necessary to ensure our security controls are robust and are working effectively.

Business Continuity Coronavirus	There is a risk that we are unable to undertake our statutory functions and strategic delivery because of the impact of the Covid-19 Coronavirus. Risk management of these risk causes has been our organisational priority since the beginning of the pandemic. All staff were working from home (and returned to the office at least one day per week, from October 2021, followed by a return to working from home in December 2021 and January 2022 as Government guidelines required). We remain able to operate on either basis. A strategy to manage inspections is in place. Communications to the sector and patients have been in place throughout and are ongoing as needed. We would revise our plans as circumstances change, as is possible in the autumn and winter.
Legal challenge	There is a risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates. We accept that in a controversial area of public policy, the HFEA and its decision-making will be legally challenged. Our Act and related regulations are complex, and aspects are open to interpretation, sometimes leading to challenge.
Leadership capability	This risk relates to loss of senior leadership (whether at Board or Management level) leading to a loss of knowledge and capability which may impact formal decision-making and strategic delivery. This risk reflects both the risks related to Board and senior executive leadership. Although the causes and impacts are different, many of the mitigations are similar, and both would have an impact on the organisation’s external engagement and potentially strategic delivery.

Going concern

The HFEA derives the majority of its income (c.80%) from licence fees charged to clinics undertaking fertility treatments. These fees are activity driven, with each IVF or Donor Insemination cycle attracting a fee of £80 (£85 from 1 April 2022) or £37.50, respectively.

Our reserves are such that operations can be maintained for a period of 6 months. We have agreed our Grant in Aid funding for the 2022/23 financial year to ensure the HFEA can fulfil its regulatory remit. In addition, the HFEA will be undertaking a review of its licence fee model during 2022/23 to ensure that it can recover the cost of regulation from the sector in future years.

We have agreed our budget for the 2022/23 year and have confirmation of our Grant in Aid from the Department of Health and Social Care.

There is no expectation that our services will not continue or that the organisation is subject to any review that may result in the HFEA being abolished or subsumed. In light of this position, we consider the use of the going concern basis of accounting remains appropriate, as there are no material uncertainties related to events or conditions that may cast significant doubt about the ability of the organisation to continue as a going concern.

Based on the above, the Board has reasonable expectation that it has adequate resources to continue in operational existence for a period of at least 12 months from the date the financial statements are authorised for issue. For this reason, the Authority and the Accounting Officer continue to adopt the going concern basis for preparing the financial statements.

Performance analysis

Measuring performance

Each year, we agree a business plan with the Department for Health and Social Care (DHSC our sponsor department) that includes strategic aims, high level objectives and key performance indicators covering delivery of our strategic plan. We record performance against key performance indicators monthly and review achievement and action needed at the Corporate Management Group (CMG) meeting. A performance report is made to the Authority every two months and DHSC every quarter.

Analysis of performance in 2021/22

Performance indicators (KPI)	Target 2021/22	KPI	Target 2020/21	KPI
A: Compliance				
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre	70 working days	**64 working days**	70 working days	49 working days
B: Communication and information				
Opening the Register requests responded to within 20 working days	100%	**Not measured**[3]	100%	Not measured
Requests for contributions to Parliamentary questions (PQs) answered within DHSC deadlines.	100%	**100% (24/24 PQs within deadline)**	100%	100% (8/8 PQs within deadline)
C: Corporate				
Staff sickness absence rate (%)	No more than 2.5%	**3.6%**[4]	No more than 2.5%	1.6%
Cash and bank balance at end of the year	Continue to move towards agreed minimum cash reserve of £1.52m	**£3.69m (increased**[5] **from £3.29m in 20/21)**	Continue to move towards agreed minimum cash reserve of £1.52m	£3.29m (increased from £2.46m at the end of 19/20)
Percentage of invoices paid within 10 calendar days	70% paid within 10 days	**92%**	70% paid within 10 days	85%
Debts collected within 40 days (previously 60) calendar days	85%	**85%**	85%	79%[6]

[3] Opening the Register (OTR) was paused due to the pandemic and clinics ability to respond to enquiries. This continued in 2021/22 as backlog was being cleared. A review of the service and process is being conducted in 2022/23

[4] Increase due to two staff absent for over 10 days

[5] The increase in the cash balance is due to reductions in activities such as inspections, increase in virtual meetings

[6] The target was changed to 40 days at the start of the year to bring it in line with credit control process. The target was not achieved due to clinics partial closure at the start of the year and the slow return to full activity

Financial review

Our accounts consist of primary statements (providing summary information about our income and expenditure in the year, our assets, and liabilities at the end of the year, and how we have managed our cashflows) and detailed notes to these statements. These accounts have been prepared based on the standards set out in the Government Financial Reporting Manual (FReM) to give a true and fair view.

Summary position as at 31 March 2022

	2021/22	2020/21
	£'000s	£'000s
Expenditure		
Staff costs	4,820	4,958
General administrative costs	1,948	1,832
Total expenditure[7]	**6,768**	6,790

Income		
Revenue from contracts with customers	5,581	4,281
Other income	111	149
Total income[8]	**5,692**	4,430

Net (expenditure)/income before interest and tax	**(1,076)**	(2,360)

Our financial results are included in the accounts on pages 57 to 76 and shows the net operating expenditure before Finance Income (bank interest) and corporation tax. This decrease from last year is largely due to the increase in our income.

In 2020/21 our staff costs were higher by £138k (2.8%) where more posts were recruited to during the pandemic. Also our temporary staff costs were lower (£559k compared to £674k in 2020/21). The temporary staff costs relate to PRISM (also known as Digital Projects). Expenditure on IT maintenance and support costs have been incurred in the 2021/22 business year totalling £295,217 and are included in running costs.

The DHSC allocated grant-in-aid towards the financing of resource expenditure of £1,356,000, (2020/21 £3,338,000 of which £2,238,000 was drawn down), plus funding for the increase in employers pension contributions £100,000 and funding for project work of £158,000. Capital expenditure funding of £100,000 (2020/21: £100,000) was also allocated. We also received non-cash income allocation (Ring-fenced

[7] This figure differs from the SoCNE due to rounding

[8] This does not include interest income

RDEL[9]) of £515,777 (2020/21 £510,121) to cover non-cash costs of depreciation and amortisation. Below is a summary of our overall position; taking into account the resource financing, interest, and tax, we had a surplus of £279,611 (2020/21 £558,692).

	2021/22[9]	2020/21[10]
Net (expenditure)/income before interest and tax	**(1,076)**	(2,360)
Resource financing[11]	**1,356**	2,918
Finance Income	**2**	1
Net income/(expenditure)	**282**	559
Taxation[12]	**(3)**	(0)
Surplus for the year[9]	**279**	559

Other areas have remained largely the same, with an increase in our total audit fees 11.7% (£9k).

Cash reserves have increased by £399k (12%), (£826k, 34% 2020/21).

Supplier payments

We aim to pay all undisputed invoices in accordance with suppliers' terms of payment, which are usually within 30 days. During the financial year, we settled 100% of all invoices received within 30 days with a value of £1,790,678 (2020/21 99% with a value of £2,111,105). We are committed to the Better Payment Practice Code (BPPC) and its target of 95% of payments made within 30 days.

Organisational structure and establishment

Our staff complement is 76 (from 1 April 2022). We have 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.

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[9] Ring-fenced RDEL is Resource Departmental Expenditure Limit and comprises depreciation, amortisation and impairment. It is not cash, but cover provided by the DHSC against this type of expenditure.

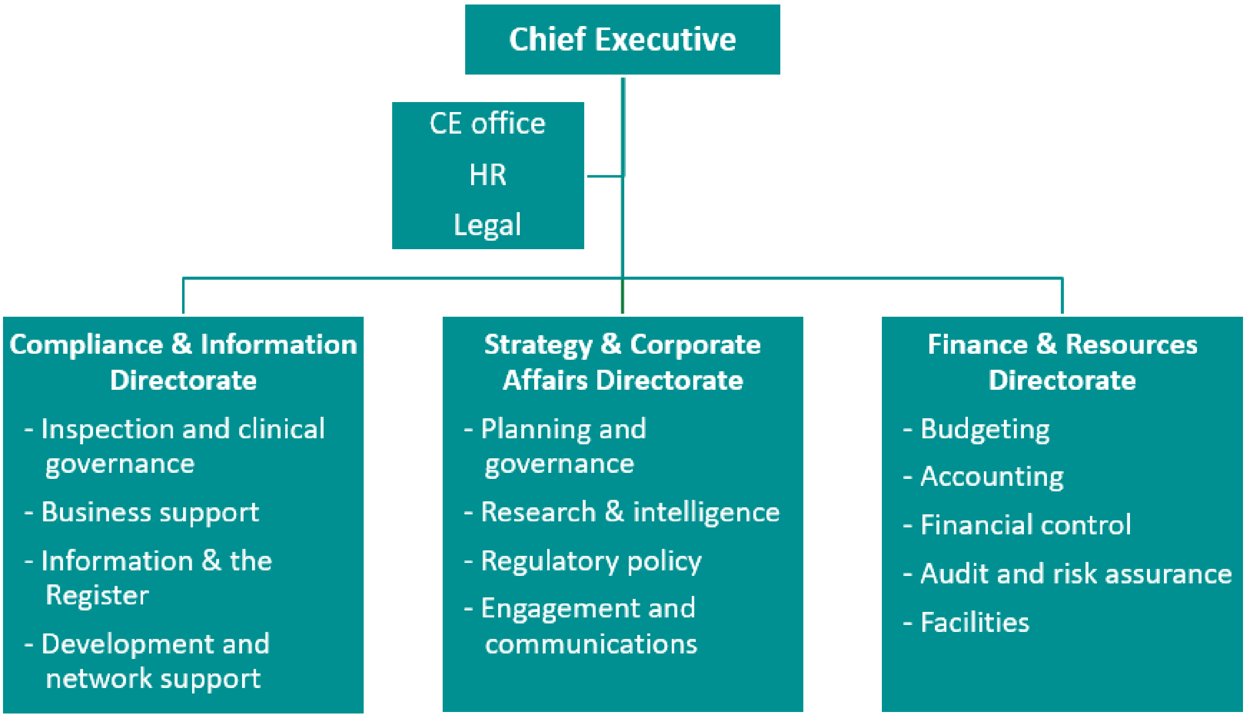
[10] Figures in these columns may vary to the accounts due to rounding

[11] Grant in aid is treated as financing within the statutory accounts and it is a requirement to report it this way. The Ring-fenced RDEL is an internal feature of government accounting.

[12] Taxation for 2020/21 is £175 for Corporation Tax.

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.



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Our people objectives for 2020 – 2024

Our people objectives as set out below support us in the delivery of our business goals

- Attract and retain a diverse and high performing workforce
- Develop and support our people so that they can deliver to a high standard, fulfil their potential and work towards achieving their career aspirations
- Improve leadership capability
- Build a culture and healthy working environment that promotes collaboration and innovation
- Create an agile workforce that is able to support the delivery of our strategic goals.

Recruitment

All appointments are made in accordance with our recruitment and selection policy so that they are made on the basis of merit and in accordance with equal opportunities.

Learning and development

We actively promote the development of our staff and encourage them to take five days a year learning. We subscribe to Civil Service Learning which provides courses and resources for developing skills to all UK civil servants. This supports a blended approach which is convenient and cost-effective. Individual needs are set out in personal development plans and are met through appropriate means, including e-learning, face-to-face learning and taking part in projects, coaching and job shadowing.

The re-allocation of a portion of our training budget, giving more flexibility to Heads of Department to authorise a range of types of learning, has continued throughout 2021/22 and has proven to be a welcome and successful change.

Staff development

We continue to encourage staff development offering the following courses and workshops for all staff:

- Freedom of Information (FOI)
- Cyber and Information Security
- Business Continuity
- Essential Management skills
- Budget management

We also continue to provide 'lunch and learn' sessions for all staff to attend, and cover topics such as: use of survey monkey effectively; patient engagement forum; fertility trends and multiple births.

Staff engagement and wellbeing

We promote staff engagement through various channels including regular all-staff and team meetings, including our annual staff conference. We have an intranet that is extensively used to keep our staff abreast of any newsworthy items, whether that be the latest courses on offer or, as recently, guidance and helpful tips for remote working during the COVID-19 pandemic and a wellbeing area of advice.

Staff Survey

In October 2021, we conducted our annual staff survey. The response rate was 72% (2020/21 83%), compared to the sector average of 70%. Our engagement score i.e., the extent to which staff feel happy at work was 80% (2020/21, 77%) compared to the average for our public sector comparators of 75%. This is an improvement on last year. The positive result demonstrating that the work around staff wellbeing throughout the year has struck a chord with staff.

Disabled employees

We have long achieved ✓✓ 'positive about disabled people' disability symbol status. We have a specific policy of inviting to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including making any reasonable adjustments to the workplace or work processes and having advice available through the occupational health service.

Ways of Working

This year has seen a move to a new more flexible set of working arrangements. A majority of our staff have adopted a hybrid way of working, spending some of the week in the office and the remainder working from home. A minority of staff have opted for a new home-worker contract where they spend the majority of the working time at home. This change has drawn a positive response which has also been helped by using in-person all-staff away-days to ensure that we can maintain our culture and ways of working.

We have taken the opportunity to utilise desk-space within other areas of the floor plate when our own areas have become full. This has also encouraged staff to engage with staff from the other Arm's Length Bodies that share the space.

Equality Act 2010 – equality and diversity

The HFEA is committed to promoting equality and diversity and promoting a culture that actively values difference. We recognise that people from different backgrounds and experiences can bring valuable insights to the workplace and enhance the way we work. We aim to be an inclusive organisation, where diversity is valued, respected, and built upon, with an ability to recruit and retain a diverse workforce that reflects the communities we serve.

We are also committed to compliance with relevant equality legislation, the Equality Act 2010, codes of practice and best practice guidance.

We aim to proactively tackle discrimination or disadvantage to ensure that no individual or group is directly or indirectly discriminated against for any reason with regard to employment or accessing our services.

As an employer committed to diversity and equality, we recognise our success depends on creating a working environment which supports the diverse make-up of our staff with supporting policies and procedures to create a framework of assistance.

Our gender breakdown at 31 March 2022, of Authority members, permanent and seconded staff, is as follows:

	Male	Female	Total
Board members	5	9	14
Senior Management Team (SMT)	2	2	4
All staff (including SMT, excluding Authority)	10	59	**69**[13]

Social, community, sustainability, human rights, and environmental issues

We have entered into a Memorandum of Terms of Occupation (MOTO) with the Department of Health and Social Care at 2 Redman Place in Stratford, London. We collaborate with the other ALBs who share our floor-plate, in particular the National Institute for Health and Care Excellence (NICE) and the Care Quality Commission (CQC) on a number of issues, including health and safety services. We follow the British Council's lead on fire evacuation procedures and fire warden liaison.

[13] (2020/21 Male 14/Female 55)

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges. 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. All staff are enabled to work from home, reducing the impact on the environment through less travelling.

Our multi-function devices (for secure printing, scanning, and photocopying) are pre-set to print on both sides of the paper.

We do not directly procure energy or other items with significant environmental impacts. These contracts are charged through the agreed MOTO with the DHSC.

We are aware of the green agenda in relation to procurement and we use the Crown Commercial Service and other frameworks which have sustainability factored in.

We pride ourselves on being a good employer, we have a range of practices and policies in place to protect the human rights of our staff, including policies on bullying, harassment and victimisation, grievance, and whistleblowing.

We manage our corporate responsibility by providing processes and policies which include but are not limited to policies on diversity; protecting human rights, equal opportunities, dignity at work and anti-fraud including anti-bribery and corruption.

Under the Greening Government Commitments, we are exempt due to our occupancy of less than $500m^2$ of floor area.

Peter Thompson
Chief Executive
Accounting Officer **11 October 2022**

Accountability Report

Corporate governance report

Directors' report

Our board (the Authority)

Our board is made up of 14 members appointed through an open public process, although for part of the year we conducted our activities with less than this number. Below are details of the current and out-going Authority members during the 2021/22 financial year. Biographies for each can be found on our website https://www.hfea.gov.uk/about-us/our-people/meet-our-authority-members/

Authority member	Appointment start date	Appointment end date[14]
Julia Chain (Chair)	1 April 2021	31 March 2024
Catharine Seddon	18 January 2021	17 January 2024
Prof Jonathan Herring	18 July 2018	17 July 2024 (re-appointed 27 July 2021)
Prof Gudrun Moore	18 July 2018	17 July 2024 (re-appointed 27 July 2021)
Tim Child	18 January 2021	17 January 2024
Jason Kasraie	18 January 2021	17 January 2024
Alison Marsden	1 April 2021	31 March 2024
Ruth Wilde	1 January 2016	31 March 2022 (term extended 15 November 2021)
Anita Bharucha	30 April 2015	31 December 2021 (term ended)
Margaret Gilmore	1 April 2015	31 March 2022 (term extended 15 November 2021)
Prof Emma Cave	1 October 2018	30 September 2021 (term ended)
Yacoub Khalaf	30 April 2016	31 December 2021 (term ended)
Rev Ermal Kirby	1 May 2019	30 April 2022 (term ends)
Anne Lampe	1 February 2016	30 April 2022 (term extended 15 November 2021)

[14] The 7 Authority Members whose terms ended prior to 31 March 2022 were replaced in April and May 2022.

Senior Management Team

Our Senior Management Team are set out below.

Peter Thompson	**Chief Executive**
Richard Sydee	**Director of Resources**
Clare Ettinghausen	**Director of Strategy and Corporate Affairs**
Rachel Cutting	**Director of Compliance and Information**

Interests of Authority members and senior staff

We maintain a register of interests which is available on our website at https://www.hfea.gov.uk/about-us/our-people/meet-our-authority-members/

Pensions

Pension benefits are mainly provided by the Principal Civil Service Pension Scheme (PCSPS). We recognise the contributions payable for the year. Full details of the pension scheme are included in the Remuneration and Staff Report.

Data incidents

Arrangements for data security and any personal data-related incidents are set out in the annual governance statement.

Our auditors

The Comptroller and Auditor General is appointed by statute to audit our financial statements.
The fees of the National Audit Office are set out in note three to the accounts. No fees were incurred for non-audit work.

Disclosure of information to our auditors

I have taken all the necessary steps to make myself aware of any relevant audit information, and to establish that our auditors, the National Audit Office (NAO), are aware of that information. So far as I and the other directors are aware, there is no relevant audit information of which the NAO is unaware.

Statement of the Authority and Accounting Officer's responsibilities

The statement of accounts is prepared in a form directed by the Secretary of State for Health in the 2021 Framework Agreement, in accordance with section six of the 1990 Act (as amended).

The accounts are prepared on an accruals basis and must show a true and fair view of our state of affairs at the year-end, our net expenditure, changes in taxpayers' equity and cash flow for the financial year.

In preparing the accounts, the Authority and the Accounting Officer are required to comply with the requirements of the Department of Health and Social Care Group Accounting Manual, and in particular to:

- observe the accounts directions issued by the Secretary of State, including the relevant accounting and disclosure requirements and apply suitable accounting policies on a consistent basis
- make judgements and estimates on a reasonable basis
- state whether applicable accounting standards, as set out in the Department of Health and Social Care Group Accounting Manual, have been followed and disclose and explain any material departures in the financial statements, and
- prepare the financial statements on a going concern basis;

The Accounting Officer of the Department of Health and Social Care (DHSC) has designated me, as the Chief Executive as the Accounting Officer for the organisation. My responsibilities include responsibility for the propriety and regularity of the public finances for which I am answerable, for keeping proper records and for safeguarding our assets, as set out in 'Managing public money' published by the HM Treasury.

I confirm that the annual report and accounts as a whole is fair, balanced, and understandable and take personal responsibility for the annual report and accounts and the judgements required for determining that it is fair, balanced, and understandable.

I confirm that, as far as I am aware, there is no relevant audit information of which the HFEA's auditors are unaware, and I have taken all the steps that I ought to have taken to make myself aware of any relevant audit information and to establish that the entity's auditors are aware of that information.

Accounts direction

The statement of accounts is prepared in a form directed by the Secretary of State for Health in 2021 Framework Agreement, in accordance with section six of the 1990 Act (as amended).

Authority statement

Our Senior Management Team (SMT), the Audit and Governance Committee and the Authority have reviewed the annual report and accounts. I confirm that the annual report and accounts are fair, complete, and understandable and provide the information necessary for stakeholders to assess our performance.

Governance statement

This statement sets out our governance and control framework during 2021/22. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the HFEA's resources in 2021/22.

Governance framework

Our governance framework is set out in the HFE Act 1990 (as amended) and its approved standing orders.

Our board (the Authority)

The Authority overseas the strategic direction and delivery of objectives and ensures that the core purpose and values of the organisation are upheld. The Authority is led by the Chair and comprises Non-

Executive Directors (NEDs). The Board is advised by the Executive Directors who are the Chief Executive, Director of Finance and Resources, Director of Strategy and Corporate Affairs and Director of Compliance and Information.

Details of Authority members and attendance are below.

Board members	Number of meetings attended	Total number of Meetings 2021/22
Julia Chain (Chair)	6	6
Catharine Seddon	6	6
Yacoub Khalaf	4	4
Margaret Gilmore	6	6
Anita Bharucha	4	4
Anne Lampe	4	6
Ruth Wilde	5	6
Professor Jonathan Herring	6	6
Professor Gudrun Moore	6	6
Professor Emma Cave	3	3
Rev Ermal Kirby	5	6
Jason Kasraie	6	6
Tim Child	6	6
Alison Marsden	6	6

The Board meets 6 times a year and these meetings are open to the public and an audio recording of the meetings are made available on our website. The Board has also held a number of workshops before its public meetings, which are used to discuss future strategy and other policy matters.

The papers on which the Board (and its committees) rely on are subject to a rigorous internal assurance process, overseen by the relevant member of the SMT. Feedback from members of the Board, and the annual review of committees, suggest that the papers are of high quality and accuracy.

Statutory and standing committees

The Authority has several committees to which it delegates a number of its functions. The following table sets out each committee alongside their frequency and attendance details.

Committee	Membership at 31 March 2022	Number of meetings 2021/22	Attendance rate
Appointments Committee	3	0	N/a
Audit and Governance Committee	4	4	97%

Executive Licensing Panel	3	12	100%
Licence Committee	4	5	81%
Register Research Panel	10	2	95%
Remuneration Committee	3	0	N/a
Statutory Approvals Committee	7	12	73%
Scientific and Clinical Advances Advisory Committee	16	2	100%

The Executive

The Board and its committees are supported in their work by the Executive, led by the Chief Executive (the Authority's Accounting Officer) and three directors, collectively the Senior Management Team (SMT) as detailed at page 24.

The SMT are the decision-making body of the HFEA responsible for leading and delivery of the HFEA's strategic aims and objectives. The SMT are supported by ten Heads of Service and collectively are responsible for the management of day to day corporate business and are known as the Corporate Management Group (CMG).

The SMT and Corporate Management Group (CMG) oversee the delivery of our business plan. CMG is chaired by the Chief Executive and attended by the directors and heads of department and meets once a month as a minimum. It also considers strategic risks before the Audit and Governance Committee (see below).

The Executive's Project Assurance Group oversees individual projects and ensures that suitable controls are in place. Risk assessment and management are substantial aspects of this oversight arrangement, with the project manager and sometimes also the project sponsor (usually a director) reporting to the Programme Board at regular intervals. In turn, the Programme Board reports to CMG every month, with a highlight report covering each live project. The HFEA's ongoing Digital project; PRISM, is overseen by a separate programme board, which meets weekly and is attended by the Chief Executive and Director of Compliance and Information.

Corporate governance

We have a framework agreement with the DHSC which defines the critical elements of our relationship with them. The way in which we work with the DHSC, and how we both discharge our accountability responsibilities effectively, is outlined in the agreement. The Chair and Chief Executive meet the Senior Departmental Sponsor (SDS) at the DHSC for a formal annual accountability review and informally throughout the year. In addition, the SMT meets other DHSC officials at quarterly intervals, and has regular contact as issues require. Representatives from the DHSC are also present as observers at Board meetings of the Authority and at the Audit and Governance Committee.

The operational objectives that help us deliver our corporate strategy are set out in the annual business plan. Drafts of this document are shared with the DHSC in advance and quarterly monitoring information is also submitted to them. Along with meetings with the SDS and other officials at the DHSC, this provides assurance that the delivery of objectives is on track.

Our system of corporate governance complies with the requirements of the ‘Corporate governance in central Government departments: code of good practice,’ in so far as they relate to ALBs. It is designed to ensure that sufficient oversight of operational matters is held by our Authority and Audit and Governance Committee, while allowing for clear accountability and internal control systems at Executive level.

Effectiveness and performance

We have achieved our core statutory functions of licensing and regulating fertility clinics, maintaining a register of treatments and a Code of Practice, and increasing and informing choice for patients. In common with all public sector organisations, we have done so under continued resource pressure on our staff.

We look to improve and make more efficient the way in which we engage with significant matters of policy and operational delivery. One of the ways in which the Authority makes better use of its time is through ‘workshop’ sessions before full Authority meetings, where the Authority has the opportunity to delve into issues that have arisen or are on the horizon. This way of working makes more efficient and productive use of member and executive time and allows better informed decision-making.

This, along with the annual review of committee effectiveness and consequent changes to governance and standing orders, gives assurance that the exercise of our statutory functions is delegated appropriately and legally, adhering to the recommendations outlined in the Harris review.

Members of the Authority and the Chief Executive have their performance assessed by the Chair (or, in the case of the Chair, by the SDS). No issues of performance have been raised and as Chief Executive I am assured that the arrangements in place for internal control are robust and fit for purpose.

Quality of data used by the Board

The papers received by the Board have been of high quality and are subject to a rigorous internal assurance process overseen by the relevant member of SMT. Feedback from members of the Board, and the annual review of committees, validates this. Meetings took place virtually and in-person and were effective. Challenge and discussion were encouraged.

The governance team provided a comprehensive secretariat service to the Board and committees to ensure the effective and efficient administration of the Board and its activities.

Annual reviews of committee effectiveness

As is good practice, every year our committees undertake a review of their effectiveness. The feedback from committee members is used as a means of improvement against indicators within our framework. In general, the feedback from the committees was positive, with defensible, evidenced decisions being made on the basis of robust paperwork.

Highlights of Authority and committee reports

Key areas of business considered by the Board, in addition to standing items over the reporting period such as performance reporting (including financial performance) and risk management, include:

- Regular updates on the progress of PRISM go-live were received by the Board;
- COVID-19 – reports were provided on the sector and the number of private clinics compared to NHS that were working at higher activity levels. Delays in patient referrals due to the number seeking fertility treatment in the UK increasing as travelling abroad was restricted.;
- Raising awareness of the HFEA for patients in order that patients understood what we do;

- Progress against actions detailed within the report on ethnic diversity in fertility published in March 2021;
- Fertility trends – frozen embryo transfers had increased over time, variations in IVF funding and multiple birth rates in patients of black ethnicities which are high;
- Licence fee review project – further work undertaken on modelling the potential impact of options agreed previously and potential increase in fees;
- Transparency and Regulation – our publications scheme and the collaboration with the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) that may result in changes to how and what we publish;
- Development of the new approach to inspections – the new methodology has been audited by our internal auditors and a 'substantial' rating received;
- Updates to our inspections process in particular desk-based assessment and the need to revise this methodology as it currently is labour intensive;
- Opening the Register (OTR) – the potential risks from increased applications and backlog and its mitigations which included recruiting additional staff. The future of OTR service from 2023 when anonymity is lifted;
- Gamete and embryo storage – changes to the storage and consent regime are being considered by Parliament and the work being undertaken is a priority.

Audit and Governance Committee

The primary role of the AGC, which reports to the Authority's Board, is to conclude upon the adequacy and effective operation of the organisation's overall internal control system. It is the responsibility of the executive to agree and implement this. The AGC provides independent monitoring and scrutiny of the processes implemented in relation to governance, risk, and internal control. Its work focuses on the framework of risks, controls and related assurances that underpin delivery of our objectives. The AGC has a crucial function in reviewing our external reporting disclosures in relation to finance and internal control, including the annual report and accounts, this statement, and other required declarations.

The AGC's membership is drawn from independent non-executive members of the Board and co-opted members appointed by the AGC for their particular skills and expertise. It is supported by the work programmes of Internal and external audit, which ensures independence from executive and operational management. At the invitation of the Chair, the Chief Executive, Director of Finance and Resources, the Director of Strategy and Corporate Affairs, the Director of Compliance and Information, the Head of Internal Audit, the external auditor, and representatives of the DHSC sponsorship team routinely attend AGC meetings. The Governance Manager attends in the function of Secretary to the Committee.

The AGC met in full on four occasions in the 2021/22 business year, it approved this Governance statement on 28 June 2022. The Chair of AGC is also a member of the Board and reports key issues to the latter after each AGC meeting.

The committee has received reports from management and internal audit in a range of areas.

In 2021/22 the internal audit plan covered five business areas. All five reviews were completed within the 2021/22 financial year. The areas covered and the assurance ratings given are set out below:

Audit	Areas reviewed	Assurance rating
Staff Wellbeing	Assessment of the adequacy and effectiveness of the processes in place	Moderate

	to support employee wellbeing within the HFEA	
Operational Risk Management	Assess the adequacy of the overall operational risk management arrangements within the HFEA	Limited
Financial Management: Budgeting	A review of the adequacy and effectiveness of the budget-setting and ongoing budget management arrangements	Moderate
Effectiveness of Inspection Processes	Follows the 20/21 audit into the Development of the Virtual Inspection Process. The assessment of the effectiveness of the inspection arrangements once the virtual inspections have been embedded and considers the effectiveness of the compliance and enforcement arrangements in place	Substantial
Release of Data	Review of the adequacy of the process and procedures in place to ensure that the Authority complies with its legislative obligations with regards publication of information and data.	Moderate

Areas of particular focus for the Audit and Governance Committee in 2021/22 were:

- Progress on the go-live of PRISM and in particular the readiness of key Electronic Patient Record System suppliers (EPRS) deployment by the deadline which was December 2021. PRISM went live on 14 September; lessons learned report was tabled in December;
- Received bi-annual HR report where the focus was upon the results of the annual staff survey and its outcomes; staff wellbeing was also a focus due to the low score within the survey in conjuction with the results of a recent audit which received a moderate rating;
- Data Security & Protection (DSP) Toolkit – an audit conducted in 2020/21 business year received an unsatisfactory rating, the committee received updates as to how the recommendations from the audit were being addressed and progress towards re-submission in June 2022;
- Deep dive into the Compliance and Information Directorate focusing on staff structure, the Inspection regime which includes a mixture of on site and desk-based assessments
- The strategic risk register which is reviewed at every meeting;
- The committee reviewed the outcomes from internal audit reports as above.
- In addition to the full meetings the committee met an additional 5 times to discuss progress with the HFEA's PRISM programme, providing oversight on progress on behalf of the Board and where necessary endorsing decisions and plans for launch.

Other committees

Our Licence Committee, Statutory Approvals Committee (SAC), and the Executive Licensing Panel (ELP) have handled the core business of considering licence applications and issues, applications for embryo testing and applications for importing or exporting embryos, sperm, and eggs.

The levels of activity in these committees continue to be significant, in particular, the Statutory Approvals Committee has seen increases in Pre-implantation genetic diagnosis (PGD) applications and a considerable number of complex and challenging cases; tricky ethical and medical issues. There has also been an increase in the number of special direction applications. This committee welcomed two new members at the start of the business year.

The Scientific and Clinical Advances Advisory Committee (SCAAC) has provided high-quality advice and exercised its delegated functions appropriately. Areas of focus for this committee included monitoring the effects of Covid on fertility assisted conception and early pregnancy;

The Appointments committee continues to consider matters pertaining to the appointment of external committee members and advisors; however they did not meet this year. The Remuneration committee considers human resources and remuneration, however, did not meet this business year due to restrictions on staff pay.

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Risk and capability

The Board determines the risk appetite and sets the culture of risk management with particular regard to new initiatives and emerging risks. The Board has ultimate responsibility for risk management with the HFEA including major decisions affecting the organisation's risk profile or exposure.

The risk management policy sets out HFEA's approach to risk management. It defines risk, outlines roles and responsibilities for risk management, and explains how risks are categorised, assessed, and escalated.

The policy outlines HFEA's risk appetite – the extent to which we will tolerate known risks, in return for the benefits expected from a particular action or set of actions. With careful management and planning we aim to operate our programmes with a low level of risk. However, we may incur and tolerate some large risks, for example, because we operate in a regulatory environment we are often involved in legal cases and our decisions are open to legal challenge. This means that we are willing to accept a higher level of legal risk, as we have limited control over the number of legal cases we must deal with.

Our system of internal risk management gives assurance that the risks we face when exercising our statutory functions are managed appropriately and mitigated against proportionately. Risks are formally managed at several different levels, as follows:

- strategic risk register – capturing risks to the delivery of our strategy and business plan
- operational risk logs – capturing team level risks to functional delivery
- project/programme risk logs – capturing risks to successful project delivery
- internal incidents system – an adjunct to the risk system, which enables understanding of, and corporate learning from, internal adverse events.

The risk registers are constantly updated, and risks are continually assessed in the context of HFEA's current strategy and external events. The Strategic Risk Register was revised in 2020/21 to reflect the current strategy.

The senior management team formally reviews the strategic risk register each month, and before its consideration by the Audit and Governance Committee and the Board, ensuring it remains relevant. This review takes account of the ongoing identification and evaluation of risks by directors and considers handling strategies and required policies to support the process of improving internal controls. In doing so the Directors consider the resources available, the complexity of the tasks, external factors that may impact on the HFEA’s work and the level of engagement required with partners and stakeholders.

The Audit and Governance Committee consider the strategic risk register at each meeting and the full board reviews it twice a year, Directors, in conjunction with their teams are responsible for ensuring risks in their directorate are identified, assessed, and captured in their own operational level risk registers, and the top risks are regularly shared at CMG risk meetings. This allows for the management of risk to be embedded in the organisation from the bottom up.

Projects are scrutinised by our Programme Board. Risk assessment and management are a substantial aspect of this oversight arrangement and the project manager (and sometimes also the project sponsor - usually a Director) must report to the Programme Board at monthly intervals. In turn, the Programme Board reports to CMG every month, with a highlight report outlining progress, risks, and issues for each live project.

Our system of internal risk management gives assurance that the risks we face when exercising our statutory functions are managed appropriately and mitigated against proportionately.

The latest internal audit of our Operational Risk Management delivered ‘limited’ assurance, with a summary of ‘There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective. This highlighted the issue that staff changes present. A plan to review our risk management process was presented to our Audit Committee in March will key workstreams taking place during 2022-23 that include a review of best practice guidance and other organisational approaches with reference to the revised Orange Book and risk improvement groups. A review of our operational risk management practices and identification and mitigation of weaknesses in line with recommendations arising from the audit. During quarters two and three of the new business year, will see the design and implementation of a rolling improvement plan for operational risk management and a revision of our risk policy.

Regulatory risk

We also take a risk-based approach to the way we regulate the fertility sector, in order to ensure that our regulatory action is targeted and proportionate. Our risk-based assessment tool allows such an approach and (like all other processes we use in carrying out our functions) is subject to a rigorous quality assurance regime, in line with the Macpherson review recommendations.

The 2021/22 business year saw the clinics we licence resume fertility treatments, however, some restrictions on travel and social distancing were still in force which required us to continue with the hybrid of desk-based assessments and site visits where necessary.

We are mindful that there are still risks around staff entering clinics and travelling. These are being mitigated against by using a desk-based approach involving virtual technology to look at specific items, providing assurance to our inspection staff and where staff are on site ensuring they are appropriately protected.

There is a higher resource requirement for this new inspection process as it is embedded and a risk around extending licences which impacts on our inspection schedule causing bottlenecks. We are managing this by extending the two-yearly site visit rule for some clinics.

Assurance from both our inspectors and the clinics that this hybrid system is broadly supported. During this busy period of inspection where we continue to use desk-based analysis (DBA), we have sent questionnaires to centres who have gone through a DBA/virtual inspection to gather feedback. This feedback will help inform how inspections will be conducted once all restrictions have been lifted.

Risk assessment

The strategic risk register captures those risks with the potential to have a significant impact on the business and on whether we achieve the objectives set out in our strategy. Each risk is owned by a member of the senior management team (SMT). Risks are reviewed and reported on each month and included as a standing item on the SMT and AGC meeting agendas.

Other risks include but are not limited to legal challenges, staff capacity and capability, cyber security, positioning and influencing and information provision. Our ongoing mitigating activities are managed and monitored through the systems described earlier. Our robust governance and decision-making arrangements mitigate against the controllable elements of the risk of legal challenge. We continue to face capability risk that we manage through good staff engagement and our performance management process.

As of 31 March 2022, the HFEA risk register captured nine risks. Of these, seven risks were considered medium (i.e., with a score of between 6 and 10) and two high risks with scores above 10. The status of these risks are five were above tolerance, and four are below tolerance. Notable risks are discussed below.

Loss of senior leadership (whether at Board or Management level) leads to loss of knowledge and capability which may impact on formal decision-making and strategic delivery, with medium rating. This risk was added this year and reflects both the risks related to the Board and senior executive leadership. We experienced a significant number of Board Members' tenure ending and there was a delay in appointment. This impacts on our external engagement and potentially strategic delivery. Changes in Board capability and capacity may also impact our legal functions. We have now recruited seven new Board members to replace the three members whose terms have already ended and four whose terms will finish at the end of March. The impact of Board member turnover is around on-boarding which can take time and also affects quoracy of committees.

The second risk that has a high rating is the risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy or our strategic work. This risk was rated low at the start of the business year and has been increased. This risk and the controls are focused on organisational capability, rather than capacity, though there some linkages between capability and capacity. There are also links with organisational change (such as hybrid working or the advent of PRISM), and risk elements that were formerly captured under an old risk (Operating Model – now discontinued), have been include in this risk. We saw an increase in turnover during quarter three of this 2021/22 business year, and recruitment has become more challenging for several reasons one of which is the constraint on public sector pay and reward.

Another risk of note is the risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates. We accept that in a controversial area of public policy, the HFEA and its decision-making will be legally challenged. Our Act and related regulations are complex, and aspects are open to interpretation, sometimes leading to challenge. There are four fundamental sources of legal risk to the HFEA, the execution of compliance and licensing functions (decision making);the legal framework itself as new technologies and science emerge; policymaking approach/decisions; individual cases and the implementation of the law (often driven by the impact of the clinic actions on patients).

Legal challenge poses two key threats: that resources are substantially diverted and that the HFEA's reputation is negatively impacted by our participation in litigation.

Information management and security

As the holder of the statutory Register of fertility treatments, we take our responsibilities for information security most seriously and have a low tolerance for information risks. Keeping secure the information we hold, particularly sensitive personal patient data, is of the highest priority, and this principle will frame our approach to the implementation of our Digital Projects in the coming year.

We are mindful of the current landscape and the risks around data security, phishing, and the current war in Ukraine. We manage these risks within our strategic risk registers.

The unsatisfactory rating received for our DSPT audit is being managed through a program of work that commenced in quarter four of 2021/22. A further audit on our submission will be conducted in quarter one of the 2022/23 business year.

There were no data losses within the last year, and we continue to work hard to ensure that remains the case.

Whistleblowing arrangements

Our Public Interest Disclosure (Whistleblowing) policy sets out how any concerns can be raised by staff and what action would be taken. It aims to reassure staff that they should raise concerns openly and that there will be no repercussions if they raise concerns in good faith. The policy has been communicated to staff through line management and our intranet.

As well as line management and HR channels, staff can approach the NAO via their hotline, via post and Protect (formerly Public Concern at Work) for advice.

During the year, there have been no concerns raised under whistleblowing arrangements. Staff raise issues and make suggestions as part of day to day working in line with our culture.

Counter Fraud

During 2021/22, we continued to make submissions to the Cabinet Office in compliance with the Government Functional Standards for Counter Fraud (GovS013). In addition, risk assessments are carried out bi-annually and an action plan has been developed to address areas of weakness identified. Key actions taken to date include mandatory training on fraud awareness for all staff and the constant sharing of information on potential fraud activities. We also feed into the Cabinet Office Consolidated Data Requests (CDR) returns where we report on detected, prevented fraud and errors.

Functional standards

Functional standards have been mandated from the end of September 2021. The HFEA as an ALB is required to have plan in place to comply with each functional standard in a way that it meets our business needs. We are already working towards full compliance of the functional standards GovS 013: Counter Fraud. We are currently putting plans in place to become compliant against those functional standards that are relevant to the HFEA.

Internal incidents

Our Executive maintains an internal incident procedure, which ensures that any process failures are quickly and thoroughly investigated. This allows SMT to learn lessons and correct potential procedural failures. The system and associated documentation is reviewed annually to ensure it remains in line with our other documentation and overall brand. A recent internal audit raised some low-level recommendations that have been implemented to strengthen our processes and documentation.

Internal Audit

In 2021/22 Internal Audit has provided assurance over HFEA's core business activities with individual reviews performed across operational, financial, and other risk areas; all informed by the organisation's risk areas, risk assessment and our independent view on HFEA's risk profile

The Head of Internal Audit's opinion is based solely on the assessment of whether controls in place support the achievement of management's objectives as set out in the 2021/22 Internal Audit Plan and individual Assignment Reports.

Head of Internal Audit Opinion

In accordance with the requirements of the UK Public Sector Internal Audit Standards, the Head of Internal Audit is required to provide the Accounting Officer with her annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes.

Her opinion is based on the outcomes of the work that Internal Audit has conducted throughout the course of the reporting year. There have been no undue limitations on the scope of internal audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned.

In summary, the overall opinion given to the Accounting Officer was 'moderate assurance' that HFEA has had adequate and effective systems of control, governance, and risk management in place for the reporting year 2021/22.

Review of effectiveness

As Accounting Officer, I place reliance on the internal system of control. These include but were not limited to:

- oversight by the Board and its sub-committees including the Audit and Governance Committee;
- the work and opinions provided by GIAA our internal auditors;
- senior managers within the organisation, who had responsibility for the development and maintenance of the system of internal control, and
- regular reporting to the Executive Team on performance and risk management.

I have noted the GIAA's annual report, which in accordance with the Public Sector Internal Audit Standards, concludes that the HFEA "has adequate and effective governance, risk and control arrangements": She has arrived at this opinion through:

- Conducting a detailed risk-based internal audit needs assessment, from which she has prioritised activity over a three-year planning period to design an internal audit strategy and annual operational plan;
- All audit conducted during 2021/22;

- Monitoring the implementation of internal audit recommendations throughout the year.

Peter Thompson
Chief Executive
Accounting Officer **11 October 2022**

Remuneration and Staff Report

Audit

Specific areas of the Remuneration and Staff report are audited by the HFEA's external auditors. These sections cover salary and pension data in the tables, non-cash benefits and amounts payable to third parties for services of senior staff.

Reward systems and approval mechanisms for staff

Our remuneration recommendations are based on the Civil Service pay guidance issued annually by HM Treasury.

Pay awards are made to eligible staff in accordance with the Government limits of a percentage of the total pay-bill. However, no pay awards were made in 2021/22.

Pay levels are reviewed annually through the Remuneration Committee, which has specific responsibility to monitor overall levels of remuneration and to approve the remuneration of the Chief Executive and the Directors (see below).

Performance appraisal

A personal objective-setting process that is aligned with the business plan is agreed with each member of staff annually and all staff are subject to an annual performance appraisal.

Duration of contracts, notice periods and termination payments

Members of staff in band two (officers) must provide six weeks' notice of termination of their contracts. Members of staff in band three (managers) and above must provide three months' notice of termination of their contracts. The HFEA has a statutory duty to provide notice to staff of between one week and twelve weeks' notice depending on continuous service in line with the Employment Rights Act 1996.

Termination payments are made only in appropriate circumstances. In cases where gross misconduct has occurred, no termination payments are made.

Authority members

The remuneration levels of Authority members are set nationally by the Cabinet Office and are summarised in the table below. Revisions are made in accordance with the agreement on the pay framework for ALB chairs and non-executive directors, first announced in March 2006. We implement the revisions when instructed.

No pension contributions or bonuses were paid on behalf of any Authority member in 2021/22.

Appeals Committee

The Appeals Committee Chair receives a fee of £580 per day. The Deputy Chair receives a fee of £490 per day and members receive a fee of £400 per day. No pension contributions were paid on behalf of any Appeals Committee member.

The Appeals Committee did not sit in 2021/22 and therefore no payments were made to any members of the Appeals Committee in the year ended 31 March 2022

End of service

Staff can access their Civil Service pension at different times, depending on the scheme they are in. The normal pension age for those in the classic/premium scheme is 60, for those in the Nuvos scheme it is 65 and for those in the Alpha scheme it is the later of 65 or the state pension age. However, some staff may wish to work beyond these ages.

Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

Health and safety

We are committed to adhering to the Health and Safety at Work Act 1974 and other related requirements to ensure that staff and visitors enjoy the benefits of a safe environment. There were no accidents or near misses reported during the year.

Trade Unions

Under the Facility Time Publication Requirements Regulations of 2017, the HFEA are required to disclose the number of staff, costs and time spent on facility time by an employee who is a relevant union official if it meets certain criteria.

The HFEA does not employ any staff members who allocate their time on trade union activities.

Remuneration and benefits to Authority members for the year ending 31 March 2022 (Audited)

Name	Salary range £000s	Expenses (to nearest £100)[15] £	Total £000s	Salary range £000s	Expenses (to nearest £100)[15] £	Total £000s
	2021/22	2021/22	2021/22	2020/21	2020/21	2020/21
Julia Chain (Chair)	45-50	1,000	45-50	N/a	N/a	N/a
Sally Cheshire[16] (ex-Chair)	N/a	N//a	N/a	45-50	3,300	50-55
Anita Bharucha	5-10 (Fye[17] 10-15)	0	5-10	10-15	0	10-15
Kate Brian[16]	N/a	N/a	N/a	5-10	0	5-10
Anthony Rutherford[16]	N/a	N/a	N/a	0-5	0	0-5
Margaret Gilmore	5-10	0	5-10	5-10	0	5-10
Catharine Seddon	10-15	0	10-15	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)
Yacoub Khalaf	5-10 (Fye 5-10)	0	5-10	5-10	0	5-10
Anne Lampe	5-10	0	5-10	5-10	800	5-10
Ruth Wilde	5-10	0	5-10	5-10	200	5-10
Johnathan Herring	5-10	0	5-10	5-10	0	5-10
Gudrun Moore	5-10	0	5-10	5-10	0	5-10
Emma Cave	0-5 (Fye 5-10)	0	0-5	5-10	0	10-15
Ermal Kirby	5-10	0	5-10	5-10	0	5-10

[15] These expenses are shown gross.
[16] Members who left in 2020/21 but have been included for comparative figures.
[17] Fye – Full year equivalent

Name	Salary range £000s	Expenses (to nearest £100)[18] £	Total £000s	Salary range £000s	Expenses (to nearest £100)[15] £	Total £000s
	2021/22	2021/22	2021/22	2020/21	2020/21	2020/21
Jason Kasraie	5-10	200	5-10	0-5(Fye 5-10) (Fye 5-10)	0	0-5(Fye 5-10)
Tim Child	5-10	0	5-10	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)
Alison Marsden	5-10	0	5-10	N/a	N/a	N/a

Benefits in kind

The monetary value of benefits in kind covers any benefits provided by us and treated by HMRC as a taxable emolument. Previously we had an agreed a PAYE settlement agreement (PSA) with HMRC in regard to taxable emoluments of Authority members and some of our compliance staff, for the travel, accommodation, meals, and subsistence for which we pay the tax and national insurance due. In 2019, the PSA was removed by HMRC. The taxable emoluments are now payrolled and the figures on the above table are the gross payments.

Information regarding travel and subsistence claimed by Authority members and senior management is published on our website https://www.hfea.gov.uk/about-us/what-we-spend-and-how/

[18] These expenses are shown gross.

Chief Executive and directors (Audited)

The Chief Executive's pay is set in accordance with the recommendation of the Chair, subject to the review of the Remuneration Committee and with the agreement of the DHSC. This is in accordance with the pay framework for very senior managers (VSM) in ALBs, informed by the Senior Staff Salaries Review Board.
Remuneration of the directors must be approved by the Remuneration Committee and is based on proposals received from the Chief Executive, in accordance with the VSM pay framework. The members of the Remuneration Committee during the year were Julia Chain (Chair), Catharine Seddon and Tim Child.

Remuneration and pension benefits of the senior management team (Audited)

Name	Salary (£'000)		Bonus payments (£'000s)		Benefits in kind (to nearest £100)		Pension benefits[19] (£'000s)		Total (£'000s)	
	2021/22	2020/21	2021/22	2020/21	2021/22	2020/21	2021/22	2020/21	2021/22	2020/21
Peter Thompson	140-145	140-145	0	0	0	0	5-7.5	52.5-55	145-150	195-200
Rachel Cutting	90-95	90-95	0	0	8,200	0	35-37.5	35-37.5	135-140	125-130
Richard Sydee[20]	45-50 (Fte[21] 95-100)	45-50 (Fte 95-100)	0	0-5	0	0	10-12.5	22.5-25	55-60	70-75
Clare Ettinghausen	90-95	90-95	0	0-5	0	0	35-37.5	35-37.5	130-135	130-135

Definitions

'Salary' includes gross salary, performance pay or bonuses and any other allowance that is subject to UK taxation.

'Total remuneration' includes salary, non-consolidated performance-related pay, and benefits in kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

'Benefits in kind' covers the monetary value of any benefits provided by the employer.

This report is based on payments made by us and thus recorded in these accounts.

[19] The value of pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less (the contributions made by the individual). The real increases exclude increases due to inflation or any increase or decreases due to a transfer of pension rights.

[20] Richard Sydee is seconded to the HTA from the HFEA for 2.5days a week and this is reflected above. The figures shown above represent 50% of his salary, pension and bonus that has been recharged to the HTA

[21] The full time equivalent (Fte) is shown in brackets

Pay ratios (Audited)

Reporting bodies are required to disclose the relationship between the remuneration of the highest paid director / member in their organisation against the 25th percentile, median and 75th percentile of remuneration of the organisation's workforce.

Total remuneration is further broken down to show the relationship between the highest paid director's salary component of their total remuneration against the 25th percentile, median and 75th percentile of salary components of the organisation's workforce.

The banded remuneration of the highest paid director in the Human Fertilisation and Embryology Authority in the financial year 2021/22 was £140-£145k (2020/21, £140-£145k). The relationship to the remuneration of the organisation's workforce is disclosed in the table below.

FY	25th percentile Total Remuneration	25th percentile Salary ratio	Median Total Remuneration	Median Salary ratio	75th percentile Total Remuneration	75th percentile Salary ratio
2021/22	4.22 : 1	4.22 : 1	3.74 : 1	3.74 : 1	2.62 : 1	2.62 : 1
2020/21	3.98 : 1	3.98 : 1	3.74 : 1	3.74 : 1	2.97 : 1	2.97 : 1

The highest paid Director for this comparison was the Chief Executive. There has been no change in the median remuneration of staff since last year. We are a London-based small expert organisation whose work requires scientific and other professional or graduate-level skills. Consequently, median pay remains higher than that for a number of other public sector bodies.

In 2021-22, 0 (2020-21, 0) employees received renumeration in excess of the highest-paid director. Remuneration ranged from £25,000 to £145,000 (2020/21 £25,000 to £145,000).

Total remuneration includes salary, non-consolidated performance-related pay, benefits-in-kind, but not severance payments. It does not include the employer pension contributions and the cash equivalent transfer value of pensions.

The total remuneration and salary figures have not changed in the above table due to small payments of benefits-in-kind that have not impacted on the total renumeration.

Percentage change in remuneration of the highest paid director (Audited)

FY	2021/22	2020/21	Change
Director – salary range	£142.5k	£142.5k	Nil
Director – performance pay	None	None	N/a

All staff – salaries[22]	£46.5k	£45.8k	1.5%
All staff – performance pay	None	None	N/a

In line with Cabinet Office pay policy, no pay award was made to HFEA staff during the reporting year. The all-staff increase is driven through the inclusion of fixed term contract appointments. No additional payments were made in 2021/22, however two members of staff received bonus payments in 2020/21.

Staff report (Audited)

The HFEA has a headcount of 69 staff members excluding Authority members and including the SMT as at 31 March 2022. Below is a breakdown of staff costs and an analysis of directly employed staff.[23]

	Permanently employed staff	Members	Temporary staff	2021/22 Total	2020/21 Total
	£'000s	£'000s	£'000s	**£'000s**	£'000s
Salaries and wages	3,008	150	559	**3,717**	3,855
Social security costs	304	7	0	**311**	309
Other pension costs	792	0	0	**792**	794
Net staff costs	**4,104**	**157**	**559**	**4,820**	4,958
Less recoveries in respect of outward secondments	(111)	0	0	**(111)**	(147)
Total Net Staff costs	**3,993**	**157**	**559**	**4,709**	4,811

Exit packages (Audited)

Exit package cost band (including any special payment element	Number of compulsory redundancies	Cost of compulsory redundancies	Number of other departures agreed	Cost of other departures	Total cost of exit packages
		£'000s		**£'000s**	**£000s**
Less than £10,000	0	0	0	0	0
£10,000-£25,000	0	0	1	19	19
£25,001-£50,000	0	0	0	0	0
£50,001-£100,000	0	0	0	0	0
£100,001-£150,000	0	0	0	0	0
£150,001-£200,000	0	0	0	0	0
>£200,000	0	0	0	0	0
Totals	**0**	**0**	**1**	**19**	**19**

[22] These are the average salary

[23] The figures in the table may differ to the financial statements due to rounding

Exit costs in this note are accounted for in full in the year of departure. Where the HFEA has agreed early retirements, the additional costs are met by the HFEA and not by the Civil Service pensions scheme. Ill-health retirement costs are met by the Civil Service pensions scheme and are not included in the table.

Average number of persons permanently employed and outwardly seconded (Audited)

	Permanently employed	Seconded	2021/22 Total	2019/20 Total[24]
SCS[25]	4	0	**4**	4
Other	57	1	**58**	59
Total	61	1	**62**	63

Staff turnover for the 2021/22 business year was 11.7% (2020/21, 21.6%). A significant reduction due in part to the earlier restrictions stemming from the pandemic. Our staff survey results also showed that staff were happy to stay with us for an average of 2 years.

The average number of contractors engaged during 2021/22 was 4.

Sickness and absences

Our sickness absence aim is to lose no more than 2.5% of time in staff sickness absence and in 2021/22 we achieved 2.9% (2020/21 1.9%). This is higher than the public-sector sickness absence rate average which is 2.7% (Office for National Statistics (ONS) 2018). The increase is due to a number of employees who were absent for over 10 days due to COVID.

Review of tax arrangement of public sector appointees - off-payroll engagements

Off-payroll engagements assurance statement

For all off-payroll engagements as of 31 March 2022, for more than £245 per day .

Number of existing engagements as of 31 March 2022	**3**
Of which…	
Have existed for less than 1 year at time of reporting	0
Have existed for between 1 and 2 years at time of reporting	1

[24] These numbers have been rounded.
[25] Includes the Shared Director

Have existed for between 2 and 3 years at time of reporting	1
Have existed for between 3 and 4 years at time of reporting	1
Have existed for 4 or more years at time of reporting	0

For all new off-payroll engagements, between 1 April 2021 and 31 March 2022, for more than £245 per day.

Number of existing engagements as of 31 March 2022	**0**
Of which…	
Not subject to off-payroll legislation	0
Subject to off-payroll legislation and determined as in-scope of IR35	0
Subject to off-payroll legislation and determined as out-of-scope of IR35	0
No. of engagements reassessed for compliance or assurance purposes during the year	0
Of which: no. of engagements that saw a change to IR35 status following review.	0

For any off-payroll engagements of board members, and/or, senior officials with significant financial responsibility, between 1 April 2021 and 31 March 2022

No. of off-payroll engagements of board members, and/or senior officials with significant financial responsibility, during the financial year	**0**
Total no. of individuals on payroll and off-payroll that have been deemed “board members, and/or, senior officials with significant financial responsibility,” during the financial year.	**4**

Consultancy

Our expenditure on Consultancy is £214,505 and relates to legal consultancy costs incurred.

Remuneration and pension entitlements

The DHSC Group Accounting Manual (GAM) requires us to provide information on the remuneration and pension rights of the named individuals who are our most senior managers.

The following table provides details of the remuneration and pensions of the Chief Executive and directors. These figures are subject to audit.

The pension entitlements of the most senior managers in the HFEA (Audited)

Name and position	Real increase in pension at pension age	Real increase in pension lump sum at pension age	Total accrued pension at pension age at 31 March 2022	Lump sum at pension age related to accrued pension at 31 March 2022	CETV at 31 March 2022	Real increase in CETV	CETV[26] at 1 April 2021	Employer's contribution to stakeholder pension
	(bands of £2,500)	(bands of £2,500)	(bands of £5,000)	(bands of £5,000)				
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Peter Thompson Chief Executive	0-2.5	0-2.5	65-70	0	1400	8	1308	0
Richard Sydee Director of Finance and Resources	0-2.5	0	35-40	80-85	667	7	623	0
Rachel Cutting Director of Compliance and Information	0-2.5	0	5-10	0	59	18	34	0
Clare Ettinghausen Director of Strategy and Corporate Affairs	0-2.5	0	5-10	0	105	18	77	0

All senior managers listed are employed on a permanent basis and are covered by the terms of the Principal Civil Service Pension Scheme.

[26] CETV is the Cash Equivalent Transfer Value is the actuarially assessed capital value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's (other allowable beneficiary's) pension payable from the scheme.

Civil Service Pensions

The Principal Civil Service Pension Scheme (PCSPS) and the Civil Servant and Other Pension Scheme (CSOPS) – known as “Alpha” are unfunded multi-employer defined benefit schemes, but the HFEA is unable to identify its share of the underlying assets and liabilities.

The scheme actuary valued the PCSPS as at 31 March 2016. You can find details in the resource accounts of the Cabinet Office: Civil Superannuation at https://www.civilservicepensionscheme.org.uk/about-us/resource-accounts/

For 2021/22, employers’ contributions of £808,169 were payable to the PCSPS (2020/21 £786,636) at one of the four rates in the range 26.6% to 30.3% of pensionable earnings, based on salary bands.

The Scheme Actuary reviews employer contributions usually every four years following a full scheme valuation. The contribution rates are set to meet the cost of the benefits accruing during 2021/22 to be paid when the member retires and not the benefits paid during the period to existing pensioners.

Employees can opt to open a partnership pension account, a stakeholder pension with employer contribution. Employers’ contributions of £6,292 were paid to one or more of the panel of three appointed stakeholder pension providers. Employer contributions are age-related and ranged from 8% to 14.75%.

Employers also match employee contributions up to 3% of pensionable earnings. In addition, employer contributions of £288, 0.5% of pensionable pay, were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service or ill health retirement of these employees.

Contributions due to the partnership pension providers at the balance sheet date were £2,216. Contributions prepaid at that date were nil.

Further details about the Civil Service pension arrangements can be found at the website www.civilservicepensionscheme.org.uk.

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member’s accrued benefits and any contingent spouse’s pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies.

The figures include the value of any pension benefit in another scheme or arrangement which the member has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their buying additional pension benefits at their own cost. CETVs are worked out in accordance with ‘The occupational pension schemes (transfer values) (amendment) regulations 2008’ and do not take account of any actual or potential reduction to benefits resulting from lifetime allowance tax which may be due when pension benefits are taken.

Real increase in CETV

This reflects the increase in CETV that is funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

Parliamentary accountability and audit report

Accountability

Fees and charges (Audited)

Our licence fees are set to recover the full cost incurred in the granting of licences and regulation. The table below shows the income from the sector for licensing activities and the associated costs of licensing.

	2021/22	2020/21
	£'000s	£'000s
Income from regulatory activity[27]	5,581	4,281
Costs allocated to regulatory activity	(5,564)	(5,503)
Surplus/(Deficit)	**17**	(1,222)

We confirm that we have complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

Licence fee income is derived from a fixed fee charged on the number of treatment cycles that are undertaken across the sector in the financial year. In some years it has proven difficult to predict the number of cycles accurately and this was true in the last 3 years and more so during the early part of 2020/21 (COVID-19 pandemic).

The increase in income compared to 2020/21 in the above table is in part due to clinics catching up in their submission post the cessation of activities in the early part of 2020. The 2021/22 levels are similar to 2019/20 levels (pre-pandemic).

In addition, there are elements of our work that do not relate directly to the cost of regulating the sectors below. The DHSC accordingly contributes to the funding of these activities through the provision of grant-in-aid.

Losses and special payments (Audited)

Losses and special payments are items that Parliament would not have contemplated when it agreed funds for health service or passed legislation. By their nature they are items that should not arise and are therefore subject to special controls. The HFEA had no losses or special payments, in 2021/22.

[27] Income includes interest received. The total differs from note 4 in the accounts due to the exclusion of income that is not related to regulatory activity.

Remote contingent liabilities (Audited)

The Department of Health and Social Care underwrite any losses due to professional negligence on behalf of the HFEA. This contingent liability is held on the DHSC register. The HFEA does not have any remote contingent liabilities.

Peter Thompson
Chief Executive
Accounting Officer **11 October 2022**

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

Opinion on financial statements

I certify that I have audited the financial statements of the Human Fertilisation and Embryology Authority for the year ended 31 March 2022 under the Human Fertilisation and Embryology Act 1990.

The financial statements comprise the Human Fertilisation and Embryology Authority's

- Statement of Financial Position as at 31 March 2022;
- Statement of Comprehensive Net Expenditure, Statement of Cash Flows and Statement of Changes in Taxpayers' Equity for the year then ended; and
- the related notes including the significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and the Department of Health and Social Care Group Accounting Manual.
In my opinion, the financial statements:

- give a true and fair view of the state of the Human Fertilisation and Embryology Authority's affairs as at 31 March 2022 and its net expenditure for the year then ended; and
- have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and Secretary of State directions issued thereunder.

Opinion on regularity

In my opinion, in all material respects, the income and expenditure recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Basis for opinions

I conducted my audit in accordance with International Standards on Auditing (UK) (ISAs UK), applicable law and Practice Note 10 *Audit of Financial Statements of Public Sector Entities in the United Kingdom*. My responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial statements* section of my certificate.

Those standards require me and my staff to comply with the Financial Reporting Council's *Revised Ethical Standard 2019*. I have also elected to apply the ethical standards relevant to listed entities. I am independent of the Human Fertilisation and Embryology Authority in accordance with the ethical requirements that are relevant to my audit of the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Conclusions relating to going concern

In auditing the financial statements, I have concluded that the Human Fertilisation and Embryology Authority’s use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work I have performed, I have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Human Fertilisation and Embryology Authority's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

My responsibilities and the responsibilities of the Authority and Accounting Officer with respect to going concern are described in the relevant sections of this certificate.

The going concern basis of accounting for the Human Fertilisation and Embryology Authority is adopted in consideration of the requirements set out in the Department of Health and Social Care Group Accounting Manual, which require entities to adopt the going concern basis of accounting in the preparation of the financial statements where it is anticipated that the services which they provide will continue into the future.

Other Information

The other information comprises information included in the Annual Report, but does not include the financial statements nor my auditor’s certificate. The Authority and the Accounting Officer is responsible for the other information.

My opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in my certificate, I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated.

If I identify such material inconsistencies or apparent material misstatements, I am required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact.

I have nothing to report in this regard.

Opinion on other matters

In my opinion the part of the Remuneration and Staff Report to be audited has been properly prepared in accordance with Secretary of State directions issued under the Human Fertilisation and Embryology Act 1990.

In my opinion, based on the work undertaken in the course of the audit,

- the parts of the Accountability Report subject to audit have been properly prepared in accordance with Secretary of State directions made under the Human Fertilisation and Embryology Act 1990; and
- the information given in the Performance and Accountability Reports for the financial year for which the financial statements are prepared is consistent with the financial statements and is in accordance with the applicable legal requirements.

Matters on which I report by exception

In the light of the knowledge and understanding of the Human Fertilisation and Embryology Authority and its environment obtained in the course of the audit, I have not identified material misstatements in the Performance and Accountability Report.

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- I have not received all of the information and explanations I require for my audit; or
- adequate accounting records have not been kept by the Human Fertilisation and Embryology Authority or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Accountability Report subject to audit are not in agreement with the accounting records and returns; or
- certain disclosures of remuneration specified by HM Treasury's Government Financial Reporting Manual have not been made or parts of the Remuneration and Staff Report to be audited are not in agreement with the accounting records and returns; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Responsibilities of the Authority and Accounting Officer for the financial statements

As explained more fully in the Statement of Accounting Officer's Responsibilities, the Authority and Accounting Officer are responsible for:

- maintaining proper accounting records;
- the preparation of the financial statements and Annual Report in accordance with the applicable financial reporting framework and for being satisfied that they give a true and fair view;
- ensuring that the Annual Report and accounts as a whole is fair, balanced and understandable;
- internal controls as the Authority and Accounting Officer determines is necessary to enable the preparation of financial statement to be free from material misstatement, whether due to fraud or error; and
- assessing the Human Fertilisation and Embryology Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going

concern basis of accounting unless the Authority and Accounting Officer anticipate that the services provided by the Human Fertilisation and Embryology Authority will not continue to be provided in the future.

Auditor’s responsibilities for the audit of the financial statements

My responsibility is to audit, certify and report on the financial statements in accordance with the Human Fertilisation and Embryology Act 1990.

My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a certificate that includes my opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Extent to which the audit was considered capable of detecting non-compliance with laws and regulations including fraud

I design procedures in line with my responsibilities, outlined above, to detect material misstatements in respect of non-compliance with laws and regulations, including fraud. The extent to which my procedures are capable of detecting non-compliance with laws and regulations, including fraud is detailed below.

Identifying and assessing potential risks related to non-compliance with laws and regulations, including fraud

In identifying and assessing risks of material misstatement in respect of non-compliance with laws and regulations, including fraud, we considered the following:

- the nature of the sector, control environment and operational performance including the design of the Human Fertilisation and Embryology Authority’s accounting policies;
- Inquiring of management, the Human Fertilisation and Embryology Authority’s head of internal audit and those charged with governance, including obtaining and reviewing supporting documentation relating to the Human Fertilisation and Embryology Authority’s policies and procedures relating to:
    - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance;
    - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud; and
    - the internal controls established to mitigate risks related to fraud or non-compliance with laws and regulations including the Human Fertilisation and Embryology Authority’s controls relating to the Human Fertilisation and Embryology Authority’s compliance with the Human Fertilisation and Embryology Act 1990, and Managing Public Money;
- discussing among the engagement team and involving relevant specialists, including IT auditors, regarding how and where fraud might occur in the financial statements and any potential indicators of fraud.

As a result of these procedures, I considered the opportunities and incentives that may exist within the Human Fertilisation and Embryology Authority for fraud and identified the greatest potential for fraud in the following areas: revenue recognition, posting of unusual journals, complex transactions, and bias in management estimates. In common with all audits under ISAs (UK), I am also required to perform specific procedures to respond to the risk of management override of controls.

I also obtained an understanding of the Human Fertilisation and Embryology Authority's framework of authority as well as other legal and regulatory frameworks in which the Human Fertilisation and Embryology Authority operates, focusing on those laws and regulations that had a direct effect on material amounts and disclosures in the financial statements or that had a fundamental effect on the operations of the Human Fertilisation and Embryology Authority. The key laws and regulations I considered in this context included Human Fertilisation and Embryology Act 1990, Managing Public Money, employment law, pensions legislation and tax legislation.

Audit response to identified risk

As a result of performing the above, the procedures I implemented to respond to identified risks included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with provisions of relevant laws and regulations described above as having direct effect on the financial statements;
- enquiring of management and the Audit and Governance Committee concerning actual and potential litigation and claims;
- reading and reviewing minutes of meetings of those charged with governance and the Board and internal audit reports;
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

I also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

A further description of my responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of my certificate.

Other auditor's responsibilities

I am required to obtain evidence sufficient to give reasonable assurance that the income and expenditure reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit

Report

I have no observations to make on these financial statements.

Gareth Davies **Date 14 October 2022**

Comptroller and Auditor General

National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Financial statements

Statement of comprehensive net expenditure for the year ended 31 March 2022

	NOTE	**2021/22 £'000s**	2020/21 £'000s
Income			
Revenue from contracts with customers	4	(5,581)	(4,281)
Other operating income	4	(111)	(149)
		(5,692)	(4,430)
Expenditure			
Staff costs	3	4,820	4,958
Purchase of goods and services	3	299	220
Depreciation, amortisation and expected credit loss charges	3	554	201
Other operating expenditure	3	1,095	1,411
		6,768	6,790
Net operating expenditure		**1,076**	2,360
Finance income	4	(2)	(1)
Net expenditure before taxation		**1,074**	2,359
Taxation		3	0
Net comprehensive expenditure for the year		**1,077**	2,359

There are no items of expenditure that should be shown as Other Comprehensive Expenditure. All items of income and expense arise from continuing activities.

Notes 1 to 15 on pages 62 to 77 form part of these financial statements.

Statement of financial position As at 31 March 2022

	NOTE	**31 March 2022 £'000s**	31 March 2021 £'000s
Non-current assets:			
Property, plant and equipment	5	70	76
Intangible assets	6	591	981
Other non-current assets	8	1	17
Total non-current assets		**662**	1,074
Current assets:			
Contract and other receivables	8	989	905
Cash and cash equivalents	9	3,688	3,289
Total current assets		**4,677**	4,194
Total assets		**5,339**	5,268
Current liabilities			
Contract and other payables	10	(569)	(752)
Provisions	12	(48)	(37)
Total current liabilities		**(617)**	(789)
Non-current assets less net current liabilities		**4,722**	4,479
Non-current liabilities			
Provisions	12	**(37)**	(73)
Total non-current liabilities		**(37)**	(73)
Total assets less liabilities		**4,685**	4,406
Taxpayers' equity			
I&E reserve		**(4,685)**	(4,406)
Total taxpayers' equity:		**(4,685)**	(4,406)

Notes 1 to 15 on pages 62 to 77 form part of these financial statements.

The financial statements were signed on behalf of the Human Fertilisation and Embryology Authority by:

Peter Thompson
Chief Executive

Date: 11 October 2022

Statement of cash flows for the year ended 31 March 2022

	NOTE	**2021/22 £'000s**	2020/21 £'000s
Cash flows from operating activities			
Net expenditure		**(1,074)**	(2,359)
Depreciation and amortisation	3	**155**	282
Impairment loss	3	**266**	0
(Increase)/Decrease in trade and other receivables	8	**(68)**	149
(Decrease)/Increase in trade and other payables	10	**(183)**	294
Taxation		**(3)**	0
(Decrease)/Increase in provisions	12	**(25)**	110
Net cash inflow/(outflow) from operating activities		**(932)**	(1,524)
Cash flows from investing activities			
Purchase of property, plant and equipment	5	**(18)**	(58)
Purchase of intangible assets	6	**(8)**	0
Proceeds of disposal of property, plant and equipment	3	**1**	0
Net cash inflow/(outflow) from investing activities		**(25)**	(58)
Cash flows from financing activities			
Grants from sponsoring department		1,356	2,408
Net cash inflow/(outflow) from financing activities		**1,356**	2,408
Net increase/(decrease) in cash and cash equivalents in the period	9	**399**	826
Cash and cash equivalents at the beginning of the period	9	**3,289**	2,463
Cash and cash equivalents at the end of the period		**3,688**	3,289

Notes 1 to 15 on pages 62 to 77 form part of these financial statements.

Statement of changes in taxpayers' equity
For the year ended 31 March 2022

	Total I&E reserve
	£'000s
Balance at 1 April 2020	4,357
Changes in taxpayers' equity for the year ended 31 March 2021	
Grant in aid from Department of Health and Social Care	2,408
Comprehensive expenditure for the year	(2,359)
Balance at 31 March 2021	**4,406**
Changes in taxpayers' equity for the year ended 31 March 2022	
Grant in aid from Department of Health and Social Care	1,356
Comprehensive expenditure for the year	(1,077)
Balance at 31 March 2022	**4,685**

Notes 1 to 15 on pages 62 to 77 form part of these financial statements.

Notes to the accounts

1. Statement of accounting policies

The 2021/22 HFEA accounts are prepared in a form directed by the Secretary of State for Health in the 2022 Framework Agreement, in accordance with section six of the 1990 Act (as amended).

The accounts are prepared in accordance with the accounting and disclosure requirements given in the DHSC Group Accounting Manual (GAM), insofar as these are appropriate to the HFEA and are in force for the financial year for which the statements are prepared. The accounting policies contained in the GAM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context.

Where the GAM permits a choice of accounting policy, the accounting policy which is judged to be the most appropriate to the particular circumstance of the HFEA for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the HFEA are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.1 Going concern

The HFEA is financed in part through Grant in Aid funding provided by the Department of Health and Social Care (DHSC), which is approved annually by Parliament. Grant in Aid has been secured from the DHSC for the 2022-23 year. In addition the HFEA licence fees for the coming year are set and the expectation is these will be collected, therefore the Board of the HFEA has prepared these financial statements on a going concern basis. Further information can be found in the Performance report on page 13.

1.2 Accounting convention

These financial statements are prepared under the historical cost convention.

1.3 Depreciation and amortisation

Depreciation is provided on all property, plant and equipment and tangible assets on a monthly basis from the date of acquisition at rates calculated to write off the cost of each asset evenly over its expected useful life.

Amortisation is provided on intangible non-current assets (which comprise constructed software and software licences) on a monthly basis at a rate calculated to write off the cost of each intangible asset over its expected useful life.

Expected useful lives are as follows:

Information technology	4 years
Office equipment	5 years
Furniture, fixtures and fittings	5 years
Constructed Software	4 - 10 Years

Impairments
An annual review is under taken of all assets to consider any changes in the useful economic life. Impairments that arise from a clear consumption of economic benefits or of service potential in the asset are charged to operating expenses.

1.4 Non-current assets

Non-current assets include property, information technology, and office equipment together with intangible assets which relate to constructed software and software licenses. Only items, or groups of related items, costing £5,000 or more are capitalised. Those costing less are treated as revenue expenditure with the exception of Laptops which are capitalised to aid tracking.

All property, plant and equipment and intangible assets held by the HFEA at 31 March 2022 are carried in the statement of financial position at depreciated (property, plant and equipment) or amortised (intangible assets) historical cost. The depreciated or amortised historical cost is used as a proxy for fair value, for the classes of assets listed above, since the useful life over which the asset class is depreciated or amortised is considered to be a realistic reflection of the consumption of that asset class.

Intangible Assets namely Constructed software are reviewed for impairment. Consideration of changes in the useful economic life are made. Any impairments that may arise from a clear consumption of economic benefits or of service potential in the asset are charged to operating expenses.

1.5 Assets under Construction (Development expenditure)

These were the costs related to the PRISM phase of our Digital projects whether that be the costs of application or developer costs. On go-live the full costs are transferred to Constructed Software .

1.6 Critical accounting judgements and key sources of estimation uncertainty

In the application of the HFEA accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

IAS 17 Leases – the most significant judgement relates to whether the signed lease for 2 Redman Place, Stratford should be classified as an Operating or Finance lease and therefore its impact and treatment in the 2021/22 accounts.

The HFEA management believe that the new lease does not meet the definition of a finance lease for the following reasons: the lease is a 10 year lease where ownership at its conclusion does not transfer to the HFEA; there is no option to purchase the building and importantly, the lease term is not a major part of the economic life of the lease. Therefore, the lease is classified as an operating lease under IAS 17 and as such rental costs have been charged to the SoCNE, on a straight-line basis over the term of the lease.

IAS 36 - Impairments - Management makes judgement on whether there are any indications of impairments to the carrying amounts of the HFEA's assets.

At the end of the year, management has made a significant judgement in relation to the impairment of PRISM (the online submission systems for the clinics we regulate). The assessment of the level of impairment recognised is subject to a degree of uncertainty. As PRISM does not generate cash and has no market value; due to its uniqueness, management sort to write down its value based upon the original business case and expected costs and benefits realised. The latter being too soon to ascertain as the asset has only just been placed into use. The value of impairment charged to the Statement of Comprehensive Net Expenditure is £266k

Income - The online submission system (PRISM) provides data that we use to raise invoices to the clinics. Management agreed that during the go-live of PRISM, clinics would be billed based upon 2020/21 activity for the period September 2021 to February 2022 with detailed reconciliations conducted at the end of the year. There are 40 clinics where a full reconciliation has not been possible due to these clinics delay in data submission. Management have taken the decision to use the estimates from the 2020/21 financial year as a basis for recognising income in 2021/22 year. Further reconciliations for these 40 clinics will be conducted during the first quarter of 2022/23.

1.7 Impairment of financial assets

The simplified approach to impairment, in accordance with IFRS 9, measures the loss allowance for trade receivables at an amount equal to lifetime expected credit losses (stage 1).
For other financial assets, the loss allowance is measured at an amount equal to lifetime expected credit losses if the credit risk on the financial instrument has increased significantly since initial recognition (stage 2).

An assessment of the HFEA's financial assets has resulted in the movement in the value of the impairment of receivables. In carrying out this assessment, account is taken of the sector, economic climate and trends. A default rating which is weighted is applied to aged debts over the periods of 35, 60 and 95 days.

DHSC provides a guarantee of last resort against debts of its arm's length bodies and other NHS bodies and therefore the HFEA does not recognise stage 1 or 2 losses against these bodies.

1.8 Grant-in-aid

Grant-in-aid received from DHSC is used to finance activities and expenditure which supports the statutory and other objectives of the HFEA and is treated as financing and credited to the I&E reserve, because it is regarded as contributions from a controlling party.

1.9 Operating income

The main source of funding for the HFEA is treatment fee income from the clinics it regulates. A smaller amount of income is received from the same clinics in respect of licence fee renewals.

Under IFRS 15 and the 5-step model, there is a contractual arrangement between the HFEA and the clinics it regulates. The underlying legislation is deemed to enforce contractual obligations on both parties and thus these arrangements are viewed as contracts under the standard. Performance obligations exist between the HFEA and fertility clinics and the human embryo research centres it regulates. The clinics and centres must maintain standards in line with our Code of Practice and submit details of treatments conducted for which they will be granted a licence.
The provision of the licence is deemed to be the performance condition for which revenue is recognised and is considered over the period to which the licence applies. The contract price is considered to comprise fees for issue and renewal of licences and a variable fee based on the number of treatment cycles.
Clinics submit information to confirm the number of patients registered on a periodic basis and therefore the revenue to be recognised, is determined to be the income it is entitled to for the number of treatment cycles in the period.

Other income received by the HFEA relates to seconded staff and is recognised on an accruals basis, with the performance obligation deemed to be the point at which these services are delivered.

1.10 Operating leases

Leases in which a significant portion of the risks and rewards of ownership is retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the income and expenditure account on a straight line basis over the period of the lease.

The HFEA has one lease assessed as an operating lease. In addition, there is a rent-free period that has been accounted for on a straight-line basis over the life of the lease which is 10 years.

1.11 Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS). The defined benefit elements of the scheme are unfunded and are non-contributory except in respect of dependents' benefits. The HFEA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the scheme, the HFEA recognises the contributions payable for the year.

Further information in respect of Civil Service Pensions is provided in the remuneration report.

1.12 Cash

Cash is cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours.

1.13 Financial instruments

Financial assets and financial liabilities arise from the Authority's normal operational activities and are recognised in accordance with standard accruals accounting principles.

The HFEA's financial assets comprise cash at bank and in hand, contracts with customer debtors, balances with central Government bodies, and other debtors. The HFEA's financial liabilities comprise trade creditors and other creditors. The fair values of financial assets and liabilities are deemed to be their book values, unless there is appropriate cause to apply an alternative basis of valuation.

The HFEA has not entered into any transactions involving derivatives.

1.14 IFRSs, amendments and interpretations in issue but not yet effective

The Treasury FReM (as adopted by the DHSC GAM) does not require the following Standards and Interpretations to be applied in 2021/22. The application of the Standards as revised would have a material impact on the accounts in 2021/22, were they applied in that year.

IFRS 16 Leases replaces IAS 17 and is effective for the public sector from 1 April 2022. The new standard amends the accounting for lessees, removing the distinction between recognising an operating lease (off balance sheet) and a finance lease (on balance sheet). The new standard requires recognition of most leases which last more than 12 months to be recognised on balance sheet.

On transition to IFRS 16 on 1 April 2022, the HFEA will apply the standard retrospectively with the cumulative effect of initially applying the standard recognised in the Income and Expenditure Reserve at that date. For existing operating leases with a remaining lease term of more than 12 months and an underlying asset value of £5,000, a lease liability will be recognise equal to the value of remaining lease payments discounted on transition at the HFEA's incremental borrowing rate. The HFEA's incremental borrowing rat will be a rate defined by HM Treasury. Currently this rate is 0.95% but this may change between now and adoption of the standard. The related right of use asset will be measured equal to the lease liability adjusted for any prepaid or accrued lease payments.

The lease for 2 Redman Place, Stratford is for a 10 year period and based upon the value of the operating lease at note 11, the impact on the accounts is likely to be material.

The HFEA has estimated the impact of applying IFRS 16 in 2022/23 on the opening statement of financial position and the in-year impact on the statement of comprehensive net expenditure and capital additions as follows:

Estimated impact on 1 April 2022 statement of financial position	**£000**
Additional right of use assets recognised for existing operating leases	981
Additional lease obligations recognised for existing operating leases	(981)
Net impact on net assets 1 April 2022	**0**
Estimated in-year impact in 2022/23	
Additional depreciation on right of use assets	112
Additional finance costs on lease liabilities	9
Lease rentals no longer charged to operating expenditure	(165)
Estimated impact on surplus/deficit in 2022/23	**(44)**

The above figures are based upon the current lease agreement and uses the HM Treasury discount rate in force

1.15 Provisions

Provisions are recognised when the HFEA has a present legal or constructive obligation as a result of a past event, it is probable that the HFEA will be required to settle the obligation, and a reliable estimate can be made of the obligation.

The amount recognised as a provision is the best estimate of expenditure required to settle the obligation at the end of the reporting period, taking into account the risks and uncertainties.

2. Operating segments

Under the definition of IFRS 8 the HFEA is a single operating segment as the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos, setting standards for, and the issue of licences to, centres together with the provision of information for the public and determining the policy framework for fertility issues.

3. Operating expenditure

	Note	**2021/22 £'000s**	2020/21 £'000s
3.1 Staff costs			
Permanently employed staff costs		4,104	4,135
Members' allowances		157	149
Agency and other temporary costs		559	674
		4,820	4,958
3.2 Purchase of goods and services			
Legal Expenses		215	145
Auditors' remuneration and expenses	(a)	84	75
		299	220
3.3 Depreciation and impairment charges			
Depreciation & amortisation	5,6	155	282
Impairment of Constructed software		266	0
Expected credit loss		134	(81)
(Profit)/loss on disposal of fixed assets		(1)	0
		554	201
3.4 Other operating expenses			
Rentals under operating leases		240	413
Running costs		710	775
Staff related costs		145	223
		1,095	1,411
Total		**6,768**	6,790

Notes

a) Audit expenditure is as follows:

	2021/22 £'000s	2020/21 £'000s
External audit	36	30
Internal audit	48	45
	84	75

External audit expenditure is the accrued fee for the NAO for 2021-22 year. The internal audit costs relate to audits carried out in 2021-22.

4. Income

Gross income is made up of licence fee and other incomes which are recorded on an accruals basis.

Analysis of income

	2021/22 £'000s	2020/21 £'000s
Licence fee income	(5,581)	(4,281)
Other income-interest	(2)	(1)
Other operating income	(111)	(149)
Total income for the year	**(5,694)**	(4,431)

5. Property, plant and equipment

	Information technology £'000s	Office equipment £'000s	Total £'000s
Cost or valuation:			
At 1 April 2021	153	6	**159**
Additions purchased	18	0	**18**
Disposals	0	0	**0**
At 31 March 2022	**171**	**6**	**177**
Depreciation			
At 1 April 2021	80	4	**84**
Charged during the year	22	1	**23**
Disposals	0	0	**0**
At 31 March 2022	**102**	**5**	**107**
Carrying value at 31 March 2022	**69**	**1**	**70**
Carrying value at 31 March 2021	73	2	75
All assets are owned			

2020/21	Information technology £	Office equipment £	Total £
Cost or valuation:			
At 1 April 2020	**177**	14	**191**
Additions purchased	58	0	**58**
Disposals	(82)	(8)	**(90)**
At 31 March 2021	**153**	**6**	**159**
Depreciation			
At 1 April 2020	**148**	**10**	**158**
Charged during the year	14	2	**16**
Disposals	(82)	(8)	**(90)**
At 31 March 2021	**80**	**4**	**84**
Carrying value at 31 March 2021	**73**	**2**	**75**
Carrying value at 31 March 2020	29	4	33
All assets are owned			

6. Intangible assets

	Software licenses £'000s	Constructed software[1] £'000s	Asset under construction £'000s	Total £'000s
Cost or valuation:				
At 1 April 2021	150	1,476	885	**2,511**
Additions purchased	8	0	0	8
Reclassification	0	885	(885)	0
Impairments	0	(266)	0	(266)
Disposals	0	(420)	0	(420)
At 31 March 2022	**158**	**1,675**	**0**	**1,833**
Amortisation				
At 1 April 2021	115	1,415	0	**1,530**
Charged during the year	19	113	0	132
Disposals	0	(420)	0	(420)
At 31 March 2022	**134**	**1,108**	**0**	**1,242**
Carrying value at 31 March 2022	**24**	**567**	**0**	**591**
Carrying value at 31 March 2021	35	61	885	981
All assets are owned				

[1]Constructed software includes the cost of HFEA's website, Choose-a-Fertility Clinic (CaFC) and the Clinic Portal which collectively were known as the Information for Quality Project that concluded in July 2017.The gross cost is £977,642 and its net book value is nil as its remaining useful life has ended although the asset is still in use.
Additions to Constructed software is the cost of developing the new data submission system (PRISM), which went live in September 2021 and will be amortised over 10 years.

2020/21	Software Licenses £'000s	Constructed Software £'000s	Asset under Construction £'000s	Total £'000s
Cost or valuation:				
At 1 April 2020	326	1,476	885	**2,687**
Disposals	(176)	0	0	(176)
At 31 March 2021	**150**	**1,476**	**885**	**2,511**
Depreciation				
At 1 April 2020	269	1,171	**0**	**1,440**
Charged during the year	22	244	0	266
Disposals	(176)	0	0	(176)
At 31 March 2021	**115**	**1,415**	**0**	**1,530**
Carrying value at 31 March 2021	**35**	**61**	**885**	**981**
Carrying value at 31 March 2020	57	306	885	1,248
All assets are owned				

7. Financial instruments

IFRS 7 Financial Instruments Disclosure requires disclosure of the role that financial instruments have had during the period in creating or changing the risks an organisation faces in undertaking its activities. Financial instruments play a much more limited role in creating or changing risk at the HFEA than would be typical of the listed companies to which IFRS 7 mainly applies. Financial assets and liabilities are generated by day-to-day operational activities rather than being held to change the risks facing the HFEA in undertaking activities.

a) Liquidity risk

The majority of the HFEA's income comes from treatment fees. The fees are based on information provided directly from licenced clinics. This information is processed and returned to clinics in the form of invoices.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts. The remaining main source of revenue is from Government grants made on a cash basis. Therefore, the HFEA is not exposed to significant liquidity risk.

b) Credit risk

The HFEA receives most of its income from the clinics it regulates. It operates a robust debt management policy and, where necessary, provides for the risk of particular debts not being discharged by the relevant party.

The recent coronavirus pandemic had some impact on clinics to meet their obligation to pay whilst their activities were temporarily halted. Therefore the HFEA was exposed to some credit risk during a short period of time as clinics got up to speed once restrictions were lifted.

c) Financial assets and liabilities

The only financial asset held at a variable rate was cash at bank of £3,688,427 (2020/21, £3,288,753). As at 31 March 2022, none of the HFEA's financial liabilities were carried at a variable rate. The fair value of the financial assets and liabilities was equal to the book value.

8. Trade and other receivables

	31 March 2022	31 March 2021
	£'000s	£'000s
Amounts falling due within one year		
Contract receivables	418	239
Impairment for expected credit losses	(156)	(22)
Contract receivables not invoiced	588	523
Prepayments	127	91
Other receivables	12	74
Total	989	905

Contracts with customers balance has increased in 2021/22 by 75%. This significant increase is due to clinics delays in payment of outstanding accounts during the implementation of PRISM (our online submissions system). During this time estimated bills have been issued to clinics. A reconciliation has been conducted at the end of the year resulting in invoices and credits being issued to those clinics whose submissions are up to date. It is expected that the balance of contract with customers will be reduced in the first quarter of 2022/23.

Prepayments and accrued income include calculations of the fees due to be invoiced to clinics after the date of the statement of financial position in respect of chargeable treatments undertaken before that date.

Amounts falling due between one and two years		
Other receivables	1	17

Other receivables include legal costs awarded from concluded court case. This is due between 1 and 2 years

9. Cash and cash equivalents

	31 March 2022
	£'000s
Balance at 1 April 2021	3,289
Net change in cash	399
Balance at 31 March 2022	**3,688**

	31 March 2022
Bank account balances	**£'000's**
Government Banking Services	3,283
Commercial Banks	405
	3,688

No cash equivalents were held during the year.

10. Trade payables and other current liabilities

	31 March 2022 £'000s	31 March 2021 £'000s
Analysis by type		
Trade Payables	143	97
Accruals and deferred income	420	490
Other taxation and social security	3	162
Other contract liabilities	3	3
Total	**569**	752

All creditors were due for settlement within one year of the Statement of Financial Position date.

11. Commitments under leases

Operating leases

Total future minimum lease payments under operating leases are given in the table below.

Obligations under operating leases for the following periods are:

	31 March 2022 £'000s	31 March 2021 £'000s
Buildings		
Not later than one year	140	140
Later than one year not later than five years	562	562
Later than five years	503	644
	1,205	1,346
	1,205	1,346

The future minimum lease payments payable as of 31 March 2021 have been re-stated to include irrecoverable VAT payable.

12. Provisions

	Office Relocation (Travel) £'000s	Exit package £'000s	Total £'000s
Balance at 1 April 2021	110	0	110
Provided in year	0	12	12
Provisions utilised in year	0	0	0
Release of provision for the period	(37)	0	(37)
Balance at 31 March 2022	**73**	**12**	**85**

Analysis of expected timing of cashflows

	Office Relocation (Travel) £'000s	Exit package £'000s	Total £'000s
Not later than one year	36	12	48
Later than one year and not later than five years	37	0	37
	73	**12**	**85**

The provision provided in 202021 reflects the cost of additional travel the HFEA has committed to reimburse its staff over a three year period as a result of the office relocation. It is expected that the provision will be released equally each year, however this may change when the next annual review takes place.

The relocation of the HFEA to new offices is a constructive obligation under IAS 37. The HFEA has consulted its staff and expects there to be a transfer of economic benefits. The estimate of the provision was based upon the number of staff who have office-based contracts.

Due to the restrictions over the year, there were only a small number of staff who claimed excess fares. One-third of the provision has been released, with a review to be conducted at an appropriate point in the 2022/23 financial year.

13. Contingent liabilities

The HFEA regulates a sector that addresses some highly charged issues, of both a personal and clinical nature, which may generate close scrutiny. Some of the projects and work that the HFEA has undertaken, as well as certain decisions that the HFEA has made may give rise to later challenge, including a risk of legal action.

At the date of finalising these accounts, there were no matters of litigation that may have financial consequences for the HFEA.

14. Related party transactions

During the period none of the Department of Health and Social Care Ministers, HFEA Board members or members of the key management staff, or parties related to any of them, has undertaken any material transactions with the HFEA.

The Department of Health and Social Care (DHSC) is regarded as a related party. During the period the HFEA had a significant number of material transactions with the Department and with other entities for which the Department is regarded as the parent department including:

The National Institute for Health and Care Excellence (NICE)
Human Tissue Authority (HTA)
Care Quality Commission (CQC)

15. Events after the reporting period

In accordance with the requirements of International Accounting Standard 10, reports after the accounting period are considered up to the date the accounts are authorised for issue. This is interpreted as the date of the Certificate and Report of the Comptroller and Auditor General.

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