

Annual report and accounts 2020/21

Human Fertilisation and Embryology Authority

Annual report and accounts 2020/21

Presented to Parliament pursuant to sections 6 and 7 of the Human Fertilisation and Embryology Act 1990 as amended by paragraph 3 of schedule 7 of the Human Fertilisation and Embryology Act 2008.

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Contents

Chief Executive's foreword	5
Performance Report	7
Overview	8
Performance analysis	12
Accountability Report	19
Corporate governance report	20
Remuneration report (Audited)	34
Parliamentary accountability and audit report	44
Financial statements	50

Chief Executive's foreword

Covid-19 has dominated the past year both for clinics and patients and for the work of the HFEA. The organisation reacted quickly to the emerging pandemic and following the decision of the NHS to cease all non-urgent treatment by 15 April 2020 issued a General Direction (0014) on 23 March requiring almost all licensed fertility treatment to cease by 15 April.

We then worked with the professional bodies to define a set of working protocols that would allow clinics to offer treatment in a Covid safe manner. The Authority issued a revised General Direction 0014 on 7 May requiring clinics to submit a Treatment Commencement Strategy to the HFEA when they felt ready to resume services. We put in place a review process to ensure those strategies were robust and that patient and clinics staff could be kept safe. Fertility clinics began to reopen in the week beginning 11 May and over 90% were operating by 12th June.

This initial lockdown period, and the continuing restrictions that were in place throughout the 2020/21 business year, had a profound impact on the HFEA. Our response and initial actions included:

- our Staff working extraordinarily long hours for many weeks to suspend and ensure a safe reopening of the fertility sector;
- like most of the public sector the HFEA moved to work from home just before the first lockdown was announced, a process that went remarkably smoothly;
- the closure of clinics had an immediate impact on the financial position of the HFEA. 80% of the income of the HFEA comes from the fees we levy on the sector and the vast majority of that fee is tied to the number of cycles performed. We covered the shortfall in income through the support of the Department of Health and Social Care (DHSC); and,
- the pandemic has also required us pause inspections and then to design and roll out a new inspection model from November 2020. This allows us to ensure clinic compliance within the constraints imposed by Government travel restrictions and the need to maintain social distancing.

Over this period the HFEA suspended its initial business plan for 2020/21, which was the first year of a new 3-year strategy. We have still delivered a number of notable strategic objectives and wider work in support of government priorities:

- revised our Compliance and Enforcement Policy, including a consultation with stakeholders. The new policy provides a more consistent basis for making regulatory decisions about clinics;
- the multiple birth rate has continued to fall with the national average well below our 10% target, at just 6%. It is easy to forget that the average stood at 25% when we first introduced the policy. Given the risk of multiple births to the health of mothers and their babies, this has been a very significant public health success story;
- we worked closely with DHSC throughout the year to ensure that we were ready for the end of the transition period on 31 December 2020 following the UK's exit from the European Union. All of the necessary legislation has been implemented and we have established a separate regime which allows for the continued regulation of licensed clinics in Northern Ireland consistent with the Northern Ireland Protocol;
- continued to issue licences for treatment and research on time and dealt with a record number of requests for access to our Register data from donor conceived people (what we term Opening the Register requests);

- successfully moved office to Stratford, East London (although we have yet to occupy the office because of Covid); and,
- our new data submission system, PRISM, is ready for launch.

Our staff, as ever, have proved to be the HFEA's most valuable asset, that we have achieved so much in such difficult operational circumstances is testament to their professionalism and the importance with which they regard their work and the sector we regulate. This organisation has always placed the patient at the centre of our efforts and making sure that the public have confidence that the fertility sector could operate throughout this business year has been a notable achievement

As we begin the new business year, we relaunch our 3-year strategy, now taking us through to the 2023/24 business year. We will continue our work with the Competition and Markets Authority and the Advertising Standards Authority to address concerns about the way that fertility services meet the requirements of UK consumer protection law and will prioritise patient, clinic and public information hoping to derive the benefits of our new PRISM systems in the provision and timeliness of the information we can provide.

This upcoming year also marks the 30th anniversary of the establishment of the HFEA. We see this anniversary as an opportunity to begin a public discussion about the modernisation of the HFE Act and to leverage our international reputation to support the Government's ambitions to position the UK as a nation where the regulatory framework can facilitate scientific innovation.

I would like to end by thanking not just the staff of the HFEA but all staff and stakeholders across the fertility sector for their work over this trying 12 months. They have worked tirelessly to ensure treatment, that is of such importance to those struggling to conceive, could continue throughout this year. We are immensely grateful for all their efforts.

Peter Thomas

Peter Thompson Chief Executive

Performance Report



As 2020-2021 began, we responded to the Covid-19 epidemic, which meant that much of the year was spent ensuring that we and the sector were able to recover safely. For the first six-months of the year, we operated without a business plan, instead focussing on managing risk and responding to changes affecting the sector. However, across the year we did make some progress towards our strategic delivery, setting the foundation for future successes. Our new strategy for 2020-2024 was launched in October 2020.

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;
- to license and inspect centres undertaking human embryo research;
- to license and inspect the storage of gametes (eggs and sperm) and embryos;
- to publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities;
- to keep a register of information about donors, treatments and children born as a result of those treatments;
- to keep a register of licences granted;
- to keep a register of certain serious adverse events or reactions;
- to 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 and Social Care on developments in the above fields, upon request.

We also function, at the time of writing, as one of the two UK competent authorities for the European Union Tissues and Cells Directive (EUTCD). This directive regulates the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

Delivery in 2020/21

Our objectives for 2020/21 were as follows:

The best care

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

We revised our Compliance and Enforcement policy, including a consultation with stakeholders. The new policy provides a more consistent ongoing basis for making regulatory decisions about clinics.

The right information

A significant area of focus was the provision of patient information about treatment add-ons, using a simple 'traffic light'- model to indicate the robustness of the evidence for each add-on. We completed a survey of patients and worked with partners from across the sector to review and improve the information available. Our aim is to ensure that patients have the information needed to make informed decisions.

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

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

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

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

Shaping the future

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

We handled a significant number of Opening the Register requests, following an earlier pause to the service because of COVID 19, and began to look at the operational arrangements for this work, to ensure that we are set up to deliver effectively into the future.

We continued to monitor areas of likely future developments, such as Artificial Intelligence (AI), which is a key consideration for our Scientific and clinical Advances Advisory Committee (SCAAC).

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

Risks as at 31 March 2021

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

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 can be found in the governance statement.

Risk area	Main strategic risks monitored	Related strategic theme
Regulatory framework	Responsive and safe regulation	The best care, the right information and shaping the future
Information provision	Delivering data and knowledge	The right information
Positioning and influencing	Strategic reach and influence	The best care, the right information and shaping the future
Financial viability	Income and expenditure	The best care, the right information and shaping the future
Capability	Knowledge and capability	The best care, the right information and shaping the future
Estates	Board Capability	The best care, the right information and shaping the future
Cyber security	Security and infrastructure weaknesses	The best care, the right information and shaping the future
Operating Model	Management of changes to HFEA operating model	The best care, the right information and shaping the future

Legal challenge	Resource diversion	Safe, ethical effective treatment; Ensure that all clinics provide consistently high quality and safe treatment
Business Continuity ¹	Coronavirus	The best care, the right information and shaping the future

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 or £37.50 respectively. The impact of the COVID19 pandemic saw a suspension of all fertility treatments for around 4 weeks in April and May 2020. In 2020/21, after the initial impact of the suspension on activity, we saw a gradual increase in activity over the remainder of the 2020/21 financial year. Clinics slowly increased their activities which resulted in our income levels reaching over 60% of 2019/20 income levels. 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 2021/22 financial year to ensure the HFEA can fulfil its regulatory remit. In addition, the HFEA will be undertaking a full review of its licence fee model during 2021/22 to ensure that it can recover the cost of regulation from the sector in future years.

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.

¹ This risk originally was categorised as coronavirus but has now been subsumed into our business continuity

Performance analysis

Measuring performance

Each year, we agree a business plan with the 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 report is made to the Authority every two months and DHSC every quarter.

Analysis of performance in 2020/21

Performance indicators (KPI)	Target 2020/21	КРІ	Target 2019/20	КРІ
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	49 working days ²	70 working days	62 working days
B: Communication and information	-			
Opening the Register requests responded to within 20 working days	100%	Not measured ³	100%	97% (512/529 requests) ⁴
Requests for contributions to Parliamentary questions (PQs) answered within DHSC deadlines.	100%	100% (8/8 PQs within deadline)	100%	100% (22/22 PQs within deadline)
C: Corporate				
Staff sickness absence rate (%)	No more than 2.5%	1.6%	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	£3.29m (increased⁵ from £2.66m in 18/19)	Continue to move towards agreed minimum cash reserve of £1.52m	£2.46m (decreased from £2.66m at the end of 18/19)
Percentage of invoices paid within 10 calendar days	70% paid within 10 days	85%	70% paid within 10 days	93%
Debts collected within 40 days (previously 60) calendar days	85%	79% ⁶	85%	86%

² Impact of COVID-19 pandemic and reduction in inspections

³ Opening the Register (OTR) was suspended due to pandemic

⁵ The increase in the cash balance is due to reductions in activity over the year

⁴ The requests have decreased by 60.8% from 2018/19 due to Parliament not sitting for large parts of the 19/20 year

⁶ The target was changed to 40 days at the start of the year. 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

We are funded from two main sources:

- licence and treatment fees from the establishments we licence (63%), and
- grant-in-aid from the DHSC (35%).
- the remainder coming from recharges for staff time and interest received

73% of our expenditure is on staff costs. Our other administrative costs include spend on legal costs (2%) and facilities expenses (6%).

Summary position as at 31 March 2021

	2020/21	2019/20
	£'000s	£'000s
Expenditure		
Staff costs	4,958	4,629
General administrative costs	1,832	2,133
Total expenditure ⁷	6,790	6,762

Income		
Revenue from contracts with customers	4,281	5,230
Other income	149	218
Total income ⁸	4,430	5,448
Net (expenditure)/income before interest and tax	(2,360)	(1,314)

Our financial results are included in the accounts on pages 51 to 54 and shows the deficit before interest and tax. This increase from last year is due to the reduction in our income, an increase in our staff costs (7% on last year) where posts were recruited to during the pandemic. Our Agency staff costs are higher (£674k compared to £591k in 2019/20). The agency staff costs relate to the PRISM project (also known as Digital Projects). Expenditure on IT consultancy and support costs have been incurred in the 2020/21 business year totalling £307,188 and are included in running costs.

The DHSC allocated grant-in-aid towards the financing of resource expenditure of £3,338,000 (2019/20 £938,000) of which £2,238,000 was actually drawn down, plus funding for the increase in employers pension contributions £100,000 and EU funding of £70,000. Capital expenditure funding of £100,000 (2019/20: £100,000) was also allocated. We also received a non-cash income allocation (Ring-fenced

⁷ This figure differs from the SoCNE due to rounding

⁸ This does not include interest income

RDEL) of £510,121 (2019/20 £503,940) 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 £558,692 (2019/20 £279,475).

	2020/21 ⁹	2019/20 ⁹
Net (expenditure)/income before interest and tax	(2,360)	(1,314)
Resource financing ¹⁰	2,918	1,582
Finance Income	1	14
Net income/(expenditure)	559	282
Taxation ¹¹	(0)	(3)
Surplus for the year ⁹	559	279

Other areas have remained largely the same, with a small increase in our internal audit fees 12.5%.

Cash reserves have increased by £826k (34%), (£198k 7% 2019/20 decreased). We have continued to use our cash reserves in the funding of the PRISM project and these costs are categorised as revenue.

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 99% of all invoices received within 30 days with a value of $\pounds 2,111,105$ (2019/20 100% with a value of $\pounds 2,448,179$).

Our staff

People Strategy

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

We make a positive difference to people's lives as we strive to remain a world class regulator of fertility treatment. Key to achieving this ambition are our people, the core strength of HFEA.

As a regulator, it is important for us to stay ahead of the curve when it comes to medical and technological advances within the world of fertility treatment. We do this by ensuring we have a responsive and highly knowledgeable workforce who can support clinics, patients, donor-conceived people and donors, and other stakeholders with high quality and timely guidance, information and data

⁹ Figures in these columns may vary to the accounts due to rounding

¹⁰ 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.

¹¹ Taxation is £175.

The People Strategy is a key driver for culture change, capacity building and performance improvement. However, it will not succeed without the commitment of our leaders, managers and staff across the organisation.

The People Strategy is an evolving document that will adapt over time in response to changes in our political and operating environment. The strategy is supported by a detailed action plan.

Our strategy and mission

Our vision for 2020-2024 is - Regulating for excellence: shaping the future of fertility care and treatment. Our People Strategy is aligned with the business strategy, which focusses on three objectives:

- The best care
- The right information
- Shaping the future

We are proud of our people and the work we do. We will only be able to achieve our vision by listening to and putting the needs of the people we serve at the core of everything we do. We will not excel without inspirational leaders and skilled and motivated employees.

Through our approach to people management and organisational development, we aim to foster a culture of high performance and one which attracts, develops, rewards and retains highly skilled and innovative managers and employees.

Our values

Our values reflect what we stand for as an organisation. They help us achieve our strategic objectives and underpin our culture.

We will:

- Work Together as One supporting and helping each other to be the best
- Look Forward and Stay Ahead by making decisions that impact the big picture
- Make it Happen by reacting positively to change and overcoming challenges
- Know our Impact by acting with integrity and compassion in everything we do.

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 elearning, 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 2020/21 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:

- Equality and diversity
- Counter-fraud awareness
- Cyber security
- Social media awareness

Workshops that looked at the development and re-design of our core values were conducted in quarter three of the business year.

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.

We engaged with staff in the creation of a new set of values through workshops and shared the final framework with staff at our annual away day.

We have trained several staff to become certified Mental Health First Aiders, providing a point of contact for staff to approach. This is more appropriate as we entered into the coronavirus pandemic and where staff mental health and wellbeing has become extremely important.

Staff Survey

In June 2020, we conducted a staff survey in order to gauge how our staff are feeling and thinking. The response rate was 83% (2018 86%), compared to the sector average of 70%. Our engagement score i.e., the extent to which staff feel happy at work was 77% compared to the average for our public sector comparators of 75%. This is a positive result, particularly as this last year has been challenging for all.

Disabled employees

We have long achieved $\checkmark \checkmark$ '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

16

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

As part of the government hub strategy, we relocated from Spring Gardens in central London to Redman Place, Stratford, in east London during 2021, though we have not yet occupied the building because of COVID 19. Due to government restrictions, staff are working remotely.

This is a significant change for the organisation that was aided by a move from on-premise infrastructures to cloud computing. The use of Microsoft Office 365 technology has ensured that the transition to remote working ran smoothly.

It is anticipated hybrid working will become the norm, where staff will be able to work flexibly according to business need. In the short-term, a limited number of staff will have access to the new office space due to the reduced number of desks affected by the need for social distancing.

Equality Act 2010 – equality and diversity on pay

We remain compliant with the requirements of the Equality Act 2010, and we continue collectively to ensure, throughout the year, that we fulfil our obligations under the Equality Act. All posts are systematically evaluated, against a formal job evaluation scheme 'Croner Reward', aiming to ensure that salaries are internally consistent, fair and equitable.

Our gender breakdown at 31 March 2021, 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)	14	55	69 ¹²

Social, community, sustainability, human rights and environmental issues

We have entered into a Memorandum of Understanding (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), 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.

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.

17

¹² (2019/20 Male 12/Female 54)

Surplus equipment is either sold or donated. All staff are enabled to work from home, reducing the impact on the environment through less travelling.

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.

Petro Thomas

Peter Thompson Chief Executive Accounting Officer

15 July 2021

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 2020/21 financial year. Biographies for each can be found on our website here.

Authority member	Appointment start date	Appointment end date
Sally Cheshire (Chair)	7 November 2006	31 March 2021 (re-appointed 9 March 2020
Kate Brian	12 November 2014	31 March 2021 (re-appointed 27 September 2017)
Anthony Rutherford	12 November 2014	11 November 2020 (re-appointed 27 September 2017)
Yacoub Khalaf	30 April 2015	31 December 2021 (re-appointed 22 January 2021)
Margaret Gilmore (Deputy Chair)	1 April 2015	31 December 2021 (re-pointed 22 January 2021)
Anita Bharucha (Chair of AGC)	30 April 2015	31 December 2021 (re-appointed 22 January 2021)
Anne Lampe	1 February 2016	31 January 2022 (re-appointed 28 June 2018)
Ruth Wilde	1 January 2016	31 December 2021 (re-appointed 28 June 2018)
Professor Jonathan Herring	18 July 2018	17 July 2021
Professor Gudrun Moore	18 July 2018	17 July 2021
Professor Emma Cave	1 October 2018	30 September 2021
Rev. Ermal Kirby	1 May 2019	30 April 2022
Tim Child	18 January 2021	17 January 2024
Jason Kasraie	18 January 2021	17 January 2024
Catharine Seddon	18 January 2021	17 January 2024

Senior Management Team

Our Chief Executive and directors, and their responsibilities, during 2020/21 are set out below.

	Peter Thompson, Chief Executive			
HR				
	Legal			
Richard Sydee ¹³ , Director of Finance and Resources	Clare Ettinghausen, Director of Strategy and Corporate Affairs	Rachel Cutting ¹⁴ , Director of Compliance and Information (appointed 11 November 2019)		
Budgeting	Governance and licensing	Inspection and clinical governance		
Accounting	Regulatory policy	Business support		
Financial control Audit and risk assurance	Engagement and communications Business planning	Information and Register Development		
Estate and Facilities	Programme management	Network support		

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/aboutus/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 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.

¹³ Richard Sydee is employed by the HFEA and is seconded to the Human Tissue Authority for 2.5 days per week. ¹⁴ Rachel Cutting was previously a member of the board member till her resignation and appointment as Director of Compliance and Information on 11 November 2019.

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 2014 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 as there are now no formal grounds to consider this inappropriate.

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 2014 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 2020/21 and the risks to HFEA performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the HFEA's resources in 2020/21.

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 2020/21
Sally Cheshire (Chair)	6	6
Kate Brian	6	6
Anthony Rutherford	4	4
Yacoub Khalaf	6	6
Margaret Gilmore	6	6
Anita Bharucha	6	6
Anne Lampe	5	6
Ruth Wilde	6	6
Professor Jonathan Herring	5	6
Professor Gudrun Moore	6	6
Professor Emma Cave	5	6
Rev Ermal Kirby	5	6
Jason Kasraie	2	2
Tim Child	2	2
Catharine Seddon	2	2

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 2021	Number of meetings 2020/21	Attendance rate
Appointments Committee	3	0	N/a
Audit and Governance Committee	4	4	83%
Executive Licensing Panel	3	12	100%
Licence Committee	5	5	75%

Committee	Membership at 31 March 2021	Number of meetings 2020/21	Attendance rate
Register Research Panel ¹⁵	8	3	83%
Remuneration Committee	3	2	100%
Statutory Approvals Committee	4	11	95%
Scientific and Clinical Advances Advisory Committee	15	3	96%

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).

The SMT are:

Peter Thompson	Chief Executive
Richard Sydee	Director of Finance and Resources (shared with the HTA)
Rachel Cutting (appointed 11 November 2019)	Director of Compliance and Information
Clare Ettinghausen	Director of Strategy and Corporate Affairs

¹⁵ Membership increased to eight in July 2019. At the last meeting in December only five were in attendance.

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 Programme Board 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 IT programme, 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 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.

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:

- Resumption of fertility treatments the Board discussed various guidance that had been issued at the start of the business year and the implementation of HFEA GD0014 and its revision in light of the revised guidance from professional bodies. Implementation of self-assessment mechanism for clinics;
- 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 clinics that had re-opened and issues that they faced with some staff still working from home and the impact that had on continuing to conduct treatments;
- Revised licence fee model four options were tabled for consideration and plans for engagement, timetable and consultation with the sector;
- Equality and diversity ensuring that the HFEA are more than just a fair employer and that in light of the Black Lives Matter (BLM) campaign that diversity and inclusion are at the forefront. Sign-up to the Race at Work Charter as we meet the five criteria;
- Resumption of inspections engagement with Persons Responsible (PR's), the inspection resumption strategy, risk assessments and government guidelines;
- The relocation of the HFEA offices to 2 Redman Place in Stratford, East London, which could impact on staff and operational activity for a considerable part of the upcoming business year;
- The Board revisited the new strategy in light of COVID-19 and its impact on our approach to delivery of the strategy, particularly in relation to collaborative working, the timing of some of the objectives.
- Compliance and enforcement the revision of the policy and consultation with the sector;
- Marking 30 years of the HFEA activities and events that could be used as an opportunity to celebrate the UK's achievements in having an effective regulatory regime, the future of fertility treatments and research.

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 the HFEA's 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 (National Audit Office) 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 2020/21 business year, it approved this Governance statement on 22 June 2021. 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, internal audit in a range of areas.

In 2020/21 the internal audit plan covered five business areas. All five reviews were completed within the 2020/21 financial year. The areas covered and the assurance ratings given are set out below:

Audit	Areas reviewed	Assurance rating
Review of Key Performance indicators	Assessment of how the processes and procedures in place within the HFEA to identify, monitor, review and communicate KPIs and any other performance measurement activity	Moderate
Consistency in the Inspection Process	Assess how HFEA monitors quality and effectiveness of the inspections which are carried out. Also assess how HFEA manages and controls the inspections planning process for any establishments submitting new licence applications	Substantial
Internal Incident Handling	Provide assurance on the controls and mitigating actions HFEA have in place to respond to and deal with any internal incidents	Moderate
Review of implementation and ongoing management of the digital programme (in particular PRISM).	Looking at the effectiveness of the controls in place to support the ongoing management of the digital programme, focusing on PRISM.	Substantial
Accounts Payable and Receivable	Review of the controls and governance in place to manage these key accounting functions	Substantial

Areas of particular focus for the Audit and Governance Committee in 2020/21 were:

- Progress on the completion and go-live of PRISM
- The strategic risk register which is reviewed at every meeting
- The committee reviewed the outcomes from internal audit reports as above.
- The committee focussed in some detail on the HFEA's response, readiness and ability to continue to operate during the restrictions put in place by the Government is response to the COVID19 pandemic. The committee was particularly concerned with the wellbeing of staff during this period, its ability to meet its regulatory obligations and the stability of IT infrastructure.
- The estates programme the committee provided significant oversight of the timetable for the completion and occupation of the new offices at Stratford, it's compliance with COVID-19 restrictions the proposed future use of the space by the HFEA;
- In addition to the full meetings the committee met an additional 7 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, and the Executive Licensing Panel 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 increased significantly over the year and we have reviewed the operational workings of the committees resulting in additional resources in committee administration.

The Scientific and Clinical Advances Advisory Committee has provided high-quality advice and exercised its delegated functions appropriately.

The Remuneration and Appointments committees continue to consider matters pertaining to human resources, remuneration, and the appointment of external committee members and advisers.

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 was updated in November 2020 to ensure it was still aligned to best practice. It was reviewed against the government's Orange Book 'Risk management – principles and concepts'.

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 dynamic, and risks are continually assessed in the context of HFEA's current strategies and external events. 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 engagements 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.

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.

At the beginning of the 2020/21 business year, the HFEA along with many other organisations were required to respond quickly to the impact of the COVID-19 pandemic. This risk, placed on both the sector and organisation, was added to our strategic risk register at the beginning of the year.

All HFEA licensed clinics ceased new activity from 15/04/21 (except for those few patients who needed to access fertility preservation before undergoing chemotherapy or radiotherapy treatment) for a period of 4 weeks. Clinics were able to re-open from 11/05/2020 following an HFEA assessment of each clinic's risk assessment and plans to operate safely and complying with all government restrictions.

The ensuing restrictions and lockdowns impacted on our ability to conduct site visits. Our legislation requires us to undertake a site visit of each licensed establishment every two years so as an alternative the HFEA developed a number of interim assurance methods to continue sector oversight whilst our ability to undertake site visits was restricted. The strategy involved issuing a 1-year extension to licences where clinics were able to demonstrate compliance through a written submission which was scrutinised by HFEA inspectors - where issues were identified, clinics were asked to provide further information to enable a further review to be undertaken before an extension was given. Although we have not conducted routine site visits the organisation has undertaken some inspections where desk-based assessments highlighted concerns or in response to concerns being raised directly with the HFEA. A recent internal audit gave 'substantial' assurance on the effectiveness of our governance, risk management and control framework.

To oversee the continued operations of the HFEA we established a business continuity team who met daily to discuss the organisations capability and respond to changing advice from government and queries from the sector and aligned professional bodies.

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 legal challenges, and our staff capacity and capability. 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. Like all public-sector organisations, we continue to face capacity and capability risks that we manage through good internal communications, staff engagement and our performance management process.

As at 31 March 2021 the HFEA risk register captured ten risks. Of these there were nine risks considered medium (i.e., with a score of between 6 and 10) and one low risk. The status of these risks were either below or at tolerance. Notable risks are discussed below.

The risk with the lowest rating relates to Board capability, which had previously (early in the year) been given a high rating as the loss in a short period of time of Board members could lead to loss of knowledge

and impact on formal decision-making. The reduction in the rating is due to a successful recruitment of four new members. Further Board vacancies later in 2021 will require us to revisit the risk rating.

The risk of HFEA experiencing unforeseen knowledge and capability gaps has reduced from earlier in the year due to successful recruitment rounds and internal promotions therefore reducing the risk of lost knowledge. It is possible that the restrictions placed upon the UK may have positively impacted upon our staff turnover which is lower this year compared to 2019/20.

The third risk relates to the Regulatory Framework within which the HFEA operates being overtaken by developments and therefore not fit for purpose. As a regulator, we are by nature removed from the care and developments being offered in clinics and we 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 the HFEA 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. We have adequate controls in place which include strengthening relationships with relevant partners and taking legal advice where developments are outside of our direct remit. Analysis of where there are gaps within our regulatory powers has been undertaken so that we may be able to make a case for further powers.

The fourth risk concerns Financial viability. Our licence fee is charged on a treatment activity basis and provides 80% of our income. The coronavirus pandemic had a significant impact on our income as clinics were mandated under General Directions (GD00014) to cease treatments from 15 April 2021 and only able to re-commence from 11 May once it could be demonstrated they could be conducted safely. Although the majority of clinics have now resumed patient treatment, we have experienced a short-fall in our income due to this pause in activity. In order to ensure the HFEA could meet its financial obligations we secured additional grant-in-aid from DHSC to ensure we could continue to operate as a going concern (please refer to 'going concern' on page 11).

At the end of 2019/20 year, we included a further risk which relates to the COVID-19 pandemic. There is a risk that we are unable to undertake our statutory functions and strategic delivery because of the impact of COVD-19. This risk has had a cascading effect across the whole risk register and is expected to do so for the immediate future. A COVID-19 risk management review was undertaken in autumn 2020 to reflect on lessons learned during the first phase of the pandemic response. These lessons were used to consider effectiveness of controls and a report was presented to AGC in December. The risk score was reduced in quarter two of 2020/21 once we could resume site inspections. Our revised inspection processes have been effective and included risk assessment and controls, (including PPE, alternative inspection teams, reducing the time on site) at each stage (from planning to execution), meaning that we are assured that we can effectively maintain this regulatory function. Our Internal Auditors undertook a review of our virtual inspection process and reported a finding of substantial assurance provided from this audit.

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.

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 hotline and 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

We have developed a Counter-fraud strategy as part of our drive to adhere to the Cabinet Office Functional Standards for Counter Fraud (GovS013). In addition, risk assessments are carried out biannually 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, particularly during the coronavirus pandemic which has seen fraud activity increase.

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 – opinion of the Head of Internal Audit

In 2020/21 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

Our opinion is based solely on the assessment of whether controls in place support the achievement of management's objectives as set out in the 2020/21 Internal Audit Plan and individual Assignment Reports. "In accordance with the requirements of the UK Public Sector Internal Audit Standards, I am required to provide the Accounting Officer with my annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes."

My 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. Therefore, in summary, my overall opinion is that I can give moderate assurance to the Accounting Officer that HFEA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2020/21.

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, to
- 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;
- Monitoring the implementation of internal audit recommendations throughout the year.

Petro Thomas

Peter Thompson Chief Executive Accounting Officer

15 July 2021

Remuneration report

Audit

Specific areas of the Remuneration report are audited by NAO, 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 were made to eligible staff in 2020/21 in accordance with the Government limit of 1% of the total pay-bill. This is the same as the previous year.

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 and are summarised in the table below. Revisions are made in accordance with the agreement on the pay framework for ALB chairs and nonexecutive directors, announced in March 2006. We implement the revisions when instructed.

No pension contributions or bonuses were paid on behalf of any Authority member in 2020/21.

Appeals Committee

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

No payments were made to any members of the Appeals Committee in the year ended 31 March 2021

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 2021 (Audited)

Name	Salary range £000s	Expenses (to nearest £100) ¹⁶ £	Total £000s	Salary range £000s	Expenses (to nearest £100) ¹⁷ £	Total £000s
	2020/21	2020/21	2020/21	2019/20	2019/20	2019/20
Sally Cheshire (Chair)	45-50	3,300	50-55	45-50	24,500	70-75
Kate Brian	5-10	0	5-10	5-10	0	5-10
Anthony Rutherford	0-5	0	0-5	5-10	3,400	10-15
Yacoub Khalaf	5-10	0	5-10	5-10	0	5-10
Margaret Gilmore	5-10	0	5-10	5-10	2,000	10-15
Anita Bharucha	10-15	0	10-15	10-15	2,100	15-20
Anne Lampe	5-10	800	5-10	5-10	4,200	10-15
Ruth Wilde	5-10	200	5-10	5-10	2,000	5-10
John Herring	5-10	0	5-10	5-10	1,800	5-10
Gudrun Moore	5-10	0	5-10	5-10	0	5-10
Emma Cave	5-10	0	5-10	5-10	6,700	10-15
Ermal Kirby	5-10	0	5-10	5-10	0	5-10
Jason Kasraie	0-5 (Fye ¹⁸ 5-10)	0	0-5	N/a	N/a	N/a
Tim Child	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)	N/a	N/a	N/a
Catharine Seddon	0-5 (Fye 5-10)	0	0-5 (Fye 5-10)	N/a	N/a	N/a

¹⁶ These expenses are shown gross

¹⁷ These expenses are shown net of tax and national insurance

¹⁸ Fye – Full year equivalent shows if member had joined at the start of the financial year

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/

Chief Executive and directors

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 Sally Cheshire (Chair), Margaret Gilmore and Anita Bharucha.

Remuneration and pension benefits of the senior management team (Audited)										
Name	Salary	r (£'000)		Bonus syments (£'000s)		Benefits in kind nearest £100)	be	Pension enefits ¹⁹ (£'000s)		Total (£'000s)
	2020/21	2019/20	2020/21	2019/20	2020/21	2019/20	2020/21	2019/20	2020/21	2019/20
Peter Thompson	140-145	140- 145	0	5-10	0	0	52.5-55	47.5-50	195- 200	195- 200
Rachel Cutting	90-95	35-40 (Fye 90-95)	0	0	0	7,000	35-37.5	12.5-15	125- 130	55-57.5
Richard Sydee ²⁰	45-50 (Fte 95- 100)	45-50 (Fte 90- 95)	0-5	0	0	0	22.5-25	17.5-20	70-75	65-70
Clare Ettinghausen	90-95	90-95	0-5	0-5	0	0	35-37.5	32.5-35	130- 135	130- 135

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

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

Median pay and multiples (Audited)

	2020/21	2019/20
Band of highest paid director's gross salary only	£140k-£145k	£140k-£145k
Median total remuneration	£38,130	£38,592
Ratio – gross salary only	3.74	3.69

The DHSC Group Accounting Manual (GAM) reporting requirements require public sector bodies to disclose the relationship between the total remuneration of the highest-paid director in their organisation and the median remuneration of the organisation's workforce including temporary and contract staff.

The banded remuneration of the highest-paid director in the financial year 2020/21 was £140k-£145k ($2019/20 \pm 140k \pm 145k$). This was 3.74 times (2019/20, 3.69) the median remuneration of the workforce, which was £38k ($2019/20 \pm 39k$). In 2020/21, 0 (2019/20, 0) employees received remuneration in excess of the highest-paid director. Remuneration ranged £25k to £145k.

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

Staff report (Audited)

The HFEA has a headcount of 69 staff members excluding Authority members and including the SMT as at 31 March 2021. Below is a breakdown of staff costs and an analysis of directly employed staff.²¹

	Permanently employed staff	Members	Temporary staff	2020/21 Total	2019/20 Total
	£'000s	£'000s	£'000s	£'000s	£'000s
Salaries and wages	3,039	142	674	3,855	3,585
Social security costs	302	7	0	309	314
Other pension costs	794	0	0	794	730
Net staff costs	4,135	149	674	4,958	4,629
Less recoveries in respect of outward secondments	(147)	0	0	(147)	(130)
Total Net Staff costs	3,988	149	674	4,811	4,499

²¹ The figures in the table will differ to the financial statements due to rounding

Exit packages (Audited)

There were no exit packages paid in 2020/21, (nil 2019/20).

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

	Permanently employed	Seconded	2020/21 Total	2019/20 Total ²²
SCS ²³	4	0	4	3
Other	58	1	59	62
Total	62	1	63	65

Sickness and absences

Our sickness absence aim is to lose no more than 2.5% of time in staff sickness absence and in 2020/21 we achieved 1.9% (2019/20 1.7%). This compares favourably with the public-sector sickness absence rate average which is 2.7% (Office for National Statistics (ONS) 2018).

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

Off-payroll engagements longer than 6 months

For all off-payroll engagements as of 31 March 2021, for more than £245 per day and that lasted for longer than 6 months.

Number of existing engagements as of 31 March 2021	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

²² These numbers have been rounded.

²³ 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, or those that reached six months duration, between 1 April 2020 and 31 March 2021, for more than £245 per day and that last for longer than six months

Number of existing engagements as of 31 March 2021	0
Of which	
No. assessed as caught by IR35	0
No. assessed as not caught by IR35	0
No. engaged directly (via PSC contracted to department) and are on the department payroll	0
No. of engagements reassessed for consistency/assurance purposes during the year	0
No. or engagements that saw a change to IR35 status following the consistency review	0

For any off-payroll engagements of board members, and/or, senior officials with significant financial responsibility, between 1 April 2020 and 31 March 2021

No. of off-payroll engagements of board members, and/or senior officials with significant financial responsibility, during the financial year	4
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 £144,958 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	at	Real increase in pension lump sum at pension age	Lump sum at pension age related to accrued pension at 31 March 2021	Real increase in pension at pension age	CETV at 31 March 2020	CETV at 31 March 2021	Real increase in CETV	Employer's contribution to stakeholder pension
	(bands of £5,000)	· ·	(bands of £5,000)	,				
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Peter Thompson Chief Executive	60-65	0	0	2.5-5	1208	1308	56	0
Richard Sydee Director of Finance and Resources ²⁴	35-40	0-2.5	80-85	0-2.5	573	623	13	0
Rachel Cutting Director of Compliance and Information	0-5	0	0	0-2.5	9	34	17	0
Clare Ettinghausen Director of Strategy and Corporate Affairs	5-10	0	0	0-2.5	51	77	18	0

²⁴ Richard Sydee's accrued pension and increase in lump sum represent 50% as the balance is accounted for by the HTA

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

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.

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 2012. 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 2020/21, employers' contributions of £786,636 were payable to the PCSPS (2019/20 £722,537) at one of the four rates in the rage 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 2018/19 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 £7,129 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.

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.

Petro Thomas

Peter Thompson Chief Executive Accounting Officer

15 July 2021

44

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. This year, we saw a drop in our income due to the COVID-19 pandemic, causing a much larger deficit. This was funded by DHSC through grant in aid.

	March 2020/21	March 2019/20
	£'000s	£'000s
Income from regulatory activity ²⁵	4,281	5,333
Costs allocated to regulatory activity	(5,503)	(5,520)
Surplus/(Deficit)	(1,222)	(187)

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 doubly so during the COVID-19 pandemic. Our forecasting model developed in 2017 continues to be used to aid income prediction.

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 2020/21.

Remote contingent liabilities (Audited)

There are no remote contingent liabilities this year.

²⁵ 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.

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 2021 under the Human Fertilisation and Embryology Act 1990. The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers' Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. The financial reporting framework that has been applied in their preparation is applicable law and the Department of Health and Social Care Group Accounting Manual.

I have also audited the information in the Accountability Report that is described in that report as having been audited.

In my opinion:

- the financial statements give a true and fair view of the state of the Authority's affairs as at 31 March 2021 and of the Human Fertilisation and Embryology Authority's net expenditure for the year then ended;
- the financial statements 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 of opinions

I conducted my audit in accordance with International Standards on Auditing (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 the 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 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 parts of the Accountability Report described in that report as having been audited, the financial statements and my auditor's certificate thereon. The Authority and the Accounting Officer are 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, based on the work undertaken in the course of the audit:

- the parts of the Accountability Report to be audited 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.

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:

- adequate accounting records have not been kept 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 to be audited are not in agreement with the accounting records and returns; or
- certain disclosures of remuneration specified by HM Treasury's Government Financial Reporting Manual are not made; or
- I have not received all of the information and explanations I require for my audit; 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 Authority and Accounting Officer's Responsibilities, the Authority and the Accounting Officer, are responsible for:

- the preparation of the financial statements in accordance with the applicable financial reporting framework and for being satisfied that they give a true and fair view;
- such internal controls as the Authority and the Accounting Officer determine are necessary to enable the preparation of financial statements to be free from material misstatement, whether due to fraud or error.
- 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 the 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.

I design procedures in line with my responsibilities, outlined above, to detect material misstatements in respect of non-compliance with laws and regulation, including fraud.

My procedures included the following:

47

- Inquiring of management, the audited entity'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 Managing Public Money;
- discussing among the engagement team regarding how and where fraud might occur in the financial statements and any potential indicators of fraud. As part of this discussion, I identified potential for fraud in the following areas: revenue recognition and posting of unusual journals;
- obtaining an understanding of the Human Fertilisation and Embryology Authority's framework of authority as well as other legal and regulatory frameworks that the Human Fertilisation and Embryology Authority operates in, focusing on those laws and regulations that had a direct effect on 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 the Human Fertilisation and Embryology Act 1990, Managing Public Money, employment legislation and regulations and tax legislation.

In addition to the above, my procedures to respond to identified risks included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with relevant laws and regulations discussed above;
- enquiring of management and the Audit and Governance Committee concerning actual and potential litigation and claims;
- reading minutes of meetings of those charged with governance and the Board;
- 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; and
- in addressing the risk of fraud in revenue recognition, reviewing the volume and value of credit notes and debt write-offs processed during the year and after the year-end for any unusual trends; substantive testing of any journal entries which impact the income lines, particularly those around the year-end; testing of pre-year-end and post-year-end receipts, to confirm whether revenue has been recognised in the correct financial year; and a comparative review of income collected from individual entities.

I also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists and significant component audit teams 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.

In addition, 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 Comptroller and Auditor General Date 16 July 2021

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 2021

	NOTE	2020/21 £'000s	2019/20 £'000s
	NOTE	20005	£ 0005
Income			
Revenue from contracts with customers	4	4,281	5,230
Other operating income	4	149	218
	_	4,430	5,448
Expenditure			
Staff costs	3	4,958	4,629
Purchase of goods and services	3	220	189
Depreciation, amortisation and expected credit loss charges	3	201	321
Other operating expenditure	3	1,411	1,623
	-	6,790	6,762
	-		0,102
Net operating expenditure		(2,360)	(1,314)
Finance income	4	1	14
Net expenditure for the year	-	(2,359)	(1,300)
Taxation*		(0)	(3)
	-	(0.0.50)	
Net comprehensive (expenditure) for the year	-	(2,359)	(1,303)

*Taxation charge is £175

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 14 on pages 55 to 69 form part of these financial statements.

Statement of financial position As at 31 March 2021

	31	March 2021	31 March 2020
	NOTE	£'000s	£'000s
Non-current assets:			
Property, information technology and office equipment	5	76	33
Intangible assets	6	981	1,248
Other non-current asset	8	17	17
Total non-current assets		1,074	1,298
Current assets:			
Contract and other receivables	8	905	1,054
Cash and cash equivalents	9	3,289	2,463
Total current assets		4,194	3,517
Total assets		5,268	4,815
		5,200	4,015
Current liabilities			
Contract and other payables	10	(752)	(458)
Provisions	12	(37)	0
Total current liabilities		(789)	(458)
Non-current assets less net current liabilities		4,479	4,357
Non-current liabilities			
Provisions	12	(73)	0
Total non-current liabilities		(73)	0
Total assets less liabilities		4,406	4,357
FINANCED BY:			
Taxpayers' equity			
I&E reserve		(4,406)	(4,357)
Total taxpayers' equity:		(4,406)	(4,357)

Notes 1 to 14 on pages 55 to 69 form part of these financial statements.

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

Petro Thomas

Peter Thompson Chief Executive

Date: 15th July 2021

Statement of cash flows for the year ended 31 March 2021

		2020/21	2019/20
	NOTE	£'000s	£'000s
Cash flows from operating activities			
Net operating surplus/(deficit) after interest		(2,359)	(1,300)
Depreciation and amortisation	3	282	289
(Increase)/decrease in trade and other receivables	8	149	(172)
Increase/(decrease) in trade and other payables	10	294	(66)
Loss on disposals of non-current assets	3	0	0
Taxation		(0)	(3)
Increase in provisions	11	110	0
Net cash inflow/(outflow) from operating activities		(1,524)	(1,252)
Cash flows from investing activities			
Purchase of property, plant and equipment	5	(58)	(24)
Net cash inflow/(outflow) from investing activities	_	(58)	(24)
Cash flows from financing activities			
Grants from sponsoring department		2,408	1,078
Net cash inflow/(outflow) from financing activities		2,408	1,078
Net financing		826	(198)
Net increase/(decrease) in cash and cash equivalents in the period	9	826	(198)
Cash and cash equivalents at the beginning of the period	9	2,463	2,661
Cash and cash equivalents at the end of the period		3,289	2,463
···· · · · · · · · · · · · · · · · · ·		-,	_,

Notes 1 to 14 on pages 55 to 69 form part of these financial statements.

Statement of changes in taxpayers' equity For the year ended 31 March 2021

	Total I&E reserve
	£'000s
Balance at 1 April 2019 Changes in taxpayers' equity for 2019/20	4,582
Grant from Department of Health and Social Care Comprehensive income/(expenditure) for the year	1,078 (1,303)
Balance at 31 March 2020	4,357
Changes in taxpayers' equity for the year ended 31 March 2021	
Grant from Department of Health and Social Care	2,408
Comprehensive income/(expenditure) for the year	(2,359)
Balance at 31 March 2021	4,406

Notes 1 to 14 on pages 55 to 69 form part of these financial statements.

Human Fertilisation & Embryology Annual Report and Accoun

Notes to the accounts

1. Statement of accounting policies

The 2020/21 HFEA accounts are prepared in a form directed by the Secretary of State for Health in 2014 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 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. The Secretary of State for Health and Social Care has directed that Parliamentary funding has been voted to permit relevant activities to continue. Grant in Aid has been secured from the DHSC for the 2021-22 year. In addition the HFEA licence fees for the coming year are set and the expectaction is these to be collected, there fore 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 11.

1.2 Accounting convention

These financial statements are prepared under the historical cost convention.

1.3 Depreciation and amortisation

Depreciation is provided on all non-current 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.

Expected useful lives are as follows:

Information technology	4 years
Office equipment	5 years
Furniture, fixtures and fittings	5 years

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. The expected useful life of this software is four years.

Human Fertilisation & Embryology Annual Report and Accoun

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.

All property, plant and equipment and intangible assets held by the HFEA at 31 March 2021 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 below, 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.

1.5 Assets under Construction (Development expenditure)

These are the costs related to the PRISM phase of our Digital projects whether that be the costs of application or developer costs. These assets are not depreciated.

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 newly signed lease for 2 Redman Place, Stratford should be classified as an Operating or Finance lease and therefore its impact and treatment in the 2020/21 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.

1.7 Impairments

The simplified approach to impairment, in accordance with IFRS 9, measures the loss allowance for trade receivables at an amount equal to llifetime 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.

An movement in the provision for expected credit loss of £81,642 was credited to the SoCNE.

Human Fertilisation & Embryology Annual Report and Accoun

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. A transaction price (for both licence fees and treatment fees) is chargeable. The recognition of this income is in the financial year in which it is submitted, this being the point in time at which the performance obligation (the granting of a licence or the ongoing regulation of treatments provided) is deemed to be satisfied.

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 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.

IFRS 16 has been deferred till 1 April 2022 and changes the way leases are recognised, this will have a significant impact on our accounts as we have rental leases. (see notes 1.14 and 11).

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 IRSs, 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 2020/21. The application of the Standards as revised would have a material impact on the accounts in 2020/21, 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.

The new lease for the 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.

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	2020/21 £'000s	2019/20 £'000s
3.1	Staff costs			
	Permanently employed staff costs		4,135	3,876
	Members' allowances		149	162
	Agency and other temporary costs		674	591
		3 (a)	4,958	4,629
3.2	Purchase of goods and services			
	Legal Expenses		145	119
	Auditors' remuneration and expenses	(b)	75	70
			220	189
3.3	Depreciation and impairment charges			
••••	Depreciation & amortisation	5,6	282	289
	Expected credit loss	,	(81)	32
	Loss on disposal of assets		0	0
			201	321
3.4	Other operating expenses			
	Rentals under operating leases		413	383
	Running costs		775	912
	Other staff costs		223	328
			1,411	1,623
	Total		6,790	6,762
Note	6			
b)	Audit expenditure is as follows:		2020/21	2019/20
			£'000s	£'000s
	External audit		30	30
	Internal audit		45	40
			75	70

External audit expenditure is the accrued fee for the NAO for 12 months. The internal audit costs relate to audits carried out in 2020-21.

3a. Staff costs

	2020/21 Total	2019/20 Total
	£'000s	£'000s
Wages and salaries	3,855	3,585
Social security costs	309	314
Other pension costs	794	730
Staff costs	4,958	4,629
Less recoveries in respect		
of outward secondments	(147)	(130)
Total Net staff costs	4,811	4,499

As set out in note 1.11, further information in respect of Civil Service Pensions is provided in the remuneration report on pages 34 to 43.

Average number of staff employed

The average numbers of persons employed during the period were as follows

	31 March	31 March
	2021	2020
	Total	Total
Directly employed	63	65
Subtotal	63	65
Contract staff	4	9
Total	67	74

4. Income

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

Analysis of income 2020/21 2019/20 £'000s £'000s **Revene from contracts** Licence fee income 5,230 4,281 Other income-interest 1 14 Other operating income 149 218 4,431 Total income for the year 5,463

Other operating income is income from seconded staff, (2019/20 included income from seconded staff (£130k), consultancy work (£71k) and compensation from concluded court case (£17k).

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5. Property, plant and equipment

	Information technology £'000s	Office equipment £'000s	Total £'000s
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	9	157
Charged during the year	14	2	16
Disposals	(82)	(8)	(90)
At 31 March 2021	80	3	83
Carrying value at 31 March 2021	73_	3	76
Carrying value at 31 March 2020 All assets are owned	29	5	33
	Information	Office	Total
2019/20	technology	equipment	
	£	£	£
Cost or valuation:			
At 1 April 2019	153	14	167
Additions purchased	24	0	24
At 31 March 2020	177	14	191
Depreciation			
At 1 April 2019	129	8	137
Charged during the year	19	2	21
At 31 March 2020	148	9	158

Carrying value at 31 March 2020

Carrying value at 31 March 2019 All assets are owned

6. Intangible assets

	Software licenses	Constructed software ¹	Asset under construction ²	Total
	£'000s	£'000s	£'000s	£'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
Amortisation				
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

¹Constructed 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 £61,103 and it has a remaining useful life of three months.

² Assets Under Construction is the cost of developing the new data submission system (PRISM), which has not yet gone live.

2019/20	Software Licenses	Constructed Software	Asset under Construction	Total
2019/20	£'000s	£'000s	£'000s	£'000s
Cost or valuation:				
At 1 April 2019	326	1,476	885	2,687
At 31 March 2020	326	1,476	885	2,687
Depreciation				
At 1 April 2019	246	926	0	1,172
Charged during the year	23	244	0	267
At 31 March 2020	269	1,171	0	1,440
Carrying value at 31 March 2020	57	306	885	1,248
Carrying value at 31 March 2019 All assets are owned	80	550	885	1,515

¹Constructed 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 £305,513 and it has a remaining useful life of fifteen months.

² Assets Under Construction is the cost of developing the new data submission system (PRISM), which has not yet gone live.

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 temporarlily halted. Therefore the HFEA was exposed to some credit risk during a short period of time as clinics gott 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 £3,288,753. As at 31 March 2021, 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 2021	31 March 2020
Amounts falling due within one year	£'000s	£'000s
Trade receivables (contract with customers) current	239	483
Impairment for expected credit losses	(22)	(104)
Prepayments and accrued income	614	592
Other receivables	74	83
Total	905	1,054

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

17	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 2021 £'000s
Balance at 31 March 2020	2,463
Net change in cash	826
Balance at 31 March 2021	3,289
	31 March 2021
Bank account balances	£'000's
Government Banking Services	2,426
Commercial Banks	863
	3,289

No cash equivalents were held during the year.

10. Trade payables and other current liabilities

	31 March	
	2021	2020
	£'000s	£'000s
Analysis by type		
Trade Payables	97	118
Accruals and deferred income	490	338
Other taxation and social security	162	0
Other contract liabilities	3	2
Total	752	458

All creditors were due for settlement within one year of the balance sheet 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 2021	31 March 2020
	£'000s	£'000s
Buildings		
Not later than one year	117	288
Later than one year not later than five years	468	0
Later than five years	537	0
	1,122	288
Other		
Not later than one year	0	4
	0	4
	1,122	292

12. Provisions

Total future minimum lease payments	Office Relocation(Travel) £'000s	Total £'000s
Balance at 1 April 2020	0	0
Provided in year	110	110
Provisions utilised in year	0	0
Release of provision for the period Balance at 31 March 2021	0 110	0 110

Analysis of expected timing of cashflows

	Office Relocation(Travel) £'000s	Total <u>£'000s</u>
Not later than one year	37	37
Later than one year and not later than five years	73	73
	110	110

The provision provided this year 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 is based upon the number of staff who currently have office-based contracts. The provision will be reviewed at an appropriate point in the 2021/22 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)

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.

The HFEA signed its Memorandum and Terms of Occupation (MOTO) with the DHSC on the 7 June 2021.

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