Authority meeting

Date: 24 January 2024 –12.45pm to 4.00pm

Venue: HFEA Office, 2nd Floor 2 Redman Place, London E20 1JQ

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of the meetings held on 15 November 2023 and matters arising (5) For decision	12.50pm
3. Chair and Chief Executive's report (15) For information	12.55pm
4. Committee Chairs' reports (20) For information	1.10pm
5. Performance Report (30) For information	1.30pm
6. Draft Business Plan 2024/25 (30) For information	2.00pm
7. Opening the Register (15) For information	2.30pm
Break	
8. Support services for those affected by donation (45) For decision	2.45pm
9. Public Bodies review – recommendations and HFEA response (30) For decision	3.30pm
10. Any Other Business (5)	4.00pm
11. Close	

Minutes of Authority meeting held on 15 November 2023

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	24 January 2024		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 15 November 2023 as a true record of the meeting.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Minutes of the Authority meeting on 15 November 2023

Members present	Julia Chain Tim Child Frances Flinter Zeynep Gurtin Jonathan Herring Alex Kafetz Jason Kasraie	Alison McTavish Alison Marsden Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Graham James	
Observer	Steve Pugh (Department of Health and Social Care – DHSC) Farhia Yusuf (Department of Health and Social Care – DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar	Paul Robinson Dina Halai Anna Wilkinson Shabbir Qureshi Alison Margrave

Members
There were 13 members at the meeting – 8 lay and 5 professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, HFEA staff and DHSC colleagues present.

1.2. The Chair also welcomed observers online and stated that the meeting was being audio recorded in line with previous meetings and for reasons of transparency. She stated that the recording would be made available on our website to allow members of the public to hear it.

1.3. Declarations of interest were made by:
- Geeta Nargund (Clinician at a licensed clinic) and
- Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting and matters arising

2.1. Members agreed that the minutes of the meetings held on 13 September 2023 were a true record and could be signed by the Chair.

Matters arising

2.2. Members were advised that all the matters arising items had been actioned as detailed in the paper presented to the meeting.

3. Chair and Chief Executive's report

3.1. The Chair noted that the HFEA's proposals for law reform had been published on 14th November 2023. She expressed her thanks to the HFEA team as well as many others including respondents to the public consultation and members of the Legislative Reform Advisory Group This marked the end of the first stage of this work and the HFEA will now consider the next steps in further work on the main areas of change.

3.2. The Chair gave an overview of her engagement with key stakeholders and her attendance at the decision-making committees of the Authority. The Chair highlighted the meeting with Fertilis, an organisation which brings together most of the large private sector clinic groups in the UK.

3.3. The Chair informed the Authority that she will attend the PET Conference and Fertility 2024 and will speak on the proposed law reform proposals.

3.4. The Chief Executive informed the Authority that as the Public Bodies Review report has not yet been published, this agenda item will not be considered today but he hoped that it would be published soon.

3.5. The Chief Executive provided an update on the key external activities in the paper presented to the Authority. He highlighted his attendance at the human embryos in medical research conference in Berlin and spoke of the high esteem in which the HFEA model is held.

3.6. The Chief Executive spoke about the CsaP (Centre for Science and Policy) Workshop he attended on the governance of stem cell-based embryo models in the UK. These models currently fall outside the current regulatory framework and there is a desire to create a voluntary code.

3.7. In response to a question, the Chief Executive provided further insight into the REAL (Research and Economic Analysis for the Long term) Challenge annual lecture on 'What will the NHS look like at 100?' It was noted that this lecture was available on YouTube and the Chief Executive undertook to send the details to members.

Decision

3.8. Members noted the Chair and Chief Executive's report.

4. Committee Chairs' reports

4.1. The Chair invited Committee Chairs to add any other comments to the presented report.

4.2. The Licence Committee Chair (Alison Marsden), gave an overview of recent meetings and spoke about the impact of the work of the inspectors and how our inspection and licensing system is making a positive difference to the work of the Authority.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further insight to the work of the committee. He explained the process that when a PGT-M condition is approved, a definition of the condition must be created that can be understood by a lay member of the public. He spoke about how the committee draws on expert advice and lived experience for preparing this definition.

4.4. The Scientific and Clinical Advances Advisory Committee Chair (Tim Child), gave an update on the work of the committee. He spoke about the presentation given to the committee on health outcomes in children born from ART. The committee had also removed artificial egg activation treatment from the list of treatment add-ons in line with professional guidelines on best practice which had been issued recently.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an update on the work of the committee, highlighting the discussion on closing recommendations from internal audit. The committee held a deep dive discussion on legal risks and the Chief Executive was thanked for preparing the discussion paper, Progress against Governmental Functional Standards continues to be monitored. Members were invited to attend the forthcoming training session on good governance. The AGC Chair reported that she will attend the Department of Health and Social Care (DHSC) Audit and Risk Committee meeting in early December with the Chief Executive and Director of Finance and Resources.

4.6. The Chair spoke about the importance of the work undertaken by the various committees and expressed her thanks to all members for their commitment to this.

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and stated that of the 17 KPIs, four are red, three amber, seven green and three neutral. As a small organisation any long-term sick leave will have a negative impact on this KPI and as reported earlier these are distinct cases not related to stress or workload.

5.2. The Chief Executive reported that the HFEA is nearly operating at full headcount, carrying one staff vacancy. The Chief Executive expressed his thanks to the staff, but especially the HR team, for filling vacancies quickly.

5.3. PRISM activity levels continue to be stable with an average error rate of just 3.4%. He reported that several clinics have an error rate above 4% so a targeted approach to address this will be taken.

5.4. The Chief Executive spoke about the benefits of the new database structure and how it will be easier for the HFEA to manipulate and manage its data.

5.5. A member congratulated the HFEA team in driving down the PRISM error rate and expressed thanks to all involved in this work.

Compliance and Information

5.6. A member asked whether there was increased pressure on the OTR team due to the success of the #WhoIsMyDonor campaign and asked whether there are any concerns regarding available resources to respond to enquiries and clear the backlog. The member questioned whether future reporting could include details on time elapsed from application to issuing information.

5.7. The Director of Compliance and Information responded that the OTR team has not been able to solely focus on processing applications as they have had to prioritise the development and testing of the system and training. The focus for the team had been to ensure that the tools were in place to be able to manage and report on the data. This development work has now been completed so the team will be able to focus on applications to start to reduce the backlog. It was noted that the time taken to deal with enquiries will depend in part on the response of others as clinics have 28 days to respond to requests from the HFEA and donors have 20 days to respond to being notified that a request for their identifiable information has been made.

5.8. The Director of Compliance and Information stated that inspector workload remains high, and this is impacted by long-term sick leave and turnover of staff. Training of the new inspectors is going well, and they are now attending inspections.

5.9. It was reported that an independent IT data back-up audit had been conducted and the results will be reported through the Audit and Governance Committee. Security penetration testing has been carried out and additional measures will be put in place to mitigate any vulnerabilities. The business continuity plan has been redrafted and this now includes critical incident management; the revised plan is currently at review stage.

5.10. The Director of Compliance and Information reported that the team are looking at the DSPT submission for the next year, noting the increased demands of this submission.

5.11. The business case for the Epicentre (inspection and licensing tool) replacement is being drafted and a meeting is planned for later this month with the DHSC procurement team.

Strategy and Corporate Affairs

5.12. The Director of Strategy and Corporate Affairs informed members that over the weekend NHS England had published information stating that they were stopping funding PGT-M. It is the HFEA's understanding that this was an error and we have received clarification that the commissioning arrangements are unchanged. NHSE have apologised for the concern and confusion that this has caused. It was noted that between 600-700 patients a year benefit from this successful, cost-effective treatment which removes the chance of having a child with significant hereditary disease.

5.13. Reference was made to the recent Government announcement on changes to the law regarding 'shared motherhood' and same-sex couples with non-transmissible HIV. An update and a timetable for this change will be shared with clinics when we have more information on it.

5.14. The Authority were informed that there had been over 260 pieces of media coverage on our law reform proposals with most focus on proposed changes to provide information about donors to parents, on request, after the birth of a child. The ethnic diversity in fertility treatment report will be published later this year and will include a call to action.

5.15. The data dashboards will go live later this year on the HFEA website, and this will make using and understanding the HFEA's data easier.

5.16. The Code of Practice update had been published and laid in Parliament at the end of October. Thanks were expressed to colleagues in DHSC for their assistance with this.

5.17. Information was provided about the publication of the treatment add-ons information and the media coverage achieved. In response to a question the Director of Strategy and Corporate Affairs stated that no negative feedback had been received from professionals in the sector.

5.18. Information was provided on the recent patient organisation stakeholder group meeting and the planned professional stakeholder group meeting. Main topics of discussion were the #WhoIsMyDonor campaign, treatment add-ons and the ethnic diversity in fertility treatment report.

Finance

5.19. The Director of Finance and Resources stated that as previously reported the HFEA is currently operating with a small deficit which can be attributed to increases in IT costs and the non-consolidated bonus for staff which was agreed by the Government but needed to be met out of the HFEA's current budget. Forecasted income has dropped slightly. He stated that the Department is aware of the deficit and has not requested any corrective action.

Decision

5.20. Members noted the performance report.

6. 2024/25 Budget Proposals

6.1. The Chair introduced this item reminding members that the HFEA is funded by a mix of fees levied on the sector it regulates and Grant In Aid (GIA) from DHSC. It is the Authority's responsibility to set the budget and consideration needs to be given to the reduction in GIA and increasing inflation costs.

6.2. The Director of Finance and Resources introduced the paper and provided further background about HFEA's operating costs stating that approximately 80% of income is raised via licence fees charged to licensed treatment and research establishments with the remainder being provided through GIA from DHSC.

6.3. The expenditure requirements for 2024/25 were explained in detail, noting that the higher levels of inflation experienced over the last couple of years have led to larger increases in staff pay as well as increases in several core areas, such as IT licences.

6.4. Whilst there are no current plans to increase the workforce headcount, the significant pressure on the OTR team needs to be explored as additional staff may be required to service this. HFEA would expect to fund additional in-year operational pressures through efficiencies and flexible use of available resources.

6.5. The Director of Finance and Resources spoke about the reduction in GIA and the expectation from DHSC that fees should be increased to cover this shortfall. An application will be made to DHSC business planning for additional GIA for a replacement system for Epicentre, as it would be difficult to fund the cost of this system through increased fees alone. The proposed increases to fees were explained in detail.

6.6. The Director of Finance and Resources stated that if the Authority approved the budget proposals he would seek agreement from both DHSC and HM Treasury for the proposed fee increases.

6.7. In response to a question from a member the Chair clarified that the proposed increase in fees and the GIA bid for replacing Epicentre are two distinct issues.

6.8. Members discussed the high importance of replacing Epicentre to ensure that the HFEA can continue to meet its statutory inspection and licensing duties. It was noted that a new system should also improve efficiency.

6.9. In response to a question regarding the proposed differential percentage increases to fees for IVF and DI, the Director of Finance and Resources explained that the income from DI is small and therefore not a significant income stream.

6.10. A member expressed their disappointment in the reduced funding from GIA and questioned whether this is being applied consistently across all ALBs. The Director of Finance and Resources responded that the Department's current preference is that regulators should be funded through their chargeable fees rather than GIA.

6.11. In response to questions the Chief Executive explained that it is very difficult to undertake an international price comparison and that over time HFEA fees have generally been below inflation.

6.12. A member stated that most IVF clinics add an 'HFEA fee' onto the patient's bill as an itemised item and they questioned whether the centres should be absorbing some costs rather than levying them all on the patient. The Chief Executive reiterated that the HFEA does not charge fees to individual patients but to licensed clinics; and these establishments then decide whether to pass the costs on or not. It was noted that whilst a round of IVF may cost (at the lower end) between £4,000 - £5,000, the proposed HFEA licence fee for safely regulating this field would be just £100.

Decision

6.13. Members agreed the proposed HFEA operating budget for 2024/25.

6.14. Members agreed the fee levels of £100 for IVF and £40 for DI as required to fully fund the HFEA in 2024/25, subject to DHSC and HM Treasury approval.

6.15. Members agreed that the HFEA should bid for £620,000 of additional urgent GIA to cover the cost of replacing Epicentre through the DHSC business planning process.

Action

6.16. The Director of Finance and Resources to seek approval from DHSC and HM Treasury and implement the decisions regarding the 2024/25 budget.

7. Strategic Risk Register

7.1. The Risk and Business Planning Manager presented this item and informed members that significant updates to the Strategic Risk Register will be undertaken after this Authority Meeting in preparation for the forthcoming December Audit and Governance Committee meeting.

7.2. The Risk and Business Planning Manager explained the proposed changes and updates for the risk categories contained in the Strategic Risk Register, noting that the strategy risk will be updated once the public bodies review report is published, and that the security risk will be updated with the results of the penetration testing.

Decision

7.3. Members noted the report.

8. Opening the Register - update

8.1. The Director of Compliance and Information presented the update on Opening the Register (OTR).

8.2. The testing of the OTR RITA reports is nearing completion and once these reports are delivered the SOP will be updated to include these new procedures.

8.3. The Director of Strategy and Corporate Affairs spoke of the success of the #WhoIsMyDonor campaign and thanked stakeholders for supporting this. Consideration will be given to the planned communications workstream so that applications do not become unmanageable, the other risks as contained in the paper remain unchanged.

8.4. A member questioned whether it is possible to know the average rate of expected enquiries per year for this service. Members of the Executive responded that whilst the numbers of potential applications are known for each year, these are cumulative as not everyone will request the information at the age of 18, and may wait for significant events in their life like marriage or the birth of their own children, and it was unknown how many of those know they are donor-conceived. It would not therefore be possible to estimate the expected average number of enquiries until this service had been operating for a number of years.

8.5. A member raised the risk of fraudulent websites being set up which could promise to fast-track applications for a fee, and questioned whether additional information regarding the importance of gov.uk email addresses could be added to the HFEA website. The Director of Compliance and Information responded that this potential risk is recorded on the strategic risk register and is being actively monitored. Information is already included on the HFEA website, but consideration would be given to see whether this could be strengthened.

8.6. In response to a question the Director of Compliance and Information reiterated that the team had been focussing on the development and testing of the required IT tools as ensuring these are correct will assist in managing the data efficiently and quickly.

8.7. The Chair drew the discussion to a close stating that this is an important standing item on the Authority's agenda.

Decision

8.8. Members noted the update on OTR.

9. Public Bodies Review

9.1. This item has been deferred to a subsequent Authority meeting as the final report has not yet been published.

10. Support Services Update

10.1. The Chair introduced this item stating that whilst a general report had been given on OTR, this focuses on the support services work. This item is brought to the Authority for information now and a further report which requires a decision will brought to the January 2024 meeting.

10.2. The Policy Manager introduced the paper and provided a recap of the current provision of support services which is in place until September 2024.

10.3. The expected increase in applicants from late 2023 with the availability of identifiable information is likely to have a substantial impact on the demand for, and cost of, a support service over time. Applicants must have been given a suitable opportunity to receive proper counselling before the HFEA is required to give them information; but there is no requirement for the HFEA to provide this counselling.

10.4. The team had looked at international comparisons and reviewed funding options. It was noted support services are not widely provided free of charge, although in some countries there is state or charitable funding, but this is limited. Discussions had been held at stakeholder roundtable meetings, including with patient organisations, professionals and academics. The key takeaways from these meetings included the importance of peer support and reliable high quality information.

10.5. A survey was run in August – September 2023 and 270 responses were received, of which 254 were complete responses. A high-level summary of the results was presented to the Authority. It was noted that respondents perceived that HFEA involvement in commissioning services would result in increased confidence and trust in the services provided. However, the most common type of support accessed was through peer support and information and responses to a question regarding funding indicated that there was some willingness to pay (in whole or in part) for specialist counselling

10.6. The Policy Manager described the next steps in this work, with final options being brought to the January 2024 meeting for a decision.

10.7. A member summarised their views of the themes arising from this work as: 1) the importance of a single source of information for quality, consistency, and sensitivity; 2) access to peer support; 3) sign posting of information; and 4) potential willingness to accept self-funding of this service.

10.8. A member questioned whether it was possible to bid for central funding for this support service work. The Director of Compliance and Information responded that it is not a realistic option to seek additional funding from DHSC for this work, especially as GIA is being reduced.

10.9. In response to a question, the Policy Manager stated that peer support was defined in the questionnaire, and it did not include ‘talking to a friend’.

10.10. A member asked whether it is possible for the January paper to include details of the number of applications accessing the current support service and the feedback on the services provided. The policy manager responded that current numbers of those accessing the service were low and there may be some data sharing issues which will prevent the HFEA accessing the feedback.

10.11. In response to a question regarding costings the Director of Compliance and Information reiterated that the HFEA did not have a statutory requirement to provide this support service.

Decision

10.12. Members noted the report.

11. Add-ons – report back on publication of new ratings systems

11.1. The Chair introduced this item and stated that the launch of the updated rating system for treatment add-ons marked the successful end of a long period of policy and communications work. The Chair thanked the members of the Scientific and Clinical Advances Advisory Committee and all members of staff who had worked on this.

11.2. The Head of Regulatory Policy (Scientific), introduced the paper and stated that the new categories of add-ons rating system went live last month. On the go live launch date over 1,000 visits were made to the HFEA website and there were over 270 pieces of media coverage.

11.3. The Head of Regulatory Policy referred to the communication activities undertaken and provided further highlights of this.

11.4. The next steps for this work were presented including developing a BAU process for reviewing the evidence base for treatment add-ons and to consider the frequency of review. The HFEA was the first regulatory body in the world to publish information for patients on the efficacy of treatment add-ons, the Cochrane Special Collection and ESHRE have also now published evidence-based reports on add-ons. The HFEA will continue to monitor new sources of reviewed evidence to ensure that HFEA resources continue to respond to UK patients' needs, and explore whether there are any collaborative opportunities in the future.

11.5. The Chair of the Scientific and Clinical Advances Advisory Committee expressed his thanks to all who had worked on this, especially regarding the tight timetable that some of this work was completed in.

11.6. Members expressed their congratulations to the team for delivering this work which had been very well received.

11.7. In response to a question the Head of Regulatory Policy stated that this information had not been sent to commissioning bodies and this would be sent to NHS England to disseminate to the commissioning bodies.

11.8. A member asked if there were any lessons learned from the management of this work which can be carried forward to other projects. The Director of Strategy and Corporate Affairs responded that the new process of reviewing evidence introduced through the add-ons work is already being used for the annual horizon scanning review.

11.9. The Chief Executive commented that this was a time-consuming project and consideration must be given to what kind of policy model suits key pieces of future policy work. The opportunity to collaborate with other organisations will also be considered to see whether efficiency measures can be achieved.

11.10. A member asked whether the HFEA was collecting information on patient treatment add-ons. The Director of Compliance and Information stated that the HFEA has an agreed data dictionary, and this could not be reviewed until PRISM was fully embedded.

Decision

11.11. The members noted the paper.

12. Any other business

12.1. The Chair thanked members for participating in a workshop immediately before the Authority meeting, where the focus of discussions was the 2025-2028 Strategy.

12.2. The Chair informed members that Jason Kasraie's term will end mid-January 2024, and this will therefore be his last Authority meeting. On behalf of the HFEA the Chair thanked Jason for his contribution and stated that he has agreed to stay as an expert adviser to the Authority on embryology until Ministers appoint a new professional with that skill set. Additionally, he will stay on SCAAC as an external member for a further 12 months.

12.3. The Chair stated that due to the vacancy on the Authority there would need to be a few changes to committee membership.

12.4. Members noted that 2024 would have been the 100th birthday of Mary Warnock.

12.5. The Chair reminded members that they can participate in a good governance training session organised by the Audit and Governance Committee being held on 7 December, and that further details are available from the Board Governance Manager.

12.6. There being no further items of any other business the Chair reminded members that the next meeting will be held on 24 January 2024, in person, at the HFEA's offices at 2 Redman Place.

Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature

Chair: Julia Chain

Date: 24 January 2024

Authority meeting

Matters Arising

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	2		
Meeting date	24 January 2024		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For discussion		
Recommendation	To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.		
Resource implications	To be updated and reviewed at each Authority meeting		
Implementation date	2023/24 business year		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Action	Date added	Assigned to	Target date	Revised date	Progress to date
3.7 Chief Executive to send details of the REAL Challenge annual lecture on what will the NHS look like at 100, to members.	15 Nov 2023	Chief Executive	Dec 2023		Email issued to members, this action is now completed and can be removed from the action log.
6.16 The Director of Finance and Resources to seek approval from HM Treasury and implement the decisions regarding the 2024/25 budget.	15 Nov 2023	Director of Finance and Resources	Jan 2024		Ongoing engagement with DHSC finance regarding decision-making process with HMT, with some delays due to changes in Finance Business Partners.

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	24 January 2024
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note the activities undertaken since the last meeting.
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	N/a

1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meetings in November 2023.
- Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

2.1 Chair activities

- The Chair has continued to engage with the decision-making functions of the Authority and with key external stakeholders:

    - 6 December – attended and spoke at the PET Conference
    - 12 December – attended the All Staff event
    - 11-13 January – attended the Fertility 2024 meeting and spoke about Regulation – 30 year on
    - 17 January – attended the Womens Health Summit

2.2 Chief Executive

- The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:

    - 1 December – attended HFEA/DHSC Quarterly Accountability Meeting
    - 4 December – presented to the DHSC Audit and Risk Committee (alongside Catharine Seddon, AGC Chair and Tom Skrinar, Finance & Resources Director)
    - 5 December – spoke at ACE CEO Public Body challenge meeting
    - 12 December – attended our All staff event

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Item number:	4
Meeting date:	24 January 2024
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is invited to note this report, and Chairs are invited to comment on their committees
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	None
Organisational risk:	Low

1. Committee reports

1.1 The information presented below summarises Committees' work since the last report.

2. Recent committee items considered

2.1 The table below sets out the recent items to each committee:

Meetings held	Items considered	Outcomes
Licence Committee:		
2 November	1 Renewal inspection, previously adjourned 1 Interim inspection	Both granted
15 January	4 interim inspections	Minutes not yet approved
Other comments:	The Committee had to reschedule its January meeting, and now plans to conduct its annual review of effectiveness at the March meeting.	
Executive Licensing Panel:		
7 November	2 Interims 1 Change of PR 3 Changes of LH	All approved
20 November	1 Renewal 3 Interims 1 Change of Licence Type 1 Change of LH	All approved
5 December	2 Renewals 2 Interims 1 Variation to add embryo testing 1 Variation to licensed premises	All approved
10 January	1 Initial 4 Interims 1 Variation of licenced premises	All approved
22 January	1 Initial 2 Renewals 2 Interims 1 Variation of licensed premises 1 Change of centre name	Minutes not yet approved
Other comments:	The Committee completed its annual review of effectiveness in December.	

Meetings held	Items considered	Outcomes
Licensing Officer decisions:		
November - December	34 ITE import certificates 1 Change of Centre Name 2 Changes of LH	All granted
Other comments:	None.	
Statutory Approvals Committee:		
31 October	2 PGT-M	All approved
27 November	3 PGT-M 1 Executive request to update the Mitochondrial Complex 1 Deficiency, Nuclear Type (MC1DN) condition types that are currently authorised for PGT-M to be consistent with the OMIM nomenclature.	All approved The committee agreed that the 35 Mitochondrial Complex I Deficiency, Nuclear Type (MC1DN) condition types that are currently on the PGT-M list should be renamed to align them with OMIM nomenclature.
12 December	4 PGT-M 2 Special Directions for import	All approved/granted
Other comments:	The committee will conduct its annual review of effectiveness at the January meeting.	
Audit and Governance Committee:		
7 December	The main items considered were: Internal audit and progress with audit recommendations External audit planning Risk update: • Strategic Risk Register • Risk Strategy Review • Discussion on deep dive list and horizon scanning Digital projects / PRISM update Resilience, business continuity and cyber security Human Resources Bi-Annual Update Government Functional Standards	
Other comments:	The Committee conducted its annual review of effectiveness at the December meeting. After the meeting, members also received governance and assurance training.	

Meetings held	Items considered	Outcomes
Scientific and Clinical Advances Advisory Committee:		
The next meeting will be held on 5 February 2024		
Other comments:	Three Authority members and an external advisor of the SCAAC visited Newcastle Fertility Centre at Life on 14 December 2023 to hear first hand about the mitochondrial donation programme. The committee will be updated at their February 2024 meeting.	

3. Recommendation

3.1 The Authority is invited to note this report. Comments are invited, particularly from the committee Chairs.

Human Fertilisation & Embryology Authority

Monthly performance report

Performance up to November 2023

Evgenia Savchyna
Corporate Performance Officer
24/01/2024

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	Item 5
Meeting date:	24/01/2024
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

Output from this paper	
For information or decision?	For information
Recommendation:	To discuss
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

Human Fertilisation & Embryology Authority

Latest review and key trends

Latest review

- The attached report is for performance up to and including November 2023.
- There were seven Green, three Amber, four Red, and three Neutral indicators.

Key trends

- The below table shows the red RAG statuses for the last three months.

September (4)	October (4)	November (4)
PTT items processed within 30 working days	Inspection reports to PR within 20 working days	End to end licensing within 70 working days
Staff sickness rate	Inspection reports to committee within 55 working days	Staff sickness rate
Debt collection	End to end licensing reports within 70 working days	Average debtor days
Invoices paid within 10 working days	Staff sickness rate	Invoices paid within 10 working days
	Average debtor days	
	Invoices paid within 10 working days	

Human Fertilisation & Embryology Authority

Management summary

IT and register performance reporting

- PRISM: 541K units from 104 clinics. The error rate is 3.4%. There are 32 clinics with errors greater than 4%.
- 10 Family Limit: Following the November clinic focus, we have eight clinics that have volunteered to be pilots for 10 family limit alerts. We anticipate starting the pilot in February.
- CaFC: We have agreed with AGC new timetable for CaFC. We will commence CaFC verification with clinics in January 2024 and run this until Summer 2024, and then start the process of sign-off and publication in Autumn 2024.

Management commentary

- Performance has been variable across KPI indicators with seven Green, three Amber, four Red, and three Neutral indicators.
- Inspection KPIs continue to be impacted by long-term sickness and staff turnover in the Compliance team. A complex renewal inspection with several management reviews and meetings with the PR was significantly over the 70 working day turnaround time. Following the clinic's licence expiry, it was placed under special directions so it could continue to operate. The clinic was eventually issued with a four-year licence with additional conditions.
- The number of OTRs received remains high following the peak in October, however, more OTRs were sent out in November compared to the last five months.
- Following periods of a high number of enquiries, there was a decrease in both email and telephone enquiries in November.
- There were six FOIs due in November. They were for HR, Finance, Clinic level data, OTR and Policy.
- The highest engagement across all social media channels was around recommendations for modernising UK fertility law.
- We can now exclude internal traffic from our website sessions data, so we are now able to provide a 'top 3' most viewed web pages on the HFEA website.
- Staff sickness remains high mainly due to long term absence, with steps being taken to support them. There were no leavers in November.
- Several clinics that were withholding payments due to estimated invoices have now had their invoices reconciled, however this continues to impact our debt collection and debtor days.

Summary financial position

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2023/2024 £'000s	Budget for 2023/24 £'000s	Variance Budget vs Forecast £'000s
Income	4,954	4,846	(108)	7,172	7,260	88
Expenditure	4,780	4,592	(188)	7,294	7,260	(34)
Total Surplus/(Deficit)	**174**	**254**	**(80)**	**(122)**	**0**	**(122)**

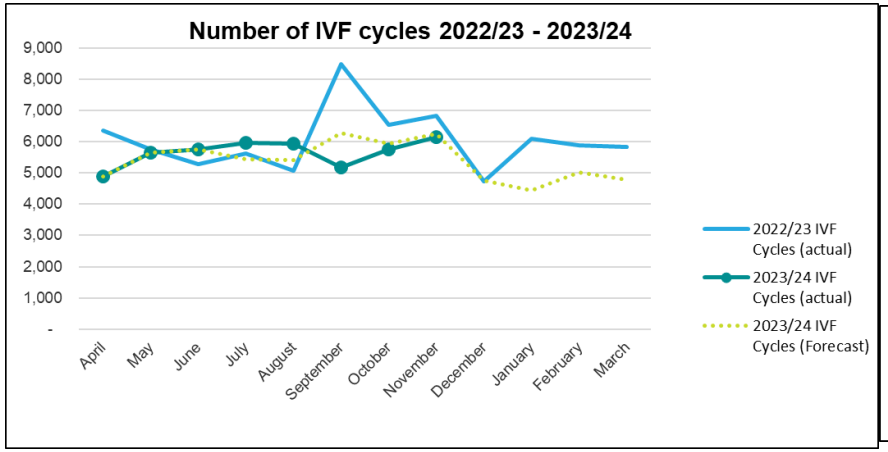
Commentary on financial performance to 30 November 2023

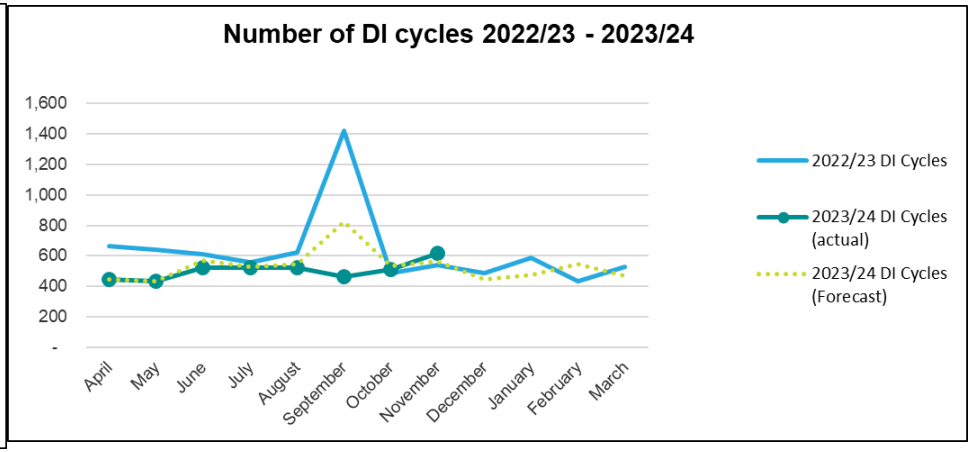
At the end of November 2023, we are showing a short-fall against budget of £80k. Year-to-date, our income is up against budget by £108k which is both treatment fees and our GIA. Our expenditure is above budget by £188k. Explanations for the increase are within the main report.

A detailed review at the end of Q3 will be undertaken, where some costs are currently being incurred at risk, and these will be reviewed in detail.

Our current forecast position is a deficit against budget of £122k which is likely to change but not significantly as the year draws to a close.

Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2022/23 IVF Cycles (actual)	49,972	4,247,620	72,493	6,161,905
2023/24 IVF Cycles (actual)	45,279	3,848,715	64,276	5,463,488
Variance	(4,693)	(398,905)	(8,217)	(698,417)

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2022/23 DI Cycles	5,549	208,088	7,589	284,588
2023/24 DI Cycles	4,039	151,463	5,975	224,050
Variance	(1,510)	(56,625)	(1,614)	(60,538)

For the eight months to 30 November, IVF volumes are down by 4,693 against the same period last year. Volumes are increasing but at a slower rate than one would have hoped. Where all clinics bar 3 are up to date with their submissions, it is expected that the budget will not be exceeded.

As with IVF, DI volumes are down 1,510 against the same period (8 months) last year. This year saw the months of October and November come in higher than last year. Should this continue to March, it will however, not have a significant impact on our income.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

HFEA Income & Expenditure Nov-23

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	628	496	(132)	(0)	951	991	40
Non-cash (Ring-fenced RDEL)	155	155	-	-	232	232	-
Grant-in-aid - PCSPS contribution	50	50	-	-	100	100	-
Licence Fees	3,985	4,090	105	0	5,720	5,829	109
Interest received	92	18	(74)	(4)	100	35	(65)
Seconded and other income	44	37	(7)	-21	69	73	4
Total Income	4,954	4,846	(108)	**(2)**	**7,172**	**7,260**	**88**
Revenue Costs							
Salaries (excluding Authority)	3,407	3,427	20	1	5,079	5,145	66
Staff Travel & Subsistence	61	29	(32)	(110)	139	100	(38)
Other Staff Costs	81	60	(21)	(34)	109	66	(43)
Authority & Other Committees costs	125	154	29	19	201	235	34
Facilities Costs incl non-cash	318	335	17	5	497	610	112
IT Costs	390	177	(213)	(121)	573	312	(260)
Legal / Professional Fees	251	269	18	7	467	521	54
Other Costs	118	115	(3)	(2)	200	223	24
Other Project Costs	29	25	(4)	(15)	29	51	21
Total Revenue Costs	**4,780**	**4,592**	**(189)**	**(4)**	**7,294**	**7,263**	**(31)**
TOTAL Surplus / (Deficit)	**174**	**254**	**(80)**		**(122)**	**(3)**	**(119)**

Income.
At the end of M08 (November) our total income is 2% (£108k) above budget. This relates in part to our grant in aid (£132k over) and is a profiling issue.
Our Treatment fee income exceeds budget by £105k year to date; however, the volumes of IVF/DI are not increasing at a significant rate. Volumes were down for the year to date by c5000 and 1500 respectively, compared to the same period in 2022/23.

Expenditure (by exception)
Year to date, expenditure is over budget by £189k.

Salaries - are under budget by £20k overall. The majority of this underspend comes from employer pension contributions (£86k); salaries (£14k) which are offset by overspends with Contingent Labour and Shared services (£80k).

Staff Travel & Subsistence - are over budget by £32k which is largely Inspection costs which have increased in line with the number being undertaken and home to office travel. The profile of this budget is different from the actual spend, contributing to this variance.

Authority & Other Committees cost - are showing a surplus against budget of £29k which is due to a reversing accrual from last year that was higher than needed and Advisor fees which are running at £11k under budget.

Facilities Costs - are under budget by £17k which relates to adjustments we have to make in accounting for the lease of our offices and underspends within Corporation Tax and Meeting costs.

IT Costs - are over budget by £213k which was foreseen at the time the budget was set. Our O365 Licence costs which have increased significantly from last year c100% which are currently overspent by £75k. Our Consultancy and Support costs are also over budget (£126k). These costs will remain over budget.

Legal/Professional fees - are under budget by £18k, with legal under-spent by £28k and the balance relating to overspends in internal and external audit fees totalling £10k. The audit fees are however expected to come within budget by year end.

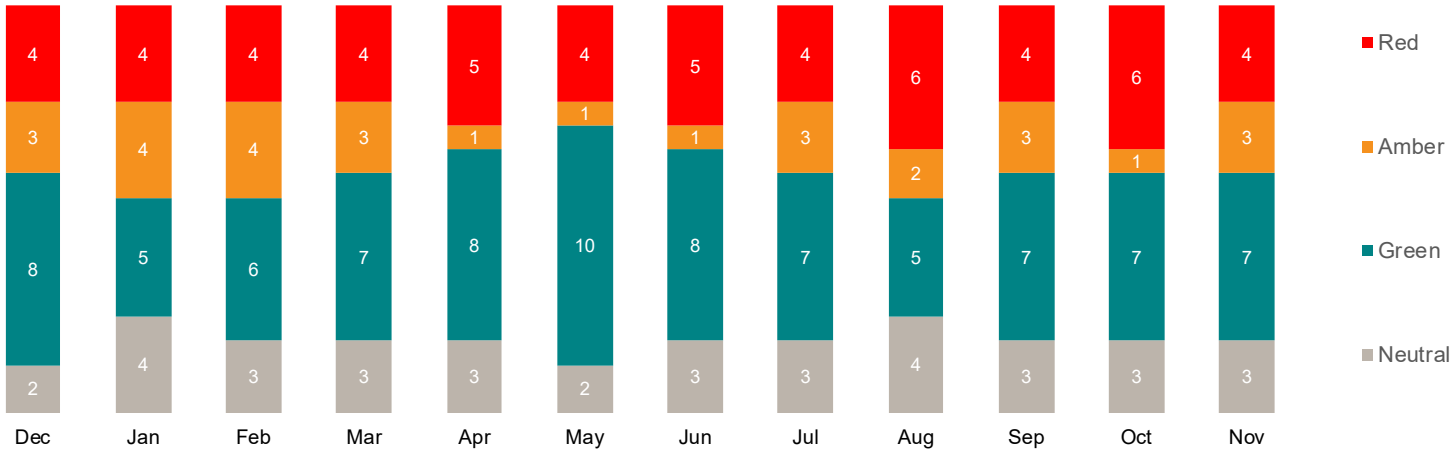
Forecast
The current forecast is an overspend of £119k for the year and against budget. This includes significant increases in our IT spend. There is an issue with our Grant in aid that is being discussed with DHSC Finance. The budget according to DHSC has been overstated due to the way they account for the lease of our offices. The adjustment for the lease has been deducted from our funding which we believe whilst correct has been allocated incorrectly. The assumption made by DHSC is that more than 80% of our lease is treated as Admin funding rather Programme (Licence fee). We hope to have resolution by the end of January.

Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

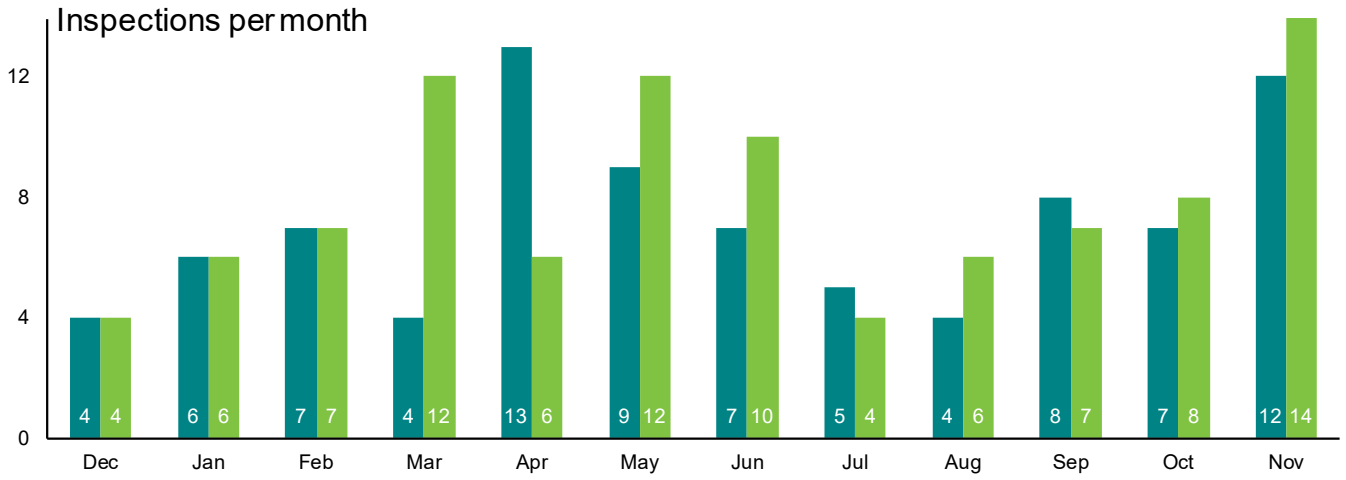
RAG status over last 12 months



RAG status over last 12 months

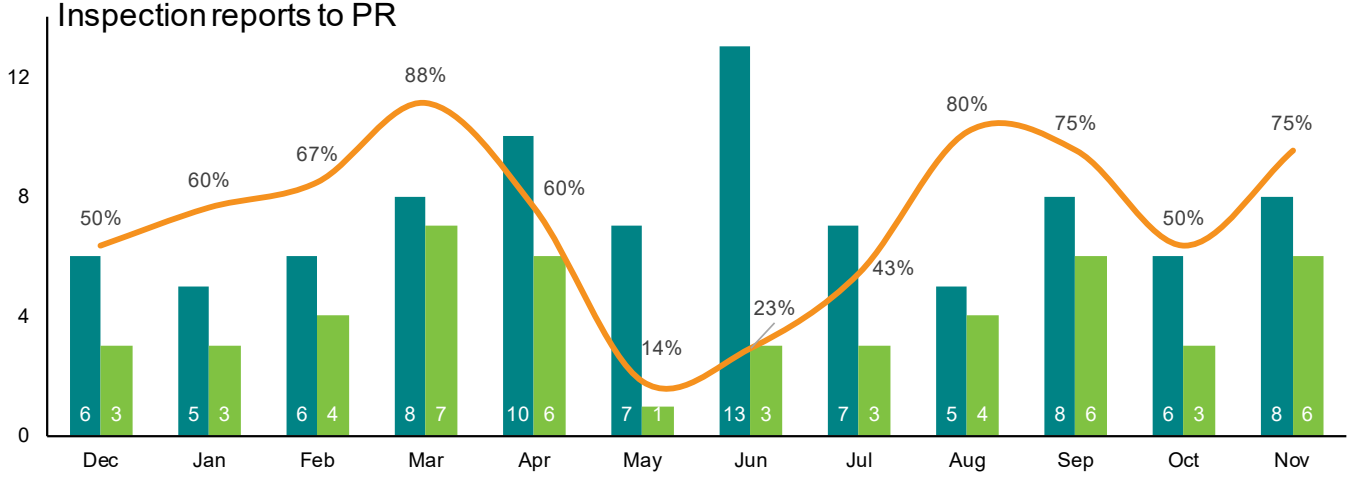
17 KPIs in total for each month

For November, the **4 Red indicators** are in these teams: **Compliance - 1; Finance - 2; HR - 1.**



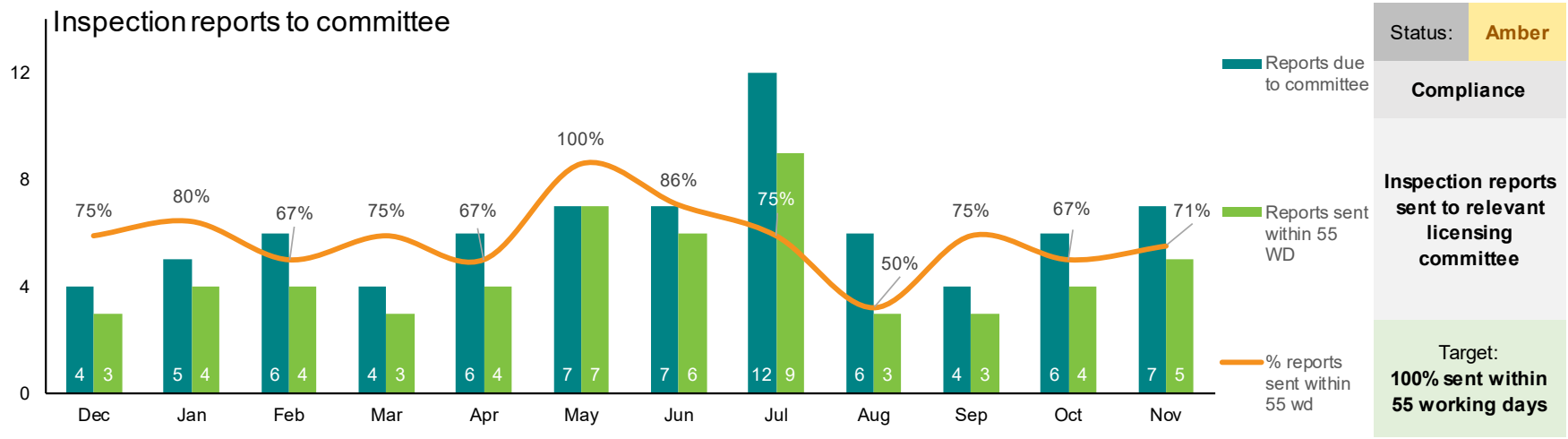
Status:	N/A
Compliance	
Inspections delivery	
Target: not defined	

More inspections were delivered this month. One inspection was rolled back from December to November due to inspector availability, and another one was an additional inspection.



Status:	Amber
Compliance	
Inspection reports sent to PR	
Target: 100% sent within 20 working days	

Two reports were delayed (one not sent to PR yet and another one sent with 9 days of delay) due to relocation of inspections and assisting new staff.



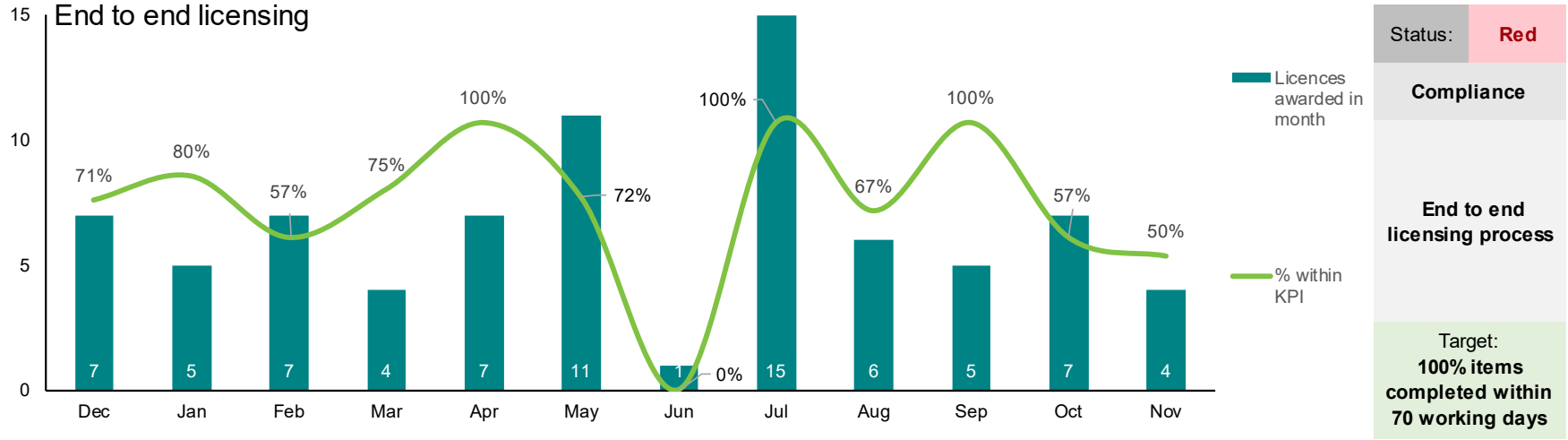
Status: **Amber**

Compliance

Inspection reports sent to relevant licensing committee

Target: **100% sent within 55 working days**

Two reports not sent to the committee yet - one due to the relocation of inspections; and another one due to the delay in providing post-inspection information by the clinic.



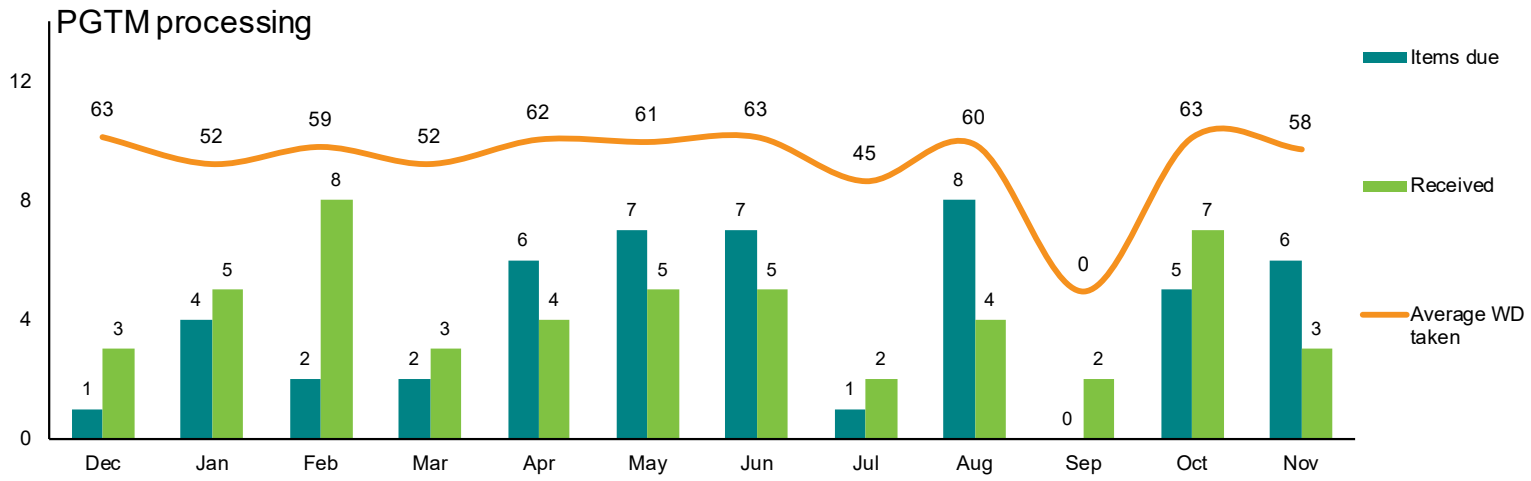
Status: **Red**

Compliance

End to end licensing process

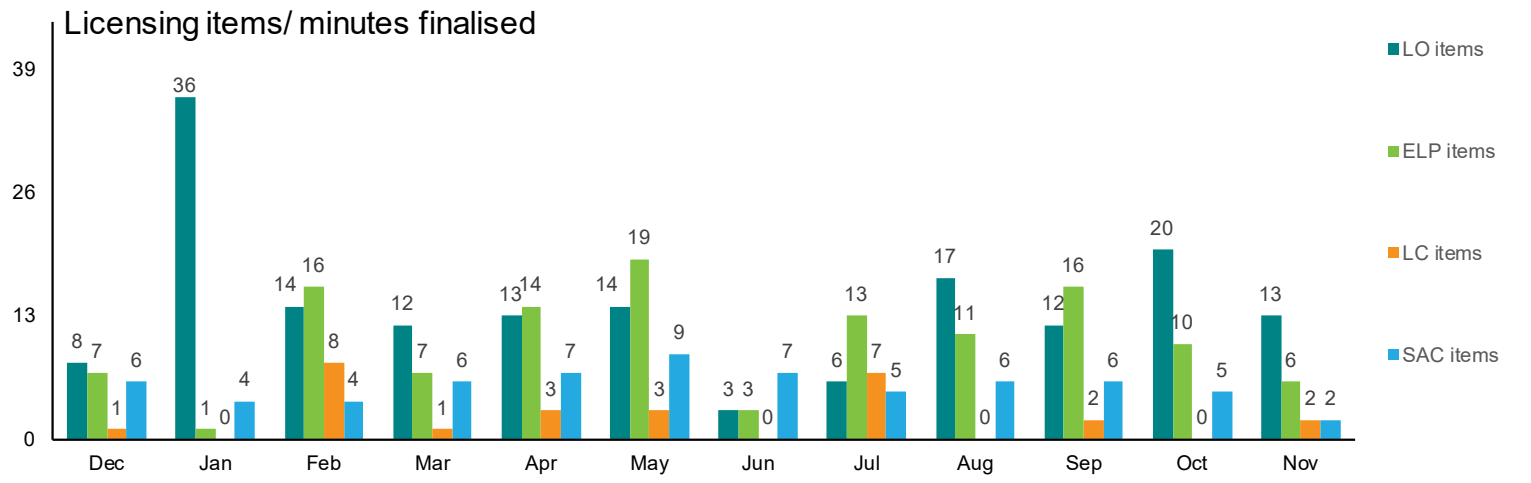
Target: **100% items completed within 70 working days**

Two of the four items were delayed. One (interim inspection) was completed with a 4-day delay due to the workload in the team. Another one (licence renewal inspection) had a significant delay of 233 days due to continuous review of non-compliances. Special directions were put into place to prevent affecting the licence continuity.



Status:	Green
Compliance	
PGTM processing efficiency	
Target: **100% within 75 working days**	

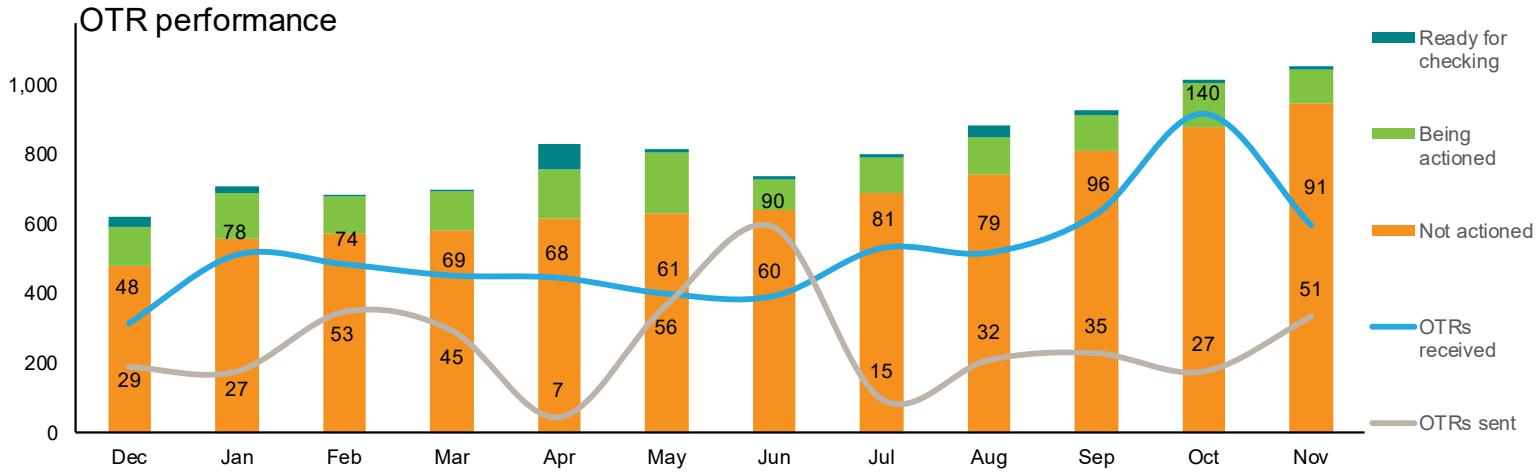
All PGTMs have been processed within KPI.



LO:	Green
ELP	Green
LC	Green
SAC	Green
PlanGo	
Licensing efficiency	
Targets: **LO - 5 WD; ELP - 10 WD: LC - 15 WD; SAC - 20 WD.**	

Another fairly regular month with targets met for all areas/meetings. SAC was slightly quieter than usual with just two items - we expect this to be an exception, not a trend.

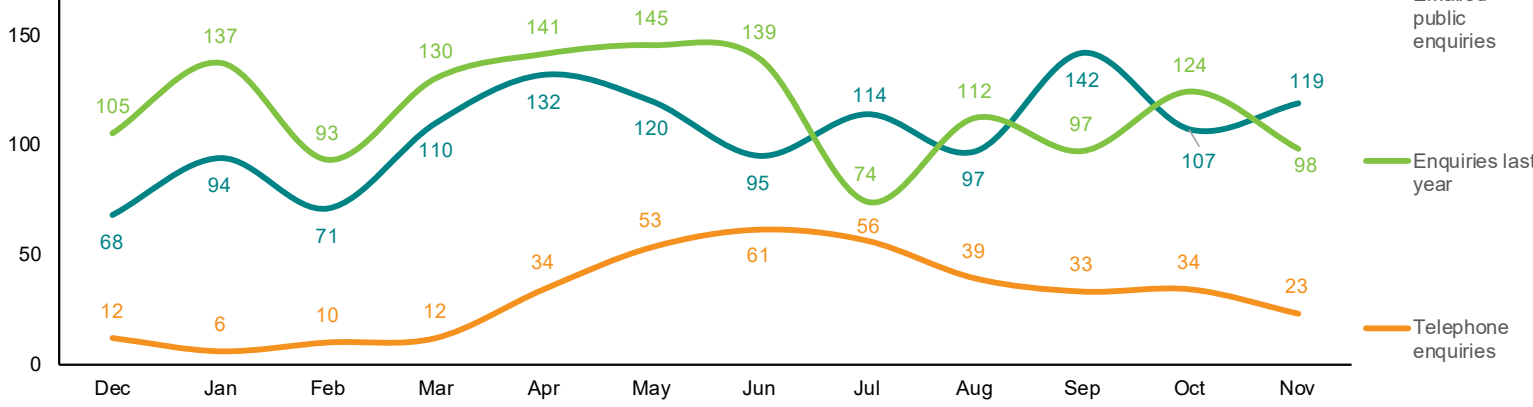
OTR performance



Status:	N/A
Information	
OTR performance	
Target: **to be developed**	

Number of OTRs received down from previous month but still high.

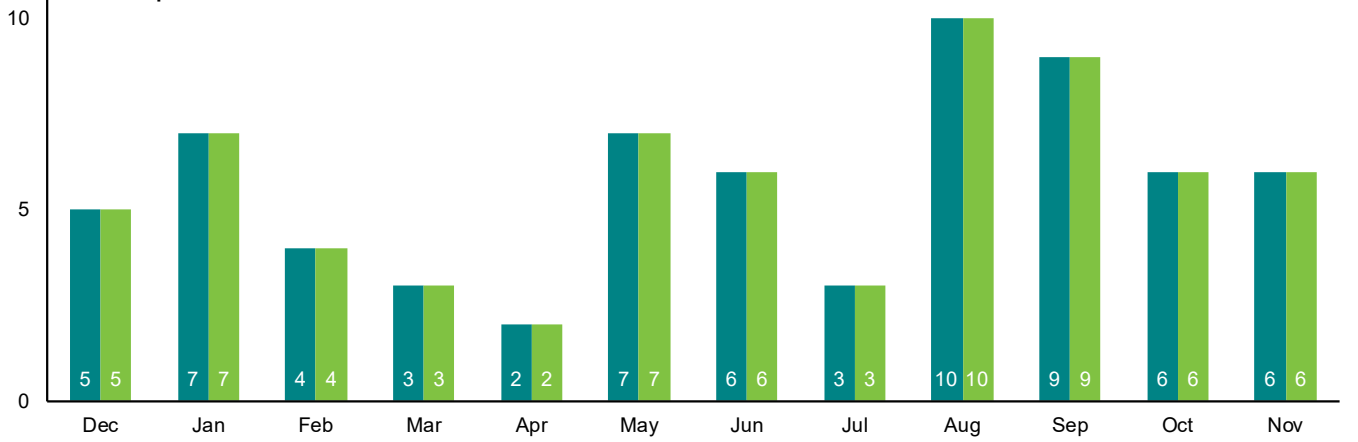
Emailed public and telephone enquiries



Status:	N/A
Policy/Comms	
Emailed public and telephone enquiries	
Target: **not defined**	

Of the 109 logged emails, 67 of them were from patients. **Themes**: Complaints (17), Licensing (10), Fertility preservation (9), Website (7), Sperm donation (6), Success rates (5). The remaining enquiries (55) fell into a variety of other themes.
Call themes: General treatment (9), OTR (8), Complaints (4) and Other (16). 3 calls out of 23 were categorised as challenging.

FOI requests



Status: **Green**

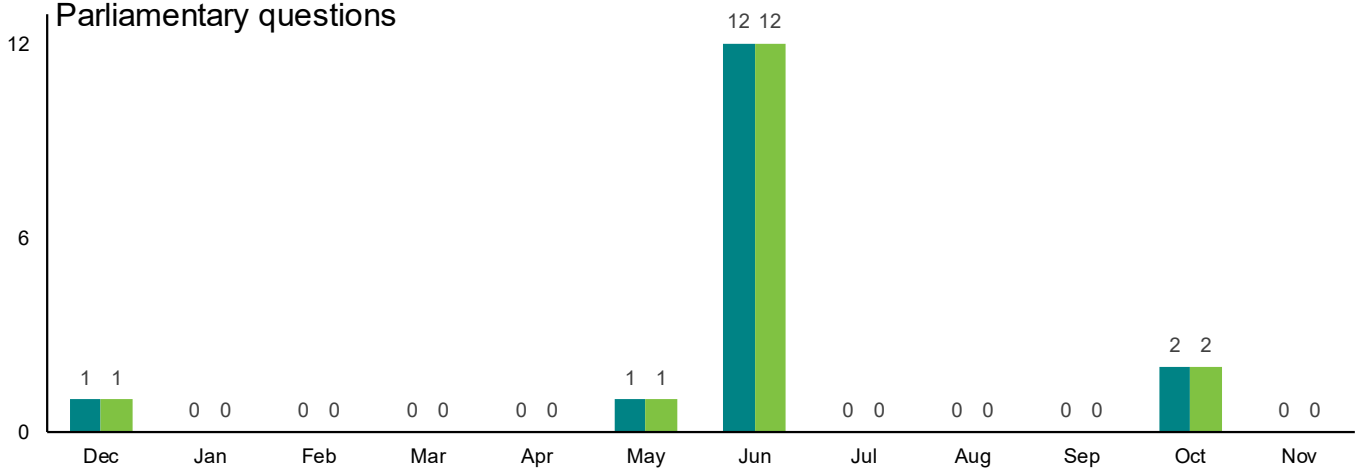
Intelligence

FOI responses

Target: **100% within 20 working days**

The FOIs due in November were about HR, Finance, Clinic level data, OTR, and Policy x2.

Parliamentary questions



Status: **Neutral**

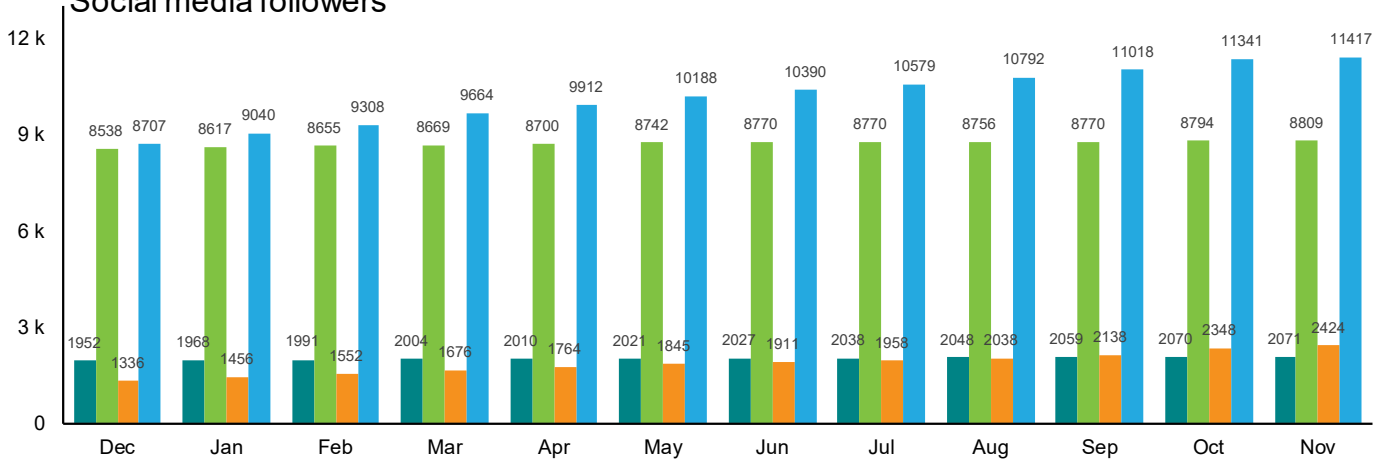
Intelligence

PQs responses

Target: **100% within deadlines set**

N/A.

Social media followers



Status: **N/A**

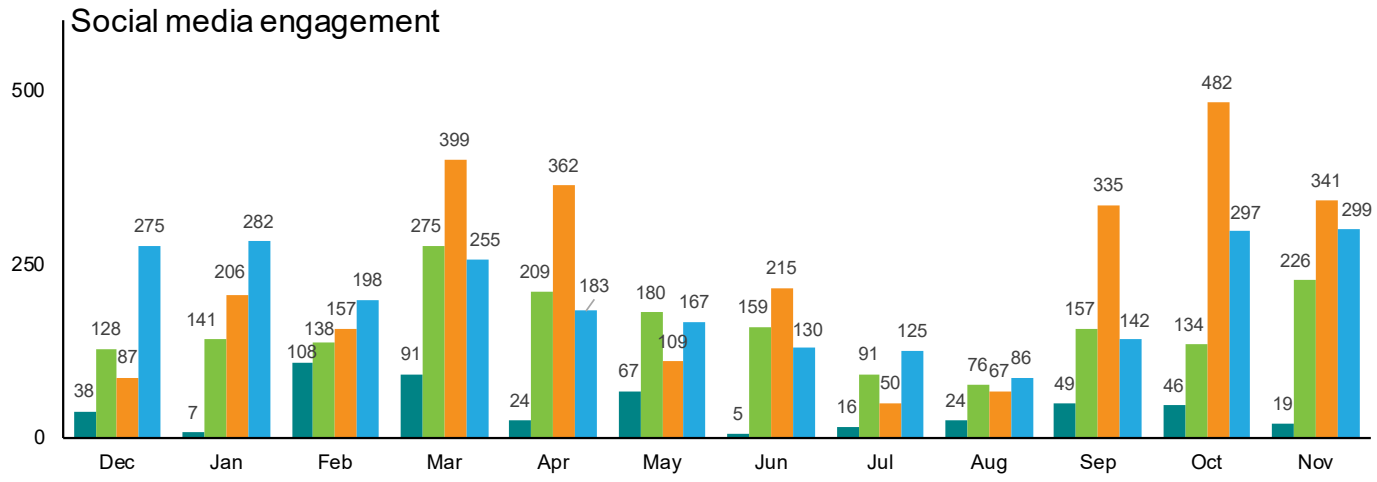
Comms

Total number of followers across social media

Target: **not defined**

Steady increase across all the channels with the largest rise in followers on Instagram and LinkedIn (76), and Facebook with the least (1).

Social media engagement



Status: **N/A**

Comms

Engagement across social media

Target: **not defined**

In November, we shared our recommendations for modernising UK fertility law. The post announcing this report had the highest engagement, and further content centred around this report was well-engaged with on all our channels. Compared to our other social media channels, Facebook posts, which seem to have been mostly interacted with by clinics, saw less of an engagement in performance.

Top 3 website sessions

	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Top	Fertility clinic search	Donating your eggs	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search	Fertility clinic search
Second	Choose a fertility clinic	Fertility clinic search	Donating your eggs	Choose a fertility clinic	Choose a fertility clinic	Choose a fertility clinic	Donating your eggs	Choose a fertility clinic	Choose a fertility clinic	Choose a fertility clinic	Treatment add-ons	Choose a fertility clinic
Third	Egg freezing	Choose a fertility clinic	Choose a fertility clinic	Egg freezing	Egg freezing	Egg freezing	Choose a fertility clinic	Donating your eggs	Donating your eggs	Donating your eggs	Choose a fertility clinic	Egg freezing

Status: **N/A**

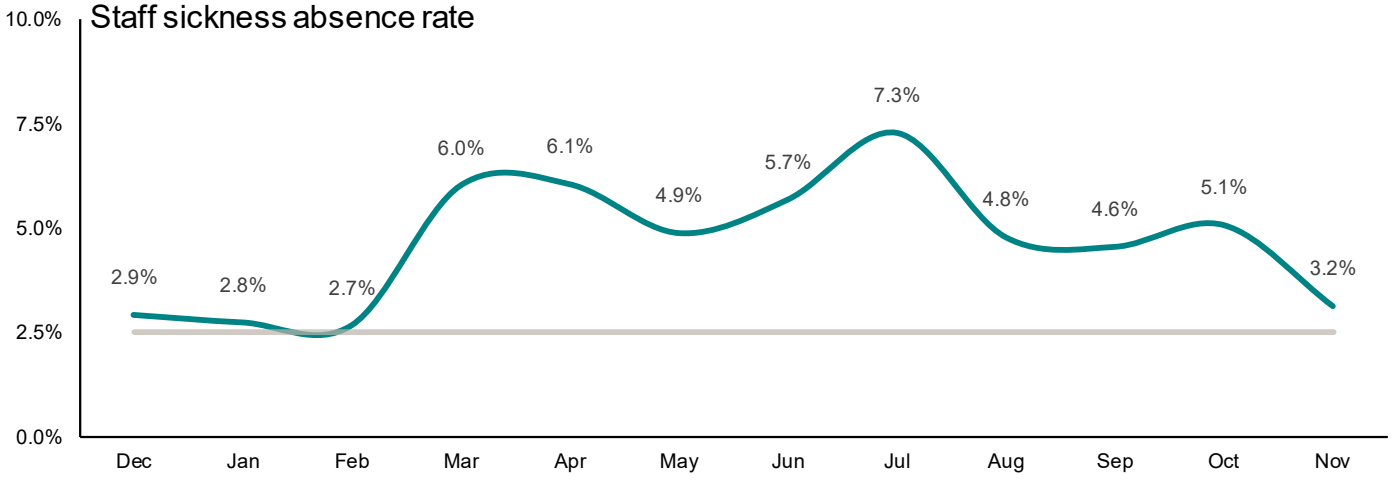
Comms

Top 3 website sessions per month

(Data from October excludes internal traffic)

Target: **not defined**

The web pages related to the Modernising the Law reform were published on 14th November, and saw a spike in page views (reaching almost 3,000) resulting in total of 8,753 views by the end of the month.



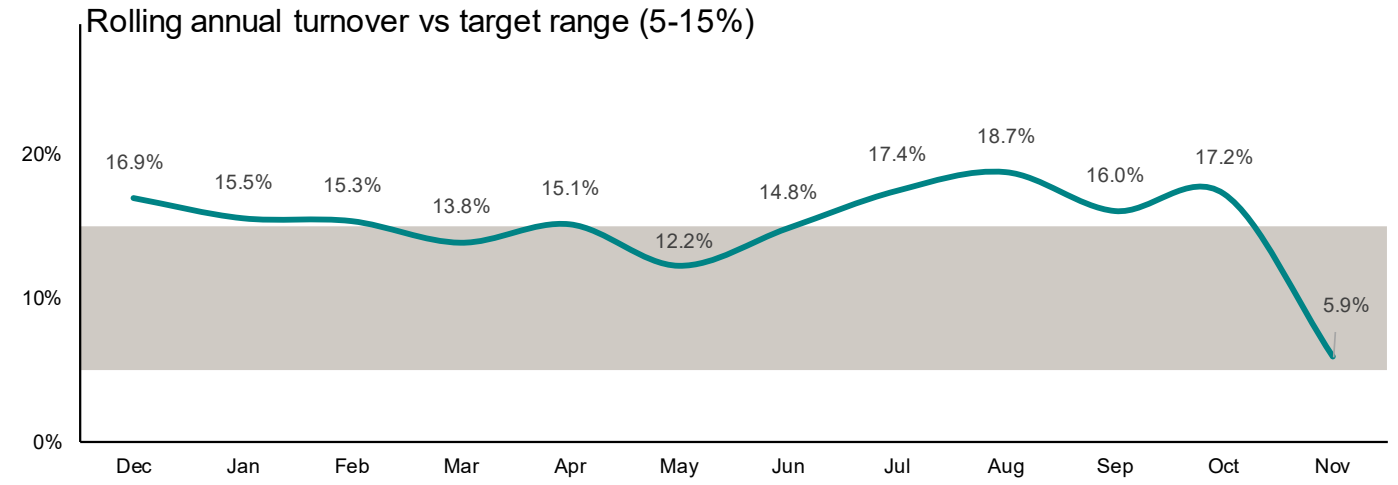
Status: **Red**

HR

Sickness

Target: **Less than or equal to 2.5%**

Our sickness absence rate without employees on long term sick is just 0.48%. Steps are being taken to support those on LTS.



Status: **Green**

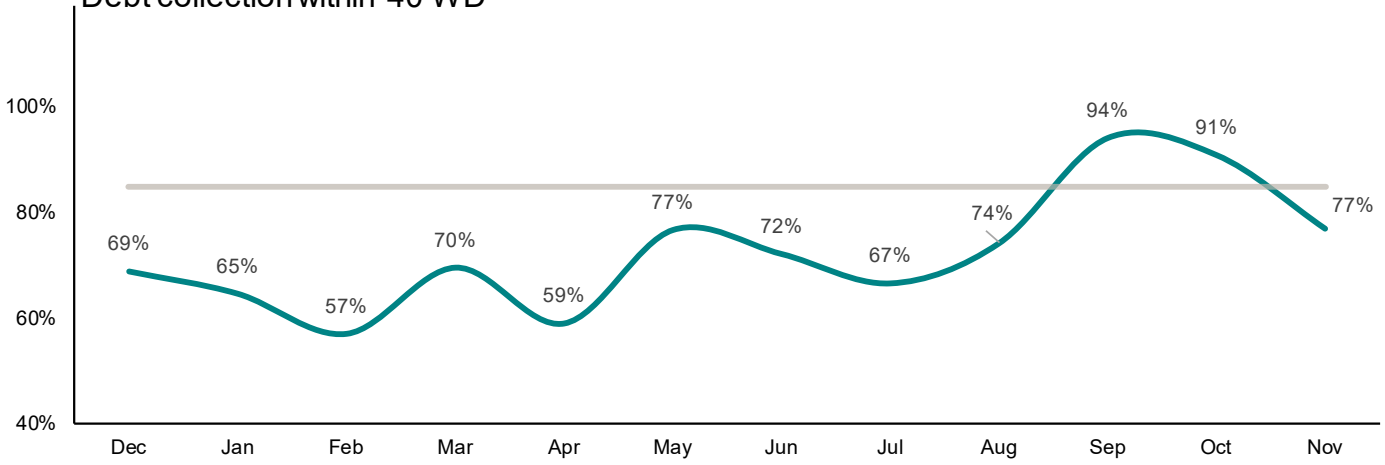
HR

Turnover

Target: **From 5% to 15%**

No leavers this month - turnover will rise next month, however, with two leavers planned for December.
Supplementary HR data: **Headcount - 76, Posts - 76, Starters - 0, Leavers - 0**.

Debt collection within 40 WD



Status: **Amber**

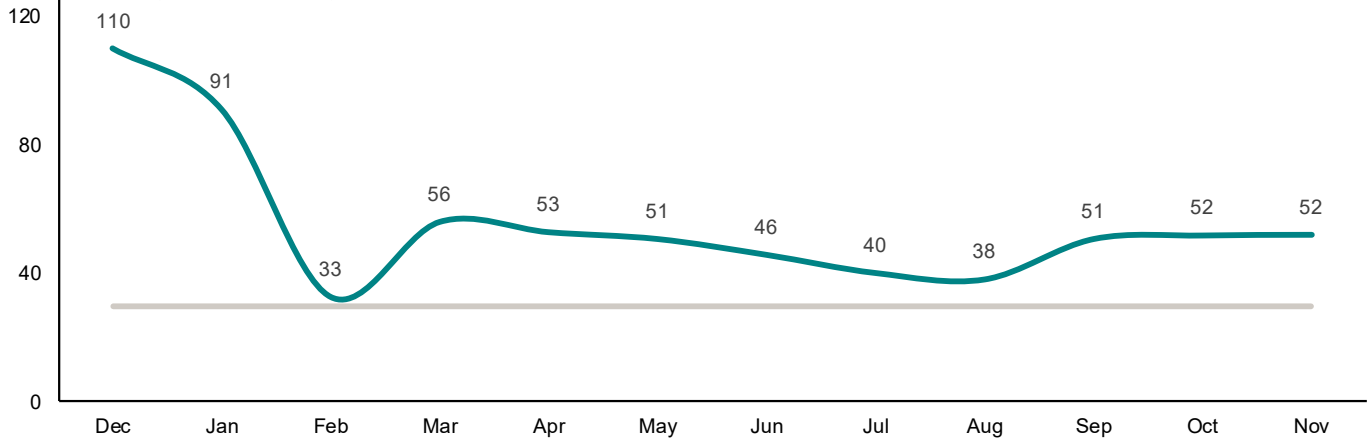
Finance

Debt collection

Target: **85% or more debts collected in the month within 40 working days from billing**

Several centres that had been witholding payment whilst estimated invoices were reconciled. All are now reconciled and we hope payment will be forthcoming.

Average debtor days



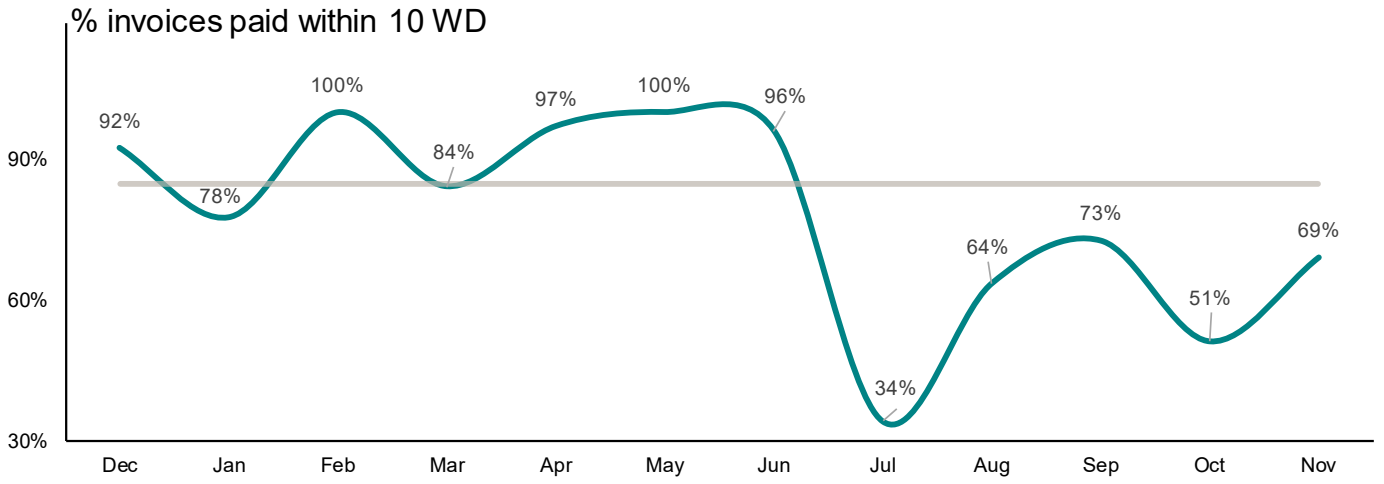
Status: **Red**

Finance

Debtor days

Target: **30 working days or less**

Several centres that had been witholding payment whilst estimated invoices were reconciled. All are now reconciled and we hope payment will be forthcoming.



Status:	Red
Finance	
Prompt payment	
Target: **85% or more invoices paid within 10 working days**	

90% of invoices were paid within 30 days of invoice. Payment of some invoices were purposely delayed whilst queries were resolved.

Draft Business Plan 2024-2025

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy: The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Authority
Agenda item:	6
Meeting date:	24 January 2024
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	6a Business Plan (main section) 2024-2025

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to approve the main section of the business plan for 2024-2025, for further development over the next two to three months.
Resource implications:	In budget
Implementation date:	1 April 2024 – 31 March 2025
Communication(s):	HFEA website
Organisational risk:	Low

1. Introduction

1.1. Following the initial paper presented to Authority at the November 2023 meeting, the annex to this paper sets out the first full draft of the activities section of the business plan for 2024-2025 and is presented for comment and approval.

1.2. Other sections of the business plan will be developed and drafted in the coming weeks and submitted to the Department for approval in February-March 2024 (on request).

1.3. The sections yet to be produced at this point in the year are

- standard material about our role, our strategy, and our legislation
- delivery of the current (2023-2024) business plan priorities
- key performance and other data
- financial information and budget
- other information required under business planning guidance

1.4. Once the business plan (incorporating our budget) is approved by the Department, it is then published on our website.

2. Planning priorities for 2024-2025

2.1. Our inspection and licensing database (Epicentre) needs to be replaced, owing to risks relating to the platform that hosts it, which is no longer supported. We have submitted to the Department a business case for funding the project and based on their response further work may be needed prior to a full programme of work being undertaken on this major project.

2.2. Following our Public Bodies Review, we will begin scoping work on a fees review; again, further support from the Department has been requested.

2.3. Other priorities in the business plan for 2024-2025, include the following

- follow through of the Authority decision on donor support services
- further work on our proposals for law reform
- work following the Women's Health Strategy to improve primary care health information about fertility
- increasing our focus on genetics and Artificial Intelligence (AI)
- completion of the review of the list of conditions approved for PGT-M
- possible work on the updates to the EUTCD
- development of our new strategy for 2025-2028, following initial conversations this business year

2.4. To note that at the time of writing, the Department has not provided the HFEA with planning priorities which should be considered by ALBs. We will update the business plan as appropriate once these have been received.

2.5. The section referring to the OTR support services will be updated following the Authority decision.

2.6. The “Maintaining the stability of our core IT systems” section will be updated once funding decisions for replacing Epicentre have been made.

3. Recommendation

3.1. Authority members are asked to approve the attached draft business plan (activities section) for 2024-2025. Further development of the business plan will follow, and Department colleagues will review the plan prior to publication.

Business plan activities for 2024-2025

This business plan represents the additional year of delivery following the extension of our 2020-2024 strategy, which launched in October 2020 and was extended by one year in 2023. The Authority will be considering its next three-year strategy during the coming year and will review outstanding items from the current strategy, and its extension, when making decisions about new priorities.

In addition to our statutory duties, our other main priorities for the year will be:

- Developing further aspects of our law reform proposals published in 2023 to expand where relevant or provide more detail focusing on scientific developments and patient safety and protection in 2024-2025.
- Replacing Epicentre, our system to manage our statutory inspection and licensing function.
- Moving to a 'business as usual' model for our PRISM system.
- Prioritising work to actively look at the potential impact of AI on the fertility sector and on new scientific developments such as synthetic gametes and embryo models.
- Implementation of relevant statutory instruments as introduced by Government and any consideration of changes to the EUTCD.
- Issuing the third HFEA national patient survey and recruitment for new members of our patient engagement forum.
- Starting work relating to the HFEA fee review.
- Implementation of recommendations from the 2023 HFEA Public Bodies Review.
- Further development of dashboards to enable greater use of data within the HFEA to support compliance activities.
- The development of a new strategy for 2025-2028.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2024-2025.

The best care

Our first aim is for effective and ethical care for everyone. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table xx - Strategic objective 1. Treatment that is effective, ethical, and scientifically robust. Planned activities for April 2024 to March 2025.

Objective 1 Treatment that is effective, ethical, and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes continuation of the revised approach developed in response to the Covid-19 pandemic.	All clinics and research establishments in the sector are: • appropriately inspected and monitored against the requirements of the Act and published performance indicators, and • if they meet the required standards issued with licences for up to five years. Clinics that are well led and see compliance and the provision of high-quality care, including excellent support, as good business. Assurance of consistent standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics publish (e.g., on their websites) and provide to us. Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances.	Throughout the year

Objective 1 Treatment that is effective, ethical, and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Collaborative and partnership working with other ALBs and health regulators UK wide as needed, to ensure streamlined regulation.	Joint working as and when required, including the ongoing provision of input into the current review of NICE fertility guidelines. Engagement with NHSE and devolved administrations as needed. Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the most effective approach if any new areas of regulatory overlap should arise. We maintain clear and appropriate memoranda of understanding (MOUs) to ensure that we have clearly defined responsibilities and ways of working collaboratively with key regulators.	Throughout the year
Follow up work to the ethnic disparities in fertility treatment report and Call to Action from December 2023 and publication of Family Formations updated data.	Continue to address disparities in access, experience, and outcomes by engaging with key stakeholdersas set out in the Call to Action. Updated report to be published on family formation in fertility treatment.	Throughout the year
Regular review of the ratings system on treatment add-ons.	A SCAAC review of new evidence on add-on treatments will provide patients and clinics with accessible information based on sound scientific evidence.	Throughout the year, as required

Objective 1 Treatment that is effective, ethical, and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Effective handling of and communication about: • clinical incidents and adverse events, including publication of a 2023-2024 'State of the Sector' report and quarterly compliance reports • complaints about clinics	Continued strong focus on learning in dialogue with the sector including engaging with clinic leaders. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to a proactive approach being taken to learning from own and others' mistakes. Learning gained, to inform future inspections. Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse events.	Throughout the year, with the state of the sector report published in Autumn 2024
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually ensuring improvements are made as required.	Throughout the year
Processing applications for the licensing of preimplantation genetic testing for monogenic gene defects (PGT-M) and mitochondrial donation.	Applications handled effectively, efficiently, and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. List of conditions approved for PGT-M audited, ensuring all approved conditions meet the statutory tests and the availability of treatment options. Mitochondrial donation and PGT-M approvals taken in an accountable and transparent way.	Throughout the year

Objective 1 Treatment that is effective, ethical, and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Review of guidance for clinics to ensure this remains fit for purpose, including: • issuing other clinic-facing communications, such as Clinic Focus, on issues that require further clarification to the sector	Guidance for clinics is up to date and reflects latest scientific developments, legal advice, and policy decisions. A clear Code of Practice as required by law and other guidance for clinics. Following legal clarification of near posthumous use, additional guidance may need to be issued to clinics. Authorised Processes review of methodology to conclude in spring 2024.	Throughout the year.
Servicing the legal information needs of the HFEA including: • provision of legal advice to inform other HFEA work • management of team of external legal advisers to support effective licensing processes • supporting any changes to the law and guidance.	HFEA licensing decisions are sound and supported by legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year
Maintain up to date information on the HFEA website about routine treatments, continuing our focus on clinics providing good support, and testing new information using the patient engagement forum.	We use our communications channels to make sure patients receive the right information at the right time to ensure our statutory duty to provide information is informed and effective. Information is reviewed on a cyclical basis to ensure that it is fit for purpose. New information added when needed. We use our social media channels to signpost people to the website information and if we include new information on the website, we promote this widely using our social media. Following the launch of ‘dashboards’ in December 2023, we will continue to develop them further. We will also commence work on ‘Family Formations’ in late spring/ early summer 2024.	Throughout the year

Objective 1 Treatment that is effective, ethical, and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing implementation and oversight of the changes resulting from the updated EUTCD.	We will engage with any changes to the EUTCD and work with others on the implications of these.	Throughout the year

Table xx - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Planned activities for April 2024 to March 2025

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	Benefits and outcomes	Timescale
	No work planned under this objective for this year.	

The right information

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

Table xx - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Planned activities for April 2024 to March 2025.

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	Benefits and outcomes	Timescale
Use our social media and other channels to communicate relevant information to the wider general public and those who are not having fertility treatment.	We will utilise feedback to improve the information provided to the public and to position our information effectively, maximising our impact. We will communicate via a range of channels and methods so people can access the right information at the right time for them. We will raise our profile and provide the general public, not just current fertility patients, with useful information. We aim to work with primary care organisations such as the Royal College of GPs and the RCN under the women's health strategy banner – with the aim of improving information for primary health care workers.	Throughout the year Summer 2024

Table xx - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Planned activities for April 2024 to March 2025.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Maintaining communication with our stakeholder groups, the patient engagement forum, and our followers on social media.	The information we publish is informed by stakeholder needs and insights. We meet with our patient and professional stakeholder groups twice a year and engage with them on a range of issues. We will involve members of the patient engagement forum to gain feedback on our work to inform what we do. We maintain our social media channels to reflect the work we are doing and try to make these as interactive as possible to encourage feedback and discussion.	Throughout the year
Ensuring that patients, partners, professionals, surrogates, donors, donor-conceived people, and their families all to have access to relevant, impartial and accurate information.	We will ensure our website is up to date and reflects the latest information. We will ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions. New Choose a Fertility Clinic (CaFC) data will be published for the first time from data in the new PRISM system in late 2024, providing the most recent information on clinic performance for pregnancy outcomes and live birth rates. We ensure quality metrics and verification reports are in place for PRISM, and that clinics are able to fix validation errors. Patients see HFEA information as ‘go to’ impartial advice. People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. People can easily find relevant information and signposting on our website to inform their next steps.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Position and promote information via our various channels.	Access to relevant and impartial information for patients, partners, professionals, surrogates, donors, donor-conceived people, and their families. Maximising the positive impact of the information we provide. We ensure we make an impact with our information by using a range of metrics to evaluate the impact of our digital and social channels and media work. We use our social media channels to drive people to our information both online and in the media. Promote information of relevance to the Government's Women's Health Strategy and work with the Women's Health Ambassador and others on this.	Throughout the year
Responding to media reports and requests.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wide range of issues.	Throughout the year
Continue to maintain our compliance with accessibility requirements and make changes as necessary.	Stakeholders' accessibility needs are considered so that they are able to access our information.	Throughout the year
Continued support for the PRISM data submission system.	PRISM fully bedded in with clinics and data being submitted into the register. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime. 'Right first time' data quality and reduction in effort by clinics submitting the data.	Throughout the year
Further development work on the Register Information Team Application (RITA), to enable us to query the new register and run reports.	Targeted support to improve data quality across the sector. New reports to ensure future CaFC data can be viewed and edited as needed. Ability for clinics to proactively assess their own data and make changes through-out the year.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Maintaining an effective Opening the Register (OTR) service.	OTR requests continue to be met in a sensitive manner, following the expected increase from October 2023 onwards. Support and monitoring of the new IT system built in 2023. Reviewing the effectiveness of the system once it has been fully in use for at least six months.	Throughout the year
Management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is effectively managed, to ensure that it remains fit for purpose. Training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet. [Text on support service to be added/updated after Authority decision.]	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI), parliamentary question (PQ), and subject access requests.	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion. We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.	Throughout the year
Continue to ensure that our data is held securely and is protected in accordance with best industry practice.	We assure ourselves that we are practising good data security and personal information is handled correctly. Maintain our oversight group for the NHS Digital Data Security and Protection Toolkit (DSPT), combining best practice from other organisations and collecting toolkit documentation on an ongoing basis to allow for faster, more complete submissions going forward. We continue to maximise the quality of our DSPT submissions, in particular the areas for improvement previously highlighted.	Throughout the year June 2024 (annual process)

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
To publish good quality statistical and other reports.	We provide the public, patients, clinic staff and others with up-to-date, high-quality information about treatments, trends, and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment through our dashboards and other data, which are accessible via our website. We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. High quality data available to develop patient information and respond to information requests.	Throughout the year
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. Promoting our Register data to ensure it is widely used in research, including the use of the new dashboards. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing compliance with government information requirements.	We respond to government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual report published including required information.	Throughout the year
Effective records management and information governance.	Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times. Information governance arrangements comply with latest requirements. Records management and information governance risks are managed effectively.	Throughout the year
Responding to external consultations, calls for evidence and reviews including from the Department of Health and Social Care, other departments, regulators, and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector. HFEA keeps abreast of significant political changes and understands the impact on our work and key stakeholders.	Throughout the year

Shaping the future

Our final aim is to embrace and engage with changes in the law, science and society. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table xx - Strategic objective 5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Planned activities for April 2024 to March 2025.

Objective 5 Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI) - methods and channels	Benefits and outcomes	Timescale
Project on patient-facing AI and data-driven new technologies that are in or potentially approaching clinical use. Continued oversight via the Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning process and reviews. Continued horizon scanning on genetics policy issues.	We understand new developments and are responsive to these, including monitoring developments in genetics and AI. We ensure that our regulatory regime and guidance is fit for purpose. Regular reports to SCAAC detailing issues raised used to inform our policy working and to be shared more widely as relevant. Our internal working group on AI meets regularly to monitor this. Regular horizon scanning information on genetics policy issues is considered by SCAAC and integrated into our other work as relevant (e.g., the work on the modernisation of the Act). Emerging new policy frameworks related to these areas are taken account of in our policy work. That responsible innovation is encouraged.	Throughout the year

Table xx - Strategic objective 6. Preparing for future legislative and operational changes. Planned activities for April 2024 to March 2025.

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
To press for legislative changes we would like to see to the Act.	Continue to pursue legislative change based on the proposals published in Autumn 2023.	Throughout the year
Respond to any requests for consultation on legislation or emerging proposals and consider how these might impact the HFEA.	We inform any work by DHSC on legislation relating to our functions. Early consideration of possible impacts of any planned changes on the sector and the HFEA.	As these arise
Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Horizon Scanning Panel meets once per year. The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues.	Throughout the year
Running an 'Opening the Register' (OTR) service to meet increased levels of demand.	OTR requests continue to be met in a sensitive manner. New IT system built in 2023 in use and monitored for effectiveness. Communication and engagement in place to ensure that the public, clinic staff, donors, donor conceived children and their families understand the changes that have been made.	Throughout the year
Considering new arrangements for the provision of support services for OTR applicants.	Consideration of the future of support services for all OTR applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information. OTR applicants feel supported and prepared to deal with the information they receive from us. [To be updated following Authority decision on OTR support services.]	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2024.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. People strategy in place, setting out our vision for ensuring we strike the right balance of staff skills, capacity, and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need through training and other means. We take into account equality and diversity in the design and implementation of our policies, to ensure that these are fair and appropriate for all staff. Staff feel valued and motivated to deliver our strategic aims, by taking action on the results of our staff survey. We reflect our values and behaviours in all our work to ensure that quality and service improvement is part of our ongoing way or working.	Throughout the year
Maintaining the stability of our core IT systems.	Core systems including Epicentre and the Clinic Portal are maintained and upgraded as necessary in order to ensure business continuity.	Throughout the year
The first phase of a structural review of the HFEA's fee regime, informed by our income forecasting model.	We ensure that we meet the financial needs for effective regulation through a fair and transparent fee structure. Following the recent public bodies review recommendation of a fees review, we will commence work on this from summer 2024.	Throughout the year Summer 2024
The development of a new strategy for the HFEA from 2025 onwards.	We set a clear vision for the future, enabling us to plan for the next three-year period.	Throughout the year

Human Fertilisation & Embryology Authority

Opening the Register – update

Rachel Cutting and Clare Ettinghausen

24 January 2024

HFEA activity during 2023/24

Three workstreams

OTR service	Future of support service	Communications
Ensuring our staffing levels and team structure are appropriate for the demand and systems are effective in processing applications	To report back to the Authority on next steps for a multi-layered support service	To ensure patients, clinic and public communications are timely, informative and relevant throughout 2023 and beyond

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OTR service

Workstream update

- New IT system for managing applications went live beginning of August (earlier than scheduled). Positive feedback received regarding use from the OTR team in terms of ease and efficiency

- Testing of the OTR RITA reports is complete. Process is being finalised before use from 22/01/24.

- Once RITA reports are delivered the SOP will be updated to include these new procedures.

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Future of support service

Workstream update

- Decision paper provided separately at ‘Support services update’ agenda item

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Communications

Workstream update

- Since the successful targeted public-facing #WhoIsMyDonor campaign went live in September, the OTR team have received over 400 requests. We decided to slow down activity to avoid overloading the team.
- Activity prioritised on Modernising fertility law to avoid clashing messages. This has kept interest high in donor anonymity/donor info
- Second phase of activity planned, starting with an Instagram live Q&A targeting DCIs and donors
- New web content updated by end January 2024 and will be promoted to stakeholders – encourage them to include in newsletters
- Continued engagement from media and documentary makers and project team identifying news ‘hooks’ to engage audiences
- Four-fold increase in views of all website pages relating to donation (321,000 in 1 Sept 2023- 4 Jan 2024 compared with 75,000 in the same period the previous year)
- More than 850 views of our FAQs for clinics.

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Risks

- Unrealistic expectations of DCI, donors and clinic staff to what the HFEA can do
- The communications campaign increased applicant numbers to a high level, creating resource pressures and has therefore been slowed down
- Reputational risk is high both for those elements we are responsible for, and those we aren't
- HFEA resources may not meet demand of applications (prediction of number of applicants very difficult)
- Unlawful practices undertaken if clinics and HFEA do not fully understand the law
- Donors and DCI not having access to information and support
- Limits of what information we can provide

Next Steps

- Through the work streams mitigate the risks where possible
- Provide internal updates at the Project Assurance Group to ensure progress is timely
- Decision in January 2024 Authority about the future of support services
- Further resources to reduce the backlog including modelling of activity against future required resources
- Provide updates and engagement as needed to Authority and external stakeholders

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Future of OTR Support services

Details about this paper

Area(s) of strategy this paper relates to:	The right information/Shaping the future
Meeting:	Authority
Agenda item:	8
Paper number:	HFEA (24/01/2024)
Meeting date:	24 January 2024
Author:	Anna Wilkinson Policy Manager
Annexes	Annex 1: Support provision outside of the UK Annex 2: Summary of expert roundtable discussions Annex 3: Survey results Annex 4: Cost estimates Annex 5: Equality Impact Assessment

Output from this paper

For information or decision?	For decision
Recommendation(s):	Set out in section 5
Resource implications:	Dependent on Authority decision
Implementation date:	Dependent on Authority decision
Communication(s):	Dependent on Authority decision – see section 7
Organisational risk:	Medium

1. Background

1.1. In 2015, the HFEA commissioned an initial pilot of a support service for donor-conceived people who have accessed (or are considering accessing) information about their donor and half-siblings from the HFEA register.[1] Support services can also be accessed by donors considering removing their anonymity or whose identifying details have been requested. Since October 2019 the **Hewitt Fertility Centre** in Liverpool has provided these services on behalf of the HFEA, although that contract is due to end in September 2024.[2]

1.2. Support services include specialist counselling and intermediary services. Specialist counselling provides the opportunity to think through the implications of accessing donor information. Intermediary services facilitate contact between donor-conceived people and donors or donor siblings, by enabling them to exchange messages anonymously before swapping contact details (a 'letterbox service'), and through counsellor-facilitated meetings.

1.3. In 2021, around 8% of those applying for information from the HFEA register (OTR applicants) went on to use the support service. However, predicting the future take up of any support service is very difficult. In October 2023, the first donor-conceived people turned 18 and became eligible to apply for their donor's identifying information[3] and it is reasonable to assume that over time demand for identifying information will increase which will in turn lead to an increase in the cost of providing support.

1.4. The Authority first discussed the future of the support service in November 2022 and, noting that the HFEA had no statutory responsibility to provide the service, agreed that the current arrangement for funding it from the organisation's core budget was not sustainable and should be reviewed. The Authority was provided with an update of that work in November 2023. This paper puts forward a range of options on the way forward.

2. Support provision outside of the UK

2.1. Similar support services are offered outside of the UK, though there is no one model with which we can compare. We reviewed support services in five countries where legislation gives donor-conceived people the right to request donor-identifying information: the Netherlands, Finland, Switzerland, Australia (Victoria and Western Australia) and New Zealand - for further details see Annex 1. Several other countries where donor-conceived people can access identifying information about their donor do not offer support services at all.

3. Stakeholder engagement

[1] The contract was initially awarded to PAC-UK who ran the service until 2019.

[2] The Hewitt Centre also run the Donor Conceived Register (DCR), a voluntary register of donors and donor-conceived individuals involved with donor-conception prior to August 1991. The future of the DCR is not being considered in this paper.

[3] Previously only donor-conceived people conceived before 2005 whose donor had re-registered as identifiable could access identifying information about their donor.

3.1. We consulted stakeholders on the future of support services, particularly with respect to the kinds of support that are necessary, who is best placed to provide support, what role clinics might play and the issues surrounding introducing fees for access to a support service.

3.2. Two expert roundtables were held in June 2023 for patient organisations, and professional organisations, practitioners, and academics. A summary of findings from the stakeholder roundtables is at Annex 2.

3.3. We also ran a survey to seek the views of a wide range of people with a stake in the provision of support services. For this reason, the survey was open to donor-conceived people and those close to them; gamete and embryo donors and people close to them; and people who have used/are considering using donor gametes or a surrogate. A summary of the survey findings can be found at Annex 3.

4. Cost analysis

Estimating future demand for support services

4.1. It is difficult to anticipate the proportion of donor-conceived people who know that they are donor-conceived; who will apply for identifying information about their donor; or who will seek support services. As such, values in this section should be treated with caution.

4.2. However, we know that from 2025 onwards more than 1,000 donor-conceived individuals a year will become eligible for identifying donor information. Individuals can seek this information at any time above the age of 18.

4.3. Academic studies suggest that between 33% and 64% of donor-conceived individuals both know they are donor-conceived and intend to seek identifying information on their donors. We should note that individuals willing to participate in academic research are likely not representative of the wider population.

4.4. The Netherlands experienced a policy development similar to the UKs in 2020, which resulted in an almost fourfold overall increase in applications for support services.

Estimating future costs of support services

4.5. Given the uncertainty outlined above, we have modelled the costs of a future support service using the costs currently paid to the Hewitt Centre (see Annex 4 for details) and assuming several possible situations. A summary is presented in Table 1, although it is important to regard these figures as approximate given the uncertainties outlined above.

4.6. Other suppliers are available for counselling service provision, with BICA-accredited counsellors expected to cost around £65 - £85 per session.[4] Intermediary counselling services are less replicable, though face-to-face meetings could be facilitated by private counsellors, and there is an option to provide a letterbox service within the HFEA OTR service. This is discussed further in section 5.

[4] Note that these figures do not include the 33% optimism bias that has been applied to the calculated costs of the Hewitt's service provision. However, even if increased by 33% (to £80 and £100) these costs are still lower than those of the Hewitt Centre.

Table 1. Costs of the provision of support services to 30% - 65% donor-conceived individuals turning 18, 2024 - 2026

Year	One counselling session	Two counselling sessions	One counselling or one intermediary session	Two counselling or one intermediary session(s)
2024	£20k - £44k	£23k - £51k	£19k - £41k	£21k - £45k
2025	£32k - £70k	£38k - £81k	£30k - £66k	£33k - £72k
2026	£37k - £80k	£43k - £93k	£35k - £75k	£38k - £82k

Note table 1: This data assumes that 40% of OTR applicants seek counselling or 20% seek counselling and 20% seek intermediary services as appropriate. Proportions of referrals translating into support service sessions have been based on historic Donor Sibling Link support service data. This data does not account for individuals over the age of 18 requesting support services. Given uncertainties associated with this data, all figures have been rounded to the nearest £1,000. 30% and 65% relate to the upper and lower bounds for the proportion of donor-conceived individuals seeking donor information found in research.

5. Options for providing support

5.1. As noted above, the HFEA has no statutory duty to provide a counselling service and one option therefore would be to stop commissioning the service. The options below cover a range of options from the status quo to ending the service, together with new ways of approaching the issue. It is important to note that any model should be sustainable and compliant with Treasury guidance **Managing Public Money** (MPM)[5].

Option 1: Fund a commissioned support service from HFEA core budget - not recommended

5.2. One option is for the HFEA to continue to fund the Hewitt Centre (or an alternative support provider) at full cost to the HFEA with funds sourced from its core budget. A decision was taken in November 2022 that the status quo could not continue without a full review.

5.3. Given the expected increase in numbers of those seeking support in the future, it is not affordable to continue with the current arrangement. Even at the lowest estimations of the future costs of a support service, the increase in cost year-to-year is significant and not sustainable. Moreover, the inherent uncertainty around these figures and the cumulative uncertainty of yearly demand, over time, further count against this model. Given the broader constraints on public spending, and the fact that the HFEA has no statutory duty to provide this service, this option may not constitute an appropriate use of HFEA funding. It might also result in negative impacts on the delivery of our statutory functions.

[5] MPM states that “the standard approach is to set charges to recover full costs” in order to “make sure that the government neither profits at the expense of consumers nor makes a loss for taxpayers to subsidise”.

Option 2: Commission a support service with funding sourced from outside the HFEA - not recommended

5.4. One potential model is to increase fertility clinic fees and use the money raised to commission a support service and this was discussed at the November 2022 Authority meeting. However, external advice suggests that this would pose significant legal risks given that the HFE Act restricts what the HFEA is permitted to charge clinic fees for.[6]

5.5. An alternative option for raising money to fund a support service is to charge OTR applicants. There are broadly two variants of such an approach: a) charging all OTR applicants a fee and b) charging only OTR applicants who access support a fee.

5.6. Option (a) involves the use of cross subsidy: charging people who don't use the service so that it is less expensive for those who do use it. This could pose challenges in terms of both fairness and compliance with MPM which says that: "…Cross subsidised charges are normally classified as taxes. They always call for explicit ministerial decision and parliamentary approval through either primary legislation or a s102 order." It might also be thought unfair to charge applicants for a service that they don't use and the HFEA might be criticised if it charged a fee before disclosing information to which donor-conceived people are legally entitled.

5.7. Option (b) would avoid the issues raised by option (a) but involve higher costs to the user (unless subsidised – see 5.8) of around £300 (see Table 4 Annex 4) for one counselling session, which are likely to be unaffordable for many people and which exceed the costs of comparable services in the private sector.

5.8. The HFEA might consider subsidising a support service, for a limited period of time, from its core budget. Decisions would need to be taken on how many years such a subsidy would last; whether it would be made available to all service users; whether a subsidy affordable for the HFEA would have any real impact on cost to the service users; whether a subsidy should be capped at a certain yearly value; whether it would be means-tested, and if so on what basis, and how this would be managed within the HFEA. There are a wide range of challenges and complexities associated with each of the options[7].

Option 3: End funding for commissioned support service and issue guidance to clinics to provide support - not recommended in isolation

5.9. The HFEA could encourage fertility clinics to provide or fund support to donor-conceived people and donors by issuing Code of Practice guidance. Guidance could be used in conjunction with other measures (see options 4 and 5) and could refer to professional guidance issued by expert bodies.

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[6] For similar reasons the HFEA would be unable to issue a new License Condition requiring clinics to provide support for donor-conceived people and donors, given the legal constraints on the purposes for which License Conditions can be imposed.

[7] For example, without a yearly cap, costs to the HFEA would be uncertain and potentially unsustainable; with a cap, the capped amount could 'run out' part way through the year, meaning those applying later in the year are less likely to benefit, raising questions of fairness.

5.10. Since the Code of Practice guidance is not mandatory this could result in patchy, poor-quality or non-existent service provision. Fertility clinics might not be best placed to provide such support, given that their day-to-day activities concern the provision of fertility treatment. A small number of clinics who provided services to donors and/or parents of donor-conceived people will have closed by the time a donor-conceived person reaches 18. Due to restrictions in the Act and GDPR requirements it is unlikely that the HFEA would be able to disclose the name of the clinic at which a donor-conceived person was conceived to them.

Option 4: End funding for a commissioned support service and improve and expand information and signposting - recommended

5.11. Under this option we would dedicate internal Policy and Communications resources to developing expanded and diversified website information for donor-conceived people and donors on the implications of the release of donor information. This might involve:

- Collaboration with organisations representing donor-conceived people to develop information sheets / FAQs about the implications of accessing donor information.
- Signposting to appropriately trained counsellors and organisations such as UK Donor Conceived and the Donor Conception Network providing peer support.
- Creating videos of counsellors discussing the main issues and challenges that they might discuss with donor-conceived people and donors in counselling sessions.
- Inviting guest blogs by donor-conceived people, donors, and people close to them on particular issues e.g. how accessing information can affect other family relationships, the impact for donor-conceived people of finding out they have donor siblings, etc.
- Providing (informal) guidance to clinics on where to direct donor-conceived people and donors if they are approached for support.

5.12. This option would enable the creation of materials suited to a range of different needs. Materials could be targeted at particular user groups (donor-conceived people, donors, parents), of different ages, with differing levels of need. We could collaborate with expert organisations to produce up-to-date high-quality information and adapt and add to materials over time. Signposting to appropriately trained counsellors would help to address concerns about confidence in seeking counselling privately. It would mitigate against any negative impacts caused by ending funding for the commissioned support service by ensuring that quality, reliable information about the practical and emotional implications of accessing donor information is accessible to donor-conceived people, donors, parents, and others.

5.13. This option would involve upfront costs of resourcing the policy and communications work of updating the website information and producing new materials for around 6 -12 months, and some further costs in monitoring and keeping information up-to-date over time. Although this option would use existing in-house resources, there would be an opportunity cost in terms of other work that couldn't be resourced, especially during the set-up phase.

Option 5: End funding for a commissioned support service and bring the letterbox service in-house - recommended

5.14. In addition to option 4, the letterbox service currently provided by the Hewitt Centre could be brought in-house and integrated into the general OTR service.

5.15. The letterbox service is currently used by a small number of people and administering the service could form one part of the role of a person working at officer level. This work could not be performed with currently available resources and would involve the addition of a new member of staff for the OTR team and any additional capacity utilised for other OTR work.

5.16. This option would represent a more predictable, ongoing cost to the organisation and would fill a gap that would otherwise not be met by the private sector. It could also mitigate potential negative impacts caused by ending funding for the commissioned support service which currently includes the letterbox service.

5.17. The pay band for the Officer grade at the HFEA is currently £28,500 - £33,000, though other costs will make the true costs to the organisation about 40% higher.

6. Risks and mitigations associated with ending funding for a commissioned support service (options 3, 4 and 5)

6.1. People who might otherwise have been directed to the support service might request information or guidance from the HFEA OTR team, impacting workload. This could be mitigated by the provision of comprehensive website information, FAQs, and signposting to support providers to which OTR staff could direct people. Any residual impacts on the OTR team should be monitored.

6.2. We conducted an Equality Impact Assessment (see Annex 5), to identify any potential negative impacts that ending funding of the commissioned support service might have on protected groups. These groups might include young people, men, same-sex couples and trans people. It is important to consider implementing as many mitigators (outlined in options 3, 4 and 5) as possible to reduce the potential impact on these groups.

6.3. As noted above, the contract between the HFEA and the Hewitt Centre includes the provision of both OTR support services and the DCR (which includes genetic testing, registration, and some support, if needed). It is possible that if the HFEA withdraws funding for OTR support service, the Hewitt Centre will not wish to continue running the DCR alone which could present a number of challenges. Seeking to identify and procure an alternative provider of the DCR service would take time, resources, and legal input. There might be lack of interest in providing the DCR service, based on the number of applications to run the DCR received in 2019. Changing the provider of the DCR would also likely result in a reduction in the size of the DCR since consent to transfer personal information would need to be sought from registrants and it is probable that not all registrants would respond to requests for consent.

7. Communications

7.1. The Authority decision on the commissioned support service will be of great interest to some stakeholders and therefore it will be important to communicate the following to the sector, stakeholders and the public:

- **The background to the review**: The current arrangements for funding support services from the HFEA's budget are not sustainable, and therefore a review was unavoidable.
- **The comprehensive work undertaken by the HFEA to explore options for the future of support services**: The HFEA fully understand the importance of support, and the decision to

review the services offered was not taken lightly. Over the last year we have engaged both directly, and with organisations representing, donor-conceived people and their families to understand their views, needs, and any concerns. As detailed in this paper, this included a survey of people impacted by donation, stakeholder roundtables with organisations represented affected groups, data collection, research, and review of academic literature.

- **The role the HFEA will continue to fulfil (depending on decision made)**: We understand that, as with all aspects of fertility treatment, there can be uncertainty around which services and resources can be trusted. As a trusted voice we will look to mitigate this. We want people impacted by donation to feel confident in the resources and services they are accessing.

7.2. We plan to work closely with organisations supporting donor-conceived people to improve and expand the information available through our website for donor-conceived people and donors, on the implications of the release of donor information.

7.3. All of the above will be communicated to stakeholders, clinics, and to the public via the relevant channels (including email, social media, and Clinic Focus).

8. Next steps

8.1. The Authority is asked to:

- Review the options and recommendations set out in this paper, considering the financial and legal risks associated with each option; and
- Decide which of options 1-5 should be implemented noting our recommendations to adopt either option 4 or 5 or a combination of both.

Annex 1 - Support provision outside of the UK

	Information and Online Services	Implications/Information Counselling	Intermediary Services	Therapeutic Counselling
Australia (Victoria and Western Australia)	Information for donor-conceived people, donors, and their families accessible online. This is provided by the health department in Victoria (VARTA) and the Department of Health in Western Australia.	Victoria: a donor-conceived person is required by law to attend an 'information session' before they are given identifying information. This session is provided and funded by VARTA. Western Australia: implications counselling is mandatory for donor-conceived people receiving identifying information. This is provided and funded by the Department of Health.	Victoria: VARTA provides and funds intermediary/letterbox services for up to 6 months. The letterbox service allows donor-conceived individuals, and their donors to get to know each other via exchange of letters anonymously before deciding on whether to exchange details. Western Australia: the Department of Health provides and funds intermediary services which facilitate contact between genetically related people when there is written consent to share the information.	Victoria: VARTA provides and funds a number of sessions with a qualified external counsellor in circumstances where applicants or subjects of information requests feel distressed throughout the application process (no information in public domain about how many funded sessions applicants can receive). Western Australia: the Department of Health provides and funds up to 6 sessions which can be accessed before, during and after contact with the donor (most referrals involve 1-3 sessions).
New Zealand	Information for donor-conceived people, donors, and	Not provided, though the Government recommends	Information not available.	Information not available.

	their families accessible online. This is provided by the **Government**.	that applicants seek counselling.		
The Netherlands	Information for donor-conceived people, donors, and their families accessible online. **FIOM** (non-profit organisation) provides information on the application process and contacting their donor, online webinars, and experiences from other donor-conceived people.	Some face-to-face 'professional support' provided by FIOM and funded by the Government.	Some intermediary services provided by FIOM and funded by the Government.	Information not available
Finland	Information for donor-conceived people, donors, and their families accessible online. This is provided by the **Family Federation of Finland** (non-profit organisation) and includes chat and phone advice, online courses, videos, podcasts, and peer support.	Information not available.	Information not available.	Information not available.
Switzerland	Information for donor-conceived people, donors, and their families accessible online. This is provided by the **Federal Office of Justice**.	Espace A (non-profit organisation) provides and funds one initial information session to donor-conceived people.	Information not available.	Information not available.

Annex 2 - Summary of expert roundtable discussions

Two expert roundtables were held in June 2023, one for patient organisations and the other for professionals and practitioners. The roundtable for patient organisations on 5th June 2023 involved representatives from Fertility Network UK, SEED Trust, Two Dads UK/My Surrogacy Journey, Donor Conception Network (DCN), Donor Conceived Register (DCR), Surrogacy UK.

The roundtable for professionals, practitioners and academics on 7th June 2023 involved representatives from British Infertility Counsellors Association (BICA), Project Group on Assisted Reproduction (PROGAR), ConnecteDNA, British Fertility Society (BFS), CARE Fertility, and other experts and academics. In both meetings, participants discussed types of support (specialist counselling, intermediary services, peer support, information and signposting) and the option to commission a support service paid for by charging applicants who access support services a fee.

Key messages

Range of support needs: There is a need for a multi-layered support service. It is important to not only have ‘lots of shapes of support’, but a service that targets and meets the needs of ‘all age ranges and groups affected by donor conception’. There is also ‘value added by having a service which isn't just counselling’.
Peer support: Peer support is ‘really useful’ for teenagers. We should look at ‘general support approaches, such as, peer support’ as this would also ‘minimise the amount of funding required’.
Single source of information: Need for useful and ‘credible forms of information in a central place’ which comes from ‘one set organisation that all other organisations can signpost to’. Such ‘credible information’ should be presented in ‘multiple ways’ as the age range of donors is usually older. Information also ‘needs to be coordinated’ and consistent. Central resource of information will also be ‘important for professionals too as they can get confused about which organisation offers what’.
Role of the HFEA: ‘The remit of the HFEA is regulation of clinics and patient experience, but someone needs to take responsibility for the support service’. There is also a ‘strong need for collaboration between the HFEA’ and other organisations. Agreement that we have to be ‘strict on what services the HFEA can provide’ due to limited funding.
Language: Language is ‘important’ for young adults especially, and there is a need to ‘set the right terminology and narrative'. The word ‘counselling', may suggest to young adults that ‘there is a problem, where they may not feel there is a problem’. The word ‘support’, for instance may be a better alternative to use.
Fees: There is a possibility of charging users of the OTR service, however this may ‘discourage people from using the services'. If users of the service are charged a fee, this 'shouldn't be mandatory' but ‘perhaps a donation, though this could mean that no one would donate’. View expressed that instead of users of the support services, ‘it should be clinics or parents’ that should pay a fee.
Role of clinics: Clinics should be able to signpost donor-conceived people and their families to support or further information as clinics may be their ‘first port of call’. Clinics should be encouraged to ‘engage with the HFEA'. Clinics may receive a number of queries which will be directed to staff members at clinics who may not have received appropriate training. Not everyone seeking support services will want to have counselling and there ‘needs to be training to give information outside of counselling’.
Accreditation schemes: FNUK implemented a gold star accreditation scheme ‘which wasn't sustainable and did not work too well’. It will not only be difficult to get ‘funding from clinics on a regular basis’, but also from ‘the DHSC’.

Annex 3 - Survey results

Objectives

- Overall, this survey aimed to gain insight into what people who may access post donation support services want or need from those services.
- A secondary objective was to gain understanding of the views about the funding of these services from people affected by donation.

Summary

- A total of 270 responses were received and 254 were complete responses. The largest response group were parents of donor-conceived individuals (43%), followed by donor-conceived individuals (22%) and donors (including egg sharers) (18%). The survey also received 38 responses (15%) from people who had used, were currently using, or thinking of using, donor conception services. A small number of responses (2%) were also received from relatives, partners, or close friends of those affected by donation, including surrogates, but no surrogates themselves responded to the survey.
- Respondents indicated that they used a range of support services and commonly accessed peer support, as well as information and signposting. More than half of respondents who accessed support, seemed to access more than one service. This might suggest that a multi-layered support service provision would be well suited to people seeking support in relation to donor conception.
- Overall, all four support services included in the survey were rated highly for usefulness. It should be noted that there appeared to be a lack of clarity of what specialist counselling is and that this may have been conflated with general therapeutic counselling or implications counselling.
- Most people affected by donation, who responded to this survey, found out about support services via an online search. This indicates that focusing on ensuring that information about support services is easily searchable and accessible online would be beneficial.
- In the future model of support services, most respondents supported specialist counselling and intermediary services, including a letterbox service and facilitated face-to-face meetings, being commissioned by the HFEA. It was considered by some respondents that this would increase the trust and confidence in the support provided.
- Overall, it was perceived that donor-conceived people should not have to fund or partially fund access to support services.
- Respondents indicated some willingness to pay a maximum amount, perceived as the standard rate or the amount they could afford, to access support services. This was most apparent for specialist counselling with just over half selecting a maximum amount to pay.
- A minority of respondents indicated a willingness to pay a maximum amount for intermediary services, including an intermediary session and letterbox service, and peer support.

- Free text responses indicated a perception that the provision of a letterbox service or online peer support would incur minimal operational costs.

Methodology

- This survey was open to individuals over the age of 16 who are personally impacted by the provision of post donation support services in the UK.
- The online survey was open from 7 August to 12 September 2023.
- The survey was shared across HFEA social media platforms, through stakeholder/partner organisations, the HFEA website, and via Clinic Focus.
- Although the survey was only available online, respondents were provided with details on how to contact the HFEA if they required the survey in a more accessible format. No requests were received.

Annex 4 - Cost estimates

1. Background information

- Support services are currently funded by the HFEA and provided by the Hewitt Fertility Centre, as part of a wider contract including their management of the Donor Conceived Register (DCR - a voluntary register of donors and donor-conceived individuals involved with donor conception prior to August 1991).
- The Hewitt are currently paid £51,730 (VAT inclusive) per annum by the HFEA for the provision of such services, in addition to the management of the DCR. This fee covers all services rendered and is not broken down into DCR costs and support services costs. As such, it is difficult for the HFEA to determine the current cost of support service provision. In 2019, it was estimated that internal management of the DCR costs £36,912 per annum. However, this estimate has not been reexamined in the subsequent four years.

2. Estimating future demand

- It is difficult for the HFEA to anticipate future demand for support services, for several reasons:
  - The 2005 legislative change on disclosure of identifiable donor information is unprecedented within the UK and international comparisons are limited in number and relevance.
  - Societal attitudes related to donor-conception and recent increases in fertility treatment use among single patients and female same-sex couples may have impacts on the number of donor-conceived individuals being aware of their donor conception.
  - While some academic research studies have been conducted on this topic, the numbers of participants are low, and the research will contain implicit bias regarding the kinds of individuals likely to participate in this research.
- However, to produce estimates we have reviewed:
  - Relevant research articles exploring the proportion of donor-conceived individuals who know of their genetic origins and intend to request identifying donor information.
  - Data published by the Dutch government on a comparable service.
  - Changes in OTR applications following the launch of the HFEA's #WhoIsMyDonor campaign.

3. Support service use

- Support services are currently available to all donors and donor-conceived individuals receiving identifying or non-identifying information from the HFEA. A breakdown of the proportion of applicants seeking this information is provided below in Table 1 by applicant type and support service type. Of those referred, the proportion who go on to take up the support service varies by referral type (Table 2).

Table 1: Proportion of OTR applicants referred for support services, 2021/22

Applicant type	Proportion referred for support services
Donor – Received non-identifying information	(<5/511) <1%
Donor – Removing anonymity	(16/60) 27%
Donor-conceived – Received non-identifying donor information	(46/599) 8%
Donor-conceived – Received identifying donor information (This includes counselling and intermediary services)	(4/10) 40%

Note table 1: Support services are also offered to other groups. For example, intermediary services are available to donor-siblings establishing contact with each other. As the HFEA does not hold records on the number of donor-siblings who may be meeting each other without support services, we were unable to calculate a proportion referred for such. Similarly, data has not been included on referrals for complex situations, donors who have been contacted by donor-conceived offspring, or donor sibling link registrants. Table 1 relates to 72% of all support service referrals in 2021/22.

Table 2: Proportion of support service referrals pursuing counselling, 2021/22

Applicant type	Proportion not pursuing referral	Proportion having one session	Proportion having two sessions
Donor-conceived – Received non-identifying donor information	81%	7%	11%
Donor-conceived – Received information on donor siblings	39%	15%	45%
Donor – Received non-identifying information	50%	25%	25%

Note table 2: This data was provided to the HFEA by the Hewitt Fertility Centre. Categories of applicant type do not match Table 1 due to data limitations. Where low number suppression of <5 was included in the data, a value of 2.5 was used in the proportion calculation.

- Donor-conceived individuals eligible to access identifiable information about their donors is soon to increase from 29 in 2023 to 766 in 2024 (Table 3). In 2025, a further 1,182 donor-conceived individuals will be eligible to apply for identifiable information on their donors.
- The following table charts how the number of people eligible to access identifiable information over the next seven years will increase.

Table 3: Persons turning 18 conceived using an egg, sperm or embryo donation made after April 2005, April 2023-2030

Year of eligibility	Donor births where donor may be identifiable	Total donor births after law change

April 2023 – December 2023	29	29
2024	737	766
2025	1,182	1,948
2026	1,349	3,297
2027	1,676	4,973
2028	1,861	6,834
2029	2,187	9,021
2030	2,406	11,427

Note table 3: This data includes only treatment cycles that began on or after 1 April 2005. The number of donor births where the donor may be anonymous is a maximum possible value based on data on our Register. Individuals conceived using anonymous donors who have voluntarily dropped their anonymity are not included in this data.

4. Estimated support services costs

Table 4: Estimated time requirements and costs associated with support service provision at the Hewitt Fertility Centre

Support service provided	Time (Administrative Assistant)	Time (Counsellor)	Cost
0 counselling sessions (referral only)	25 minutes	60 minutes	£100
1 counselling session	25 minutes	220 minutes	£310
2 counselling sessions	25 minutes	280 minutes	£390
Intermediary service	120 minutes	120 minutes	£270

Note table 4: Cost estimates were calculated from these time estimates provided by the Hewitt Fertility Centre using 2021 **PSSRU** figures adjusted for inflation and a 33% optimism bias determined by the project team. Standard monthly activities (training and similar) were not included in these estimates. Administrative time may have been counted twice in some places. Given uncertainties associated with this data, all costs have been rounded to the nearest £10. For methodology details, see the below.

- Administrative assistant costs were determined using Band 4 “Hospital-based scientific and professional staff” cost estimates developed by the **Personal Social Services Research Unit** (PSSRU) in 2021 to be a rate of £35 per hour. Similarly, counsellors were associated with Band 6 “Hospital-based scientific and professional staff” and estimated to cost £51 per hour. While PSSRU counsellor costs include an administrative component, we included such separately given their large time requirements.
- Inflation (7.9% for 2022 and 7.7% for Q1-3 of 2023) was added to these values. The **Green Book**, the government guidelines on costing programs, advises adding an

"optimism bias" to cost estimates. A bias of 33% has therefore been determined appropriate for this service and added to the resulting costs.

- BICA-accredited counsellors are available privately for between £60 and £90 per session, but administrative costs would likely increase the costs of these. An 33% optimism bias should be applied to these figures before comparison with the Hewitt Fertility Centre costs, to account for over-optimism around staff time required per patient. Counsellors would be able to provide counselling sessions and facilitated meetings but not the letterbox service.

5. Estimating the number of OTR requests in the future

Academic research

- As noted above we reviewed a number of academic papers:
  - Experiences of offspring searching for and contacting their donor siblings and donor
  - Adolescents with open-identity sperm donors: reports from 12–17 year olds
  - Secrecy, disclosure and everything in-between: decisions of parents of children conceived by donor insemination, egg donation and surrogacy
  - A Longitudinal Study of Families Formed Through Third-Party Assisted Reproduction: Mother–Child Relationships and Child Adjustment From Infancy to Adulthood
  - Families created via identity-release egg donation: disclosure and an exploration of donor threat in early childhood
  - 'I know it's not normal but it's normal to me, and that's all that matters': experiences of young adults conceived through egg donation, sperm donation, and surrogacy
- Findings from these majority UK-focused studies would suggest that around 60-85% of donor-conceived individuals know about their conception and 55-75% of these individuals then wish to seek identifying donor information. This would mean that 33%-64% of donor-conceived individuals both know they are donor-conceived and intend to seek identifying information on their donors.
- These papers discuss individuals who have agreed to participate in research on attitudes to donor-conception, meaning there will be an inherent bias and the findings are likely not representative of the wider population. The sample sizes involved in these papers are often small, which reduces the reliability of the findings. We were unable to identify papers discussing what proportion of donor-conceived individuals receiving donor information were likely to request support services.

Donor identifiability in the Netherlands

- The Artificial Fertilization Donor Data Act (2004) gave donor-conceived individuals in the Netherlands similar rights to The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 in the UK. In addition to cultural differences such as attitudes towards donor conception, there are two particular differences to highlight:

- Donor-conceived individuals in the Netherlands become eligible for donor information at the age of 16, rather than the age of 18 in the UK. As such, the Netherlands has already experienced the impact of increased eligibility for information on donors from their law change.
- A system like the Donor Conceived Register operates for donations before 2004, and this has a large number of registrants. Through such, identifying information was already being released on more than 170 donors a year prior to the law change coming into effect.

- However, the following key statistics from the Netherlands may be of some relevance:
  - Overall, OTR applications (both identifying and non-identifying) increased around 30% from 2020 to 2021 once the law change came into effect.
  - Applications for identifying donor information increased from 177 in 2020 to 359 in 2021 (103% increase).
  - Requests for support services increased from 40 in 2020 to 158 in 2021 (295% increase).

#WhoIsMyDonor

- The HFEA recently launched our #WhoIsMyDonor campaign, highlighting the availability of identifying donor information for donor-conceived individuals born in or after 2005. Since the campaign launch, OTR applications have increased by around 95% on the same period in 2022. This change is unlikely to be sustained upon the campaign's conclusion.

6. Costs associated with the provision of support services to eligible individuals

- Given the degree of the uncertainty surrounding the future demand for support services, we have provided estimates of costs associated with several possible situations. We have used the Donor Sibling Link data from Table 2 to estimate the proportion of referrals likely to lead to one or two counselling sessions or an intermediary services session as appropriate (Table 5). This data assumes individuals request donor information at the age of 18 exclusively. It is important to emphasise that this assumption is likely false, meaning true costs in later years would likely be higher than figures given.
- This data uses costs associated with the Hewitt Fertility Centre continuing to serve as the support service provider and may differ were an alternative provider considered.

Table 5: Costs associated with the provision of support services to 30% / 45% / 65% of donor-conceived individuals turning 18 each year, 2024-2028

Year	One counselling session	Two counselling sessions	One counselling or one intermediary session	Two counselling or one intermediary session(s)

2024	£20,000 / £30,500 / £44,000	£23,500 / £35,000 / £50,500	£19,000 / £28,500 / £41,000	£20,500 / £31,000 / £44,500
2025	£32,500 / £48,500 / £70,500	£37,500 / £56,500 / £81,500	£30,500 / £42,5000 / £66,000	£33,000 / £49,500 / £71,500
2026	£37,000 / £55,500 / £80,000	£43,000 / £64,000 / £93,000	£35,000 / £52,000 / £75,500	£37,500 / £56,500 / £81,500
2027	£46,000 / £69,000 / £99,500	£53,000 / £80,000 / £115,500	£43,000 / £65,000 / £93,500	£47,000 / £70,000 / £101,500
2028	£51,000 / £76,500 / £110,500	£59,000 / £88,500 / £128,000	£48,000 / £72,000 / £104,000	£52,000 / £78,000 / £112,500

Note table 5: This data assumes either 40% of OTR applicants seek counselling or 20% seek counselling and 20% seek intermediate services as appropriate. Proportions of referrals translating into support service sessions have been based on historic Donor Sibling Link support service data. This data does not account for individuals over the age of 18 requesting support services. 30% / 45% / 60% relate to the bottom / middle / top of the range for the proportion of donor-conceived individuals seeking donor information found in research. Given uncertainties associated with this data, all figures have been rounded to the nearest £500.

Annex 5 - Equality Impact Assessment

Name of project/policy/activity	OTR Support Services
Staff member(s) completing EIA screening questions	Anna Wilkinson
Key objectives	To assess the potential impact that changes to the OTR support services (specifically, the possibility that funding for this could be withdrawn) could have on groups with protected characteristics/ vulnerable groups.
Telephone	Anna.wilkinson@hfea.gov.uk
Date	20/12/2023
1. What is the main purpose of the project or policy?	To review the future provision of support services for OTR applicants and donors. In 2015 the HFEA commissioned an initial pilot of a support service for donor-conceived people who have accessed (or are considering accessing) information about their donor and half-siblings from the HFEA register. Support services can also be accessed by donors considering removing their anonymity or whose identifying details have been requested. Since October 2019 the **Hewitt Fertility Centre** in Liverpool has provided these services on behalf of the HFEA, although that contract is due to end in September 2024. Support services include specialist implications counselling (two, one-hour sessions) and intermediary services to facilitate contact between donor-conceived people and their donors or siblings. Both have been funded by the HFEA to date, even though it has no statutory duty to do so. Given the expected increase in qualifying OTR applications (from 2023 onwards) it was accepted by the Authority that the current arrangements for funding support services are not sustainable. This project was authorised in order to explore options for the future of support services in a sustainable way, going forward. Please see section 5 of the Authority paper for details of the Options being proposed.

2. List the main activities that comprise the project or policy:	Review of support provision outside the UK Stakeholder engagement Expert roundtables Public survey targeted at people affected by post donation issues. Review and costing of possible support models.
3. Who will be the main beneficiaries of the project or policy?	Donors Donor-conceived people Parents of donor-conceived people

4. Use the table overleaf and tick:

(a) where you think the project or policy could have a negative impact on any of the equality target groups.

(b) where you think that the project or policy could have a positive impact or improve relations within equality target groups.

Equality areas	Equality groups	Negative impact or disadvantage	Positive impact or benefit	Reason
Age	Older people (60 +)			
	Younger people (17-25) and children	✓		Any changes to the OTR service could affect some age groups more than others as people can only make OTR applications to request the identity of their donors once they turn 18. We have no data to accurately assess the actual demographic of people making OTR applications (given that the first group of eligible donor-conceived people only just turned 18) but it is possible that there may be a larger proportion among this younger age group than in other age brackets. Please see Appendix for an analysis of how each Option could have a negative impact on this category of OTR applicant and what mitigations

			were considered as part of the project and what is being proposed to Authority to try to mitigate this impact.
	Age range affected by a particular fertility issue		
Disability	Disabled people		
Ethnicity or race*	Asian or Asian British people		
	Black or Black British people		
	Chinese people and other people		
	People of mixed race		
	White people (including Irish people)		
Religion	Religious or belief groups		
Gender	Women		
	Men	✓	It is plausible that men would be more affected than women because there are more sperm than egg donations (and historically, sperm donors have been proportionately more likely to remove their anonymity than egg donors). However, other factors will be relevant including how likely it is

			that a donor-conceived person will seek donor information and how likely it is that male/female donors would use the support services. Please see the Appendix for an analysis of how each Option could have a negative impact on this category of OTR applicants and what mitigations were considered as part of the project and what is being proposed to Authority to try to mitigate this impact.
Sexual orientation & identity	Lesbians, gay men and bisexuals	✓	Same- sex couples are more likely than heterosexual couples to have had fertility treatment using donor gametes, but they are unlikely to be personally affected by any change to the support services as they are not currently entitled to HFEA-funded support services (it is the child who can request identifying information not the parents). There may be some impact as their children will be affected (if Options 2-5 are adopted) but this is quite remote, and the impact has been mitigated through recommendations outlined in the Appendix.
	Trans people	✓	Trans people in certain situations may be more likely to need to use donor gametes but as parents they would not automatically have been entitled to free support services under the current regime. Their children may be affected as outlined in the Appendix. Mitigations have been considered and proposed to reduce this impact – see the Appendix.
Human rights	Human rights of any group		
Other	E.g. socio-economic status, refugee/asylum seeker, or criminal background	✓	As with any private service, people on lower incomes may find it more difficult to afford private support services if free counselling is withdrawn. The stakeholder discussions, however, have suggested that information provision and peer support are also highly valued forms of support.

* The categories used in the Race section are those used in the 2001 census. Consideration should be given to the needs of specific communities within the broad categories such as Bangladeshi people and to the needs of other communities such as Turkish/Turkish Cypriot, Greek/Greek Cypriot, Italian and Polish people, that do not appear as separate categories in the census.

Religious or belief groups includes a wide range of groupings, the most common of which are Muslims, Buddhists, Jews, Christians, Sikhs and Hindus. Consider religion and belief categories individually and collectively when considering positive and negative impacts.

5. If you have indicated there is a negative impact on any group, circle the appropriate responses below to indicate the nature of that impact:	Legal impact? No Is it discriminatory under anti-discriminatory legislation? i.e. race, disability or gender Intended? No Level of impact? Low
6. Summarise the likely negative impacts:	Please see the Options set out in the January 2024 Authority paper and summaries of their potential impact outlined in Appendix A.

7 (a) What external consultation has been planned on this activity, policy topic or project with groups/individuals from the relevant equality target areas.

Group(s) or organisation(s) to be consulted	Summary of consultation carried out or planned
Affected individuals (through survey), patient organisations, professional organisations, academics and experts (see Authority paper, Annex 2 for full list)	Two expert roundtables discussing support needs of donor-conceived people and donors and the possible alternative forms of support that could be provided. Roundtables were with: Patient organisations Practitioners, academics and other experts in the field Survey of people affected by donation issues, including younger people. 1-1 meetings with experts and professionals and organisations e.g. DCN, Marilyn Crawshaw, Anna McLeod (CEO of VARTA) Sophie Zadeh

7 (b) If there has already been some consultation, what has it indicated or revealed about the negative	If any of Options 2-5 are adopted, there might no longer be free access to services that respondents to our public survey told us they would find useful for working through issues that arise (counselling) or that could play a role in safeguarding (intermediary services)

impact of this activity, policy or project?	People might feel uncertain about how to access quality specialist counselling services in which they could have high levels of confidence and trust, if the HFEA were not involved in commissioning it (if Options 3-5 adopted). This can however be mitigated by signposting to appropriately trained, including BICA-accredited, counselling. Some organisations were concerned that people might be deterred from accessing counselling due to the cost (on the assumption that Option 1 is not adopted).
8. What internal consultation and involvement has taken place or is planned with HFEA staff or members, including those that have, or will have, direct experience of implementing the activity, policy or project?	Authority meeting in Nov 2022 where decision taken to review options for a sustainable support service. Regular discussions with CMG, PAG and SMT. Project group containing members from Legal, OTR service, Intelligence, Comms and Policy. Ongoing liaison with OTR senior manager who manages OTR applications and worked on the commissioning the OTR support service. Discussion with OTR service and Comms on distributing survey. Ongoing regular input from project sponsor, Head of Compliance, who has extensive experience of working in the fertility sector.
9. Use the table below to record what research has been (or will be) carried out to guide and inform the equality and diversity aspects of the activity, policy or project.	
Equality target areas	Details of research (reports, surveys, literature searches etc.)
Age	Our survey gathered views of donor-conceived people, donors etc. (see above for details). Stakeholder roundtables with organisations representing affected groups. Data collected from the Hewitt Centre on the proportion of service users who are donors, donor-conceived people etc. However, for data protection reasons, we have not requested access to data on gender, age or sexual orientation from the Hewitt Centre. Research/policy review into support provision for donors/donor-conceived people accessing identifying information outside of the UK. Research into the costs and availability of the current, or alternative, support services going forward e.g. private counselling, peer support, etc.

	Review of academic literature on proportion of donor-conceived people who know they are donor -conceived/ which proportion who are likely to make OTR applications.
Disability	
Ethnicity or race	
Faith	
Gender	As above 2023 report on donation found that roughly equal numbers of male and female donors had removed their anonymity – though proportionately sperm donors have historically been more likely to remove their anonymity
Sexual orientation & identity	As above Stakeholder roundtables with organisations included those representing same sex parents.
Human Rights	
10. If there are gaps in your previous or planned consultation and research, are there any experts/relevant groups that can be contacted to get further views or evidence on the issues?	No: Our public survey was open to anyone aged 16 and over. We considered gathering the views of younger people directly (16 and under) and it was challenging/not possible given the project timeline to arrange for this in an environment in which it could be done sensitively. If Option 4 is adopted, we would like to involve younger people in the development of information and other support materials to help build content tailored towards younger people, as part of the second phase of the project.

11 (a) As a result of this assessment and evidence collected through consultation and research, state what changes (if any) will now be made to the policy, activity or project	**The objective of the project was to identify ways of providing support to those with support needs in a sustainable way within the confines of the resources available to us. The potential impact on protected groups has been highlighted in the Authority paper and has informed our decision to recommend as many mitigation options as possible to reduce the impact as far as possible. These include:**

	Significantly improving and expanding information and signposting as detailed in section 5 of the Authority paper. **Bringing the letterbox service in-house (an option which was not originally considered).**
11 (b) As a result of this assessment and available evidence, is it important that HFEA commissions or requests specific research on this issue, or that we consider any additional monitoring and data collection?	No – our internal and external stakeholder engagement has been extensive and so commissioned research was not needed. We consulted the stakeholders most directly affected. We have also had some discussions with Dr Sophie Zadeh who has conducted research with donor -conceived people independently of our work.
12. How will your planned changes ensure that any negative impact is now legal (i.e. not discriminatory under antidiscrimination legislation), intended and low impact?	We think the impact will be low and we have also proposed some mitigating measures to ensure that concerned parties have ongoing access to support.
13 (a) Have you set up a monitoring, evaluation and review process to check the successful implementation of the activity, project or policy?	This will be considered as part of phase 2 of the project (commencing Jan 2024) which is about implementation. Monitoring might include some data collection and analysis (of those making OTR applications and/or using any HFEA-provided services, such as visits to relevant webpages and use of a letterbox service (if adopted)) as well as continuous communication with the sector through ongoing stakeholder engagement and through our established channels such as PSOG and PSG.
13 (b) How will this monitoring, and evaluation further assess the impact on the equality target groups and ensure the activity, project or policy is non-discriminatory?	We will continue to communicate closely with organisations representing the affected groups and will work on monitoring systems with them in due course.

Signature of Director:
Date:

Appendix: Options, Impact and Mitigations

Option 1**: Fund a commissioned support service from HFEA core budget**.
Negative Impact: None in the short term but financially not viable (so services could not continue in the long term). Impact will likely be same for all affected protected groups.

Mitigations: Looking at long term solutions.

In the short-term, this option would not have any detrimental impact on any service users, including those who have a protected characteristic and have been identified (in section 1(4) of this Equality Impact Assessment) as being more likely to be impacted by changes to the services in general. However, it is unlikely to be sustainable going forward and therefore is not an option being recommended to the Authority.

Option 2: Commission a support service with funding sourced from outside the HFEA.
Negative impact: Applicants required to pay for service previously free. This impact will be the same for all affected protected groups.

Mitigations: Cross-subsidising/subsidising considered but found not to be feasible or effective mitigators.

We considered increasing clinic fees to cover the cost of the support service but were advised that this carried significant legal risk. The other options (charging all OTR applicants or just those accessing support services) would involve charging for a service (OTR applications) that is currently provided for free. However, as detailed in the Authority paper, the first amounts to cross-subsidising, raised issues on fairness and compliance with the Government's Managing Public Money Guidelines. As a result, the only feasible possibility within this model was to charge only those applicants who access the service. Our research concluded that commissioning a service would be significantly more expensive to the applicant, even with an HFEA subsidy (at a sustainable level) than individuals obtaining similar services privately and for this reason, this option is not recommended.

Option 3: End funding for commissioned support service and issue guidance to clinics to provide support.
Negative Impact: May require users to fund their own services. Impact will be the same for all affected protected groups.

Mitigations: Issue Guidance to Clinics to provide services directly.

This option involves the withdrawal of the free counselling and intermediary services currently offered, which means that if people want these services, they would have to access and fund them privately. One potential mitigation is to encourage clinics to offer or fund the services themselves, but this is not enforceable, and is therefore likely to lead to patchy provision of support both in terms of quality and quantity. It may also not assist donor-conceived people (who aren't affiliated with any given clinic). This therefore has limited mitigating effect if adopted alone (as the only mitigating option).

Option 4: End funding for a commissioned support service and improve and expand information and signposting.
Negative Impact: Users will be required to fund own counselling and intermediary services. Impact will be the same for all affected protected groups.

Mitigations: Offering streamlined, quality advice and signposting.

This option involves the withdrawal of the free counselling and intermediary services currently offered, which means that if people want these services, they would have to access and fund them privately. In order to mitigate the impact of this, we will recommend working on improving the online information, advice, and signposting. Feedback from our stakeholder meetings indicated that this would be beneficial for many affected. There was also some suggestion that younger people may prefer to access advice anonymously through, for example, social media and other online content rather than speak to a counsellor. This option may therefore be more useful to some than the currently provided counselling/intermediary services.

Option 5: End funding for a commissioned support service and bring the letterbox service in-house.
Negative Impact: Users will be required to fund own counselling and part of the intermediary services (facilitated meetings). Impact will be the same for all affected protected groups.

Mitigations: Bringing the letterbox service in-house.

This option involves the withdrawal of the free counselling service and facilitated meetings currently offered, which means that if people want these services, they would have to access and fund them privately. However, under this option, the impact is reduced by bringing the letterbox service in-house. This is a service that is not available in the private sector, and we had feedback that it was useful to assist with safeguarding people who wish to make contact. Under this option, people who want to contact their donor or donor siblings without exchanging contact details would still be able to do so.

Public Body Review 2023

Details about this paper

Area(s) of strategy this paper:	The best care/The right information/Shaping the future
Meeting:	Authority
Agenda item:	Number
Meeting date:	24 January 2024
Author:	Peter Thompson, Chief Executive Clare Ettinghausen, Director of Strategy and Corporate Affairs
Annexes	Annex 1: Recommendations and responses

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority are asked to discuss the proposed responses to the review recommendations and agree a timeline for any relevant actions
Resource implications:	As set out in Annex 1
Implementation date:	Ongoing from January 2024
Communication(s):	Relevant communications for specific actions as they arise
Organisational risk:	Low

1. Background

1.1. The Public Bodies Review programme was announced in April 2022 and all Departments are expected to conduct regular reviews of their ALBs ('Arm's Length Bodies'). The HFEA was the second ALB of the Department of Health and Social Care (DHSC) to be reviewed.

1.2. Cabinet Office guidance sets out the process that departments are expected to follow when conducting public body reviews. ALBs are scrutinised against four main quadrants of: accountability, efficacy, efficiency and governance. Having completed a self-assessment exercise, the Review decided that the primary focus would be on accountability, efficacy and efficiency, as well as looking at the adequacy of the legal framework, given our own focus on law reform. The review considered the HFEA to have good governance arrangements, so this was not a focus for the review.

1.3. The HFEA has been subject to several previous reviews, most recently, the **Triennial Review** in 2017 and the **McCracken Review** in 2013.

1.4. This review began in February 2023 and the **report** was published in November 2023. The review gave a broadly positive assessment of the HFEA. It noted that:

> "HFEA performs important functions. It regulates a discrete and specialised area of medical practice and scientific research, which can raise sensitive clinical, legal and ethical issues."

Continuing, the review noted that:

> "HFEA has a small, highly experienced and capable executive management team to support its chair and members. The effectiveness of HFEA is dependent upon the breadth of skills and experience its members bring as well as the quality of support they receive from the management team."

The central conclusion of the review was that: HFEA should remain an executive non-departmental public body. The review identified 19 recommendations; this paper sets out our proposed responses to those recommendations.

2. Recommendations

2.1. The 19 recommendations are listed below, with more details of the HFEA response set out in Annex 1.

Efficacy

1. HFEA should remain an executive non-departmental public body.

Efficiency

2. HFEA should continue to learn from the effectiveness of regulators in both the UK and overseas and set objectives in this area linked to its business priorities as appropriate.

3. Subject to HM Treasury approval, the department and HFEA should implement the proposed fee increase from the 2024 to 2025 financial year.

4. Within the next 18 months, HFEA should establish plans to allow it to conduct a review of its fee model.

5. The department should work with its ALBs to scope the merits of shared service functions to determine whether there is opportunity for improved overall efficiency in the areas identified by this review.

6. Within 12 months of all the functionalities of the Patient Register Information System (PRISM) being embedded, HFEA should review the efficiency of PRISM.

Effectiveness

7. The department should include the fertility sector in any evaluation of cross-border healthcare services, for example the costs, benefits and risks to UK citizens.

8. Over the next 18 months, HFEA should evaluate the PRISM data it now holds with the aim of improving the use of technology and data to enable a more risk-based approach to inspection.

9. As resources allow, now that HFEA has published the updated code of practice, it should engage with stakeholders to determine whether there is scope for the code of practice to be shorter and more user-friendly. The review notes that the timing of this work will also depend on progress on law reform.

10. HFEA should review how it would use any new powers to delegate the responsibilities of the person responsible, including to improve the effectiveness of regulation of fertility centres with common ownership.

11. Now that HFEA's adapted add-on rating system has been published, it should work with the department and professional bodies to determine how best a voluntary data collection programme for treatment add-on usage in clinics could be introduced.

12. Within the next 18 months, the department should, with the assistance of HFEA, put in place arrangements to regularly review the potential implications of recent research and innovations, for example, the use of synthetic tissues, in the context of the current regulatory framework.

13. HFEA should review its digital capability and identify options to enhance its digital offering, including working with the wider ALB community to share resources.

14. The department should consider how it could further support HFEA's communication function to improve the impact of trusted and evidence-based information when it reaches patients.

15. The department should work with HFEA and NHSE to collectively review its current approach to joint working and propose options to strengthen collaboration to improve delivery on fertility and wider women's health priorities.

Legal framework

16. As part of its response to HFEA's proposals, the department should explore whether some of the areas for law reform could be pursued through secondary legislation. The department should also explore the merits of designating HFEA as a consumer law enforcer.

Accountability

17. The sponsor team should seek to ensure that annual ministerial accountability meetings are reinstated from 2024.

18. The department should, in the next 18 months, develop and consider succession plans within the sponsorship team to mitigate risk and maintain the effectiveness of its sponsorship arrangement.

19. The department should, within the next 12 months, develop improved arrangements for co-ordinating responses from its ALBs to information requests from across government.

3. Next steps

3.1. The Senior Management Team will be updating our DHSC sponsor team at each quarterly accountability meeting on progress against the recommendations as set out in Annex 1.

4. For decision

4.1. The Authority is asked to discuss the planned responses to the Public Bodies Review recommendations set out in Annex 1 and agree a timeline for any relevant actions.

Annex A – Public Body Review 2023 – Recommendations and HFEA response

	Recommendation	Response	Timing
		Efficacy	
1	HFEA should remain an executive non-departmental public body.	N/A	N/A
		Efficiency	
2	HFEA should continue to learn from the effectiveness of regulators in both the UK and overseas, and set objectives in this area linked to its business priorities as appropriate.	We do look to international comparators when appropriate, e.g. in relation to data collection and reporting, releasing register information and managing public information. We also note that many other countries turn to the UK for help and guidance, e.g. most recently, Ireland, Israel and Japan.	Ongoing as resources allow in relation to relevant activities.
3	Subject to HM Treasury approval, the department and HFEA should implement the proposed fee increase from the 2024 to 2025 financial year.	Agreed by Authority in November 2023.	Implementation from 1 April 2024 subject to approval from HM Treasury.
4	Within the next 18 months, HFEA should establish plans to allow it to conduct a review of its fee model.	This has long been an ambition for the HFEA but was delayed during the Covid pandemic.	Planned to start during 2024/25 business year.
5	The department should work with its ALBs to scope the merits of shared service functions to determine whether there is opportunity for improved overall efficiency in the areas identified by this review.	Ongoing contribution to DHSC work.	Ongoing.
6	Within 12 months of all the functionalities of the Patient Register Information System (PRISM) being embedded, HFEA should review the efficiency of PRISM.	We have long agreed that it would be appropriate to review the efficiency of PRISM, but this can only be carried out following final	To review in 2025/26

	Recommendation	Response	Timing
		completion of related PRISM tools (OTR and CaFC).	
		Effectiveness	
7	The department should include the fertility sector in any evaluation of cross-border healthcare services, for example the costs, benefits and risks to UK citizens.	Some UK citizens do seek fertility treatment overseas, but the numbers are not known and there is no obvious mechanism for establishing reliable estimates. Given the cost of treatment in the UK for the majority of patients, it is unclear how this could be reduced without a significant shift in policy.	Not for the HFEA.
8	Over the next 18 months, HFEA should evaluate the PRISM data it now holds with the aim of improving the use of technology and data to enable a more risk-based approach to inspection.	This has been a long-term ambition of the PRISM programme and some of this work was undertaken as part of that programme. Data dashboards will be published shortly and mark the next step in providing more data to evaluate clinic performance and we have plans to replace our Inspection and licensing tools subject to DHSC and Treasury approval.	Starting in 2024/25 and likely to continue 2025/26 and 2026/27 as resources allow.
9	As resources allow, now that HFEA has published the updated code of practice, it should engage with stakeholders to determine whether there is scope for the code of practice to be shorter and more user-friendly. The review notes that the timing of this work will also depend on progress on law reform.	We have long wanted to change the Code of Practice from a long document to a more manageable HTML resource but have not had capacity to do so. However, any change will require consultation with the sector and some research on this was carried out in recent years, including surveying clinic staff and discussions with the Licence Centre Panel stakeholder group, which suggested that the current style was acceptable, and the depth of content was supported. We would need significant financial and staff investment to do this.	As resources and priorities allow.

	Recommendation	Response	Timing
10	HFEA should review how it would use any new powers to delegate the responsibilities of the person responsible, including to improve the effectiveness of regulation of fertility centres with common ownership.	Further discussion as part of the development of law reform proposals	Ongoing.
11	Now that HFEA's adapted add-on rating system has been published, it should work with the department and professional bodies to determine how best a voluntary data collection programme for treatment add-on usage in clinics could be introduced.	We are supportive of the idea that data collection, whether from a sample or all licensed clinics, could potentially enable robust conclusions to be drawn about the effectiveness of an add-on. A change in the law as per law reform proposals may make this more easily achievable, but in the meantime, we will keep ongoing discussions with the professional bodies and SCAAC about this.	Following the completion of PRISM, so likely not able to start planning until 2025/26 business year.
12	Within the next 18 months, the department should, with the assistance of HFEA, put in place arrangements to regularly review the potential implications of recent research and innovations, for example, the use of synthetic tissues, in the context of the current regulatory framework.	There will be ongoing reviews of these type of innovations as part of our SCAAC programme of work, which the DHSC observe.	Ongoing.
13	HFEA should review its digital capability and identify options to enhance its digital offering, including working with the wider ALB community to share resources.	This is ongoing as part of the shared services ALB working group.	Ongoing.
14	The department should consider how it could further support HFEA's communication function to improve the impact of trusted and evidence-based information when it reaches patients.	Improving our communications functions along these lines is an important strategic aim, but it will require significantly more capacity if we are to reach wider audiences in new ways.	Awaiting views from DHSC.
15	The department should work with HFEA and NHSE to collectively review its current approach to joint working and propose options	We will be sharing regulatory actions for centres with NHSE, and a way forward has been agreed. However such joint working can only apply to NHS treatment in England, which	Ongoing to be determined priorities for 2024/25 and 2025/26.

	Recommendation	Response	Timing
	to strengthen collaboration to improve delivery on fertility and wider women's health priorities.	is not applicable to the majority of treatment cycles. We have also instigated regular meetings with the relevant NHSE staff.	
		Legal framework	
16	As part of its response to HFEA's proposals, the department should explore whether some of the areas for law reform could be pursued through secondary legislation. The department should also explore the merits of designating HFEA as a consumer law enforcer	HFEA will continue to work with DHSC to consider options for law reform through secondary legislation.	Ongoing.
		Accountability	
17	The sponsor team should seek to ensure that annual ministerial accountability meetings are reinstated from 2024.	N/A	N/A
18	The department should, in the next 18 months, develop and consider succession plans within the sponsorship team to mitigate risk and maintain the effectiveness of its sponsorship arrangement.	N/A	N/A
19	The department should, within the next 12 months, develop improved arrangements for co-ordinating responses from its ALBs to information requests from across government.	N/A	N/A