Human Fertilisation & Embryology Authority

Authority meeting

Date: 12 March 2025 – 12.45pm – 3.30pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of the meeting held on 22 January 2025 and matters arising (5) For decision	12.50pm
3. Chair and Chief Executive's report (10) For information	12.55pm
4. Committee Chairs' reports (15) For information	1.05pm
5. Performance Report (25) For information	1.20pm
6. Draft Business Plan 2025/26 (20) For information	1.45pm
7. Effective Governance (15) For decision	2.05pm
Comfort break – 10 minutes	2.20pm
8. Multiple Birth Target (45) For decision	2.30pm
9. Update on Public Body Review (PBR) actions (15) For information	3.15pm
10. Any other business (verbal) (5)	3.30pm
11. Close	

Minutes of Authority meeting held on 22 January 2025

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	12 March 2025		
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 22 January 2025 as a true record of the meeting.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Minutes of the Authority meeting on 22 January 2025

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Catharine Seddon Christine Watson Geeta Nargund Rosamund Scott Anya Sizer Stephen Troup
Apologies		
Observers	Steve Pugh, Department of Health and Social Care (DHSC) (online)	
Staff in attendance	Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Rachel Cutting (Director of Compliance & Information) Tom Skrinar (Director of Finance & Resources) Paula Robinson (Head of Planning and Governance) Dina Halai (Head of Regulatory Policy) Rebecca Taylor (Scientific Policy Manager) Caroline Pringle (Head of Licensing) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members
There were 14 members at the meeting – 9 lay and 5 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and HFEA staff to the first Authority meeting of 2025.

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

1.3. Declarations of interest were made by:
- Geeta Nargund (Clinician at a licensed clinic and licence holder)
- Anya Sizer (Freelance advisory work with a licensed clinic)
- Stephen Troup (Consultancy work within the fertility sector)

2. Minutes of the last meeting and matters arising

2.1. The minutes of the meeting held on 20 November 2024 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

2.2. The Chair introduced the report and informed members that the four ‘matters arising’ items had either been completed or were brought forward to this meeting for consideration as an agenda item.

2.3. Members noted the matters arising report.

3. Chair and Chief Executive's report

3.1. The Chair gave an overview of her engagement with key stakeholders and her attendance at decision-making committees of the Authority.

3.2. The Chair informed members that she had attended the all-staff event in late November and that this had been a lovely event with high attendance from staff, including inspectors. The event had been a mixture of presentations and activities, and it was pleasing to see the significant level of happiness and engagement of staff.

3.3. The Chair spoke about attending the Fertility Conference 2025 which was held in Liverpool from 8-11 January. This is the main conference for the fertility sector and the session that she spoke at was well attended and her presentation had been well received with several good, engaging questions being asked. The British Fertility Society (BFS) had paid tribute to the work being done by the HFEA and attendees at the conference were generally complimentary about the HFEA.

3.4. The Chief Executive informed members that he and the Chair had attended the Progress Educational Trust (PET) Conference in early December and had spoken about the decision the Authority had taken in November about extending the time limit on embryo research.

3.5. The Chief Executive provided further information about the interviews he had given with the New York Times and Times Radio.

Decision

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

4. Committee Chairs' reports

4.1. The Chair introduced the report reminding members of its new format, following the decisions made by the Authority in September 2024 regarding communicating licensing, regulatory activity and incident information. Members were informed that the HFEA website has a new page which shows the latest regulatory decisions. The Chair invited Committee Chairs to add any other comments to the presented report.

4.2. The Licence Committee Chair (Graham James) stated that the committee had met last week, and the minutes had not yet been approved. The committee welcomed three new members, who had observed a previous meeting. At the November Authority meeting it had been agreed to enlarge the number of committee members and this extra resilience was welcomed. He referred to the recommendations on law reform discussed at the November Authority meeting to propose a wider range of regulatory sanctions and how this would be of benefit.

4.3. The Statutory Approvals Committee (SAC) Chair (Frances Flinter) stated that the committee had also welcomed three new members, who had observed a previous meeting. She referred to the new format of the committee chairs' report and the enhanced information which is now provided about the SAC decisions. She explained the process for considering PGT-M applications and the benefit of having an independent peer reviewer and excellent reports from the Genetic Alliance. The committee consider all this information and when considering a condition may also consider

licensing additional similar conditions. She referred to the special direction applications for import or export of items.

4.4. The Chair stated that Genetic Alliance had been a speaker at the Fertility 2025 Conference and had mentioned the good working relationship with the HFEA. The Chair spoke of the importance of such a good collaborative relationship.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had received the internal audit reports on Opening the Register (OTR) and Government Functional Standards (GFS) and had explored at length the difference of opinions on the findings. There were a number of audit recommendations which had not been accepted by management and the committee had proposed an amendment to the memorandum of working with GIAA. The AGC Chair provided information on the closure of audit actions, the audit plan for the preparation of the accounts, bi-annual HR report and the plans for CaFC publication. Members were informed that the committee had received training on assurance mapping from GIAA and this session had been attended by representatives from other small Health ALBs.

4.6. The Chair thanked all Committee Chairs for the reports and stated that committee papers and minutes are published on the HFEA website.

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and reminded members that the Key Performance Indicators (KPIs) measure various operational aspects of the business conducted by the HFEA.

5.2. The Chief Executive informed members that the report includes data up to the end of December. Performance continues to be consistently strong across the KPI indicators with 13 green, two red and two neutral indicators. He provided further information on the two red KPI's and stated that these were not a cause for concern.

5.3. The Chief Executive referred to the HR KPIs contained in the paper and informed members that staff turnover remains green, at 9.2% and is within the 5 - 15% target band.

5.4. Staff sickness was the lowest it had been at 1.6%, the Chief Executive remarked that HR revisited the numbers in January to ensure that they were a reflection of the actual sickness in the reported period.

Compliance and Information

5.5. The Director of Compliance and Information referred to the publication of independent reports on the CQC (interim and full) and Ofsted and how both reports were critical of aspects of the inspection regime used in each organisation. As a regulatory body it was important for the HFEA to use these reports for self-refection to see where improvements could be made.

5.6. The Director of Compliance and Information remarked that whilst there are aspects of the CQC's and Ofsted's approach and responsibilities which are different to the work of the HFEA, there is much in the reports which is relevant and this allowed the HFEA to analyse where its strengths and weaknesses lie and where there are opportunities for improvement.

5.7. Members were reminded that the HFEA's inspection regime had undergone significant change in the last few years and these changes were independently audited by GIAA on two separate occasions and the regime as a whole was independently assessed by the Public Bodies Review of the HFEA in 2023.

5.8. The strengths identified by the review were the expertise of the HFEA's inspectors and clinical governance team, a robust regulatory regime which ensure clinics are inspected in a defined timeframe and PRs having a named inspector to communicate with. The HFEA also benefits from strong oversight from the Authority and the accountability meetings with the sponsor team at DHSC.

5.9. Opportunities for improvement were identified regarding the IT platform and the HFEA had prioritised replacing its licensing IT system and clinic portal over the next 18 months. Inspectors had also received specific training on how to identify stress in individuals on inspection and how to handle these situations calmly, confidently and with empathy.

5.10. A learning point raised in the review of Ofsted was the importance of respectful and productive engagement between inspectors and those inspected. The Director of Compliance and Information reminded members that the HFEA asks for direct feedback from clinics to help it gauge whether this is the case for HFEA inspections. Survey findings for the first quarter of 2024 found that 89% of responses were positive about the support provided by inspectors at inspection. In addition, 80% of respondents strongly agreed/agreed that the inspection visit had promoted learning and improvements to the way that they work.

5.11. Members were informed that an article explaining the HFEA's analysis and reflection will be published in the next Clinic Focus newsletter.

5.12. The Chair thanked the team for the analysis. It was reassuring for the Authority to note the strengths identified and the new training for inspectors will assist even further in the positive relationships with clinics.

5.13. The Director of Compliance and Information informed members that the scoping exercise which is the new essential part of the cyber assessment framework (CAF) aligned with DSPT is in draft form and will be circulated to the Information Governance steering group before final agreement.

5.14. During 2024 the OTR team had provided information to almost 1,300 people and the waiting list is at the lowest it has been since the first quarter of 2023/2024, standing at 972.

5.15. The waiting times for all types of OTR have gone down in the last 3 months but applications continue to be received at the rate of 70-90 a month.

5.16. The Chair congratulated the OTR team for managing the situation in a systematic way to reduce the waiting list.

Strategy and Corporate Affairs

5.17. The Director of Strategy and Corporate Affairs stated that the family formations report was published at the end of November 2024 and all major news outlets had covered it. The national patient survey report is due to be published in March and the next Fertility Trends report will be published later this year.

5.18. The new data research newsletter had just been issued and included details of the webinar that the HFEA will host in early February regarding accessing the UK national fertility register for

research. 80 attendees had already registered for this event. A poster presentation of the latest data from the family formations report was showcased at the Fertility Conference 2025.

5.19. Members were informed that the recruitment process for the Patient Engagement Forum (PEF) had closed and that the HFEA team looked forward to working with the new members of this forum.

5.20. The Director of Strategy and Corporate Affairs welcomed Caroline Pringle, Head of Licensing, who had joined the HFEA recently. Members were reminded that Licensing will now function as a distinct team under her directorate.

5.21. The Director of Strategy and Corporate Affairs spoke of the work being done to implement the recent changes in law relating to screening in fertility treatment. The changes meant that enhanced screening is no longer necessary for couples having reciprocal IVF, and people who are HIV+ with an undetectable viral load can now donate their gametes for use in treatment as 'known donors'. To implement the second change a licence update is required and already four applications from clinics have been processed. We will be looking at how we can make it easier for patients to find clinics with these licences on our website.

5.22. Members were informed that the next SCAAC meeting will be held in early February and will consider a number of topics including health outcomes in children conceived by ART, impact of stress on fertility treatment outcomes and prioritisation of topics for horizon scanning.

5.23. The Chair on behalf of the Authority extended a warm welcome to Caroline. The Chair remarked that the HFEA holds a wealth of wonderful data, and it is encouraging that this is made available for research projects and interest in the data is shown by the high number of registrations for the webinar. The Chair stated that at the Fertility 2025 Conference the BFS had spoken of the use of the HFEA's data in their research.

Finance, Planning and Technology

5.24. The Director of Finance, Planning and Technology informed members that an overspend of £132,000 is being forecast, before taking into account any accounting adjustments such as potential provisions reversals. It has been agreed with the department that unused Grant in aid (GIA) will be returned and he stated that this has been factored into the forecast.

5.25. The Director of Finance, Planning and Technology spoke of the thorough procurement exercise for the Epicentre replacement. As this had taken longer than first anticipated, the timescales for the project had changed with the bulk of work commencing in 2025/26; therefore, not all the additional GIA funding had been drawn down.

5.26. Members were informed that whilst the DHSC Finance Team were supportive of rolling over the GIA funding there were no guarantees, and it may be necessary to increase fees next financial year to fund this project. The Director of Finance, Planning and Technology informed members that the 2025/26 budget would be brought to the next Authority meeting.

5.27. The Director of Finance, Planning and Technology informed members that Sophie Tuhey will join the HFEA as Head of Planning and Governance in early February and recruitment of an IT Project Manager for the Epicentre project is currently underway.

5.28. The Planning and Governance Team had been busy with the preparation of the new Strategy, managing the review of committee effectiveness and development of the new strategic risk register.

5.29. Members were informed that the business continuity and disaster recovery plans were made available to staff via the Hub and an exercise is planned for later in the year. Security testing will also take place later in the year.

5.30. The Chair reminded members that as of 1 January, Tom Skrinar, was employed full time by the HFEA and his remit had been extended to include technology and planning. Members would be kept appraised of the developments of the Epicentre replacement project.

5.31. In response to a question the Chief Executive explained the difference between the PRISM and Epicentre projects. He spoke of the realisation and benefits of PRISM and that funding and staffing is now in the on-going maintenance phase; some resources will be redirected to assist with the Epicentre project and there may be opportunities for some savings but this would be limited.

5.32. In response to a question regarding business transformation and the Epicentre project the Chief Executive informed members that the main internal users of Epicentre were the inspection and licensing teams and these had been involved in the procurement process and will be heavily involved in the testing phase.

Decision

5.33. Members noted the performance report.

6. Strategic Risk Register

6.1. The Risk and Business Planning Manager introduced the paper and reminded the Authority that they review the strategic risk register (SRR) twice a year.

6.2. Members were informed that the Audit and Governance Committee (AGC) had reviewed the register at their December 2024 meeting and the version before the Authority includes amendments suggested by the AGC.

6.3. The Risk and Business Planning Manager summarised the recent changes to the SRR as:

- Commercial: risk title has been amended, following AGC feedback, to better reflect the risk.
- Financial: the sub risk around DHSC spending controls remains following the latest DHSC update in September 2024.
- Governance: this risk will be reviewed in its entirety as part of the SRR review accompanying the new strategy, planned for the June AGC meeting. The sub risk about reviews of other regulators has been updated.
- Information: this risk will be reviewed in its entirety as part of the SRR review accompanying the new strategy, planned for the June AGC meeting.
- Information 2: risk updated to reflect AGC's comments about pace of delivery and the impact from DNA testing. Minor updates made to the risk as the OTR system is now getting more stable and reference to the waiting list added.

- Operational: this risk has been updated with the procurement and delivery timelines for Epicentre. The CaFC sub risk has been amended with an interim CaFC being considered.
- People: this risk will be reviewed in its entirety as part of the SRR review accompanying the new strategy, planned for the June AGC meeting.
- People 2: this has been closed at the recommendation of AGC.
- Reputational: AGC considered the primary risk to be around the discussions Authority is willing to engage in which may have reputational impact.
- Security: minor updates had been made.

6.4. The Risk and Business Planning Manager informed members that the SRR will be completely revised to align with the new strategy and this will be presented to the AGC in June and then brought to the July Authority meeting.

Decision

6.5. Members noted the strategic risk register.

7. Strategy 2025-2028

7.1. The Chair introduced the item stating that like all public bodies the HFEA is required to agree a strategy which sets out the HFEA's vision and provides a framework for key activities. The Chair commented that the draft strategy had come to the Authority in various iterations with members having had plenty of opportunities to comment on it.

7.2. The Chair thanked the Head of Planning and Governance for her hard work in creating this strategy and noted that the document before the Authority reflects the discussions with members.

7.3. The Head of Planning and Governance introduced the paper and reminded the Authority of the process for preparing the proposed new strategy and the input and feedback which had been sought from Authority members, staff and stakeholders.

7.4. The Head of Planning and Governance explained the changes to the strategy since the Authority last considered this item in November 2024.

7.5. Members were reminded that the goal for this strategy is to ensure a well-regulated fertility sector, which is trusted by patients and the wider public, that the information provided is useful and accessible and that biosciences that lead to innovations in treatment can flourish, within an ethical framework.

7.6. The vision for the period 2025-2028 is "regulating for confidence: – safe treatment – right information – supported innovation". The main strategic themes are regulating a changing environment and supporting scientific and medical innovation.

7.7. The Head of Planning and Governance stated that the HFEA's goal of achieving law reform in the short to medium term remains central, but that the possible timing of this work is unknown. Any announcement of a parliamentary timetable for this work would necessitate a fresh look at strategic priorities, since focus would need to shift towards legislative change and implementation. Therefore, a degree of flexibility around how both the strategy and corresponding business plans would be delivered needs to be kept.

7.8. Members were informed that the Corporate Management Group (CMG) will be considering what these plans might look like in the next couple of weeks and the 2025/26 business plan will be brought to the March Authority meeting.

7.9. The Head of Planning and Governance stated that another unknown is the Government's new 10-year plan for health, which is likely to be published this Spring. The HFEA will need to ensure that its strategy and business plans are appropriately aligned with the 10 year plan.

7.10. The Head of Planning and Governance stated that if any final editorial changes are needed in response to events just before publication, in April 2025, then these will be communicated to members via email.

7.11. Several members congratulated the Head of Planning and Governance on the strategy and the priorities identified in the paper.

7.12. A member questioned whether the data from the recent national patient survey will be used to influence the HFEA's work.

Decision

7.13. The Authority approved the strategy for 2025-2028.

8. Law Reform – Stem cell-based embryo models (SCBEMs)

8.1. The Chair spoke about the suite of proposals on law reform which the HFEA had published in 2023. Within these proposals were several items which required further work and therefore these two agenda items are brought to the meeting today for debate and decision. As an expert regulatory body, it is expected that the HFEA advises the Government on proposed changes to the law.

8.2. Rosamund Scott informed the Authority that she is currently the Chair of the UK Stem Cell Bank (UKSCB) Steering Committee. She also advised that she was previously a member of the working group that drafted the first UK code of practice for the governance of stem cell-based embryo models (SCBEMs), first published in July 2024, but that, upon her appointment as a member of the HFEA in October 2024, she had left the working group. Frances Flinter informed the Authority that she had been a member of the Nuffield Council working group on SCBEMs.

8.3. The Head of Regulatory Policy introduced the paper and stated that despite their biological similarity to embryos, SCBEMs are not explicitly regulated by the HFE Act. The paper before the Authority looks in more detail at this policy area and makes recommendations for change.

8.4. Members were informed that the Scientific and Clinical Advances Advisory Committee (SCAAC) considered the technical issues associated with SCBEMs at their October 2024 meeting.

8.5. The Head of Regulatory Policy referred to the paper and stated that the Authority is asked to consider the questions in section seven.

8.6. The Chair of SCAAC summarised the committee discussions and agreements that SCBEMs should be regulated in their own right and that there had been absolute agreement that these should not be transferred to humans. He spoke of the difficulties in defining a fixed upper limit and that different types of models would require different limits.

8.7. Members discussed that whilst SCBEMs do not have the same special status as human embryos they (particularly the more complex models) should still be treated with respect and therefore regulation was necessary.

8.8. Members discussed the difficulties of defining an upper fixed limit for these models due to the way that SCBEMs develop, meaning that their age in days does not equate to the same developmental point as live human embryos (SCBEMs do not have a clear day zero to equate to the fertilisation of an egg by a sperm). It was suggested that any time limit needs a description of the development stage reached, rather than a specific timing.

8.9. In response to a question the Chief Executive explained that the term 'sandboxing' means a regulatory regime that allows conditional approvals in tightly controlled circumstances. It is an idea that has been used in a variety of regulatory environments and is not unique to bio-sciences regulation.

8.10. Members discussed whether it would be the HFEA who would regulate SCBEMs or the Human Tissue Authority (HTA) which regulates the use of human tissue and cells for medical treatment. The Chief Executive stated that this was ultimately a decision for government, but the debate so far had focused on the HFEA being the regulator for both principled and practical reasons.

8.11. Members discussed the research opportunities that SCBEMs could provide for what is considered the "black box" of research and concluded that the learning potential is great.

8.12. Members discussed the Oversight Committee proposed in the Code of Practice for the Generation and Use of Human Stem Cell-based Embryo Models, and endorsed in the Nuffield Council report and what role the HFEA could take in this committee, resources allowing.

Decision

8.13. The Authority agreed the following:

- that there was a case for recommending that SCBEMs are subject to some form of statutory regulation.
- that SCBEMs should be regulated on their own terms, separately from human embryos.
- that it should be explicit in law that SCBEMs must not be transferred to a human.
- that having a fixed upper limit on embryo model culture time is important and will be necessary in the future, but that this limit could not be fixed now and should be informed by consensus over time.

Action

8.14. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

9. Law Reform – In vitro gametes (IVGs)

9.1. The Scientific Policy Manager introduced the paper and explained that in vitro gametes (IVGs) are gametes (sperm or eggs) created in a laboratory using cells. The cell source can vary and include immature germ cells, embryonic stems cells and somatic cells (e.g. skin cells).

9.2. The cells are reprogrammed to become functional egg or sperm cells (gametes) through the process of in vitro gametogenesis (IVG). The Scientific Policy Manager explained that IVGs have

the potential to vastly increase the availability of human gametes for research and, if proved safe and effective, to provide new treatment options for people experiencing infertility.

9.3. Members were informed that in many countries there is interest in the use of IVGs for research and clinical use, and research is being undertaken in both public and private institutes in the UK, Japan, the USA, the Netherlands and Belgium. To date though only the Netherlands and Norway have addressed IVGs in legislation.

9.4. The Scientific Policy Manager stated that the HFEA and other regulators are looking at using 'sandboxing' to develop and test new approaches to regulating innovations like IVGs and that the HFEA has engaged with UK Regulation Innovation Office (RIO) and the Regulatory Horizon Council (RHC) on this. The RHC is now planning a regulatory sandboxing project using IVGs as a test case and the HFEA will be involved with this initiative.

9.5. Members were informed that the Scientific and Clinical Advances Advisory Committee (SCAAC) considered the issue of IVGs at their October 2024 meeting

9.6. A member explained the difference between single and 'solo parenting': in single (social) parenting the sperm and egg come from two different people but solo parenting would involve the sperm and egg coming from the same person (through in vitro gametogenesis). The high risk of recessive conditions through solo parenting was explained.

9.7. The Scientific Policy Manager explained "multiplex parenting" which is where two couples create embryos which are then used to make in vitro gametes to create a further embryo. Any resulting child would be the genetic grandchild of all four "parents", and its genetic parents would be the embryos used. As long as the "parents" are not closely genetically related, this does not pose greater risk of genetic disorders, but it raises many social and ethical questions.

9.8. The Chair of SCAAC summarised the committee discussions and agreements regarding IVGs. He spoke of the significant financial investments which is being made in this research because of the huge potential it could offer.

9.9. In response to a question the Chief Executive explained the potential use of secondary legislation and how this could be used to future proof the Act. He referred to how secondary legislation was used when the Act was last amended in 2008 with respect to mitochondrial donation.

9.10. Members discussed that whilst the ultimate aim of IVGs is to produce children who are genetically related to their parents, it must be done safely. The risk of serious inherited diseases, which had a high chance of arising through 'solo parenting', was an extremely serious concern for members.

9.11. Members discussed that IVGs may provide solutions in the future for people with fertility problems and potentially for at least some of those in same-sex relationships but that regulation was necessary to ensure patient safety.

9.12. Members discussed the current prohibition on the clinical use of IVGs as they are not 'permitted gametes' under the HFE Act. Consideration was given to whether a clear statement to that effect would negate the need to specify that they cannot be transferred into a human.

9.13. Members highlighted some ethical matters in relation to IVGs including the possible future impact of IVGs on the special status of the human embryo.

9.14. Members discussed the potential for IVGs to enable parents to have a genetically related child, should they wish, when they could not otherwise do so. One member noted that, from an ethical

and legal point of view, there are strong arguments supporting the right to have a genetically related child, and therefore that there is a strong case to legalise IVGs in the future, provided that research establishes that their use is sufficiently safe. It was noted that the legal arguments are supportable with reference to the European Convention on Human Rights and other international law.

9.15. Members asked for clarity in relation to the current (implicit) ban on clinical use of IVGs and future legislation. The Chief Executive explained that this was a matter of timing. It was necessary to close any current loopholes now and to maintain a ban on clinical use, then to develop a workable regulatory regime for clinical use in due course.

Decision

9.16. The Authority agreed the following:

- to recommend that IVGs are subject to some form of statutory regulation in time.
- that secondary legislation would be one means regulating the clinical use of IVGs in time.
- that there should be a clear statement that "IVGs are not permitted gametes" to avoid any confusion about current legislation.
- that the biologically dangerous and socially distasteful use of IVGs like 'solo parenting' should not be permitted.
- that it was premature to decide whether IVGs should be permitted for ethically complex clinical use, and this should be kept under review as the science develops.

Action

9.17. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

10. Any other business

10.1. The Chair thanked everyone for their active participation in the meeting which had considered a full and detailed agenda.

10.2. There being no further items of any other business the Chair closed the meeting and reminded members that the next Authority meeting will be held on 12 March 2025.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 12 March 2025

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	12 March 2025		
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	2024/25 business year		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
22/01/2025 minute 8.14 and 9.17	The HFEA to continue to discuss with DHSC and Government the law reform proposals	Senior Management Team	Ongoing		Ongoing discussions with DHSC and as part of our quarterly accountability meetings.

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:	12 March 2025
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 meeting in January 2025.
- 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:

    - 28 January - attended the ALB senior leaders meeting for all Chair and CEO's. On the same day Peter and I attended *For Thought*, a thought leadership summit by the British Science Association (BSA)
    - 3 February – attended our SCAAC meeting
    -

2.2 Chief Executive

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

    - 28 January – gave an interview on the Today programme on invitro derived gametes
    - 28 January – attended the ALB senior leaders meeting for all Chair and CEO's. On the same day Julia and I attended *For Thought*, a thought leadership summit by the British Science Association (BSA)
    - 3 February – attended our SCAAC meeting
    - 6 February – attended event on the future of the 'Civil Service Policy Profession: The end of the generalist?' at the Institute for Government
    - 26 February – spoke at the ACE-PCF Annual Conference on Public Bodies data, technology and innovation
    - 27 February – attended Health and Social care Regulators Forum
    - 28 February meeting with Regulatory Horizons Council
    - 4 March – attended the Audit & Governance Committee
    - 7 March – chaired HFEA/BFS/ARCS joint working meeting
    - 10 March – participated in roundtable event on Stem cell based embryo models at Nuffield Council on Bioethics

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:	12 March 2025
Author:	Caroline Pringle, Head of Licensing
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):	This information will be published on our website.
Organisational risk:	Low

1. Committee reports

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

2. Recent committee items considered

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

Date	Items considered	Centres	Outcomes
Licence Committee:			
16 January	Renewal inspection report	NewLife Fertility Centre	Reserved Decision
	Renewal inspection report	The Fertility & Gynaecology Academy	Reserved Decision
	Variation of premises	Guys Hospital	Approved – licence varied
Other comments:	The Committee's next meeting is on 20 March.		
Executive Licensing Panel:			
7 January	Initial inspection report	Roylance Stability Storage Limited ta ('trading as') Sampled	Approved – 2 year licence
	Research renewal report	Wellcome Centre for Cell Biology	Approved – 3 year licence
	Interim inspection report	Sunderland Fertility Centre	Approved – continuation of licence
	Interim inspection report	TFP Nurture Fertility Ltd	Approved – continuation of licence
	Interim research inspection report	Institute of Reproductive and Developmental Biology	Approved – continuation of licence
	Variation to add embryo testing	Centre for Reproductive Medicine, Coventry	Approved – licence varied
21 January	Variation – change of PR	Leicester Fertility Centre	Approved – licence (and ITE certificate) varied
	Variation – change of LH and variation of SLC T52 without application	TFP Thames Valley Fertility	Approved – licence varied
	Variation - change of LH and variation of SLC T52 without application	Andrology Unit, Hammersmith Hospital	Approved – licence varied

Date	Items considered	Centres	Outcomes
	Variation – change of LH and variation of SLC T52 without application	TFP Boston Place Fertility	Approved – licence varied
	Variation of Licence to include new Standard Licence Condition T52	London Women's Clinic	Approved – licence varied
	Variation of Licence to include new Standard Licence Condition T52	Agora Clinic Brighton	Approved – licence varied
	Variation of Licence to include new Standard Licence Condition T52	Agora Clinic Eastbourne	Approved – licence varied
4 February	Interim inspection report	The Fertility Home	Approved – continuation of licence
	Variation of LH and variation of SLC T52 without application	Cambridge IVF	Approved – licence varied
	Variation to licensed premises and change of centre name	Wellcome Centre for Cell Biology	Approved – licence varied
	Variation of PR	Guys Hospital (Research)	Approved – licence varied
	Variation of PR and variation of SLC T52 without application	Guys Hospital (Treatment and Storage)	Adjourned – referred to LC to consider
	Variation of PR and variation of SLC T52 without application	Centre for Reproductive and Genetic Health City	Approved – licence (and ITE certificate) varied
17 February	Interim inspection report	CREATE Fertility, Manchester	Minutes not yet approved
	Interim inspection report	Care Fertility Birmingham	Minutes not yet approved
	Interim inspection report and variation of SLC T52 without application	Aria Fertility	Minutes not yet approved
	Interim inspection report and variation of SLC T52 without application	Avenues	Minutes not yet approved
	Variation of LH and variation of SLC T52 without application	Complete Fertility Centre Southampton	Minutes not yet approved
	Variation of LH and variation of SLC T52 without application	TFP GCRM Fertility	Minutes not yet approved

Date	Items considered	Centres	Outcomes
	Variation of LH and variation of SLC T52 without application	TFP Nurture Fertility	Minutes not yet approved
	Variation of PR (Research)	Newcastle Fertility Centre at Life	Minutes not yet approved
3 March	Interim inspection report	Agora Clinic Brighton	Minutes not yet approved
	Interim research inspection report	Centre for Human Reproductive Science	Minutes not yet approved
	Variation of PR and variation of SLC T52 without application	Fertility Unit Barking, Havering and Redbridge Hospitals Trust	Minutes not yet approved
	Variation of premises and name	Physiology Laboratory	Minutes not yet approved
	Special Directions to allow continuation of licensed activity	The Francis Crick Institute	Minutes not yet approved
Other comments:	None.		

Licensing Officer decisions:

January and February	28 ITE import certificates	Various	All granted
	Change of LH	Leicester Fertility Centre	Licence varied
	Change of LH, Research	Newcastle Fertility Centre at Life	Licence varied
Other comments:	None		

Statutory Approvals Committee:

10 December	PGT-M: Intellectual Disability-Hypotonic Facies Syndrome, X-Linked, 1 (MRXHF1), OMIM #309580	Aria Fertility	Approved
	PGT-M: Deafness, Autosomal Dominant 11 (DFNA11), OMIM #601317	Care Fertility Nottingham	Refused
	PGT-M: Macular Dystrophy, Patterned, 1 (MDPT1), OMIM	TFP Oxford Fertility	Approved

Date	Items considered	Centres	Outcomes
	#169150		
	PGT-M: Split-Hand/Foot Malformation 4 (SHFM4), OMIM #605289	Guy's Hospital	Approved
	PGT-M: Pycnodysostosis, OMIM #265800	Guy's Hospital	Approved
	Special direction for export of sperm to US	TFP Oxford Fertility	Approved
27 January	PNT for a specified patient to avoid m.4300A>G mutation in the MT-TI gene coding for mitochondrial isoleucine tRNA (mt-RNA (Ile)), OMIM*590045.0006. (case ref. M0034)	Newcastle Fertility Centre at Life	Approved
	PGT-M: Hao-Fountain Syndrome (HAFOUS), OMIM #616863	TFP Oxford Fertility	Approved
	PGT-M: Asparagine Synthetase Deficiency (ASNSD), OMIM #615574	Care Fertility Nottingham	Approved
	Special direction for import of embryos from South Africa	Care Fertility Woking	Approved
	Special direction for import of embryos from GB to Northern Ireland	TFP Belfast Fertility	Approved
25 February	PGT-M: Three M Syndrome 1 (3M1), OMIM #273750	TFP Oxford Fertility	Minutes not yet approved
	PGT-M: Coenzyme Q9 Deficiency, OMIM *612837	TFP Oxford Fertility	Minutes not yet approved
	PGT-M: Structural Heart Defects and Renal Anomalies Syndrome (SHDRA), OMIM #617478	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved
	PGT-M: Spherocytosis, Type 1 (SPH1), OMIM #182900	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved
	Special direction to import sperm from South Africa	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved
Other comments:	When considering PGT-M applications, the Committee frequently considers not only the specific condition applied for, but also other similar conditions. In such cases, more than one condition may be authorised for testing.		

Date	Items considered	Centres	Outcomes
	The Committee conducted its annual review of effectiveness at the January meeting.		

Audit and Governance Committee:

Date	Items considered	Outcomes
5 March	Papers can be found **here** Internal audit – proposed 2025/26 internal audit plan Progress with current audit recommendations External audit report Accounting policies Risk update Deep dive discussion - Functional Standards processes Digital projects – PRISM and Epicentre replacement Resilience, business continuity management & cyber security Draft annual governance statement Fraud risk assessment Anti-fraud, bribery and corruption policy Public interest disclosure (whistleblowing) policy Government functional standards	The Chair will report on this meeting verbally.
Other comments:	None.	

Scientific and Clinical Advances Advisory Committee:

Date	Items considered	Outcomes
3 Feb	The agenda and papers for this meeting are published on the SCAAC webpage. Items considered included:	The SCAAC Chair will report on this meeting verbally. Key takeaways are as follows:
	Health outcomes in children conceived by ART (including the impact of culture media)	Members discussed the challenges of studying the impact of culture media, the limitations of linkage studies, and use of HFEA Register data. It was agreed that health outcomes for ART patients (including gestational surrogates, egg donors and the impact of treatment using donated eggs) should become a separate SCAAC horizon

		scanning topic.
	The impact of stress on fertility treatment outcomes	Members considered research developments on stress and its associations with fertility treatment outcomes, including stress as a factor in the decision to discontinue fertility treatment. The Committee recommended that the Executive publish a statement on the website to highlight that there is no conclusive evidence linking stress to fertility treatment outcomes.
	Mitochondrial donation: polar body transfer	Research on polar body transfer, an alternative method for mitochondrial donation, was discussed. Members agreed that, despite the promise of lowering the risk of carryover of affected mitochondria, polar body transfer is still experimental and there is not yet sufficient evidence to make a strong case for further review or legislative change.
	Prioritisation of horizon scanning topics and Committee workplan 2025/26	The SCAAC reviewed the prioritisation of horizon scanning topics and agreed their workplan for 2025/26. Research developments in the topics of 'Reproductive organoids' and 'Health outcomes for ART patients (including gestational surrogates and egg donors)' will now be considered through the SCAAC's horizon scanning function, alongside the 13 existing prioritised topics. A watching brief function has also been incorporated into the horizon scanning process to allow the committee to monitor developing topics that may present opportunities or concerns, but do not yet meet the threshold for becoming a low priority horizon scanning topic.
	Androgen supplementation as a treatment add-on	During the June 2024 SCAAC meeting, the Committee advised that androgen supplementation met the criteria to be eligible for an HFEA treatment add-on rating. The Committee agreed ratings for both dehydroepiandrosterone (DHEA) and testosterone.
Other comments:	The Committee conducted its annual review of effectiveness at the February meeting. The Executive are also seeking to recruit two new External Advisers to the SCAAC with expertise in:	

(1) andrology/urology (with a focus on male fertility) and
(2) artificial intelligence, machine learning and big data in fertility treatment OR automation and robotic in fertility treatment OR biostatistics and assessing the quality of research in fertility treatment.

3. Recommendation

1.3 The Authority is invited to note this report. The information will be updated on the HFEA website.

1.4 Comments are invited, particularly from the committee Chairs.

Human Fertilisation & Embryology Authority

Monthly performance report

Performance up to January 2025

Evgenia Savchyna
Corporate Performance Officer
12/03/2025

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Meeting date:	12/03/2025
Agenda item:	Item 5
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 Corporate Management Group (CMG) 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 CMG meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the CMG 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 January 2025.
- Starting from January 2025, we will be reporting on a total of 19 KPIs, including two new KPIs related to OTR.
- There were twelve Green, two Red, two Amber and three Neutral indicators.

Key trends

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

November 2024 (1)	December 2024 (2)	January 2025 (2)
Debt collection within 40 days	Debt collection within 40 days	Debt collection within 40 days
	Inspection reports to committee within 65 working days	Inspection reports to PR within 25 working days

Human Fertilisation & Embryology Authority

Management summary

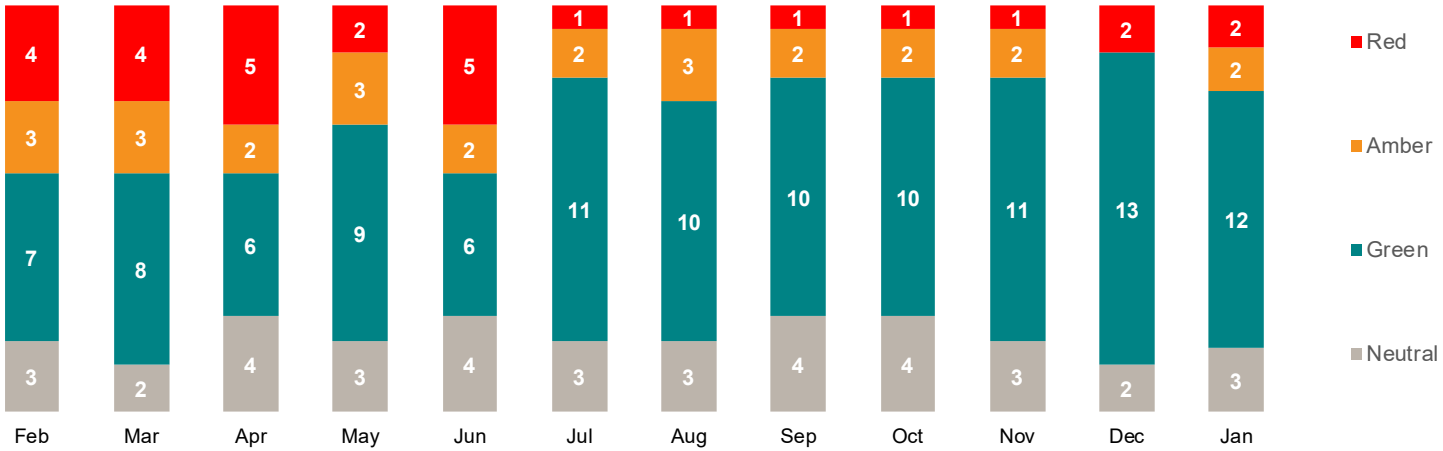
Management commentary

- Two new KPIs for the OTR team have been introduced, bringing the total number of KPIs to 19.
- Performance across KPI indicators in January remained good, with twelve Green, two Amber, two Red, and three Neutral indicators.
- The Compliance team continues to perform well against their targets. Although the 'Inspection Reports to PR' KPI was rated Red, this was due to just one report being delayed. All other inspection KPIs remained in Green.
- The PGT-M KPI remained in Green with an average of 44 days taken to process the item.
- January was a standard month for the Licensing team, with no LC items reported.
- Following the OTR KPI review, two new KPIs have been introduced: ‘OTR waiting list change’ and ‘OTRs closed in month’. Both new KPIs are currently rated Amber. The new charts in the performance report also represent the breakdown of the OTR waiting list and closed OTRs categories.
- Three FOIs and one PQ were completed and processed within targets in January.
- The total number of website sessions saw a spike in January, likely due to people planning to start treatment in the new year. Social media engagement was also higher on Instagram and LinkedIn compared to last month. The Guardian article generated significant media coverage.
- Seasonal viruses contributed to an increase in staff sickness, though it remains under the target. Turnover was the lowest in January, at 6,6%.
- The Debt Collection KPI remains Red, primarily due to old debt. However, the targets for Average debtor days and percentage of invoices paid within 10 days have been met.
- The number of email enquiries increased to the usual level after the drop off in November and December 2024. Phone calls has also increased to 53, up from last month.

Key performance indicators

Human Fertilisation & Embryology Authority

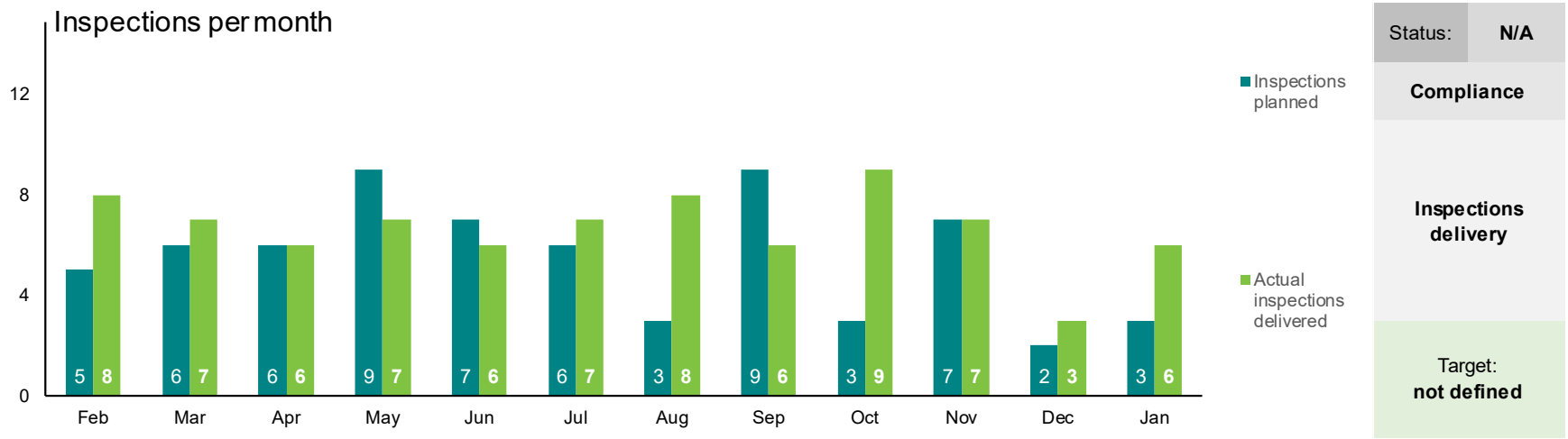
RAG status over last 12 months



RAG status over last 12 months

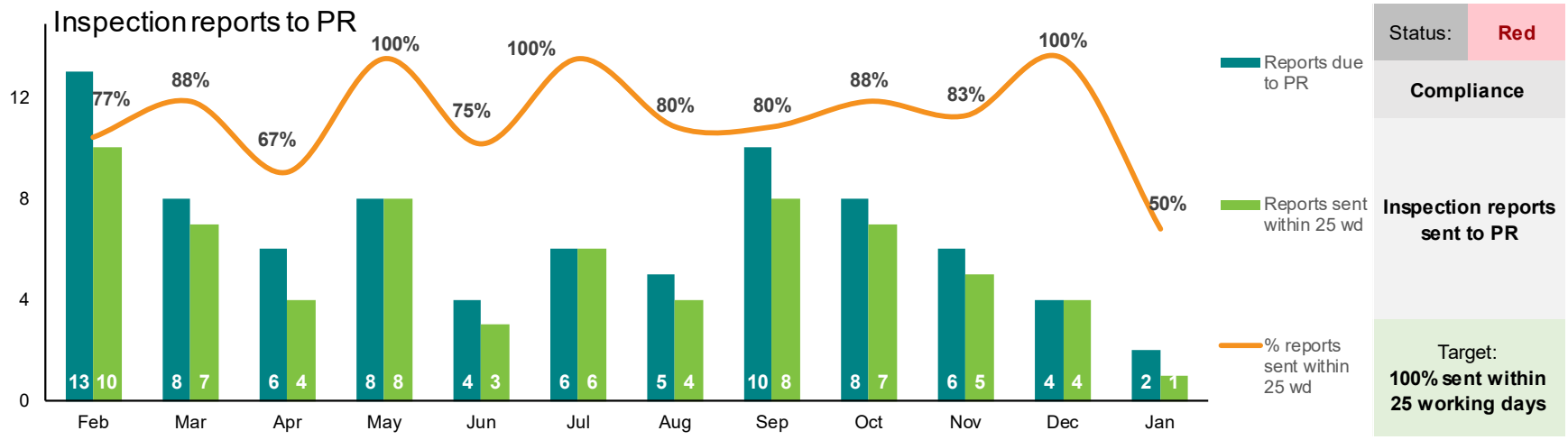
19 KPIs in total for each month starting from Jan 2025

The number of KPIs increased to 19 as of January 2025, with two new KPIs added for the OTR team.
For January, the 2 red indicator are in these teams: Compliance (1) and Finance (1).



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

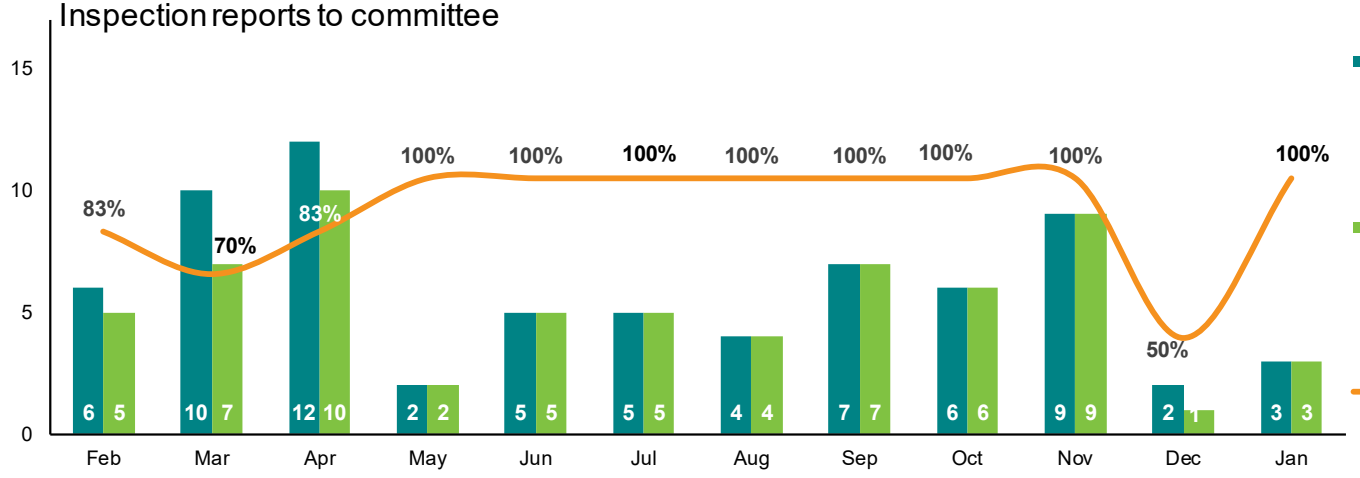
Three more inspections were delivered in January than planned. One of them was an interim inspection due to the initial center opening on 4 March 2024. The others were variations of premises and targeted interim inspections.



Status:	Red
Compliance	
Inspection reports sent to PR	
Target: **100% sent within 25 working days**	

One inspection report exceeded the KPI by 41 days due to the complexity of the report following a serious incident.

Inspection reports to committee



Status: **Green**

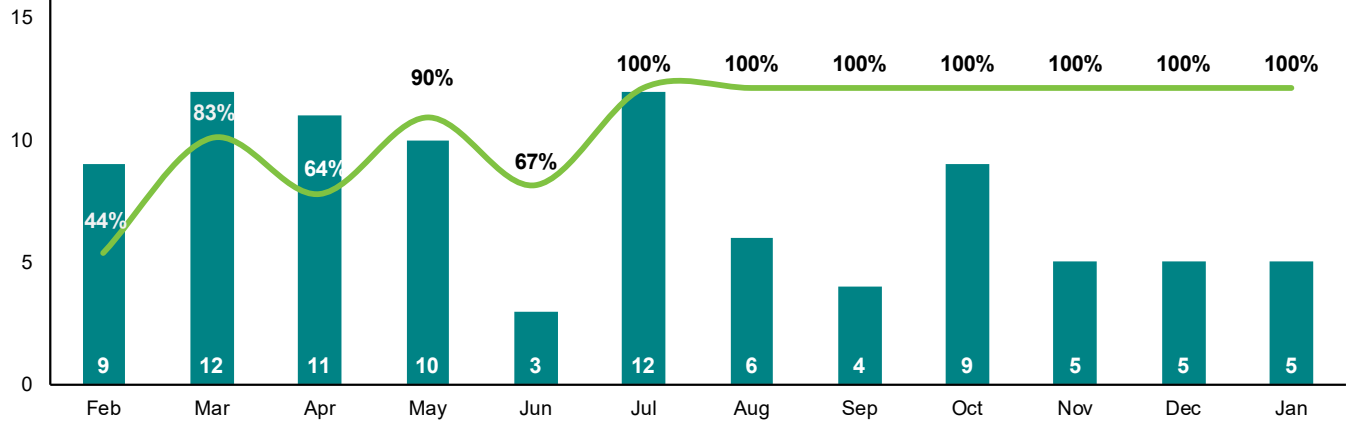
Compliance

Inspection reports sent to relevant licensing committee

Target: **100% sent within 65 working days**

All reports sent within KPI.

End to end licensing



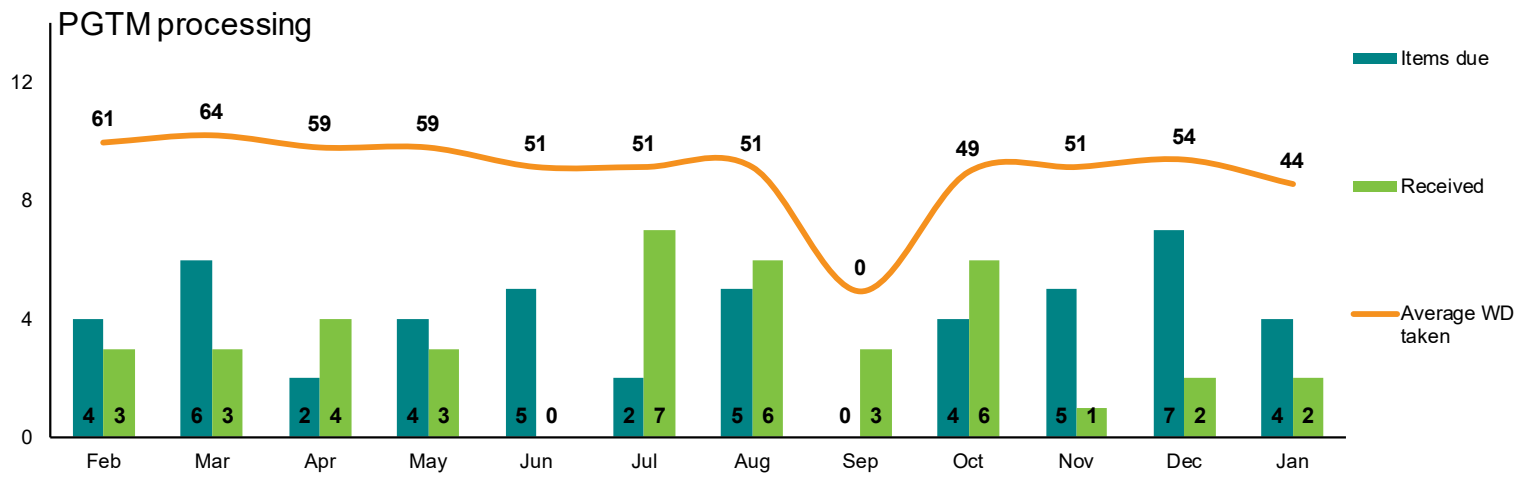
Status: **Green**

Compliance

End to end licensing process

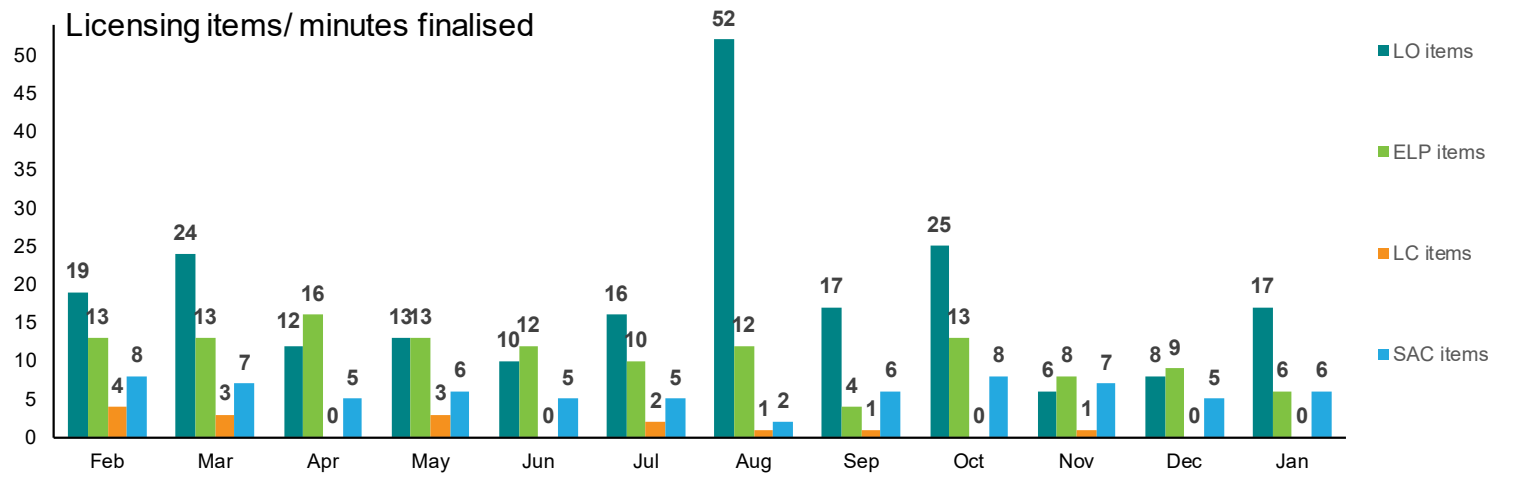
Target: **100% items completed within 80 working days**

All within KPI.



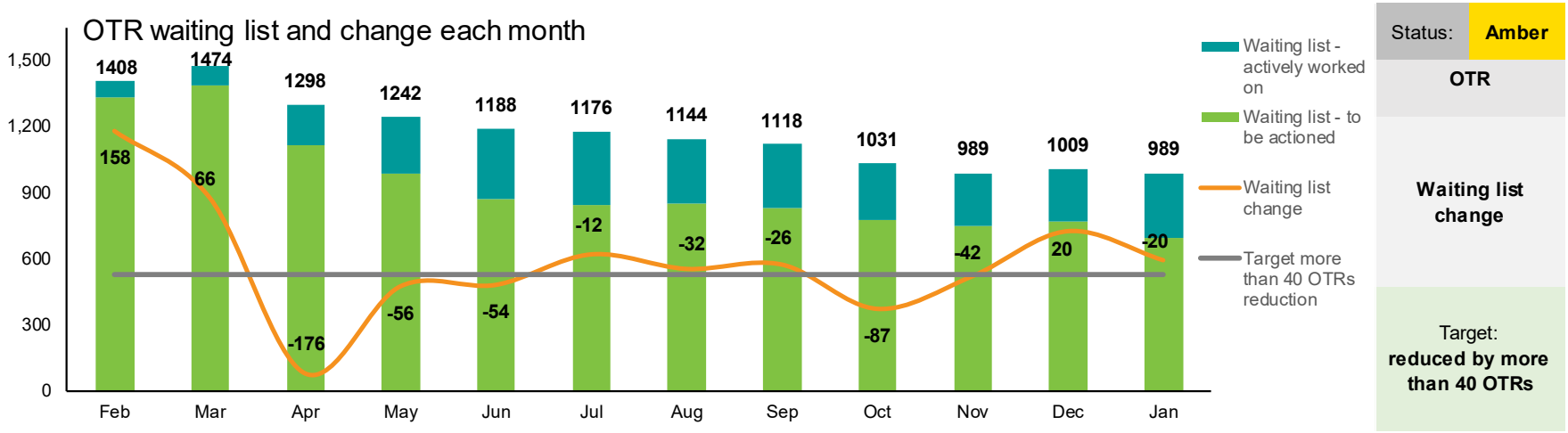
Status:	Green
Compliance	
PGTM processing efficiency	
New target - Dec 24: **100% within 60 working days**	

All PGTMs have been processed within KPI.



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

Lots of ITE certificates (16 out 17 LO items). Other meetings fairly standard with just one ELP meeting included in this month's data.



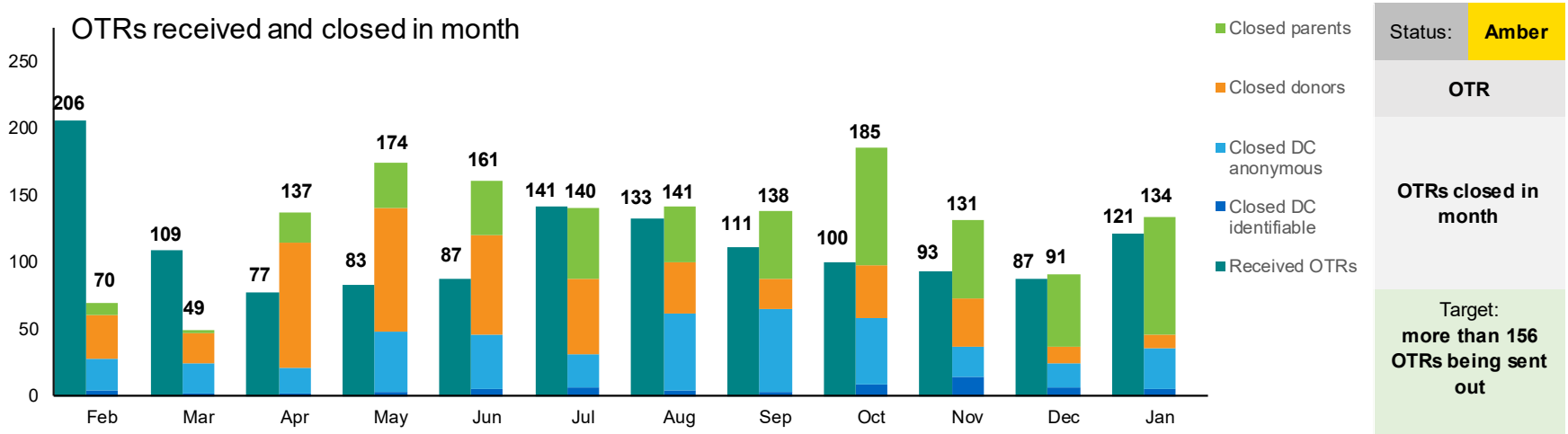
Status: **Amber**

OTR

Waiting list change

Target: **reduced by more than 40 OTRs**

Supplementary data of OTRs to be closed : **Donors OTRs - 214; DC identifiable - 56; DC anonymous - 240; Parents - 481** (*subcount numbers provided on 11 Feb 2025). The size of the waiting list has slightly decreased. Some resource still being spent on dealing with various issues which slows down the amount of OTRs processed.



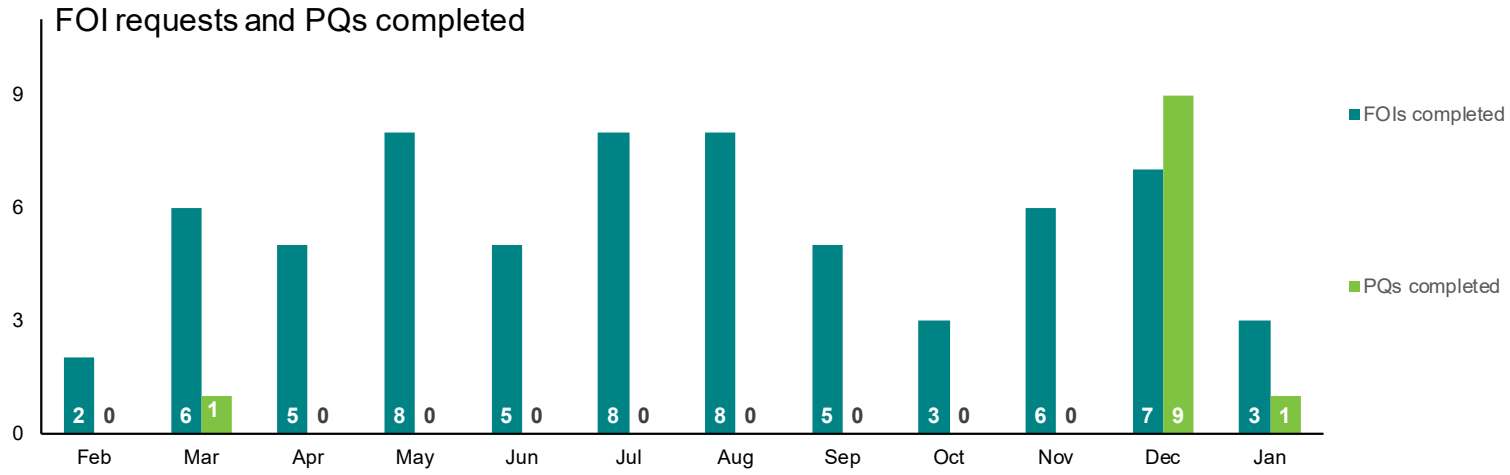
Status: **Amber**

OTR

OTRs closed in month

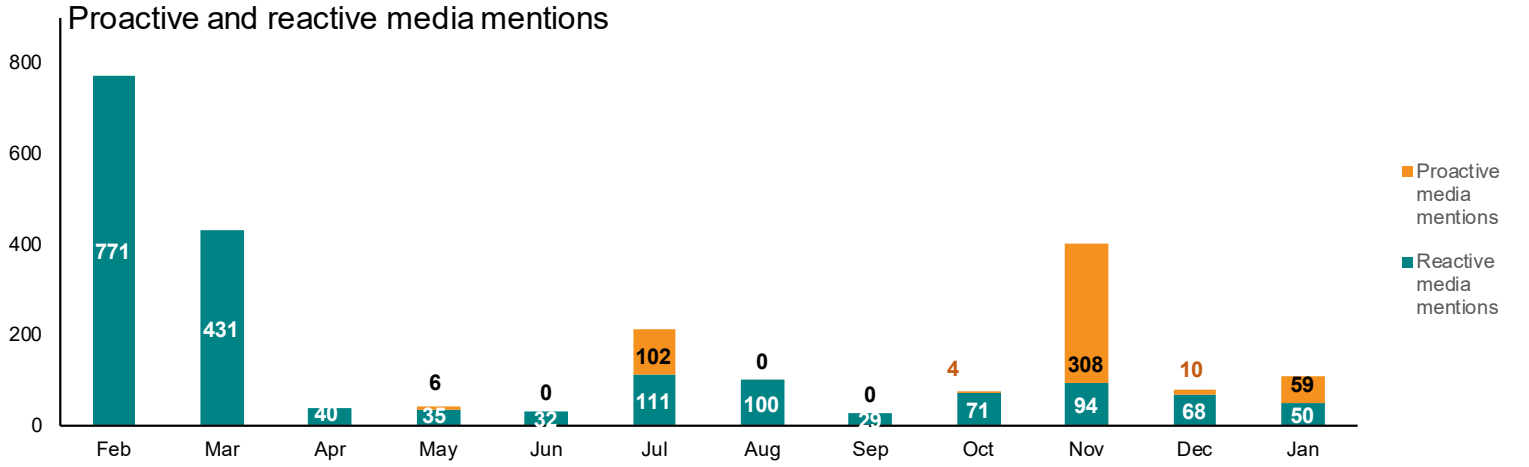
Target: **more than 156 OTRs being sent out**

Total number of OTRs sent out - **134**. OTRs sent out supplementary data: **Donors OTRs - 10; DC identifiable - 5; DC anonymous - 31; Parents - 88.** Many identifiable OTRs still paused while we check the identifiability status with clinics. The average waiting time has decreased in the last 3 months, most notably for D-C and donor applicants.



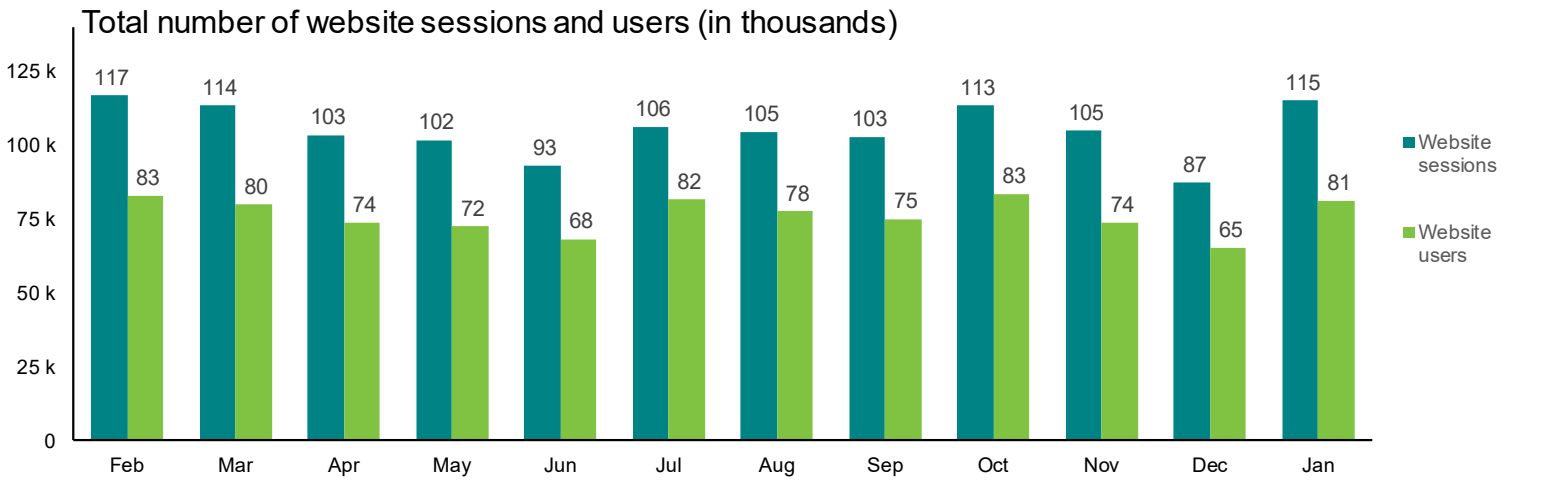
FOI:	Green
PQ:	Green
Intelligence	
FOI and PQ completed	
Targets: **FOI - 20 WD PQ - set by DHSC**	

FOIs were turned around within KPI timescales. FOI topics were related to donation, clinic information, and gene editing.
PQ about HFEA use of AI was turned around within KPI timescales too.



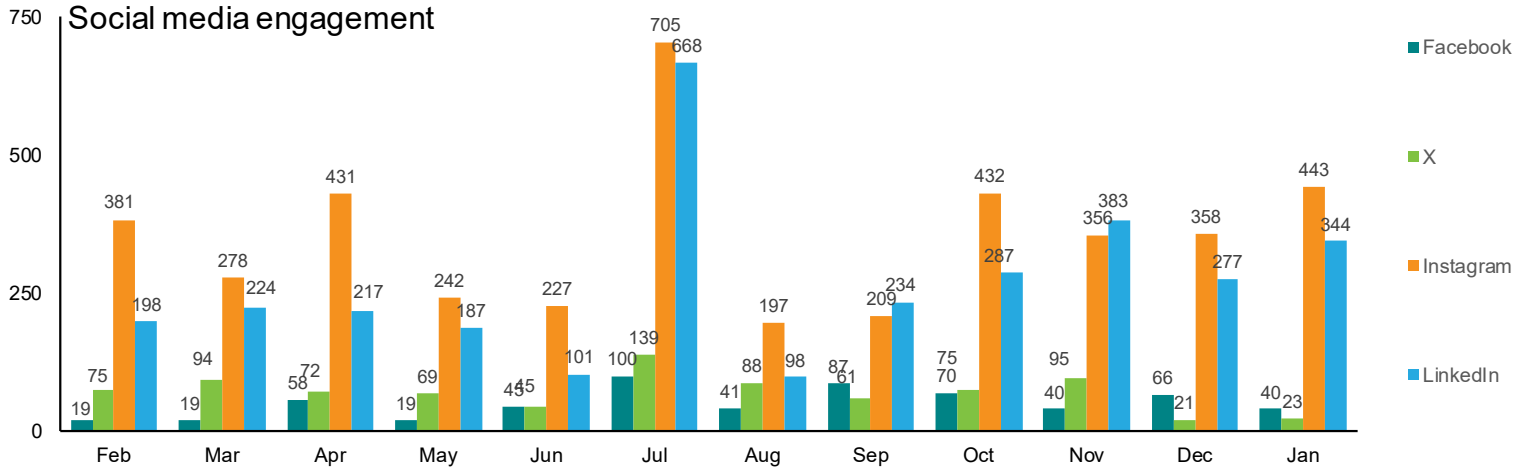
Status:	N/A
Comms	
Total media mentions (proactive and reactive split from April 2024)	
Target: **not defined**	

In January, Authority members discussed in vitro gametes (IVGs) and whether they should be regulated in the future. The Guardian wrote an article about the discussion and this led to a high amount of media coverage. Other topics covered were the Apricity closure, egg donation, fertility, IVF and surrogacy.



Status:	N/A
Comms	
Total number of website sessions and users (Internal traffic excluded from October 2023)	
Target: not defined	

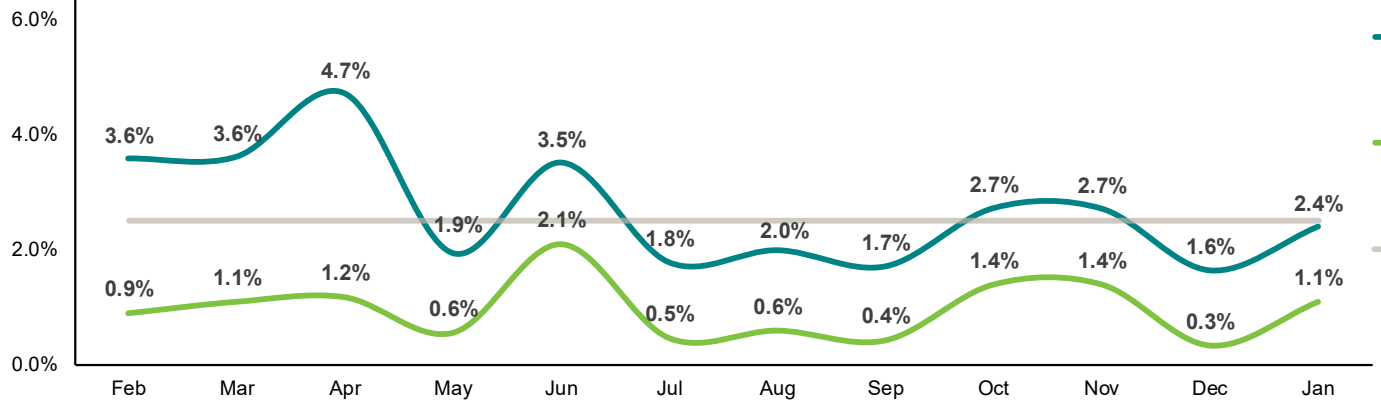
The most popular web pages in January were those focused on choosing a clinic and fertility drugs, most likely as a result of people planning to start treatment in a new year.



Status:	N/A
Comms	
Engagement across social media	
Target: not defined	

January saw high engagement across our channels, with an increase on Instagram, X and LinkedIn and a slight decrease on Facebook. Our post on 'IVF pregnancy and birth rates by age' achieved record engagement on Instagram and LinkedIn, likely related to the Channel 4 documentary Katie Price: Making Babies.

Staff sickness absence rate



Status: **Green**

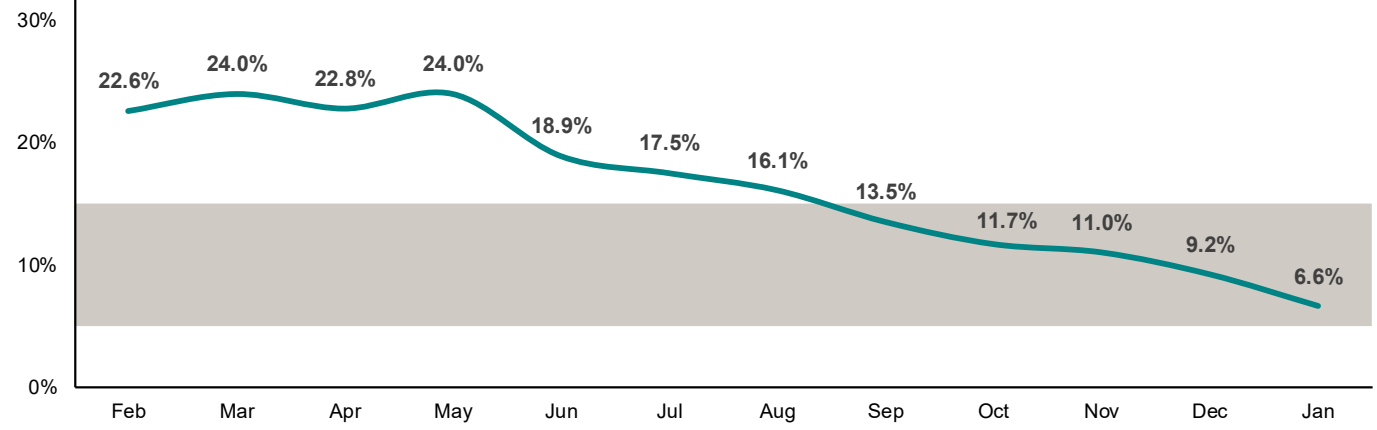
HR

Sickness

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

Sickness absence is slightly higher this month which is expected with seasonal viruses.

Rolling annual turnover vs target range (5-15%)



Status: **Green**

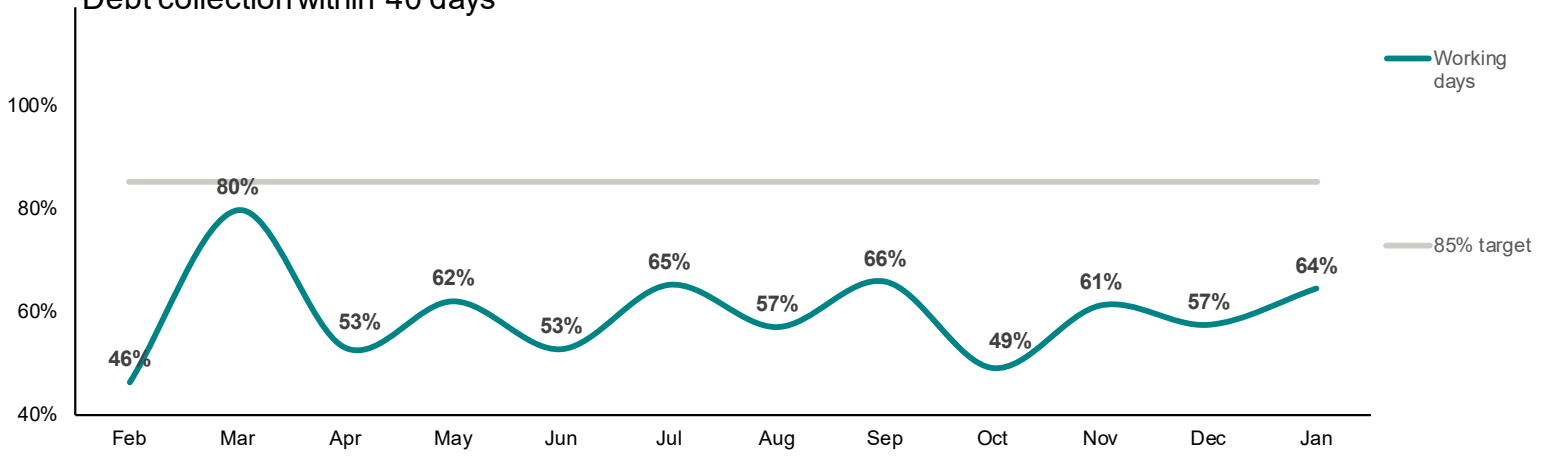
HR

Turnover

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

Turnover remains low for January.
Supplementary HR data: Headcount - 78, Posts - 76, Vacant posts -1, Starters - 0, Leavers - 0.

Debt collection within 40 days



Status: **Red**

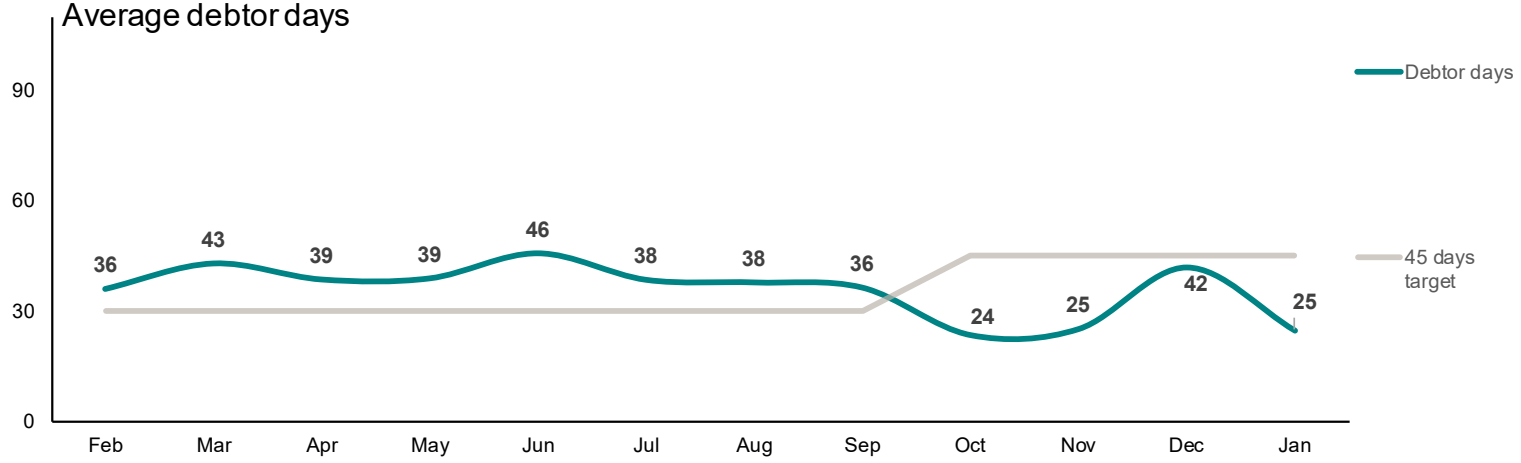
Finance

Debt collection

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

A fantastic push from the Finance Officer has collected a total of 46 payment for invoices totalling £265k that have been long outstanding. This has had a significant impact on our debtors position.

Average debtor days



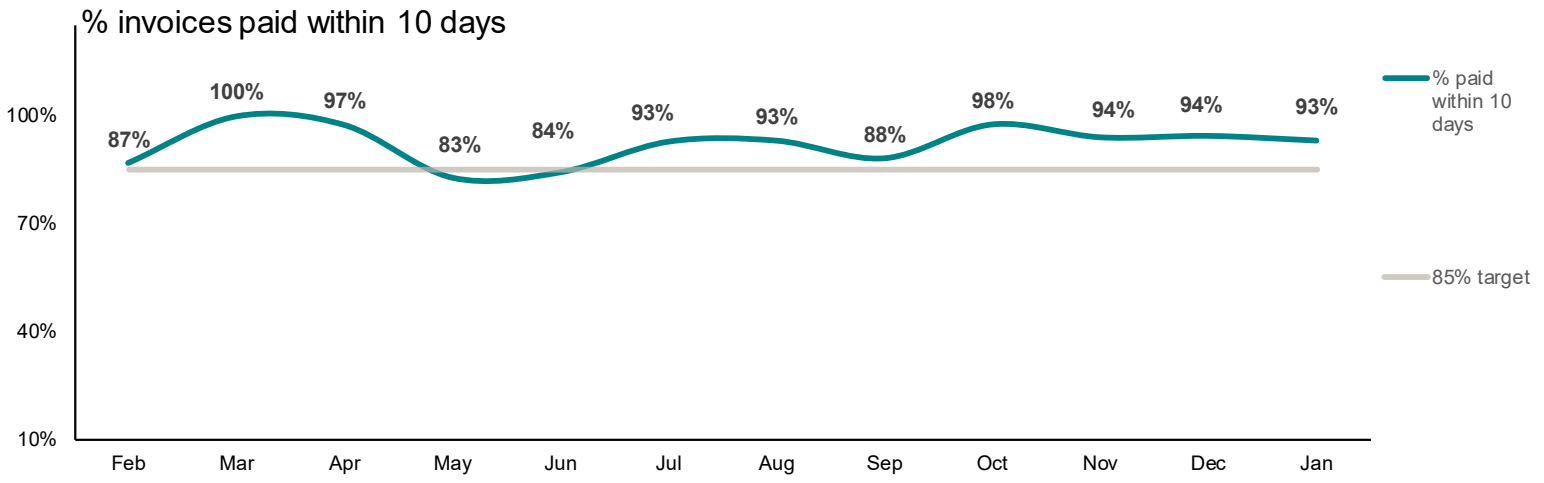
Status: **Green**

Finance

Debtor days

New target
from Oct 2024:
45 days or less

The target has been met.



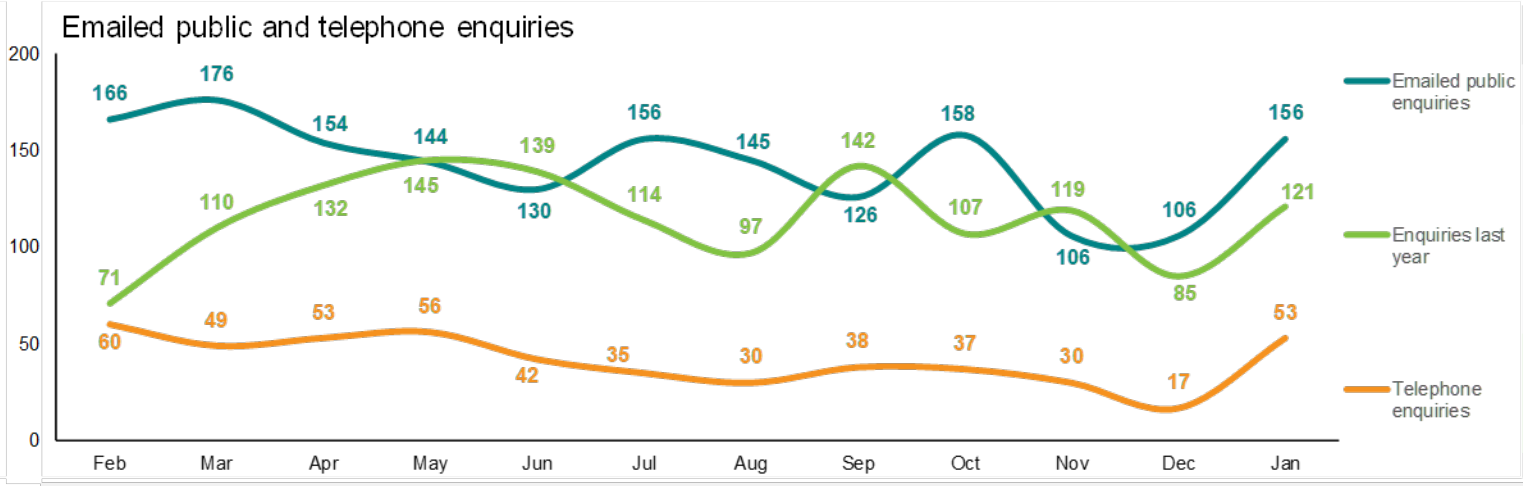
Status: **Green**

Finance

Prompt payment

Target: **85% or more invoices paid within 10 days**

The target has been met.



Status: **N/A**

Policy/Comms

Emailed public and telephone enquiries

Target: **not defined**

While the themes of enquiries in January varied, we continued to receive a number of enquiries about Apricity following their closure in December. Call themes included Beginning treatment (7), Opening The Register (7), Medical queries and concerns (6), Donation (5) and Complaints (4). 51 calls were categorised as Straightforward and 2 calls were categorised as Challenging.

Human Fertilisation & Embryology Authority

Finance Report

Period to January 2025

Tom Skrinar
Director of Finance
12/03/2025

www.hfea.gov.uk

Summary financial position as at 31 January 2025

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Full year Forecast £'000s	Full year Budget £'000s	Variance £'000s
Income	(6,144)	(6,823)	(679)	(7,430)	(8,231)	(801)
Expenditure	5,999	6,167	168	7,514	8,231	717
Total Surplus/(Deficit)	**145**	**656**	**(511)**	**(84)**	**0**	**(84)**

As at Month 10 (January 2025) we are showing a surplus of £145k but against the year-to-date budget we are significantly under (£511k). This is largely due to our Grant in Aid of which only the core funding element has been drawn down. The remainder relating to the Phoenix (Epicentre) project has not been drawn as the project is expected to require this funding in 2025/26. In addition to the reduced GIA, our treatment fee income remains below budget as clinics continue to make corrections and some are creditable. Our expenditure continues to remain under budget as we near year end.

We are forecasting a small overspend which we expect to change once all audit adjustments have been made.

Human Fertilisation & Embryology Authority

2024/25 Income – YTD & Forecast Budget

As of January	YTD Actual	YTD Budget	Variance	Forecast	Full Year Budget	Variance
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Income						
DHSC Funding	503	828	(325)	642	1,078	(436)
Licence Fees	5,450	5,920	(470)	6,579	7,052	(473)
Other income	191	75	116	209	101	108
Total	**6,145**	**6,823**	**(679)**	**7,430**	**8,231**	**(801)**

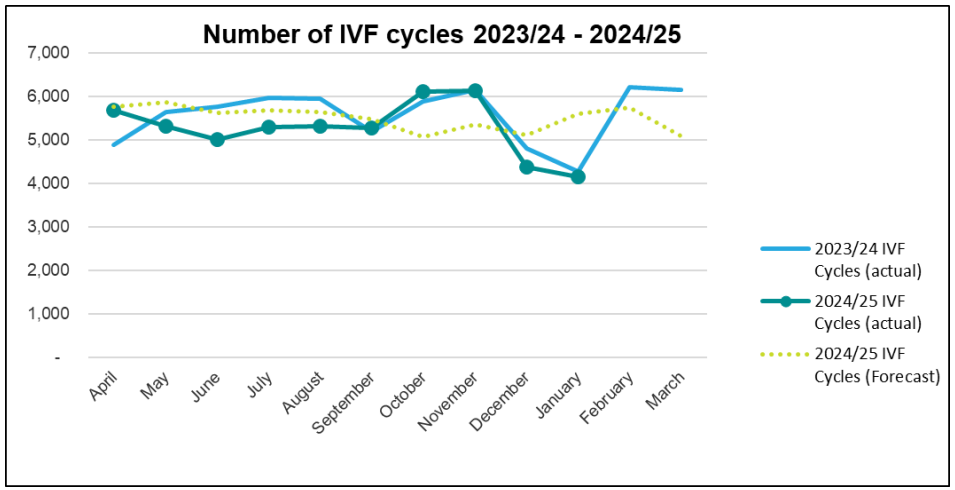
INCOME

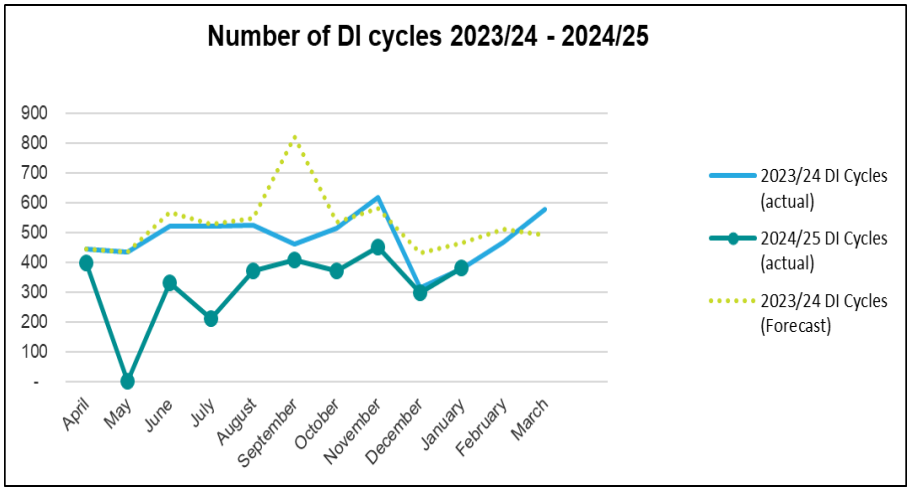
Year to date, our total income is under budget by 10%. The key factors affecting this variance are:

- Grant in aid (GIA) – we have not drawn down our full allocation as timing of the replacement for Epicentre (our licence and inspection management system) has slipped against our original plans, meaning that the bulk of the work will take place in 2025/26, with only 4-6 weeks of work being delivery in 2024/25. Funding from DHSC has been secured in full to cover Epicentre costs in 2025/26.
- IVF/DI activity is impacted by the corrections/adjustments that our clinics make to submissions which result in a credit (refund) and reductions in our income. A significant amount of work is being undertaken to ensure we can assure all refunds and also compile the information required to determine whether a further income provision (year-end adjustment) may by required to our 2025/26 accounts.

Human Fertilisation & Embryology Authority

2024/25 Income - YTD Actual vs Budget





IVF / DI Activity

The above graphs depict the volumes of IVF and DI cycles, comparing activity for the 2023/24 and 2024/25 financial years as of M10 (January). As mentioned previously, refunds of IVF/DI cycles impact activity levels. In some periods, levels are much lower than forecast, where our forecast was based upon pre-PRISM periods.

We are at a point where we have detailed analysis that allows identification of duplicate cycles and value. This work will continue till the end of the financial year where management will need to make a critical judgement as to the value of any provision that may need to be created to ensure our accounts give a true and fair view.

2024/25 Expenditure-YTD Actual vs Budget

As of October	YTD Actual	YTD Budget	Variance	Year Forecast	Year Budget	Variance
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Expenditure						
Salaries/Wages	4,632	4,622	10	5,609	5,552	57
Other Staff costs	202	168	34	227	211	16
Other costs	170	188	(18)	224	246	(22)
Project Costs	0	38	(38)	65	791	(726)
Facilities (estates) costs	332	400	68	513	492	21
IT Costs	438	484	(46)	559	587	(28)
Legal and Professional	225	267	(42)	317	353	(36)
Total	**5,999**	**6,167**	**168**	**7,514**	**8,231**	**718**

Key Variances

Salaries/wages – year to date are under budget by 0.2%, this is mainly on-costs (pension) where the budget assumed all staff are in the pension scheme.

Other Staff costs – are over budget by £34k. These costs are mainly represented by travel and subsistence for inspections, training, recruitment and staff welfare. Inspection Travel costs are £20k below budget and have been consistently under, these are offset by overspends within other areas and in particular Training (£34k) and Staff welfare (£28k). The balance is made up of small over/underspends within administration costs.

Other costs – are £18k below budget. Significant areas of underspend are within Strategy and Corporate Affairs directorate (£34k) which is offset by overspends within Compliance and Information (£25k).

Human Fertilisation & Embryology Authority

2024/25 Expenditure-YTD Actual vs Budget

- **Project costs -** significant underspend due to the Epicentre project kicking off late in February hence the lack of expenditure against budget (£38k).
- **Facilities (estates) costs** – these are the accommodation costs for 2 Redman Place and non-cash costs which are depreciation of our computer equipment. We are underspending by £68k year to date due to the accounting treatment of our rent. By year end there will be a small overspend - a sum equal to unrecoverable VAT assuming no further charges are received from the Department.
- **IT Costs –** are underspent by £46k which is due to reduced spend against support costs £44k (where utilisation of Alscient our supplier of technical consultancy has reduced); offsetting this are our IT Subscriptions costs for Office 365 licences are slightly higher than budget (£15k) and the balance is represented by smaller underspends within telephony, consumables and low value equipment and software.
- **Legal and Professional** – our legal spend year to date is showing an underspend of £42k. This is an area where spend could increase as there is at least one case pending.
- Offsetting this underspend is an overspend on both internal and external audit fees. The fees are increasing as the auditors increase their scope. In particular, the external audit fee increase reflects the work conducted around the duplication of cycles billed. It is expected that the fee for 25/26 be as high as 24/25 if not higher.

2024/25 Income/Expenditure-Forecast vs Budget

- **Forecast outturn** – We are forecasting a small overspend of £84k.
- Components of the underspend are £718k underspend on expenditure before any adjustments such as release of contingencies or provisions. For income, we have agreed with the department that unused Grant in aid will be returned which has been factored into our forecast in addition to a prudent level of Licence fee income for the remaining two months of the year, therefore resulting in the small underspend.

Human Fertilisation & Embryology Authority

HFEA funding overview for 2025/26

Almost 83% of HFEA's funding in 2025/26 to come direct from treatment fees (86% budgeted in 2024/25)

- Fees are driven directly from IVF and DI treatment volumes, with 97% of treatment fee income coming from IVF treatments
- We are not planning to increase fee values in 2025/26

Remaining funding from the following areas:

- Direct Grant in Aid (GIA) from DHSC to fund core activity (£277k) as well as additional funding for the completion of IT projects (£793k).
- In addition, we receive further budget cover against our depreciation & amortisation costs (229k)
- A small amount of additional income relating to bank interest, license applications and research licenses
- If the additional IT funding is excluded, almost 92% if the HFEA's income should come from treatment fees in 2025/26.

Human Fertilisation & Embryology Authority

Income and Expenditure 2025/26 draft budget, compared to 2024/25

	Draft 2025/26	Final 2024/25
	£,000s	**£'000's**
Income		
Licence Fees	7,186	7,052
Interest	150	35
Other	-	66
DHSC Funding	1,299	1,078
Total Income	**8,635**	**8,231**
Expenditure		
Salaries and wages	6,072	5,552
Other Staff costs	290	219
Authority & Committee costs	51	47
ICT	464	649
Legal	220	242
Other Non-staff	332	226
Accommodation costs	249	255
Projects	740	809
Non-cash	229	232
Total Expenditure	**8,647**	**8,231**
Balance	*-12*	*0*

Human Fertilisation & Embryology Authority

2025/26 Financial Plan

Income/Expenditure – plans and assumptions

The 2025/26 baseline budget includes assumptions relating to:

- Income activity (IVF cycles 69k / DI 6.7k)
- Pay increases of 3.5% factored in
- Maintaining a litigation reserve
- Funding for IT project completion
- CPI based inflation in key external contracts and expenditure

With funding secure for IT projects, there is currently no contingency against falls in income during the upcoming financial year. The budget of £8.6m provides sufficient funds to meet planned activity for 2025/26.

The budget will be finalised in detail as we complete business planning.

Human Fertilisation & Embryology Authority

Draft business plan 2025 - 2026

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy 2025-2028: - Regulating a changing environment - Supporting scientific and medical innovation
Meeting:	Authority
Agenda item:	6
Meeting date:	12 March 2025
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	6a Business plan 2025/26 activities section

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to approve the main activities of the business plan for 2025/26, for further development over the next month.
Resource implications:	In budget
Implementation date:	1 April 2025 – 31 March 2026
Communication(s):	HFEA website
Organisational risk:	Low

1. Introduction

1.1. The draft business plan has been developed following the Corporate Management Group (CMG) meeting in September 2024 and the Authority's strategy development work. A further CMG meeting was held at the end of January, to continue the detailed planning process.

1.2. The business plan will be drafted in full in the coming weeks and submitted to the Department of Health and Social Care (DHSC) for approval in April 2025 (on request).

1.3. The sections to be produced during March and early April are:

- standard material about our role, our strategy, and our legislation
- delivery of the current (2024/25) business plan priorities
- financial information and budget
- other information required under business planning guidance

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

2. Planning priorities for 2025/26

2.1. A major programme of work (the Phoenix programme) to replace our inspection and licensing database (Epicentre) and our information storage system with SharePoint has just commenced and this is expected to be completed by Spring/Summer 2026. We will need to manage resource allocation carefully during this process as this will have an operational impact across the HFEA.

2.2. An interim update to the headline statistics on Choose a Fertility Clinic (CaFC) is due to be published in Spring 2025; following this, further work to publish a full CaFC update will commence, with a view to publishing two updates, in Summer 2025 and in Winter 2025/26.

2.3. Support for our key finance system (SAGE) has ended and we will start work on a replacement system, which will better integrate with the other systems we are replacing.

2.4. Following publication of the government's 10-year health plan in spring 2025, we will also assess what work is needed.

2.5. Other priorities in the business plan for 2025/26 include the following:

- further work to progress our proposals for law reform
- a fees review
- work relating to implementing the new European Regulation on standards of quality and safety for substances of human origin intended for human application (the SoHO Regulation) for clinics in Northern Ireland
- an update to the multiple births policy if required following a discussion at the March 2025 Authority
- ongoing monitoring of the OTR service, including capacity, future demand and resources
- potential for ongoing work to review AI use in the fertility sector and related developments

- review of horizon scanning processes and related communications
- using our data to highlight changes in fertility treatment, particularly where inequalities occur.

2.6. Some activities currently listed would be de-prioritised if law reform activity goes forward with the government, notably aspects of the donation related work following earlier discussion with the Authority.

2.7. We have recognised previously that in both our business plan for 2025/26 and our longer-range three-year plan for delivering the strategy, we need to build in the flexibility to deal with the additional work that would be entailed, if and when the government decides to progress on law reform.

2.8. As part of our new three-year strategy, we are also considering the scheduling of work below over the three years:

- AI use within the HFEA (this will mostly be after the SharePoint implementation)
- establish a 'data review board' to review the data collected on add-ons and other areas (for example, reasons for infertility)
- review patient and inspection ratings on Choose a Fertility Clinic
- update the inspection reports to be more lay-friendly
- develop criteria and an HFEA 'trust mark' to help patients identify licensed and regulated sources of treatment.
- a 'single view' for data used within the HFEA
- expand the reach of our data via other online sources

3. Recommendation

3.1. Authority members are asked to approve the draft business plan activities section for 2025/26. Further development of the business plan and confirmation of our budget will follow, and Department colleagues will review the plan prior to publication.

3.2. Authority members are also asked to note the ongoing possibility that we may have to reprioritise some areas of work, in the event of having a confirmed timetable for legislative changes to go through Parliament.

Human Fertilisation & Embryology Authority

Business plan

Activities section

April 2025 to March 2026

Activities for 2025/26

This business plan represents the first year of our 2025-2028 strategy and the activities have been developed with a view to implementing the strategic aims over this three-year period.

We have recognised that in both our business plan for 2025/26 and our longer-range three-year plan for delivering the strategy, we need to build in the flexibility to deal with the additional work that would be entailed, if and when the Government bring forward law reform. The items listed below may not all be possible to deliver if it is necessary to focus significant time on legislative changes.

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

- further work to progress our proposals for law reform
- a fees review
- publishing an interim CaFC by Summer 2025 and a full CaFC in winter 2025/26
- work relating to implementing the new European Regulation on standards of quality and safety for substances of human origin intended for human application (the SoHO Regulation) for clinics in Northern Ireland
- update multiple births policy if required following a discussion at the March 2025 Authority
- ongoing monitoring of the OTR service, including capacity, future demand and resources
- potential for ongoing work to review AI use in the sector and developments following this year's project work
- a review of our horizon scanning processes and external communication of our horizon scanning work and findings
- a major programme of work to replace our inspection and licensing database (Epicentre and the Clinic Portal) and our information storage system (CM)
- commencing work to replace our finance systems (SAGE and WAP)
- working with the new Cyber Assessment Framework (CAF) for cyber security and information governance assurance which replaces the DSPT
- a review of the approved PGT-M conditions list published on our website
- making improvements to the HFEA website to enhance user experience
- donation related work to cover topics discussed with the Authority (capacity dependant based on law reform work)

The activities set out over the next few pages will help us to deliver our strategic objectives in 2025/26.

Regulating a changing environment

Strategic objective 1 To effectively regulate a changing fertility sector	Benefits and outcomes	Timescale
Continuing to perform our regulatory duties to a high standard, publishing outcomes, and making improvements where we can, using learnings from reviews of other regulators as relevant.	Conduct our regulatory work with fertility centres in an effective, efficient, consistent and transparent manner, publishing outcomes on our website and reducing the regulatory burden where possible. Provide assurance for patients that the UK fertility sector is well regulated, and provides high quality care, regardless of the choice of clinic. Implementation work for the new SoHO regs (Substances of Human Origin) that will affect the NI clinics. Draw learnings from reviews of other regulators as relevant.	Throughout the year
Fees review.	Undertake a full review of our fee structure, to ensure the cost of the HFEA's regulatory activities continues to be effectively and fairly shared across the sector we regulate.	Review in 2025/26, with implementation in year two or three

Regulating a changing environment

Strategic objective 2 To continue to increase the availability and benefit of our data for patients, clinics and researchers.	Benefits and outcomes	Timescale
Choose a Fertility Clinic data updated.	We will publish an interim CaFC with some data and this will be followed by a fully updated CaFC in winter 2025/26.	Summer 2025 to Winter 2025/26
The HFEA website.	Make improvements to the HFEA website to enhance user experience.	Capacity dependant for Spring 2025 to Winter 2025/26

Regulating a changing environment

Strategic objective 3 To ensure that the HFEA responds well to issues related to donation.	Benefits and outcomes	Timescale
Continue to develop and monitor our systems to streamline and improve the efficiency of the OTR process.	We will continue our ongoing monitoring of the OTR service, including capacity, future demand and resources.	Throughout the year
Produce effective communications and clear policy responses on donation issues when these are required.	We will carry out donation related work to cover topics discussed with the Authority.	Capacity dependant throughout the year
	We will review and make changes where necessary to patient information about the implications of using imported donor gametes and exporting donor gametes overseas with regards to the 10-family limit.	Capacity dependant throughout the year

Regulating a changing environment

Strategic objective 4 **To make a difference on issues that matter to patients.**	**Benefits and outcomes**	**Timescale**
Update our policy on multiple births.	Implement changes to the multiple births policy following the March 2025 Authority discussion, if required.	Throughout the year
Update the list of PGT-M conditions.	A review of the approved PGT-M conditions list published on our website to ensure all conditions on the list still qualify for the testing and that terminology is correct.	Capacity dependant for Spring 2025 to Winter 2025/26
Continue to highlight issues relating to inequality of access to fertility treatment and use our data and publications to provide evidence.	Following the publication of reports highlighting inequalities in access to and outcomes from fertility treatment based on ethnicity and family type, we will continue to highlight inequalities within the fertility sector and work with others in reducing these inequalities.	Throughout the year
Work collaboratively with stakeholders and other parts of the healthcare system with a shared interest, for example in relation to inequalities or legislative reforms.	We will continue to call for law reform as a priority area.	Throughout the year

Supporting scientific and medical innovation

Strategic objective 5 To ensure the safe regulation of emerging new science and technology under a clear ethical framework.	Benefits and outcomes	Timescale
Lead policy formation and the development of regulatory criteria in response to new treatment advances and scientific developments.	We will review our horizon scanning processes and external communication of our horizon scanning work and findings.	Throughout the year
	Respond to emerging areas as and when they arise.	Throughout the year

Supporting scientific and medical innovation

Strategic objective 6 To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA.	Benefits and outcomes	Timescale
Through our IT development activities explore the use of AI and automation to streamline certain administrative tasks.	A major programme of work to replace and update our core systems (our inspection and licensing database and our information storage system) has commenced.	Throughout the year
	We will be replacing and updating our finance systems to identify options for automation, increase efficiency and to integrate with our updated core systems.	Starting towards the end of 2025/26, depending on core system replacement

Supporting scientific and medical innovation

Strategic objective 7 To inform and advise Government in relation to new developments and their regulation.	Benefits and outcomes	Timescale
Speak up for patients, using our expertise and our voice to inform and advise policymakers and legislators in relation to new bioscience developments and their regulation.	Ad hoc work in response to developments.	Throughout the year
Work to ensure that changes to the Act are made in such a way as to build in some degree of 'futureproofing', so that future, as yet unknown, developments can be regulated effectively without requiring changes to the law on each occasion.	This work will be subject to parliamentary time being scheduled for the Act.	Dependent on parliamentary time

Effective governance

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
Agenda item:	7
Meeting date:	12 March 2025
Author:	Alison Margrave, Board Governance Manager
Annexes	

Output from this paper

For information or decision?	For decision
Recommendation:	Agree the proposed changes to Standing Orders, effective 1 April 2025 (vote required). Note the annual reviews of committee effectiveness and the action points for each committee.
Resource implications:	In budget
Implementation date:	1 April 2025
Communication(s):	The Standing Orders are published on our website and on the staff intranet (Hub). They are also included in the standard licensing pack, which will be updated.
Organisational risk:	Low

1. Introduction

1.1. As a public body, the HFEA is committed to adopting best practice in corporate governance and adhering to Government functional standard GovS 001.

1.2. The HFEA has a number of committees established under the Standing Orders and which are made in accordance with the powers of the HFE Act.

1.3. High-quality decision-making processes are essential to maintain the integrity of the HFEA as a regulator and licensing body and trust in the conduct of operational activities as it applies to everyone affected by fertility treatment including licensed centres, patients and the wider public.

1.4. This paper is intended to provide assurance over the structures established by the Authority, effectiveness of committees, decisions taken, and that activities of the HFEA are aligned with its statutory duties, responsibilities and objectives.

1.5. The reports published in 2024 on regulators CQC (interim and full) and Ofsted and the ongoing Review of patient safety across the health and care landscape provide a reminder of the importance of all regulatory bodies ensuring that their decision making processes are aligned with their statutory duties, responsibilities and objectives.

1.6. This review also provides members with updates and recommendations related to the governance of the Authority. The HFEA is committed to an annual review of its governance arrangements consisting of a review of each committee's effectiveness and of the Standing Orders.

1.7. In accordance with the Standing Orders, Authority members received notification and motion regarding the intention to amend the Standing Orders at the March Authority Meeting.

2. Annual review of committee effectiveness

2.1. On an annual basis all committees are required to review their own effectiveness using a standard template. Between September 2024 and March 2025 this exercise was conducted by the Licence Committee, Executive Licensing Panel, Statutory Approvals Committee, the Scientific and Clinical Advances Advisory Committee and the Register Research Panel.

2.2. The Audit and Governance Committee used the specific effectiveness tool for Audit Committees produced by the National Audit Office (NAO) and carried out a 360 review whereby feedback was received not just from committee members, but also the Senior Management Team and the Internal and External Auditors.

2.3. The Corporate Management Group (CMG) and Project Assurance Group (PAG) also completed committee effectiveness reviews but, as they are operational groups, they are not included in this report to the Authority.

2.4. All Authority members sit on at least one committee which means that they all participated in the review of their respective committee(s).

2.5. Given that the HFEA team services over 50 meetings a year it is reassuring that all committees stated that the meetings and papers were well prepared and that they had sufficient information necessary to take decisions.

2.6. Generally, the feedback from committees has been positive. There are a number of recommendations for improvement and the table below summarises the feedback from each committee and possible actions which the committee/staff could take.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or staff)
Audit and Governance Committee (AGC)	Committee requested greater awareness of the implementation of external audit recommendations and performance of the external auditors.	The committee agreed that this should be a topic for their training session in December 2025.
	Committee requested greater clarity as to whether the Chair holds an annual meeting with the Head of Internal Audit.	The Chair holds quarterly meetings with the Head of Internal Audit and regular pre-meets with the responsible Director and Committee Secretary. Chair to give overview of her meetings at the start of each committee meeting.
	Formal conflicts of interest information to be collected annually from external committee members.	For external members we will include an annual update of interests declared whenever we do the annual process each year for Authority members' interests.
	To consider whether there are any gaps in expertise.	Committee skills audit to be conducted. The Chair will then consider whether there is a need to fill the second external member position.
	Awareness of topical legal and regulatory issues.	Staff to seek an appropriate regular update that covers these topics. The committee to consider any particular topical issues that arise for future training sessions.
	Committee members to have greater oversight of the work of the Authority.	Invite AGC members to observe an Authority meeting.
Licence Committee (LC)	Enhanced contextual information in inspection reports about the reasoning behind recommendations.	Implemented in January 2025.
	Increased understanding of the inspection approach for members.	Training conducted by the Chief Inspector in January 2025. For members who have not worked in a clinic, a clinic visit (ideally an inspection) will be arranged.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or staff)
	Observer feedback should be sought in order to identify any useful learning.	This has been implemented (November 2024 onwards). A standard set of questions is now sent to observers after each meeting.
	The Chairs and Deputy Chairs of Licence Committee and the Executive Licensing Panel should hold a regular annual meeting.	Annual meeting to be arranged as agreed.
Executive Licensing Panel (ELP)	Annual meeting with the Chair and Deputy Chair of Licence Committee.	Annual meeting to be arranged as agreed.
	Follow up on clinic visits/inspection visits for those who have not had them yet.	Chair to follow up with Compliance team.
	Discussion held on communication of post-decision actions and reassuring ELP that actions had been undertaken.	Understanding that this was a role for Compliance unless actions are not taken and are escalated back to ELP or LC. However, for any particular concerns relating to specific decisions, ELP can ask for an update to come back to a future meeting.
	ELP members would find it helpful when there are any substantive changes to how inspection is carried out or to inspection reports, for that to be explained to members.	To be carried out as and when this happens.
Statutory Approvals Committee (SAC)	Some areas of the standing orders are unfamiliar to the committee, such as the fact that in the event of a tie, the SAC Chair has the casting vote.	Licensing Manager to send committee members the standing orders and highlight pertinent areas relevant to SAC.
	Feedback from observers would be helpful and internal observers are welcomed.	Licensing team to contact other HFEA members and staff about the possibility of observing SAC meeting. Licensing team to start requesting feedback from observers.
	It may be possible/more desirable to hold meetings on a set day of the week.	Licensing team to explore options when the 2026 committee calendar is created.
	Check if any response has been received from a centre to whom feedback has recently been provided.	Licensing team to liaise with the Inspectorate.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or staff)
Scientific and Clinical Advances Advisory Committee (SCAAC)	Inform members of the delegation of responsibilities to subsets of the Committee, for example the add-ons review panel.	Policy staff can circulate details of panel compositions, functions and outputs as and when utilised.
	Provide updates on actions taken by the Authority (board) in relation to recommendations given by the SCAAC.	Updates will continue to be brought to SCAAC meetings. Members can sign up for **Clinic Focus** or observe meetings for interim updates on Authority discussions.
	Inform members of the roles of the Executive attending SCAAC meetings.	Introductions will be made at the beginning of each SCAAC meeting.
	Address conflicts of interest (COIs) ahead of the meetings.	Policy staff will regularly clarify what constitutes a COI with members and the appropriate level of detail, giving examples relevant to the upcoming meeting agendas (eg declaring add-ons offered in affiliated centres). Updated affiliations and COI will also be requested on an annual basis.
	Distribute papers slightly further in advance of the meetings.	Policy staff will aim to circulate meeting papers at least two weekends in advance of the meeting to allow members more time to review research.
	Utilise the expertise members for specific feedback or detailed recommendations.	Staff may approach members in advance of upcoming meetings for their feedback on a specific development or topic paper.
	Consider varying the length and structure of SCAAC meetings to possibly spread the workload more evenly across the year.	Due to the capacity of the team, it will not be possible to hold an additional meeting of the SCAAC. Where required, additional meetings may be scheduled ad hoc. The number of topic discussions scheduled for 2025/26 will be limited to two to three per meeting, allowing time for longer, more detailed discussions.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or staff)
Register Research Panel (RRP)	Queries about meeting the quorum with the maternity leave upcoming of one Panel member and apologies in inspectorate members more common due to clashes with inspections.	Ongoing discussion with compliance to see if additional inspector(s) are able to join the Panel.
	Queries about internal legal advisor and the role of the legal team in RRP meetings	To query with Legal about whether the HFEA legal advisor should observe and/or feature as part of the Panel or Executive
	Queries about the usability of the decision tree and its adherence to HFEA format	Decision tree to be updated. Refer to LC/SAC/ELP decision trees and software
	Query about consistency of decision making	Look into the possibility of a 'library of precedents/decisions'.
	Query about staying up to date with new research publications from both RRP projects and anonymised register projects	Add a new item to the template agenda to prompt discussion of new publications.
	Query about usability of the existing data specification sheet	Continue work on the data specification sheet to make this more accessible for researchers as well as Panel members.
Remuneration committee	Formal review not undertaken due to infrequency of meetings.	-

3. Review of the Standing Orders

3.1. A review of the Standing Orders has been undertaken, including any recommendations arising from the results of the committee effectiveness review. The proposed changes to the Standing Orders are shown below, if members would like to see a full tracked changes copy of the Standing Orders, they may request this from the Board Governance Manager.

3.2. It is proposed to amend article 2.6 d) of Annex A (page 31) of the Standing Orders, the proposed amendment is shown below (colour legend used: yellow highlight is text to be deleted and green highlight is text to be added):

2.6 d) up to two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise, if required.

3.3. The reason for this proposed change is to clarify that the Audit and Governance Committee does not have to fill both these places. This will depend on the committee's needs at any given time, taking a view on any skills gaps that are identified.

3.4. It is also proposed to amend article 2 of Annex B (page 43) of the Standing Orders. The proposed amendment is shown below (colour legend used: yellow highlight is text to be deleted and green highlight is text to be added):

> Authorisation to undertake ~~HLA tissue typing~~ pre-implantation tissue typing (PTT) for genetic conditions previously authorised by the Authority

3.5. The reason for this proposed change is to update our terminology in the Standing Orders, to match earlier updates to the relevant decision tree and other documentation.

3.6. As detailed in Article 3.1 of the Standing Orders any proposed changes to the Standing Orders require a majority vote by the Authority.

3.7. The Authority is asked to review and approve these proposed minor change(s) to the Standing Orders as set out above. If approved the new Standing Orders would come into effect on 1 April 2025.

4. Recommendations

4.1. The Authority is asked to:

- Approve, by a majority vote, the revised Standing Orders to come into effect from 1 April 2025.
- Note the feedback from the annual reviews of committee effectiveness and the action points for each committee.

Multiple births target: next steps

Details about this paper

Area(s) of strategy this paper relates to:	The best care
Meeting:	Authority
Meeting date:	12 March 2025
Author:	Annabel Salisbury, Regulatory Policy Manager
Annexes	Annex A: Summary of proposed options Annex B: Proportion of licensed treatment clinics with over 150 IVF cycles by multiple birth rate, 2022

Output from this paper

For information or decision?	For discussion
Recommendation:	To agree next steps in relation to the multiple births policy.
Resource implications:	Depending on Authority decision.
Implementation date:	Pending Authority decision and wider organisational priorities
Communication(s):	Pending Authority decision, further stakeholder engagement, Clinic Focus articles, updates to inspection templates, General Directions and patient information.
Organisational risk:	Low

1. Introduction

1.1. The Authority is asked to discuss a set of options on the next steps for the multiple births policy and agree a way forward. Section 2 sets out the background, Section 3 sets out the policy options, and Section 4 sets out the recommendation.

2. Background

2.1. Multiple births are the single biggest risk of fertility treatment. In the early 1990s the multiple birth rate was around 28%. The HFEA, with professional bodies and patient groups, launched the One at a Time campaign in 2007, and in 2012 set the maximum multiple birth rate at 10%. This target was reached for the first time in 2017 and is still in place. Practices to reduce multiple births – such as elective single embryo transfer – have become common-place in the sector.

2.2. Latest figures (from 2022) show that **the national average multiple birth rate is at 4%** - the lowest it has ever been. At the same time, birth rates have **continued to increase**. Figures show that 92% of clinics with over 150 IVF cycles are below the 10% rate (see Annex B). However, multiple birth rates are highest amongst Black patients (**Ethnic diversity in fertility treatment 2021**). The reduction in multiple births from IVF has been a huge public policy success in relation to the health of mothers and babies and the reduction in costs to the NHS of multiple pregnancies and any follow up health issues.

2.3. The multiple births target set out in **General Direction 0003** and **Code of Practice** guidance states that clinics should not have a multiple birth rate that exceeds the figure listed in the Directions (that is, 10%). Direction 0003 also requires that clinics maintain a multiple births minimisation strategy. Inspectors check whether the clinic is compliant with this requirement. However since the launch of the PRISM data submission system in September 2021, we are unable to report on up-to-date multiple births data in inspection reports. This will be the case until the data submitted since then has been validated.

2.4. The multiple births target was last discussed by Authority at the **September 2021 meeting**, where members agreed:

- to maintain the 10% multiple births target for now and continue to monitor on inspection;
- to encourage clinics to be mindful of their multiple birth minimisation strategy in relation to patients from ethnic groups;
- a report should be published outlining the data presented to the Authority to stimulate further discussion and following that;
- discussions should be opened over time with key stakeholders, patients and clinics, with the aim of considering a future review of the 10% rate;
- that the four clinics that were outliers, should be asked why this was the case.

2.5. As agreed, the data presented to the Authority in 2021 was published in this **Multiple births in fertility treatment report**. Also in this report, we encouraged clinics to be mindful of the higher multiple birth rate among Black patients and to review their multiple births strategy where necessary.

2.6. Whilst the multiple births policy has been a success there continues to be a small number of clinics who consistently exceed the maximum rate (see Annex B). For those centres with

consistently high multiple birth rates, they fed back that it is appropriate to recommend a multiple embryo transfer for patients with a more complex history eg, where they have had a number of unsuccessful cycles elsewhere. Review of patient records indicates that patients at these centres are given suitable information about the risk of multiple pregnancy. However, given that multiple births have decreased across the majority of clinics while success rates have increased, more work would be needed to understand this rationale for high multiple birth rates at these centres. Crucially, we currently lack the necessary enforcement powers to directly address this problem and this will be the case until we have new powers as part of our law reform proposals.

2.7. Since the average national multiple birth rate has fallen well below 10% for a sustained period of time, discussions have been underway to look at whether, and if so how, the target should be changed. We have held discussions with key stakeholder groups to get views on reviewing the target. These options are presented at section 3 below.

3. Proposed options

3.1. In looking at next steps for the multiple birth rate target, several options have been considered which are outlined below.

3.2. We sought stakeholder views on options for the multiple births policy from the Licensed Centres Panel (LCP), the Professional Stakeholder Group (PSG), and the Patient Organisation Stakeholder Group (POSG). A summary of their feedback is set out below and in Annex A. Stakeholders generally agreed that the policy should be changed but had mixed opinions about whether lowering the target figure or changing to an upper limit was the best approach. Some also questioned whether any change to policy within the current legal framework would bring about the intended effect.

Option 1: BAU

3.3. This option would keep the existing maximum multiple birth rate at 10% until we have new enforcement powers following law reform.

3.4. Most stakeholders disagreed with maintaining the status quo and said that the policy should change as the average national multiple birth rate is well below the 10% rate. However, some stakeholders questioned whether change would be effective given the limitations of our current enforcement powers. This option responds to that concern because we would review the policy again in light of any new enforcement powers brought about by law reform.

3.5. While most stakeholders supported change, it is worth considering whether the resource implications of changing the policy now are justified given that we may need to dedicate further resources to this again should the Act be amended in future. Our law reform proposals include that the Act should be amended to include an over-arching focus on patient protection. The HFEA has no interest in intervening in the relationship between doctor and patient however patients expect us to act where they feel they are at risk. As already set out, multiple births are the single biggest risk of fertility treatment and the HFEA currently has no regulatory powers to act in this area in the interests of patients. Therefore it is possible that any future changes to the Act would enable us to act where clinics have a higher multiple birth rate.

3.6. Leaving the rate at 10% would have no resource implication and mean there is no risk work is repeated should there be future law reform.

Option 2: Leave the rate at 10% and change how multiple birth rates are reported

This option would keep the existing maximum multiple birth rate at 10% but change how a clinic's multiple birth rate is reported. As noted above, we are currently unable to report on a clinic's multiple pregnancy rate until the data submitted since the switchover to PRISM has been validated. Before the launch of PRISM we reported each clinic's multiple birth rate and whether or not they were likely to meet the 10% target rate. One way to shift focus more towards clinics with a high multiple birth rate could be to only reference multiple birth rate in inspection reports by exception – where a clinic has exceeded the target. This would draw attention to those small number of clinics that have a higher than 10% multiple birth rate. This will be possible once the post 2021 data has been validated (on present plans by the end of 2025).

3.7. Maintaining the 'target' policy was a generally popular option with stakeholders who felt that it is well-understood in the sector and the messaging is clear. However, most stakeholders also agreed that the policy should change as the average national multiple birth rate is well below the 10% rate and did not agree with maintaining the status quo. Although this option involves maintaining the target, changing the inspection approach to one of reporting by exception would shift the focus onto those clinics that are above the 10% target while reducing the reporting requirement and oversight for the majority of clinics that are below the target.

3.8. Leaving the rate at 10% would have no resource implication but the change in reporting would require modest resource to update inspection templates and processes.

Option 3: Lower the target rate

3.9. This option would maintain the current policy position but change the maximum rate from 10% to a lower number. This was popular among some stakeholders because of the clear message this would send and because the existing policy is well understood. Lowering the target would reflect that the national average has fallen and could encourage clinics to reduce their multiple birth rate even further. Whilst lowering the target was popular, some stakeholders questioned whether this is the right time for change given the possibility of law reform (see the Recommendation section at 4.1 below).

3.10. If Members agreed to lower the target rate, further work would be needed to recommend a suitable target that would reduce multiple births without risking a decrease in success rates. For example, one approach could be to incrementally lower the target over a number of years or lower the target for specific cohort(s) eg, under 38s on their first cycle. This would include stakeholder engagement and an Equality Impact Assessment (EIA) to ensure there are no unintended consequences for any groups of patients. Under this option, it would be possible to either continue with the current reporting method or to only report by exception (as in option 2).

3.11. This option would require some resources to consider the impact of a different lower target and the consequential implementation of that across our guidance, General Directions and inspection templates and processes and patient information.

Option 4: Change the target to an upper limit

3.12. This option would see a change in terminology, moving away from a 'target' to an 'upper limit' with the aim to shift the focus to those clinics exceeding the maximum rate. Some stakeholders questioned whether we had the tools to enforce an upper limit and worried that an upper limit might be seen as something to aim for, rather than a limit.

3.13. However, this was a generally popular option, with stakeholders generally agreeing that an upper limit could shift the focus to clinics with a high multiple birth rate and reduce the

regulatory burden for other clinics with a low multiple birth rate. Some thought that a 'target' is no longer meaningful and that, if the Act were updated in line with our law reform proposals on patient safety, an upper limit could more straightforwardly convert into a figure that clinics would be required to comply with.

3.14. Further work would be needed to establish whether 10% or another lower figure would be a suitable upper limit to continue to reduce multiple births without risking a decrease in success rates. This would be brought to a future Authority meeting for decision. Work may include an EIA and stakeholder engagement.

3.15. Resource would be needed to establish a figure for the upper limit. Guidance, General Directions, inspection templates and processes and patient information would also need to be amended. Given the change from a target to an upper limit, this would likely require more resource compared to only lowering the target rate.

4. Recommendation

4.1. The multiple birth rate policy has been an outstanding success. Stakeholder feedback demonstrates that the sector is ready for change and there is a risk that if we continue with a target rate that most clinics are already well below, we could undermine that success. However there is a discussion to be had about whether this is the right time to change the policy in the light of our limited enforcement powers in this area and the possibility of law reform. Even if members think change is appropriate, the timing of its implementation could be delayed until we know more about if and when law reform might happen.

4.2. Members are asked to discuss and agree which of the options to take forward in that context.

Annex A: Summary of proposed options

Option 1: BAU

Pros	Cons	Resource implications
• A maximum multiple births rate at 10% is a well-established policy that clinics understand • If the policy is reviewed once we know more about the future of law reform, the policy could be more effectively future proofed	• 'Target' language suggests clinics should be aiming at this figure, and is no longer useful now that the national multiple birth rate has fallen below this rate • Target far above actual national multiple birth rate is confusing for patients and clinics, and doesn't represent the reality of the sector where practices to reduce multiple births are widely adopted • Although the messaging is well understood in the sector, there is an implication that clinics should aim at the target which is not the intended outcome, especially for clinics with a multiple birth rate well below 10% • Without a timeframe for the Act to be amended or a guarantee that any changes would include new enforcement powers in relation to multiple births, it may be some time before the policy is reviewed • May be unpopular with stakeholders, who in general felt that the time is right for change	• No resource implication and means there is no risk work is repeated if and when there is future law reform

Option 2: Leave the rate at 10% and change how multiple birth rates are reported

Pros	Cons	Resource implications
• A maximum multiple births rate at 10% is a well-	• 'Target' language suggests clinics should be aiming at	• No resource implication to leave the rate at 10%

established policy that clinics understand • Stakeholder feedback indicates that the 'target' language is well understood by the sector and the messaging is clear • Changing reporting could encourage centres to reduce their multiple birth rate even further and would shift focus to centres with a high multiple birth rate	this figure, and is no longer useful now that the national multiple birth rate has fallen below this rate • Target far above actual national multiple birth rate is confusing for patients and clinics, and doesn't represent the reality of the sector where practices to reduce multiple births are widely adopted • Although the messaging is well understood in the sector, there is an implication that clinics should aim at the target which is not the intended outcome, especially for clinics with a multiple birth rate well below 10% • May be unpopular with stakeholders, who in general felt that the time is right for change	• Change in reporting would require modest resources to inspection processes eg, report templates and the inspection notebook

Option 3: Lower the target rate

Pros	Cons	Resource implications
• A multiple births target is a well-established policy that clinics understand • Reflects that national average has fallen • Could encourage centres to reduce their multiple birth rate even further • Some stakeholder support for this option given the 'target' language is well understood by the sector and the messaging is clear • Option to incrementally reduce the rate over a number of years would give the sector time to adjust	• Risk that lowering rate will not effectively target centres with a high multiple birth rate • Although the messaging is well understood in the sector, there is an implication that clinics should aim at the target which is not the intended outcome • A further reduction in multiple birth rate could start affecting success rates (although no current data to support this) • Possible that now is not the right time to lower the target in light of potential law reform eg, guidance may need to be updated again in the future if the Act is amended	• Resource will be needed to find a suitable lower figure eg, to engage with stakeholders, analyse data and complete EIA • Some resource needed to update terminology in guidance, General Directions, inspection templates and processes and patient information

Option 4: Change the target to an upper limit

Pros	Cons	Resource implications
• Using 'target' language no longer relevant now that most clinics are compliant and the national average multiple birth rate is significantly below the target • Would shift focus to centres with a high multiple birth rate, reducing regulatory burden for other centres • Reflects that practices to reduce multiple births are widely adopted • Some stakeholder support for this option on the basis that 'target' language is no longer relevant and due to the change of focus	• A 'limit' might be less flexible and harder to apply in practice • Unclear what regulatory action the HFEA could take against centres breaching a limit • Some stakeholder confusion around messaging eg, concern that clinics might aim at the upper limit • Possible that now is not the right time to lower the target in light of potential law reform eg, guidance may need to be updated again in the future if the Act is amended	• Resource will be needed to find a suitable upper limit eg, to engage with stakeholders, analyse data and complete EIA • Resource needed to update terminology in guidance, General Directions, inspection templates and processes and patient information

Annex B: Proportion of licensed treatment clinics with over 150 IVF cycles by multiple birth rate, 2022

92% of clinics below 10% target

Multiple birth rate	Proportion of clinics	Number of clinics
≤2%	21%	17
2.1-4%	31%	25
4.1-6%	16%	13
6.1-8%	15%	12
8.1-10%	9%	7
10-15%	8%	6
>15%	0%	0
All clinics >150 cycles	100%	80

Note: This data includes all UK licensed clinics at which more than 150 IVF treatment cycles took place. Data provided is from a live register and may not match data provided in previous requests or published elsewhere. One treatment centre has been excluded due to data quality issues. Data is preliminary and has not undergone validation yet. Data is thought to be missing from a small number of clinics, including three with a multiple birth rate >20% in the last validated year. Multiple births presented as above 10% target may be consistent with national average and may not relate to a non-compliance.

Update on actions responding to 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:	9
Meeting date:	12 March 2025
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs
Annexes	Annex 1: Recommendations and status of actions

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority are asked to note the actions taken in response to the 2023 Public Body Review
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 under the previous government 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.

1.5. In **January 2024**, the Authority discussed the recommendations from the review and the proposed actions in response. The **Authority agreed responses** to the recommendations from the review, which have been discussed at the quarterly accountability meetings with our Department of Health and Social Care (DHSC) sponsor team.

1.6. This paper sets out an update to the actions agreed in January 2024 and proposes to fold further updates into existing reporting structures such as Authority or Audit and Governance Committee meetings on an issue arising basis.

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 actions agreed in Annex 1 are set out and have been updated as of February 2025.

3.2. The PBR has been a standing item on the HFEA quarterly accountability meeting with our sponsor team at DHSC until January 2025 when it was agreed that this was no longer needed.

3.3. We remain ready to respond to any further information requests from the DHSC or Cabinet Office in relation to actions take in response to this review.

4. For decision

4.1. The Authority is asked to discuss the update to Public Bodies Review recommendations set out in Annex 1 and agree to close future reviews from this meeting.

Annex A – Public Body Review 2023 – Recommendations and HFEA response – as of February 2025

	Recommendation	Response	Timing	February 2025 update
		Efficacy		
1	HFEA should remain an executive non-departmental public body.	N/A	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.	• The HFEA has joined the Health and Social Care regulators forum that meets quarterly. • The HFEA has regular bilateral updates with other health regulators including the HRA, HTA, CQC and MHRA. • Specific discussions on areas such as dashboards and law reform have taken place and continue to do so with non-health regulators. • Presented and participated in international discussion on AI and fertility September 2024 • Presented and participated in a conference on invitro derived gametes • Participated in the NCOB review of Stem Cell-Based Embryo Models • Carried out an internal review to reflect on recommendations made following CQC and OFSTED reviews, which was discussed with the Authority, shared with DHSC sponsor team and summarised to the sector in January 2025 via **Clinic Focus**.
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	• This was implemented see https://emails.hfeaclinicfocus.co.uk/d0ed87d0/178

	Recommendation	Response	Timing	February 2025 update
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. • Began with Authority in July 2024 **https://www.hfea.gov.uk/media/s13gcqxn/2024-07-03-authority-papers.pdf** • Set to continue during 2025-26
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.	• Considered at periodic meetings of ALB Chief Executives with DHSC
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 completion of related PRISM tools (OTR and CaFC).	To review in 2025/26	• Ongoing reporting of PRISM/OTR/CaFC to AGC. Publication of updated CaFC Spring (interim) and Autumn (full) 2025. Will discuss how this review can be carried out once the data in CaFC is fully updated.
		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.	N/A
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	Starting in 2024/25 and likely to continue 2025/26 and 2026/27 as resources allow.	• External dashboard using Register extracted data published Dec 2023 and regularly updated https://www.hfea.gov.uk/about-us/hfea-dashboard/ • Internal inspection focused dashboard in development to be delivered during 2025.

	Recommendation	Response	Timing	February 2025 update
		plans to replace our Inspection and licensing tools subject to DHSC and Treasury approval.		
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.	• No further development pending any future legislative reform. • Regular Code edits have taken place following policy and legislative changes in the last year which can be seen here https://portal.hfea.gov.uk/knowledge-base/read-the-code-of-practice/.
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.	• Ongoing as part of discussions on law reform with DHSC.
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	Following the completion of PRISM, so likely not able to start planning until 2025/26 business year.	• Planned to be discussed with SCAAC following completion of PRISM and given SCAAC priorities, likely to begin in 2026/27.

	Recommendation	Response	Timing	February 2025 update
		professional bodies and SCAAC about this.		
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.	• The Authority have made recommendations in this area as part of their discussions on law reform. Further advice submitted to the Minister in February 2025 on 14 day rule on embryo research, Stem-Cell Based Embryo Models and Invitro Derived Gametes. • **Authority meeting papers - 20th November 2024** • **Minutes of Authority meeting held on 20th November 2024** • **Authority meeting papers - 22nd January 2025**
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.	The HFEA has a digital programme starting to replace outdated technology and better support carrying out our statutory functions.
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.	No further update
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.	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 is not applicable to the majority of treatment cycles. We have also instigated regular meetings with the relevant NHSE staff.	Ongoing to be determined priorities for 2024/25 and 2025/26.	The HFEA and NHSE have quarterly meetings to discuss fertility and wider women's health priorities.
		Legal framework		

	Recommendation	Response	Timing	February 2025 update
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.	This is subject to ongoing discussion with DHSC.
	Accountability			
17	The sponsor team should seek to ensure that annual ministerial accountability meetings are reinstated from 2024.	The Sponsor team has approached the minister in regard to chairing the HFEA annual accountability meeting and has declined. Will reapproach in 2025.	N/A	Ministerial introduction meeting held in July 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	The sponsorship team has recruited a new SEO, discussions are being held in within the branch to loop other team members into the sponsorship arrangements.	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	To be discussed with ALB Oversight team.	N/A	N/A