Authority meeting

Date: 20 May 2026 – 12.45pm – 3.20pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of previous meeting and matters arising (15) Amendments to the Standing Orders For decision	12.50pm
3. Chair and Chief Executive's report (10) For information	1.05pm
4. Committee Chairs' reports (20) For information	1.15pm
5. Annual Performance Report (30) For information	1.35pm
Comfort break (10)	2.05pm
6. Embryo Testing (60) For decision	2.15pm
7. Any other business (verbal) (5)	3.15pm
8. Close	

Minutes of Authority meeting held 11 March 2026

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment / Supporting scientific and medical innovation
Meeting:	Authority
Agenda item:	2
Meeting date:	20 May 2026
Author:	Alison Margrave, Board Governance Manager
Annex	11 March 2026 Authority Minutes

Output from this paper

For information or decision?	For decision
Recommendation:	Members are asked to confirm the minutes of the Authority meeting held on 11 March 2026 as a true record of the meeting.
Resource implications:	n/a
Implementation date:	n/a
Communication(s):	Final signed minutes to be published on the HFEA website.
Organisational risk:	Low

Minutes of the Authority meeting on 11 March 2026 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish (on-line) Geeta Nargund (on-line) Catharine Seddon Rosamund Scott Anya Sizer Stephen Troup Christine Watson
Apologies	Tim Child	
Observers	Jacky Cooper, Department of Health and Social Care (DHSC) (on-line)	
Staff in attendance	Peter Thompson (Chief Executive) Rachel Cutting (Director of Compliance and Information) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Tom Skrinar (Director of Finance, Planning and Technology) Joanne Anton (Head of Policy) Rachel Cooper (Head of Legal) Amanda Evans (Head of Research and Intelligence) Caroline Pringle (Head of Licensing) Sophie Tuhey (Head of Planning and Governance) Evgenia Savchyna (Corporate Performance Officer) Alison Margrave (Board Governance Manager)	

Members

There were 13 members at the meeting – 9 lay and 4 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 meeting.

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:

- Anya Sizer (freelance advisory work within the fertility sector)
- Stephen Troup (consultancy work within the fertility sector)

2. Previous minutes and matters arising

2.1. The Chair introduced the minutes from the meeting held on 21 January 2026.

2.2. A member proposed an amendment that there should be an action arising from minute 5.36 that the Executive are to confirm to the next Audit and Governance Committee meeting that future suppliers meet the NHS clinical risk management standards, where relevant.

2.3. The amended minutes of the meeting held on 21 January 2026 were agreed as a true record of the meetings and could be signed by the Chair.

Matters arising

2.4. The Chair informed members that the matters arising from the previous meeting had been actioned as detailed in the report or are not yet due.

2.5. 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 together with the Chief Executive she had met with Lucy Chappell, Chief Scientific Adviser DHSC, to discuss life sciences and HFE law reform proposals. The Chief Scientific Adviser understood the need for law reform noting that the HFEA regulates effectively but that the Act in which it operates is now 35 years old. The Chief Scientific Adviser had undertaken to consider how the HFEA's law reform proposals could be taken forward.

3.3. The Chair informed members that a meeting is scheduled for the next day with Samantha Jones, Permanent Secretary of DHSC, and this will be attended by herself and the Chief Executive. That same day the HFEA Chair and Chief Executive will attend the regular ALB Chair and Chief Executive's meeting.

3.4. The Chief Executive informed members that together with the other representatives of the Senior Management Team, he had attended the quarterly accountability meeting with the HFEA's sponsor team at DHSC. The Chief Executive spoke of the strong and productive relationship with the sponsor team. He informed members that the formal annual accountability meeting for 2025-26 will be held shortly.

Decision

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

4. Committee Chairs' report

4.1. The Chair introduced the report and noted that the opportunity for Authority members to observe an inspection, once during their term, was progressing with several visits being diarised.

4.2. The Chair informed members that following the Licence Committee Chair's comment at the last meeting, regarding more experienced HFEA staff observing meetings, an article had been published on the staff intranet reminding all staff of the opportunity to observe committee meetings.

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

4.4. The Statutory Approvals Committee (SAC) Chair (Frances Flinter) stated that the committee continues to meet monthly. The minutes from their most recent meeting in February have not yet been approved.

4.5. The SAC Chair stated that the PGT-M conditions which the committee had considered are listed in the report. These are a wide range of conditions with increasingly rare conditions coming to the committee. The Chair commented that occasionally the committee will receive an application for a

condition which does not yet have an OMIM reference number and when this occurs the committee consults with the relevant research bodies for further advice and information.

4.6. The Licence Committee (LC) Chair (Graham James) informed the Authority that the committee had met in January and also last week. The minutes from the latest meeting were not yet approved.

4.7. The LC Chair spoke of the role and purpose of the LC. He noted that at their January meeting the committee granted a three-year licence to a centre which had its licence suspended and special directions put in place less than two years' previously. The LC acknowledged with gratitude the considerable work involved in this centre's turnaround including by the PR, centre staff and the HFEA Inspectors. This illustrated a regulatory system working well.

4.8. The LC Chair commented that whilst such suspension is rare, special directions are then used to ensure that certain activities can still take place and that patients' needs are protected. He commented on the value of special directions more generally to the LC, given the limited range of powers open to the committee. He reflected also on the overall high compliance of the sector as reflected in the summary paper on licensing activity in the following agenda item.

4.9. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had met online on 24 February 2026, they were joined by the HFEA's Finance Business Partner from DHSC which was useful for the discussions with National Audit Office (NAO).

4.10. The AGC had received progress reports from the Government Internal Audit Agency (GIAA) noting that 80% of the 2025-26 internal audit plan was complete with the remaining 20% at fieldwork stage. The committee also formally ratified the 2026-27 audit plan.

4.11. The AGC received a report from the NAO and their external auditors (KPMG) which set out the audit plan for 2025-26 and noted that the intention is to lay the HFEA's accounts in Parliament before summer recess. The committee expressed strong concern and disappointment over the large increase in audit fees and the way this had been communicated to the HFEA. The committee had requested greater transparency on how the fee had been set.

4.12. The AGC had received and approved several policies including the Risk Management Policy, Counter Fraud and anti-theft Policy and Public Interest Disclosure Policy.

4.13. The AGC noted that work was progressing well on the cyber assessment framework and received a deep dive on business contingency which provided assurance to the committee.

4.14. The Scientific and Clinical Advances Advisory Committee (SCAAC) Deputy Chair (Steve Troup) informed member that SCAAC met online on 4 February 2026 and the minutes from this meeting are not yet approved.

4.15. The committee received a paper summarising research developments in the last 10 years covering organoids of the male and female reproductive tract and thanks were given to Dr Margherita Yayol Turco, from the Friedrich Miescher Institute for Biomedical Research in Basel, Switzerland who presented on female reproductive tract organoids. The committee had agreed that in future the topic should be split into two separate horizon scanning topics: Female reproductive tract organoids and Male reproductive tract organoids.

4.16. The committee discussed artificial intelligence, robotics and automation in fertility treatment, noting the complexity around regulatory oversight of large language models (LLMs) and challenges with implementing LLMs in clinical practice given that not all AI tools are classified as

medical devices and do not therefore fall within existing regulatory frameworks. The committee agreed to consider 'AI' and 'robotics and automation' as two separate topics.

4.17. The committee had discussed and confirmed that the current inclusion of calcium ionophore on the authorised processes list does not include its use for embryo development and that a novel processes application would be required for its use for embryo development.

4.18. The committee also discussed the prioritisation of horizon scanning topics and agreed its workplan for 2026-27.

4.19. The Chair noted the update from the Register Research Panel (RRP) and commented that this was a welcome addition to the report and provides additional oversight for the Authority.

4.20. The Chair thanked the Committee Chairs for the reports and expressed thanks to the committee members and the staff who service the various committees for their hard work. The Chair stated that committee papers and minutes are published on the HFEA website.

4.21. Members noted the Committee Chairs' reports.

5. Summary of Licensing Activity 2025

5.1. The Chair commented that licensing lies at the heart of the HFEA's responsibilities and whilst licensing performance is reported at each meeting through KPI's in the performance report and supplemented by the Committee Chair's report; the HFEA had not had the opportunity to stand back and review the whole year and this paper does that.

5.2. The Head of Licensing introduced the paper noting that clinics and human embryo research projects can only operate if they hold an appropriate licence from the HFEA authorising their activities.

5.3. The Head of Licensing then directed the Authority's attention to the key points in the report. As of 31 December 2025 there were 134 licensed centres, holding 142 licences, 89% of which were for the maximum licence length. There had been a marked increase in licence variations to appoint new Person Responsible's (PR). No enforcement action was taken in 2025 and there were no representations or appeals against licensing decisions.

5.4. Continuing, the Head of Licensing stated that the workload of SAC had increased by 24% compared to the previous year, with a spike in PGT-M applications in May 2025 and to a lesser degree in June and July which had caused pressure on agendas from July to October; however the committee had met KPI targets for minute production throughout the year.

5.5. The Head of Licensing introduced the three options contained in the paper which could be considered to create more capacity for SAC.

5.6. The Authority discussed the increase in variations of PR, noting the demands which are placed on PR's and the difference which the right PR can make for a clinic.

5.7. The Authority discussed option one, noting that there are different types of applications for special directions. Whilst the Authority agreed that straightforward applications could go to ELP, the more complicated and complex changes should be heard by SAC. This is because SAC is supported by a multi-disciplinary team, including external professionals who can offer guidance and advice to the committee.

5.8. In response to a question the Chief Executive commented that this change would not create a longer waiting period for patients as the ELP is the committee which meets most frequently.

5.9. The Authority discussed option two, noting that the number and composition of SAC members is working well with the mix of lay and professional members benefiting the work of SAC. The Authority noted that SAC benefits from the advice and guidance from external expert consultants including input from Genetic Alliance.

5.10. Members discussed the workload of SAC and felt that an expectation of attending six meetings was not onerous. Members spoke of the richness of Authority members taking these decisions and that it was not necessary to co-opt members.

5.11. The Chair informed members that Alex Kafetz had agreed to be joint Deputy SAC Chair with Geeta Nargund. This appointment will build resilience if the Chair was not available for a meeting. The Chair thanked the SAC Chair and Deputy Chairs.

5.12. The Authority discussed option three and felt that it would not be beneficial to undertake a root and branch review of the PGT-M approval process at present. The Authority were mindful that if proposal one was implemented this could reduce the workload of SAC.

Decision

5.13. The Authority decided:

- To implement option one that straightforward special directions applications could go to the ELP.
- To discard option two regarding co-option.
- To keep under review option three regarding a root and branch review of the PGT-M approval process, but that it was not required at present.

Action

5.14. Head of Licensing to implement option one regarding straightforward special directions applications to go to ELP.

6. Effective Governance

6.1. The Chair introduced the agenda item and stated that it is good practice that public bodies review their governance arrangements and the HFEA does this on an annual basis. All committees were required to review their own effectiveness using a standard or bespoke framework and the Authority undertook their board effectiveness review in November 2025.

6.2. The Board Governance Manager highlighted that the purpose of this annual review is to provide assurance over the structures established by the Authority and that their activities are aligned with the HFEA's statutory duties, responsibilities and objectives.

6.3. The Board Governance Manager stated that each committee had proposed a few actions that could be taken to enhance the work of the committee and the HFEA staff will work with the relevant committee chairs to implement these.

6.4. The proposed minor changes to the standing orders were introduced. The Board Governance Manager informed the Authority that a full-scale review of the standing orders will be undertaken during 2026-27 to ensure proportionality, relevance and clarity.

6.5. The Chair thanked all members, both the of Authority and committees, who had participated in the review and spoke of the importance of undertaking this review.

Decision

6.6. Members unanimously voted in favour of the changes to the standing orders.

6.7. Members noted the summary of actions arising from the annual review of committee effectiveness.

Action

6.8. The Board Governance Manager to publish the revised standing orders.

7. Performance Report

7.1. The Chief Executive introduced the performance report and reminded members of the Key Performance Indicators (KPIs) which are used to measure performance.

7.2. The HFEA's performance across all KPIs had been good in January, with 10 indicators rated Green, four Neutral, three Amber and two rated red. He remarked that operations are performing well with no indication of any structural issues.

7.3. The Chief Executive informed members that the two HR KPIs both remain green. The staff turnover KPI has reduced to 10.8% and is within the target range of 5-15%.

7.4. The Chief Executive spoke of the reasons for staff turnover, noting the limited promotions which the HFEA, as a small ALB can offer. He commented that indications are that staff morale within the HFEA continues to be high.

Strategy and Corporate Affairs

7.5. The Director of Strategy and Corporate Affairs informed members that preparations are underway for the Patient Organisation Stakeholder Group (POSG) and Professional Stakeholder Group (PSG) meetings which will take place in April and May. We had recently sought feedback on the groups from the members which was helpful.

7.6. The Director of Strategy and Corporate Affairs spoke of the forthcoming PR event which is being held in April and provided further details on expected attendance and agenda.

7.7. Members were reminded that the European Society of Human Reproduction and Embryology (ESHRE) Annual Conference is being held in London later this year. The HFEA has a session on the main agenda entitled "Past, present and future: Regulating a changing fertility sector" this will be in addition to the Horizon Scanning meeting that the HFEA hosts.

7.8. The Director of Strategy and Corporate Affairs informed members that work is progressing on the website improvements work and while changes are not being made to the overall design, they are important to maintain HFEA's rankings within search engines.

7.9. Members were informed of work within her directorate regarding supporting the Phoenix Programme and preparation for the publication of the annual Fertility Trends report later in the year.

7.10. A member asked whether it would be possible to either broadcast or record the HFEA's session at ESHRE for those who are unable to attend in person.

7.11. A member commented that a large percentage of the HFEA's media work is reactive and questioned whether more proactive work could be looked at, which would be considered by the communications team. In response to a separate question the Director of Strategy and Corporate Affairs reminded members that it had been agreed that no proactive media releases would be issued regarding the CaFC update released earlier in the year.

Compliance and Information

7.12. The Director of Compliance and Information informed the Authority that compliance KPI performance was good with all reports submitted to committee on time and completed within the set target.

7.13. Members were informed that the 'Inspection Reports to PR' KPI was rated Red, as two out of the six reports were slightly delayed by only three and seven days, due to annual leave over the Christmas period and one report requiring further QA work. The PGT-M indicator was rated Amber due to one application being delayed.

7.14. The Director of Compliance and Information informed members that the inspector's portfolio of clinics had been reviewed and reshuffled and explained the reasons for doing this every few years.

7.15. Further to the report given to members in November 2025 regarding post inspection feedback the Director of Compliance and Information stated that this is included in the Chief Inspector's monthly update to the inspection team, where feedback received is discussed and any actions identified.

7.16. The Opening the Register (OTR) team had processed 130 requests in January 2026, which is more than in December 2025 but less than in previous months, resulting in both OTR KPIs being rated Amber. The Director of Compliance and Information highlighted that the waiting list had been reduced to 269 applications with the average waiting time reduced to 34 days.

7.17. Members were informed that as of this week the OTR waiting list is 238, with a current average waiting time of just over five weeks. The Director of Compliance and Information cautioned that the waiting time for identifiable OTRs can be longer due to issues ascertaining donor identifiability. It was reported that approximately 30% of the donors whom the HFEA have contacted to notify them that the HFEA is releasing their identifying details have updated their details with the HFEA, and will continue to monitor data around this.

7.18. The Director of Compliance and Information informed members that the Head of Information, who took up position in December 2025, was working on updating the HFEA's Data Dictionary and explained the purpose of this dictionary.

7.19. Members were informed that a Data Quality and Metadata working group is planned with appropriate technical and functional representation to support Data Quality processes and Metadata definition work on an ongoing basis for Register improvements.

7.20. The Director of Compliance and Information informed members that the Register Team had completed 12 planned clinic audits during the year. The purpose of these audits is to compare the internal records of activity against that which the licensed centre has submitted to the Register of treatments. These audits allow the HFEA to identify any unsubmitted treatments and other record keeping issues.

7.21. The HFEA team provide advice to the clinics on complicated reporting like surrogacy and same sex couple treatments. In general, issues raised and discussed during audit visits include missing cycles discovered during the audit, validation errors review, EPRS/PRISM system issues and gamete movement issues and outstanding early outcome and pregnancy outcome updates where applicable.

7.22. A member congratulated the team for the reduction in the OTR waiting list and average waiting time and asked whether this target could be sustained and be reflected in the OTR KPIs. The Director of Compliance and Information reminded members of the complexity of some OTR requests, the various steps in verifying information and that the HFEA is reliant on responsiveness of clinics.

Finance, Planning and Technology

7.23. The Director of Finance, Planning and Technology stated that the Framework Agreement with DHSC has been finalised and is awaiting final Departmental sign off. The final agreement will be published on GOV.UK, the HFEA website and in the libraries of both houses.

7.24. The Planning and Governance team has been supporting the Chair in planning members' appraisals and supporting the HFEA teams prepare their service delivery plans for 2026-27.

7.25. Members were informed that the Phoenix programme is progressing well, although there have been complications as we approach the end of the development stage. There has been some slippage in the core Dynamics work but the team are managing this alongside the planned data migration and it shouldn't be necessary to push back the go live date.

7.26. The Director of Finance, Planning and Technology spoke of the prudent forecasting in the change assumptions for this programme and stated that he is meeting with the Programme Manager and Sponsor fortnightly and with the external supplier monthly to try to manage any further work over-runs.

7.27. The Director of Finance, Planning and Technology informed members that the cyber consultancy work is progressing well and the team will need to plan carefully how to manage these proposals going forward.

7.28. Continuing the Director of Finance, Planning and Technology stated that several meetings had been held with the new DSPT auditors and a plan has been developed for the 2026 CAF-aligned DSPT audit.

7.29. As reported previously the HFEA has been forecasting a fairly significant deficit since the end of summer which has largely been driven by lower-than-expected income. The Director of Finance, Planning and Technology spoke of the range of activities which had been undertaken to try to reduce this deficit.

7.30. The Director of Finance, Planning and Technology informed members of the significant and unexpected, last-minute increase in the HFEA's external audit fee for the year and how this increase has effectively cancelled the good work the HFEA had done in January to reduce costs.

7.31. The Director of Finance, Planning and Technology commented that it was unlikely that the HFEA would be able to hit the £200,000 target proposed to DHSC in October 2025, but DHSC are aware of this and close communications are being maintained. The year-end deficit will either be covered by the HFEA's reserves or additional Grant in Aid, or a combination of both.

Decision

7.32. Members noted the performance report.

8. Consent to Storage

8.1. The Chair introduced this agenda item and commented that members will be aware that the High Court recently handed down a judgment on an action brought by 15 sets of patients regarding consent errors.

8.2. The Head of Legal introduced the paper and informed members that a group action was heard in the family division of the High Court in October 2025. The action was brought by 15 sets of patients, all seeking a declaration that they could continue to store their gametes or embryos even though their consent had expired and had not been renewed within the timeframes required by law. The Head of Legal informed members that 82-page judgment was handed down last month (AA and others - Courts and Tribunals Judiciary).

8.3. The Head of Legal spoke of the decision taken by the Authority in 2019 where they had agreed to allow storage to continue despite gaps in consent, however as it was noted in the 2019 Authority paper this option applied a generous interpretation of the law with the aim of reducing the likelihood of patients having to go to court and that clinics that have storage consent cases will still face regulatory action. The Head of Legal explained that the recent court decision made it clear that this generous interpretation was no longer possible. Storage following gaps in consent would be unlawful without a Court declaration in all cases.

8.4. The Head of Legal spoke of planned communications to the sector regarding this case and the implications for the sector.

8.5. The Chair noted the implications of this judgement for both patients and clinics. The Chair referred to the HFEA's proposals for law reform regarding consent and hoped that this judgement will help to strengthen the HFEA's proposal.

8.6. In response to a question the Head of Legal confirmed that there is some learning which can be taken from the case and these will be conveyed to the sector through the planned communications.

8.7. In response to a question the Head of Legal explained that the Judge considered each application on its own merit and this is why judgement had been given on 14 out of the 15 sets of applicants.

8.8. A member questioned whether the HFEA should set expectations that clinics try two out of three avenues of communication in reaching patients, rather than just sending a letter through the post. The Director of Compliance and Information responded that the Code of Practice is not prescriptive and says that clinics must make reasonable attempts to contact the patient. If the HFEA felt that a clinic was not taking a robust approach to contact a patient, it could be addressed via inspection and through the Compliance and Enforcement Policy.

8.9. A member questioned whether this topic could be addressed at the forthcoming PR event. The Chief Executive responded that the PR agenda is already very full and the proposed communications, as detailed in the paper, should be sufficient.

8.10. In response to a question the Head of Legal stated that she believed that there will be some further cases to come, but she did not think the number would be large.

8.11. The Chair drew the conversation to a close and commented that the Executive will keep a watching brief on the number of cases.

Decision

8.12. Members noted the change on policy on gaps in consent to storage driven by the recent High Court decision in AA and Others [2026] and agreed the planned communications to the sector.

Action

8.13. Executive to implement the planned communications to the sector as detailed in the paper.

9. Business Plan Activities 2026-27

9.1. The Chair introduced this agenda item and noted that the Authority is required to agree a Business Plan at the beginning of each financial year.

9.2. The Head of Planning and Governance introduced the paper and stated that the proposed Business Plan activities for 2026-27 had been developed following engagement with Authority members and the Corporate Management Group (CMG).

9.3. The Head of Planning and Governance noted that the 2026-27 Business Plan represents the second year of the HFEA's strategy for 2025-28. The activities have been developed with a view to implementing the strategic aims and objectives over this three-year period.

9.4. The process for drafting the full Business Plan, including the additional information which is required under business planning guidance, was explained. It is anticipated that the 2026-27 Business Plan would be sent to DHSC in April 2026 and once approved will be published on the HFEA website.

9.5. The Head of Planning and Governance spoke about the BAU and additional activities, the priorities for these and which strategic objectives they support.

9.6. The Head of Planning and Governance informed members that the proposed activities have been drafted on the assumption that if the Government brings forward law reform proposals, then some of the priority activities would be dropped to free up staff capacity.

9.7. The Chair commented that the Authority had been involved in various iterations of the proposed 2026-27 Business Plan activities and had fed their views and ideas into the process, so it was satisfying to see the final proposal before the Authority today.

9.8. The Chair noted that the Department will recruit three key Authority members over the coming year. Her term as Chair will conclude in March 2027. The terms of two additional members will end in January 2027; those members currently serve as AGC Chair and Deputy Chair of the HFEA, and as Chair of SCAAC.

9.9. The Chair outlined the proposed recruitment timeline, which should allow incoming members a period to observe and shadow current Authority members. The Chair emphasised the importance of having a skilled and diverse Authority and noted that, once the DHSC published the appointment adverts, members will be encouraged to share these widely.

Decision

9.10. Members approved the Business Plan activities for 2026-27.

Action

9.11. Head of Planning and Governance to develop the full 2026-27 Business Plan and liaise with DHSC for approval and publication.

10. Budget Proposals 2026-27

10.1. The Chair reminded members that the draft budget was last discussed in November 2025, the paper before this meeting provides an update and details of the HFEA's settlement for 2026/27.

10.2. The Director of Finance, Planning and Technology introduced the paper and reminded members, that as indicated in November 2025, the HFEA will need to increase its overall expenditure requirements by about 5% for the forthcoming year.

10.3. Whilst the HFEA has not received formal confirmation of its Grant In Aid settlement for 2026-27, we can be sufficiently confident in the indicative budget that IVF fees can be set at £115. This is the lower of the two options that were presented to the Authority in November 2025.

10.4. The Director of Finance, Planning and Technology commented that this settlement should cover of all of the HFEA's core costs for the year, though the risk of fee income variability will still need to be managed. The GIA settlement also provides additional programme funding in a few areas that the HFEA bid for during the Spending Review last year. This includes funding to invest in cyber, IT improvements, the finance system and the website.

10.5. The HFEA Team will aim to identify and prioritise where they want to invest these programme funds over the coming months. It is going to be another busy year therefore the HFEA will need to be pragmatic and return funds to DHSC where it looks like the HFEA won't be able to spend them effectively.

10.6. The Director of Finance, Planning and Technology commented that the indicative Spending Review settlement provides the HFEA with funding in the two years after 2026-27, although this will be dependent on DHSC business planning in each of these years.

10.7. The HFEA will start developing a longer-term investment plan although he cautioned that this would need to remain flexible in case the settlement is adjusted in future years.

10.8. The Chair thanked the Finance Team for their work in preparing the budget and managing the finances. The HFEA has a number of statutory duties which it must carry out, these activities cannot be deferred and the proposed budget feels manageable. The Chair asked whether there had been any feedback from the clinics on the increased IVF fee.

10.9. The Director of Finance, Planning and Technology responded that a few clinics had commented that the information had been given to them late in the year.

10.10. A member spoke of the proactive actions that the HFEA had taken to manage its financial position and the paper before the Authority provided the required assurances.

10.11. The Chief Executive commented that the HFEA planned to move to a new fee mechanism where income is more stable and predictable.

Decision

10.12. The Authority noted the current position regarding the HFEA's expected GIA settlement and the final draft budget for the year.

11. Women & Equalities Select Committee Inquiry

11.1. The Chair reminded members that the HFEA had submitted written evidence to the House of Commons Women and Equalities Select Committee regarding egg donation and freezing and will give oral evidence next week. The Chair informed members that Zeynep Gurtin had given oral evidence in her professional capacity.

11.2. The Head of Policy provided further information on the scope of the inquiry into egg donation and freezing, noting that the inquiry is looking at whether women donating and freezing their eggs do so with sufficient information about the process, health impacts and consequences.

11.3. The inquiry has received 74 written evidence submissions and has heard three oral evidence sessions so far and as mentioned previously the HFEA will give oral evidence later. The written evidence has come from a range of respondents including DHSC, academics, individuals, charities and campaign groups.

11.4. The Head of Policy informed members that the HFEA had been monitoring the discussions and evidence so far and she brought to the Authority's attention several key challenges which had been identified.

11.5. The Head of Policy informed members that witnesses have generally agreed that the IVF process is considered safe, but like SCAAC had found more long-term research would be beneficial and provide more robust data.

11.6. Some witnesses have stated the quality of counselling is variable across the sector and agreed that implications counselling for donors should be mandatory, which is in line with the HFEA's law reform proposals.

11.7. The Head of Policy referred to the level of compensation for egg donation and the inquiry's question whether this induces vulnerable women to donate. Most of the witnesses have stated that there is no evidence that this has been a concern and the HFEA doesn't have any evidence to suggest that this is happening.

11.8. The inquiry is interested in advertising and the Head of Policy reminded members that advertising is not within the HFEA's remit but noted that the HFEA had done with the Advertising Standards Agency (ASA) and provided guidance given to clinics.

11.9. The inquiry has also discussed how to present success rates, especially on egg freezing and whether the UK market is becoming more commercialised. There had also been some discussion whether the HFEA should be leading global discussions on donation issues such as 10 family limit, cycle limits and changing technologies.

11.10. The Director of Strategy and Corporate Affairs spoke of the breadth of evidence which the committee had received and that it was pleasing to see that the UK was considered by many as leaders in the regulation of fertility treatment.

11.11. The Director of Strategy and Corporate Affairs stated that this is an ethically difficult area, with real issues that affect lives and the HFEA's role is to balance ethical decisions with the available evidence.

11.12. A member welcomed the focus of the select committee and spoke of the vulnerability of some fertility patients.

11.13. A member spoke of the way young people are accessing information and this tends to be via story telling platforms, such as fertility influencers on social media rather than fact-based information such as the HFEA website.

11.14. A member commented that this was a useful and interesting discussion for the Authority to hold and highlighted two items to reflect on. The first being the lack of long-term research in some areas and the second being the need for international co-ordination and consensus. The member spoke about the varied attitudes and understanding across countries and how it would be virtually impossible to set a global arrangement. The value of collaborative research was raised and the member wondered whether this could be raised at the forthcoming PR event.

11.15. A member commented that research into what proportion of women who freeze eggs and then go on to use them and the success rate would be useful.

11.16. Members spoke about the complexity of people's understanding regarding egg donation and freezing and spoke of the HFEA's regulatory remit. If any changes were proposed to this remit, then the HFEA must be given the appropriate powers and finances to implement these.

11.17. Members spoke about the HFEA's proposals for law reform and how these relate to the inquiry, noting that whilst the HFEA has clearly set out its proposals for law reform it is for Parliament to take these proposals forward.

11.18. The Chair drew the discussion to a close and commented that the Executive will report back to the Authority after the hearing.

Decision

11.19. The Authority noted the verbal report on the Women and Equalities Committee inquiry into egg donation and egg freezing.

12. Future of Data Presentation

12.1. The Chair began by reminding the Authority of the decision that they had taken at the last meeting regarding updating the Choose a Fertility Clinic (CaFC) data in Summer 2026.

12.2. The Chair spoke about the changes in data presentation via CaFC and the hugely successful dashboard and noted that as the process for updating CaFC has commenced this gave the Authority the chance to review the full range of data it provides for both patients and the public.

12.3. The Director of Strategy and Corporate Affairs introduced this item and stated it is an opportunity for the Authority to look at how data is presented and to develop some parameters for the staff team to work to.

12.4. The Director of Strategy and Corporate Affairs referred to the HFEA's statutory duty to collect data from clinics and provide information to the public. The HFEA provides this data in a variety of different ways including clinic level data on CaFC; national register data on the HFEA dashboards; annual reports looking at trends in register data and deep dives; data set for projects approved via the Register Research Panel and the anonymised register.

12.5. The Director of Strategy and Corporate Affairs showed examples of data presentation by several different organisation's and noted there was a range between being complex, patient friendly and customisable.

12.6. The Director of Strategy and Corporate Affairs suggested that principles for discussion regarding the future of data presentation could include:

- Transparent – to publish as much information as possible with the data that the HFEA holds within the boundaries of the law.
- Useful – aim of any data presentation should be to help patients and the public understand different treatment types and outcomes and draw comparison between clinics.
- Simple – data presentation should, as far as possible, use a single source of information and consistent metrics that is relevant to the user needs including clinic staff and researchers.
- Usable – presented in a way that is usable to patients and the public allowing users to tailor the information to their needs. This could be under licence if required.
- Freely available – data should be available in the most accessible way, i.e. not behind sign-ups or paywalls.
- Fit for wider government/health service principles – HFEA data presentation should align with DHSC/NHSE principles.

12.7. Continuing, the Director of Strategy and Corporate Affairs suggested that some issues for consideration by the Authority could be:

- What is the appetite for streamlining the HFEA's data into a single data format?
- Is it more important to have up to date unverified data or older verified data?
- Is it more important to make as much data freely and easily available than using interpretations?
- Are inspection and patient rating still relevant in an environment where there are numerous rating available?

12.8. The Director of Strategy and Corporate Affairs concluded the presentation by outlining the next steps.

12.9. Members commented that the data HFEA provides is a useful resource that is available to everyone and that it should continue to be easily accessible to both patients and researchers.

12.10. Members suggested working with the different users of the HFEA's data, including patients' groups, so that a wide range of views can be taken into consideration when planning changes to the presentation of HFEA's data.

12.11. A member commented that health care workers, including commissioners, should be included in the group of users and their requirements for data and how they will use it should be taken into consideration.

12.12. Members talked about how people are accessing information, with the younger generation moving away from fact-based websites to influencer generated content. Any changes to the presentation of HFEA's data must ensure that it is applicable to the next generation.

12.13. A member raised the issue of the growth of AI and how this could affect and change data presentation in the future. The member cautioned how much time, effort and resources should be allocated to future data presentation when the true effect of AI has not yet been realised.

12.14. Members discussed verified versus unverified data noting the benefit of providing up-to-date information for patients. A member questioned what the gap between verified and unverified data

was. The Director of Compliance and Information reminded members of the verification process that clinics undertake to ensure the data they have submitted is correct for CaFC, it could be possible in the future to move away from the large piece of verification work if clinics continued to improve their data submission.

12.15. A member cautioned against using unverified data as it could be wrong, reasonable caveats would be required and that the general public using this data might not understand the caveats. Other members were more enthusiastic about unverified data if it meant that the available data could be more recent.

12.16. The Chief Executive spoke about the possibility of building incentives into data submission, so that the data that clinics submit the first time, is accurate and useable.

12.17. Members discussed the interpretation of the data which the HFEA undertakes and the quality of the reports which the HFEA produces such as the fertility sector 2024/25 and fertility treatment trends and figures 2023.

12.18. There was a discussion regarding the patient and inspection ratings on CaFC, and the general consensus was the patient ratings added little; the small number of reviews from patients for some clinics could be viewed as misleading and comments and reviews in other social media platforms could provide patient reviews/feedback.

12.19. The Chair drew the discussion to a close noting that usefulness and accessibility were top topics in the Authority's preliminary discussions. The Authority also noted that AI could change the landscape regarding data presentation and this should be kept in mind as plans are developed. The Chair commented that as the age profile of fertility patients is younger than the general health cohort, i.e. 45 years and younger, the HFEA must keep under review how this age group of people accesses information and ensure that the HFEA's remains relevant to them.

13. Any other business

13.1. The Chair thanked everyone for their active participation in the meeting and for the high quality of papers before the Authority. There being no further items of any other business, the Chair closed the meeting and reminded members that the next full Authority meeting is being held on 20 May 2026. Details of this meeting, including how to request to observe, is posted on the HFEA website.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 20 May 2026

Authority meeting matters arising

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment / Supporting scientific and medical innovation
Meeting:	Authority
Agenda item:	2
Meeting date:	20 May 2026
Author:	Alison Margrave, Board Governance Manager
Annexes	N/A

Output from this paper

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:	2026/27 business year
Communication(s):	
Organisational risk:	Low

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
25/09/2025 Item 7.28	The HFEA to develop the proposed guidance for the sector and bring back to the Authority for further consideration	Director of Compliance & Information/Head of Policy (Scientific)	Summer 2026		Kick off meeting with some Authority members took place in November 2025. Scoping and development underway with plan to bring back to Authority later in 2026. Guidance drafted. Paper on genetic testing guidance being presented to May Authority meeting
11/03/2026 Item 5.20	Head of Licensing to implement option one regarding straightforward special directions applications being heard by the ELP.	Head of Licensing	June 2026		See item agenda item 2 for proposed changes to the standing orders.
11/03/2026 Item 6.8	Board Governance Manager to publish the revised standing orders.	Board Governance Manager	April 2026		This item has been completed and the standing orders were published **here** Standing orders also sent to sponsor team at DHSC and internal and external auditors.
11/03/2026 Item 9.11	Head of Planning and Governance to develop the full 2026-27 Business Plan and liaise with DHSC for approval and publication.	Head of Planning and Governance	May 2026		Business Plan has been finalised and sent to DHSC for approval and publication.

Matters arising – amendments to Standing Orders

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment
Meeting:	Authority
Agenda item:	2
Meeting date:	20 May 2026
Author:	Caroline Pringle, Head of Licensing
Annexes	Annex A: Standing Orders proposed changes

Output from this paper

For information or decision?	For decision
Recommendation:	Agree the proposed changes to Standing Orders, effective 1 June 2026 (vote required).
Resource implications:	In budget
Implementation date:	1 June 2026
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. Amendments to Standing Orders

1.1. At its meeting on 11 March 2026 the Authority agreed that the Executive Licensing Panel should be able to consider straightforward applications for special directions for the import and export of gametes and embryos (minute 5.13).

1.2. To put this into effect, minor amendments are required to Standing Orders. In reviewing the existing delegations to the Statutory Approvals Committee it was also noted that Standing Orders do not currently include reference to all relevant parts of the Human Fertilisation and Embryology Act 1990 (the Act), as it pertains to the making of special directions for import and export.

1.3. The proposed changes are shown at Annex A. If members would like to see a full tracked changes copy of the Standing Orders, they may request this from the Board Governance Manager.

1.4. Annex A includes:

- proposed changes to give Executive Licensing Panel the authority to consider applications for special directions for the import and export of gametes and embryos; and
- proposed changes to SAC's existing delegations to include all sections of the Act which pertain to the making of special directions.

1.5. In accordance with the Standing Orders, Authority members received notification and written motion regarding the intention to amend the Standing Orders at the May 2026 Authority Meeting.

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

1.7. The Authority is asked to review and approve the proposed changes to the Standing Orders as set out above. If approved the new Standing Orders would come into effect on 1 June 2026.

2. Recommendations

2.1. The Authority is asked to:

- Approve, by a majority vote, the revised Standing Orders to come into effect from 1 June 2026.

Annex A: Standing Orders – proposed changes

Colour legend used: yellow highlight is text to be deleted and green highlight is text to be added

Page 21 article 6.3.2(b)

the power to issue directions under sections 24(4)-24(4AF), 24(5A) to (5E) and section 24(13) of the Act.

Page 33 annex A section 3.2(e)

the issuing of special directions for the import/export of gametes or embryos (under section ~~24(4AA)~~ 24(4)-24(4AF) of the Act).

Page 44 annex B section 2

Exercise of the Authority's power to issue special directions for the import/export of gametes or embryos (under section 24(4)-24(4AF) of the Act).

Page 51 annex C section 15.3

The Authority has delegated to the panel the power to issue directions for the import/export of gametes or embryos under section 24(4AA) of the Act when the application is straightforward and does not raise complex or controversial issues.

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:	20 May 2026
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 March 2026.
- 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:

    - 12 March – Peter and I met the Permanent Secretary and Chief Scientific Officer to discuss Life Sciences and law reform
    - 12 March - Peter and I attended the DHSC ALB Chairs and Chief Executives meeting
    - 14 April – Peter and I met the team leading the DHSC ALB data insights work
    - 30 April – attended the HFEA PR event

2.2 Chief Executive

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

    - 12 March – as above
    - 18 March – Clare Ettinghausen, Rachel Cutting and I gave evidence to the Woman and Equalities Committee to support their inquiry into egg donation and egg freezing
    - 14 April – as above
    - 15 April – I attended Nuffield Council on Bioethics to discuss their project on the 14-day rule
    - 30 April – as above

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment
Meeting:	Authority
Agenda item:	4
Meeting date:	20 May 2026
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

2.1. The table below sets out the recent items considered by each committee:

Date	Items considered	Centres	Outcomes
Licence Committee:			
5 March	Interim inspection report	Living Systems Institute	Approved – licence continued
	Variation to add an additional named PNT practitioner	Newcastle Fertility Centre at Life	Approved – licence varied
7 May	New research licence executive update	Edinburgh Fertility Preservation – Research project R0215	Minutes not yet approved
	New research licence application	Francis Crick Institute Laboratory – Research project R0221	Minutes not yet approved
	Research renewal inspection report	Newcastle Fertility Centre at Life – Research project R0152	Minutes not yet approved
	Research renewal inspection report	University of Cambridge, Centre for Trophoblast Research, Physiology Building – Research project R0162	Minutes not yet approved
	Research renewal inspection report	University of Cambridge, Centre for Trophoblast Research, Genetics Building – Research project R0162	Minutes not yet approved
	Variation of licensed activities executive update	Human Embryo Research Centre – Research project R0193	Minutes not yet approved
Other comments:			
Executive Licensing Panel:			
2 March	Renewal inspection report	Hewitt Fertility Centre, Knutsford	Approved – 4 year licence (and ITE certificate)
	Research renewal inspection report	MRC Laboratory of Molecular Biology	Approved – 3 year licence

Date	Items considered	Centres	Outcomes
	Interim inspection report and variation of SLC T52 without application	IVF London	Approved – licence continued and varied
	Interim inspection report	Bourn Hall Clinic, Wickford	Approved – licence continued
	Interim inspection report	CREATE Fertility, Leeds	Approved – licence continued
	Variation of PR	Centre for Reproductive and Genetic Health City	Approved – licence varied (and ITE certificate)
17 March	Renewal inspection report	Wales Fertility Institute	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Barts Health Centre for Reproductive Medicine	Approved – 4 year licence (and ITE certificate)
	Interim inspection report and variation of SLC T52 without application	Royal Surrey Hospital NHS Foundation Trust	Approved – licence varied and continued
	Variation to change Research PR	Centre for Reproductive Medicine, Coventry	Approved – licence varied
	Variation to change Research PR and LH	Hartshorne and Genesis Group	Approved – licence varied
	Variation to change Research PR and LH	Mechanochemical Cell Biology	Approved – licence varied
	Variation to change PR	TFP Wessex Fertility	Approved – licence varied (and ITE certificate)
	Executive update	St Mary's Hospital	Noted
31 March	Interim inspection report and variation of SLC T52 without application	Lanarkshire Acute Hospital NHS Trust	Approved – licence varied and continued
	Research interim inspection report	Guys Hospital	Approved – licence continued
	Variation to change Research PR	MRC Human Genetics Unit	Approved – licence varied
	Variation to change PR	TFP Simply Fertility	Approved – licence varied (and ITE certificate)
14 April	Renewal inspection report	Newcastle Fertility Centre at Life	Approved – 4 year licence (and ITE certificate)
	Variation of PR and variation SLC T52 without application	Manchester Fertility	Approved – licence varied (and ITE certificate)
28 April	New Treatment & Storage licence application	Genus Medical Fertility Edinburgh	Approved – 2 year licence
	Renewal inspection report	Cambridge IVF	Approved – 4 year licence (and ITE)

Date	Items considered	Centres	Outcomes
	Renewal inspection report	Leicester Fertility Centre	Approved – 4 year licence
	Renewal inspection report	The Fertility Centre at Whittington Health	Approved – 4 year licence
	Variation of licensed activities	Centre for Reproductive and Genetic Health City	Approved – licence varied
Other comments:	None.		

Licensing Officer decisions:			
February 2026	5 x ITE import certificate	Various	All granted
March 2026	11 x ITE import certificate	Various	All granted
April 2026	4 x ITE import certificate	Various	All granted
Other comments:	None.		

Statutory Approvals Committee:			
24 February	Short stature, facial dysmorphism, and skeletal, OMIM #617877	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved for applicant patients only
	Maple syrup urine disease Type 1b [No OMIM]	The Lister Fertility Clinic	Approved
	Import of embryos from USA	London Women's Clinic	Approved
	Import of embryos from Portugal	Care Fertility London	Adjourned for further information
	Import of embryos from USA	Evewell (Harley Street)	Approved
	Import of embryos from USA	Evewell (Harley Street)	Approved
	Import of eggs from USA	Care Fertility London	Approved
30 March	Retinitis pigmentosa 60, OMIM #613983	TFP Oxford Fertility	Approved
	Rippling muscle disease 2 OMIM # 606072	Guys Hospital	Approved
	Bryant-li-bhoj neurodevelopmental syndrome 1; brylib1 and Bryant-li-bhoj neurodevelopmental	The Lister Fertility Clinic	Approved

Date	Items considered	Centres	Outcomes
	syndrome 2, OMIM #619720 and #61921		
	Oculocutaneous albinism type IV (OCA4), OMIM #606574	Guys Hospital	Approved
	Leukoencephalopathy, Hereditary Diffuse, With Spheroids 1, OMIM #221820	Guys Hospital	Approved
	Breast-Ovarian Cancer, Familiar susceptibility to 3, BROVCA3, OMIM # 613399	Aria Fertility	Approved
	Import of eggs from Greece	Care Fertility London	Approved
	Export of sperm to Cyprus	Care Fertility Manchester	Approved
27 April	Developmental delay with short stature, dysmorphic facial features, and sparse hair 1 (DEDSSH1), OMIM #616901	Care Fertility Nottingham	Minutes not yet approved
	FOXG1-related encephalopathy, OMIM #613454	Care Fertility Nottingham	Minutes not yet approved
	Myopathy with extrapyramidal signs, OMIM # 615673	Guys Hospital	Minutes not yet approved
	Neonatal onset 'Citrullinemia type 2', OMIM #605814	TFP Oxford Fertility	Minutes not yet approved
	Hyper Ig-D syndrome (HIDS), OMIM # 260920 and Hyperimmunoglobulinemia D (with periodic fever) mevalonate aciduria, OMIM #610377	The Lister Fertility Clinic at The Portland Hospital	Minutes not yet approved
	Leukodystrophy, hypomyelinating, 14;HLD14, OMIM #617899.	Guys Hospital	Minutes not yet approved
	Import of embryos from USA	IVI London	Minutes not yet approved
	Import of sperm from New Zealand	CREATE Fertility Bristol	Minutes not yet approved
	Import of eggs from Ukraine	The Fertility & Gynaecology Academy	Minutes not yet approved

Date	Items considered	Centres	Outcomes
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.		

Audit and Governance Committee:

Outside of the planned committee meetings the AGC has reviewed and commented on the draft Governance Statement for the 2025 Annual Report and Accounts.
The next AGC meeting is scheduled for 16 June 2026 and therefore a report will be given to the July Authority meeting.

Scientific and Clinical Advances Advisory Committee:

SCAAC has not met since the last Authority meeting.

Register Research Panel:

RRP has not met since the last Authority meeting.

3. Recommendation

3.1. The Authority is invited to note this report. This information is published on the HFEA website.

3.2. Comments are invited, particularly from the committee Chairs.

Human Fertilisation & Embryology Authority

Annual performance report

April 2025 - March 2026

Evgenia Savchyna
Corporate Performance Officer
20/05/2026

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:	20/05/2026
Agenda item:	Item 5
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

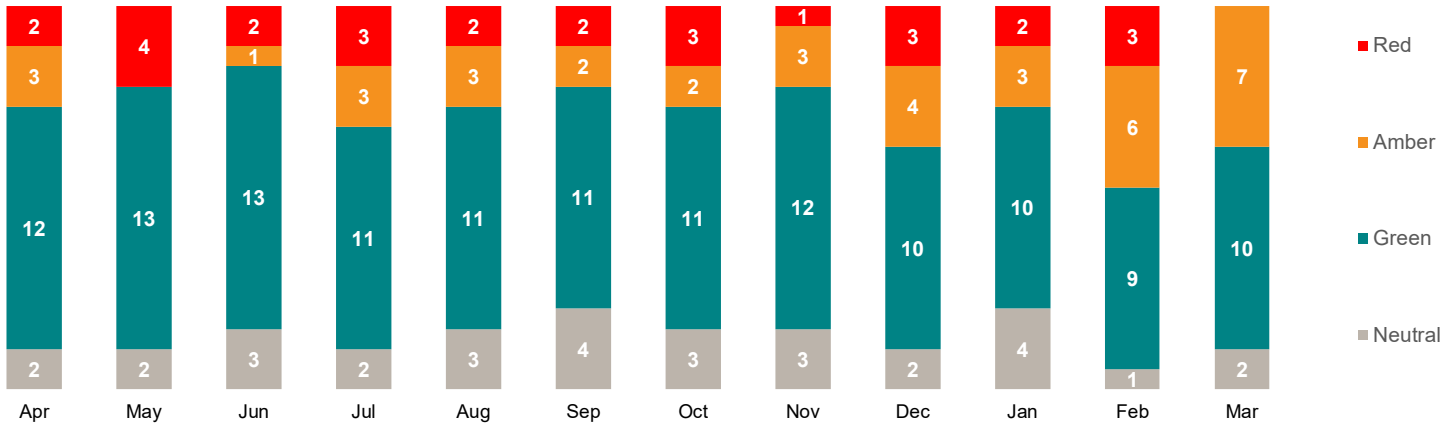
Output from this paper	
For information or decision?	For information
Recommendation:	To discuss
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Corporate Management Group (CMG) reviews performance in advance of each Authority meeting, and their comments are incorporated 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

Summary for 2025/26

- HFEA performance across all 19 KPIs has remained consistently strong throughout the year (Red 1-4, Amber 1-7, Green 9-13, Neutral 1-4). In March 2026, ten indicators rated Green, seven Amber, two Neutral, and none Red.
- Compliance performed consistently well throughout the year, completing all scheduled inspections alongside a number of additional visits in response to regulatory concerns. End-to-end licensing KPIs were achieved in half of the reporting periods, with an average KPI performance of 87% across the year, and all licensing decisions were delivered on time.
- The number of applications for embryo testing increased significantly to 84, compared with 45 in the previous year, and applications also increased in complexity. While this impacted KPI performance, which was rated Amber for the past eight months, the team continued to process PGT-M applications with minimal delay.
- All licensing decisions met the KPIs for each committee: Licensing Office, Executive Licensing Panel, Licence Committee and Statutory Approvals Committee.
- The OTR waiting list reduced significantly during the year, decreasing from 768 requests in April 2025 to 226 in March 2026. The average waiting time for closing applications during the January–March 2026 quarter was 61 days. The majority of the current waiting list is actively being worked on and is expected to be closed within two months of receipt.
- Information requests were managed within KPI targets, with the exception of three particularly complex FOI requests. All PQs were responded to within the timescales set by DHSC, despite the number of PQs tripling compared with the previous year (27 vs 10). The number of email enquiries decreased by approximately 22% compared with last year (1300 vs 1659), while telephone enquiries reduced by around 40% (240 vs 391).
- Proactive media coverage was driven by the publication of the Fertility Trends report in June 2025, alongside periods of increased reactive coverage throughout the year. Website users and sessions showed a downward trend, likely reflecting a growing use of generative AI for fertility information, as well as users refusing our website cookies.
- Staff sickness, including both short and long-term absence, and turnover remained largely within tolerance throughout the year.
- Debt collection within 40 days was challenging to achieve across the year due to the timeframes in which most clinics pay their bills. This KPI will be replaced from next year with a new ‘Debt over 60 days’ KPI. The average number of debtor days remained low and well within target. Invoices were consistently paid within 10 days, with the exception of April and May 2025.

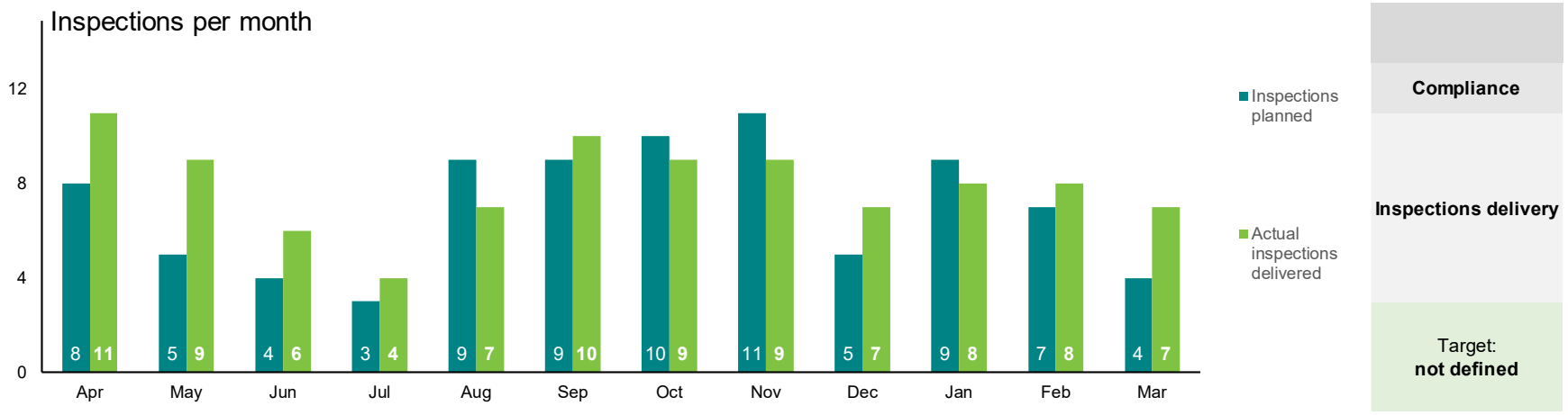
RAG status over last 12 months



RAG status over last 12 months

19 KPIs in total for each month

KPI performance over the last year has been variable with the following averages across the year:
Red = 2.25 Amber = 3.1 Green = 11.1 Neutral = 2.6

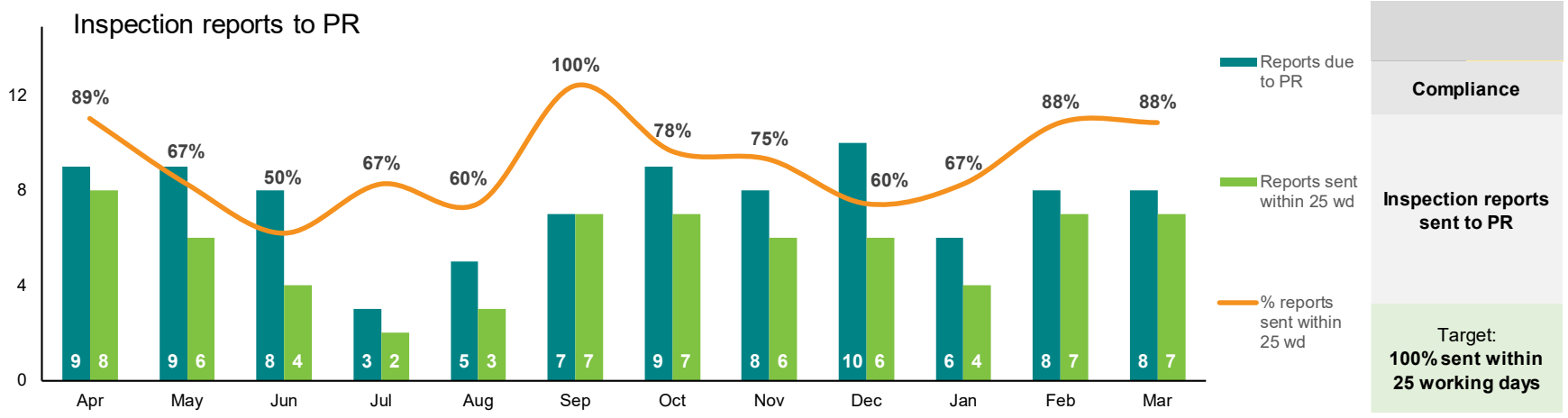


Compliance

Inspections delivery

Target: **not defined**

Undertook 95 inspections over the year, 11 more than planned. Additional inspections/clinic visits were due to regulatory oversight.

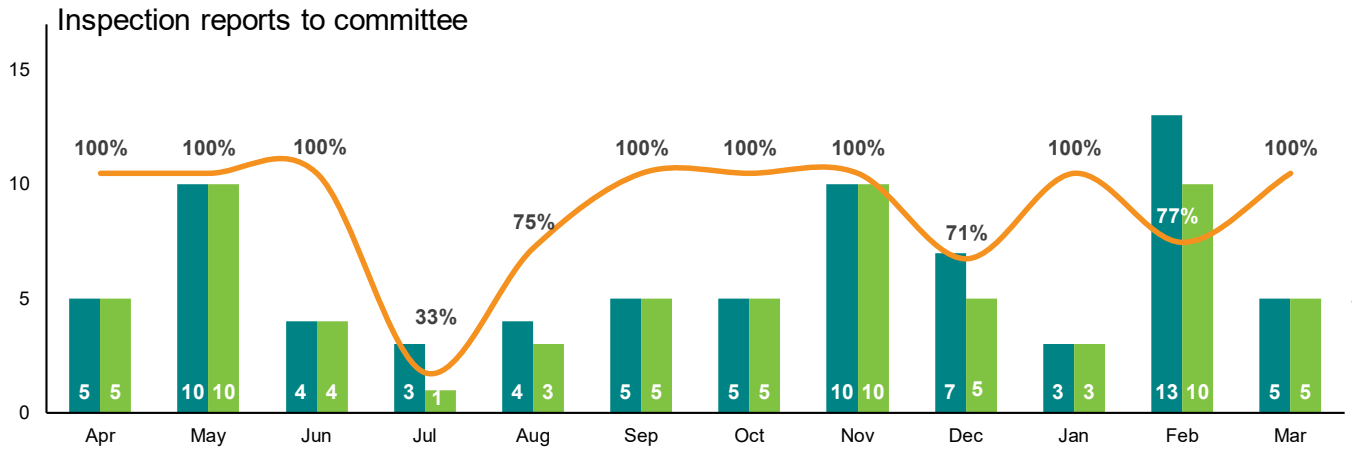


Compliance

Inspection reports sent to PR

Target: **100% sent within 25 working days**

Complex inspection reports often require extensive quality assurance. KPI also impacted by any delays in reports being returned to inspectors.

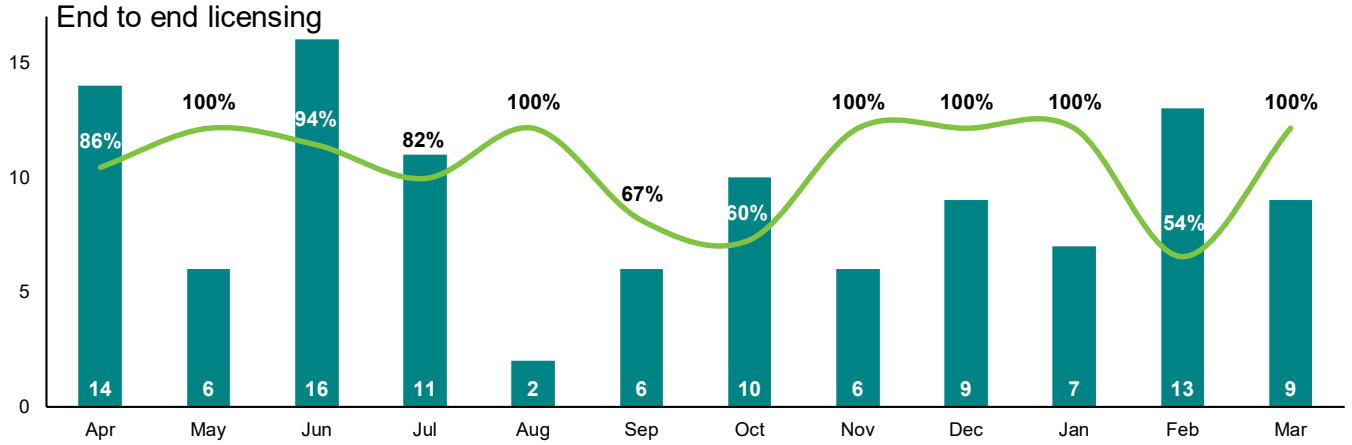


Compliance

Inspection reports sent to relevant licensing committee

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

KPI met in 8 months across the year. Many reports continue to be complex frequently requiring extensive review.

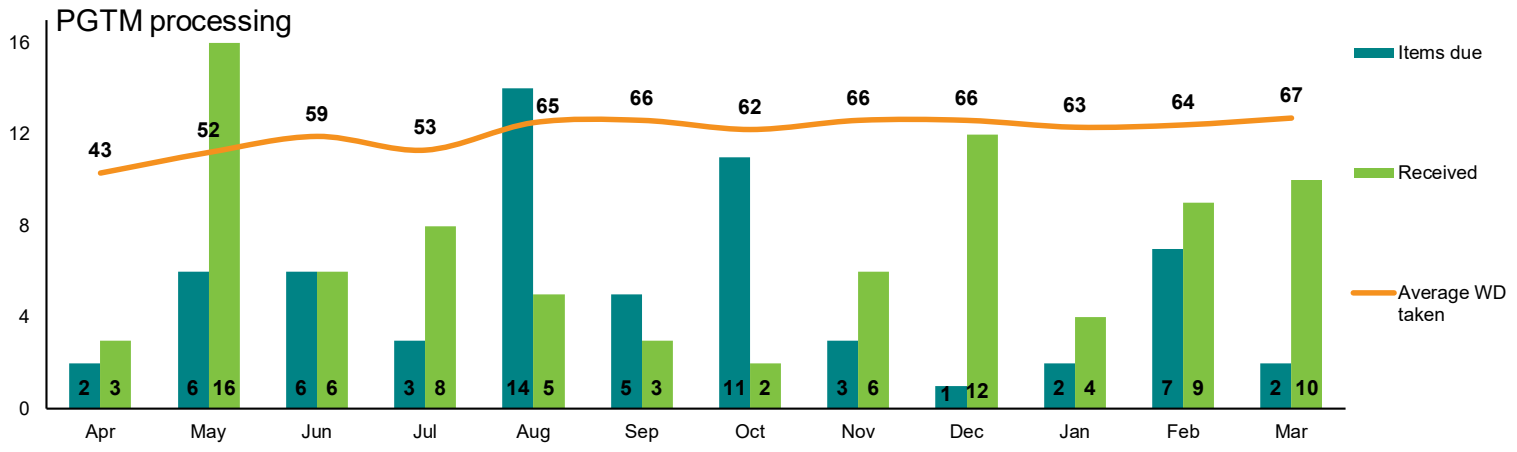


Compliance

End to end licensing process

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

KPI met in 6 months out of 12; an average KPI of 87% has been achieved for 'End to end licensing'. All licences issued on time.

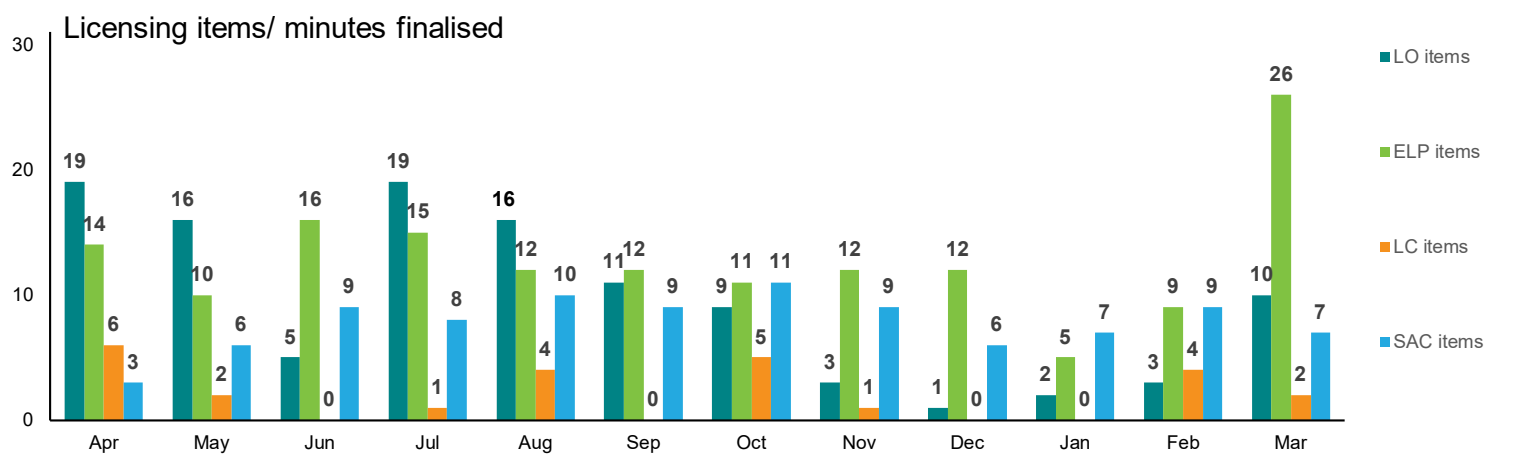


Compliance

PGTM processing efficiency

New target - Dec 24: **average time within 60 working days**

84 PGT-M applications have been received in this reporting year with an average processing time of 67 working days. This is a considerable increase compared to the previous year (45 applications). Many PGT-M applications show an increase in complexity requiring extensive quality assurance.

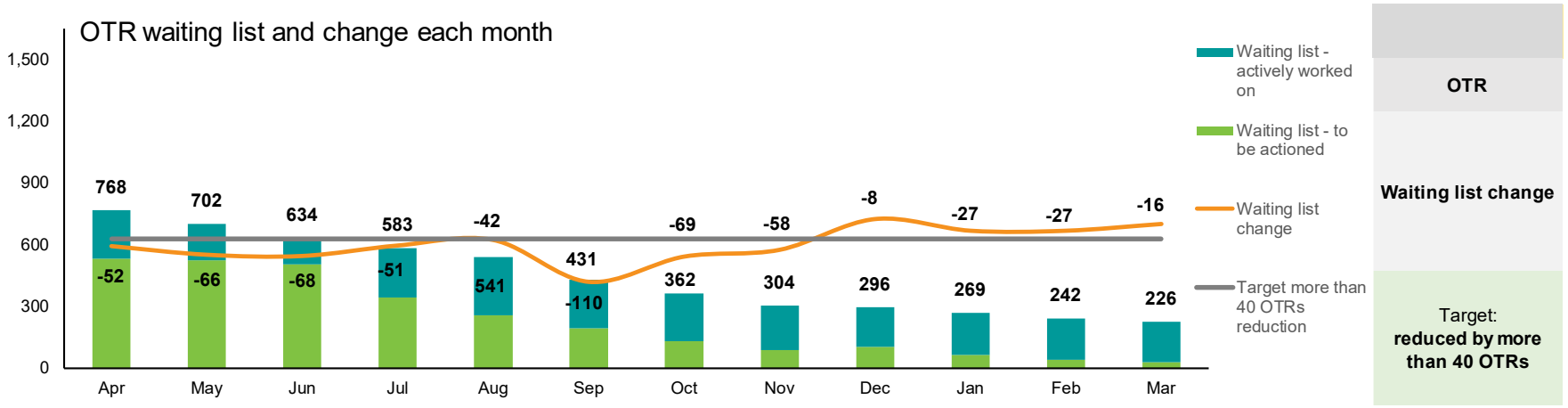


Licensing

Licensing efficiency

Targets:
LO - 5 WD
ELP - 10 WD
LC - 15 WD
SAC - 20 WD

The overall number of items minuted has been largely consistent with the previous year although the balance through committees has shifted; notably, a reduction in the number of Licensing Officer items and an increase in SAC items compared to last year. The high numbers through ELP in March is the result of three meetings falling into this reporting period, as opposed to the usual two, rather than a particular increase in this committee's activity. KPIs for minutes have been met throughout the year.

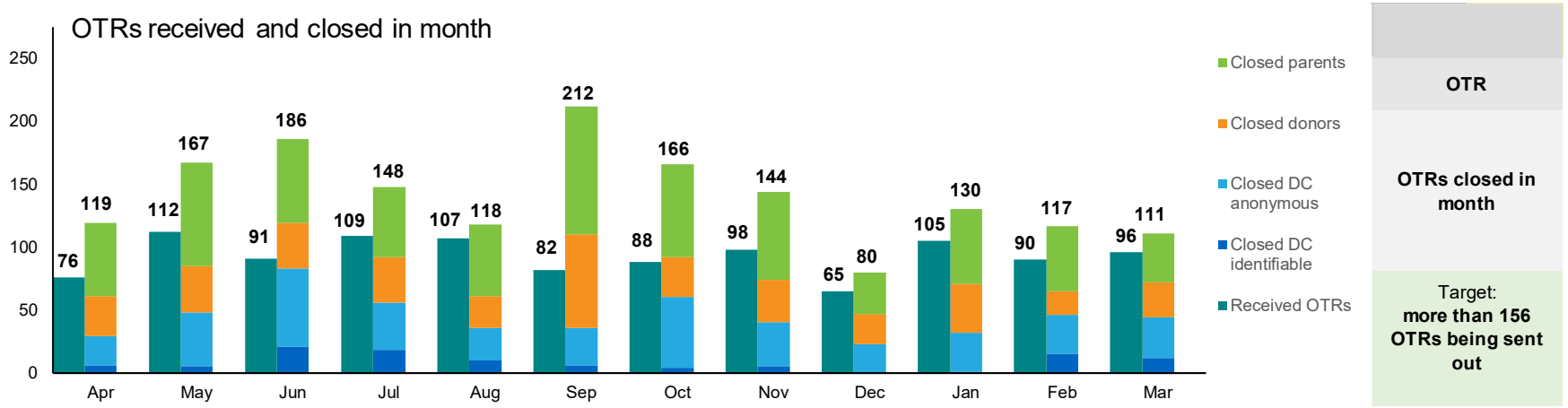


OTR

Waiting list change

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

There has been a consistent reduction in OTR waiting list from 768 at the beginning of the year to 226 at the end of the year. The trend points towards a continuing reduction in OTR waiting list.

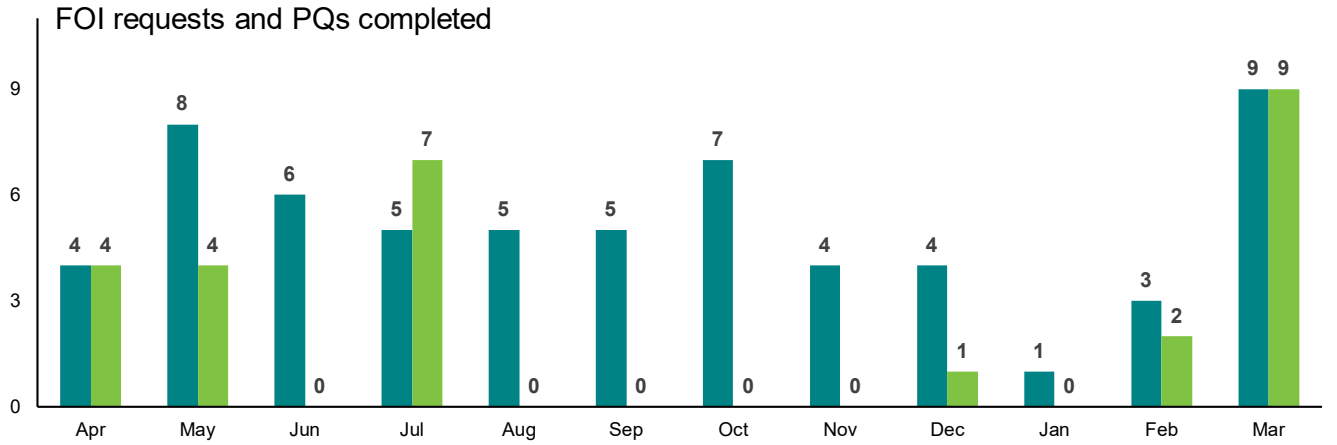


OTR

OTRs closed in month

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

The number of OTRs closed has been consistently higher than the number of OTRs received in the year with average waiting time of 61 days in January – March 2026 quarter, although more recent less complex applications can be closed within a month. The key constraints in reducing waiting time further is the turnaround time required by clinics for OTR queries and PRISM (internal and external) issues. .

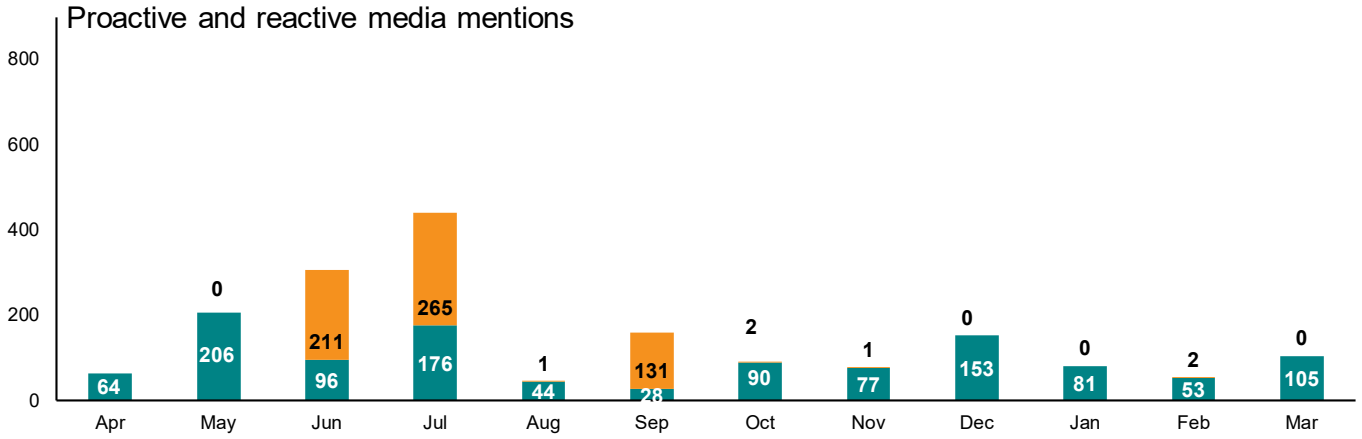


Intelligence

FOI and PQ completed

Targets:
FOI - 20 WD
PQ - set by DHSC

FOI were responded to within deadline across the year, with the exception of three complex requests that required additional time. Many FOIs this year have been complex with requests mainly relating to clinic information, donation, human resources, and finance. All PQs were responded to DHSC on time, with most relating to egg donation or freezing.

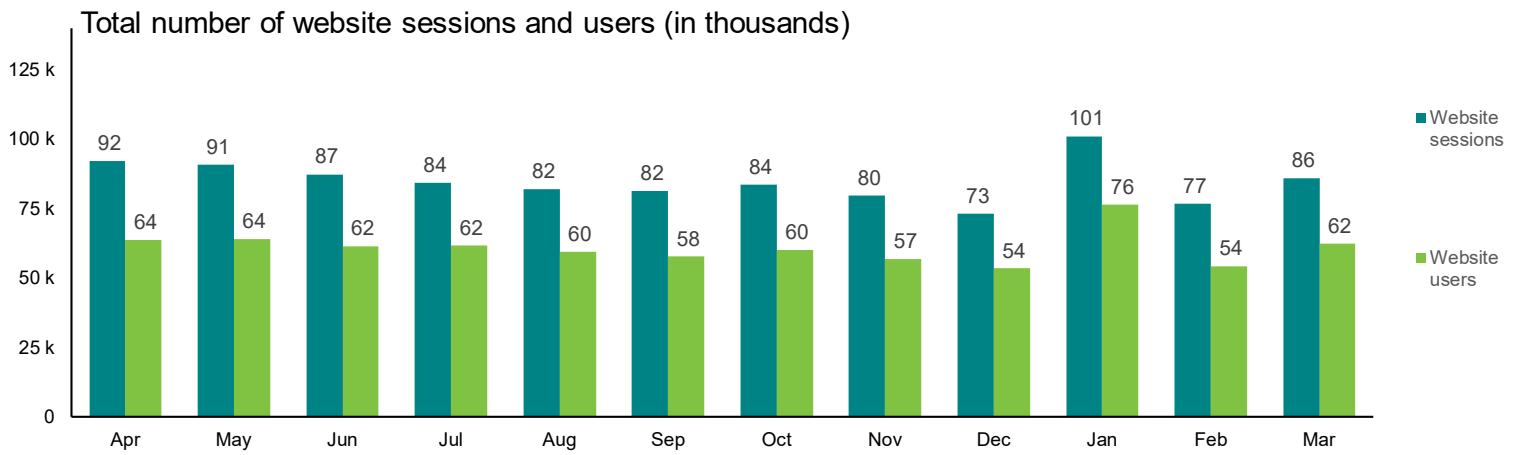


Comms

Total media mentions (proactive and reactive split from April 2024)

Target:
not defined

The spike in reactive press coverage in May followed a BBC piece on polygenic testing in IVF. Our Fertility Trends report in June generated another spike in coverage, particularly proactive media generated by the HFEA headline "one child in every classroom is now born from IVF". In July the story about 8 babies born from mitochondrial donation treatment saw higher than usual levels of reactive coverage. And in March, news of Rita Ora's egg freezing drove reactive coverage.

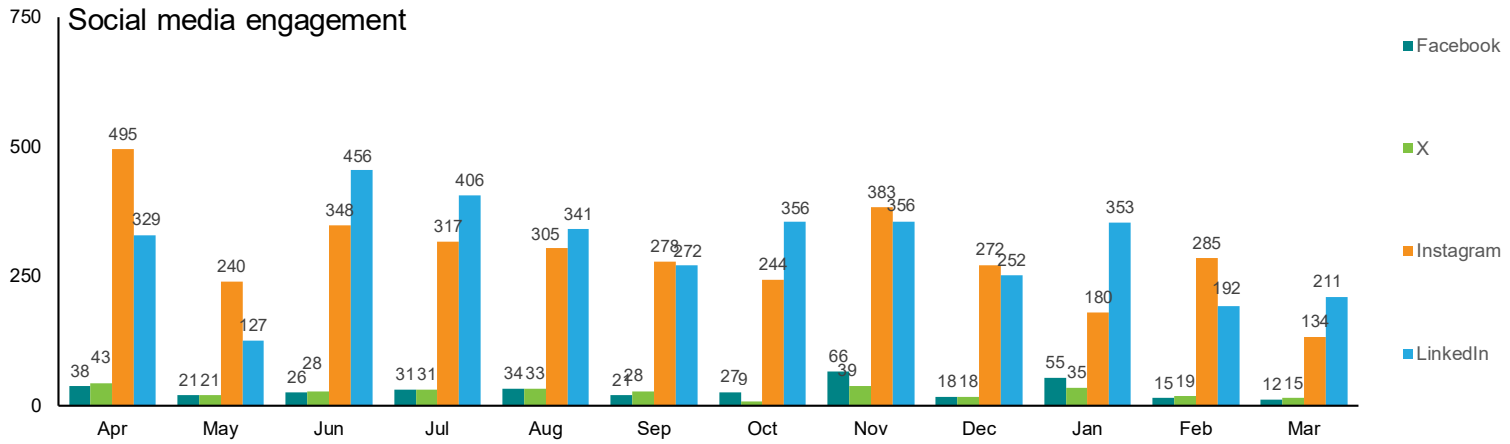


Comms

Total number of website sessions and users (Internal traffic excluded from October 2023)

Target: **not defined**

In 2025-26, we observed approximately 240,000 fewer website sessions and 180,000 fewer users compared with the previous year. This may be attributed to users turning to Generative AI for fertility information, as well as users refusing our website cookies, either manually or via automated browser extensions. The website improvement works this year aim to address some of these factors.

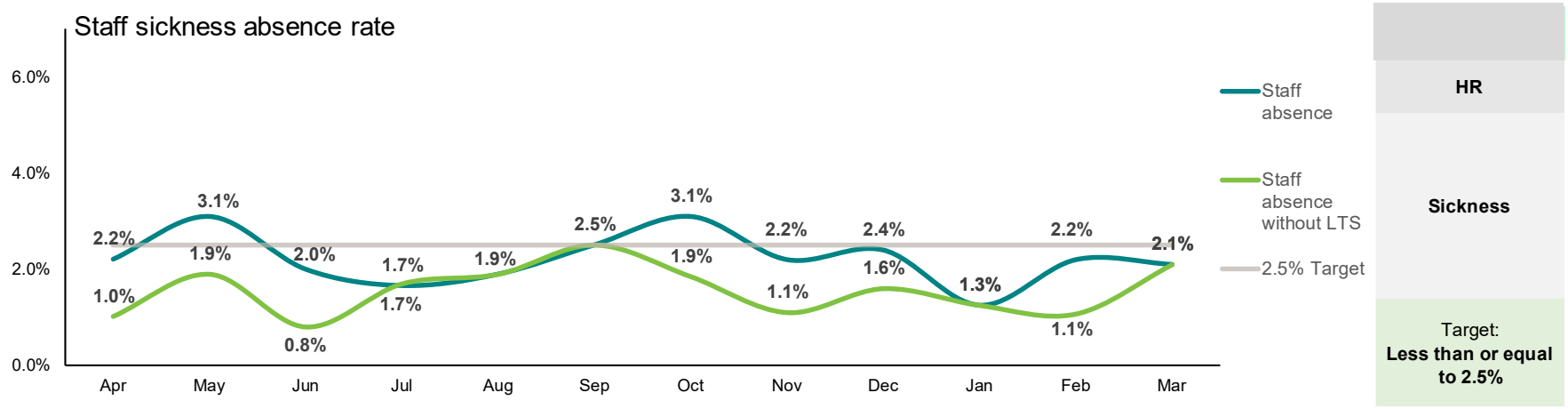


Comms

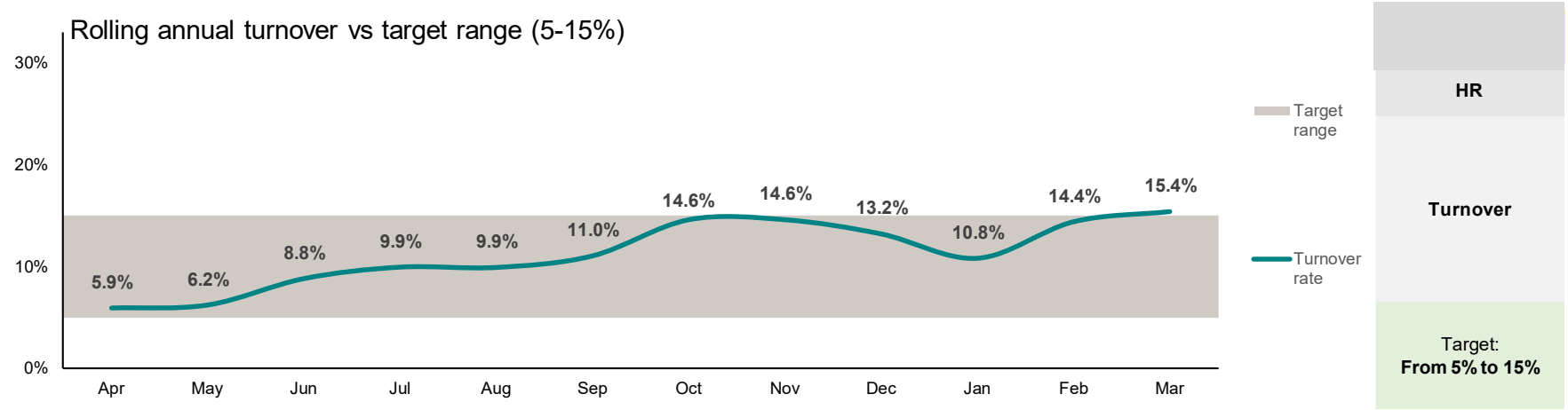
Engagement across social media

Target: **not defined**

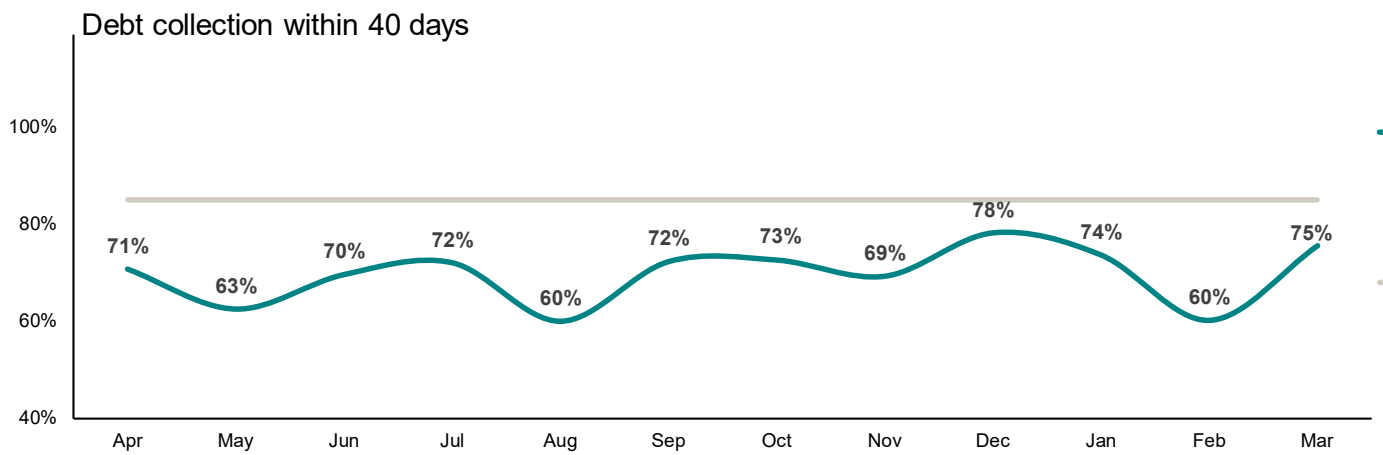
Performance remained steady throughout the year. Engagement was driven by both HFEA publications, stakeholder activity and fertility-related news stories. LinkedIn and Instagram continue to be our best-performing channels for engagement and reach.



We continue to maintain below target figures for sickness absence, both short and long-term. Ongoing support is in place to provide managers with necessary guidance and tools to help manage any sickness absence, including the use of return-to-work interviews.



Turnover currently stands slightly above our 15% target but remains tolerable. It is hoped that we will see a plateau in this area in the coming months. In the meantime, HR continues to conduct exit interviews to help better understand the reason for turnover.

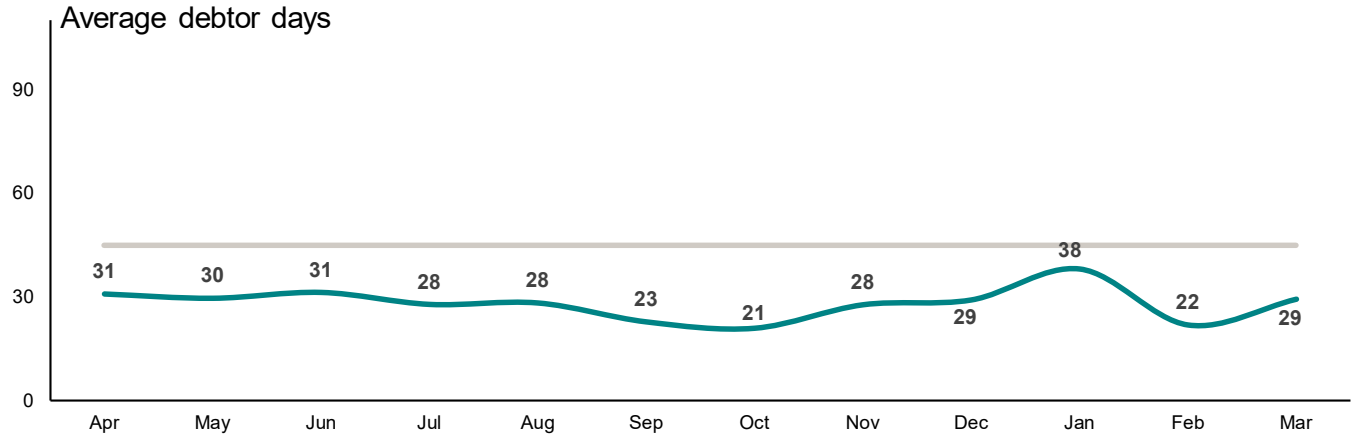


Finance

Debt collection

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

This KPI was always challenging to achieve due to the time-frame in which most of the clinics pay their bills. The majority fall within the 60 days.

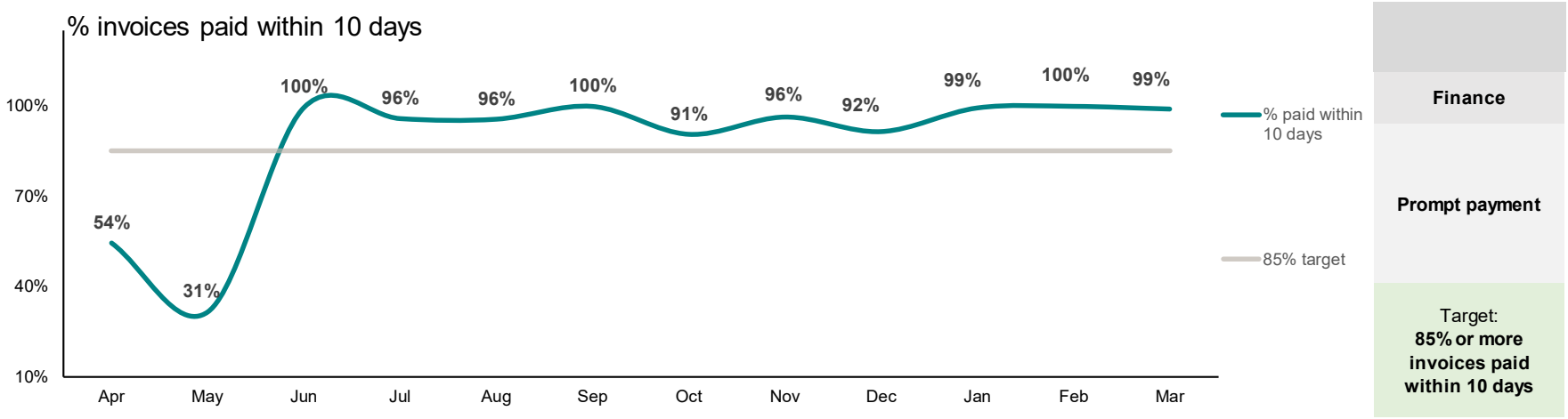


Finance

Debtor days

New target
from Oct 2024:
45 days or less

The annual figure for debtor days is 29 days which we comfortably achieved this year due to consistency of closing debtors and despite the slight drop in overall income which are the 2 components the calculation uses.

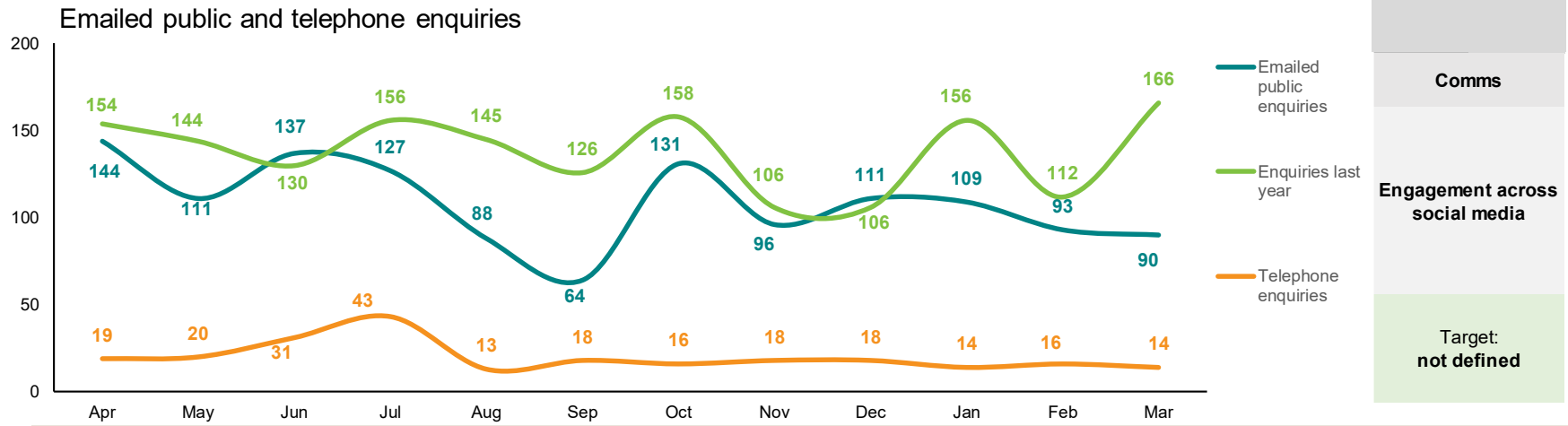


Finance

Prompt payment

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

The hiccup in April and May was due to payment delays for 5 high value invoices. Had these been excluded, we would have exceeded our target, however, ended the year at almost 100%.



Comms

Engagement across social media

Target: **not defined**

The number of emailed public enquiries this year has generally been lower than the previous year. Telephone enquiries have been mostly consistent throughout the year.

Human Fertilisation & Embryology Authority

Finance Report

Twelve months to 31 March 2026

Tom Skrinar
Director of Finance, Planning and Technology
20 May 2026

www.hfea.gov.uk

Summary financial position as of 31 March 2026

Type	Actual YTD	Budget YTD	Variance Actual vs Budget
	£'000s	£'000s	£'000s
Income	8,304	8,647	(343)
Expenditure	(8,603)	(8,647)	44
Total Surplus/(Deficit)	**(299)**	**0**	**(299)**

Year-end KPIs
Bank balance: £2.8m (target £1.52m)
Debts 60 days old 4% (target <10%) (excludes 3 clinics)

The year has ended with a reduced deficit of £299k against a balanced budget. The deficit is a 37% reduction to that reported at month 10 (January). This reduction has been driven by slightly higher than expected income at the end of the year with the end of year result being an income deficit of £343k (we had previously forecast a deficit of £379k) .

Our expenditure was originally forecast to show an overspend of £126k at year end, but the reversal of our bad debt provision has reduced the forecast overspend to an underspend of £44k.

These figures are subject to audit and may change, however, we do not expect the changes to be significant.

The following pages give the detail of variances.

Human Fertilisation & Embryology Authority

2025/26 Income – YTD 31 March 2026

	Actual £000's	Budget £000's	Variance £000's	Variance %ge
INCOME				
DHSC Funding	1,367	1,299	68	5%
Licence fees	6,834	7,186	(352)	-5%
Other	103	162	(59)	-36%
Total income	**8,304**	**8,647**	(343)	-4%

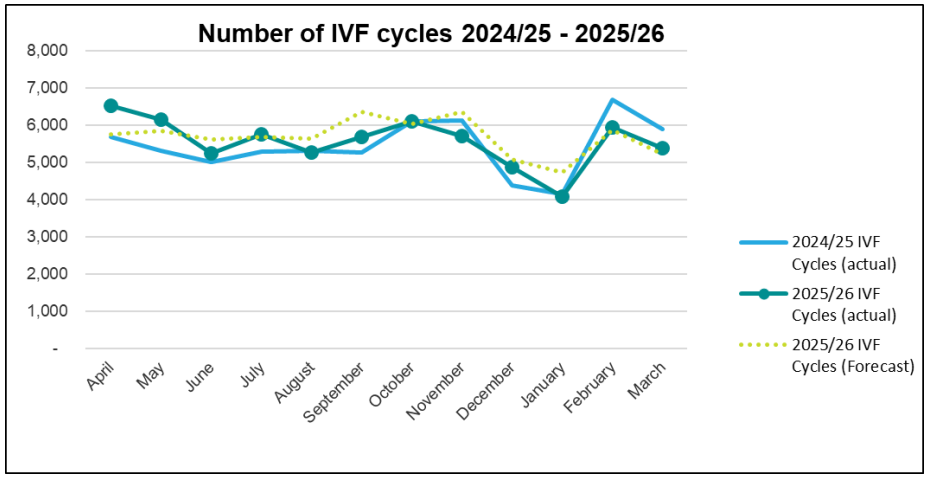
Income

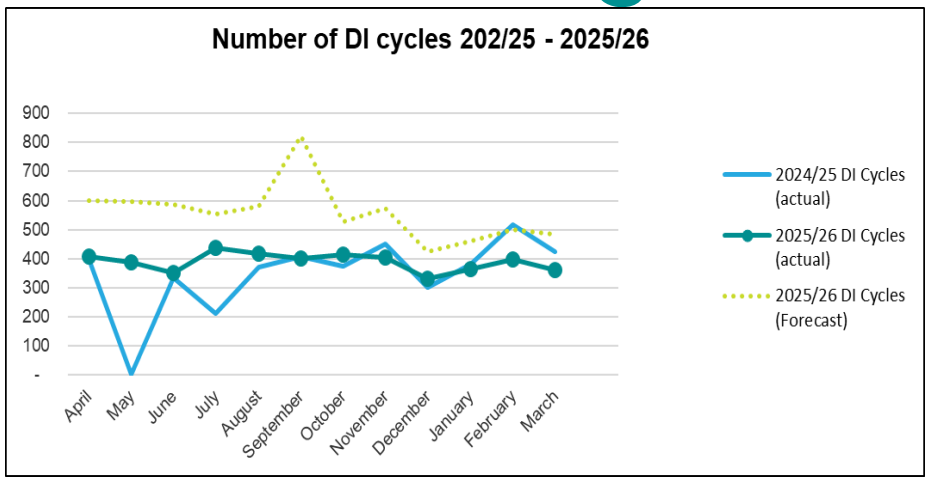
Grant in Aid is £68k above budget due to securing funding from the cyber investment fund for the work on cyber security that commenced at the end of the year. The funding also includes non-cash income that we receive which should cover the cost of depreciation/amortisation of our fixed tangible and intangible assets.

Of the £352k licence fee under-recovery, IVF and DI fees ended the year £377k below budget with the balance relating to renewal and other fees which were £25k over budget.

Other income is bank interest which has seen a reduction due to interest rates.

2025/26 Income - YTD Actual vs Budget





IVF / DI Activity at year end

The above graphs show the volumes of IVF and DI cycles, comparing activity for the 2024/25 and 2025/26 financial years as of March 2026

IVF cycles have ended the year at 66,733 which is 3% below budgeted levels. DI cycles have ended the year at 4,672 which is more than 30% less than expected (but 12% higher than 2024/25 which was 4,170).

For context, the budgeted activity levels for both IVF and DI cycles were based on a 3-year average. Whilst our IVF activity does not appear to be reducing (3-year average was 66,200), DI activity does appear to be reducing from previous years (where the average was 4,993).

2025/26 Expenditure YTD 31 March 2026

	Actual £000's	Budget £000's	Variance £000's	Variance %ge
EXPENDITURE				
Salaries and wages	6,123	6,072	51	1%
Other Staff costs	197	262	(65)	-25%
Other costs	241	258	(17)	-7%
Project costs	672	740	(68)	-9%
Estates costs	377	527	(150)	-28%
IT costs	684	464	220	48%
Legal and Professional	308	324	(16)	-5%
Total Expenditure	**8,603**	**8,647**	(44)	1%
Surplus/(Deficit)	**(299)**	0	(299)	

Variances

Salaries and wages - £51k over budget due to some overlap of salaries covering maternity leave; a settlement which did not complete until July 2025 whilst it commenced in the 2024/25 business year and was partially provided for, the balance has impacted this year.

Other staff costs under budget by £65k, the main area of underspends are within Compliance inspection travel costs (£13k); training (£41k); recruitment(£25k). These are offset by overspends within Staff welfare (£25k) and smaller underspends across other related staff costs.

Human Fertilisation & Embryology Authority

2025/26 Expenditure continued

- **Other Costs** - are £17k under budget, assisted by delaying some spend to 26/27 mainly within the Strategy & Corporate Affairs directorate and Committee costs.
- **Project Costs** – the Pheonix project which is due to complete in mid 2026/27 has come in under budget, however, costs have been pushed into 2026/27 to cover additional work packages.
- **Facilities (incl estates) costs** – are under budget (£150k) at the end of the year due to a reduction in our non-cash costs (depreciation) and the reversal of a bad debt provision c£101k. The provision was created at the end of 2024/25 after reviewing the debtor balances. A very prudent view was taken around some of the clinics ability to pay. As of April, 3 of these clinics sit within the 'more than 60 days old' category, however, we still believe these accounts will be cleared, just not at a normal rate.
- **IT Costs –** are overspent against budget by £220k. We had previously forecast an overspend of £193k. This slight increase is mainly driven by price changes.
- **Legal and Professional** – is over budget by £16k driven by increased audit fees (internal and external) totalling £60k. The issue around the external audit fee has been resolved with the final figure reducing by £25k, though still remaining above budget. Legal spend came in under budget by £76k.

2025/26 Expenditure continued

The figures presented are from the final draft accounts pending the audit which commences in the first week of May. Key items that may change include;

- Treatment fee income – to date we have raised estimated invoices to 3 clinics and have posted an accrual in 24/25 of £133k. The audit may require that this figure is adjusted downwards although they would need to provide a sensible rationale.
- Expected credit losses or bad debt provision is currently c£70k relating to the same 3 clinics mentioned above. Audit may suggest we have not been prudent enough and could ask that the provision be increased,

If the above audit changes materialised, the impact would push our year end deficit of £302k closer to the £500k mark in a worst-case scenario.

Embryo Testing

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment
Meeting:	Authority
Agenda item:	6
Meeting date:	20 May 2026
Author:	Dina Halai, Head of Regulatory Policy, Scientific (job-share) Rachel Cooper, Head of Legal Anna Coundley, Policy Manager
Annexes	Annex A: Wording on genetic testing in the Human Fertilisation and Embryology (HFE) Act 1990 (as amended), standard licence conditions and code of practice

Output from this paper

For information or decision?	For decision
For decision:	Members are asked to: • agree the recommended approach of requiring clinics to record the reason for testing under 1(a) and 1(e); • decide the position we take on additional genetic information that can be obtained and used in clinical decision making when testing under 1(b); • agree the recommended approach with regard to incidental findings • agree to the removal of the umbrella “chromosomal rearrangements (various)” authorisation from the approved list of conditions that can be tested for under 1(b); and • delegate sign off on consequential changes to General Directions and Standard Licence Conditions, and the guidance, to the Chair.
Resource implications:	Within budget - resource will be required to implement from the Policy, Compliance, Licencing and Legal and Communications.
Implementation date:	To be decided post Authority discussion

Communication(s):	To be decided post Authority discussion
Organisational risk:	Low/**Medium/**High

1. Background

1.1. The Human Fertilisation and Embryology (HFE) Act 1990 (as amended) (the "1990 Act") prohibits embryo testing except for one of the purposes permitted in the Act (the "Permitted Purposes"; see Annex A for exact wording in the Act). In summary, a permitted purpose can be:

a. Testing for an abnormality which may affect capacity to result in a live birth ("1(a)")
b. Where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, testing to establish whether it has that abnormality, or any other abnormality, in both cases only if there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, illness or medical condition ("1(b)")
c. Where there is a particular risk that any resulting child will have or develop - (i) a gender-related serious physical or mental disability, (ii) a gender-related serious illness, or (iii) any other gender-related serious medical condition, establishing the sex of the embryo ("1(c)")
d. Testing for Human Leukocyte Antigen (HLA) tissue-typing ("1(d)")
e. Testing where there is uncertainty about whose gametes were used to create the embryo ("1(e)")

1.2. 'Testing embryos' is a licensable activity – ie clinics need to have a licence that includes 'testing embryos' to be able to carry this out.

1.3. Furthermore, testing embryos under 1(b) and 1(c) can only take place for conditions approved by the HFEA's Statutory Approvals Committee (SAC), and testing embryos under 1(d) can only take place on a patient-by-patient basis following approval by SAC.

1.4. The methodologies for carrying out genetic testing have advanced significantly since the law was passed. Previously, different technologies were employed to look for chromosomal abnormalities and single gene disorders, now the same technology can be used to look for both. In recent years whole genome sequencing (WGS) which reveals the embryo's full genetic information, has become much cheaper and therefore more widely available. Such sophisticated testing now routinely generate data which goes beyond simple binary results for which the testing was originally sought. These developments raise the question of what, if any, additional information may lawfully be obtained from permitted testing. There is also the possibility of coming across genuinely accidental and unavoidable incidental findings, which, unlike additional findings, are not sought.

1.5. The Authority last considered the current practice and emerging issues relating to embryo testing at their September 2025 meeting and agreed that guidance for the sector is needed and should be brought back to the Authority for review. This paper provides an update on progress made on several related issues since and requests Authority decisions as follows:

- A draft of the guidance on embryo testing has been developed, see section 2. In order to finalise it, the Authority now need to make some decisions, as outlined in sections 3, 4, and 5.
- This year's business plan has a commitment to conduct an audit of the current list of approved conditions that can be tested for under 1(b) (see section 7 for information). As part of this work, we have considered the removal of the broad 'group' approval for "chromosomal rearrangements (various)" following the Authority's direction last September and are seeking an Authority decision on this (section 6).

- Following legal analysis, we have issued public statements on the unlawfulness of PGT-P (see section 7 information).
- Suggested next steps in the light of any decisions the Authority makes are set out in section 8.

2. Draft guidance on embryo testing

2.1. The intended purpose of the proposed guidance on embryo testing is to:

- Clarify the law regarding embryo testing and approvals required
- Provide licensed clinics with guidance on what the HFEA expects from clinics when carrying out embryo testing in accordance with the law for each Permitted Purpose
- Clarify if any additional genetic information can be obtained and used in clinical decision making
- Clarify the position on incidental findings

2.2. Points to note about the draft guidance:

- Some Authority members have already contributed to the drafting.
- Further, detailed legal analysis has been undertaken and incorporated into the draft guidance.
- We have avoided referring to the type of test (eg PGT-A, PGT-M etc) and are instead referring to the Permitted Purposes in the 1990 Act where possible. This is because there is varied understanding within the sector of the purposes for which embryo testing is permitted. This seems to be exacerbated by the use of terminology focused on specific tests (PGT-A, PGT-M and PGT-SR) rather than focusing on the purpose of the testing as set out in the legislation.
- We have avoided being overly prescriptive on which tests are and are not allowed, the onus is on the clinic to think about the Permitted Purposes and whether any test they are considering would satisfy those purposes. This also future proofs the guidance given the pace of advances in types and methods of testing.

2.3. There are some decisions that we need the Authority to consider, as outlined in sections 3, 4 and 5 after which we will finalise the guidance based on Authority's direction. See section 8 for next steps.

3. Requiring clinics to record the reason for testing under 1(a) and 1(e) – for decision

3.1. As noted above, testing under 1(a) is only lawful for an abnormality which may affect capacity to result in a live birth. Testing under 1(a) can, in theory, include abnormalities that are not limited to whole chromosome abnormalities (which we know do affect capacity to result in a live birth). We therefore propose requiring clinics to record the reason for testing under 1(a) where the test is for an abnormality that is not a whole chromosomal abnormality (eg chromosome rearrangements, microdeletions, microduplications), along with the supporting evidence and date on which the test has been requested, on a clinic form (eg a treatment booking form) before embryo testing is requested. Clinics would not be required to submit that information to the HFEA, but it may be the subject of inspection in the usual way.

3.2. Similarly, we propose requiring clinics to record the reason for testing under 1(e) before embryo testing is requested.

3.3. Should the Authority approve this way forward, we would set out what information must be recorded and will update General Directions 0005 as required.

3.4. **The Authority are asked to agree the recommended approach of requiring clinics to record the reason for testing under 1(a) and 1(e).**

4. The position on additional genetic information being obtained and used in clinical decision-making when testing under 1(b) – for decision

4.1. As noted above, under the 1990 Act embryo testing is allowed for one (or more) of the Permitted Purposes and the information obtained from the test(s), received by the clinic and acted upon by the clinic must be limited to the information permitted under that/those purpose(s).

4.2. However, the wording of the Act for testing under 1(b) is quite broad:

Schedule 2, 1990 Act
Para 1ZA – Embryo Testing

(1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality ***or any other*** *gene, chromosome or mitochondrion abnormality.*

4.3. Since 1(b) refers to 'any other' abnormality, the HFEA has the power to authorise testing for other HFEA-approved abnormalities for which there is not a particular risk. However, this is only where the precondition of a 'particular risk' to the embryo is first established in relation to an initial abnormality, and only where 'any other' abnormality likewise presents a significant risk that the child will have or develop a serious condition (ie is on the SAC approved list of conditions). This would, for example, allow for testing of an embryo where there is a particular risk the child will have a serious condition that has been approved by the SAC, whilst also allowing the receipt of information on any other approved conditions for which there is a significant risk. Embryos could be selected for on the basis of this additional information received (except for social sex selection).

4.4. Whilst the Authority has the power to authorise the testing of other SAC-approved abnormalities, it has a wide discretion in respect of whether and how to use this power. The 1990 Act provides that any testing licence authorised by the Authority may be subject to any conditions specified in the licence and may specify the manner in which it should be performed (Schedule 2, para 1). These provisions give the HFEA control over embryo testing.

4.5. In January 2016, the Authority agreed to allow testing of more than one genetic condition (provided the second disease was serious enough to be on the approved list), so long as patients consented to receive (or not receive) the information generated. This decision best reflected the legal position, and the Authority could see no evidence for being more stringent

than the law allowed. However, at that time there were only 438 conditions on the PGT-M list (today there are over 2,000) and testing methodologies were not as cheap and sophisticated as they are today. This meant that in practice, the number of other conditions that could be tested for was limited. Today, genome sequencing technologies are able to analyse the entire genome, allowing for many genetic abnormalities to be identified simultaneously.

4.6. The Authority agreed at the **September 2025 meeting** that the Act permits additional genetic information to be obtained and used in clinical decisions, provided it meets a Permitted Purpose and the testing was originally conducted for a Permitted Purpose.

4.7. Following on from the previous Authority discussions, and given that the HFEA has discretion as to whether to licence testing for other HFEA-approved abnormalities (as explained at paragraphs 4.3 and 4.4), **the Authority are now asked to decide which of the following positions to take on obtaining information on additional SAC-approved conditions with the intention of using that information in clinical decision making when testing under 1(b):**

a. Information on other HFEA-approved conditions **cannot be obtained**;
Potential benefits:

- Avoids population screening altogether and avoids unnecessary data collection.
- Reduces risk of unnecessary discard of embryos.
- Avoids inequality. Patients who have embryos known to have particular risk of a condition will not have unfair access to testing for a range of other conditions that other patients would not be permitted to access.

To consider:

- May be perceived as being too restrictive, patients may feel that this removes an opportunity to find out about other abnormalities and prepare for the challenges ahead.
- Failure to use the flexibility in this power may be seen as being overly restrictive and contrary to the Government and the HFEA's drive towards innovation.

b. Information on **some** other HFEA-approved conditions **can be obtained**.
Potential benefits:

- Gives patient(s) an opportunity to find out about other abnormalities and prepare for the challenges ahead.
- Could be viewed as promoting innovation.

To consider:

- We will have to be clear on where the boundaries lie; consent would serve as one natural boundary if we insist that each condition that the patient is consenting to testing of, needs to be discussed with a genetic counsellor and individually consented to (eg a tick box for each condition). A different way of thinking about the issue is setting a boundary that is scientifically/clinically appropriate allowing information to be obtained only for additional serious conditions that, for example, have a relationship (in a way that justifies testing for them too) to the condition for which there is a particular risk.
- We could require clinics to record the reason for testing for the 'other' HFEA-approved condition(s) along with the supporting evidence of relation to the initial condition and date on which the test has been requested, on a clinic form (eg a treatment booking form) before embryo testing is requested, as outlined in section 3.

- May not be in the patients' best interest as increases risk of unnecessary discard of embryos.
- May be considered as not equitable, as patients whose embryos qualify for testing under 1(b) are able to screen for other serious conditions.

4.8. Clinics should not seek to conduct what would amount to population screening for *all* other approved conditions using 1(b). This is because testing for 'any other' abnormality can only be done where the presence of the other abnormality/abnormalities each present a significant risk that the embryo in question will have or develop the associated serious condition. This will depend on patient-specific factors as well as the nature of the abnormality in question.

4.9. Furthermore, it is not possible to obtain fully informed consent for every potential SAC-approved condition in one test. The significance of each condition would need to be explained, and the patient would need to be offered implications counselling about each one. Clearly, this is not possible for over 2,000 conditions.

4.10. In considering these positions it should be noted that in recent years population screening of people in the UK has developed considerably, both in research and clinical settings, eg as part of the 100,000 Genomes Project | Genomics England, NHS England's NHS Genomic Medicine Service, Newborn Genomes Programme | Genomics England. However, the law on embryo testing set out in the 1990 Act is more prescriptive as explained at 4.8.

5. Approach to incidental findings being used in clinical decision making – for decision

5.1. In this paper, when we refer to 'incidental findings', we are referring to genuinely accidental and unavoidable incidental findings. Unlike additional findings, incidental findings are not sought. In the case of incidental findings, the patients would not have received counselling or given fully informed consent. Furthermore, in some cases the incidental finding may be of uncertain significance. Given modern methods of testing which allow for the filtering of information, such incidental findings should no longer arise.

5.2. However, it might be possible that limited incidental findings are unavoidably identified, therefore, it seems necessary to provide the sector with guidance on how to deal with truly incidental findings.

5.3. **The Authority are asked to agree the following recommended approach with regard to these unavoidable incidental findings**:

- The incidental finding must be truly incidental, and unavoidably identified, incidental findings are not sought for.
- If an incidental finding meets one of the Permitted Purposes, a clinic can report it back if the requirements for that Permitted Purpose are satisfied, including for 1(b) and 1(c) that there is a significant risk that the abnormality, that is on the SAC-approved list, will lead to a serious condition for that particular embryo.
- If an unavoidable incidental finding identified is one which has not been approved for testing by the HFEA under 1(b), but is one which the Person Responsible deems to be associated with a serious condition, then an application should be made to the SAC to have the condition approved.

5.4. This approach would be in conjunction with existing requirements for clinics around ensuring that an individual is available who understands and is able to explain to patients the nature of

the tests conducted, the scope and limitations , the accuracy and implications, and the meaning of the test results, and ensuring that patients have access to clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors as needed.

6. Removal of the 'Chromosomal rearrangements (various)' authorisation – for decision

6.1. In September 2025, the Authority agreed to a review of where a previous broad 'group' approval has been given for various conditions – that is, "chromosomal rearrangements (various)".

6.2. "Chromosomal rearrangements (various)" was approved as a group (prior to the law on embryo testing being codified in 2009), allowing testing under 1(b) for various chromosomal abnormalities without the need for individual approvals.

6.3. The methodologies for carrying out genetic testing have advanced significantly since this group approval, and it is now possible to receive additional information on rearrangements that would not meet the bar for risk/seriousness as is required under 1(b).

6.4. Given that the assessment of 'seriousness' is reserved to the HFEA, we propose removing the group "chromosomal rearrangements (various)" approval altogether as we have concerns (highlighted by recent clinic queries about 'technically approved' microdeletions where clinical implications are minimal or even unknown) that the existing group approval is allowing testing that may not satisfy the statutory threshold, making such testing potentially unlawful.

6.5. In Spring 2026, we carried out a survey of some clinics/companies that offer embryo testing which showed that most testing for chromosomal rearrangements is undertaken under provision 1(a). Therefore, we can determine that testing would largely continue without the need for additional approval by SAC if the "chromosomal rearrangements (various)" authorisation was removed. However, it is likely that a small subset of cases currently justified under 1(b) would now require SAC approval where in practice this may not have previously been sought, however the number is difficult to predict. In these cases, this would require clinics to apply to SAC in order to test.

6.6. Some (likely a small number) abnormalities which are currently being tested for under the "chromosomal rearrangements (various)" authorisation may neither fall under 1(a), nor meet the risk/seriousness threshold under 1(b). The removal of the existing group approval would prevent testing that does not satisfy the statutory threshold from taking place and may not therefore be welcomed by patients and organisations which represent them, clinics and testing companies. In such cases we can assist clinics to manage patient expectations by setting a transitional period for any changes.

6.7. **The Authority are asked to agree to the removal of the umbrella "chromosomal rearrangements (various)" authorisation from the approved list of conditions that can be tested for under 1(b).**

6.8. If the Authority agrees, the executive will consider the most appropriate process for removing the umbrella "chromosomal rearrangements (various)", see section 8 on next steps. including having a potential transitional period.

7. Other work carried out since September 2025 – for information

Audit of the list of conditions that can be tested for under 1(b)

7.1. As noted earlier, the HFEA, through SAC as a delegated committee, has a statutory responsibility to approve conditions that can be tested for under 1(b). SAC needs to be satisfied that there is (1) a significant risk that a person with the abnormality will (2) have or develop a serious condition. One of the factors taken into account when making such assessments is the treatability of that condition. Once a condition has been considered sufficiently serious, it is added to the **list of approved conditions**.

7.2. If the circumstances around treatability change, this could have an impact on assessments of seriousness. To ensure that we have only approved conditions which continue to meet the statutory criteria, the Authority made a commitment in July 2013 that the list of approved conditions would be reviewed every 5 years commencing from the date when the last review ended. The list was last reviewed in 2017 and was therefore due to be reviewed again in 2022 but was delayed.

7.3. The review of PGT-M conditions is included in the 2025/26 business plan and is currently ongoing. Clinics were notified of the commencement of this piece of work in the **September 2025 edition** of the HFEA's newsletter, Clinic Focus. We will notify the sector of the audit's outcomes, including where approval for conditions that can be tested for under 1(b) has been removed, if any.

PGT-P is not lawful and that there is no legal requirement to disclose genetic information to patients – for information

7.4. The Authority will be aware that much of the public discussion of embryo testing in recent months has concerned the use of preimplantation genetic testing involving polygenic scores, (PGT-P). In February 2026, the HFEA published a **blog on PGT-P** and an **article** in BioNews (publication by the Progress Educational Trust (PET)) to explain that PGT-P is unlawful in the UK as it does not identify a particular gene, chromosome or mitochondrial abnormality. These public statements also explain that embryos can only be selected for transfer based on information from testing that meets a specified purpose in law, and that the prohibition on performing PGT-P in the UK cannot therefore be circumnavigated by having the analysis carried out in another jurisdiction, and then using the results to select embryos.

7.5. Data about an embryo that cannot lawfully be used to make treatment decisions in the UK is not regarded as the patient's personal data. Therefore, patients do not automatically have a right to the embryo's full sequence of raw genetic data under UK's data protection laws. We will consider adding a requirement to make this a condition in Third Party Agreements with embryo testing companies.

8. Next steps

8.1. The guidance on embryo testing will be finalised based on the Authority's direction on sections 3, 4 and 5).

- We will gather feedback on the understandability and clarity of the guidance before it is finalised from, for example, some centres with a licence for embryo testing and relevant professional bodies.
- We may revert back to Authority members for further review, as needed.

8.2. Based on the Authority decision, the executive will consider the most appropriate process for removing the umbrella “chromosomal rearrangements (various)”, including having a potential transitional period. This could set out for, for example, that patients who have already started treatment and are in discussion about genetic testing may be able to proceed with testing as they would have done previously, however this testing should not be offered to new patients.

8.3. We will also update the Code of Practice, the Standard Licence Conditions, General Directions, the inspection notebook and other ancillary documents, where required. **We ask the Authority to delegate final sign off on these updates and the embryo testing guidance to the Chair.**

8.4. In due course, the Executive will remove terminology referring to the type of test (eg PGT-A, PGT-M etc) and instead refer to the permitted purposes in the act where possible across all our documents and platforms.

8.5. The Executive will develop a plan for communicating with centres, patients and stakeholders, as appropriate. This will likely include (but not limited to):

- Publication of the embryo testing guidance to the Clinic Portal
- Updates to our website
- A Clinic Focus article
- Updates at a SCAAC meeting and various stakeholder meetings eg Patient Organisation Stakeholder Group (POSG), Professional Stakeholder Group (PSG), Licensed Centres Panel

9. Annex A – Wording on genetic testing in the HFE Act 1990 (as amended), standard licence conditions and code of practice

Section 13, 1990 Act: Conditions for treatment

(1) The following shall be conditions of every licence under paragraph 1 of Schedule 2

to this Act….

(9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop—

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

(10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop—

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

(11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if—

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

(1) A licence under paragraph 1[1] cannot authorise the testing of an embryo, except for one or more of the following purposes—

(a) establishing **whether** the embryo has a gene, chromosome or mitochondrion abnormality that may affect its **capacity to result in a live birth,**

[1] Licences for treatment

(b) in a case where there is a **particular risk** that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing **whether** it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a **particular risk** that any resulting child will have or develop—

(i) a gender-related serious physical or mental disability,

(ii) a gender-related serious illness, or

(iii) any other gender-related serious medical condition,

establishing the **sex** of the embryo,

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

(e) in a case where **uncertainty has arisen** as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the **Authority is satisfied**—

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),

that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

(3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

(4) In sub-paragraph (1)(d) the reference to "other tissue" of the resulting child does not include a reference to any whole organ of the child.

Paragraph 1ZB - Sex selection

(1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where there is a particular risk that a woman will give birth to a child who will have or develop—

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition.

(4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Standard Licence Conditions on embryo testing:

T86. Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability
b. a serious illness, or
c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

T87. Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

a. a gender-related serious physical or mental disability
b. a gender-related serious illness, or
c. any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

T88. With respect to any embryo testing programme involving biopsy the centre must ensure that:

a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and
b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

T89. With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.

T90. This licence condition has been removed.

T91. Centres may use non-invasive procedures, for example metabolomics, to test and select for the viability of embryos. However, centres must not use these procedures to test for specific gene, chromosome or mitochondrion abnormality without prior authorisation from the Authority.

Extracts from the Code of Practice:

- Prohibitions on embryo selection are as follows:
  - Embryos with known abnormality where significant risk child will be born with a serious condition cannot be preferred to those that are not known to have that abnormality
  - Embryos where there is a particular risk that child will have a serious, gender-related condition cannot be preferred to those not known to carry such a risk
  - Any practice designed to secure social sex selection is prohibited

- The use of PGT-M or PGT-SR should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGT-M or PGT-SR in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.