Human Fertilisation & Embryology Authority

# Authority meeting

## Date: 25 September 2025 – 1.15pm – 4.10pm

## Venue: 2 Redman Place

| Agenda item | Time |
|---|---|
| 1. Welcome, apologies and declarations of interest (5) | 1.15pm |
| 2. Minutes of the meeting held on 9 July 2025 and matters arising (5)<br>For decision | 1.20pm |
| 3. Chair and Chief Executive's report (10)<br>For information | 1.25pm |
| 4. Committee Chairs' reports (20)<br>For information | 1.35pm |
| 5. Performance Report (30)<br>For information | 1.55pm |
| 6. Update from July horizon scanning meeting (verbal) (30)<br>For information | 2.25pm |
| Comfort break (10) | 2.55pm |
| 7. Embryo testing (60)<br>For decision | 3.05pm |
| 8. Any other business (verbal) (5) | 4.05pm |
| 9. Close | |

# Minutes of Authority meeting held on 9 July 2025

| Details: | |
|---|---|
| Area(s) of strategy this paper relates to: | Regulating a changing environment<br>Supporting scientific and medical innovation |
| Agenda item | 2 |
| Meeting date | 25 September 2025 |
| Author | Alison Margrave, Board Governance Manager |
| **Output:** | |
| For information or decision? | For decision |
| Recommendation | Members are asked to confirm the minutes of the Authority meeting held on 9 July 2025 as a true record of the meeting. |
| Resource implications | |
| Implementation date | |
| Communication(s) | |
| Organisational risk | Low |

# Minutes of the Authority meeting on 9 July 2025 held at 2 Redman Place, London

| | | |
|---|---|---|
| Members present | Julia Chain (Chair)<br>Tim Child<br>Frances Flinter<br>Tom Fowler<br>Zeynep Gurtin<br>Alex Kafetz | Alison McTavish<br>Geeta Nargund<br>Catharine Seddon<br>Rosamund Scott<br>Anya Sizer<br>Stephen Troup<br>Christine Watson |
| Apologies | Graham James<br>Rachel Cutting (Director of Compliance & Information) | |
| Observers | Steve Pugh, Department of Health and Social Care (DHSC) (online)<br>Amy Parsons, Department of Health and Social Care (DHSC) (online) | |
| Staff in attendance | Peter Thompson (Chief Executive)<br>Clare Ettinghausen (Director of Strategy & Corporate Affairs)<br>Tom Skrinar (Director of Finance & Resources)<br>Sophie Tuhey (Head of Planning and Governance)<br>Shabbir Qureshi (Risk and Business Planning Manager)<br>Amanda Evans (Head of Research and Intelligence – items 8 and 9)<br>Kazuyo Machiyama (Senior Research Manager – items 8 and 9)<br>Alison Margrave (Board Governance Manager) | |

**Members**

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

## 1. Welcome, apologies and declarations of interest

**1.1.** The Chair opened the meeting by welcoming Authority members and HFEA staff to the 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:

- Geeta Nargund (Pro Chancellor at Portsmouth University)
- Anya Sizer (freelance advisory work within the fertility sector)
- Stephen Troup (consultancy work within the fertility sector)
- Tim Child (consultancy work within the fertility sector overseas)
- Alex Kafetz (non-executive director (Board Member) of the Care Quality Commission)

## 2. Minutes of the last meeting and matters arising

**2.1.** The Chair informed the meeting that a proposed amendment had been received for minute 5.33 to amend the wording “outstanding good performance” to “consistently very good performance”. This amendment was agreed by the Authority.

**2.2.** The amended minutes of the meeting held on 21 May 2025 were agreed as a true record of the meeting and could be signed by the Chair.

**2.3.** The Chair informed members that there were no matters arising from the previous meeting.

## 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 attended the annual accountability meeting with the HFEA's sponsor team in May and spoke of the positive relationship that the HFEA has with the Department.

**3.3.** At the beginning of June, the Chair had attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting and had also participated in the shortlisting exercise for the SCAAC external adviser vacancy who has expertise in the use of artificial intelligence, machine learning and big data in healthcare or biological science/research.

**3.4.** The Chair informed the Authority that she and the Chief Executive had met with representatives from the Fertilis Group of clinics, a group of private clinics. She spoke of the positive ways in which the HFEA engages with the sector and this meeting is just one example of this engagement.

**3.5.** The Chief Executive informed the Authority that he had met with the Regulatory Horizons Council (RHC) to discuss their work on IVGs. He explained that the RHC is an independent expert committee that identifies the implications of technological innovation, and provide government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction.

### Decision

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

## 4. Committee Chairs' reports

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

**4.2.** The Statutory Approvals Committee (SAC) Chair (Frances Flinter) stated that the committee continues to meet monthly with full agendas, often considering complicated and challenging issues. As detailed in the paper, on occasion it has been necessary to adjourn decision making to gather further information. The SAC Chair praised the work of the staff who manage the workload of this committee.

**4.3.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC held its last meeting on 17 June 2025 and had considered the draft Annual Report and Accounts and had recommended that these be signed. The committee also received the management letter from the auditors which gave the HFEA a clean bill of health. The committee had endorsed Alex Kafetz as the committee's Information Security lead for working with the Executive. The committee had discussed the ways of working with GIAA and agreed plans to close outstanding audit recommendations. The committee had discussed the proposals for the assessment under the new Cyber Assessment Framework (CAF) DSPT. Additionally, the committee had considered the Strategic Risk Register and the new HR strategy.

**4.4.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed the Authority that the committee had last met on 9 June 2025. They had considered and approved an application for platelet-rich-plasma (PRP) to be added to the HFEA's rated treatment add-on-list. The SCAAC Chair explained to members the committee's recommendation to amend the definition of treatment add-ons to include tests. The committee had also discussed the impact of the microbiome on fertility and fertility treatment outcomes, as well as health outcomes for ART patients, including gestational surrogates and egg donors and relevant public health developments and research findings. He reported that the HFEA had held its annual horizon scanning meeting at ESHRE 2025 and an update from this will be brought to the September Authority meeting. The SCAAC Chair also informed members that two new external advisors had been appointed to the committee: Asif Muneer, an urological surgeon and andrologist; and Sarah Martins da Silva, a consultant gynaecologist and reproductive medicine researcher. Recruitment is ongoing for an advisor with expertise in the use of artificial intelligence, machine learning and big data in healthcare or biological science/research.

**4.5.** The Licence Committee Deputy Chair (Alison McTavish) informed the Authority that the committee had last met on 16 June 2025 and had considered the interim inspection report of the Homerton Fertility Centre, a centre that has been under considerable regulatory scrutiny in recent years, including a 5-month period of suspension in 2024. The committee had been pleased that the PR of this centre is engaging well with the HFEA inspectorate. The interim inspection report was very positive and found no areas of practice that required improvement, so the Licence Committee was able to continue this centre's licence.

**4.6.** The HFEA Chair stated that this was a very encouraging report from the Licence Committee and acknowledged the support which the HFEA had provided for this centre to improve its work.

**4.7.** The Chair thanked all Committee Chairs for the reports and expressed sincere 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.

## Decision

**4.8.** The Authority agreed the proposal from SCAAC to amend the definition of treatment add-ons to include tests, as set out below (new proposed wording underlined):

*Treatment add-ons are optional non-essential treatments <u>and tests</u> that may be offered in addition to such proven fertility treatment. The HFEA provides information on add-ons that meet the following criteria:*

- *Additional treatments <u>and tests</u> (to the core treatment e.g. IVF or IUI), that are being offered to the general patient population in licensed fertility clinics in the UK,*
- *where there are published scientific studies which claim to demonstrate that the treatment add-on improves the chances of having a baby or other treatment outcomes rated by the HFEA; but*
- *where evidence of effectiveness for the use of the treatment in a clinical setting is lacking or absent; and*
- *where patients need unbiased information about the effectiveness and risks of this <u>test or</u> treatment.*

**4.9.** Members noted the Committee Chairs' reports.

### Action

**4.10.** Executive to implement the agreed changes to the definition of treatment add-ons.

## 5. Performance report

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

**5.2.** The Chief Executive stated that the HFEA's performance across all 19 KPIs had been strong in May, with 12 indicators rated Green, three Neutral and four rated Red. For those KPIs which are rated red there is a particular reason for this, rather than a structural issue.

**5.3.** The Chief Executive referred to the HR KPIs and commented that there had been a small increase in staff sickness, and this can be contributed to seasonal illnesses. The Chief Executive reported that the issue of long-term sick leave will reduce due to ill health retirement being approved for a member of staff.

**5.4.** Whilst there has also been an increase in staff turnover, this is within the bottom end range of the HFEA's target and is still manageable. The Chief Executive remarked that as a small ALB with limited scope for promotion it is inevitable that staff will move on from their employment with the HFEA to seek promotion. He informed the Authority that the new HR strategy was presented to the AGC in June 2025, and an all-staff event is planned for next week.

### Compliance and Information

**5.5.** The Chief Executive presented the Compliance and Information KPIs and informed the Authority that the HFEA measures the outcome and process for licensing. The KPIs for 'inspection reports to committee' and 'end-to-end-licensing' are both green with the targets being met.

**5.6.** The KPI for 'inspection reports to PR' was red. The Chief Executive explained that these delays were for genuine reasons such as a complex report, or further engagement with PR required, and assured the Authority that there are no structural issues for concern.

**5.7.** The Chief Executive reported that 16 PGT-M applications were received in May. All applications due in May were processed within target, with an average processing time of 52 days. The Chief Executive explained in detail the amount of work required to process PGT-M applications.

**5.8.** A member questioned whether the high number of PGT-M applications could be linked to media stories championing PGT-M. The Chief Executive responded that PGT-M applications fluctuate and is a demand led process, the HFEA does not solicit applications; these are driven by clinics.

**5.9.** A member commented that 5-10 years ago, PGT-M was used only for the more common genetic disorders such as Huntington Disease or Cystic Fibrosis, but due to developments in genomics it is now possible to diagnose more complex disorders. There is also an increased take-up of carrier testing before treatment which could also contribute to the increase in PGT-M applications.

**5.10.** In response to a question on whether there was any learning from the extensive QA that was needed for a few inspection reports, the Chief Executive explained the QA system and the nuances of some of the recent complex cases.

**5.11.** The Authority was informed that the three Opening the Register (OTR) KPIs were green, with 171 OTRs being processed and a reduction in the waiting list being achieved. The Chief Executive

reported that a higher number of OTRs were received and there were no specific reason for this increase.

**5.12.** In response to a question, the Chief Executive stated that OTR applications are broadly following expectations, with a steady increase. It is hoped that the investment in the new IT systems and increased staffing levels will help to ensure that applications are manageable, but in the future it may be necessary to increase resources.

### Strategy and Corporate Affairs

**5.13.** The Director of Strategy and Corporate Affairs highlighted some of the main points arising from the Fertility Trends report which was published last month, and spoke of the high media interest in this report. Over 200 pieces of individual media coverage were achieved, with every national outlet covering the publication. The 'one child in every classroom' headline was used across much of the media coverage. The Director of Strategy and Corporate Affairs stated that this coverage highlighted that the HFEA's data is viewed as accurate and informative.

**5.14.** The Director of Strategy and Corporate Affairs spoke of the media requests regarding licensing questions, private sperm donors and egg donation. The Authority was informed that there was a short debate in Westminster Hall on egg donation and related issues.

**5.15.** The Director of Strategy and Corporate Affairs stated that work has started on the annual 'State of the Fertility Sector' report, which is published in Autumn, reporting on compliance, non-compliance, incidents and safety of the fertility sector.

**5.16.** The Director of Strategy and Corporate Affairs informed the Authority that the KPIs for Freedom of Information (FOI) requests and Parliamentary Questions (PQs) are both green, with the targets for response times being met. Authority members were informed that the range of FOI requests are increasing in complexity.

**5.17.** The Director of Strategy and Corporate Affairs stated that the Licensing team is working well and managing the workload. The process for PGT-M applications was explained and the level of work across different teams highlighted.

**5.18.** In response to a question regarding the dip in social media usage, the Director of Strategy and Corporate Affairs stated that Communications team may take the decision to pause or delay pushing out social media interactions due to other events happening nationally and internationally. Social media usage was expected to increase in June due to the media interest in the Fertility Trends report.

**5.19.** The Authority congratulated the Executive for the media coverage obtained for the Fertility Trends report, with members stating that the headline had been extremely good and helped to raise awareness. In response to a question, the Director of Strategy and Corporate Affairs confirmed that the HFEA can track how long users stay on HFEA website pages and stated that after each major publication there is a lessons learnt exercise conducted which helps shape future work.

**5.20.** In response to a question regarding proactive media activity around routine publications and using the HFEA's authoritative voice, the Director of Strategy and Corporate Affairs commented that these types of activities are planned under the "use our voice" section of the new HFEA Strategy for 2025-2028.

## Finance, Planning and Technology

**5.21.** The Director of Finance, Planning and Technology informed members that the HFEA's business plan for 2025-26 has been completed and the final version has been shared with DHSC for publication.

**5.22.** The Strategic Risk Register (SRR) had a grass roots review conducted in line with the new strategy for 2025-2028. This was reviewed by the Audit and Governance Committee in June 2025 and is brought to the Authority for consideration later in the agenda.

**5.23.** Together with the Chair, a review of the Board Effectiveness documents has taken place and further work on these will be undertaken.

**5.24.** The Director of Finance, Planning and Technology reported that the Phoenix Programme is progressing well and is within time and budget tolerance. There continues to be good engagement across the teams within the HFEA in designing and testing the new systems and tools.

**5.25.** The Director of Finance, Planning and Technology informed the Authority that the team had been working closely with an external consultant regarding testing and developing the HFEA's business continuity plan. An exercise with the Senior Management Team has been held and a further activity is planned for the forthcoming all-staff meeting.

**5.26.** The Director of Finance, Planning and Technology spoke of the hard work across the IT and Information Governance teams to gather all the necessary evidence which is required to support the new Cyber Assessment Framework aligned DSPT requirements.

**5.27.** The Director of Finance, Planning and Technology stated that it has been an extremely busy time for the Finance Team in preparing the annual accounts, especially responding to National Audit Office (NAO) requests regarding PRISM data. He thanked both the IT and Finance teams for their work in this regard.

**5.28.** The Director of Finance, Planning and Technology referred to the draft annual accounts which the Authority will consider at later agenda item and stated that the bottom line for 2024-45 is a surplus of £475,000. This position is higher than expected due to several accounting adjustments made during the audit. He commented that it is too early to have a clear picture of the 2025-26 position and a full Q1 review is currently taking place.

**5.29.** The Director of Finance, Planning and Technology informed the Authority that the extent of work that was required to support the NAO audit has put pressure on the Finance team, although this is expected to reduce now that the audit has been completed.

**5.30.** In response to a question, the Director of Finance, Planning and Technology informed the Authority that the KPI regarding payment of invoices is on value rather than volume. There were a few large invoices relating to the Phoenix Programme which needed checking by both IT and Finance, so this delayed approval. He explained further the aged debt and the work being undertaken to collect this.

## Decision

**5.31.** Members noted the performance report.

## 6. Publication of the HFEA Annual Report and Accounts for 2024/25

**6.1.** The Director of Finance, Planning and Technology introduced the paper and informed the Authority that the Audit and Governance Committee had considered the draft Annual Report and Accounts at their June 2025 meeting and had agreed that subject to any NAO changes, the Accounting Officer could sign the Annual Report and Accounts.

**6.2.** The Director of Finance, Planning and Technology explained the engagement of the NAO and KPMG in the preparation of this document and that the audit was completed without any qualifications. It is anticipated that the Comptroller and Auditor General will sign the accounts shortly which would allow them to be laid in Parliament before recess.

**6.3.** As defined in the HFEA's standing orders, approval is now sought from the Authority for the Accounting Officer to sign the Annual Report and Accounts. The Director of Finance, Planning and Technology stated that a small number of typographical errors had been identified and these will be corrected.

### Decision

**6.4.** The Authority agreed that subject to NAO changes, the Accounting Officer could sign the Annual Report and Accounts.

### Action

**6.5.** Executive to continue liaising with NAO to lay the HFEA Annual Report and Accounts 2024-25 in Parliament before recess.

## 7. Strategic Risk Register

**7.1.** The Chair introduced this item by informing the Authority that when a new strategy is approved, a grass roots review of the Strategic Risk Register (SRR) is conducted to ensure that it aligns with the new strategy. The Chair reminded the Authority that the SRR is brought to the Authority twice a year for review.

**7.2.** The Risk and Business Planning Manager introduced the paper and informed the Authority of the process of the grass roots review of the SRR.

**7.3.** The Risk and Business Planning Manager explained that the existing categories for the SRR, as per the Orange Book, have been maintained. The Senior Management Team (SMT) had considered the strategic risks facing the HFEA in light of the current environment and these key risks are recorded in the SRR.

**7.4.** The Risk and Business Planning Manager informed the Authority that the SRR had been presented to the Audit and Governance Committee (AGC) in June 2025 and after discussions, had been agreed by the AGC.

**7.5.** The AGC Chair informed the Authority that the AGC had welcomed the zero-based review conducted by the SMT and this has made the SRR an active, dynamic management tool.

**7.6.** Several members congratulated the HFEA team for the clear, easy to read presentation of the SRR.

**7.7.** In response to a question, the Director of Finance, Planning and Technology commented that the majority of the DSPT focuses on managing cyber risk, and where appropriate the HFEA seeks external advice on managing these risks. A member commented that the HFEA would also be following the National Cyber Security Centre advice, which is attuned to cross governmental advice.

**7.8.** In closing the discussion, the Chair recorded the Authority's thanks to the SMT and the HFEA team for all their hard work.

Decision

**7.9.** The Authority noted the Strategic Risk Register.

## 8. Register Research Panel (RRP) Annual Report

**8.1.** The Chair introduced the agenda item and informed the Authority that they will be sitting as the Oversight Committee to consider this item.

**8.2.** The Head of Research and Intelligence introduced the paper and reminded members that the HFE (Disclosure of Information for Research Purposes) Regulations 2010 allow the disclosure of information for research purposes, and that the Authority has delegated authorisation for this to the Register Research Panel (RRP).

**8.3.** The HFEA holds a statutory register of all patients, partners, donors, treatments and children born as a result of fertility treatment and it is believed to be the longest running national database of assisted reproduction treatment in the world.

**8.4.** One of the HFEA's key strategic ambitions is to continue to increase the availability and benefit of its data for patients, clinics and researchers.

**8.5.** The Head of Research and Intelligence spoke of the reason why the HFEA collects data and how it can be used to have an oversight of the fertility sector and to look for trends and where improvements can be made. Reference was made to making data available to researchers conducting important research and the range of data reports which the HFEA publishes.

**8.6.** The Head of Research and Intelligence stated that the HFEA regularly publishes data research reports which receive wide media coverage. The Fertility trends report was published in June 2025, and this report is the HFEA's annual statistical release and is the main point of reference for all data-related enquiries received throughout the year. Members were informed that the Family formations in fertility treatment 2022 report was published in November 2024.

**8.7.** In March 2025, the HFEA published the third edition of the National Patient Survey. The survey explored how patient experience of fertility treatment in the UK has changed over the last decade, including satisfaction of treatment which remains high, as well as waiting times and treatment add-on use. The Head of Research and Intelligence stated that there were 1,500 responses to this survey.

**8.8.** The Head of Research and Intelligence reminded the Authority that in 2024 the award-winning HFEA dashboard was launched as a new tool to better enable public access to a wider breadth of data in a simplified and customisable format. Since release, the dashboard has been updated annually alongside Fertility Trends to include a new year of data, as well as updated to add improvements or include further data. The dashboard received over 65,000 views in its first year

of operation and presentations on the dashboard were given at various meetings and events including Royal Statistical Society (RSS), Data Bites by Public Digital and DataConnect24. The HFEA dashboard also won the 2024 Trustworthiness, Quality & Value Award presented by the Office for Statistics Regulation in partnership with the RSS.

**8.9.** The Senior Research Manager informed the Authority that the RRP had met six times during the year and had fully approved two projects and another one with conditions. The Senior Research Manager spoke of the projects which had been approved in 2024-25 and provided a brief overview of each project.

**8.10.** The Senior Research Manager informed the Authority that since 2010 there had been 26 peer-reviewed academic articles published from RRP approved research projects and 32 from anonymous HFEA data sources such as the anonymised register.

**8.11.** The Senior Research Manager spoke of the activities undertaken to support the strategic aim to increase the availability and benefit of the HFEA's data. This included the launch in July 2024 of the HFEA Data Research Update Newsletter. The Authority was informed that there have been four editions published so far, with a high open rate of around 60%.

**8.12.** The Authority was informed that the Research and Intelligence team had hosted their first webinar titled 'Accessing the UK fertility national register for research' in February 2025. This webinar provided an introduction to the HFEA, an overview of data the HFEA holds on the register, how to access register data, and finished with a Q&A session. 180 people signed up for the webinar, 82 attended the session live, and feedback received was very positive. The Authority was informed that the full recording has been made available on the HFEA YouTube channel and the data research webpage.

**8.13.** The Authority congratulated the Research and Intelligence Team for the work which has been done to make the HFEA's data accessible in an easy-to-understand format and the increased engagement through the newsletter and webinar.

**8.14.** In response to a question, the Director of Strategy and Corporate Affairs confirmed that each approved project has its own page on the data research page of the HFEA website.

**8.15.** In response to a question, the Senior Research Manager stated that whilst there has been some international interest, it is a requirement of applications that these must be from a UK-based research establishment.

**8.16.** In response to questions about what the HFEA does or can do to stimulate future applications to the RRP, the Head of Research and Intelligence referred to the work which is set out in the new HFEA Strategy for 2025-2028. The Head of Research and Intelligence referred to the positive feedback received on the webinar and how this will be used to help shape future engagement activities with researchers.

**8.17.** A member referred to the Fit for the future: 10 Year Health Plan for England, the emphasis this places on data research and questioned whether the HFEA had explored whether its data could be used as part of this plan. The Senior Research Manager responded that the HFEA is in contact with DHSC regarding increasing data availability to researchers and will consider how this may align with the HFEA's strategic aims.

**8.18.** The Chair drew the discussion to a close and thanked the Head of Research and Intelligence and the Senior Research Manager for their informative presentation on the use of the HFEA's data.

### Decision

**8.19.** The Authority, sitting as the Oversight Committee, noted the Annual Report of the Register Research Panel.

## 9. Choose a Fertility Clinic (CaFC): focussed consultation

**9.1.** The Director of Strategy and Corporate Affairs introduced the paper and reminded the Authority that they last discussed Choose a Fertility Clinic (CaFC) in May 2025. At that meeting, the background to CaFC was set out including updates to the headline metrics which were then published as an 'interim CaFC' in May 2025.

**9.2.** At this meeting the Authority noted that by the end of 2025, CaFC will be updated with detailed data to the end of 2023 (births) and 2024 (pregnancies) and the metrics used in this publication would be decided following a focused consultation with the sector and patient groups on the most appropriate metrics for the upcoming 'full' CaFC publication. The Authority also agreed that following the publication of the full CaFC later in 2025, the HFEA should review the different information sources held on the HFEA website and consider whether they should be brought together in a more unified or different way.

**9.3.** The Director of Strategy and Corporate Affairs stated that this paper outlines only the planned focused consultation on the headline metrics for the full CaFC publication in late 2025. The metrics, as presented in the paper, were explained and in response to a question, clarification was provided by professional members on the difference between 'births per embryo transfer' and 'births per embryo transferred'. A member suggested that defining the former as 'births per embryo transfer *procedure'* may help aid understanding.

**9.4.** The Director of Strategy and Corporate Affairs reminded the Authority that they last discussed multiple births in March 2025 when it was noted that the national average multiple birth rate is now below 3.5% and 92% of clinics with over 150 IVF cycles are below the 10% rate. The Authority agreed at the meeting that the current multiple birth rate of 10% should be maintained, but that reporting at inspection and in the following inspection reports should only be *by exception* when a clinic is above the 10% rate. The Authority is therefore being asked whether the multiple birth rate for every clinic should be removed from the headline rate on CaFC and only reported by exception where the rate is above 10%.

**9.5.** In response to a question, the Director of Strategy and Corporate Affairs stated that the focussed consultation will be built using 'Survey Monkey', which is user friendly and there will be a free text comment box included. Respondents will be able to select in what capacity they are completing the survey and that individual staff members from clinics would be encouraged to complete the focussed consultation in addition to any formal response from the clinic that they are working in.

**9.6.** A member who had reviewed the proposed text and questions for the focussed consultation confirmed that it had been written with a lay person viewpoint in mind and that there is explanatory text included.

**9.7.** The Authority discussed the potential outreach of the focussed consultation and whether this should be expanded by sending it to other professional bodies, such as obstetricians and midwives, as well as ensuring that minority groups are represented. The ability to capture patient views and not just professionals was discussed. The Director of Strategy and Corporate Affairs

referred to the different stakeholder groups that the HFEA works with and who will be invited to participate in the focussed consultation, and explained the range of professional bodies in the Professional Stakeholder Group (PSG) and the outreach in the Patient Engagement Forum (PEF) and Patient Organisation Stakeholder Group (POSG). The Director of Strategy and Corporate Affairs commented that there is also a balance to be struck between quantity of responses versus ability to report back to Authority in the Autumn on this.

**9.8.** In response to a question, the Chief Executive reminded members that respondents to the survey will be asked to rank the proposed metrics as to their preferred options.

**9.9.** The Authority discussed that as a national regulator, it is necessary and appropriate for the HFEA to publish up-to-date data on the website as quickly as possible pursuant to its statutory duty under s.8(1)(c) of the Human Fertilisation and Embryology Act 1990 (as amended). The Authority noted the importance of having an authoritative source of data to help inform choice and that this is in the interest of the public and patients.

**9.10.** The Authority discussed the question regarding displaying the multiple births data and they agreed that the metric on reporting multiple births should be retained with no changes and should therefore be excluded from the focussed consultation.

**9.11.** The Authority discussed the staged approach, noting this focussed consultation is the first step in the HFEA's review of the different information sources held on the HFEA website and whether these can be brought together in a more unified or different way.

**9.12.** The Chief Executive reminded the Authority that the results of the focussed consultation can be used to help inform the decisions the Authority makes, but as a statutory regulatory body it is the responsibility of the Authority to make such decisions. This focussed consultation is a means of gathering information which can help inform the Authority's decisions.

### Decision

**9.13.** The Authority agreed that:

- a focussed consultation is published over the summer with a read out of the responses coming to Authority in Autumn 2025 for discussion and decision over the full CaFC publication.
- the HFEA should seek views on the four metrics set out at paragraph 4.3 of the paper before the Authority, noting that the inclusion of "procedure" within some of the metrics might help aid understanding of the questions being asked.
- the metric on reporting multiple births should be retained as currently presented and therefore no requirement to consult on this metric.

### Action

**9.14.** The Executive to implement the Authority's decisions regarding the focussed CaFC consultation.

## 10. Any other business

**10.1.** The Chair thanked everyone for their active participation in the meeting. There being no further items of any other business the Chair closed the meeting and reminded members that the next Authority meeting will be held on Thursday 25 September 2025.

## Chair's signature

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

Signature

Chair: Julia Chain

Date: 25 September 2025

# 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: | 25 September 2025 |
| 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: | 2025/26 business year |
| Communication(s): | |
| Organisational risk: | Low |

| Date and item | Action | Responsibility | Due date | Revised due date | Progress to date |
|---|---|---|---|---|---|
| 09/07/2025 item 4.10 | Executive to implement the agreed changes to the definition of treatment add-ons | Director of Strategy and Corporate Affairs | September 2025 | | Changes are being implemented. |
| 09/07/2025 item 6.5 | Executive to continue liaising with NAO to lay the HFEA Annual Report and Accounts 2024/25 in Parliament before recess. | Director of Finance, Planning and Technology | August 2025 | | The accounts were successfully laid in Parliament before recess on 17 July 2025. |
| 09/07/2025 item 9.14 | The Executive to implement the Authority's decision regarding the focused CaFC consultation. | SMT | Autumn 2025 | | The focused consultation was launched on 18 August 2025 and a report will be made to Authority in the Autumn. |

# 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: | 25 September 2025 |
| Author: | Julia Chain, Chair and Peter Thompson, Chief Executive |
| Annexes | N/a |

## Output from this paper

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

# 1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meeting in July 2025.
- Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

# 2. Activities

## 2.1 Chair activities

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

    - 14 July –attended the twice yearly all-staff event.
    - 16 July – Chaired the Remuneration Committee.
    - 17 July – attended the ALB Senior Leaders meeting (all ALB Chairs and Chief Executives, plus senior DHSC leaders) with the newly appointed Permanent Secretary of DHSC.
    - 28 July – Tim Child, Alex Kafetz and I conducted interviews for the external adviser vacancy on SCAAC.

## 2.2 Chief Executive

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

    - 11 July – attended the DHSC/HFEA quarterly accountability meeting.
    - 14 July –attended the all-staff event.
    - 16 July – attended the Remuneration Committee meeting
    - 17 July – attended the ALB Senior Leaders meeting.
    - 23 September – attended the ALB Senior Leaders meeting.
    - 25 September – met a delegation from the French Parliamentary Office for Scientific and Technological Assessment (OPECST).

# 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: | 25 September 2025 |
| Author: | Caroline Pringle, Head of Licensing |
| Annexes | - |

## Output from this paper

| | |
|---|---|
| For information or decision? | For information and decision |
| 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:** | | | |
| 17 July | Interim research inspection | University of Cambridge, Centre for Trophoblast Research, Physiology Building | Approved – licence continued |
| | Interim research inspection | University of Cambridge, Centre for Trophoblast Research, Genetics Building | Approved – licence continued |
| | New research licence | Edinburgh Fertility Preservation | Adjourned pending further information |
| | Executive update on renewal inspection | The Fertility & Gynaecology Academy | Approved – 4 year licence |
| 11 September | Renewal inspection report | Birmingham Women's Hospital | Minutes not yet approved |
| | Renewal inspection report | St Jude's Women's Hospital | Minutes not yet approved |
| | Executive update | Bourn Hall Clinic | Minutes not yet approved |
| | Variation of PR | Homerton Fertility Centre | Minutes not yet approved |
| | Variation of PR | Bridge Clinic | Minutes not yet approved |
| Other comments: | Licence Committee will next meet on 6 November 2025. | | |
| **Executive Licensing Panel:** | | | |
| 24 June | Initial inspection report | Semovo Sheffield | Approved – 4 year licence |
| | Renewal inspection | Jessop Fertility | Approved – 4 year licence (and ITE certificate) |
| | Interim inspection report and variation of SLC T52 without application | Gloucestershire Hospitals NHS Trust | Approved – licence varied |

| Date | Items considered | Centres | Outcomes |
|---|---|---|---|
| | Interim inspection report and variation of SLC T52 without application | Care Fertility Northampton | Approved – licence varied |
| | Variation of PR | TFP Simply Fertility | Approved – licence (and ITE certificate) varied |
| | Variation of PR, LH, and SLC T52 without application | The James Cook University Hospital | Approved – licence varied |
| | Variation of PR and LH | Hull & East Riding Fertility | Approved – licence (and ITE certificate) varied |
| 8 July | Renewal inspection report | University College London Hospitals | Approved – 4 year licence (and ITE certificate) |
| | Interim inspection report and variation of SLC T52 without application | Semovo Glasgow | Approved – licence varied |
| | Variation of premises | MRC Laboratory of Molecular Biology | Approved – licence varied |
| | Variation of PR and variation of SLC T52 without application | Care Fertility Nottingham | Approved – licence (and ITE certificate) varied |
| | Variation of PR and variation of SLC T52 without application | St Mary's Hospital | Approved – licence (and ITE certificate) varied |
| 23 July | Renewal inspection report | Wolfson Fertility Centre – Hammersmith Hospital | Approved – 4 year licence (and ITE certificate) |
| | Renewal inspection report | Royal Derby Hospital | Approved – 4 year licence |
| | Renewal inspection report | Shropshire and Mid-Wales Fertility Centre | Approved – 4 year licence (and ITE certificate) |
| | Interim inspection report and variation of SLC T52 without application | London Women's Clinic, Darlington | Approved – licence varied |
| | Variation of PR | Wolfson Fertility Centre – Hammersmith Hospital | Approved – licence (and ITE certificate) varied |
| | Variation to add embryo testing and variation of SLC T52 without application | Concept Fertility | Approved – licence varied |
| | Variation of PR and variation of SLC T52 without application | Sussex Sperm Bank | Approved – licence (and ITE certificate) varied |
| 5 August | Research renewal inspection report | Human Embryo Research Centre | Approved – 3 year licence |
| | Variation of premises | The Francis Crick Institute | Approved – licence varied |

| Date | Items considered | Centres | Outcomes |
|---|---|---|---|
| | Variation of PR and variation of SLC T52 without application | Aberdeen Fertility Centre | Approved – licence (and ITE certificate varied) |
| 19 August | Renewal inspection report | Centre for Reproductive Medicine, Coventry | Approved – 4 year licence (and ITE certificate) |
| | Variation of PR | NUH Life Fertility Services | Approved – licence varied |
| | Special directions to allow the continuation of licensed activities | St Jude's Women's Hospital | Approved – special direction granted |
| 2 September | Renewal inspection report | In-OVO Fertility Clinic | Minutes not yet approved |
| | Renewal inspection report | Hewitt Fertility Centre | Minutes not yet approved |
| | Interim inspection report and variation of SLC T52 without application | Care Fertility Cardiff | Minutes not yet approved |
| 15 September | Renewal inspection report | Care Fertility London | Minutes not yet approved |
| | Variation of premises | TFP GCRM Fertility | Minutes not yet approved |
| Other comments: | None. | | |

## Licensing Officer decisions:

| | | | |
|---|---|---|---|
| June | 8 x ITE import certificates | Various | All granted |
| July | 14 x ITE import certificates | Various | All granted |
| August | 18 x ITE import certificates | Various | All granted |
| 1 July 2025 | Variation – Change of LH | Living Systems Institute | Approved – licence varied |
| 26 August 2025 | Voluntary Revocation | The Francis Crick Institute | Approved – licence revoked |
| 26 August 2025 | Change of Address | Avenues | Approved – licence (and ITE certificate) varied |
| Other comments: | The two research projects licensed at The Francis Crick Institute are also licensed at other HFEA licensed centres and will continue at those locations, following the voluntary revocation of the licence at The Francis Crick Institute. | | |

## Statutory Approvals Committee:

| | | | |
|---|---|---|---|
| 23 June | PGT-M: Intellectual Development Disorder with or without Peripheral Neuropathy, OMIM #619844 | Guys Hospital | Approved |

| Date | Items considered | Centres | Outcomes |
|---|---|---|---|
| | PGT-M: Leukoencephalopathy with Brainstem and Spinal Cord Involvement and Lactate Elevation, OMIM #611105 | The Centre for Reproductive and Genetic Health Trading as CRGH Portland | Approved |
| | PGT-M: Deafness, Autosomal Dominant 11, OMIM #601317 (Patient-specific licence) | Care Fertility Nottingham | Approved |
| | PGT-M: Hypotonia—Cystinuria Syndrome, OMIM #606407 | TFP Oxford Fertility | Approved |
| | PGT-M: Medical sex selection in addition to Breast Ovarian Cancer Familial Susceptibility (BRCA2 and BRCA1), OMIM numbers: *113705, *600185 and #612555 | Care Fertility Nottingham | Approved |
| | Special directions for import of embryos from USA | Bourn Hall Clinic Norwich | Approved |
| | Special direction for import of embryos from Spain | Chelsea & Westminster Hospital | Adjourned pending further information |
| | Special direction for import of embryos from Czech Republic | The Fertility & Gynaecology Academy | Adjourned pending further information |
| 29 July | Diastrophic Dysplasia (DTD), OMIM #222600 | Birmingham Women's Hospital | Approved |
| | Fibrochondrogenesis 1, (FBCG1), OMIM #228520 & FBCG2 OMIM #614524 | The Centre for Reproductive and Genetic Health t/a CRGH Portland | Approved |
| | GM2-Gangliosidosis, AB Variant, OMIM #272750 | Care Fertility Nottingham | Approved |
| | Galloway-Mowat Syndrome 7 (GAMOS7), OMIM #618348 | Glasgow Royal Infirmary | Approved |
| | Perlman Syndrome (PRLMNS), OMIM #267000 | Birmingham Women's Hospital | Approved |
| | Pierson Syndrome (PIERS), OMIM #609049 | TFP Oxford Fertility | Approved |

| Date | Items considered | Centres | Outcomes |
|---|---|---|---|
| | Spastic Tetraplegia, Thin Corpus Callosum, and Progressive Microcephaly (SPATCCM), OMIM #616657 | The Centre for Reproductive and Genetic Health t/a CRGH Portland | Approved |
| | Special direction for export of sperm to Nigeria | Herts and Essex Fertility Centre | Approved |
| | Special direction for import of eggs from Taiwan | The Centre for Reproductive and Genetic Health t/a CRGH Portland | Approved |
| | Special direction for import of embryos from USA | Care Fertility Woking | Approved |
| 26 August | Mitochondrial donation: M0035 - to avoid Pure Mitochondrial Myopathy, caused by the m.5650G>A pathogenic variant within the *MT-TA* gene, OMIM *590000 | Newcastle Fertility Centre at Life | Minutes not yet approved |
| | Acromicric Dysplasia (ACMICD), OMIM #102370 | Wolfson Fertility Centre – Hammersmith Hospital | Minutes not yet approved |
| | Hemochromatosis, Type 1 (HFE1), OMIM #235200 | Birmingham Women's Hospital | Minutes not yet approved |
| | Pulmonary Fibrosis and/or Bone Marrow Failure Syndrome, Telomere-Related, 1 (PFBMFT1), OMIM #614742 | Birmingham Women's Hospital | Minutes not yet approved |
| | Brachyolmia Type 4 with Mild Epiphyseal and Metaphyseal Changes (BCYM4), OMIM #612847 | TFP Oxford Fertility | Minutes not yet approved |
| | Chordoma, Susceptibility to (CHDM), OMIM #215400 | Care Fertility Nottingham | Minutes not yet approved |
| | Ectodermal Dysplasia 1, Hypohidrotic, X-Linked (XHED), OMIM #305100 | TFP Oxford Fertility | Minutes not yet approved |
| | Vertebral, Cardiac, Renal, and Limb Defects Syndrome 2 (VCRL2), OMIM #617661 | Care Fertility Nottingham | Minutes not yet approved |
| | Special direction to import embryos from USA | The Centre for Reproductive and Genetic Health t/a CRGH Portland | 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:

The next meeting of the Audit and Governance Committee will be held on 14 October, and a full report will therefore be given to the November Authority Meeting. Some of the items which the AGC will discuss in October are:

Internal audit and progress with current internal audit recommendations
Resilience, business continuity management and cyber security
Risk update – strategic risk register and horizon scanning
Digital projects – PRISM and Phoenix
Counter Fraud Strategy and action plan
Fraud Risk Assessment
Reserves Policy

### Scientific and Clinical Advances Advisory Committee:

SCAAC has not met since the last report to Authority. The next meeting is on 6 October 2025.

## 3. Recommendation

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

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

Human Fertilisation & Embryology Authority

# Monthly performance report

## Performance up to August 2025

**Evgenia Savchyna**
Corporate Performance Officer
25/09/2025

www.hfea.gov.uk

# About this paper

| Details about this paper | |
|---|---|
| Area(s) of strategy this paper relates to: | Whole strategy |
| Meeting: | Authority |
| Meeting date: | 25/09/2025 |
| Agenda item: | Item 5 |
| Author: | Evgenia Savchyna, Corporate Performance Officer |
| Contents | Latest review and key trends<br>Management summary<br>Summary financial position<br>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.<br>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.<br>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the CMG paper). |
| Organisational risk: | Medium |

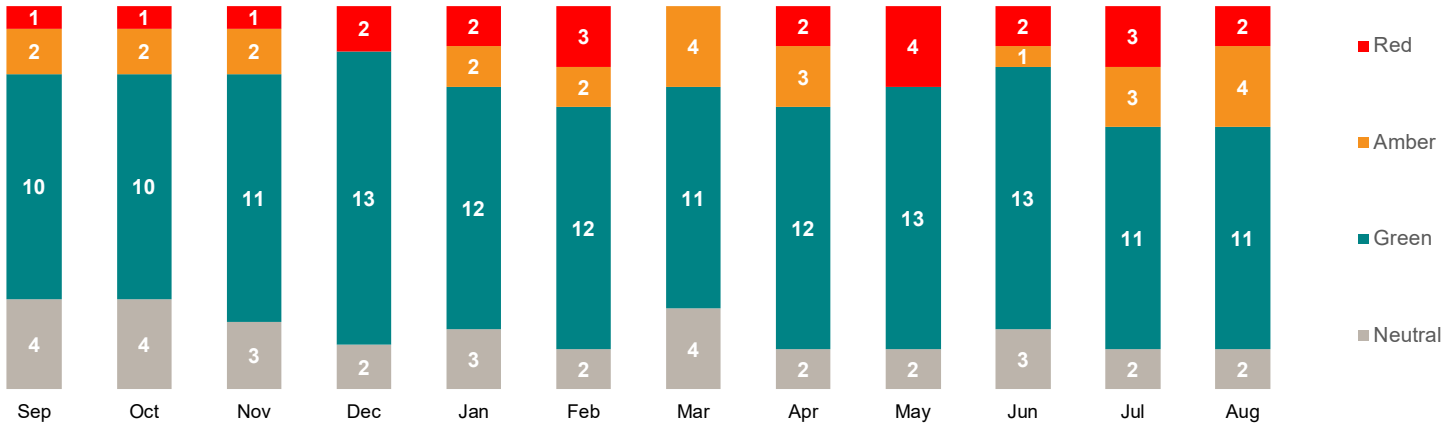
# Management summary

- Performance across KPIs in August 2025 was variable, with twelve KPIs rated Green, two Neutral, three Amber and two rated Red.
- Compliance performance varied: the ‘Inspection Reports to PR’ KPI was rated Red due to complex non-compliances; the ‘Inspection Reports to Committee’ KPI was rated Amber; but importantly the ‘End-to-End Licensing’ KPI was rated Green. Two research licences were voluntarily revoked, reducing the number of inspections from nine to seven in August.
- There has been an increase in the PGT-M applications received since May 2025. This led to14 applications due in August, of which eight were completed, four went to SAC (with minutes still pending), and the remaining two are scheduled to go to the next SAC. The average processing time for completed applications was 65 working days, resulting the PGT-M KPI being rated Amber.
- Since September 2024, the OTR team has halved the OTR waiting list (from 1118 in September 2024 to 541 in August 2025). Out of 541 applications remaining, 274 are from parents, 127 from donors and 140 from donor-conceived people. Although the team processed fewer OTRs last month due to annual leave, they still achieved the Waiting list change target.
- There has been a significant decrease in both email enquiries (from 127 to 88) and telephone enquiries (from 43 to 13) in August compared to July. The enquiries KPI review is scheduled to commence in September 2025.
- Five FOIs within KPIs in August. In addition, one complex FOI that missed the deadline in July has been carried over to September. No PQs were due in August.
- Comms activity returned to BAU following the Fertility Trends 2023 report publication. The team published varied content across social media channels, which was generally well received. Website sessions and user numbers have shown a downward trend since March 2025, which may be linked to the increasing use of AI as a search tool for finding information about fertility treatment.
- There have been no cases of long-term sickness since July 2025. The overall sickness rate remains within target, as does the turnover rate. Three new starters joined HFEA in late July, and these figures are reflected in the August report.

# Key performance indicators

Human Fertilisation & Embryology Authority

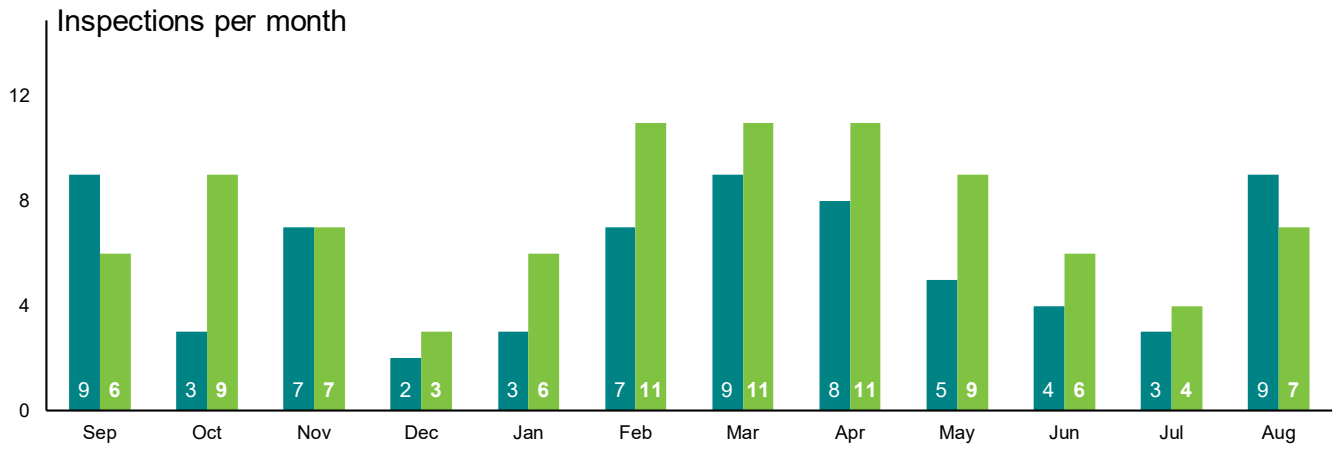
RAG status over last 12 months




**RAG status over last 12 months**

19 KPIs in total for each month starting from Jan 2025

In August 2025, the 2 red indicators were in Compliance ('Inspection reports to PR') and Finance ('Debt Collection within 40 days').



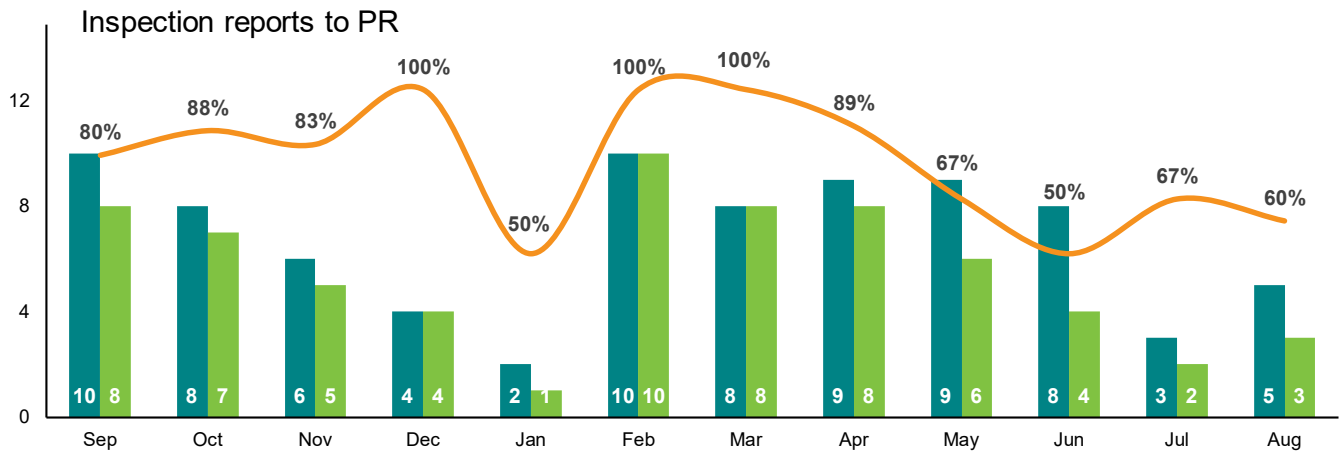

Status: **N/A**

**Compliance**

**Inspections delivery**

Target: **not defined**

Two research licences voluntarily revoked so planned inspections in August did not take place.



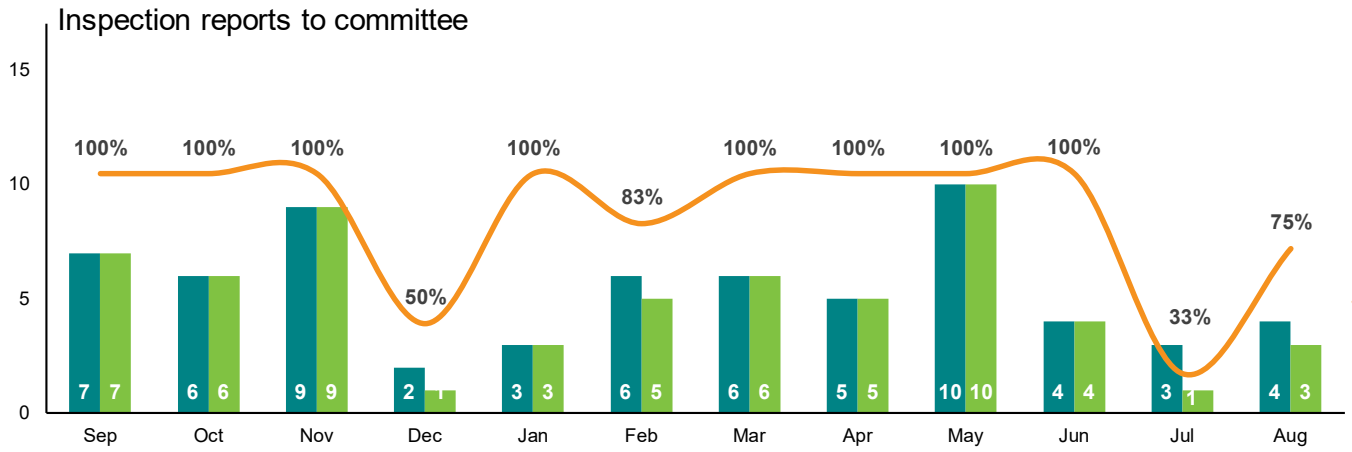

Status: **Red**

**Compliance**

**Inspection reports sent to PR**

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

Two reports were delayed in QA due to complex non-compliances which required discussion.



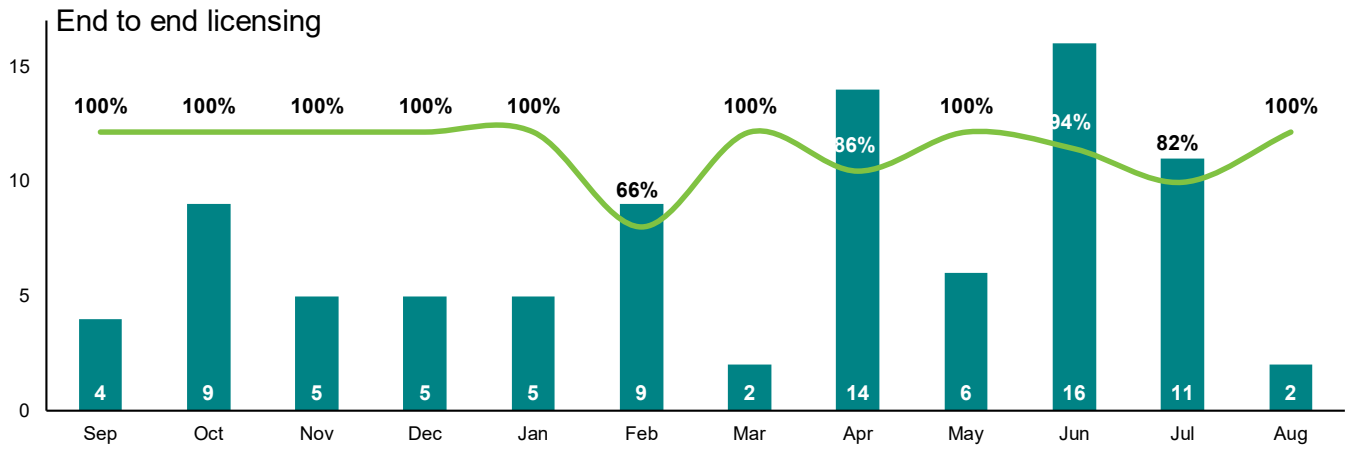

Status: **Amber**

**Compliance**

**Inspection reports sent to relevant licensing committee**

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

One report experienced a long delay at the initial stage, which in turn delayed its submission to the committee.



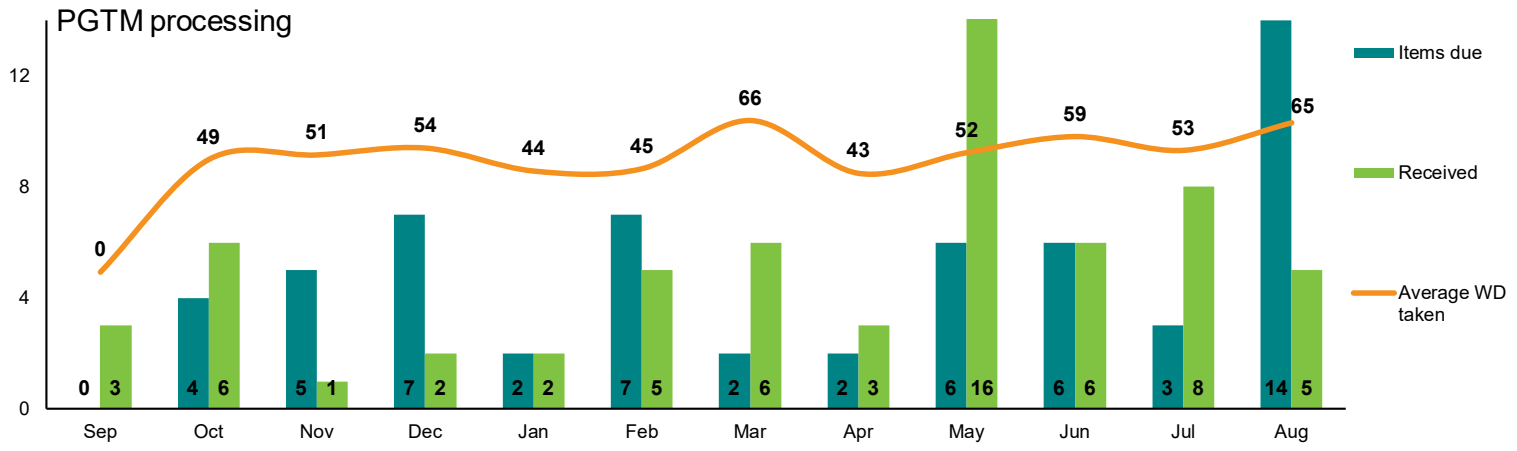

Status: **Green**

**Compliance**

**End to end licensing process**

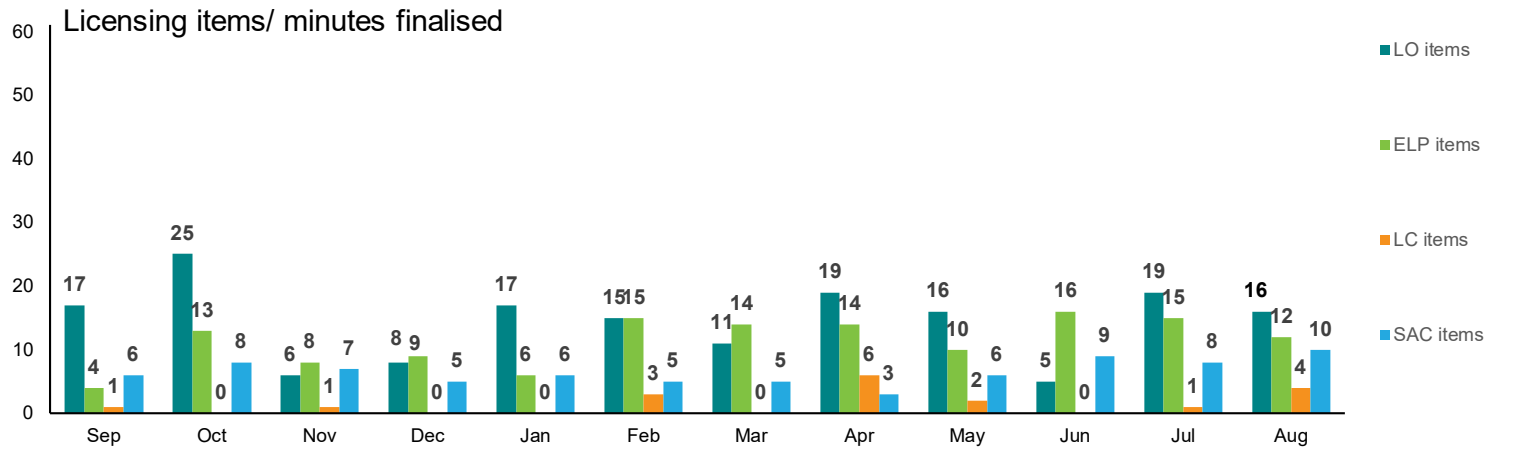
Target: **100% items completed within 80 working days**

All reports completed within KPI.



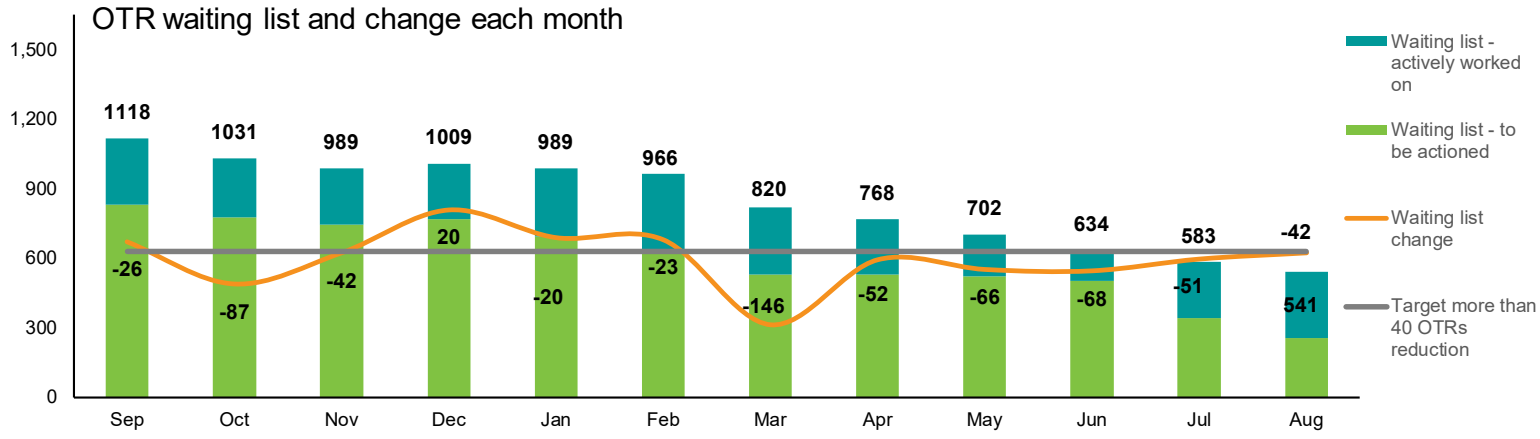

| Status: | Amber |
|---|---|
| **Compliance** | |
| **PGTM processing efficiency** | |
| New target - Dec 24: **average time within 60 working days** | |

Eight out of fourteen applications due were completed in August. Two applications yet to go to SAC due to busy agenda and influx of PGT-M applications in the last couple of months. The other four applications went to SAC in August, but minutes not signed yet.




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

SAC remains busy with the number of items minuted in month at peak for 2025 so far (including one MD application). A standard month for ELP and LO (all ITE certificates).



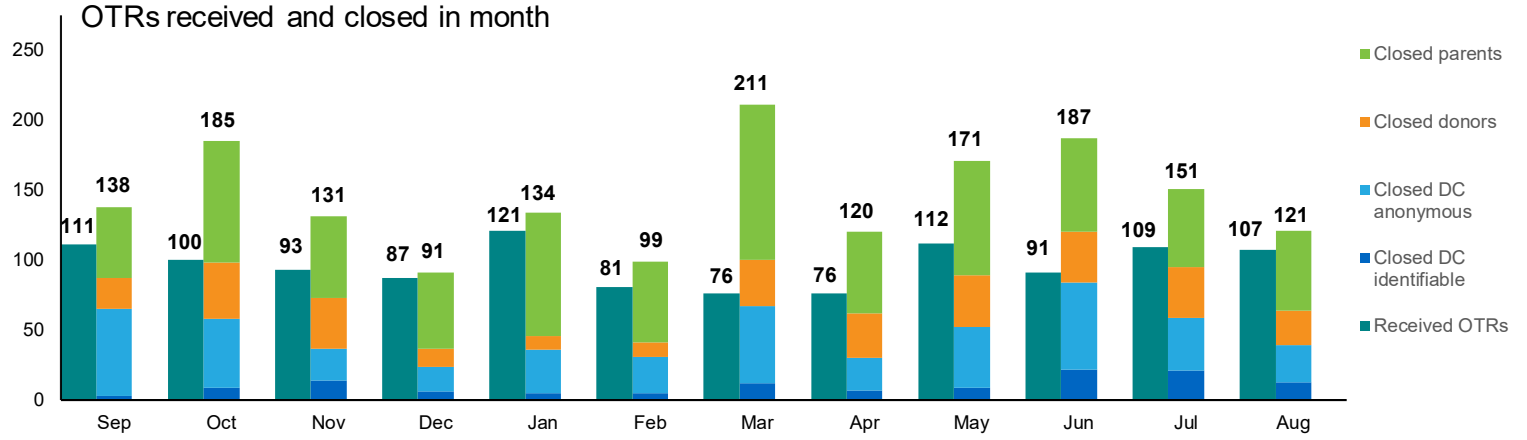

Status: **Green**

**OTR**

**Waiting list change**

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

OTRs in the waiting list: **Donor - 127; DC identifiable - 32; DC anonymous - 108; Parents - 274.**
Team processed slightly fewer OTRs this month due to annual leave but still lowered the waiting list.



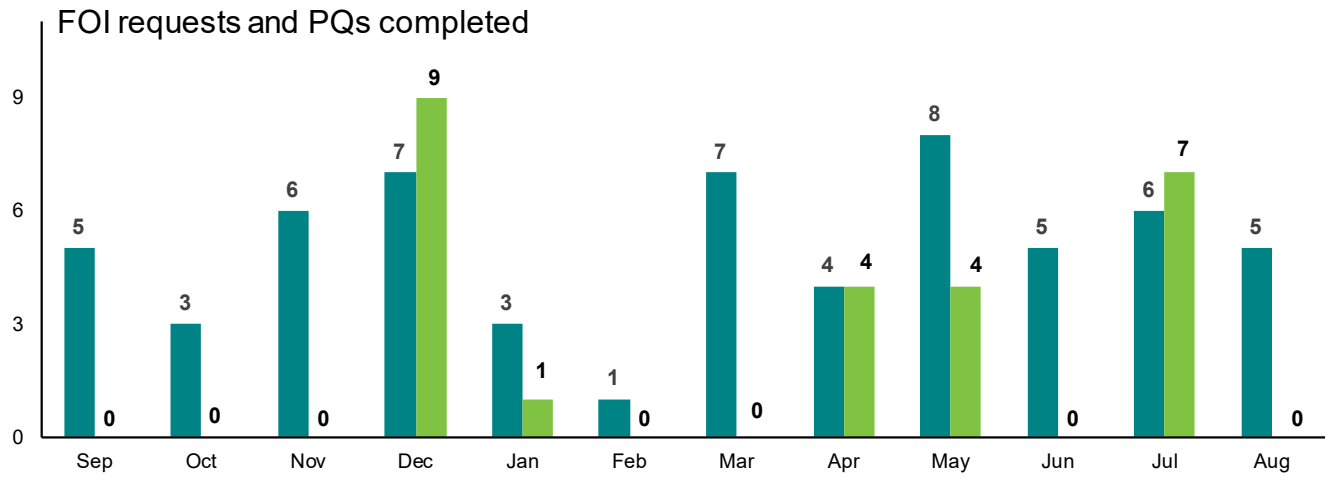

Status: **Amber**

**OTR**

**OTRs closed in month**

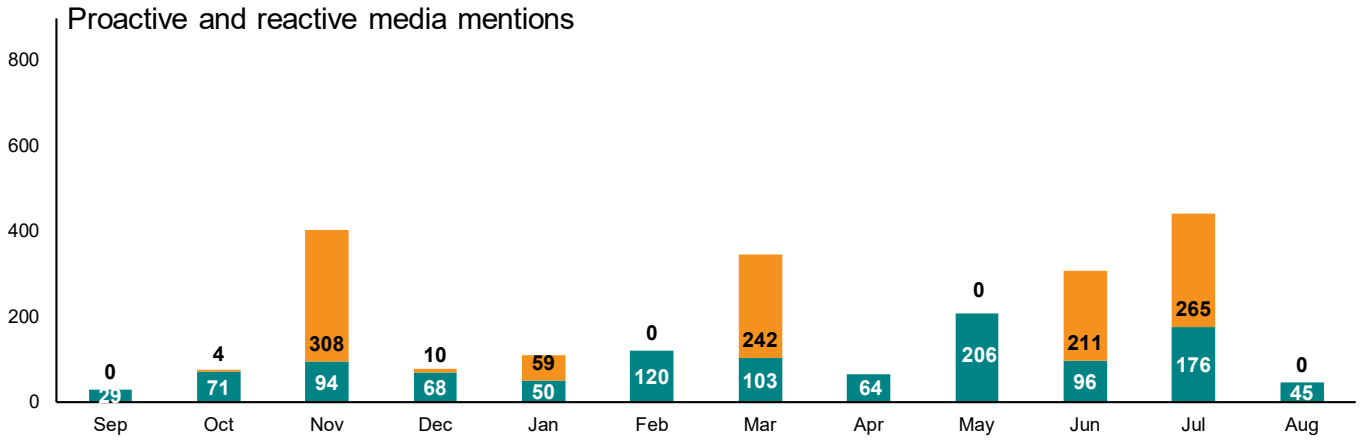
Target: **more than 156 OTRs being sent out**

OTRs sent out: **Donor - 25; DC identifiable - 13; DC anonymous - 26; Parents - 57.**
The number of OTRs received remained similar to last month. The number of parents waiting for information has dropped by around 300 applicants since the beginning of the year, and the number of anonymous DC and donor applicants waiting have halved in the same period.



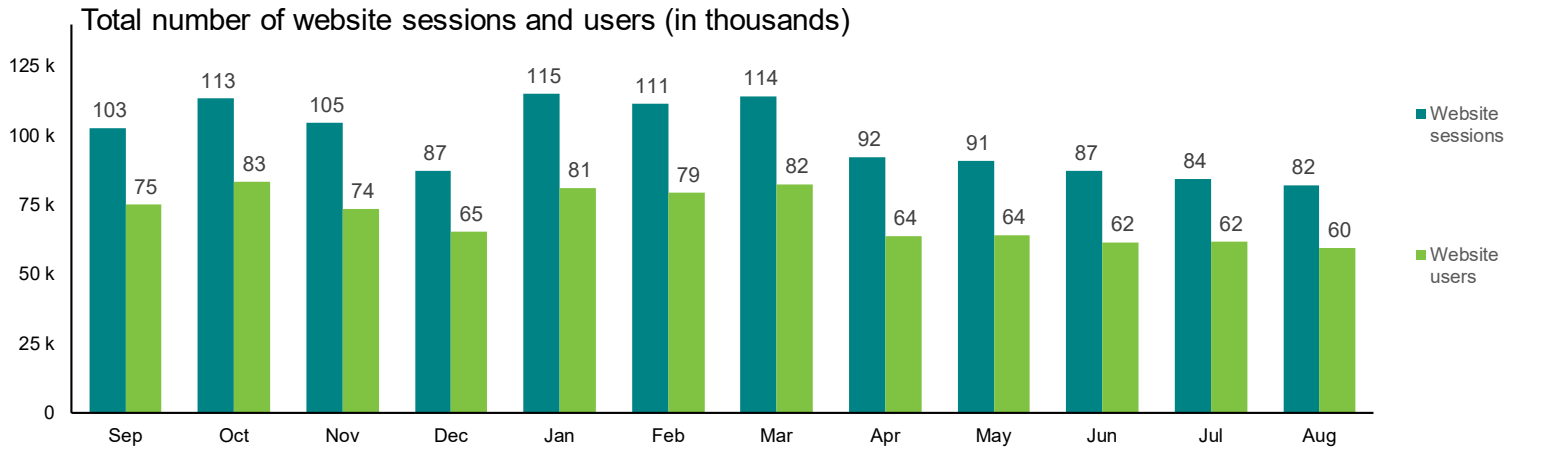

| | |
|---|---|
| FOI: | Green |
| PQ: | Neutral |
| **Intelligence** | |
| **FOI and PQ completed** | |
| Targets: **FOI - 20 WD** **PQ - set by DHSC** | |

FOIs were related to CaFC, Fertility trends, Regulation, HR/finance, IT/Security. Additional FOI due in July which missed the deadline has been carried over and response due in September, due to ongoing complexity. No PQs due.



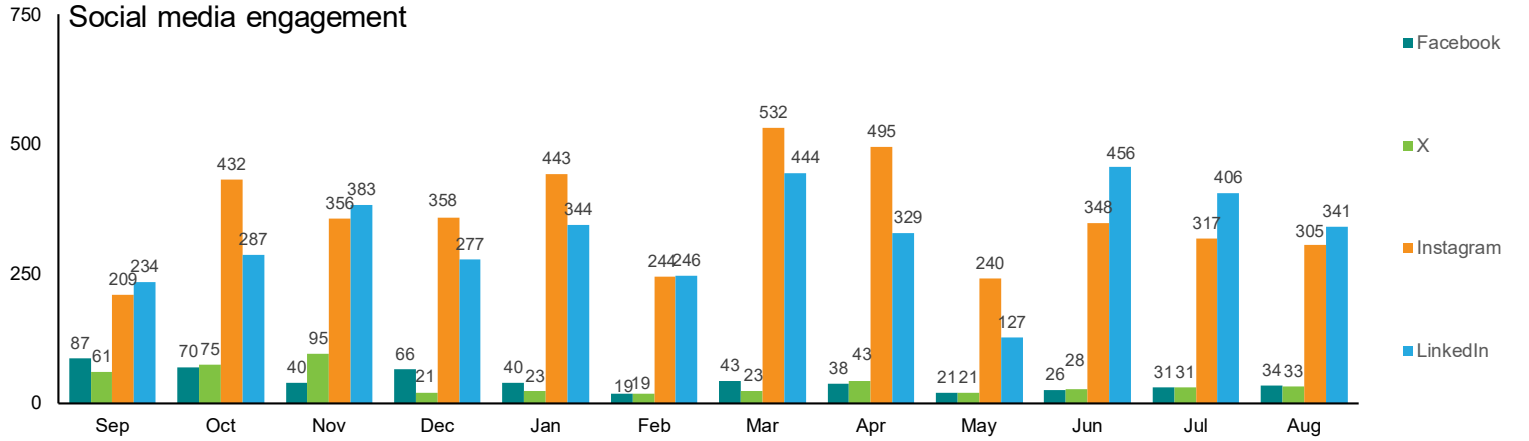

| | |
|---|---|
| Status: | N/A |
| **Comms** | |
| **Total media mentions (proactive and reactive split from April 2024)** | |
| Target: **not defined** | |

In August, coverage themes included IVF, egg freezing and donation. The lower levels of coverage can be attributed to a return to BAU following the publication of the Fertility Trends 2023 report.



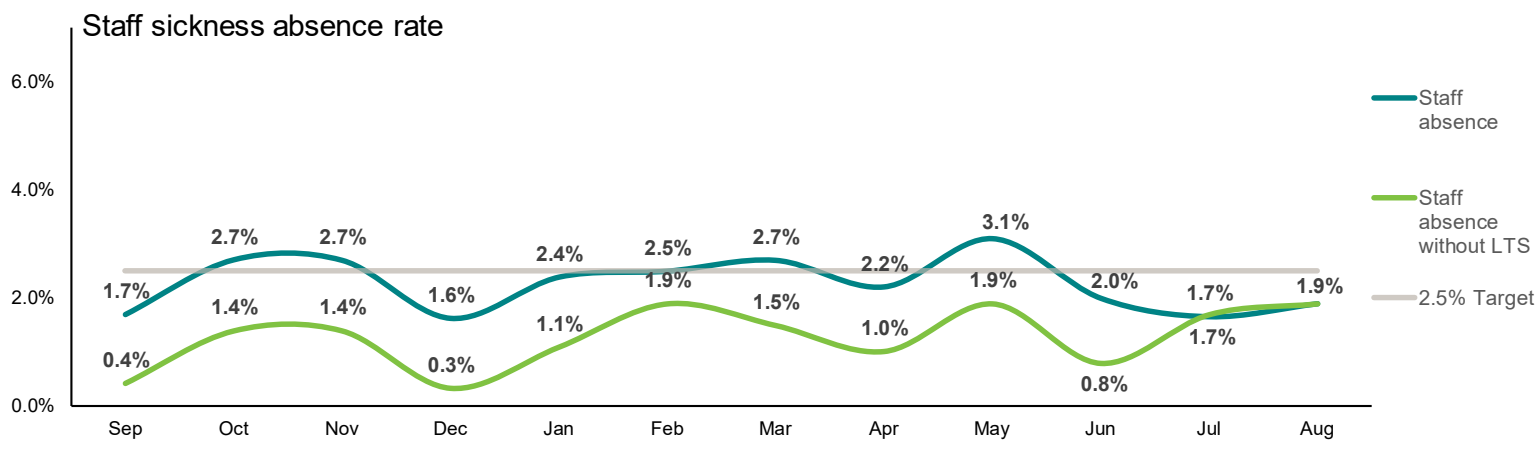

| Status: | N/A |
|---|---|
| Comms | |
| Total number of website sessions and users (Internal traffic excluded from October 2023) | |
| Target: not defined | |

The website had fewer sessions and users. We are looking into reasons for this slowdown, which may include users turning to Generative AI when searching for information on fertility, declining our website cookies manually or via automated browser extensions.




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

Our channels continued to see high numbers of engagement during August. Content was varied meaning the top post differed across the channels. Our collaborative post with Genetic Alliance UK explaining PGT-M was most popular on LinkedIn and X, and our post on options for unused embryos was top on Instagram.



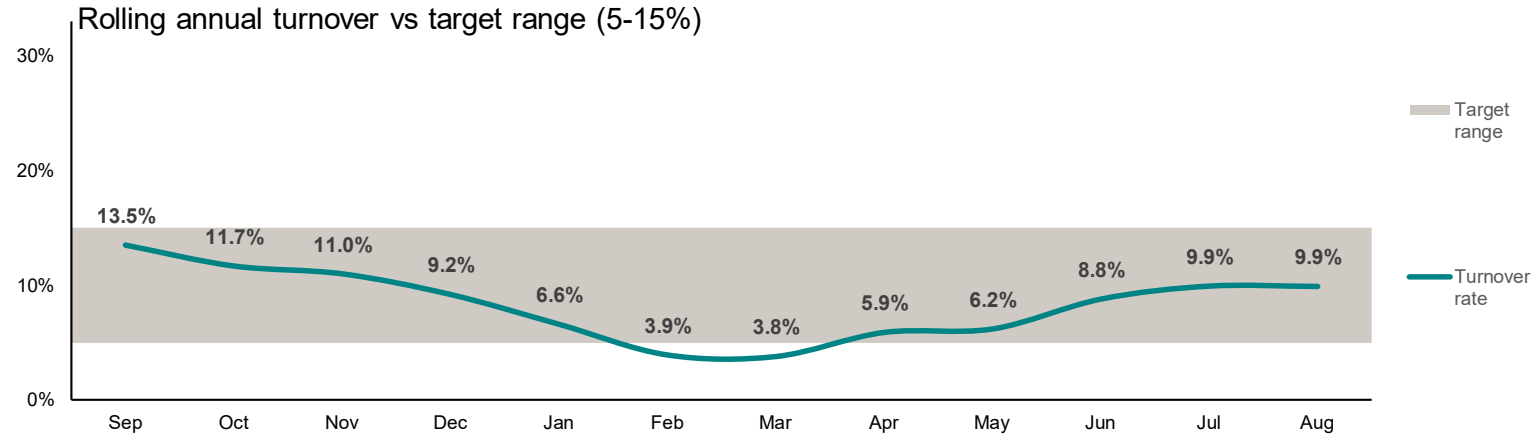

Status: **Green**

**HR**

**Sickness**

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

Sickness absence remains low. Part of this absence includes pregnancy related absence.



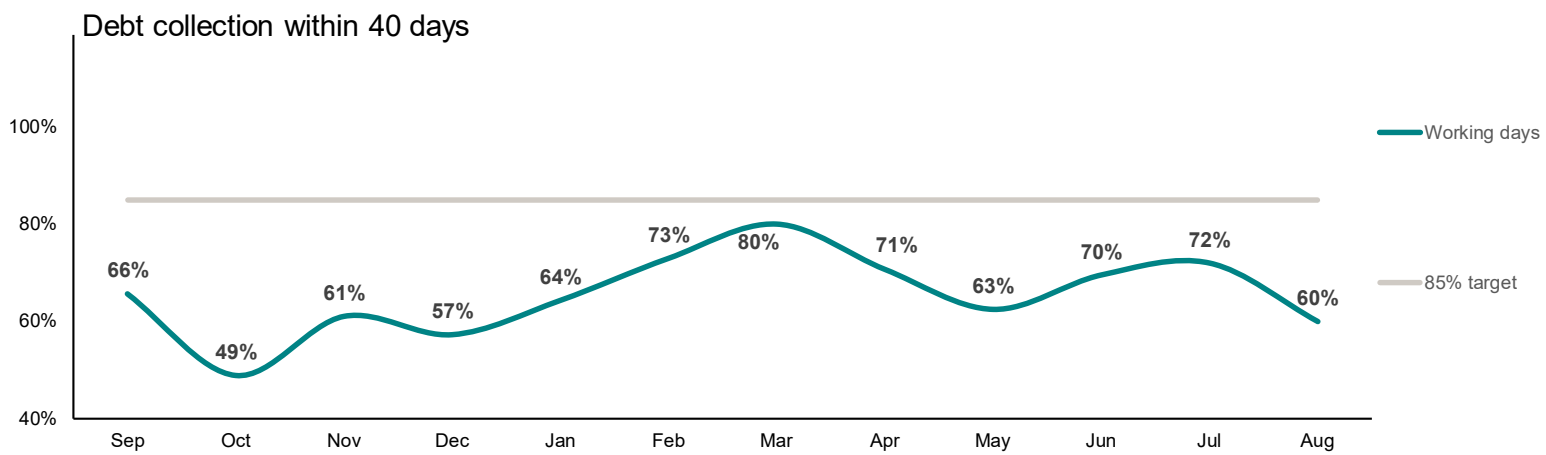

Status: **Green**

**HR**

**Turnover**

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

Our Scientific Officer left this month and has been replaced by an internal applicant.
Supplementary HR data: **Headcount - 83, Budgeted posts - 84, Vacant posts -1, Starters - 3, Leavers - 1.**



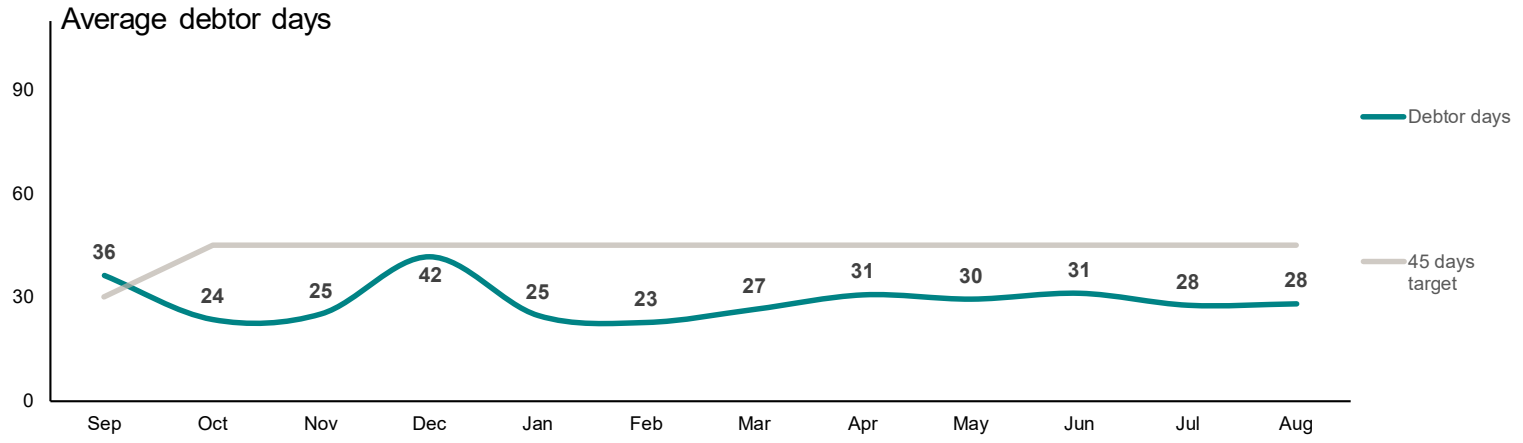

Status: **Red**

**Finance**

**Debt collection**

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

22 clinics made payments outside of our payment terms. One clinic in particular has been through a finance team transition and made payment for 5 months invoices totalling £31k. In total 10 clinics made payment for invoices older than 2 months and these total £52k.



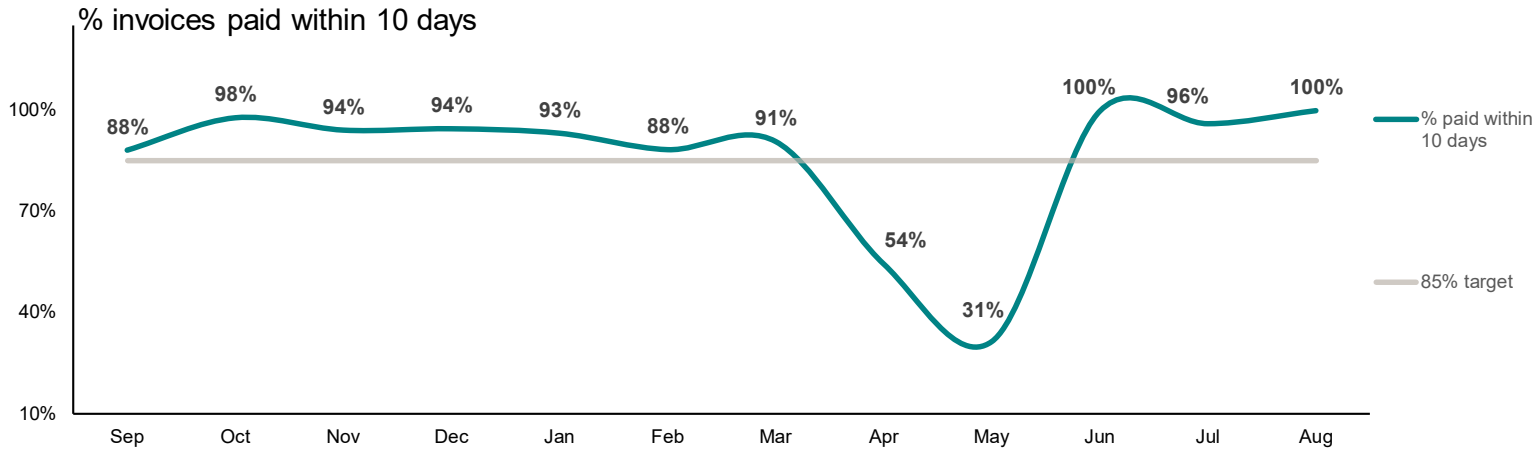

Status: **Green**

**Finance**

**Debtor days**

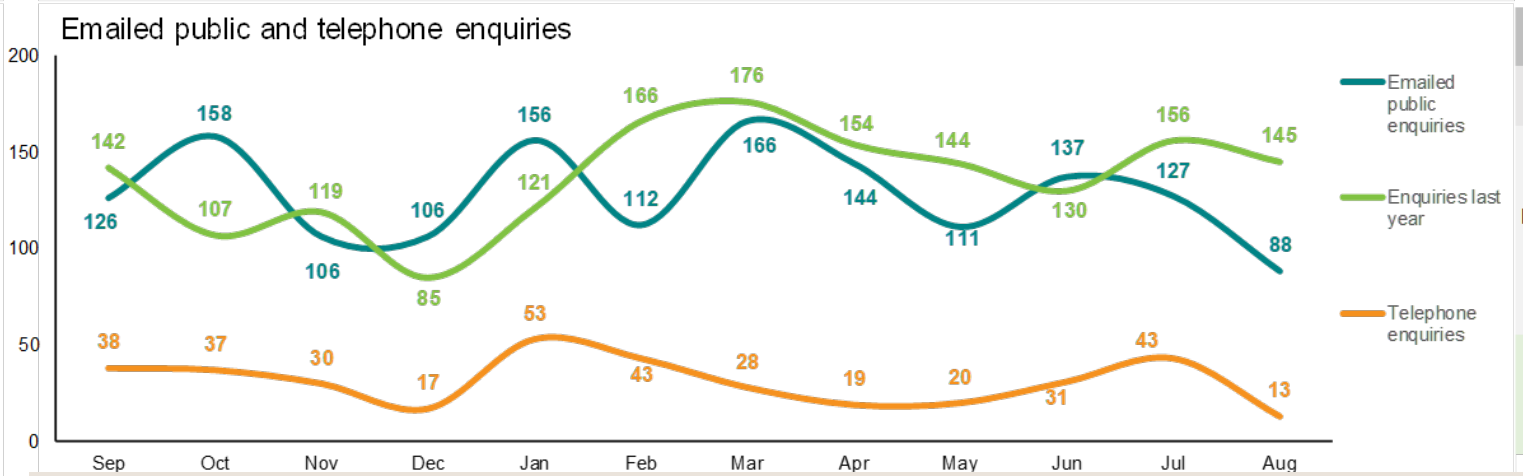
New target from Oct 2024:
**45 days or less**

The target has been met.




| Status: | Green |
|---|---|
| **Finance** | |
| **Prompt payment** | |
| Target: **85% or more invoices paid within 10 days** | |

The target has been met.




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

88 enquiries were received in August, which is lower than in July. The themes of these enquiries varied but there was an increase in the number of enquiries about screening requirements. Out of 13 calls were received in August, 1 was categorised as Challenging. Themes included Other (6), Beginning treatment (2), Opening The Register (2), Donation (2) and Medical queries and concerns (1).

Human Fertilisation & Embryology Authority

# Finance Report

## Period to August 2025

**Tom Skrinar**
Director of Finance, Planning and Technology
25 September 2025

www.hfea.gov.uk

# Summary financial position as at 31 August 2025

| Type | Actual YTD £'000s | Budget YTD £'000s | Variance Actual vs Budget £'000s | Forecast Full year £'000s | Budget Full year £'000s | Variance Forecast vs Budget £'000s |
|---|---|---|---|---|---|---|
| Income | 3,511 | 3,471 | (40) | 8,366 | 8,647 | 281 |
| Expenditure | (3,592) | (3,482) | (110) | 8,791 | 8,647 | (144) |
| **Total Surplus/(Deficit)** | **(81)** | **(11)** | **(70)** | **(425)** | **0** | **(425)** |

For the 5 months ended 31 August we have a deficit of £81k against a year-to-date budget deficit of £11k resulting in a £70k (overspend) variance. There are some variances detailed on the following pages that will be challenging to mitigate or control.

Currently, we are forecasting a year-end deficit of £425k. We will undertake a review of expenditure in September and October with the aim of reducing this deficit as much as possible.

A breakdown of key items can be found on the following pages.

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# 2025/26 income as at 31August 2025

| Year end | YTD Actual | YTD Budget | Variance | Forecast Full yr | Budget Full yr | Variance |
|---|---|---|---|---|---|---|
| | £'000s | £'000s | £'000s | £'000s | £'000s | £'000s |
| **Income** | | | | | | |
| DHSC Funding | 470 | 268 | (202) | 1,070 | 1.070 | 0 |
| DHSC Funding – non-cash | 97 | 95 | (2) | 229 | 229 | 0 |
| Licence Fees | 2,895 | 3,040 | 145 | 6,947 | 7,186 | 239 |
| Other income | 49 | 68 | 19 | 120 | 162 | 42 |
| **Total** | **3,511** | **3,471** | **(40)** | **8,366** | **8,647** | **281** |

**INCOME – Grant in aid and treatment fees only**

Year to date, our total income is over budget by 1.2%. The key factors affecting this variance are:

**Grant in aid (GIA)** – we are drawing this down in alignment with project spend (Pheonix). Will draw down the full allocation by the end of the year.

**Licence fees** - IVF/DI activity are below budget by (£145k). Forecasting the volume of cycles to the end of the year will be challenging. For the 5 months to August, we are tracking above budget by 1% (9% vs last year). The forecast takes the remaining 7 months budget plus the 5 actual to arrive at a total of 67k cycles. Due to ongoing catch-up of data collections, these cycles can be at varying values dependent on when the cycles became chargeable (ie £85 rather than £100), which means it is possible that the £'s value budgeted will not be achieved. This will also apply to DI cycles which for the 5 months to August are below budget by 31% (52% above last year).

The forecast for the year is a short-fall of income of £281k of which 85% is due to licence fee income not achieving levels close to budget.

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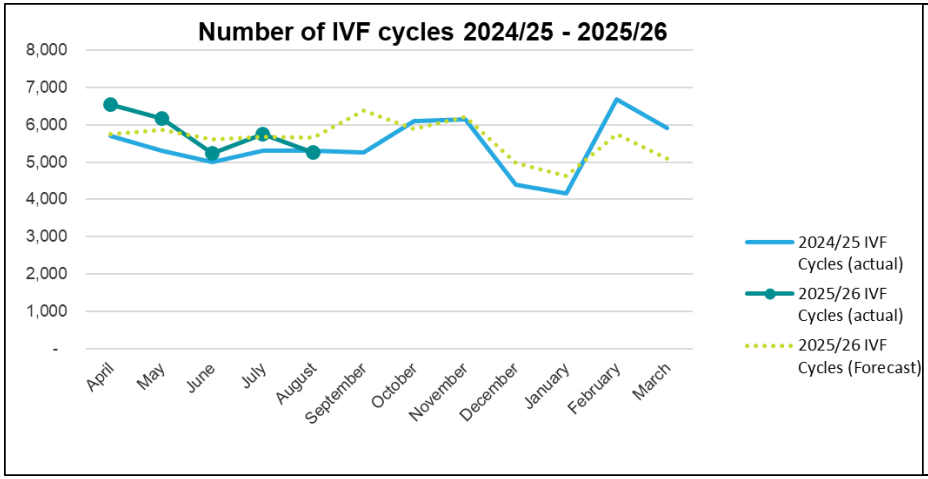
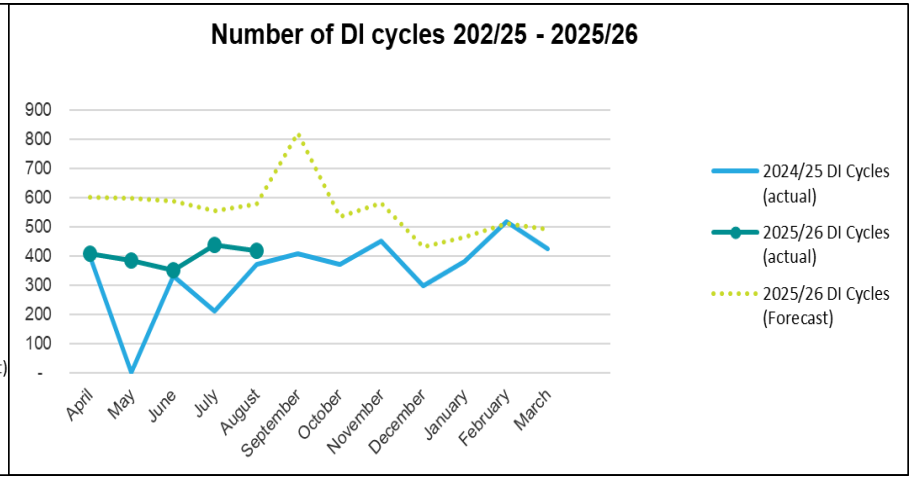
# 2024/25 Income - YTD Actual vs Budget




**IVF / DI Activity**

The above graphs depict the volumes of IVF and DI cycles, comparing activity for the 2024/25 and 2025/26 financial years as of M05 (August).

Year-to-date IVF activity actual vs budget are 28,951 and 28,554 respectively. Our DI volumes are 2,000 and 2,917.

The above data includes all but 3 clinics who continue to submit their cycles at a pace that is unlikely to see them caught up by the end of the financial year.  We will need to make an assumption on the value of these cycles by review of previous years activity multiplied by an average price.

# 2025/26 Expenditure YTD August 2025

| As of March-25 | YTD Actual | YTD Budget | Variance | Full yr Forecast | Full yr Budget | Variance |
|---|---|---|---|---|---|---|
| | £'000s | £'000s | £'000s | £'000s | £'000s | £'000s |
| **Expenditure** | | | | | | |
| Salaries/Wages | 2,482 | 2,530 | (48) | 6,204 | 6,072 | 132 |
| Other Staff costs | 68 | 91 | (23) | 228 | 262 | (34) |
| Other costs | 112 | 80 | 32 | 257 | 258 | (1) |
| Project Costs | 332 | 308 | 24 | 715 | 740 | (25) |
| Facilities (estates) costs | 244 | 193 | 51 | 504 | 527 | (23) |
| IT Costs | 219 | 186 | 33 | 531 | 464 | 67 |
| Legal and Professional | 135 | 94 | 41 | 352 | 324 | 28 |
| **Total** | **3,592** | **3,482** | **110** | **8,791** | **8,647** | **144** |

**Key Variances** (variances may be subject to profiling issues which will be reviewed at the end of each quarter)

- **Salaries/wages** – year-to-date are under budget by £48k, however we are forecasting an overspend of £132k. Small increases in temporary staff costs; maternity leave cover within the Inspections team; additional fixed term post and a settlement have contributed to this overspend.
- **Other Staff costs** – year-to-date are under budget by £23k and are expected to continue as per the forecast (£34k). Underspends within Inspection travel and subsistence (year-to-date £14k); and staff training £11k. It is expected that the year-end training costs will be close to budget. These are offset by small overspends within other areas.

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# 2025/26 key variances as at end August 2025 (continued)

- **Other Costs** - are overspent by £32k which is largely due to Donor Information costs which include Q4 24/25 charges (£27k) that were not accrued for in 24/25. This arose due to confusion over the contract which has now been agreed with an expected credit due of £14.7k.
- **Project Costs** – these costs are for the Pheonix project which is ongoing. Whilst slightly over budget year-to-date, we expect this first phase to come in slightly under due to deferment of some of the work packages.
- **Facilities (incl estates) costs** – are over budget year to date due to accruals for the increase in rent, rates and service charge costs (£41k). Included is an accrual for tax and national insurance for benefits in kind relating to staff wellbeing. This unfortunately was not budgeted for. The other balances within this area include an overspend on staff travel (remote workers attending 2RP). We are forecasting a small underspend as we expect to make accounting adjustments to our rent (lease) at year end.
- **IT Costs –** are overspent by £33k and are forecast to end in an overspend of £67k. A review of IT spend, specifically for Office 365 and Dynamics licences has been undertaken. There have been steep increases in prices which were not budgeted for and arose during the early part of this year. Agreements are being entered into which will allow us to fix the value of a majority of the licences for three years which will make budgets for 2026/27 onwards more predictable.
- **Legal and Professional** – is over budget by £41k, represented by our legal spend year to date over budget by £15k. Budgeting for legal costs has historically been challenging. The forecast overspend of £67k does not take into account the current JR being addressed. A further review of this area will be conducted in October. In addition, there are overspends on both internal and external audit fees (£26k in total). The overspends reflect general price increases and the additional work that external audit undertook for 2024/25.
- Due to the challenge around our income, the quarterly reviews that will be undertaken in October and January, will focus heavily on whether spend against the above areas, can be deferred or stopped in order to bring our closing position down to a more manageable level.

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# 2025 Horizon Scanning Meeting

**Rebecca Taylor**

Scientific Policy Manager

25 September 2025

**www.hfea.gov.uk**

# Why undertake Horizon Scanning?

**Build knowledge and relationships and shape strategic direction**

**Keep up to date** with scientific and regulatory developments

**Build relationships** with researchers and clinicians and build **HFEA reputation**

Use knowledge to **shape current and future work**

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# How we do Horizon Scanning

Literature reviews

Consulting experts

Attending conferences and meetings

**Annual horizon scanning meeting**

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# Annual Horizon Scanning Meeting

**Convening international experts to discuss up and coming topics**


- At European Society of Human Reproduction and Embryology (ESHRE) annual meeting
- Invite only, confidential, in-person meeting
- 3-4 topics, 1 speaker per topic
- Chaired by SCAAC Chair

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# Horizon Scanning Meeting 2025

## Participants

- 22 participants (inc 3 SCAAC members) plus Chair and HFEA staff
- From Europe and beyond: UK, USA, France, Germany, Italy, Spain, Belgium, Netherlands, Denmark, Ireland and Mexico

## Wide range of backgrounds

- Embryology
- Reproductive medicine
- Bioethics and law
- Stem cell biology
- Endocrinology
- Bioengineering
- Computer Science

## Topics

1. Non disease related mitochondrial donation

2. Male fertility preservation - in vitro spermatogenesis

3. Robotics and automation in fertility treatment

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# Mitochondrial donation for infertility

**Talk title**

Future use of Mitochondrial Donation? Going Beyond Preventing Inherited Disease

**Speaker**

Dr Nuno Costa Borges, Scientific Director, Embryotools, Spain

Author of paper on 1st pilot study on MDT for repeated IVF failure

**Why this topic?**

MDT is HS topic and permitted in UK for disease prevention

Discussions in recent years on using MDT for infertility to improve oocyte (egg) quality

Pilot study paper published.

**Discussions covered**

Clinical safety including mitochondrial reversion

Target patient population – repeated embryo development arrest

Use of maternal spindle transfer technique

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# In vitro spermatogenesis

**Talk title**

Emerging Techniques in Male Fertility Preservation: The Role of In Vitro Spermatogenesis

**Speaker**

Dr Christine Rondanino, Associate Professor, University of Rouen, France

**Why this topic?**

Male fertility preservation is difficult especially in pre-pubescent boys (invasive, low success rate)

In vitro spermatogenesis shows promise, but the science is still developing

**Discussions covered**

In vitro maturation (IVM) of prepubertal testicular cells/tissues

Successful studies in mice – similar quality sperm generated

Safety concerns – epigenetics

Public perception

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# Robotics and automation in IVF

**Talk title**

Remote Control IVF – The Potential of Robotics and Automation to Revolutionise Fertility Treatment

**Speaker**

Dr Eduardo Mendizabal-Ruiz, Professor of Computer Science, University of Guadalajara, Mexico/ VP Exploration, Conceivable Life Sciences

Author of paper on “remote control” ICSI

**Why this topic?**

HS topic due to increasing and expanding use of automation in IVF clinics

1st paper on “remote control” ICSI published in January 2025

**Discussions covered**

Automation as solution to global shortages of qualified staff

Increase embryologist productivity through standardisation

Risk landscape: technology, cyber security, algorithmic bias

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# Topic Prioritisation – 2025/26

## High:

- Alternative methods to derive embryonic/like stem cells
- AI, robotics and automation in fertility treatment
- Emerging technologies embryo & gamete testing
- In vitro derived gametes
- Mitochondrial donation
- Scientific considerations of '14-day rule'
- Stem cell-based embryo models
- Health outcomes in children conceived by ART
- Health outcomes for ART patients (inc egg donors & surrogates)

## Low:

(none)

## Medium:

- Impact of microbiome on fertility/treatment outcomes
- Testicular tissue transplantation to restore male fertility
- Germline genome editing
- Impact of long-term cryopreservation

## Watching brief:

- Artificial wombs (ectogenesis)
- Impact of environmental toxins on fertility treatment outcomes
- Impact of stress on fertility treatment outcomes
- Understanding genetic basis of infertility
- Use of ICSI for non-male/mild-male factor infertility

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# Committee work plan 2025-2026

| Date | Topics discussed/to be discussed |
|---|---|
| **February 2025** | Horizon scanning and agreeing workplan for 2025/26 |
| | Health outcomes in children conceived by ART (including impact of culture media) |
| | Impact of stress on fertility treatment |
| **June 2025** | Treatment add-on rating: Androgen supplementation |
| | Application for treatment add-on: Platelet-Rich Plasma (PRP) |
| | Impact of long-term cryopreservation of gametes and embryo |
| | Impact of the microbiome on fertility and fertility treatment outcomes |
| **October 2025** | Alternative methods to derive embryonic and embryonic-like stem cells |
| | Testicular tissue transplantation to restore fertility in males |
| | Treatment add-on rating: Platelet-Rich Plasma (PRP) |
| **February 2026** | Horizon scanning and agreeing workplan for 2025/26 |
| | Artificial intelligence (AI), robotics and automation in fertility treatment |
| | Reproductive Organoids |
| | Treatment add-on rating - microbiome testing and sperm DNA fragmentation |

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# Thank you

**Any questions?**

**Email: Rebecca.Taylor@hfea.gov.uk**

# Embryo Testing

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | Regulating a changing environment |
| Meeting: | Authority |
| Agenda item: | 7 |
| Meeting date: | 25 September 2025 |
| Author: | Dina Halai, Head of Regulatory Policy, Scientific (job-share)<br>Rachel Cutting, Director of Compliance and Information<br>Rachel Cooper, Senior Legal Adviser |
| Annexes | Annex A: Wording on genetic testing in the HFE Act 2008 |

## Output from this paper

| | |
|---|---|
| For information or decision? | For decision |
| For decision: | Members are asked to:<br>• Consider the position on embryo testing in regard to the law; and<br>• Agree to the review of where wide 'group' approval has been given for various conditions – "chromosomal rearrangements (various)" |
| Resource implications: | Resource will be required from the Policy, Compliance and Legal teams and possibly external legal advice and genetic expertise as needed |
| Implementation date: | N/A |
| Communication(s): | To be decided post Authority discussion |
| Organisational risk: | Low/**Medium**/High |

# 1. Background

**1.1.** The HFE Act 2008 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
b. Testing for an abnormality which presents a significant risk the child will have a serious condition
c. Testing for HLA tissue-typing
d. Testing where there is uncertainty about whose gametes were used to create the embryo.

**1.2.** The Act also prohibits practices designed to prefer one sex over the other except where one sex presents a much greater risk of having a serious condition than the other.

**1.3.** Following testing, the Act requires that embryos that are known to have a genetic abnormality which present a significant risk that the child will have a serious condition must not be preferred to those that are not known to have such an abnormality.

**1.4.** 'Testing embryos' is a licensable activity – ie clinics need to have a licence to be able to carry this out. Currently, the testing methods permitted by the HFEA for clinics that are licensed to test embryos are: PGT-M, PGT-SR, PTT and PGT-A.

**1.5.** Furthermore, testing embryos for an abnormality which presents a significant risk that the child will have a serious condition, can only take place once the HFEA is satisfied that the abnormality is sufficiently serious. That decision is made by the HFEA's Statutory Approvals Committee (SAC). SAC approval is required to specifically test for the following authorised processes:

- Monogenic or single gene disorders (PGT-M) – once a specific disease-causing gene variant is known, it is possible to use PGT-M to test for that specific variant. There is a list of approved PGT-M conditions available online. Once a condition has been approved by SAC any licensed PGT-M clinic can offer the test for that condition. If a specific condition is not on the approved list, a HFEA clinic licensed to carry out PGT-M can, on the patient's behalf, apply to have the condition considered for approval by SAC for licencing. Once approved for an individual patient, it moves to the approved list for any future patients with the same condition. There are currently 1982 approved PGT-M conditions.
- Chromosomal structural rearrangements (PGT-SR) – in 2010, SAC approved 'Chromosomal rearrangements (various)' as a wide 'group' approval for which embryo testing can be applied if a case complies with legal criteria related to the risk of transmission and the seriousness of the genetic abnormality to be tested for. Since SAC approved PGT-SR, the science has developed significantly and now even small rearrangements – such as microdeletions – can be detected, many of which will

not cause a serious condition and accordingly a review of this group approval is planned (see paragraph 5.6).

- Pre-implantation tissue typing (PTT) – parents can use PTT treatment to only select embryos that are an exact tissue match to their older sibling in order to help save the older sibling from life-limiting blood disorders. It is for this reason that PTT is sometimes referred to as 'saviour siblings' technology. In order to be able to carry out PTT, both the condition to be treated and its use in specific patients must be approved by the HFEA. On average, PTT applications are received once every other year (The last one was in 2023 and, before that, 2021).

**1.6.** Specific HFEA approval is not required to test for abnormalities which may affect capacity to result in a live birth (eg aneuploidy testing via PGT-A) or for parental testing where there is uncertainty about whose gametes were used to create the embryo.

**1.7.** The methodologies for carrying out genetic testing have advanced significantly since the law was passed. Previously, different technologies were employed to look for chromosomal rearrangements 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. Taken together, these developments raise the question of what, if any, additional information can be obtained from what might be termed 'opportunistic' testing or screening. In other words, although the reason for testing may be lawful (as laid out in 1.5 and 1.6), there is a question about whether receipt of some of the information generated from the test is legally permitted.

**1.8.** This mismatch between what is lawful in the UK and advances in the information that can be derived from particular tests does mean that where those advances are in the best interest of the patient, and supported by robust evidence, the law could now be seen as restrictive in preventing potentially relevant tests from being undertaken. However, there is no best interest test in the law.

**1.9.** The HFEA has a duty to promote compliance with the Act as it stands, and to ensure testing is carried out lawfully, by, for example, providing clinics with guidance, and inspecting clinic activities. The advancements in methodologies and variation in clinic practices suggests that it is now time to consider whether any additional advice or action is required.

**1.10.** This paper outlines the emerging issues associated with embryo testing and additional information in the UK, proposes a position on embryo testing at 4.3, and further action(s) for the Authority to consider in Section 5.

**1.11.** The Authority will be aware that much of the public discussion of embryo testing in recent months has concerned the use of PGT-P to assess polygenic risk scores. SCAAC considered the evidence regarding PGT-P in **June 2024** and concluded that it was a controversial process that required further research, information on this has also been added to our **website**. Regardless, this paper does not consider PGT-P as it is unlawful in the UK as it does not meet

the criteria for genetic testing in the Act, as it cannot be used to identify a particular gene, chromosome or mitochondrian abnormality.

## 2. Current practice

**2.1.** In the last few months we have become aware, from a small number of queries from licensed clinics and discussions with Authority members and commercial companies that offer genetic testing, that practice in the sector is changing with sophisticated testing (WGS and others, for example, tests that assesses the mitochondrial DNA quantity in embryos) now routinely generating data which goes beyond simple binary results for which the testing was originally sought.

**2.2.** This new information also suggests there is an inconsistent approach to testing and embryo selection. In summary:

- 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 Act.
- There are variations in what information is garnered and reported back to clinics. Commercial companies commissioned to carry out the genetic testing occasionally report more than is requested, and in-house NHS laboratories report back only what is requested. Examples include: (a) testing for an abnormality which may affect capacity to result in a live birth by performing PGT-A and receiving additional information on a microdeletion that may or may not present a significant risk of a serious condition alongside the PGT-A results; and (b) reporting on whose gametes were used to create the embryo (quality control tests) where an uncertainty has not been indicated. This then impacts on what is reported to patients. For further detail on these sorts of examples see table at 3.1.
- There is varied understanding by clinics and testing labs about the possible options for testing and how results are collated and can be received. This seems to be exacerbated by the commercial nature of genetic testing and testing companies, especially those that operate internationally trying to streamline the format of reports sent back to clinics.

**2.3.** As mentioned above, tests offered by commercial companies are usually much broader in scope than the specific purpose for which testing is permitted under the Act. For example, "PGT-A" tests often provide clinics with a variety of genetic information about the embryo. There can be advantages to receiving the additional information from opportunistic screening, including:

- Testing for other approved PGT-M conditions at the same time may find another abnormality which presents a significant risk, and patients/clinics can then act to avoid inheritance of that abnormality.
- Testing for whose gametes were used to create the embryo as a matter of course could be a valuable quality control approach, although the incidence of gametes being mixed up is rare.

- Performing parental origin aneuploidy testing to determine whether aneuploidy in the embryos is of maternal or paternal origin could help guide further treatment decisions, eg whether to use donor gametes or to carry out sex selection to transfer embryos of one sex only.

  Furthermore, receipt of additional information may promote positive health outcomes and may reduce fertility tourism (outside the UK) for patients seeking these results elsewhere.

**2.4.** However, there are disadvantages to receiving additional information from opportunistic screening, including:

- Receipt of additional information may not be in line with the intention set out in UK law, which is that embryo testing should *only* be allowed for one of the permitted purposes and the information obtained from the test and received by the clinic should satisfy a permitted purpose.
- It puts clinics in a difficult position of determining whether to act on the information or not – this is of particular concern when testing isn't for one of the permitted purposes and therefore is outside of the law but knowledge of the results is considered to be in the patients' interests.
- It may be that some embryos are not being selected for transfer based on additional information being received, which may well reduce the chance of having a baby in the long term.
- If a clinic determines they will not act on the additional information, the patient(s) concerned may feel that the clinic's decision removed the opportunity to explore alternative reproductive options or prepare for the challenges ahead, for example:
  - May find single gene alterations that would not be considered as being serious by the SAC.
  - An incidental finding of PGT-A is that all the embryos carry an approved PGT-M condition where one sex presents a much greater risk of having a serious condition than the other, however the condition has not been approved for sex selection. Regardless, the couple concerned wish to select only the male embryos as the risk of a man getting the condition is much lower.
- The need to explain the significance of additional results to patients and offer counselling.
- Informed consent not being in place for the testing and receipt of any additional information.
- There may be insufficient evidence to support the implication(s) of genetic variations found which could open the door to repeated testing and selection. For example, as noted in paragraph 1.11, PGT-P has emerged as a new test which involves simultaneously identifying the presence of many gene variants to show whether a person has a higher genetic risk compared with others for developing certain diseases. As noted earlier, PGT-P is unlawful for use in the UK as it cannot be used to identify a particular risk.

# 3. Emerging issues

**3.1.** Some emerging issues based on discussions with commercial companies, clinicians, bioinformaticians and enquiries received from clinics are laid out below (this should not be considered to be a complete list). We have assessed the level of concern based on the Permitted Purposes set out in the law (see 1.1).

| Type of testing | Additional information revealed by the testing (sought for and incidental) | How the Permitted Purposes set out in the law apply |
|---|---|---|
| **(1) PGT-M for approved condition** | Another condition that is also an approved PGT-M condition | Allowed under the Act (Schedule 2, para 1ZA(1)(b) and (2)).<br>Where there is a particular risk, testing for an abnormality which presents a significant risk the child will have a serious condition |
| | Another condition that is not currently approved but would be considered to be a "serious condition" | Not allowed under the Act.<br>The HFEA needs to be satisfied that the abnormality is sufficiently serious and a HFEA licence that is approved by SAC is required before testing is undertaken. If an incidental finding is identified, then an application should be made to the SAC. |
| | A condition that would not be considered a "serious condition" | Not allowed under the Act.<br>Does not meet the statutory test of seriousness and may mean that an embryo is being potentially discarded unnecessarily. |
| **(2) For 'Chromosomal rearrangements (various)' (PGT-SR)** | A microdeletion which will cause a condition that is not currently approved but would be considered to be a "serious condition" | Not allowed under the Act.<br>The HFEA needs to be satisfied that the abnormality is sufficiently serious and a HFEA licence that is approved by SAC is required before testing is undertaken. If an incidental finding is identified, then an application should be made to the SAC. |
| | A microdeletion which will not cause a "serious condition". | Not allowed under the Act.<br>Does not meet the statutory test of seriousness and may mean that an embryo is being potentially discarded unnecessarily. |
| **(3) PGT-A** | A condition that is an approved PGT-M condition | Allowed under the Act (Schedule 2, para 1ZA(1)(b) and (2)).<br>Where there is a particular risk, testing for an abnormality which presents a significant risk the child will have a serious condition |
| | A condition that is not currently approved but would be considered to be a "serious condition" | Not allowed under the Act.<br>The HFEA needs to be satisfied that the abnormality is sufficiently serious and a HFEA licence that is approved by SAC is required before testing is |

| | |
|---|---|
| | undertaken. If an incidental finding is identified, then an application should be made to the SAC. |
| A condition that would not be considered a “serious condition” | Not allowed under the Act.<br>Does not meet the statutory test of seriousness and may mean that an embryo is being potentially discarded unnecessarily. |
| Sibling QC - the testing identifies that one of the embryos is not ‘similar’ to the others which suggests either that the sample was contaminated or that there was a potential mix-up with another patient’s gametes or embryos. Sibling QC is described as a quality control test to determine contamination. | Not allowed under the Act.<br>It seems unlikely that the law intended such a test to be permitted as a matter of course rather than only in specific cases where there is uncertainty. Furthermore, this test determines whether embryos are related to each other (which is not a permitted purpose under the Act), and not whose gametes were used to create the embryo. |
| Parental QC - similar to sibling QC but requires a further test – a cheek swab from the parents to compare to the embryos and make sure they are related to the parents. Parental QC is described as a quality control test to determine contamination. | Allowed under the Act if there is uncertainty about whose gametes were used to create the embryo. (Schedule 2, para 1ZA(1)(e))<br>It seems unlikely that the law intended such a test to be permitted as a matter of course (rather than only in specific cases). |
| Patient requests their whole genome sequence and sends results to a non-UK based company for PGT-P, following which the patient requests that their UK clinic select embryos based on the results of PGT-P. | Not allowed under the Act.<br>PGT-P is unlawful for use in the UK as it cannot be used to identify a particular risk and therefore does not meet a permitted purpose for testing. |
| Another condition that is an approved PGT-M condition but not approved for sex selection and is likely to manifest in one sex over the other, therefore sex selection takes place. | Not allowed under the Act.<br>The HFEA needs to be satisfied that the abnormality is sufficiently serious and a HFEA licence that is approved by SAC is required before testing is undertaken. |
| Information required to use ‘mitoscore’ (which grades embryos according to the number of mitochondria). | Not allowed under the Act.<br>Testing for purposes of grading and does not look for a specific abnormality, therefore does not meet a permitted purpose for testing. |
| Origin of aneuploidy (provides a direct assessment of gamete contribution to embryo aneuploid – i.e. whether the aneuploid is likely to come from the sperm or egg). | Not allowed under the Act.<br>Testing does not meet a permitted purpose for testing. |
| Pronuclear (PN) confirmation (confirms whether an embryo is 1PN (can develop and look like a normal blastocyst but will not implant), 2PN (considered normal) or 3PN (can cause a molar pregnancy). | Allowed under the Act (Schedule 2, para 1ZA(1)(a)).<br>Testing for an abnormality which may affect capacity to result in a live birth. |

## 4. Our position in relation to the law

**4.1.** As noted above, there now appears to be different practices within the sector with some patients having more information reported back to them than others. The HFEA has a duty to promote compliance with the Act and to this end, we must consider whether we ought to provide further clarity on this issue to ensure consistent application.

**4.2.** It is clear that at the time when the law was drafted, the intention was that embryo testing should only be allowed for one of the Permitted Purposes and the information obtained from the test and received by the clinic must be limited to the information necessary for that purpose. Additionally, embryos can only be selected for (or against) on the basis of the limited information necessarily obtained for a Permitted Purpose, even though this restricts the types of tests that clinics can carry out.

**4.3.** We consider that the law does allow for any additional genetic information that satisfies a permitted purpose to be obtained and used in clinical decisions provided that the testing was initially carried out for a permitted purpose. For example, this would allow for testing of an embryo where there is a significant risk the child will have a serious condition that has been approved for PGT-M testing by the SAC, whilst also allowing the receipt of information on any other approved PGT-M conditions, abnormalities which may affect capacity to result in a live birth, HLA tissue-typing and quality checks on whose gametes were used to create the embryo. Embryos can be selected for on the basis of this additional information received (except for social sex selection unless permitted).

## 5. Options and next steps

**5.1.** A policy decision is needed to provide consistency and certainty in practice. Should the Authority agree to the approach set out in 4.3 the Authority are asked to consider the following proposed policy positions:

- As stated in law:
  - Testing is only allowed for one or more of the Permitted Purposes.
  - Clinics cannot select an embryo known to have a serious condition over one that does not.
  - Social sex selection is not permitted.
  - Informed consent needs to be in place.
- With regards to additional findings:
  - All testing has to have been carried out for a permitted purpose.
  - Clinics should not go looking for additional findings and should set this expectation, as set out in UK law, with any providers of genetic testing.
  - Only additional information that satisfies a permitted purpose and is supported by robust evidence should be received by clinics and can be used to make clinical decisions. Where clinics claim that tests do fall within a permitted purpose, they will need to have robust evidence.
  - Informed consent should be in place for the testing and receipt of any additional information.
  - Patients should be provided with appropriate information and counselling before testing is carried out to inform them about the consequences of any additional information so that they have the choice of whether they do in fact want this information.

**5.2.** Based on the Authority's direction on 4.3 and 5.1, the Executive will develop guidance/information for the sector, seeking expert advice as needed. That guidance is anticipated to include:

- Clarity regarding how to deal with additional information received.
- Reminding clinics of their legal obligations. It is important for PRs to ensure only testing permitted in law is carried out and that evidence justifying the particular test(s) should be recorded in the patient's medical record.
- A clinic should seek legal advice/justification of any test, as needed.
- If a clinic is not sure whether a particular condition has been approved by the Authority as being sufficiently serious, then a query or new application should be submitted to SAC for consideration.

**5.3.** It is likely that there will be a need to review guidance over time as methodologies develop. We will develop a structured approach to this which considers the law and the evidence base.

**5.4.** Based on the Authority's direction, the Executive will communicate with patients.

**5.5.** We will continue to advocate for law reform as appropriate given technological advances.

**5.6.** As noted at para 1.5, a review of where wide 'group' approval has been given for various conditions – "chromosomal rearrangements (various)" is to take place as part of a project being undertaken to audit the approved PGT-M list. As part of this, geneticists with appropriate expertise will help us determine specifically which types of chromosomal rearrangements would (or would not) fall under that wide 'group' approval (ie satisfying the seriousness test), and which types of chromosomal rearrangements should be individually approved by SAC.

# 6. Annex A – Wording on genetic testing in the HFE Act 2008

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,**

(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—

[1] Licences for treatment

(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.

Extracts from the Code of Practice:

**6.1.** 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

Furthermore, **SLC T89** states that “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.”.