Authority meeting

Date: 19 November 2025 – 12.45pm – 4.00pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of the meeting held on 25 September 2025 and matters arising (5) For decision	12.50pm
3. Chair and Chief Executive's report (10) For information	12.55pm
4. Committee Chairs' reports (20) For information	1.05pm
5. Performance Report (30) For information	1.25pm
6. 2026/27 Budget Proposal (20) For decision	1.55pm
Comfort break (10)	2.15pm
7. The Fertility Sector report and review of inspection feedback (verbal) (30)	2.25pm
8. The Regulation of AI in Fertility Treatment (45)	2.55pm
9. Any other business (verbal) (5)	
10. Close	

Minutes of Authority meeting held on 25 September 2025

Details:	
Area(s) of strategy this paper relates to:	Regulating a changing environment Supporting scientific and medical innovation
Agenda item	2
Meeting date	19 November 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 25 September 2025 as a true record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	Low

Minutes of the Authority meeting on 25 September 2025 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Frances Flinter Tom Fowler Graham James Zeynep Gurtin Alex Kafetz	Alison McTavish Geeta Nargund Catharine Seddon Rosamund Scott Anya Sizer Stephen Troup Christine Watson
Apologies	Tim Child	
Observers	Amy Parsons, Department of Health and Social Care (DHSC) Samantha West, DHSC (online)	
Staff in attendance	Peter Thompson (Chief Executive) Rachel Cutting (Director of Compliance & Information) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Tom Skrinar (Director of Finance & Resources) Sophie Tuhey (Head of Planning and Governance) Dina Hall (Head of Policy, Scientific) Rebecca Taylor (Scientific Policy Manager) Evgenia Savchyna (Corporate Performance Officer) 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 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 (post meeting note: appointed as the International Advisory Board member for Lancet Obstetrics, Gynaecology and Women's Health)
- Anya Sizer (freelance advisory work within the fertility sector)
- Stephen Troup (consultancy work within the fertility sector)
- Alex Kafetz (non-executive director (Board Member) of the Care Quality Commission)

2. Minutes of the last meeting and matters arising

2.1. The minutes of the meeting held on 9 July 2025 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

2.2. The Chair introduced the report and informed members that the items had been actioned as detailed in the report.

2.3. Members noted the matters arising report.

3. Chair and Chief Executive's report

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

3.2. The Chair informed the Authority that in July she had attended the HFEA all-staff event which is held twice a year. This had been a very positive and engaging event which had been reflected in staff feedback.

3.3. The Chair informed the Authority that she had chaired a meeting of the Remuneration Committee in July.

3.4. The Chair informed the Authority that together with the Chief Executive she attended the ALB (Arm's Length Body) Senior Leaders Meeting with the newly appointed Permanent Secretary of DHSC.

3.5. The Chair informed the Authority that Laura Shallcross, Professor or Public Health and Translational Data Science had been appointed as an external adviser to the Scientific and Clinical Advances Advisory Committee (SCAAC).

3.6. The Chief Executive referred to the Remuneration Committee meeting which was held in July and informed the Authority that this committee had agreed the annual staff pay award, within the Civil Service pay remits. This proposal had been submitted to the Department of Health and Social Care (DHSC) and we are awaiting a response.

3.7. The Chief Executive informed the Authority that together with Professor Frances Flinter he had met this morning with a delegation from the French Parliamentary Office for Scientific and Technological Assessment (OPECST). This delegation is considering potential updates to the French bioethics law and are comparing the French legal framework and practices with that of neighbouring European countries. The Chief Executive informed the Authority that he would keep them updated on any interesting proposals arising from this review.

Decision

3.8. 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) spoke of the important work of the committee in reviewing and approving the PGT-M applications, which allows families the opportunity to avoid passing on a serious inherited disease to their children. The SAC Chair spoke of the increasing number of applications being considered by the committee, reflected in the report before the Authority. Previously 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. The SAC Chair also commented that there is an increased take-up of carrier testing before treatment which could contribute to the increase in PGT-M applications.

4.3. The SAC Chair informed the Authority that every five to six years the existing list of PGT-M conditions is reviewed, to consider whether up-to-date treatment available on the NHS makes a difference to the assessment by SAC of the seriousness of the condition. The PGT-M conditions will be categorised into different sections and then external reviewers will be engaged to review the material. This work will take several months to complete as there are over 1,900 conditions on the PGT-M list.

4.4. The Chair spoke of the increasing number of applications which the SAC are being asked to review and the impact that this has on the work of the committee. The Authority will keep this under review to ensure that it is possible within the existing time commitments for committee members.

4.5. The Licence Committee Chair (Graham James) informed the Authority that the committee had met twice since the last Authority meeting and these meetings had considered a wide range of items including research applications and two changes in Person Responsible (PR) at clinics.

4.6. The Licence Committee Chair spoke of the role of the PR and how rapid turnover of PRs could indicate turbulence and non-compliance within some clinics. He remarked that some clinics are finding it a challenge to appoint suitability qualified PRs and he questioned how the sector is equipped for the next generation of PRs.

4.7. The Chair spoke of previous PR events hosted by the HFEA, noting that several PRs had highlighted the benefits of these events for networking and learning. The Chair informed the Authority that the Executive were considering whether a PR event could be hosted in 2026.

4.8. The Chair noted that both the Audit and Governance Committee (AGC) and the Scientific and Clinical Advances Advisory Committee (SCAAC) are due to meet in October and therefore a report on these meetings will be brought to the November Authority meeting.

4.9. Geeta Nargund informed the meeting that she had represented the HFEA at the Royal College of Obstetricians and Gynaecologists (RCOG) roundtable on Fibroids. This event brought together experts, policymakers and women to create recommendations for better screening, diagnosis and treatment. She had taken the opportunity to highlight the HFEA's report on ethnic diversity in fertility treatment.

4.10. 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.

4.11. Members noted the Committee Chairs' reports.

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 variable in August, with 12 indicators rated Green, two Neutral, three Amber and two rated Red. For those KPIs which are rated red there are particular reasons for this, rather than a structural issue, and the Senior Management Team were comfortable with these KPIs not being met.

5.3. The Chief Executive referred to the HR KPIs and commented that these can be used to measure the health of the organisation. He noted that the overall sickness rate remains within target.

5.4. The Chief Executive noted that while staff turnover has increased, it remains within target and is manageable. As a small ALB with limited promotion opportunities, some staff inevitably leave for advancement elsewhere. Vacancies are spread across teams and not concentrated in one area. The HFEA continues to attract strong applicant numbers, although civil service salary constraints affect recruitment for some roles.

5.5. The Chief Executive concluded that overall the HFEA is in good health, with staff remaining positive and engaged.

Strategy and Corporate Affairs

5.6. The Director of Strategy and Corporate Affairs referenced the recent publication of two papers in the *New England Journal of Medicine*, regarding eight babies born through a pioneering IVF technique that reduces the risk of mitochondrial diseases. She noted the HFEA comments on these publications, available on the HFEA website, and highlighted the significant national and international press interest these publications have generated. Thanks were extended to Frances Flinter for doing a number of press interviews on this.

5.7. The Director of Strategy and Corporate Affairs referred to the recent number of website views and noted that this has seen a slight downturn, attributed partly to the summer holidays and potentially to the rise of search tools that use generative AI. There are planned improvements to the HFEA website over the next year, including possibly a chatbot tool, to help people find information more easily.

5.8. The Director of Strategy and Corporate Affairs reminded the Authority that the Choose a Fertility Clinic (CaFC) consultation was launched in mid-August and that the consultation closes next week. Thanks were expressed to all these who have responded to the consultation. Once the consultation closes, the results will be analysed and brought to the Authority in November.

5.9. The Director of Strategy and Corporate Affairs informed the Authority that work is progressing on the next publication of the annual state of the fertility sector report, which details the performance of fertility clinics in the UK over the last year.

5.10. Following the SCAAC meeting in June 2025 where the committee considered the health outcomes for ART patients - including gestational surrogates and egg donors - the HFEA website has now been updated with information based on that review.

5.11. The Director of Strategy and Corporate Affairs informed the Authority that the Patient Organisation Stakeholder Group (POSG) and Professional Stakeholder Group (PSG) meetings are planned for October and November 2025, respectively.

5.12. The Director of Strategy and Corporate Affairs informed the Authority of the work to implement the new European Union (EU) regulations on Substances of Human Origin (SoHO) which come into force in August 2027. Relevant material will be brought forward to the Authority for approval.

5.13. The Director of Strategy and Corporate Affairs noted Channel 4's recent investigation into donor information and referred to the HFEA statement on this matter. It was noted that clinics are responsible for providing accurate information to the HFEA's register, and in cases where DNA

evidence suggests that a clinic has not provided the HFEA with the correct information, the clinic would be expected to investigate any errors and report them to the HFEA.

Compliance and Information

5.14. The Director of Compliance and Information informed the Authority that since September 2024 the OTR team has halved the OTR waiting list. In September 2024 the OTR waiting list stood at 1,118 and as of August 2025 this had been reduced to 541. Out of the 541 applications remaining, 274 are from parents, 127 from donors and 140 from donor-conceived people.

5.15. The Director of Compliance and Information noted that whilst there had been fewer OTRs processed last month due to annual leave and other work, the waiting list change target was still achieved. The OTR team are consistently achieving a higher number of applications closed to being received, demonstrating the benefits of the new system and processes.

5.16. The Director of Compliance and Information informed the Authority that the current Head of Information leaves the HFEA shortly and that there will be a short delay in the new appointee taking up the position.

5.17. The Director of Compliance and Information highlighted the busy schedule for the Inspections team, not only in conducting inspections but also in supporting the work of the IT Phoenix project. Engagement and dialogue with PRs over complex reports was highlighted as a positive aspect of the inspection team's work, although it was noted that this can affect the relevant KPI.

5.18. The Director of Compliance and Information informed the Authority of the British Fertility Society (BFS) Study Week which was held from 22 to 25 September 2025 in London. This included a joint BFS/HFEA day focussing on topics such as challenges for fertility services, integrating counselling and supporting patients and surviving in a cost-of-living crisis. During the Study Week, the HFEA's Regulatory Policy Manager presented on the topic of consent, and the Donor Information Manager presented on the OTR service at the Creating Modern Families Day.

5.19. Frances Flinter informed the Authority that she also presented at the BFS Study Week on how the HFEA regulates PGT-M applications.

5.20. In response to a question regarding what contingency is in place to manage the increase in PGT-M applications, the Director of Compliance and Information highlighted the dedicated position within the compliance team to review these applications. The Director of Corporate Affairs and Strategy informed the Authority that the Head of Licensing was reviewing trends and the wider decision-making process to see whether anything could be streamlined. Whilst there may be some contingency within the Licensing and Inspection Team, SAC already meets 12 times a year so there is no opportunity to increase the number of meetings.

Finance, Planning and Technology

5.21. The Director of Finance, Planning and Technology informed members that the Planning and Governance team have been working with the Government Internal Audit Agency (GIAA) to complete the audit on the 2023 Public Bodies Review (PBR) and commence the audit on operational risk management. The team are also working with DHSC to update the Framework Agreement.

5.22. The HFEA's business continuity plan has now been successfully tested with the Senior Management Team and all staff. The Director of Finance, Planning and Technology stated that

business continuity planning will be a future deep-dive discussion topic for the Audit and Governance Committee.

5.23. The Director of Finance, Planning and Technology reported that the Corporate Management Group Plus meeting was held recently with a forward look to the 2026 Business Plan.

5.24. The Director of Finance, Planning and Technology reported that the Phoenix Programme is progressing well, with completed work being signed off by the relevant teams. The migration to SharePoint has been pushed back, which will give the team more time to plan the required architecture for SharePoint. Windows 11 upgrade is being rolled-out to all corporate devices and should be completed within a couple of weeks.

5.25. The Director of Finance, Planning and Technology informed the Authority that the HFEA's Cyber Assessment Framework aligned Data Security and Protection Toolkit (DSPT) submission had been submitted, and an 'approaching standards' score had been received. An application has been made to NHS England for additional cyber funding.

5.26. The Director of Finance, Planning and Technology referred to the Financial KPIs and informed the Authority that the KPI regarding aged debt is due to be reviewed with the team in the Autumn.

5.27. The Director of Finance, Planning and Technology informed the Authority that the current forecasting of the HFEA's year-end financial position is for a £425kdeficit. This position is largely driven by income raised from the sector, which is driven by clinic activity, being considerably lower this year than budgeted for. A review of expenditure will be taken in September and October 2025 with the aim of reducing this deficit as much as possible.

5.28. The Director of Finance, Planning and Technology spoke of the increased staff costs for temporary staff and maternity leave cover; increases were also seen in legal costs and Microsoft licences. The Director of Finance, Planning and Technology informed the Authority that he is in contact with DHSC regarding the HFEA's financial position.

5.29. The Chair commented that the HFEA's options for additional savings are limited and that the HFEA is a well-run organisation with very little unaccounted spending.

5.30. A member questioned how the Executive Team can ensure that any cost savings actions will not negatively impact staff morale and how they could safeguard against additional pressure on staff. The Chief Executive responded that the Executive Team would continue to be open and transparent with staff, monitoring any feedback and focussing on delivery of essential tasks.

Decision

5.31. Members noted the performance report.

6. Update from July 2025 Horizon Scanning Meeting

6.1. The Chair introduced this item stating that fertility treatment and research involving human embryos is a fast-moving area of science and that the HFEA has several mechanisms for keeping up to date with new developments. One mechanism is the horizon scanning meeting held during the annual European Society of Human Reproduction and Embryology (ESHRE) conference, which brings together experts from across the world.

6.2. The Scientific Policy Manager informed the Authority that the horizon scanning function was set up in 2004 to identify developments in research and technology that could have an impact on

assisted reproduction or embryo research. It helps to build relationships with researchers and clinicians and build the HFEA's reputation. The HFEA uses knowledge gained from this function to shape current and future work, including helping to shape the SCAAC's work programme and updating clinic guidance and patent information.

6.3. The Scientific Policy Manager explained that the HFEA conducts its horizon scanning function through a variety of ways including:

- literature reviews which are presented in SCAAC papers
- consulting experts including SCAAC members and external experts
- HFEA staff attending conferences and meetings such as ESHRE, and the Annual Fertility Conference hosted by the Association of Reproductive & Clinical Scientists, the British Fertility Society, and the Society for Reproduction and Fertility.
- SCAAC members raising topics or research papers to the committee at each meeting
- Annual horizon scanning meeting during the ESHRE conference.

6.4. ESHRE is one of the biggest fertility conferences in the world and, as noted above, the HFEA holds its annual horizon scanning meeting, usually chaired by the SCAAC Chair, alongside this event. The Scientific Policy Manager explained that the horizon scanning meeting is an invite only, in-person international meeting with speakers on 3-4 topics. The Scientific Policy Manager explained that notes providing an overview of the meeting will form part of the papers for the October 2025 SCAAC meeting and will be published on the HFEA website.

6.5. The Scientific Policy Manager informed the Authority that 22 participants from a wide range of backgrounds attended the HFEA's 2025 Horizon Scanning Meeting in Paris. The three topics which were discussed were non-disease related mitochondrial donation, in vitro spermatogenesis for male fertility preservation and robotics and automation in fertility treatment.

6.6. The first speaker at the 2025 horizon scanning meeting was Dr Nuno Costa Borges, Scientific Director of Embryotools, Spain whose talk was titled "*Future use of Mitochondrial Donation? Going beyond preventing inherited disease*." The Scientific Policy Manager explained that mitochondrial donation treatment (MDT) can only be undertaken in the UK to prevent children being born with mitochondrial disease and each application requires an HFEA licence. However, in recent years there have been discussions on the use of MDT for infertility rather than disease prevention. The meeting discussed clinical safety including mitochondrial reversion, target patient population and the use of maternal spindle transfer technique.

6.7. The second speaker at the 2025 horizon scanning meeting was Dr Christine Rondanino, Associate Professor, University of Rouen, France whose talked was titled "*Emerging Techniques in Male Fertility Preservation: The Role of In Vitro Spermatogenesis*". The Scientific Policy Manager explained that male fertility preservation, particularly in children, is a growing research area with current methods in pre-pubescent boys being difficult and invasive. The meeting discussed in vitro maturation (IVM) of prepubertal testicular cells/tissues, success studies in mice which has achieved proof of concept, safety concerns and public perception of IV derived sperm.

6.8. The third speaker was Dr Eduardo Mendizabal-Ruiz, Professor of Computer Science at the University of Guadalajara, Mexico and VP Exploration at Conceivable Life Sciences, whose talk was titled *"Remote Control IVF – the potential of robotics and automation to revolutionise fertility treatment"*. The Scientific Policy Manager explained that this is a horizon scanning topic due to

increasing and expanding use of automation in IVF clinics. The Scientific Policy Manager noted that a case report was published earlier this year by Professor Mendizabal Ruiz and others on "remote control ICSI", where a clinician was 3,700 miles away from the patient remotely operating the digital ICSI system. The meeting discussed automation as a solution to global shortages of qualified staff, increased embryologist productivity through standardisation, and the risk landscape including technology, cyber security and algorithmic bias.

6.9. The Scientific Policy Manager outlined the 2025-26 topic prioritisation process, using categories of high, medium, low, and watching brief, and explained the criteria used for classification. Prioritisation of topics is reviewed annually by SCAAC in February, and high-priority topics inform the Authority's work. The Scientific Policy Manager highlighted the 2025–26 SCAAC workplan.

6.10. The Scientific Policy Manager informed the Authority that ESHRE 2026 will be held in London during July 2026.

6.11. The Deputy Chair of SCAAC praised the horizon scanning meeting as a valuable forum that brings together international experts to discuss emerging issues. He highlighted the high calibre of discussion and noted that the topics covered were at varying stages of development. He expressed confidence that, through the horizon scanning function and the work of SCAAC, the HFEA is well positioned to address emerging issues, while also acknowledging the pressure on the HFEA as the regulator to provide guidance on these topics.

6.12. Members acknowledged the vital role of the HFEA's horizon scanning function and its contribution to the Authority's broader work. The supporting team was congratulated for their efforts.

6.13. A member commented that they were reassured that the meeting had discussed the risk landscape regarding robotics and automation in IVF. They questioned whether this had also considered the impact of patient trust and confidence. The Scientific Policy Manager responded that the meeting did have a discussion concerning patient confidence.

6.14. A member questioned whether the concept of making IVF accessible should be added to the items for consideration by horizon scanning as there is currently work being undertaken on this subject.

6.15. A member spoke of an event they had attended on circadian neuroscience and asked whether this should be added to the watching brief list of topics.

6.16. A member raised the importance of public trust and asked how the HFEA could best engage the public around the horizon scanning meeting, including exploring ways to proactively reach a wider audience. The Director of Strategy and Corporate Affairs outlined the ways that the HFEA engages with members of the public through the Patient Organisation Stakeholder Group (POSG) and the Patient Engagement Forum (PEF). In thinking about this issue, it was important to acknowledge that the HFEA Horizon Scanning meeting discusses highly scientific matters, often where there are small indicative studies which have not yet proven to be effective.

6.17. In response to a question the Chief Executive explained that the HFEA's horizon scanning meeting is held at ESHRE for historical reasons but had proven to be cost effective and it is useful for the HFEA to have SCAAC consider and understand these emerging topics.

6.18. The Chair drew the conversation to a close, noting that ESHRE will be in London in 2026 and that the HFEA will be considering how best to take advantage of the event being in the UK.

Decision

6.19. The Authority noted the verbal update from the July 2025 Horizon Scanning Meeting.

7. Embryo Testing

7.1. The Chair introduced this item stating that the ability to test embryos is changing fast and this paper sets out a range of policy issues that flow from these scientific developments.

7.2. The Head of Policy introduced the paper and informed the Authority that the HFE Act 2008 prohibits embryo testing except for one of the purposes permitted in the Act. 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. The Act also prohibits practices preferring one sex over the other except where one sex presents a much greater risk of having a serious condition than the other.

7.3. The Head of Policy explained that there is no "best interest" test of relevance to the legal scope of testing; rather what is permitted is set out in the Act.

7.4. The Head of Policy stated that the HFEA's role is to promote compliance with the Act and to ensure that testing is carried out lawfully, for example by providing clinics with guidance and inspecting clinic activities. The testing of embryos is a licensable activity, and clinics must have a licence to undertake this work.

7.5. The testing methods permitted by the HFEA for clinics that are licensed to test embryos are PGT-M, PGT-SR and PTT (which require SAC approval) and PGT-A.

7.6. Continuing, the Head of Policy explained that the methodologies for carrying out genetic testing had significantly advanced since the law was passed. In addition, technology such as whole genome sequencing (WGS) can now reveal the embryo's full genetic information.

7.7. These developments in testing can raise the question of what, if any, additional information can be obtained from what might be termed opportunistic testing or screening. While the initial reason for testing may be lawful, there is a question about whether receipt of some of the information generated from the test is legally permitted. The Head of Policy stated that the law could now be seen as restrictive in preventing some potentially relevant tests, which are claimed to be in the interests of the patient and supported by robust evidence, from being undertaken.

7.8. There are also variations in what information is collected and reported back to clinics - the commercial companies commissioned to carry out the genetic testing often report more than is requested.

7.9. The Head of Policy explained that when the law was drafted, the clear intention was to permit embryo testing only for one of the defined Permitted Purposes. Clinics may receive only the information necessary for that Permitted Purpose and embryos may only be selected for (or against) based on that limited information.

7.10. The HFEA has a duty to promote compliance with the Act and it considers that the law does allow additional genetic information to be used in clinical decisions, provided this satisfies a Permitted Purpose and the testing was originally conducted for that purpose.

7.11. The Head of Policy referred to the options and next steps outlined in the paper and invited the Authority's discussion and decision.

7.12. The Chair thanked the Head of Policy and noted that this is another example of scientific and medical advances pushing the boundaries of existing law.

7.13. The Authority congratulated the HFEA staff for a well written and clear paper on a complicated area.

7.14. A member noted that rapid technological developments are outpacing the HFEA's ability to regulate them. Many companies now offer tests internationally and are reluctant to alter how they analyse and report results specifically for UK clinics. In response to a question, it was confirmed that these companies could filter results but that they are choosing not to.

7.15. A member spoke of the consequence of extended population screening without due consideration of the full family history, which could lead to some embryos being discarded when they could develop into a viable pregnancy with no particular risk of inherited diseases.

7.16. A member highlighted the need to balance informed consent, appropriate counselling, clinical decision-making, and patient data protection in clinics. They felt the clarification in section 4.3 of the paper was robust, and the proposed next steps in paragraph 5.1 were clear and likely to be welcomed by clinics.

7.17. A member noted the HFEA's limited ability to sanction clinics that fail to follow guidance and questioned whether a trusted supplier list could be developed for companies offering the required testing.

7.18. A member emphasised the importance of protecting patients and supporting those taking steps to avoid passing on serious inherited diseases. While updating the information on the HFEA's website was discussed, it was noted that the primary responsibility lies with clinics to provide relevant information to their patients.

7.19. Members discussed the clinical responsibilities involved in offering such testing, emphasising that clinics must have the necessary expertise to explain and manage these areas, including providing appropriate counselling. They stressed the importance of clinics understanding the challenges involved and noted the need for infrastructure to support the new patient pathway.

7.20. Members noted that whilst many clinics offer fertility counselling, access to genetic counselling may not be as easily provided by some clinics. It was noted that genetic counselling is offered under the NHS pathway for PGT-M treatment.

7.21. Members spoke of the genome sequencing work that is being undertaken, especially through the NHS Genomic Medicine Service and the National Genomic Test Directory.

7.22. Members noted the varying approaches across the sector and agreed that the HFEA's proposed policy positions and guidance would provide valuable clarity. They supported the proposed guidance and welcomed the range of information it could include. Members also emphasised the need to review the guidance over time as methodologies evolve and were pleased with the structured approach planned for future updates.

7.23. Members were appreciative of the continued advocacy for law reform, as appropriate, given technological advances.

7.24. The Chair informed the Authority that whilst the Chair of SCAAC could not attend this meeting he had asked that his support for the position as laid out in paragraph 4.3 of the paper and the proposed guidance to the sector be recorded.

Decision

7.25. The Authority, by clear majority, agreed that the law permits additional genetic information to be obtained and used in clinical decisions, provided it meets a Permitted Purpose and the testing was originally conducted for a permitted purpose. Guidance for the sector will need to be developed and the principles therein will be brought back to the Authority for review.

7.26. The Authority agreed to a review of where broad 'group' approval has been given for various conditions – that is, "chromosomal rearrangements (various)".

Action

7.27. The HFEA to develop the proposed guidance for the sector and bring back to the Authority for further consideration.

7.28. The HFEA Executive to continue with their watching brief on these developments.

8. Any other business

8.1. Geeta Nargund referred to the email circulated to members by the Director of Strategy and Corporate Affairs regarding the NICE guidance regarding "Fertility problems: assessment and treatment". She encouraged members to respond within the requested timeframe to help formulate the HFEA's official response.

8.2. The Chair thanked everyone for their active participation in the meeting. She reminded members that their next meeting will be held virtually on 5 November 2025 to discuss the publication of the full CaFC. The next full Authority meeting will be on 19 November 2025. Both meeting dates are published on the HFEA website.

8.3. The Chair reminded members that the Board Effectiveness Review material would be issued to them shortly and requested that they complete the review within the required timeframe.

8.4. There were no further items of any other business and the Chair closed the meeting.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 19 November 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:	19 November 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
25/09/2025 Item 7.28	The HFEA to develop the proposed guidance for the sector and bring back to the Authority for further consideration	Director of Compliance & Information/Head of Policy (Scientific)	Summer 2026		Kick off meeting with some Authority members to take place in November 2025.
25/09/2025 Item 7.29	The HFEA Executive to continue with their watching brief on these developments	HFEA Executive	On-going		Watching brief has been added to the relevant team's service delivery plan. This item can now be considered as 'business as usual' so can be removed from the matters arising list.

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:	19 November 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 September 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:

    - 26 September –attended the Robert Edwards Centenary celebration of his research in Cambridge.
    - 6 October – attended SCAAC Committee.
    - 4 November – participated in a workshop at Nuffield Council on Bioethics on the agile regulatory frameworks needed to responsibly govern fast emerging technologies.
    - 5 November – attended the online Authority meeting.

2.2 Chief Executive

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

    - 14 October –attended the Audit and Governance Committee
    - 16 October – attended the Quarterly Accountability meeting DHSC/HFEA
    - 27-29 October – FA and others, Royal Courts of Justice
    - 28 October – attended Health and Social Care Regulators Forum
    - 5 November – attended the online Authority meeting.

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:	19 November 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:			
11 September	Renewal inspection report	Birmingham Women's Hospital	Approved – 4 year licence
	Renewal inspection report	St Jude's Women's Hospital	Adjourned pending further update
	Executive update	Bourn Hall Clinic	Update noted
	Variation of PR	Homerton Fertility Centre	Approved – licence (and ITE certificate) varied
	Variation of PR	Bridge Clinic	Approved – licence (and ITE certificate) varied
6 November	Focused inspection	Bourn Hall Clinic	Minutes not yet approved
Other comments:	Licence Committee will next meet on 15 January 2026.		
Executive Licensing Panel:			
2 September	Renewal inspection report	In-OVO Fertility Clinic	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Hewitt Fertility Centre	Approved – 4 year licence (and ITE certificate)
15 September	Renewal inspection report	Care Fertility London	Approved – 4 year licence (and ITE certificate)
	Variation of premises	TFP GCRM Fertility	Approved – licence varied
30 September	Renewal inspection report and variation of licence to add embryo testing	Acorn Fertility	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Centre for Reproductive and Genetic Health City	Approved – 4 year licence (and ITE certificate)
	Interim inspection report and variation of SLC T52 without application	Semovo Wigan	Approved – licence varied

Date	Items considered	Centres	Outcomes
3 October	Interim inspection report and variation of SLC T52 without application	Care Fertility Cardiff	Approved – licence varied
13 October	Renewal inspection report	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Andrology Unit, Hammersmith Hospital	Approved – 4 year licence
	Interim inspection report and variation of SLC T52 without application	The Evewell West London	Approved – licence varied
	Interim inspection report and variation of SLC T52 without application	London Women's Clinic, Wales	Approved – licence varied
	Voluntary revocation of licence	Cryos International – UK Ltd	Approved – licence revoked
20 October	Variation of PR	CREATE Fertility, Birmingham	Approved – licence (and ITE certificate) varied
	Variation of PR	CREATE Fertility, Manchester	Approved – licence (and ITE certificate) varied
	Variation of PR	CREATE Fertility, Leeds	Approved – licence (and ITE certificate) varied
28 October	Renewal inspection report	Regional Fertility Centre, Belfast	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Sussex Sperm Bank	Approved – 4 year licence (and ITE certificate)
	Variation of PR	London Women's Clinic, Darlington	Approved – licence varied
	Variation of activities and variation of SLC T52 without application	Chelsea & Westminster Hospital	Approved – licence varied
	Variation of PR	CARE Fertility Plymouth	Approved – licence varied
11 November	Renewal inspection report	CARE Fertility Tunbridge Wells	
	Interim inspection	Fertility Exeter	
	Interim inspection report, variation of PR and variation of SLC T52 without application	Beginnings at Epsom & St Helier NHS University Trust	
Other comments:	None.		

Date	Items considered	Centres	Outcomes
Licensing Officer decisions:			
September	6 x ITE import certificates	Various	All granted
October	8 x ITE import certificates	Various	All granted
3 October 2025	Voluntary Revocation	Cornwall Centre for Reproductive Medicine (CCRM)	Approved – licence revoked
9 October 2025	Voluntary Revocation	London Women's Clinic Eastbourne	Approved – licence revoked
9 October 2025	Voluntary Revocation	Fertility Unit Barking, Havering And Redbridge Hospitals	Approved – licence revoked
Other comments:	None.		
Statutory Approvals Committee:			
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	Approved
	Acromicric Dysplasia (ACMICD), OMIM #102370	Wolfson Fertility Centre – Hammersmith Hospital	Approved
	Hemochromatosis, Type 1 (HFE1), OMIM #235200	Birmingham Women's Hospital	Refused
	Pulmonary Fibrosis and/or Bone Marrow Failure Syndrome, Telomere-Related, 1 (PFBMFT1), OMIM #614742	Birmingham Women's Hospital	Approved
	Brachyolmia Type 4 with Mild Epiphyseal and Metaphyseal Changes (BCYM4), OMIM #612847	TFP Oxford Fertility	Approved
	Chordoma, Susceptibility to (CHDM), OMIM #215400	Care Fertility Nottingham	Approved
	Ectodermal Dysplasia 1, Hypohidrotic, X-Linked (XHED), OMIM #305100	TFP Oxford Fertility	Approved

Date	Items considered	Centres	Outcomes
	Vertebral, Cardiac, Renal, and Limb Defects Syndrome 2 (VCRL2), OMIM #617661	Care Fertility Nottingham	Approved
	Special direction to import embryos from USA	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
29 September	Obesity, Early-Onset, with Adrenal Insufficiency and Red Hair (OBAIRH), OMIM #609734	Birmingham Women's Hospital	Approved
	Glomuvenous Malformations (GVM), OMIM #138000	Birmingham Women's Hospital	Approved
	Purine Nucleoside Phosphorylase Deficiency (PNPD) OMIM #613179	Care Fertility Nottingham	Approved
	Short Stature, Amelogenesis Imperfecta, and Skeletal Dysplasia with Scoliosis (SSASKS), OMIM #618363	Care Fertility Nottingham	Approved
	Renal Hypodysplasia/Aplasia 3 (RHDA3), OMIM #617805	Guys Hospital	Approved
	Intellectual Developmental Disorder, Autosomal Recessive 39 (MRT39), OMIM #615541	TFP Oxford Fertility	Approved
	Proliferative Vasculopathy and Hydranencephaly-Hydrocephaly Syndrome (PVHH), OMIM #225790	Birmingham Women's Hospital	Approved
	Al Kaissi Syndrome (ALKAS), OMIM #617694	Birmingham Women's Hospital	Approved
	Export sperm to Greece	CARE Fertility Manchester	Approved
	Import eggs and embryos from Denmark	TFP GCRM Fertility	Approved
	Import embryos from Australia	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
28 October	Cornelia De Lange Syndrome 1 (CDLS1), OMIM #122470	Fertility Exeter	Minutes not yet approved
	Dyssegmental Dysplasia, Silverman-Handmaker Type (DDSH), OMIM #224410	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved

Date	Items considered	Centres	Outcomes
	Optic Atrophy 12 (OPA12), OMIM #618977	King's Fertility	Minutes not yet approved
	Epilepsy, Nocturnal Frontal Lobe, 3 (ENFL3), OMIM #605375	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved
	Rubinstein-Taybi Syndrome 2 (RSTS2), OMIM #613684	Care Fertility Nottingham	Minutes not yet approved
	Anemia, Sideroblastic, 2, Pyridoxine-Refractory (SIDBA2), OMIM #205950	Guys Hospital	Minutes not yet approved
	Short Stature and Advanced Bone Age with or without Early-Onset Osteoarthritis and/or Osteochondritis Dissecans (SSOAOD)	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved
	Import embryos from Czech Republic	The Fertility & Gynaecology Academy	Minutes not yet approved
	Import eggs from Spain	IVI London (Wimpole Street)	Minutes not yet approved
Other comments:	When considering PGT-M applications, the Committee frequently considers not only the specific condition applied for, but also other similar conditions. In such cases, more than one condition may be authorised for testing.		

Audit and Governance Committee:

AGC met on 14 October and the papers can be found here. Items considered by the committee included:

- Internal Audit
- Global Internal Audit Standards
- Progress with current audit recommendations
- Risk update
- Deep dive discussion on whistle blowing
- Digital project – PRISM and Phoenix Programme
- Resilience, business continuity manager and cyber security
- Faud
- Reserves policy
- Committee effectiveness review

The Chair will report on this meeting verbally.

Scientific and Clinical Advances Advisory Committee:

Date	Items considered	Outcomes
6 October	The agenda and papers for this meeting are published on the SCAAC webpage.	The SCAAC Chair will report on this meeting verbally.

	Items considered included:	Key takeaways are as follows:
	Relevant public health developments and research findings	Under this item, members discussed the two recent papers published by the Newcastle Fertility Centre reporting on **mitochondrial donation by pronuclear transfer** and the **reproductive care pathway** for mitochondrial donation patients. They then went onto consider a paper reporting on IVF outcomes in same-sex female couples using their partner eggs versus own eggs. The findings of this paper resulted in a minor change being made to information on the risks of IVF on the HFEA website regarding reciprocal IVF. Media attention surrounding the paper on the development of human oocytes from adult somatic (skin) cells was also discussed. Members noted that the paper did not add many further insights on the topic but may have caused a false sense of hope and worry amongst the public. The committee finally considered an abstract review describing the role of rescue in vitro maturation and rescue ICSI in cases of low/failed maturation and fertilisation, recommending that clinics are reminded of the professional body guidelines.
	Alternative methods to derive embryonic and embryonic-like stem cells	Members reviewed research developments on methods of establishing and maintaining stem cell populations derived from human embryos, including extraembryonic stem cell lines, and discussed the implications for stem-cell based embryo models the improved study of human embryogenesis. To reflect developments in the research, the title of this topic was updated.
	Testicular tissue transplantation to restore fertility in males	The topic of testicular tissue transplantation to restore fertility in males was considered for the first time since it was added to the SCAAC's list of prioritised topics. The literature search highlighted findings from pre-clinical animal research and a case report of the first autologous grafting of adult human testis tissue.

		Other research focused on methodology and protocols used for testicular tissue culture and cryopreservation, including safety and health outcomes as well as the impact of cancer and cancer treatment on fertility. Studies on attitudes and experiences of providers, patients and families were also considered. Members noted that men who previously had tissue cryopreserved as prepubertal boys are beginning to return to treatment hospitals wishing to use the tissue, although this has not yet been attempted in the UK. There is a joint HFEA and Human Tissue Authority (HTA) statement currently in place to address the regulatory overlap.
	Rating review for treatment add-ons: Platelet rich plasma (PRP)	During the June 2025 SCAAC meeting the Committee agreed that platelet-rich plasma (PRP) for intrauterine and intraovarian infusion/injection met the criteria to be rated as an HFEA treatment add-on. During the meeting, the Committee agreed ratings for both intrauterine and intraovarian PRP across five patient groups. Further information will be added to the 'Treatment add-ons with limited evidence' webpage in due course.
Other comments:	Professor Laura Shallcross was welcomed to the SCAAC as new External Adviser. Professor Shallcross brings expertise in public health and translational data science and has been appointed for an initial term of three years. The Executive are currently recruiting for a pool of expert biostatisticians, with experience in systematic review and evidence assessment using the GRADE methodology, to assist the SCAAC with their add-ons review process.	

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 October 2025

Evgenia Savchyna
Corporate Performance Officer
19/11/2025

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:	19/11/2025
Agenda item:	Item 5
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

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

Human Fertilisation & Embryology Authority

Management summary

- Performance across KPIs in October 2025 was variable, with eleven KPIs rated Green, three Neutral, two Amber and three rated Red.
- The Compliance KPI performance was mixed in October: ‘Inspection Reports to PR’ KPI was rated Amber due to two complex reports; ‘Inspection Reports to Committee’ KPI was rated Green;, and the ‘End-to-End Licensing’ KPI was rated Red with four out of ten reports missing their targets mainly due to report complexity and staff annual leave.
- The high number of PGT-M applications received in May have continued to impact our performance; however, this backlog has now been processed, and we expect the performance to return to within KPI tolerance
- October was a particularly busy month for Licensing, with two emergency ELP meetings held, and their minutes expedited. Additionally, one set of LC meeting minutes were also expedited.
- Both OTR KPIs were rated Green with 166 OTRs closed, reducing the waiting list to 362.
- The number of email enquiries in October (131) returned to the monthly average compared to September (64) which was a quiet month. The number of calls remained low at 16. Themes of both enquiry types were varied.
- Seven FOIs were completed within the KPI. In addition, one complex FOI that had missed the deadline in July, was completed in October. No PQs were due in October.
- In October, pregnancy related long-term sickness absence led to the Sickness KPI turning Red. The Turnover KPI remains within the target but positioned at the upper threshold (14.6%).

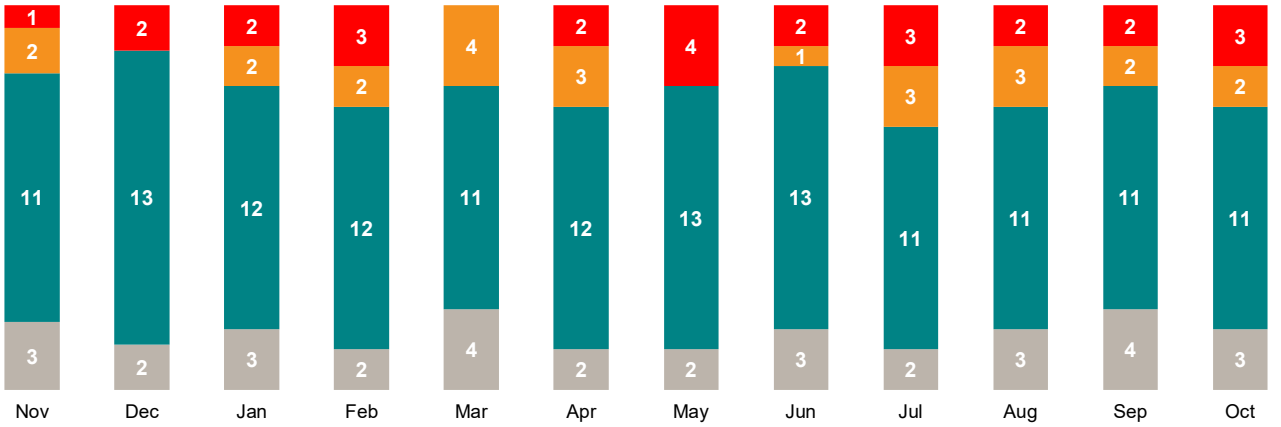
KPI reviews

- The Enquiries KPI review was completed in October. While it did not affect the current reporting of enquiries, it identified several potential risks. A new Dynamics-based enquiries system, scheduled for implementation in early 2026, will address these risks and streamline the enquiries process.
- The Finance KPI review has commenced in October and due for completion in December 2025.

Key performance indicators

Human Fertilisation & Embryology Authority

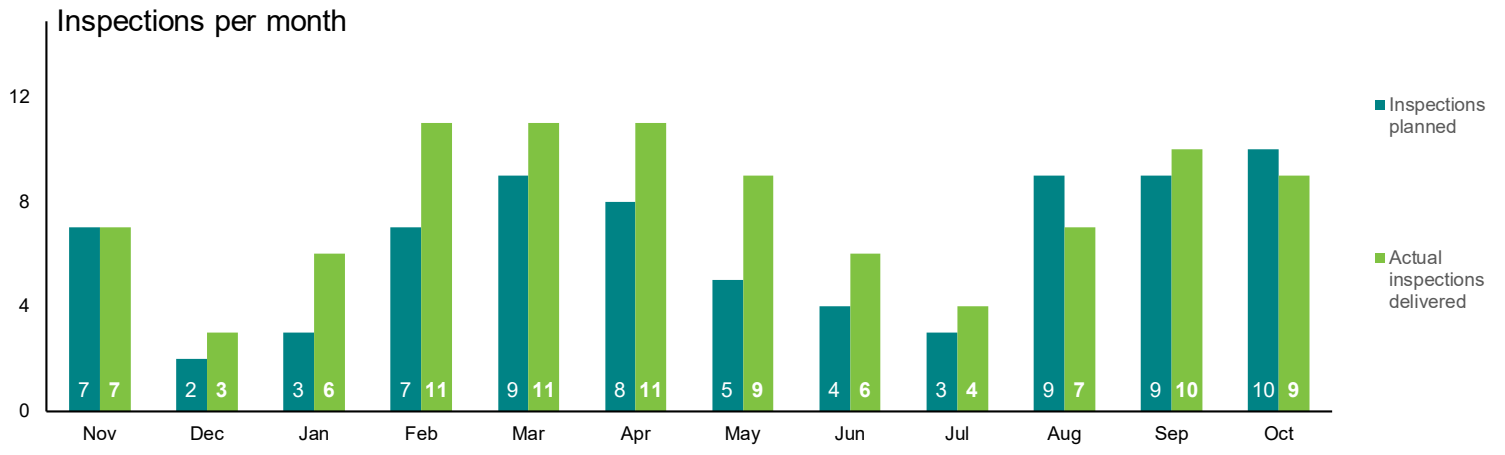
RAG status over last 12 months



RAG status over last 12 months

19 KPIs in total for each month starting from Jan 2025

For October, the 3 red indicators are in these teams: **Compliance** - 1 ('End to End licensing'), **HR** - 1 ('Sickness rate'), and **Finance** - 1 ('Debt collection within 40 days').



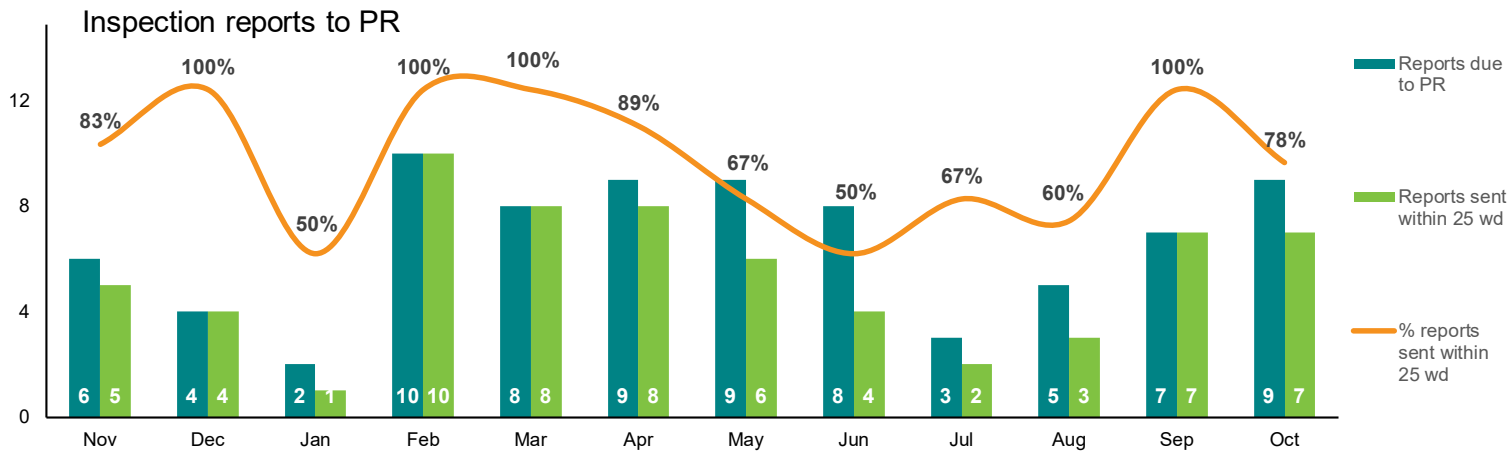
Status: **N/A**

Compliance

Inspections delivery

Target: **not defined**

Ten inspections were planned for October, and nine were delivered following a reshuffle of the inspection schedule.



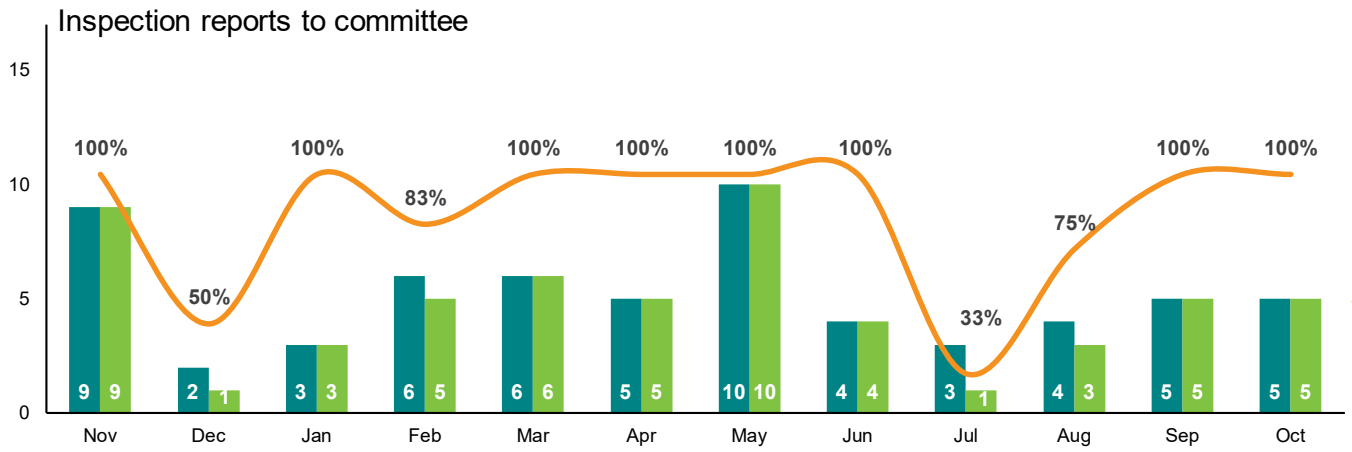
Status: **Amber**

Compliance

Inspection reports sent to PR

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

Two reports missed their KPIs (28 wd and 37 wd) due to the complexity of the report and the need for an additional inspection.



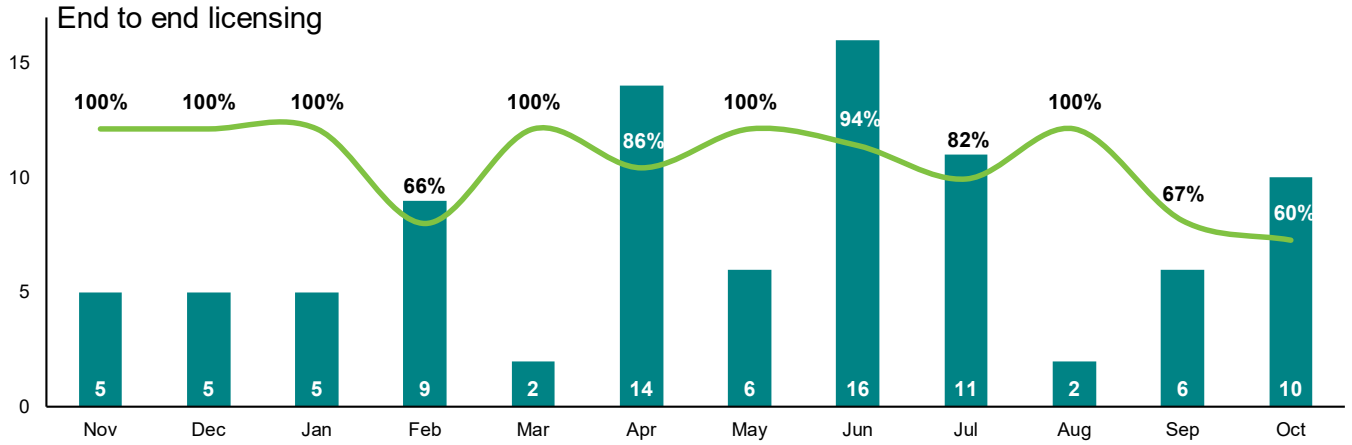
Status: **Green**

Compliance

Inspection reports sent to relevant licensing committee

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

All reports have been submitted to committee within KPI.



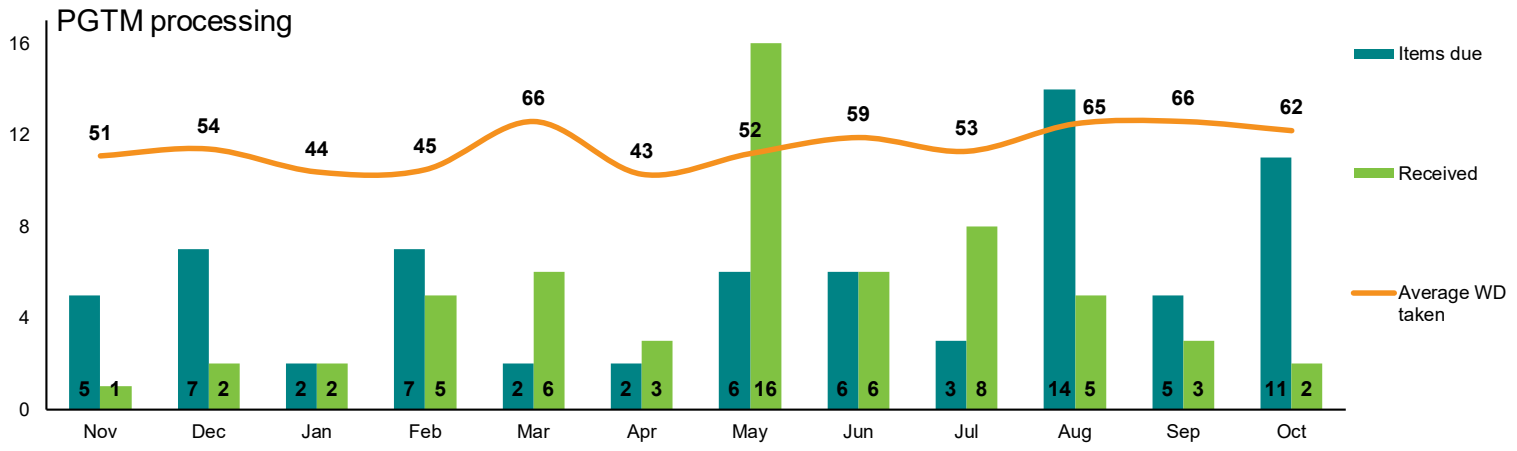
Status: **Red**

Compliance

End to end licensing process

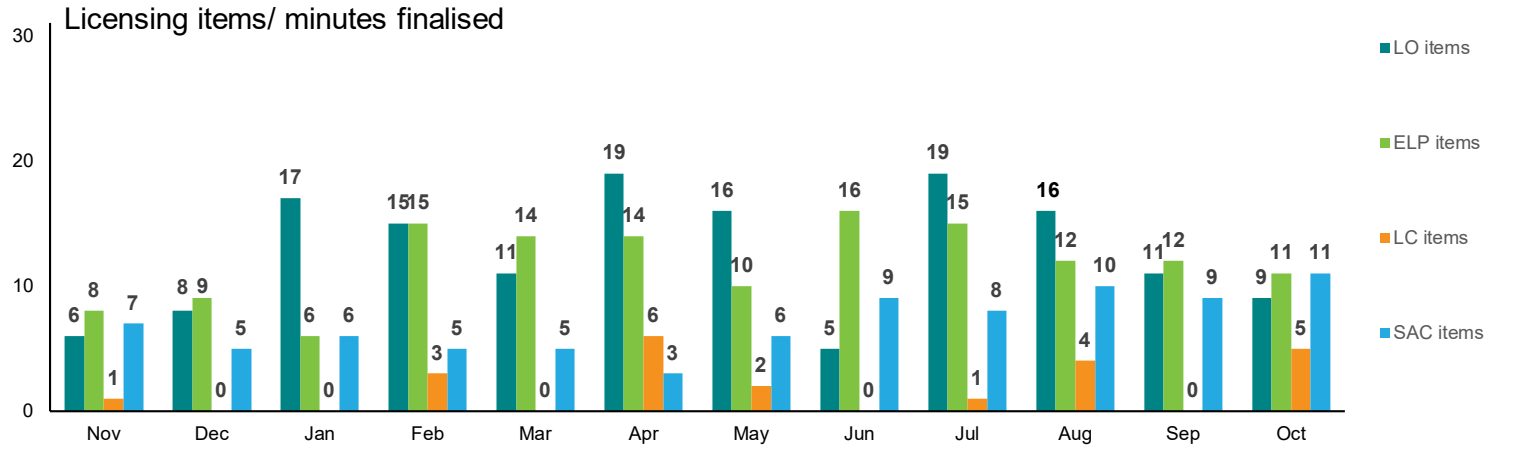
Target: **100% items completed within 80 working days**

Four out of ten reports missed their KPIs. Two of these (82 and 109 WD) were renewal reports delayed due to the centre's, and our own annual leave. Due to delays with PR responses, a Special Direction was issued for one centre (105 WD) to continue with licensed activity. A complex interim inspection report (183 WD) was also delayed, requiring several meetings with Legal as per our Compliance and Enforcement policy.



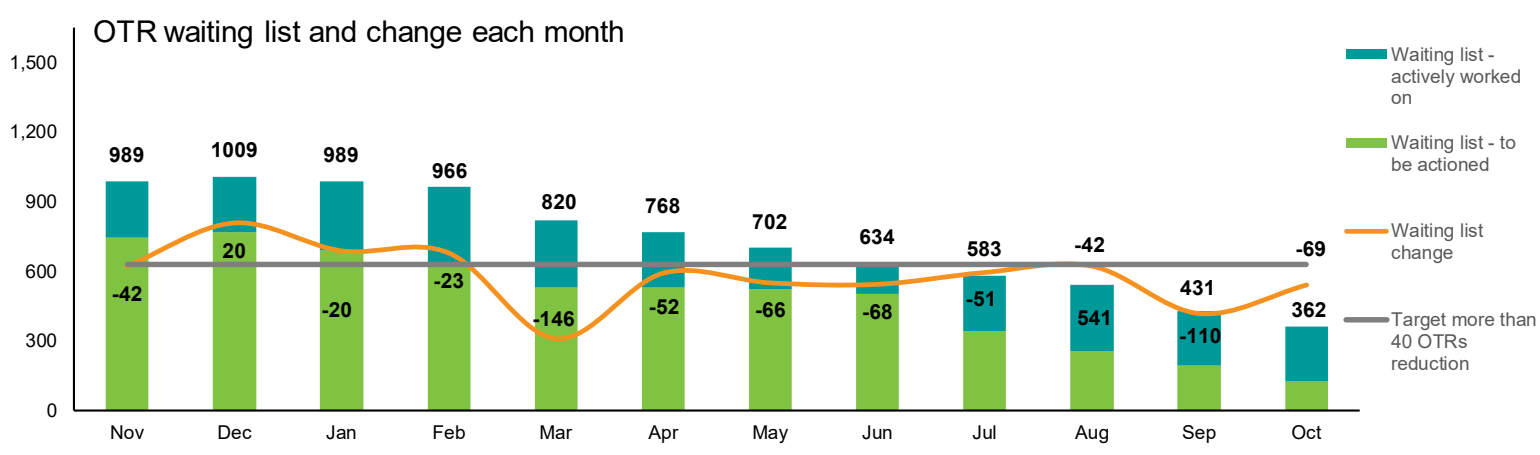
Status:	Amber
Compliance	
PGTM processing efficiency	
New target - Dec 24: **average time within 60 working days**	

We have missed the target the last three months but only by a few days. The dip in performance has been due principally to a very high number of PGT-M applications in May, but this bulge has now been processed. Looking ahead, if the number of applications return to the norm then we expect performance to return to within KPI tolerance.



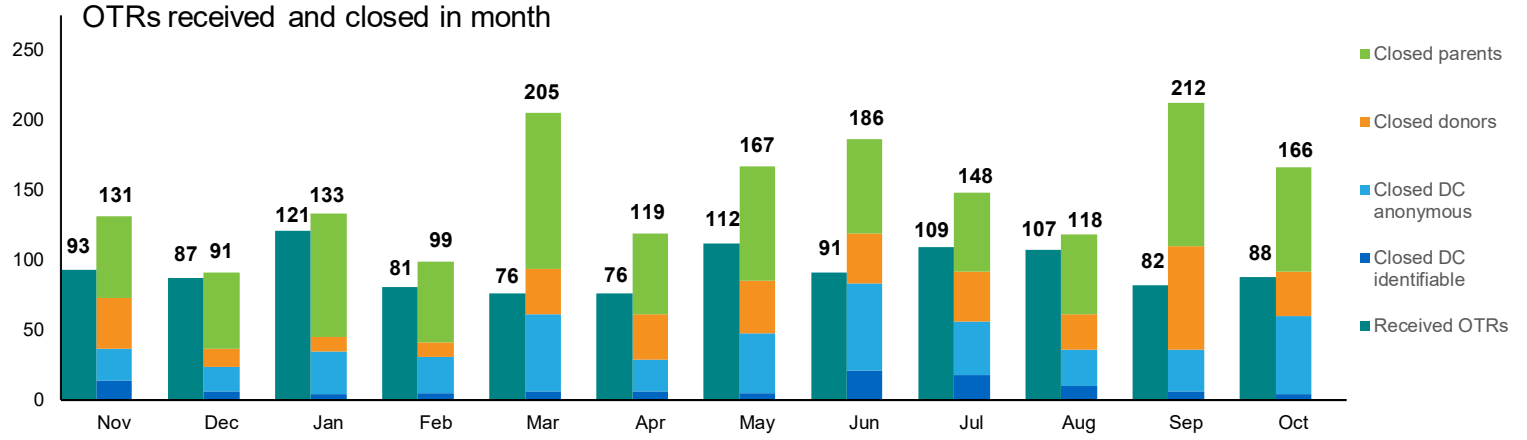
LO:	Green
ELP:	Green
LC:	Green
SAC:	Green
Licensing	
Licensing efficiency	
Targets: **LO - 5 WD ELP - 10 WD LC - 15 WD SAC - 20 WD**	

Another busy month for SAC. Two urgent ELP meetings were held. LO - three voluntary revocations were processed; all other LO items were ITEs. One set of LC minutes were expedited (5-days). One set of ELP minutes were expedited (1-day).



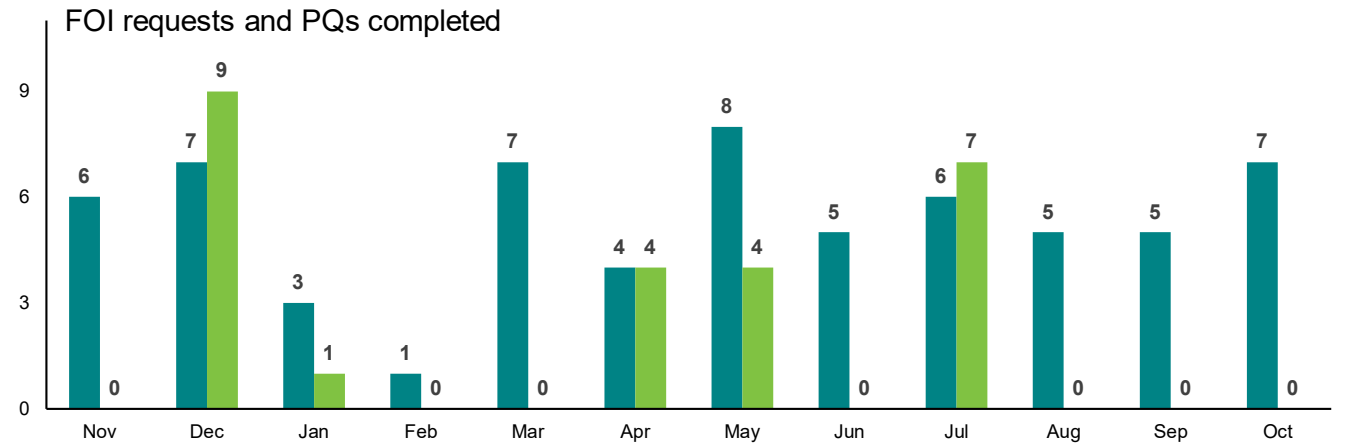
Status:	Green
OTR	
Waiting list change	
Target: **reduced by more than 40 OTRs**	

OTRs in the waiting list: **Donor OTRs - 88; DC identifiable - 17; DC anonymous - 81; Parents – 176.**
Further evidence of a steady reduction in the waiting list.



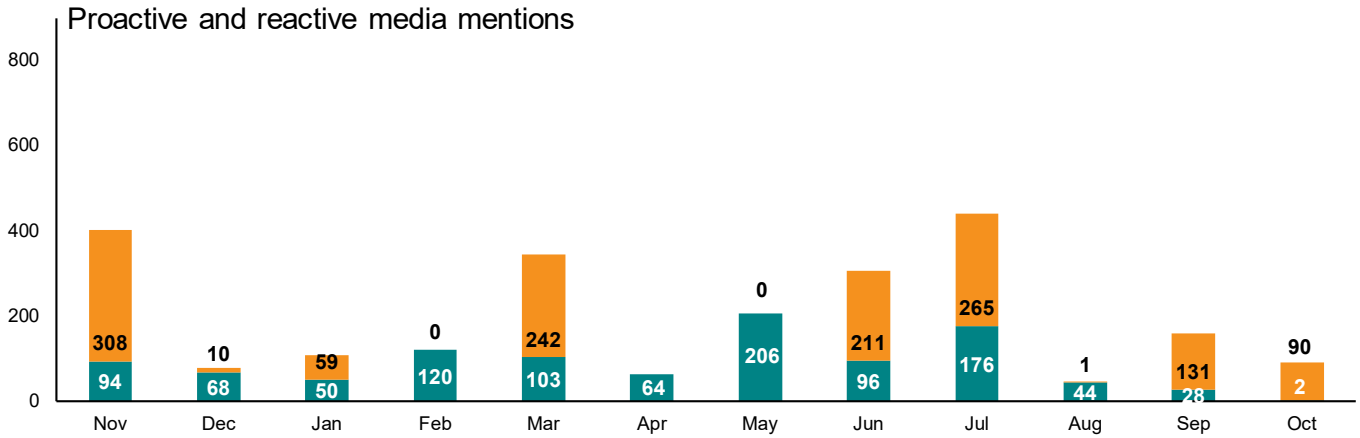
Status:	Green
OTR	
OTRs closed in month	
Target: **more than 156 OTRs being sent out**	

OTRs sent out: **Donor OTRs - 32; DC identifiable - 4; DC anonymous - 56; Parents – 74.**
A high number of anonymous D-C and parent responses were sent out. We continue to receive a small number of identifiable D-C OTRs.



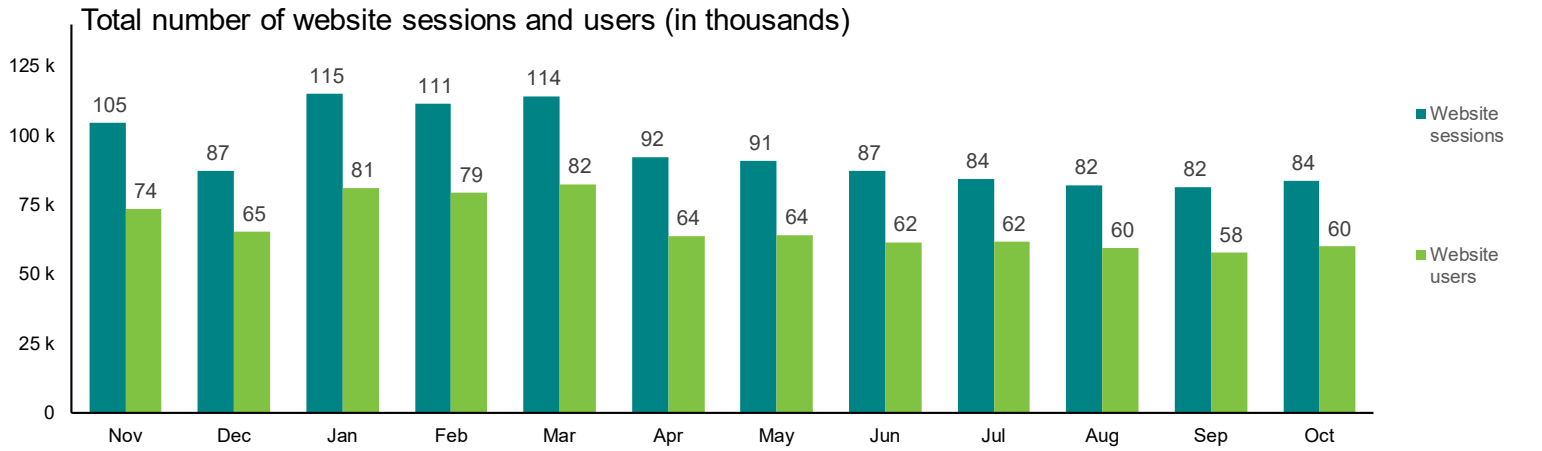
FOI:	Green
PQ:	Neutral
Intelligence	
FOI and PQ completed	
Targets: **FOI - 20 WD** **PQ - set by DHSC**	

FOIs KPI timescales were met. FOI topics were related to information on cycles by clinic, HR/Finance, IT security and donation.



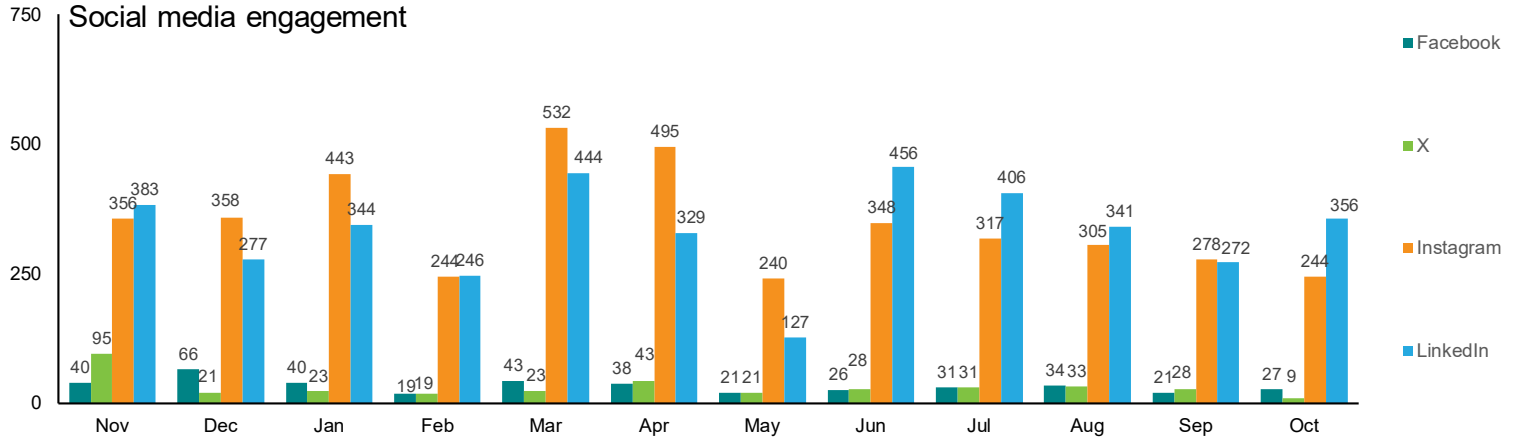
Status:	N/A
Comms	
Total media mentions (proactive and reactive split from April 2024)	
Target: **not defined**	

October coverage themes included treatment add-ons, IVGs, IVF and unregulated donation. Coverage was driven largely by an article about the growth of the fertility market, and an interview with LBC on scientists creating functional eggs from human skin cells.



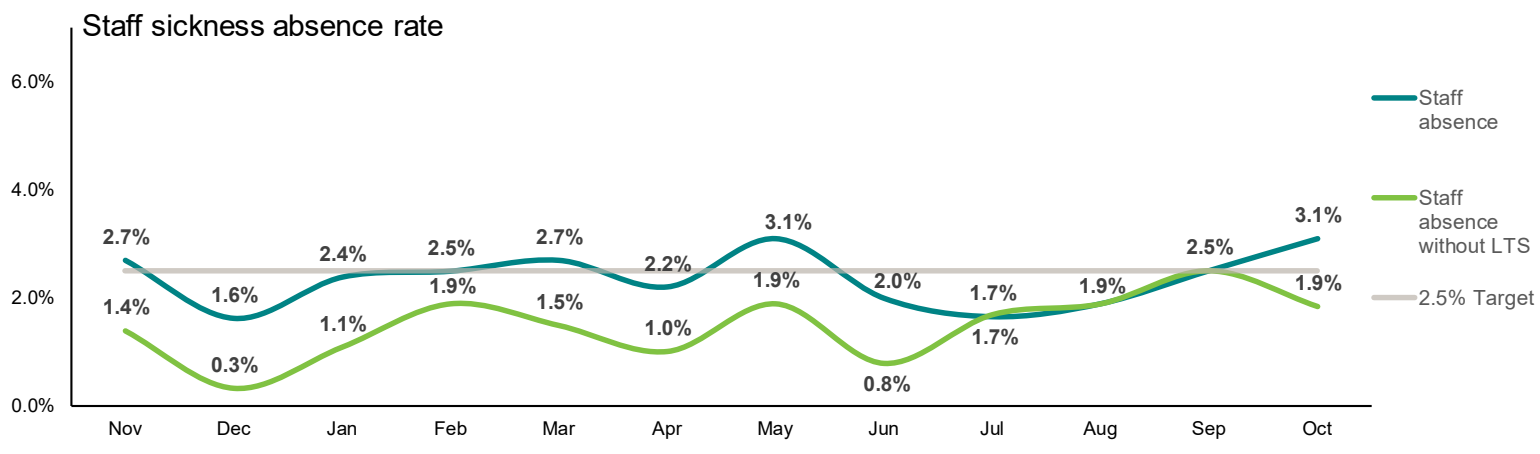
Status:	N/A
Comms	
Total number of website sessions and users (Internal traffic excluded from October 2023)	
Target: not defined	

The website saw a small increase in sessions and users, but we have now had seven months of below average activity.



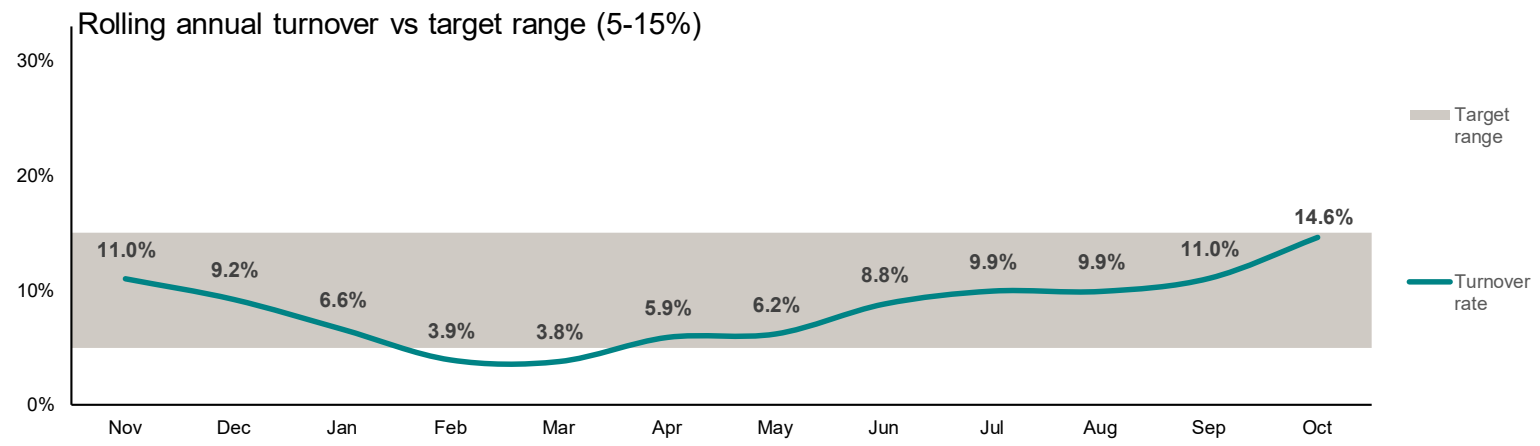
Status:	N/A
Comms	
Engagement across social media	
Target: not defined	

Our channels saw similar engagement to last month, with engagement highest on LinkedIn. The top post on Instagram and X focused on IVF birth rates by age. Tim Child's quote on new research about eggs made from skin cells was the top performer on LinkedIn and Facebook.



Status:	Red
HR	
Sickness	
Target: **Less than or equal to 2.5%**	

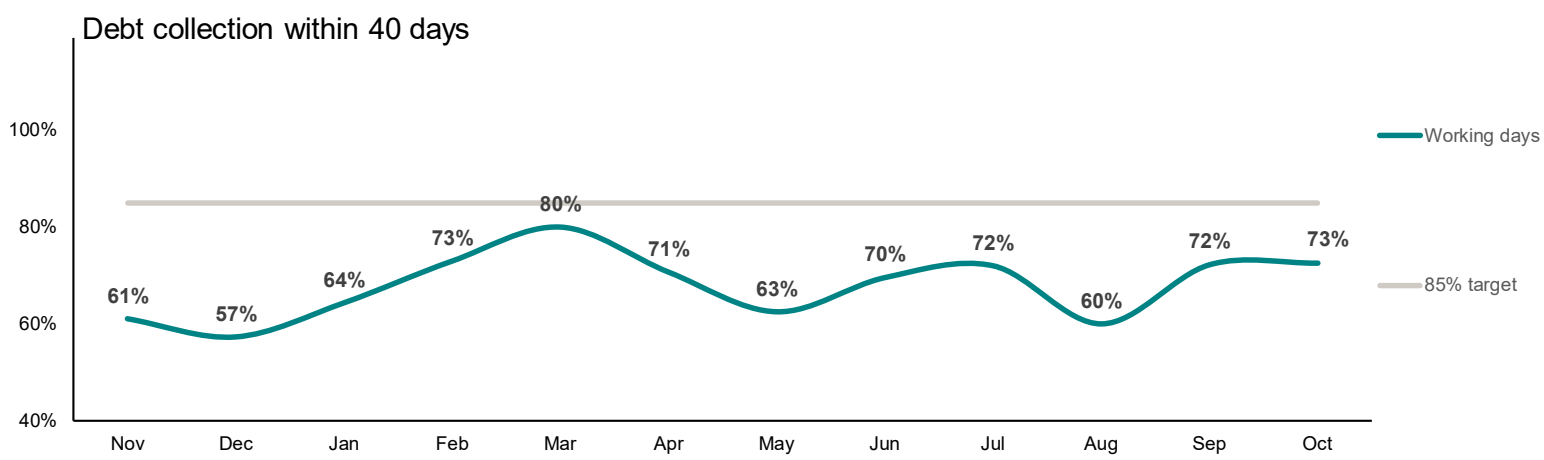
Sickness absence is higher than recent trend but includes pregnancy related sick leave.



Status:	Green
HR	
Turnover	
Target: **From 5% to 15%**	

Turnover is increasing but still just within target. Vacant posts include: Head of Information, Research Officer, Register Analyst.
Supplementary HR data: **Headcount - 82, Budgeted posts - 84, Vacant posts -4, Starters - 1, Leavers - 2.**

Debt collection within 40 days



Status: **Red**

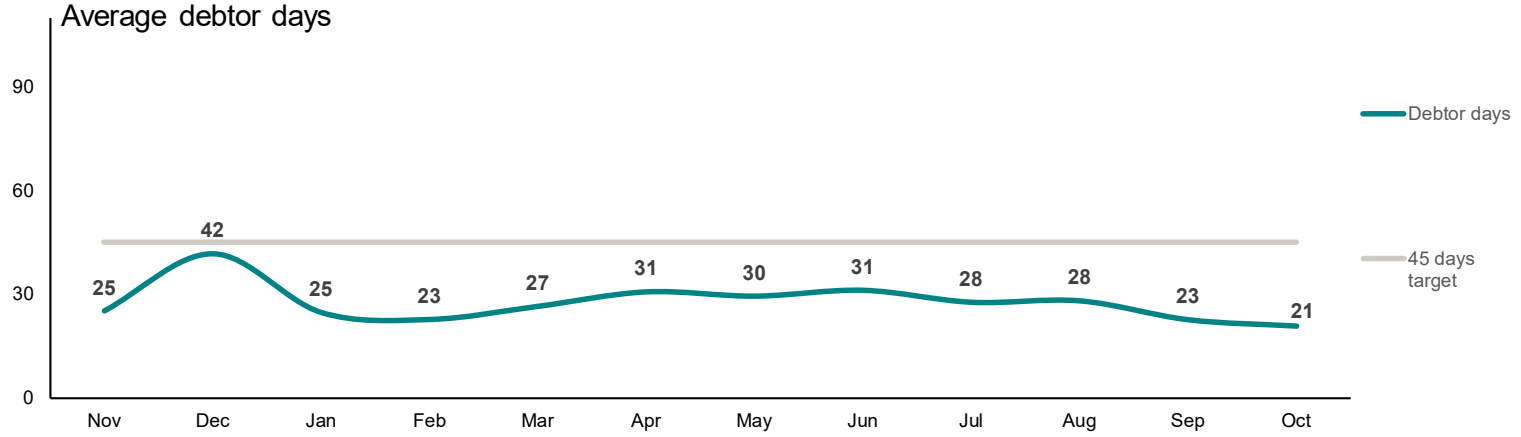
Finance

Debt collection

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

91/102 invoices were paid within 60 days. Of the 11 invoices paid later than 60 days, two relate to clinics receiving estimated bills.

Average debtor days



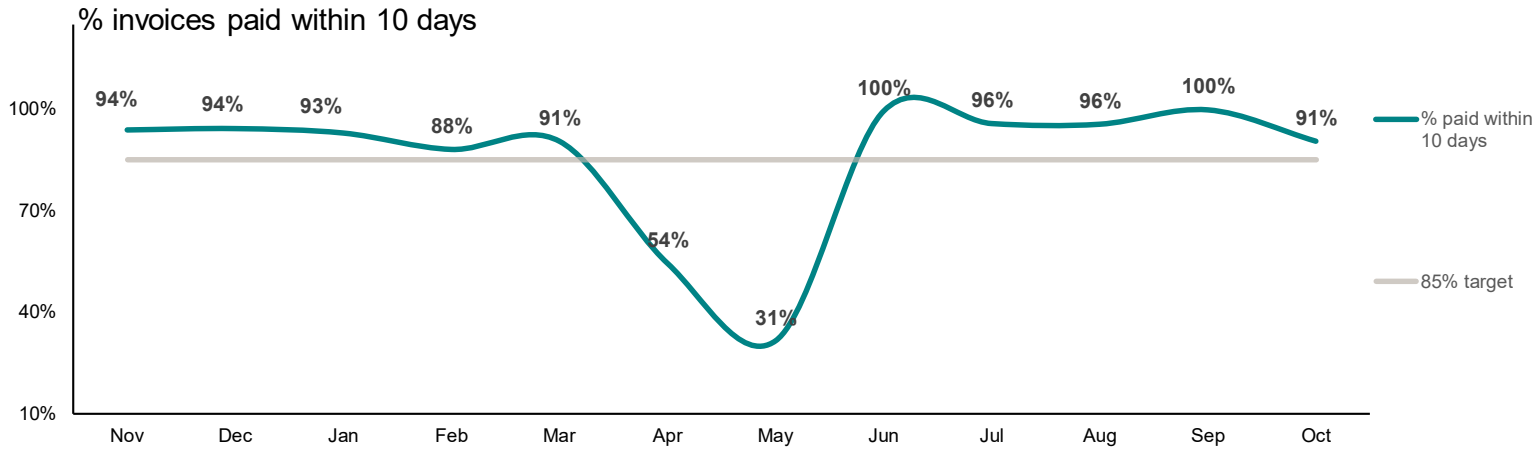
Status: **Green**

Finance

Debtor days

New target from Oct 2024:
45 days or less

The target has been met.



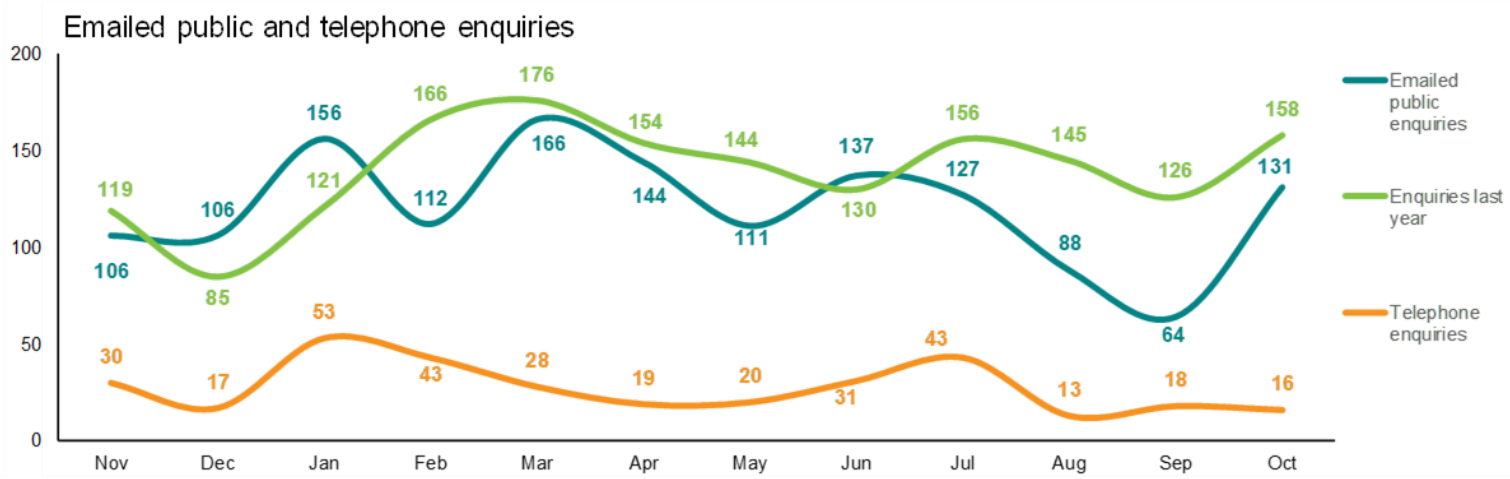
Status: **Green**

Finance

Prompt payment

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

The target has been met.



Status: **N/A**

Comms

Engagement across social media

Target: **not defined**

We received 131 enquiries in October, higher than the number received in September but still below last year. Themes varied, but the number of complaint-related enquiries rose. We received 16 calls in October. Themes included OTR (3), Beginning Treatment (2), Donation (2) and Movement of Materials (2). Out of the 16, 15 were categorised as straightforward and one as challenging.

Human Fertilisation & Embryology Authority

Finance Report

Period to October 2025

Tom Skrinar
Director of Finance, Planning and Technology
19 November 2025

www.hfea.gov.uk

Summary financial position as of 31 October 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	4,967	5,222	(255)	8,361	8,647	(286)
Expenditure	(5,067)	(4,984)	(83)	8,772	8,647	(125)
Total Surplus/(Deficit)	**(100)**	**238**	**(338)**	**(411)**	**0**	**(411)**

For the 7 months ended 31 October we have a deficit of £100k against a year-to-date budget surplus of £238k resulting in a £338k deficit against budget.

Currently, we are forecasting a year-end deficit of £411k. The forecast position has not moved much since we reported to the Department as part of the Q2 Consolidation process. Areas that savings could be made have also been communicated to the Department. We are monitoring month by month the forecast spend and where possible have deferred work or removed spend altogether.

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

Human Fertilisation & Embryology Authority

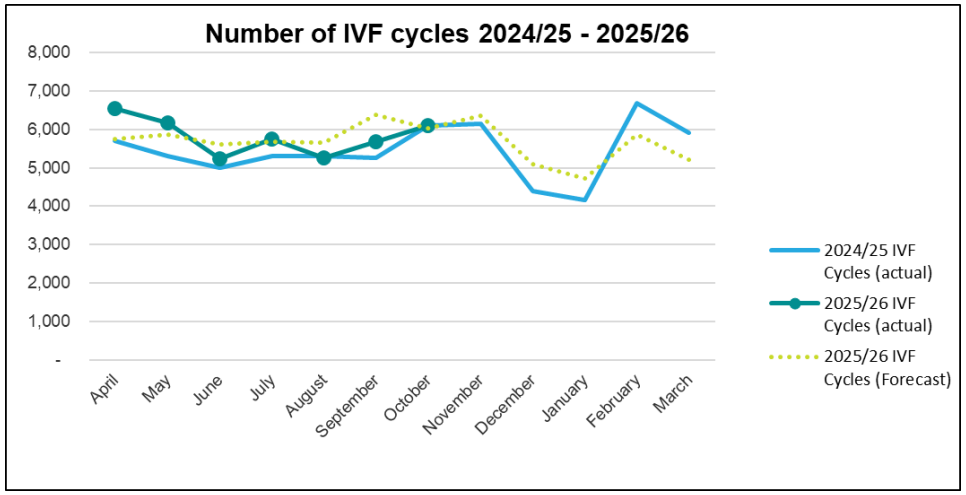
2025/26 Income – YTD 31October 2025

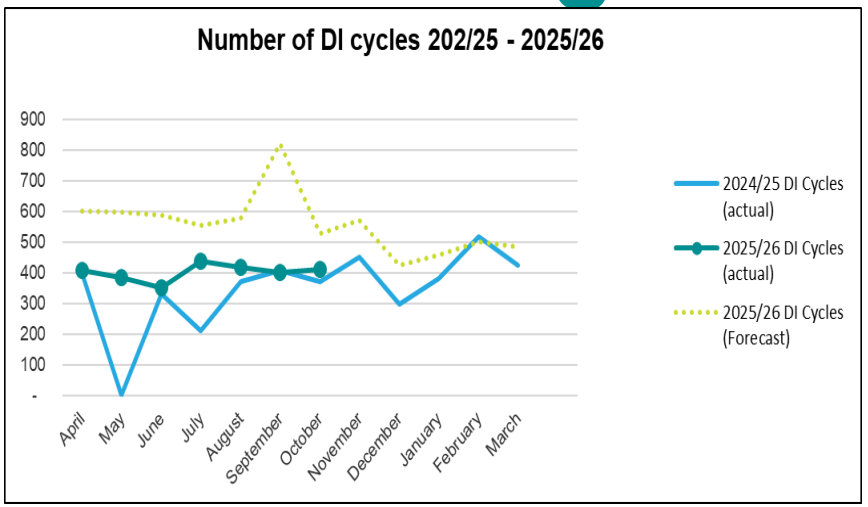
Year end	YTD Actual	YTD Budget	Variance	Forecast Full yr	Budget Full yr	Variance
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Income						
DHSC Funding	640	640	0	1,076	1.070	6
DHSC Funding – non-cash	135	133	2	229	229	0
Licence Fees	4,126	4,354	(228)	6,956	7,186	(230)
Other income	66	95	(29)	100	162	(62)
Total	**4,300**	**4,565**	**(255)**	**8,358**	**8,647**	**(286)**

INCOME

Year to date, our total income is below budget by 5.6%. The key factors affecting this variance are:
Licence fees - IVF/DI are below budget by (£228k). The challenge here is forecasting the volume of cycles to the end of the year. For the 7 months to October, we are tracking below budget (IVF) by 2% (7% above vs last year). The forecast takes the remaining 5 months budget plus the 7 months actual to arrive at a total of 68k cycles. These cycles however are at varying values dependent on when the cycles become chargeable, which means it is possible that the £'s value budgeted will not be achieved. This will also apply to DI cycles which for the 7 months to October are below budget by 24% (34% above last year).
The forecast for the year is a short-fall of income of £286k of which 80% is due to licence fee income not achieving levels close to budget.

2025/26 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 Q2 (September).

Actual cycles are tracking close to forecast which should result in forecast income being close to budget, however, due to the timing of cycles submitted, the pounds value of income is falling short both year-to-date and for the full year. Due to the reliance on clinics submitting their data, there is little that can be done to mitigate the projected short-fall (c£247k) at year end.

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. At year end, a detailed review of the 3 clinics will be undertaken which will result in an accrual.

2025/26 Expenditure YTD 31 October 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	3,525	3,542	(17)	6,176	6,072	104
Other Staff costs	99	143	(44)	204	262	(58)
Other costs	141	138	3	258	258	0
Project Costs	461	432	29	660	740	(80)
Facilities (estates) costs	319	294	25	502	527	(25)
IT Costs	315	267	48	618	464	154
Legal and Professional	206	168	38	354	324	30
Total	**4,292**	**4,306**	**14**	**8,772**	**8,647**	**125**

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 £17k, however we are forecasting an overspend of £104k. Small increases in temporary staff costs; maternity leave cover (higher than previous years) within the Inspections team; additional fixed term post and a settlement are contributing to this overspend.

Other Staff costs – year-to-date is under budget by £44k and is expected to continue as per the forecast (£58k). Significant underspends are within Inspection travel and subsistence (£15k); recruitment (£9k), staff training £22k plus, smaller underspends. We are overspent on Staff Welfare (£7k) relating to job evaluation costs. It is expected that these forecast costs will not change significantly.

Human Fertilisation & Embryology Authority

2025/26 Expenditure continued

- **Other Costs** - are overspent by £3k which is made up of various underspends, key expenditure lines include compliance other (Genetic Alliance costs £10k); non-committee fees £7k. A majority of the cost lines are low where teams have agreed not to spend the budget (stakeholder events, external reviewers are just two).
- **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 under budget 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 which do not match the profiled budget. We are forecasting a small underspend as we expect to make accounting adjustments to our rent (lease) at year end.
- **IT Costs –** overspent by £48k and forecast to end in an overspend of £154k. A review of IT spend, specifically for Office 365 and Dynamics licences has been undertaken. There have been increases in prices which were not budgeted for and arose during the early part of this year. In addition, there are costs of licences that have arisen as a result of the project currently underway. Agreements are being entered into which will allow us to fix a majority of the contracts which will ensure budgets for 2026/27 onwards more accurately reflect costs.
- **Legal and Professional** – over budget by £38k due to internal and external audit fees higher than planned. We were advised of the internal audit fee increased after the budget had been set. The external audit fee increased due to the additional audit of PRISM. The forecast takes account of these increases. We are currently forecasting legal costs at budget, this could change (increase or decrease depending on the outcome of current cases.

Going forward, we will continue to monitor costs closely, and continue to make savings where we can, in particular when considering recruitments.

We are waiting to hear from the Department as to whether our forecast deficit will need to be reduced. Should this be the case, there are a few areas where costs can be eliminated or reduced. In addition, we expect to reverse certain provisions which will have a positive impact on the deficit.

We will report our position again in January 2026 for the period ended December 2025.

2026/27 Budget proposal

Details about this paper

Area(s) of strategy this paper relates to:	Whole Strategy
Meeting:	Authority
Agenda item:	6
Meeting date:	19 November 2025
Author:	Tom Skrinar, Director of Finance, Planning and Technology
Annexes	

Output from this paper

For information or decision?	For decision
Recommendation:	That members provisionally agree proposals (dependent on our Grant-In-Aid settlement from DHSC) to increase the HFEA's expenditure budget for 2026/27 and to increase the HFEA licence fee to £120 for IVF and to £45 for DI per treatment cycle from 1 April 2026
Resource implications:	Budget and fee requirements for 2026/27
Implementation date:	1 April 2026
Communication(s):	Subject to final budget agreements and HM Treasury sign off, Licensed Centres will be advised of any change in early 2026.
Organisational risk:	High

1. Introduction

1.1. As Authority members are aware, the HFEA is funded by a mix of fees levied on the sector we regulate and Grant In Aid (GIA) from the Department of Health and Social Care (DHSC). Due to inflationary pressures, growing IT costs and short-term pressures relating to our IT development programme, we will need to increase the level of fees charged to clinics in 2026/27, balanced against the amount of GIA we will receive.

1.2. Budget and fee proposals agreed by the Authority require approval by the Department as well as HM Treasury. Decisions made today by the Authority will allow us to commence more detailed discussions with the Department around our budget requirements, fee levels and the approvals process we will need to go through.

1.3. As a reminder, fees are levied on licensed clinics and *not* on patients. We see most clinics passing on the fee directly to patients for those who are funding their own treatment (over three-quarters of patients across the UK).

1.4. We are currently reviewing our fee mechanism, but this will not impact income-raising in 2026/27.

2. Historic finances

2.1. For many years the majority of the HFEA's income has come from sectoral fees, largely based on activity levels, with the remainder provided through GIA (and a small amount of other income, mainly bank interest). However, the proportion of fees to GIA has varied considerably over time.

2.2. Prior to 2024/25 the HFEA has only had to increase its fee levels twice since 2012 (when fee levels were reduced) as we have generally been able to meet increases in our cost base through internal savings, though there have also been several years where growth in the volume of IVF cycles increased overall income without fee increases:

- 2006/07 – 2011/12: IVF - £104.50; DI - £52.00 (£37.50 from 1/10/11)
- 2012/13 – 2015/16: IVF - £75; DI - £37.50
- 2016/17 – 2021/22: IVF - £80; DI - £37.50
- 2022/23 - 2023/24: IVF - £85; DI - £37.50
- 2024/25 - 2025/26: IVF - £100; DI - £40

2.3. In 2023, DHSC asked us to reduce core GIA from 20% to less than 5% of our operating budget, effectively covering the cost to deliver the Opening the Register (OTR) service only (approximately £300k p.a.), though the Department has provided additional GIA to support one-off investments in our IT systems.

2.4. This change required us to increase our fee levels significantly in 2024/25 to balance the reduction in GIA as well as high levels of inflation reflected in staff pay increases and prices, especially for IT licences.

2.5. Overall spend and income trends over the past five years can be seen in Table 1 below (to note, core GIA is £331k in 2025/26, with a further £739k to cover IT investments and the remainder covering non-cash such items as depreciation). As can be seen, there has been slow

and steady growth in staff costs, driven by pay increases and some headcount growth, in particular from 2022/23 onwards, largely driven by pressures in OTR, Compliance and IT development. Our other costs have grown significantly, mainly driven by IT costs. The higher costs in 2025/26, and to some extent also headcount growth, are driven by the Phoenix IT development programme.

Table 1: HFEA finances and headcount historic and current year.

	2021/22	2022/23	2023/24	2024/25	2025/26
Income	£000	£000	£000	£000	£000 (forecast)
Licence Fees	5,581	5,875	5,632	7,010	*6,956*
Other income	111	143	217	214	*100*
GIA & Ring fenced RDEL	1,356	992	951	410	*1,305*
Total income	**7,048**	**7,010**	**6,800**	**7,634**	***8,361***
Expenditure					
Staff Costs	4,820	5,198	5,219	5,650	*5,977*
Other costs	1,948	2,043	1,811	1,741	*2,795*
Total expenditure	**6,768**	**7,241**	**7,030**	**7,391**	***8,772***
Surplus (Deficit)	**280**	**(231)**	**(230)**	**243**	***(411)***
Headcount (Establishment)	69	80	78	85	***86***

3. Expenditure Requirements for 2026/27

3.1. The higher levels of inflation experienced over the last couple of years have led to larger increases in staff pay as well as price increases in a number of core areas, in particular IT, where Microsoft licences have increased in price by c.13% in 2025/26. The Phoenix programme will modernise our IT and end our reliance on out-dated legacy systems, but it will also change how we pay for our IT, including greater exposure to Microsoft pricing. As we approach go-live for the new system in summer 2026, we will undertake a full review of our IT contracting to ensure we are getting the best deals possible.

3.2. The HFEA does not have the freedom to set pay levels higher than centrally mandated limits and the considerable increases in staff pay over the past couple of years (by 5% in 2024/25 and by 3.25% in 2025/26) reflect government pay policy. Although inflation remains fairly high, we do not expect the pay increase to be as high next year and the current assumption set by DHSC is at 2.5% for 2026/27. We have factored in 3% to provide us with some leeway to allow strategic adjustments to our pay banding in the summer of 2026 if required (we commissioned an independent pay banding review in autumn 2025).

3.3. As Authority members are aware, the HFEA is experiencing significant financial pressures in 2025/26. This is in part due to an under-recovery of income against budget, but we are also overspending against our expenditure budget. This is driven by 2025/26 being a particularly

busy year – due to both an increase in the number of inspections, and the impact of an organisation-wide IT change programme – and the increase in fixed term appointments to cover maternity leave or to support Phoenix will continue into the new year.

3.4. We will clearly need to make a number of organisational adjustments as Phoenix completes, and also as PRISM transition reaches its final stage, but we will continue to be 'running hot' in the first half of 2026/27. We expect our total core budget requirement to grow by just over 5% (£460k) to £9,106k, based on inflationary pressures and current project planning and staffing profiles (to note, this includes the cost of the Phoenix programme which is funded by the Department in 2025/26 rather than by fees).

3.5. An overview of our expenditure requirements for 2026/27, showing growth from 2025/26 (both against our original budget and our current forecast outturn), is shown below:

Table 2: Draft 2026/27 HFEA expenditure budget compared to 2025/26 budget & forecast outturn

Expenditure	2026-27 (Budget) £000's	2025-26 (Forecast) £000's	Growth	2026-27 (Budget) £000's	2025-26 (Budget) £000's	Growth
Salaries & Wages	6,566	6,006	9%	6,566	5,911	11%
Other Staff costs	231	157	47%	231	206	12%
Audit and Inspection costs	191	221	(14%)	191	192	(1%)
IT and Office costs	679	618	10%	679	464	47%
Legal Fees	263	207	27%	263	220	20%
Authority & Committee costs	220	213	3%	220	212	3%
Communication costs	92	47	94%	92	77	20%
Finance & Facilities	263	300	(12%)	263	293	(10%)
Professional Fees	126	147	(15%)	126	104	21%
Projects	281	660	(57%)	281	740	(62%)
Non-cash	195	196	(1%)	195	229	(15%)
TOTAL(S)	9,107	8,772	4%	9,107	8,648	5%

3.6. The main areas of cost growth are as follows:

- **Staffing**. Salaries and wages will grow by 11% (£655k) against the 2025/26 budget (9% against forecast outturn). This is driven by a range of factors:
  - Our budget headcount for 2026/27 is 93, which is higher than our establishment (our standing headcount) due to maternity leave cover at the start of the year and fixed term appointments relating to the Phoenix programme. Our actual headcount should reduce as the year progresses and project work completes. 2026/27 will be a busy year, like 2025/26, but we hope there should be greater capacity to absorb gaps where necessary e.g. due to maternity leave.

  - Our establishment will increase due to plans to bring some IT resource that is currently sourced either through support contracts or through contingent labour onto payroll. These changes will increase our formal headcount but should provide greater resilience and reduce costs (there are corresponding cost reductions in IT contracting and consultancy).

- **IT.** IT costs will grow by 47% (£216k) against the original 2025/26 budget (though only by 10%, or £61k, against currently forecast outturn for 2025/26). We have reviewed and clarified IT costs considerably in 2025/26 due to significant unexpected budgetary pressures, driven largely by price increases and additional Microsoft licences required to facilitate the Phoenix programme. The additional costs in 2026/27 are based on expected price increases as well as providing Microsoft licences to the rest of relevant HFEA staff once Phoenix goes live. We will review our IT contracting in 2026/27 to ensure we are getting the best value for money.
- **Legal.** Legal costs are difficult to predict, but we are increasing our budget by around 20% (£43k) as a prudent estimate considering the range and complexity of potential legal requirements.
- **Project spend.** The majority of the Phoenix programme, funded through GIA in 2025/26, should have completed by July 2026, therefore the annual costs will reduce considerably. We have set aside some contingency, not least to manage any slippage from 2025/26 (planned or otherwise). We are also funding post go-live support for 12 months and some limited additional budget for improvements and fixes to our new IT systems throughout the year, as well as some investment in cyber resilience. We also have some limited funding set aside for policy and other projects. Overall, our project budget will reduce by 62% in 2026/27, assuming no additional funding from DHSC.

3.7. We have bid for additional funding from DHSC in the 2025 spending review that should fund Phoenix and potentially allow us to do more should we be successful, in particular replacing our finance system and undertaking further investment in automating our business systems (including AI) to drive improvement in efficiency and effectiveness, as well as investment in cyber resilience. We will review our project plans and budgets accordingly, once we receive a decision from the Department on our bids.

4. Income expectations and fee requirements for 2026/27

4.1. We made a number of bids for GIA in the 2025 spending review. These bids have now flowed into DHSC business planning, and we expect to hear back from the Department in the coming months, hopefully by Christmas. As ever, the lack of certainty as to exact levels of GIA makes budgeting complicated, therefore we are planning based on three core scenarios:

Table 3: GIA income scenarios for 2026/27, based on SR25 bids

No.	Description	Value (£k)	Note
1	Core admin RDEL required to fund OTR	368	Original admin RDEL bid, March 2025
2	Core admin RDEL, required to fund OTR plus, Phoenix cover	501	Revised admin RDEL bid, October 2025
3	Core admin RDEL, funding OTR and Phoenix cover, plus additional programme RDEL to support IT and other investments	835	Revised admin RDEL bid plus original programme RDEL bid

4.2. As a prudent measure, recognising the difficult financial position the Department is in currently, we are assuming that we will receive the lower of the three possible values, but the exact level of GIA we receive will have an impact on the level of fees we should set for 2026/27.

4.3. A further complication is the variability of fee activity volume and the fact that, following PRISM transition and the slow submission of activity data from some clinics, a proportion of the activity submitted to the HFEA, and consequently the fee invoicing of clinics, relates to earlier years, and therefore is set at the corresponding year's fee rate.

4.4. The table below shows IVF and DI activity from the past 3 years, forecast outturn for this year as well as an expected rate for 2026/27. COVID had a significant impact on activity, and PRISM transition has also put some pressure on activity data over recent years for some clinics, therefore forecasting has been difficult, particularly the relatively high levels of refunds in 2024/25. That said, there has generally been a trend in increasing levels of IVF over the past ten years, and we therefore believe it is prudent to broadly match where we think chargeable activity is likely to end up in 2025/26.

Table 4: Chargeable IVF and DI volumes from 2022/23 to 2026/27

	2022/23	2023/24	2024/25	*2025/26 (forecast)*	Budgeted 2026/27
IVF volumes	72,493	64,153	64,442	*68,000*	68,000
DI volumes	6,638	5,746	4,236	*6,000*	6,000

4.5. Regarding the proportion of activity data submitted by clinics that relates to activity from previous years, as data submissions have now caught up for the vast majority of clinics, we think this proportion is reducing, but we have included an assumption of 5% of activity in 2026/27 being charged at a lower rate (e.g. £100) rather than the new rate proposed for 2026/27.

4.6. In order for us to generate enough income to meet our budget requirements for 2026/27, we need to raise between £7,860k and £8,160k, depending on the levels of GIA we receive. After assessing the various scenarios, we think it would be prudent to increase fees significantly, by up to 20% on IVF fees, though potentially lower if we receive our full settlement from the Department (currently IVF fees are £100 per cycle, with DI fees at £40):

- GIA scenario 1: GIA £368k. Set IVF fees at £120 per cycle, DI at £45. This will be a fairly tight budget and will provide limited scope for improvement investments or contingency should pressures arise or income assumptions be too high.
- GIA scenario 2: GIA £501k. Set IVF fees at £120 per cycle, DI at £45. The higher GIA rate will cover Phoenix costs and will also cover some limited investment in systems and cyber improvement.
- GIA scenario 3: GIA £835k. Set IVF fees at £115 per cycle, DI at £45. This level of GIA will cover Phoenix costs as well as additional investments in service improvements (though this will need to be balanced against general contingency requirements).

4.7. We feel it is prudent at this stage to assume the lower end of GIA settlement (scenario 1 or 2), and that the Authority should provisionally agree to increase IVF fees to £120 per cycle and DI to £45 per cycle. Should we receive the full value of our bid, we would need to revise our budget and currently we feel that we should be able to manage a lower fee increase, depending on the value.

4.8. Clearly this is a significant increase in fees that will likely be passed on to patients who self-fund or will need to be met by the NHS (though given the small element the fee makes up of the total cost of treatment is will not impact on the overall viability of a private or public service). The fact that we did not increase fee levels in 2025/26 is relevant here, though, and as we are halfway through 2025/26, it is apparent that if we had raised fees this year, it would not be such a big jump to increase fees for the next financial year.

4.9. As can be seen in paragraph 2.2 above, we have not regularly increased fees levels and have generally been successful in keeping increases low. Increasing IVF fees to £120 in 2026/27 will mean they have grown by 60% in the 14 years since the fee level revisions in 2012/13 (though if we take the £104.50 fee level from 2006/07 to 2011/12, the increase is less than 15%), over which period inflation (based on GDP deflators) grew by roughly 45% (our overall income requirement grew by about around 50% over that period) and our core GIA funding has reduced from circa £1,000k per annum (in 2013/14, when GIA was c.20% of income) to circa £300k (2024/25, when core GIA was less than 5% of income).

5. Recommendation & engagement with the sector, DHSC & HMT

5.1. We think that the budgetary requirements outlined in section 3 above are realistic and prudent, driven by current expectations regarding pay and price increases, as well as recognising the need to continue investing in key areas of work, in particular Phoenix and cyber. Therefore, the fee increase provisionally proposed here is necessary for us to continue delivering our duties and ensuring we have modern, effective business infrastructure.

5.2. Clearly, the size of our GIA settlement from the Department will have an impact on the level of fees we will need to set. The scenarios we have are quite broad, but it is difficult to tell at this stage how much we will receive, considering general pressures on the health and care sector. That said, we have been encouraged to bid for funding to at least cover final Phoenix costs by DHSC colleagues, and the overall scale of the ask is low within the overall DHSC settlement, therefore we do need to be able to respond to a higher level of GIA.

5.3. Section 35A of the HFE Act 1990 establishes that any increase in licence fee proposed by the Authority would need the agreement of DHSC and HM Treasury. If the Authority is content to

approve the proposed fee increase (to £120 for IVF cycles and £45 for DI cycles), then we will commence discussions with DHSC finance and sponsor team in December.

5.4. When we learn the outcome of DHSC business planning and our SR bid (potentially before Christmas), we will adjust our budget accordingly, potentially reducing the IVF fee increase to £115. Until then, planning on the basis of £120 would be prudent and we can start preparing information for engagement with the Sector accordingly. Assuming we are able to agree the increase with DHSC and HMT in a reasonable amount of time, we expect to be able to start communicating publicly from January.

5.5. As the Authority is aware, the HFEA is conducting a full review of its fee structure, to be carried out in 2026/27 with a view to implementing from April 2027. A major objective of this work will be to reduce the variability of fee charging and its impact on both the HFEA and clinic's ability to robustly forecast costs/income, as well as spreading the cost of regulation as fairly as possible across the bodies that we regulate.

6. For Decision

6.1. Members are asked to agree the following:

- The proposed HFEA operating budget for 2026/27 of £9,106k (noting the potential to increase the budget for additional systems investments should we receive a higher GIA settlement based on our SR bid).
- Fee levels of £120 for IVF and £45 for DI as required to fully fund the HFEA in 2026/27 (noting the potential to reduce the IVF fee to £115 should we receive a higher GIA settlement).

The Regulation of Artificial Intelligence in Fertility Treatment

Area(s) of strategy this paper relates to:	Supporting scientific and medical innovation: *Objective 6. To prepare for the ways in which AI and its future potential is likely to impact on the sector and HFEA.*
Meeting:	Authority (board)
Agenda item:	008
Paper number:	HFEA (19/11/2025) 008
Meeting date:	19 November 2025
Author:	Molly Davies, Policy Manager
Annexes	Annex A: Regulatory and advisory remits of the UK healthcare bodies Annex B: Uses of AI across the patient pathway

Output from this paper

For information or recommendation?	For information and decision
Recommendation:	The Authority is asked to note: • The uses of AI technologies across the fertility sector (as set out at annex B) • The position set out in 4.2 – 4.4 on new technology being deployed by a licensed centre including deployment of AI tools. The Authority is asked to consider: • Whether we should take steps to develop our regulatory stance now or respond as needed in respect of, e.g. further patient information, stakeholder engagement, or work on regulatory expectations.
Resource implications:	Within budget
Implementation date:	Ongoing

Communication(s):	Dependent on Authority decisions
Organisational risk:	Low

1. Introduction

1.1. Across the UK fertility sector, artificial intelligence (AI) is increasingly being adopted to support the provision of fertility services. AI, and its constituent models (e.g. machine learning), refer to software systems that perform tasks typically requiring human intelligence, for example pattern recognition, prediction, and decision support.

1.2. The HFEA's Strategy (2025 – 2028) outlines our commitment to preparing for the ways in which innovative technologies are likely to impact on the sector to ensure that patients and clinic staff feel confident in the use of AI tools as they are deployed, and that regulation keeps pace with innovation.

1.3. The Authority has been monitoring research and clinical developments in AI through our Scientific and Clinical Advances Advisory Committee (SCAAC) and its horizon scanning function since February 2019, last discussing research developments in February 2024. Following recommendations made by the Committee, the HFEA has carried out a scoping project aiming to improve our understanding of how AI and other emerging technologies (including robotics and automation) are being used in fertility treatment, map the UK's regulatory landscape, and consider how the HFEA as a regulator can best support the responsible adoption of these tools across the sector in the interest of patient care.

1.4. This paper provides a summary of this scoping work, in so far as it relates to AI, examines how the HFEA's existing regulatory framework, whilst limited, is currently applied to support the safe integration of AI technologies, and proposes next steps to be discussed by the Authority.

2. Mapping the UK's regulatory landscape on AI

2.1. The UK Government has adopted a pro-innovation approach to the regulation of AI, seeking to balance effective oversight with flexibility to support technological development within the UK. Rather than establishing a single statutory framework, the current model relies on existing regulators to apply five high-level principles to the adoption of AI:

- Safety, security and robustness
- Appropriate transparency and explainability
- Fairness
- Accountability and governance
- Contestability and redress

This guidance-directed approach is intended to manage the risks associated with AI adoption whilst promoting innovation and regulatory agility.

2.2. Legislative proposals currently making their way through the UK parliament, such as the **Artificial Intelligence (Regulation) Bill**, demonstrate steps towards the establishment of a more unified framework to the UK government's approach to AI.

2.3. Within healthcare, this model is reflected in the shared regulatory oversight of AI adoption, which depends upon a technology's intended purpose, data use, and clinical context. Where an AI tool intersects with the statutory remit of a regulatory body, the appropriate authority will assess its compliance with its applicable legislation and regulatory requirements. Both developers and adopters of AI technologies in healthcare are subject to regulatory requirements, but the nature of those obligations will differ depending on their role.

2.4. Annex A provides a summary of the bodies involved in the regulation of the use of AI in healthcare. In practice, these remits often intersect as this example demonstrates:

- Where AI technologies are utilised for clinical decision support, the AI algorithm may be classified as a medical device. Medical devices are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA), and are subject to ongoing MHRA post marketing surveillance and, where necessary, enforcement action.
- Professional regulators, such as the General Medical Council (GMC), expect clinicians to apply professional standards when using clinical decision support tools and remain responsible for decisions taken when using AI.
- If the tool involves the input or processing of personal data (including patient health information), the Information Commissioner's Office (ICO) requires compliance with the UK General Data Protection Regulation and Data Protection Act.
- Should the technology be deployed in a clinical setting, sector-specific regulators such as the HFEA or Care Quality Commission (CQC) will assess on inspection that the provider can show evidence of systems and processes which ensure that use of the technology is safe and compliant with standards and regulations.

2.5. Given these intersecting responsibilities, regulators need to be aligned to ensure consistency and minimise duplication of oversight. Coordination is being achieved through multi-agency advisory mechanisms (such as the AI and Digital Regulations Service), continued alignment of regulatory regimes, and inter-regulatory working group meetings. Longer term strategic alignment will be directed by emerging expert advisory groups, including the National Commission into the Regulation of AI in Healthcare, established by the Department of Health and Social Care (DHSC) in September 2025, to review and make recommendations on the future regulatory framework.

2.6. To support regulatory agility, some regulators have also introduced tailored initiatives to test and refine how AI technologies can be safely adopted within their existing statutory framework. For example, the MHRA piloted a regulatory sandbox (termed the AI Airlock) to proactively investigate the unique challenges for regulating AI as a Medical Device (AIaMD).

2.7. As a sector-specific regulator, the HFEA is responsible for monitoring how AI technologies are being adopted in practice. We do this by ensuring that licensed clinics who are using AI-assisted tools are able to demonstrate that they are meeting the required standards and that the technology is being deployed in a way which is compliant with the Human Fertilisation and Embryology Act (HFE) 1990 (as amended) and associated guidance. This includes ensuring that licensed centres are able to provide evidence of validation, risk assessments, staff competence and human oversight, data assurance, and compliance with regulatory standards (including MHRA registration, if applicable).

2.8. It is important to highlight that the HFEA does not have the in-house expertise to assess the underlying algorithm or technical architecture of AI tools, including those classified as a medical device. However, we can exercise secondary enforcement powers should the use of such technologies breach our Licence Conditions or Directions (see section four for further details). This includes citing non-compliance on inspection if centres fail to evidence the appropriate regulatory diligence or tool governance.

2.9. This underlines the HFEA's role within the wider model of shared oversight, whereby specialist regulators operate within defined statutory remits. Further details on the HFEA's regulatory tools and associated limitations are provided in sections four and five of this paper.

3. Current and emerging AI applications in fertility treatment

3.1. AI technologies are increasingly being integrated across fertility treatment pathways, supporting clinical, laboratory, and operational functions within licensed clinics. As illustrated in the diagram at Annex B, these systems are being introduced to support laboratory analysis, clinical decision-making, workflow management, and patient engagement. Examples include AI-driven image analysis algorithms developed to support embryo grading and selection, and personalised predictive models designed to estimate the treatment outcomes based on patient data.

3.2. Innovative AI technologies have the potential to bring great benefits to the fertility and embryology sector. Potential benefits include:

- **Better use of clinical data** - to inform personalised treatment e.g. pre-treatment counselling, medication regime, gamete and embryo assessment
- **Streamlining administrative and patient management processes** - such as appointment scheduling and medication reminders, freeing up clinicians for patient care and reducing treatment costs
- **Greater objectivity** - in data analysis
- **Improving standardisation and consistency** - in patient care
- **Identification of novel markers or trends** - for future research

3.3. As with other emerging technologies in healthcare, the pace of innovation brings uncertainties around safety, transparency, and accountability. Some potential risks of AI technologies are:

- **Data bias** – AI systems trained on limited, non-representative, or poorly labelled datasets may perpetuate demographic or clinical bias, leading to inequality in care or limited use for certain populations.
- **Inadequate validation** – Insufficient validation may result in models that perform well when using controlled datasets, but fail to demonstrate accuracy, reliability, or safety when interpreting real-world data.
- **Uncontrolled adaptation and performance drift** – AI systems that adapt over time may incorporate new data without revalidation or oversight, leading to performance drift and unpredictable outputs.
- **Lack of transparency and explainability** – Clinicians and patients may not always be able to understand, justify, or contest outputs where the underlying reasoning of the decision made by the AI model is unclear.
- **Data privacy and commercialisation** – Where data is used for algorithmic development and/or commercial purposes, there is a risk that both adopters and patients are unaware of how their information they have submitted may be reused for other purposes (eg training AI models), and whether this aligns with the scope of initial consent.
- **Lack of contextual sensitivity and nuance** – Algorithms alone may not take into account the specifics of a patient's circumstances and lead to recommendations without appropriate clinical judgement.
- **Overreliance on tools and impact on clinical expertise** – Routine dependence on AI systems may reduce a clinicians' abilities to critically assess, interpret, or challenge automated outputs.

3.4. The development and deployment of AI tools in the fertility sector is occurring through both commercial providers and clinic-led initiatives.

4. The HFEA's regulatory framework and AI

4.1. The HFEA regulates fertility treatment and embryo research through a framework of statutory powers established under the HFE Act 1990 (as amended) and its related regulations. Compliance is achieved through licensing and monitoring of clinical (and research) practice through our inspection regime, supported by the provision of guidance.

4.2. Any new technology being deployed by a licensed centre must be integrated in a way that upholds our existing regulatory requirements, including compliance with the Code of Practice, licence conditions, General Directions, and the authorised processes framework. While these instruments were not designed specifically for AI systems, AI tools are not exempt from them and centres remain responsible for ensuring that systems are validated, governed, and monitored appropriately. This could be considered as a similar approach to treatment add-ons.

4.3. The HFEA can take regulatory action where non-compliances are identified. For example, if a licensed centre were to introduce an AI-based medical device that had not been appropriately registered or validated with the MHRA, the HFEA could determine that the clinic had failed to meet its obligations under the licence conditions.

4.4. The Authority's existing regulatory tools provide a framework through which the responsible adoption of AI (and other emerging technologies) can be overseen. This regulatory framework is laid out in the HFEA Code of Practice (9th edition, version 4), key elements of which can be applied in relation to the use of AI within licensed clinics and cover the following aspects:

- Information provided prior to consent
- Electronic methods for taking consent
- Record keeping and document control
- CE marking
- Quality management system
- Validation and documentation of modified processes
- Auditing processes and activities
- Electronic witnessing to ensure patient and donor identification
- Third party relations
- Reporting adverse incidents
- Confidentiality and privacy

4.5. We have had informal discussions with some of our stakeholder groups on AI use in the fertility sector including the Licensed Centres Panel (LCP) who highlighted that receiving guidance specific to the use of AI from the HFEA could help to ensure consistent standards across clinics and provide clarity on how the use of such tools will be assessed upon inspection. In response, a Clinic Portal webpage was developed stating our current regulatory position and directing clinics to guidance produced by other healthcare regulators. This was highlighted in Clinic Focus.

5. Limitations of the current framework

5.1. The degree to which the HFEA has oversight for the use of AI technologies in licensed centres, is limited by the statutory framework under which we regulate and our interdependence with the positions of other regulatory bodies. The HFEA currently does not state where an AI tool is safe and/or effective.

5.2. For example, it is expected that the MHRA will revise requirements for AI and software classification (when meeting the medical device criteria) through their Change Programme. AI tools used in fertility treatment may therefore be reclassified and subject to enhanced requirements.

5.3. It is therefore important for the HFEA to be aware when these changes come into force, so that on inspection we are able to inspect against evidence of compliance with the standards required by the MHRA, and other regulators. This will rely upon inspectors being competent in recognising inappropriate or unsafe deployment of AI systems.

5.4. Whilst MHRA's Change Programme is in transition, our expectations of clinics should provide sufficient assurance for the safe and responsible integration of AI within clinics. We will continue to engage with the MHRA on their change plans and other regulators as needed and escalate our concerns where necessary.

5.5. In future, there may be a case to consider some form of principles of responsible innovation (for example as with those defined in the add-on's consensus statement) to encompass the use of AI tools deployed during the provision of fertility treatment. .

5.6. AI tools can also be subject to an HFEA add-ons ratings, for example **time-lapse incubation and imaging** which uses AI-algorithms, is rated as black as this has no effect on the treatment outcome.

5.7. SCAAC noted that technologies should only be considered as an add-on if there is a patient choice and a direct cost involved (**February 2024**).

5.8. Regardless of movement within the regulatory framework, healthcare practitioners retain ultimate responsibility for safe and effective use of AI tools in healthcare treatment.

6. Provision of patient information

6.1. Providing accurate and unbiased information to patients and the public is a key statutory function. SCAAC have previously suggested that lay summaries covering the uses and regulation of AI tools within fertility care would be of benefit to both clinic staff and patients (February 2024).

6.2. Last summer we conducted a very small survey with members of our Patient Engagement Forum (PEF) to understand patients' views on the use of AI in fertility treatment and to consider what information (if any) respondents would find most valuable.

6.3. Results indicated that most respondents had some knowledge of AI generally, but low knowledge of its use in fertility treatment. Patients surveyed expected to receive the same level of information on how and why AI is being used in their treatment, and associated risk, benefits and costs – similar to the information on any aspect of their fertility treatment provided by the clinicians.

6.4. We may want to consider the need for adding some information and links to other useful sources on AI to our website for patients and the wider public.

7. Next steps

7.1. We will continue to monitor developments in the use of AI technologies across the fertility sector (as set out at annex B) through our horizon scanning function and to identify any particular uses

of AI which raise particular issues of regulatory concern. The topic is next scheduled for discussion at the SCAAC meeting in February 2026.

7.2. We will update the Clinic Portal webpage on the use of AI with information for centres, as needed.

7.3. The HFEA will continue to engage with the other oversight bodies on their approach to regulating AI. This includes reengaging with the MHRA as it implements its AI and Software as a Medical Device Change Programme, ensuring that any new or revised requirements that intersect with the HFEA's remit are understood. Where concerns are identified these will be escalated to the MHRA as appropriate. We will also continue to monitor our regulatory position in relation to the use of AI given the interlocking remits of the various bodies charged with regulating AI in the UK (as set out in annex A).

7.4. We will continue engaging with our stakeholder groups as needed and respond to their concerns as appropriate.

7.5. We will use inspection findings to assess whether there are any further areas of concern in relation to AI. This may include assessing whether AI uses are introducing new processes that may fall outside the current authorised processes list.

8. For decision

8.1. The Authority is asked to note:

- The uses of AI technologies across the fertility sector (as set out at annex B)
- The position set out in 4.2 – 4.4, ie that any new technology being deployed by a licensed centre must be integrated in a way that upholds our existing regulatory requirements continues to be our position in regard to deployment of AI tools.

8.2. The Authority is asked to consider:

- Whether we should take steps to develop our regulatory stance now or respond as needed in respect of, e.g. further patient information, stakeholder engagement, or work on regulatory expectations.

9. Annex A: UK Healthcare Regulatory Bodies and AI

9.1. This annex provides a summary of the regulatory and advisory remits of the oversight bodies involved in the regulation of AI in healthcare in the UK.

Care Quality Commission

9.2. The Care Quality Commission (CQC) is the independent regulator of health and adult social care services in England[1], ensuring the health and social care services provide people with safe, effective, compassionate, and high-quality care. Under the Health and Social Care Act 2008, any organisation providing or intending to provide a regulated activity in England, must register with the CQC. The CQC then monitor, inspect, and rate services to ensure compliance with the fundamental standards.

9.3. Supported by the Regulators Pioneer Fund, the CQC have established a regulatory sandbox which has been applied to identify and consider how to regulate innovative products being introduced into the health and care sector. This has included the use of machine learning applications for diagnostic purposes.

9.4. A key finding from the CQC/MHRA report on machine learning for diagnostic purposes was that most suppliers of machine learning applications in diagnostics will not need to be registered with the CQC. Only those suppliers that deliver clinical activity themselves as part of a regulated activity need to register. To regulate the few suppliers that do become registered providers, and to assure the public that their services are safe and effective, the CQC will need other national bodies to develop technical standards and assess against them.

9.5. To support organisations deploying AI within GP services, the CQC has published a 'mythbuster' which outlines the CQC's expectations for the safe use of AI, including requirements for human oversight, staff training, transparency and consent, and compliance with clinical safety risk assessments, MHRA requirements, and data protection.

9.6. The CQC also contributes to the AI and Digital Regulations Service, where they have published information explaining how they regulate, alongside a series of case studies illustrating developments in the use and testing of innovative technologies.

Health Research Authority

9.7. The Health Research Authority (HRA) oversees health and social care research approvals in England and manages the Research Ethics Committees (RECs) systems and the Confidentiality Advisory Group (CAG).

9.8. The HRA have produced specific guidance on the legal requirements for using health and care data in the context of data-driven technologies, including compliance with data protection legislation, the common law duty of confidentiality, and requirements for gaining explicit consent.

9.9. The HRA also provide information on the regulations governing the use of data in the context of AI and digital technology on the AI and Digital Regulations Service webpages.

9.10. The Health Research Authority (HRA) are also actively improving their review of research using AI and data-driven technologies to improve the approval process for people applying to start

[1] Equivalent bodies regulate services in the devolved nations, including the **Healthcare Inspectorate Wales** (HIW), the **Healthcare Improvement Scotland** (HIS), and the **Regulation and Quality Improvement Authority**.

data-driven research involving AI or other technologies. This includes streamlining data driven research approvals to allow developers of technologies to get access to data quickly and to clarify which activities are research and what approval they require.

Information Commissioners Office

9.11. The Information Commissioner's Office (ICO) is the UK's independent authority established to uphold information rights in the public interest. It enforces compliance with a number of acts and regulations, including the UK General Data Protection Regulation (GDPR), Data Protection Act (DPA), and Freedom of Information Act (FOIA).

9.12. The ICO remit is engaged across all stages of the AI lifecycle wherever personal data is processed. To support organisations developing or deploying AI, the ICO has produced the following resources[2]:

- Guidance on AI and data protection (last updated 15 March 2023) – provides a detailed overview of how to apply the principles of UK GDPR to the use of information in AI systems.
- Explaining decisions made with AI (developed in collaboration with The Alan Turing Institute) – gives practical advice to help explain the processes, services, and decisions delivered or assisted by AI, to the individuals affected by them.
- Biometric data guidance: Biometric recognition – explains how data protection law applies when using biometric data in biometric recognition systems, including recommendations for good practice.
- AI and data protection risk toolkit – an AI toolkit designed to provide further practical support to organisations assessing the risks to individual rights and freedoms caused by their own AI systems.
- Data analytics toolkit – to support organisations to recognise the central risks to the rights and freedoms of individuals created by the use of data analytics.

9.13. Alongside these resources the ICO actively participates in a number of initiatives to help ensure that different AI innovations are being adopted safely across sectors. This includes chairing and participating in national and international working groups and non-statutory forums, such as the Regulators and AI Working Group and the Digital Regulation Cooperation Forum (DCRF).

9.14. Through its Innovation Services, the ICO have launched further initiatives, such as a regulatory sandbox and innovation advice service, to support organisations developing innovative systems to use data in a way that meets requirements.

Medicines and Healthcare Products Regulatory Agency

9.15. The Medicines and Healthcare products Regulatory Agency (MHRA) are responsible for ensuring that medicines, healthcare products and medical devices (including Software and AI as a medical device) are safe, effective, and of high quality. Software and AI enabled tools fall within remit of the MHRA if classified as a medical device under the Medical Device Regulations.

9.16. The MHRA regulates the UK medical device market by providing guidance on certification requirements, conformity marking, and device registration to support compliance with legislative requirements. This includes the post-market surveillance requirements (as amended in 2024) and the requirement to report adverse incidents through the Yellow Card scheme[3].

[2] Due to the Data (Use and Access) Act coming into law on 19 June 2025, some ICO guidance is currently under review and may be subject to change.

[3] Apart from the Yellow Card system, Health Facilities Scotland also need to be informed where incidents occur in a public health facility in Scotland.

9.17. A UKCA mark is a logo that is placed on medical devices to show they conform to the requirements in the UK Medical Device Regulations (MDR) 2002 (SI 2002 No 618, as amended) and can be freely marketed in Great Britain. In Northern Ireland, a CE or CE UKNI marking is required to demonstrate that medical devices meet the EU MDR (2017/745). Both markings demonstrate that a device works in accordance with its intended purpose and has met the legislative requirements relating to safety and performance.

9.18. The classification of a medical device determines the assessment route required to obtain a UKCA or CE marking, including who can issue the mark (UK approved or EU notified bodies) and the level of evidence needed to pass the conformity assessment:

- Class I (non-sterile/non-measuring) – self-certified by the manufacturer.
- Class I (sterile/measuring)/IIa/IIb/III – must involve a UK approved body for conformity assessment.

Devices are classified based on the device classification rules (laid out in legislation) and guidance retained from the European Union (see MEDDEV 2.4/1 rev9), which consider the intended purpose of the device and its inherent risk.

9.19. To ensure that the medical device regulation remains fit for purpose, the MHRA are undertaking the Software and AI as a Medical Device Change Programme to ensure that regulatory requirements for software and AI are clear and patients are protected. This includes making numerous reforms across the software and AI as a medical device lifecycle, including:

- improving clarity as to what qualifies as software as a medical device (SaMD) and the concept of the “manufacturer”;
- ensuring that classification rules are proportionate to the risk that devices may pose to patient and public safety;
- providing clearer premarket requirements that provide assurance that devices are supported by adequate safety data and clinical evidence;
- strengthening the post market surveillance system to enable stronger vigilance, risk mitigation, and response to change management;
- implementing cybersecurity and IT requirements and affiliated guidance to mitigate against cyber security risks;
- clarifying how to meet the medical device requirements for products utilising artificial intelligence (AIaMD) through AI Rigour;
- developing guidance regarding human interpretability of AIaMD to ensure models are transparent and trustworthy; and
- streamlining the existing requirements around notification and management of change for AIaMD.

9.20. In addition, the MHRA are reviewing the guidance for in-house manufacturing of medical devices in Great Britain.

9.21. All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market. The Public Access Registration Database (PARD) allows for registered Medical Device types (by Global Medical Device Nomenclature) and their manufactures to be identified.

9.22. Under existing regulations, gamete and embryo assessment software are registered as class I ‘general medical devices’ which are non-sterile and non-measuring.

NHS England[4] (formerly NHS Digital)

[4] NHS England is being reincorporated into the DHSC, a process which was announced in March 2025 and is expected to take two years.

9.23. Following the merger of NHS Digital and NHS England in 2023, NHS England became responsible for designing and operating national data infrastructure and digital systems in the NHS. Its remit includes setting digital standards and supporting the safe procurement and deployment of AI technologies.

9.24. NHS England provides criteria and assurance tools to support healthcare organisations adopting digital and AI technologies. For example, the NHS Digital Technology Assessment Criteria (DTAC) is designed to help healthcare organisations to make sure digital technologies meet the minimum baseline standards. NHS organisations are encouraged to use the DTAC when procuring or evaluating new digital and AI tools.

9.25. In addition, NHS England have also issued two clinical risk management standards which require developers and adopters to perform a risk assessment on digital technology:

- DCB0129 – applies to developers, to help them to show evidence of the clinical safety of their technology; and
- DCB0160 – applies to adopters, to assure them that the technology is safe to use in health and social care environment.

9.26. Further resources are hosted within NHS England's AI Knowledge Repository, which includes educational resources, case studies, and outputs from previous work programmes.

National Institute for Health and Care Excellence

9.27. The National Institute for Health and Care Excellence (NICE) supports practitioners and commissioners working in the National Health Service (NHS) to deliver the best care, while ensuring value for the taxpayer. It does this by assessing evidence and producing guidance, quality standards, and indicators to improve care.

9.28. In relation to digital health technologies, NICE evaluations help inform adoption of products into the health and care system. This includes assessing products under its established evaluation methods, as well as through its early value assessment (EVA) approach for medtech.

9.29. To support healthcare providers to make informed and consistent decisions about adopting digital healthcare technologies, NICE have also developed a specific evidence standards framework (ESF). The ESF describes the types and levels of evidence the technology should demonstrate to be adopted by a health or social care service, including standards on security and data governance. It was updated in August 2022 to support the evaluation of AI and data-driven technologies with adaptive algorithms.

9.30. The ESF for 'mature' digital technologies has 21 standards which are grouped into 5 areas of the technology's life cycle: design factors, describing value, demonstrating performance, delivering value and deployment considerations. For technologies which do not have a full evidence base, there are 16 ESF standards.

9.31. Adopters are encouraged to review any relevant NICE guidelines ahead of implementing new technologies in NHS. Best practice guidance has been built into the resources produced through the AI and digital regulations service.

Professional Regulators

9.32. Professional regulators set and enforce standards of competence, conduct, and professional accountability for individuals exercising professions that are involved in delivering health and care services. In relation to the use of AI technology, their standards apply whenever professionals interact with an AI-enabled tool.

9.33. These include the:

- General Medical Council (GMC) – regulates doctors, anaesthesia associates (AAs) and physician associates (PAs) in the United Kingdom;

- Nursing and Midwifery Council (NMC) – regulates nurses and midwives in the United Kingdom, and nursing associates in England; and
- Health and Care Professionals Council (HCPC) – regulates health, psychological and care professionals including embryologists, in the United Kingdom.

9.34. The General Medical Council has provided a resource to address questions on the use of innovative technologies in healthcare and how the professional standards should apply when using them. This includes stating that:

"Doctors, physician associates and anaesthesia associates are responsible for the decisions they take when using new technologies like AI, and the principles in our professional standards continue to apply. For example, it's important to discuss the use of innovative technologies with patients, what other options may be available and any uncertainties and limitations, so they can make informed decisions. This is in line with the principles set out in Good medical practice, and our guidance on decision making and consent".

10. Annex B: Uses of AI across the patient pathway