Human Fertilisation & Embryology Authority

Authority meeting

Date: 1 July 2026 – 12.45pm – 3.35pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of previous meeting and matters arising (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. Annual Report and Accounts (10) For information verbal report	1.55pm
Comfort break (10)	2.05pm
7. Strategic Risk Register and Risk Appetite Statement (15) For decision	2.15pm
8. Register Research Panel (RRP) Annual Report (30) For information	2.30pm
9. SoHO Regulations update (30) For decision	3.00pm
10. Any other business (verbal) (5)	3.30pm
11. Close	

Minutes of Authority meeting held 20 May 2026

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment / Supporting scientific and medical innovation
Meeting:	Authority
Agenda item:	2
Meeting date:	1 July 2026
Author:	Alison Margrave, Board Governance Manager
Annex	20 May 2026 Authority Minutes

Output from this paper

For information or decision?	For decision
Recommendation:	Members are asked to confirm the minutes of the Authority meeting held on 20 May 2026 as a true record of the meeting.
Resource implications:	n/a
Implementation date:	n/a
Communication(s):	Final signed minutes to be published on the HFEA website.
Organisational risk:	Low

Minutes of the Authority meeting on 20 May 2026 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Geeta Nargund (online for items 1-5) Catharine Seddon Anya Sizer Christine Watson
Apologies	Rosamund Scott Stephen Troup	
Observers	Emma Heslington, Department of Health and Social Care (DHSC) (on-line)	
Staff in attendance	Peter Thompson (Chief Executive) Rachel Cutting (Director of Compliance and Information) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Tom Skrinar (Director of Finance, Planning and Technology) Dina Halai (Head of Policy, Scientific) Rachel Cooper (Head of Legal) Sophie Tuhey (Head of Planning and Governance) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members

There were 12 members at the meeting – 8 lay and 4 professional members.

1. Welcome, apologies and declarations of interest

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

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

1.3. Declarations of interest were made by:

- Tim Child (consultancy work within the fertility sector overseas)
- Anya Sizer (freelance advisory work within the fertility sector)
- Alex Kafetz (member of The Advisory Board to the Patient Safety Commissioner)

2. Previous minutes and matters arising

2.1. The Chair introduced the minutes from the meeting held on 11 March 2026 and thanked those members who had contributed to the minutes.

2.2. The minutes of the meeting held on 11 March 2026 were agreed as a true record of the meetings and could be signed by the Chair.

Matters arising

2.3. The Chair informed members that the matters arising from the previous meeting had been actioned as detailed in the report.

2.4. Members noted the matters arising report.

Standing Orders

2.5. The Chair reminded the Authority that at its last meeting they had agreed to implement changes regarding straightforward special directions applications being heard by the Executive Licensing Panel (ELP) and tasked the Head of Licensing to implement these proposals.

2.6. The paper before the Authority presents the required amendments to the standing orders.

2.7. The Board Governance Manager introduced the paper and explained in detail the proposed amendments to the standing orders for straightforward special directions applications to be heard by the ELP.

2.8. The Board Governance Manager stated that the Authority had received notification via a written motion regarding the intention to amend the standing orders at this meeting.

Decision

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

Action

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

3. Chair and Chief Executive's report

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

3.2. The Chair informed members that she and the Chief Executive had attended a meeting with the Permanent Secretary and Chief Scientific Officer to discuss life sciences and law reform; this was a positive meeting. The Chair stated that it was disappointing that The King's Speech did not include any reference to the HFEA's proposed law reform.

3.3. Again, with the Chief Executive the Chair had attended the DHSC ALB Chairs and Chief Executives meeting.

3.4. The Chair informed members that unfortunately the annual accountability meeting with DHSC had to be postponed to June due to a scheduling conflict with DHSC sponsors.

3.5. The Chief Executive commented that there were two bills of interest in The King's Speech, the first being the NHS Modernisation Bill notably the provision of information and a single patient record.

3.6. The second bill being the Regulating for Growth Bill and he explained how certain elements of this bill could assist regulators.

3.7. He informed members that he had attended an event regarding the 14-day rule project hosted by Nuffield Council on Bioethics. It is anticipated that their report will be published in the Autumn and he would keep members appraised of this report.

3.8. The Chief Executive informed members that the HFEA had given oral evidence to Woman and Equalities Committee inquiry on egg donation and egg freezing on 18 March 2026.

Decision

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

4. Committee Chairs' report

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

4.2. The Statutory Approvals Committee (SAC) Chair (Frances Flinter) stated that the committee continues to meet monthly and the recent set of minutes have just been approved.

4.3. The SAC Chair reminded members of the process for considering Pre-Implantation Genetic Testing for Monogenic Disorders (PGT-M) applications and the benefit of having an independent peer reviewer and reports from the Genetic Alliance. The committee considers all this information, including evidence submitted by the clinic, when considering a PGT-M application.

4.4. The SAC Chair informed the Authority of the progress in reviewing the PGT-M list. As medical treatment has advanced it is prudent to review the conditions authorised for testing to see whether they still meet the legal threshold for being licenced. Several expert reviewers are working with the HFEA to complete this work and review the over 2,000 licensed conditions; thanks were expressed to all working on this project. It is anticipated that this work will be presented to the Authority in the Autumn.

4.5. The Chair commented that this is a large project but it is essential to see whether the previously licensed conditions still meet the legal threshold for being licensed.

4.6. The Licence Committee (LC) Chair (Graham James) informed the Authority that the committee had met on the 7 May and the minutes are not yet approved.

4.7. The LC Chair informed members that the May meeting was unusual in that all items before the committee related to research applications. Two items were executive updates when the committee had adjourned decision making previously and requested further information and clarification.

4.8. The LC Chair spoke of the detailed review of papers which committee members undertake on all applications. He spoke about the number of eggs and embryos which are required for some research applications.

4.9. The LC Chair remarked that five observers had attended this meeting.

4.10. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the whilst the AGC has not formally met since the last Authority meeting, they had reviewed and commented on the draft Governance Statement for the 2025 Annual Report and Accounts. The AGC will consider the full draft Annual Report and Accounts at its next meeting and this document will then be brought to the July Authority for approval.

4.11. The AGC Chair reminded members that she had informed them at a previous meeting of the very significant fee increases which had been set by the National Audit Office (NAO). Following discussions with NAO regarding HFEA's concerns, this increase had been reduced by 50%.

4.12. Members were informed that NAO had also undertaken to have early and more transparent discussions with HFEA regarding future audits and a meeting had been set up for early June.

4.13. The Chair thanked the AGC Chair for her work in leading the discussions with NAO and for securing a fee reduction.

4.14. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed members that the HFEA will host its annual horizon scanning meeting at ESHRE 2026. As the event is being held in London the HFEA had been able to expand the attendee list.

4.15. The SCAAC Chair spoke about the format of the horizon scanning meeting with experts presenting key topics which are then discussed by the attendees. A report from this meeting will be presented to the Authority later in the year.

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

4.17. The Chair referred to the PR event which the HFEA had hosted in April. This was an extremely good event with an engaging agenda and good organisation.

4.18. The event had achieved a 97% satisfaction rate from attendees which demonstrates the strong and trusted relationship between the HFEA and the sector.

4.19. 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. The report before the Authority measures the performance for the period April 2025 to March 2026.

5.2. The HFEA's performance across all 19 KPIs has remained consistently strong throughout the year. The compliance KPIs had moved up and down throughout the year but this did not indicate any structural problems just that some reports were more complex than the others and required more engagement with centres. The Chief Executive stressed that all licenses were issued on time throughout the year.

5.3. Throughout the year applications for embryo testing increased from 45 in the previous year to 84 this year. All PGT-M applications were processed with minimal delay and the Chief Executive thanked the members of SAC and relevant staff members.

5.4. The Chief Executive informed members that the OTR waiting list had reduced significantly during the year. Decreasing from 768 requests in April 2025 to 226 in March 2026. Members were informed that between 120 to 200 requests are being dealt with each month

5.5. The Chief Executive explained that the average waiting time for closing applications in the last quarter of the year was 61 days. Although some applications are more complex and take longer due to the increased communications with clinics and checking of data that is required.

5.6. Regarding the HR KPIs an average sickness absence of 2.5% was recorded and staff turnover was within the 5-15% tolerance, with the upper limit being breached just once. Staff morale and satisfaction continue to be high and the HFEA measures these through a variety of different activities.

5.7. The Chief Executive informed members that the time which the HFEA takes to fill vacancies is very swift compared to other public bodies and this played an important role in managing

workload and maintaining morale. The AGC will receive a detailed report on HR issues in June 2026.

5.8. The Chief Executive concluded by stating that performance for March 2026 continued to be strong with 10 indicators rated Green, seven Amber, two Neutral and none Red.

Strategy and Corporate Affairs

5.9. The Director of Strategy and Corporate Affairs informed members of the Patient Organisation Stakeholder Group (POSG) and Professional Stakeholder Group (PSG) meetings which took place in April and May. Both groups continue to feedback that they find these meetings valuable.

5.10. The Director of Strategy and Corporate Affairs informed members that organisational updates were circulated to both meetings a week beforehand and this meant that the meetings could focus on the substantive agenda items. The Director of Strategy and Corporate Affairs provided further information on agenda items for both groups.

5.11. Members were informed that work is progressing on the Fertility Trends report and it is anticipated that this will published toward the end of June.

5.12. The Director of Strategy and Corporate Affairs informed members that the FAQs relating to unregulated sperm donation had been updated on the HFEA's website. This work had also been supported by posting across the HFEA's social media channels.

5.13. Members were informed that the Director of Strategy and Corporate Affairs had spoken at the recent BICA annual conference and spoke about the latest trends shaping the fertility sector.

5.14. The Director of Strategy and Corporate Affairs highlighted the event which the HFEA will host at ESHRE 2026.

5.15. In response to a question regarding declining number of enquiries via phone and email the Director of Strategy and Corporate Affairs stated that this is consistent with other organisations and can be attributed to the increased use of AI Google summaries and use of other AI models. Changes have been made to the HFEA website which should make information easier to find so we would expect the number of enquiries to continue to fall.

Compliance and Information

5.16. The Director of Compliance and Information referred to the inspection schedule for the year and highlighted the 11 additional inspections which were carried out due to whistleblowing, complaints or regulatory concerns. She commented that this highlighted the HFEA's agile response to regulatory concerns.

5.17. Members expressed their appreciation to the OTR team for their efforts in reducing the waiting list during the year.

5.18. A member questioned whether the level of OTR applications is expected to stay steady or could there be a surge in applications? The Director of Compliance and Information responded that the team continues to carefully monitor demand, but there could be additional surges in demand which would require strategic decisions on resources.

5.19. The Director of Compliance and Information reminded members of the technology improvements which had been made during the year and the positive impact these improvements had in responding to OTR requests.

5.20. The Chief Executive commented on the increase in donation treatments and that if the percentage of people requesting information increased too then the HFEA would need additional resources to meet this demand.

5.21. A member spoke of the assurance provided by the Chief Executive and Director of Compliance and Information in monitoring OTR demand and the reassurance this provided to the Authority.

5.22. A member spoke of the important role of the OTR service in providing sensitive information. They noted that the average waiting time from application is 61 days but less complex applications can be processed in under 30 days and this reflected the efficient handling of applications. They also complimented the Authority's ability to manage such a delicate area of information.

5.23. The Director of Compliance and Information thanked members for their positive comments which will be fed back to the OTR team. The Director of Compliance and Information reminded members of the OTR process and the time constraints in which clinics are meant to respond to the HFEA's communications. Unfortunately, some clinics do not adhere to these deadlines and the HFEA will continue to raise awareness of this requirement through publications such as clinic focus.

Finance, Planning and Technology

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

5.25. In addition, the formal Business Plan 2026-2027 had been finalised and approved by the Department and published on the HFEA's website.

5.26. The Director of Finance, Planning and Technology informed members that the HFEA is recruiting additional IT resource, based on an IT plan which had been developed earlier in the year. This will provide further capability and resilience for the team.

5.27. Members were informed that the Phoenix programme is moving at full tilt with a huge effort from the IT team and staff across the organisation in designing and testing the new systems. It is anticipated that the HFEA will migrate from its current document management system to SharePoint at the end of June. The switch over for Epicentre is planned for the end of July.

5.28. The Director of Finance, Planning and Technology informed members that he meets weekly with the internal team managing the Phoenix programme and monthly with the suppliers. The SMT have also held a few discussions about possible contingencies which might be required for the programme.

5.29. Members were informed that an interim DSPT audit was conducted in April and the HFEA is currently awaiting detailed feedback which will help the team firm up the evidence for the final submission in June. The Director of Finance, Planning and Technology stated that the SIRO report, which will be presented to the June AGC, will also provide an overview of information governance work throughout the year.

5.30. The Director of Finance, Planning and Technology reminded members that the HFEA had been forecasting a deficit for 2025/26 since the summer and this had been driven largely by lower then expected income and a particularly busy 12 months which meant that it was harder to reduce costs in-year. The HFEA had undertaken a range of actions to reduce this deficit and the

starting pre-audit year end position is a deficit of £299k, which is net of an under-recovery of income against budget of £343k and expenditure being below budget by £44k. This deficit will be covered either by the HFEA's reserves or through additional Grant-in-Aid.

5.31. Members were informed that the audit is progressing well and thanks were given to the Finance Team for their work in compiling all the information for the auditors. The Director of Finance, Planning and Technology gave an overview of the audit process and highlighted a few areas which may need additional reporting to satisfy the auditors.

5.32. The Director of Finance, Planning and Technology commented that whilst Departmental and HMT clearance for this year's fee change was received later than hoped for, the HFEA had been able to ensure clinics were aware of the changes in time. He informed members that an update was provided on the fee review at the recent PR event.

5.33. A member questioned the underspend in training and commented on the importance of training and staff being able to access this. The Director of Finance, Planning and Technology responded that the HR budget had been increased last year and a few projects, such as targeted leadership training had been delayed but will commence later this year.

5.34. The Chair requested delegation from the Authority under article 6.1 of the standing orders to approve amendments to General Direction 0005. This General Direction sets out the specific mechanism by which PRs must submit and verify data for Choose a Fertility Clinic (CaFC) and updates are required to reflect PRISM.

Decision

5.35. The Authority agreed delegation to the Chair to approve amendments to General Direction 0005.

5.36. Members noted the performance report.

Action

5.37. Executive to liaise with the Chair regarding General Direction 0005.

6. Embryo Testing

6.1. The Chair introduced this agenda item and reminded members that they last considered the current practice and emerging issues relating to embryo testing at their September 2025 meeting and agreed that guidance for the sector is needed and should be brought back to the Authority for review.

6.2. The paper at this meeting sets out the work that has been undertaken since September 2025 and identifies the areas on which decisions are required by the Authority. The Chair thanked the staff and Authority members who had worked on this.

6.3. The Head of Policy introduced the paper and stated that that the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) (the "1990 Act") prohibits embryo testing except for one of the purposes permitted in the Act (the "Permitted Purposes").

6.4. The Head of Policy explained that testing embryos is a licensable activity and clinics need to have a licence that includes testing embryos to be able to carry out this function. In addition, testing embryos under 1(b) can only take place for conditions approved by the HFEA's Statutory Approvals Committee (SAC), and testing embryos under 1(d) can only take place on a patient-by-patient basis following approval by SAC.

6.5. Members were informed that the methodologies for carrying out genetic testing have advanced significantly since the law was passed. Sophisticated testing now routinely generates data which go beyond simple binary results for which the testing was originally sought. These developments raise the question of what, if any, additional information may lawfully be obtained from permitted testing. Continuing, the Head of Policy stated that there is also the possibility of coming across genuinely accidental and unavoidable incidental findings, which, unlike additional findings, are not sought.

6.6. The Head of Policy referred to the Authority discussion regarding current practice and emerging issues relating to embryo testing which took place at the September 2025 meeting and their request that guidance for the sector is needed and should be brought back to the Authority for review.

6.7. The Head of Policy also referred to the draft guidance which had been developed with the assistance of several Authority members.

6.8. The Chair thanked the Head of Policy for the introduction of the paper and asked that the Authority now consider the paper section by section.

6.9. The Head of Policy summarised the proposal to require clinics to record the reason for testing in each case under 1(a) and 1(e). Members were informed that clinics would not be required to submit this information to the HFEA, but it may be the subject of inspection in the usual way.

6.10. In response to a question the Head of Policy explained that testing under 1(b), 1(c) and 1(d) requires approval from the SAC, so there was no need to apply this proposal to testing for those purposes as the reason for testing was already recorded. Members noted the framework in which the SAC operates and the decision tree it follows to ensure that conditions meet the legal threshold for being licenced.

6.11. The Head of Policy referred to section four of the paper regarding what positions the Authority could take regarding obtaining information on additional SAC-approved conditions with the intention of using that information in clinical decisions making when testing under 1(b). The potential benefits and considerations in relation to each option were explained in detail.

6.12. There was a discussion about whether the principles of the 100,000 Genomes Project / Genomics England were relevant to embryo testing. A member highlighted that it is important to differentiate between population screening in research settings and in clinical settings. Population screening of people in the UK as part of this project was carried out in a research setting.

6.13. Members noted that whole genome sequencing is reducing in cost and the time that it takes and therefore that it is becoming easier to find out about many if not all SAC approved conditions in one go. However, the Head of Policy pointed out that it would not be possible to obtain fully informed consent for testing of all SAC approved conditions in one test. The significance of each condition would need to be explained, and the patient would need to be offered implications counselling about each one and clearly, this is not possible for over 2,000 conditions.

6.14. Overall, members were supportive of option ‘b’ in paragraph 4.7 of the paper, ie information on some other HFEA-approved conditions can be obtained and used in clinical decision-making when testing under 1(b), since it is consistent with the wording of the act but were concerned about how the parameters on which other conditions could be tested for would be drawn. A member expressed a view that unless there is a known predisposition due to parents carrying a

faulty gene, clinics should not go looking for conditions where there is no particular risk. Members requested that the Authority have the opportunity to see the guidance before it is issued to clinics so that they have the opportunity to review what option 'b' would look like in practice.

6.15. Members suggested that the Executive reach out to the National Screening Committee to help determine which additional conditions could be tested for.

6.16. Option 'a' in paragraph 4.7, ie information on other HFEA-approved conditions cannot be obtained and used in clinical decision-making when testing under 1(b), was thought to be too restrictive and not in the patients' interest.

6.17. Members discussed the inequity in the law between allowing additional testing when there is no particular risk under 1b but not 1a.

6.18. The Head of Policy referred to section five of the paper regarding the proposed approach to incidental findings being used in clinical decision making. The Head of Policy explained the difference between additional findings and incidental findings.

6.19. Members agreed that receipt of incidental findings should be rare but that there is a small chance that clinics may receive information on incidental findings therefore it is important to provide clinics with guidance on how to act in such an event.

6.20. Members noted that if an unavoidable incidental finding identified is one which has not been approved for testing by the HFEA under 1(b), but is one which the Person Responsible deems to be associated with a serious condition, then an application should be made to the SAC to have the condition approved.

6.21. A member highlighted that data collection cannot be avoided by the laboratories that undertake testing, therefore the guidance should place the onus on clinics avoiding unnecessary data analysis.

6.22. A member referred to the information provided by The British Society for Genetic Medicine (BSGM) regarding incidental findings and the clear pathway identified between the laboratory and clinic. The member commented that this may be a useful source of information and that the HFEA could consider including flowcharts as part of the guidance.

6.23. The Head of Policy reminded the Authority that at the September 2025 meeting it had agreed to review where a previous broad 'group' approval has been given for what was termed, "chromosomal rearrangements (various)". The Head of Policy explained the reason for the recommendation to remove this 'umbrella' authorisation from the approved list of conditions that can be tested for under 1(b). Members agreed to this proposal and noted the proposed next steps in section eight of the paper, including having a transitional period.

6.24. The Authority discussed that the use of preimplantation genetic testing involving polygenic scores (PGT-P) is not lawful and noted that the HFEA had published earlier in the year a blog on PGT-P and an article in BioNews (publication by the Progress Educational Trust (PET)) to explain that PGT-P is unlawful in the UK as it does not identify a particular gene, chromosome or mitochondrial abnormality.

6.25. The Authority noted that these public statements also explain that embryos can only be selected for transfer based on information from testing that meets a specified purpose in law, and that the prohibition on performing PGT-P in the UK cannot therefore be circumnavigated by having the

analysis carried out in another jurisdiction, and then using the results from that analysis to select embryos for treatment in the UK.

6.26. The Head of Legal informed members that data about an embryo that cannot lawfully be used to make treatment decisions in the UK is not regarded as the patient's personal data. Therefore, patients do not automatically have a right to the embryo's full sequence of raw genetic data under UK's data protection laws.

6.27. The Authority felt that a clear statement setting out the HFEA's position regarding data about an embryo that cannot lawfully be used to make treatment decisions in the UK not being part of the patient's personal data would be beneficial for clinics.

6.28. The Chair drew the discussion to a close and thanked all for their in-depth discussion.

Decision

6.29. The Authority agreed:

- the recommended approach of requiring clinics to record the reason for testing under 1(a) and 1(e)
- that in principle information on some other HFEA-approved conditions can be obtained with the intention of using that information in clinical decision making when testing under 1(b), with the caveat that they need to see what the guidance looks like
- the recommended approach of requiring clinics to record the reason for testing additional conditions under 1(b)
- the recommended approach with regard to unavoidable incidental findings
- the removal of the umbrella "chromosomal rearrangements (various)" authorisation from the approved list of conditions that can be tested for under 1(b)
- the final draft guidance to be circulated to the full Authority for any last minute comments (substance not style) and then sign-off of the final draft guidance to be delegated to Frances Flinter, Tim Child and Rosamund Scott.
- to delegate sign off on consequential changes to General Directions and Standard Licence Conditions, to the Chair
- that the HFEA should publish a clear statement setting out the HFEA's position on PGT-P and that data about an embryo that cannot lawfully be used to make treatment decisions in the UK is not regarded as the patient's personal data.

Action

6.30. Executive to implement the Authority's decisions.

7. Any other business

7.1. The Chair thanked everyone for their active participation in the meeting and for the high quality of papers before the Authority. There being no further items of any other business, the Chair closed the meeting and reminded members that the next full Authority meeting is being held on 1 July 2026. Details of this meeting, including how to request to observe, is posted on the HFEA website.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 1 July 2026

Authority meeting matters arising

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment / Supporting scientific and medical innovation
Meeting:	Authority
Agenda item:	2
Meeting date:	1 July 2026
Author:	Alison Margrave, Board Governance Manager
Annexes	N/A

Output from this paper

For information or decision?	For discussion
Recommendation:	To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.
Resource implications:	To be updated and reviewed at each Authority Meeting
Implementation date:	2026/27 business year
Communication(s):	
Organisational risk:	Low

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
25/09/2025 Item 7.28	The HFEA to develop the proposed guidance for the sector and bring back to the Authority for further consideration	Director of Compliance & Information/Head of Policy (Scientific)	Summer 2026		This item can be removed
20/05/2026 Item 2.10	The Board Governance Manager to publish the revised standing orders.	Board Governance Manager	June 2026		Completed standing orders published on the HFEA website: **Standing orders - from 1st June 2026**
20/05/2026 Item 5.37	Executive to liaise with Chair regarding General Direction 0005	Policy Team			Chair approved revisions to GD0005.
20/05/2026 Item 6.28	Executive to implement the Authority's decisions regarding Embryo Testing	Head of Policy	September 2026		Work has commenced with an aim of reporting back to the Authority in September 2026

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:	1 July 2026
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

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

1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meeting in May 2026.
- Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

2.1 Chair activities

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

    - 3 June – attended the SCAAC meeting
    - 5 June – assisted DHSC in shortlisting potential new Board members
    - 10 June – annual accountability meeting with senior DHSC sponsor (with Peter)
    - 22 June – attended the all-staff event
    - 23/25 June – Interviews for new Board members (DHSC led)
    - 24 June – meeting with National AI Chairs commission (with Peter and other senior executives)

2.2 Chief Executive

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

    - 10 June – as above
    - 16 June – attended the Audit & Governance Committee
    - 18 June – gave talk to students at Countesthorpe Academy in Leicester as part of the Speakers for Schools programme
    - 22 June – all staff event
    - 23 June – attended the ALB Chairs and Chief Executives meeting
    - 24 June – as above

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment
Meeting:	Authority
Agenda item:	4
Meeting date:	1 July 2026
Author:	Caroline Pringle, Head of Licensing
Annexes	-

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is invited to note this report, and Chairs are invited to comment on their committees.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	This information will be published on our website.
Organisational risk:	Low

1. Committee reports

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

2. Recent committee items considered

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

Date	Items considered	Centres	Outcomes
Licence Committee:			
7 May	New research licence executive update	Edinburgh Fertility Preservation – Research project R0215	Approved – 1 year licence
	New research licence application	Francis Crick Institute Laboratory – Research project R0221	Approved – 1 year licence
	Research renewal inspection report	Newcastle Fertility Centre at Life – Research project R0152	Approved – 3 year licence
	Research renewal inspection report	University of Cambridge, Centre for Trophoblast Research, Physiology Building – Research project R0162	Approved – 3 year licence
	Research renewal inspection report	University of Cambridge, Centre for Trophoblast Research, Genetics Building – Research project R0162	Approved – 3 year licence
	Variation of licensed activities and research purposes - executive update	Human Embryo Research Centre – Research project R0193	Approved – licence varied
Other comments:			
Executive Licensing Panel:			
12 May	Initial inspection report	King's Fertility at Harley Street	Approved – 2 year licence
	Renewal inspection report	Care Fertility Manchester	Approved – 4 year licence (and ITE certificate)
	Research renewal inspection report	Centre for Reproductive Health	Approved – 3 year licence

Date	Items considered	Centres	Outcomes
	Renewal inspection report	Ayreshire Fertility Unit, University Hospital Crosshouse	Approved – 4 year licence
	Renewal inspection report	King's Fertility	Approved – 4 year licence (and ITE certificate)
	Interim inspection report and variation of SLC T52 without application	Care Fertility Cheshire	Approved – licence continued and varied
	Interim inspection report and variation of SLC T52 without application	London Women's Clinic Bromley	Approved – licence continued and varied
	Executive update	Avenues	Noted
27 May	Renewal inspection report	Edinburgh Fertility Centre	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	TFP GCRM Fertility	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Wales Fertility Institute - Neath	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Complete Fertility Centre Southampton	Approved – 4 year licence (and ITE certificate)
	Variation of PR and variation of SLC T52 without application	Care Fertility Birmingham	Approved – licence varied
9 June	Renewal inspection report	X&Y Fertility	Approved – 4 year licence (and ITE certificate)
	Variation of PR and variation of premises	In-OVO Fertility Clinic	Approved – licence varied
	Variation of PR	Care Fertility Leeds	Approved – licence varied
	Variation of PR	Care Fertility Bath	Approved – licence varied
	Variation of PR	Care Fertility Tunbridge Wells	Approved – licence varied
	Import of embryos from USA	Care Fertility London	Approved
24 June	Renewal inspection report	IVI London (Wimpole Street)	Minutes not yet approved
	Renewal inspection report	Semovo Leeds	Minutes not yet approved
	Renewal inspection report	St Mary's Hospital	Minutes not yet approved
	Renewal inspection report	Chelsea & Westminster Hospital	Minutes not yet approved
	Interim research inspection report	The Babraham Institute	Minutes not yet approved

Date	Items considered	Centres	Outcomes
	Variation of research premises	Guys Hospital	Minutes not yet approved
	Import of oocytes from UAE	IVI London (Wimpole Street)	Minutes not yet approved
Other comments:	None.		

Licensing Officer decisions:

1 May 2026	Variation of Licence Holder	Bourn Hall Clinic Norwich	Approved
7 May 2025	Voluntary Revocation of Research Licence	London Women's Clinic	Approved
14 May 2026	Variation of Licence Holder	Bourn Hall Clinic	Approved
May 2026	12 x ITE import certificate	Various	All granted
Other comments:	None.		

Statutory Approvals Committee:

27 April	Developmental delay with short stature, dysmorphic facial features, and sparse hair 1 (DEDSSH1), OMIM #616901	Care Fertility Nottingham	Approved
	FOXG1-related encephalopathy, OMIM #613454	Care Fertility Nottingham	Approved
	Myopathy with extrapyramidal signs, OMIM # 615673	Guys Hospital	Approved
	Neonatal onset 'Citrullinemia type 2', OMIM #605814	TFP Oxford Fertility	Approved
	Hyper Ig-D syndrome (HIDS), OMIM # 260920 and Hyperimmunoglobulinemia D (with periodic fever) mevalonate aciduria, OMIM #610377	The Lister Fertility Clinic at The Portland Hospital	Approved
	Leukodystrophy, hypomyelinating, 14;HLD14, OMIM #617899.	Guys Hospital	Approved
	Import of embryos from USA	IVI London	Approved

Date	Items considered	Centres	Outcomes
	Import of sperm from New Zealand	CREATE Fertility Bristol	Approved
	Import of oocytes from Ukraine	The Fertility & Gynaecology Academy	Approved
26 May	Homocystinuria-megaloblastic anaemia, cblG complementation type (MTR gene) OMIM #250940	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
	Juvenile polyposis/hereditary haemorrhagic telangiectasia syndrome (SMAD4 gene) OMIM #175050	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
	GATA6 related diabetes and congenital heart disease OMIM # 600001	TFP Oxford Fertility	Approved
	ITSN1-related disorder no OMIM number	TFP Oxford Fertility	Approved for applicant family only
	Nystagmus 1, congenital, X-linked OMIM #310700	Care Fertility Nottingham	Approved
	Hydrops, Lactic Acidosis and Sideroblastic Anemia (HLASA), OMIM #617021	Birmingham Women's Hospital	Approved
	Neurologic, Endocrine and Pancreatic Disease, Multisystem, Infantile-Onset 2; IMNEPD2, OMIM #619418	Birmingham Women's Hospital	Approved
	Import of oocytes from USA	The Lister Fertility Clinic at The Portland Hospital	Approved
	Export of embryos to Cyprus	TFP Nurture Fertility	Approved
	Import of oocytes from USA	Avenues	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:

The AGC held its meeting on 16 June 2026 and discussed the following items:

- Internal audit – results and annual opinion

- Progress with current internal audit recommendations
- Annual report and accounts – including the governance statement
- External audit completion report
- Resilience, business continuity management and cyber security
- Information assurance and security (SIRO report)
- Risk update – strategic risk register and horizon scanning
- Phoenix Programme
- Human resource strategy
- Government Functional Standards
- Estates
- Fraud Risk Control Test

Scientific and Clinical Advances Advisory Committee (SCAAC):

Items considered	Topic	Outcomes
3 June	The agenda and papers for this meeting are published on the SCAAC webpage. Items considered included:	The SCAAC Chair will report on this meeting verbally. Key takeaways are as follows:
	Relevant public health developments and research findings	SCAAC considered eight recently published studies on areas including outcomes of embryo donation, evidence of PGT-A outcomes, automation of embryology laboratory procedures, new European Department for the Quality of Medicines (EDQM) add-on guidelines Australian guidelines on male infertility, and the new NICE guideline on fertility.
	Emerging technologies in embryo and gamete testing	Members discussed research and technology developments related to genetic testing of sperm, AI driven sperm selection, oocyte selection, non-invasive ploidy analysis for embryos, metabolomic profiling and PGT-P. The Committee will monitor more closely emerging developments in epigenetics testing of embryos and gametes.
	Impact of the microbiome on fertility and fertility treatment outcomes	Members discussed research developments related to the impact of reproductive tract microbiome on reproductive health and ART

		outcomes, microbial signatures in different patient populations, effects of male reproductive tract microbiome on fertility, and the role of oral and gut microbiome as systemic regulators of reproduction.
	Rating review for treatment add-ons: microbiome testing	This is the first time the HFEA has rated a test as an add-on. The Committee agreed ratings across three patient groups. General fertility population: grey for live birth rate (LBR) Recurrent Implantation Failure (RIF): grey for LBR Chronic endometritis: grey for LBR and miscarriage rate Anti-microbial resistance will be addressed as a safety concern, including the risks of general use of antibiotics without an identified infection. Further information will be added to the 'Treatment add-ons with limited evidence' webpage in due course.
	Rating review for treatment add-ons: Sperm DNA fragmentation testing	The Committee agreed ratings for two patient groups: Male factor infertility: grey for LBR RIF: grey for LBR Members also agreed ratings across three interventions to treat men with high sperm DNA fragmentation: Antioxidants: rating will be finalised once an additional study identified at the meeting assessed by biostatisticians. Sperm selection: grey for LBR Surgical sperm retrieval (TESE/TESA): red for LBR for being an invasive procedure with patient risks Further information will be added to the 'Treatment add-ons with limited evidence' webpage in due course.

	Review of authorised process In Vitro Maturation (IVM)	Members discussed a clinic enquiry on undertaking a new form of IVM on fresh immature oocytes from ovarian tissue. The Committee decided this activity did not fall within the scope of the existing authorised process of IVM and agreed that a new processes application would be required should a clinic want to do IVM on fresh immature oocytes from ovarian tissue.

Other comments:

The annual Horizon Scanning meeting will take place during the ESHRE conference in London's Excel Centre on Monday 6 July from 2-5pm. There will be four topics discussed: emerging interventions in oocyte rejuvenation, advances in in vitro maturation of oocytes, non-invasive ploidy assessment, and environmental determinants of fertility. Apart from invited speakers and experts who will discuss the four topics, SCAAC members, HFEA Authority members and HFEA SMT members have also been invited to observe the meeting.

The HFEA is also holding another event at the ESHRE conference on Wednesday 8 July. The session entitled "Past, present, and future: Regulating a changing fertility sector" is part of the ESHRE programme and will examine the changing regulatory environment of the UK fertility sector.

The next SCAAC meeting (7 October 2026) will be Tim Child's last meeting as Chair of the Committee. The SCAAC Chair must be an Authority member and is appointed to the role by the Authority Chair. Recruitment is underway.

Register Research Panel:

The Register Research Panel (RRP) met on 26 May 2026

Items considered	Topic	Outcomes
New project application	'Development of a predictive cumulative live-birth model for donor-oocyte recipients using HFEA registry data'	Approved with conditions
Updates on projects' approval	**Disability data collection in IVF** **Chief investigator:** Joanne Leitch and Catherine Best **Research establishment:** University of Stirling	Fully approved
Enquiries to access the HFEA register		Four enquiry forms submitted Two meetings with prospective applicants
Project changes and project renewals	**The impact of duration of freezing of IVF embryos on pregnancy and perinatal outcomes – analysis of U.K.**	Two-year renewal and request for more recent data

	national data **Chief investigator:** Edwin Amalraj Raja **Research establishment:** University of Aberdeen	
	Educational outcomes in children born after assisted reproductive technology: a population-based linkage study **Chief investigator:** Alastair Sutcliffe **Research establishment:** UCL	Two-year renewal
New publications	'PGT-A is associated with reduced live birth rates in routine practice: evidence from the UK National ART register' in journal 'Reproductive BioMedicine Online'.	RRP project publication
	'Predictors of success for human assisted reproduction' in journal 'Heliyon'.	Anonymised register publication

3. Recommendation

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

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

Human Fertilisation & Embryology Authority

Monthly performance report

Performance up to May 2026

Evgenia Savchyna
Corporate Performance Officer
01/07/2026

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Meeting date:	01/07/2026
Agenda item:	Item 5
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

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

Human Fertilisation & Embryology Authority

Management summary

- Performance across KPIs in May 2026 was good, with ten KPIs rated Green, three Neutral, four Amber and two rated Red.
- Compliance KPI performance was very good with the ‘Inspection reports o PR’ and ‘Inspection reports to committee’ KPIs achieving Green. Only one report missed the ‘End-to-end licensing’ KPI due to its complexity.
- Seven of the eleven PGT-M applications due in May 2026 were completed during the month, with an average processing time of 60 working days, resulting in the PGT-M KPI being rated Green. Four remaining applications have been scheduled for the May SAC.
- Licensing KPIs were all rated Green, despite the increased number of the LO items (15).
- Both OTR KPIs were rated Red. The current OTR targets (‘the OTR waiting list reduced by 40 OTRs’ and ‘156 OTRs closed per month’) are no longer relevant, as the waiting list has decreased significantly and most of the OTRs on the waiting list are being worked on. New KPIs will be set following the OTR KPI review, which is currently in progress. The average waiting time for applicants decreased from 29 days in April 2026 to 23 days in May 2026.
- Seven out of eight FOI requests were completed within the statutory deadline, resulting in the KPI being rated Amber; the missed one was due to the complexity of the requested information and was answered in June 2026.
- The website sessions and users dropped in May 2026. This could be a result of issues with the HFEA website and especially CaFC pages in May, which have now been resolved. Social media engagement remained steady.
- The ‘Sickness absence’ KPI remains Green with no long-term absence. The ‘Turnover’ indicator was above the threshold at 16.5%.

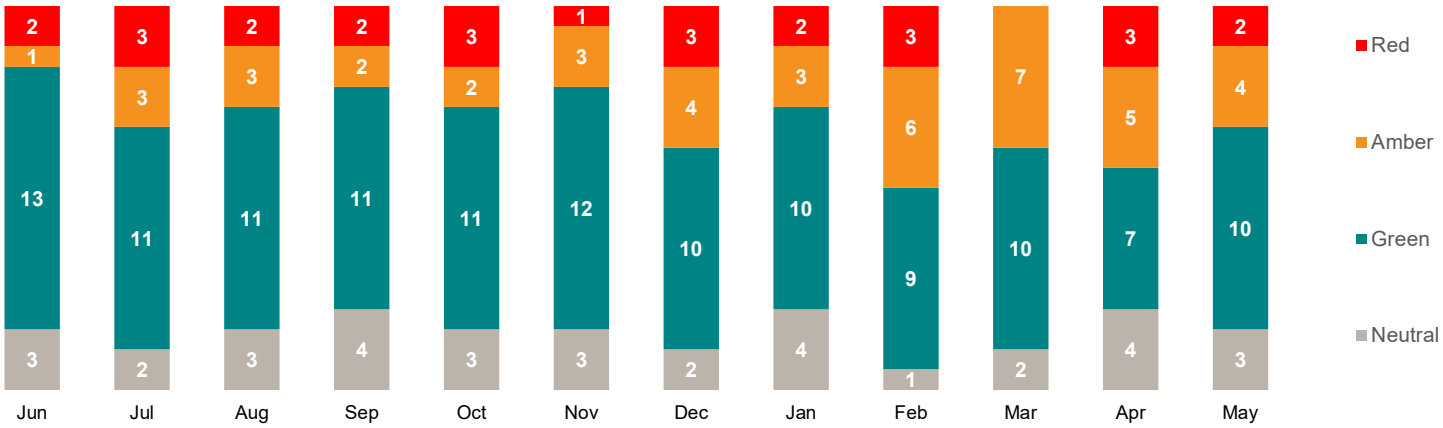
KPI reviews:

- The OTR review commenced in May 2026: the OTR KPIs are likely to be changed following this review.

Key performance indicators

Human Fertilisation & Embryology Authority

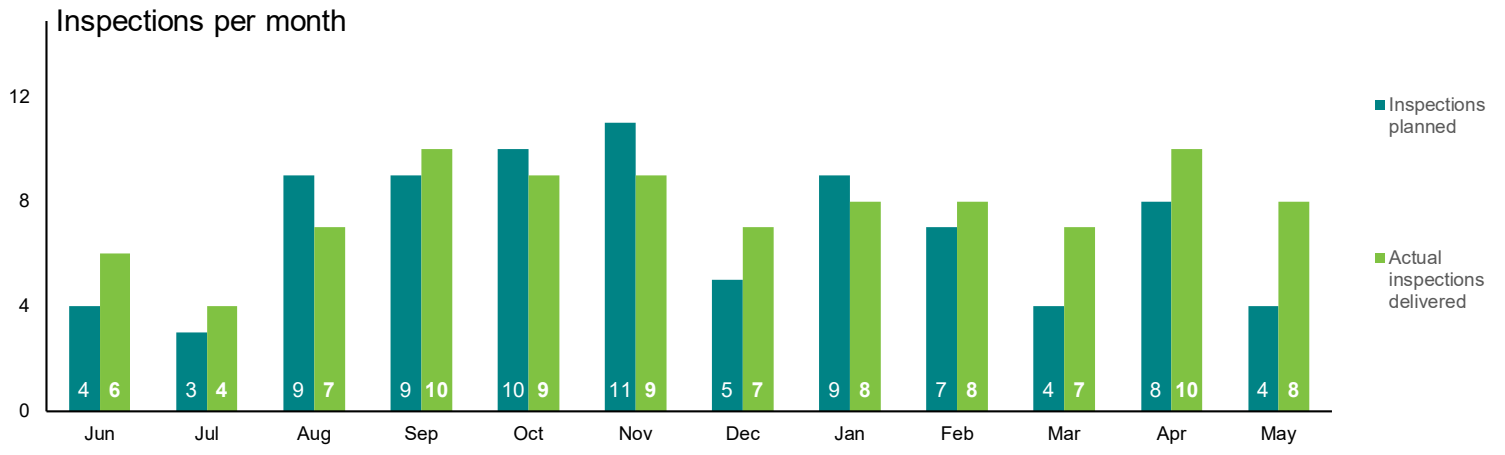
RAG status over last 12 months



RAG status over last 12 months

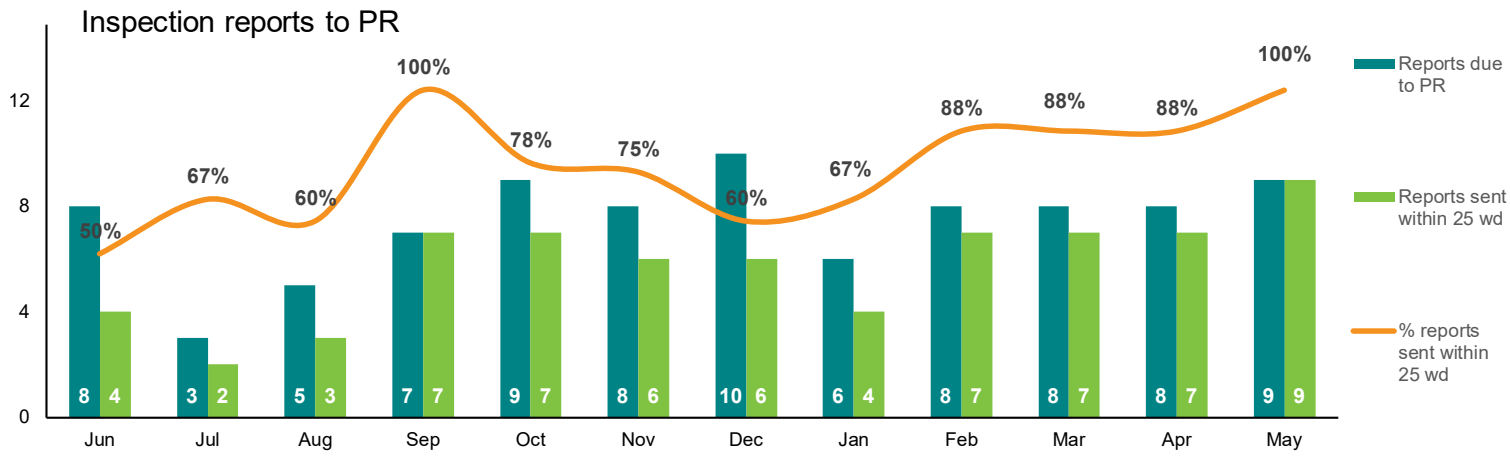
19 KPIs in total for each month

For May, the 2 red indicators are for these KPIs: **Information – 2** ('OTR waiting list change' and 'OTRs closed in month).



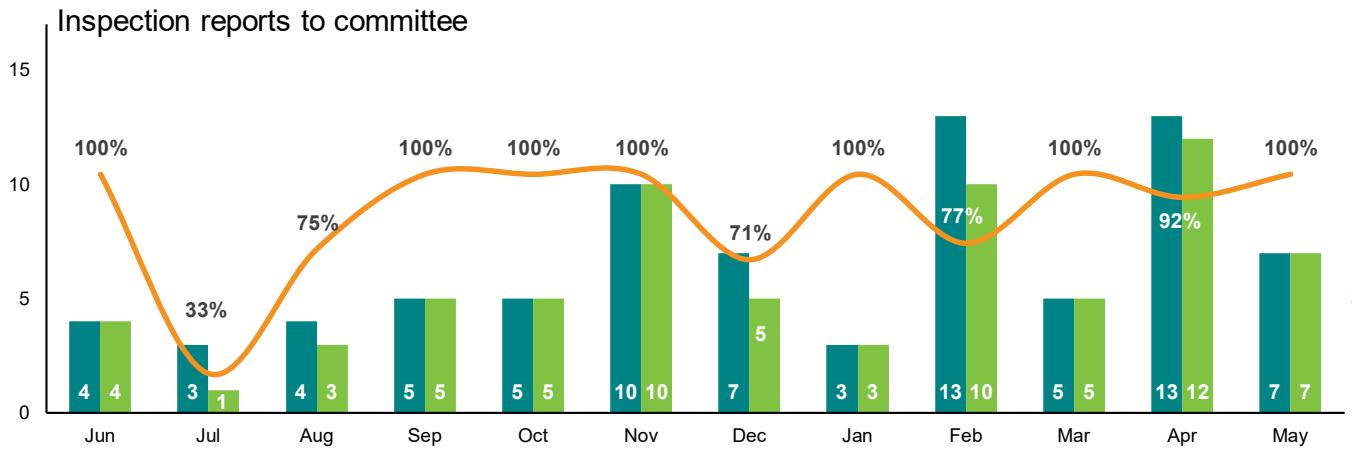
Status:	N/A
Compliance	
Inspections delivery	
Target: **not defined**	

Four inspections were planned for May 2025, and eight were delivered following a reshuffle of the inspection schedule and initial inspections added to the schedule.



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

All reports sent within KPI.



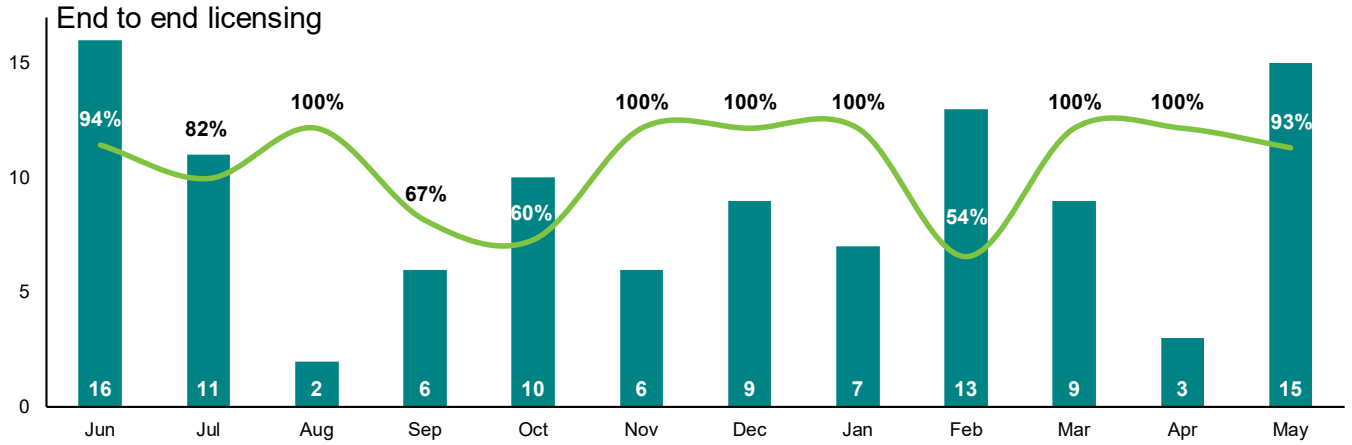
Status: **Green**

Compliance

Inspection reports sent to relevant licensing committee

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

All reports sent within KPI.



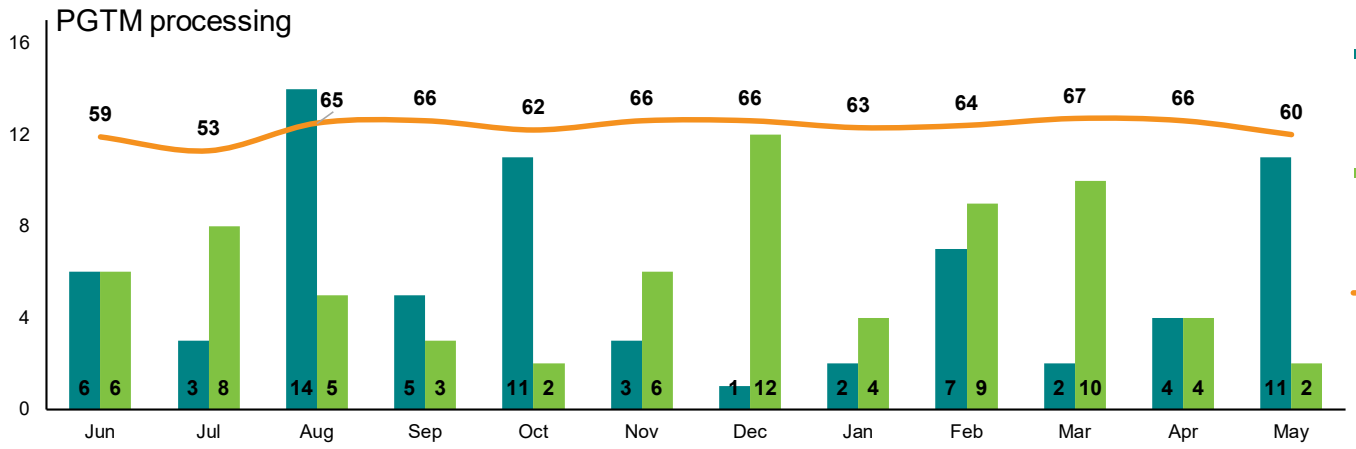
Status: **Amber**

Compliance

End to end licensing process

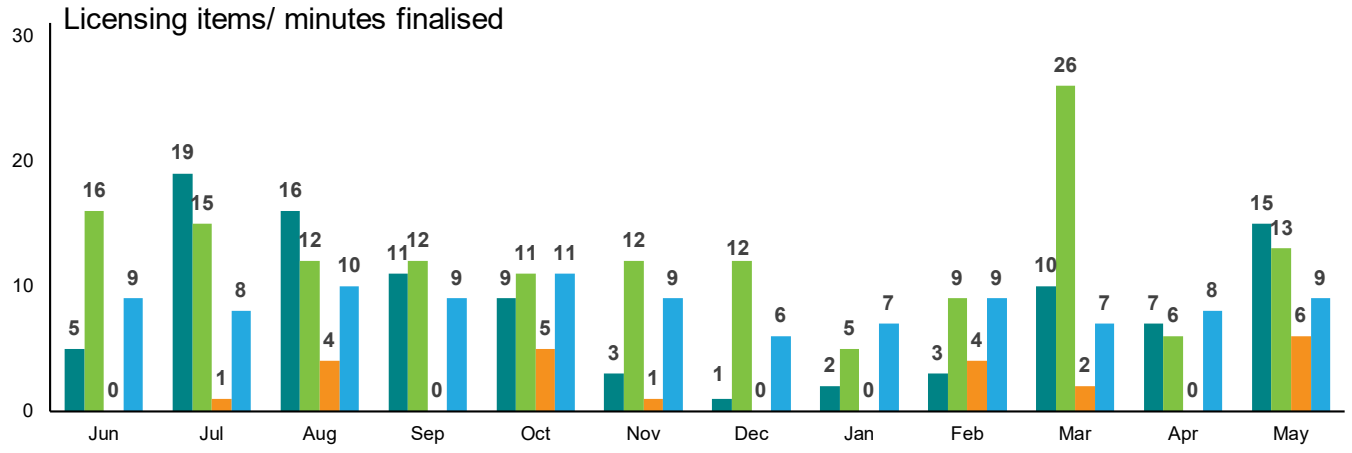
Target: **100% items completed within 80 working days**

One of the 15 reports was not completed on time due to the complexity and the required post-inspection actions.



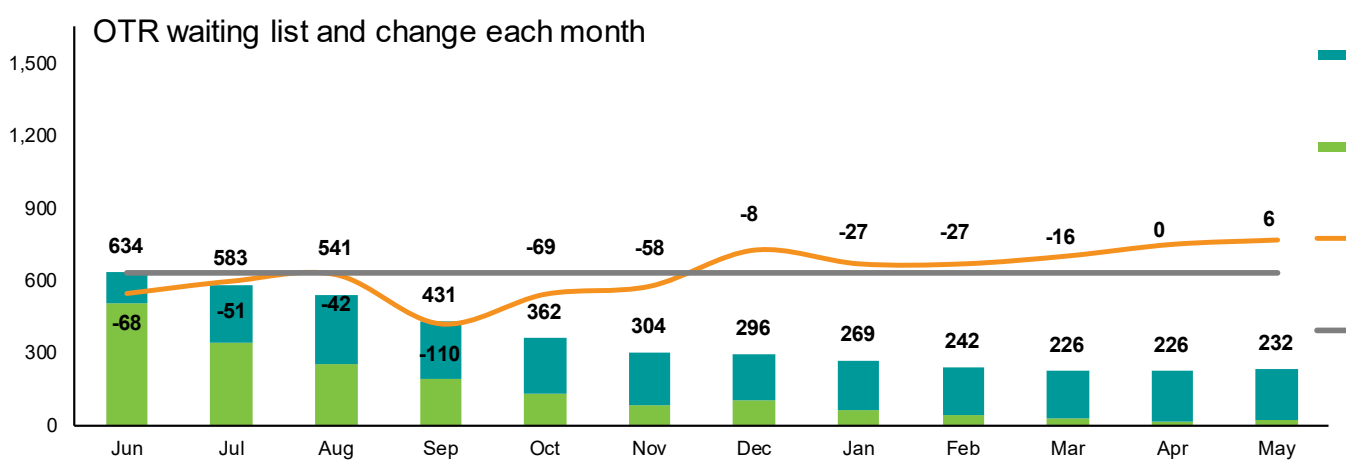
Status:	Green
Compliance	
PGTM processing efficiency	
New target - Dec 24: **average time within 60 working days**	

11 applications due to be completed in May. Seven completed within 69, 67, 62, 59, 56, 55, 50 working days. One scheduled for March SAC and six for April. Four other applications, that have not been completed, are scheduled for May SAC as next available agenda.



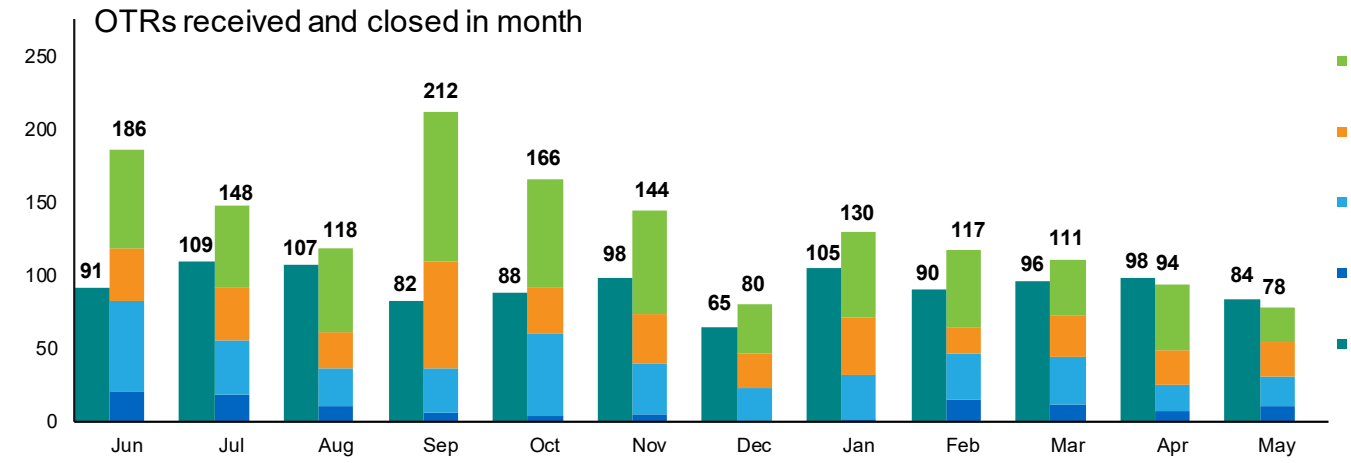
LO:	Green
ELP:	Green
LC:	Green
SAC:	Green
Licensing	
Licensing efficiency	
Targets: **LO - 5 WD** **ELP - 10 WD** **LC - 15 WD** **SAC - 20 WD**	

An increase in Licensing Officer items (one voluntary revocation, two variations of LH, all others were ITEs). An unusual Licence Committee meeting as all items were research. The ELP agendas were steady.



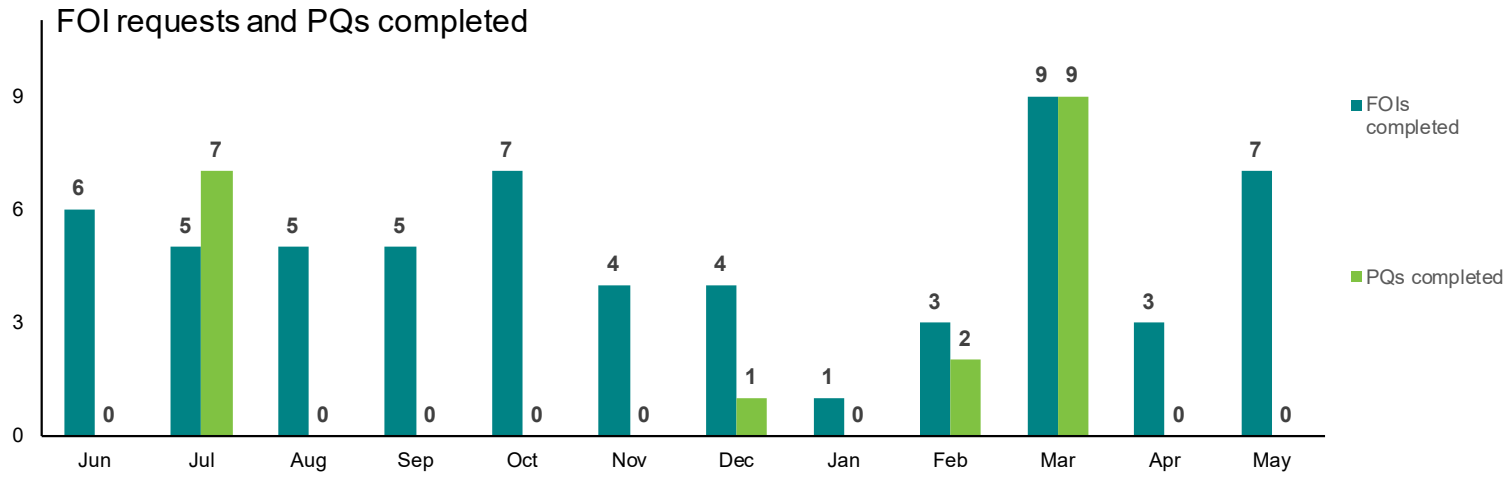
Status:	Red
OTR	
Waiting list change	
Target: reduced by more than 40 OTRs	

OTRs in the waiting list: **Donor OTRs - 46; DC identifiable - 51; DC anonymous - 38; Parents - 74.**
Waiting list was not reduced.



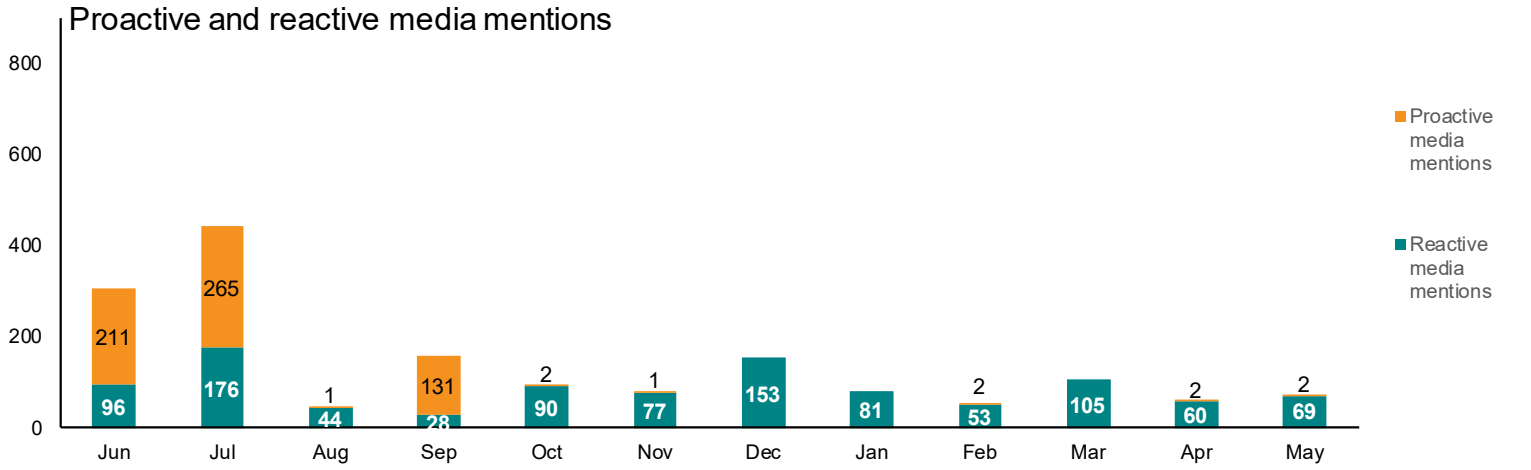
Status:	Red
OTR	
OTRs closed in month	
Target: more than 156 OTRs being sent out	

OTRs sent out: **Donor OTRs - 23; DC identifiable - 10; DC anonymous - 21; Parents - 24.**
We processed fewer OTRs due to a number of OTRs held up by clinic lack of replies and data issues. There are also fewer new OTRs to start working on. We did not lower the waiting list, but the average waiting time went down slightly from 29 days to 23 days in the last month.



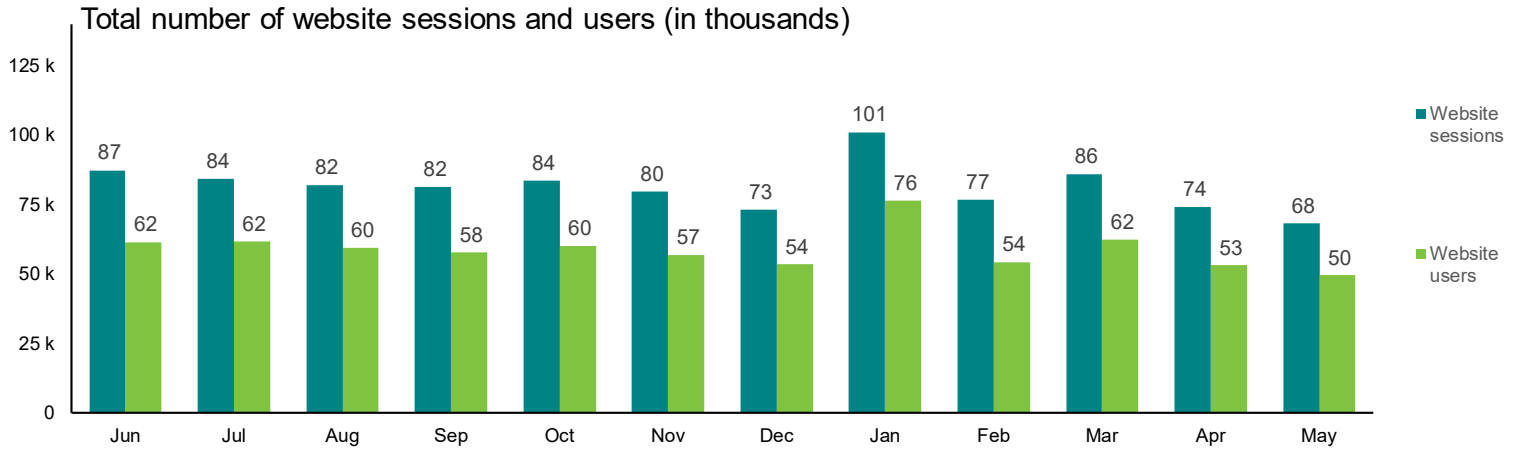
FOI:	Amber
PQ:	Neutral
Intelligence	
FOI and PQ completed	
Targets: **FOI - 20 WD PQ - set by DHSC**	

Seven of the eight FOIs due were completed within the statutory deadline. One FOI deadline was missed due to complexities with requested information and was answered in June 2026. FOI topics related to: clinic incidents, information relating to donor codes, number of IVF cycles and births using donor eggs to patients 40 and over, cross border reproductive care, cyber security, spend/transparency data and staffing.



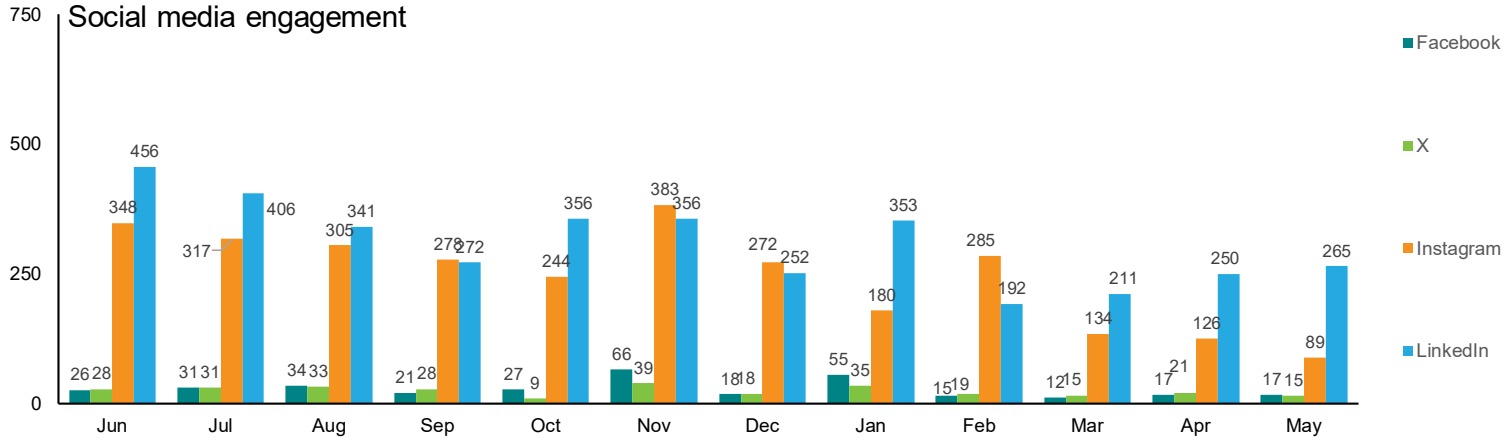
Status:	N/A
Comms	
Total media mentions (proactive and reactive split from April 2024)	
Target: **not defined**	

In May, coverage themes included unregulated donation, fertility and PGT-P. No stories drove coverage levels, but growing media interest in unregulated donation led us to publish FAQs on our website to address common questions.



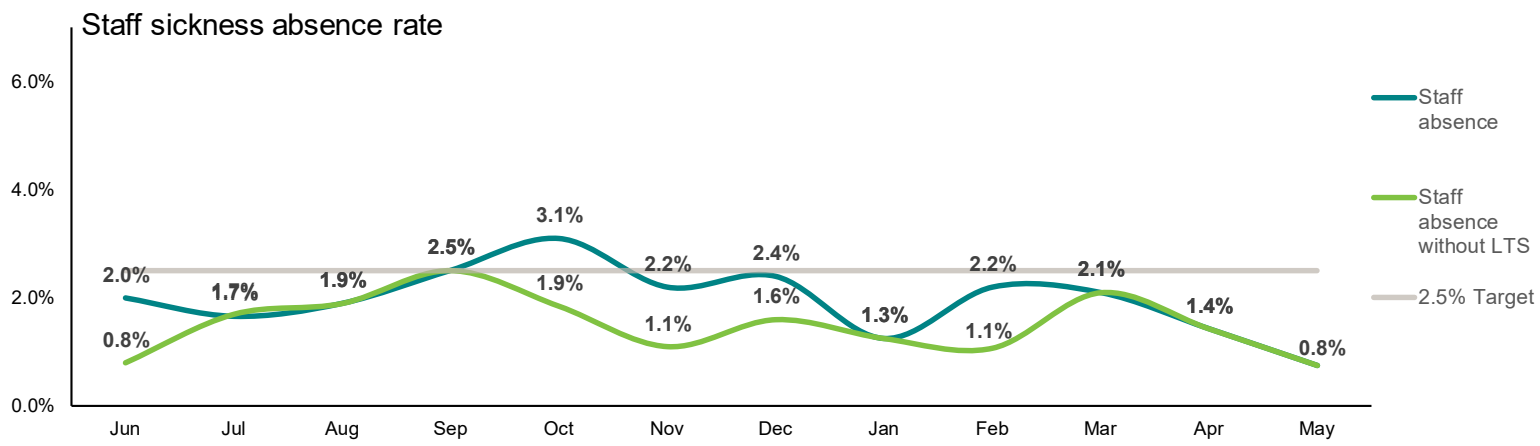
Status:	N/A
Comms	
Total number of website sessions and users (Internal traffic excluded from October 2023)	
Target: not defined	

The website's performance is generally in line with overall trends, but is affected by issues outside our remit, where either CaFC or the entire website are unavailable. This is currently being investigated with support from Microsoft who will make recommendations on a resolution. The 'Treatment add-ons' page has moved into the top three pages for the month.



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

In May, engagement remained steady across most channels, with LinkedIn seeing particularly strong performance following the PR Event. While Instagram engagement continues to be affected by algorithm changes, follower growth remains positive, indicating our content continues to reach our audiences.



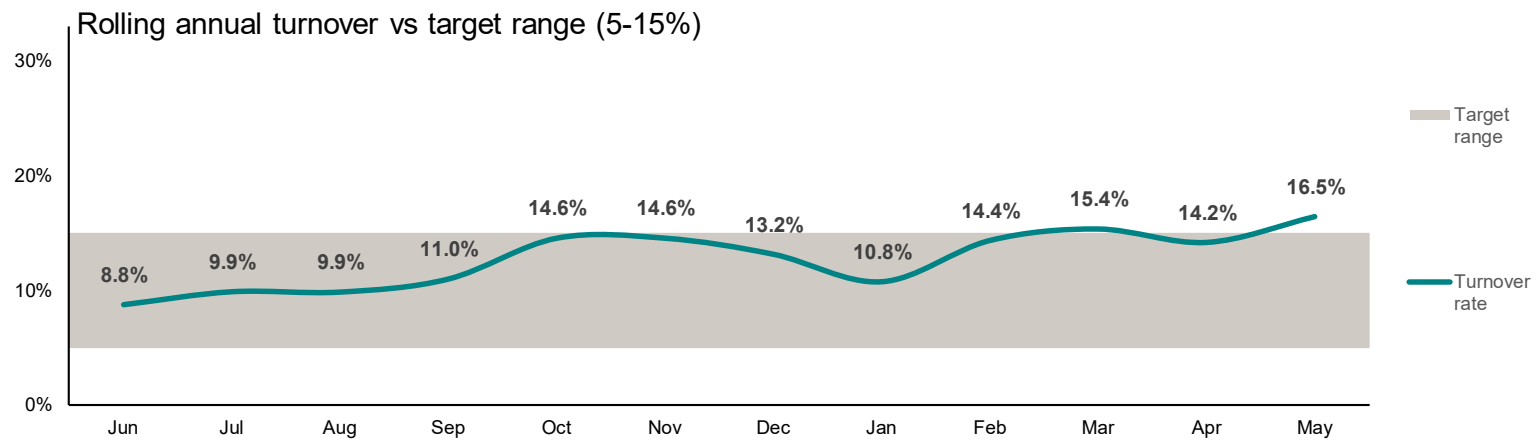
Status: **Green**

HR

Sickness

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

Sickness absence is low at present with no LTS.



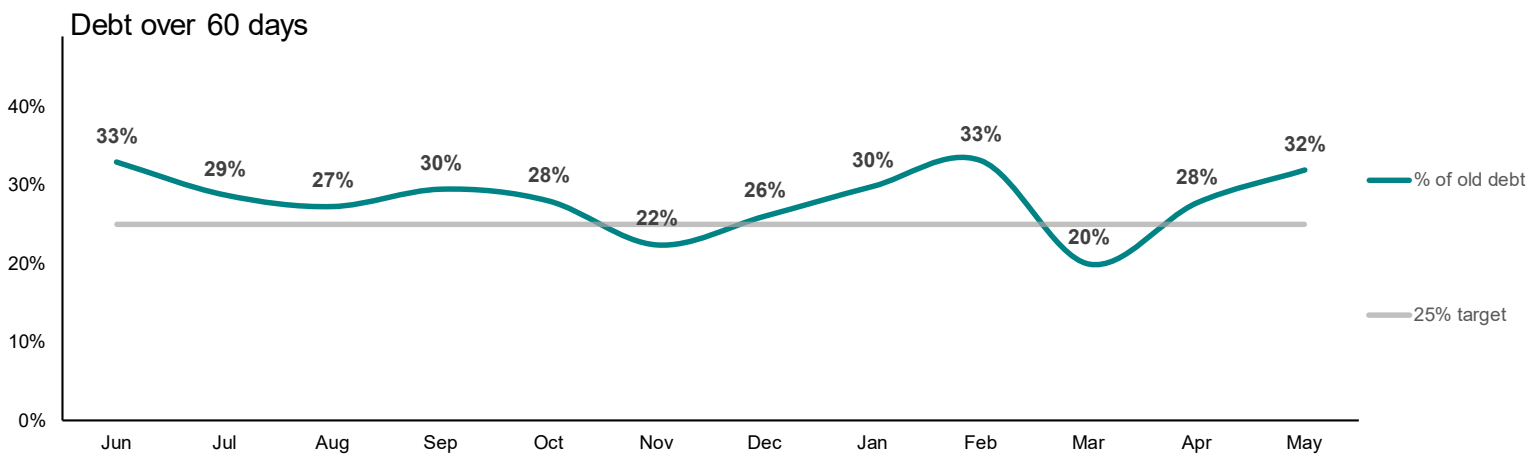
Status: **Amber**

HR

Turnover

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

This turnover rate includes planned leavers (retirements, end of FTC's). Without planned leavers the figure is 12.96%.
Supplementary HR data: **Headcount - 89, Budgeted posts - 84, Vacant posts -2, Starters - 0, Leavers - 0.**



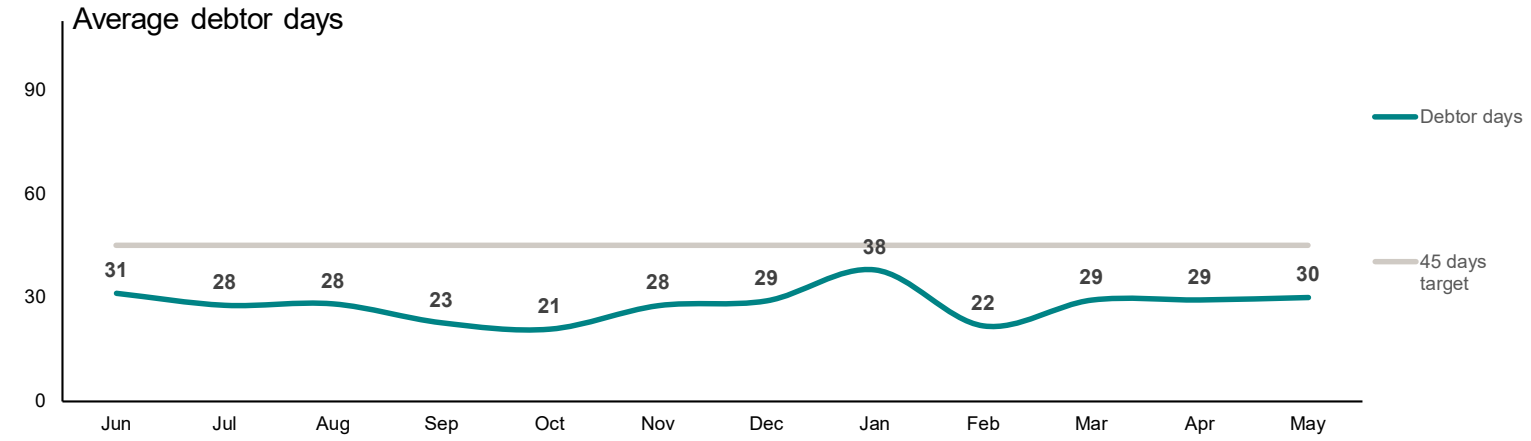
Status: **Amber**

Finance

Debt collection

Target:
25% or less of older than 60 days debt

Excluding estimated clinics, the 60+ days debt is £39,870.76 which is 10% of the total debt.



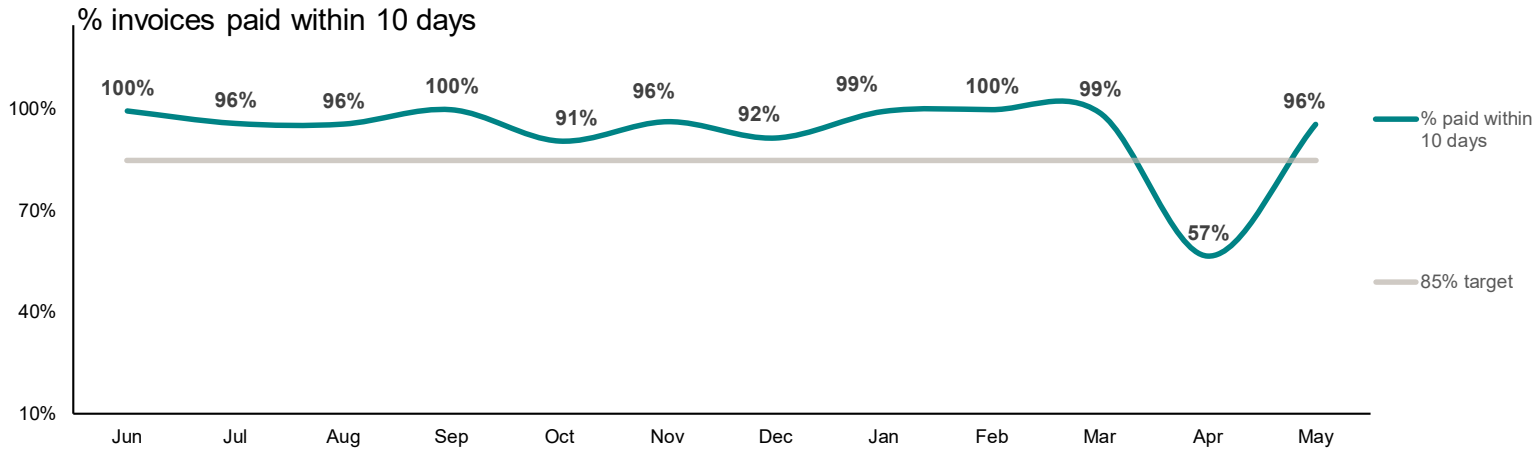
Status: **Green**

Finance

Debtor days

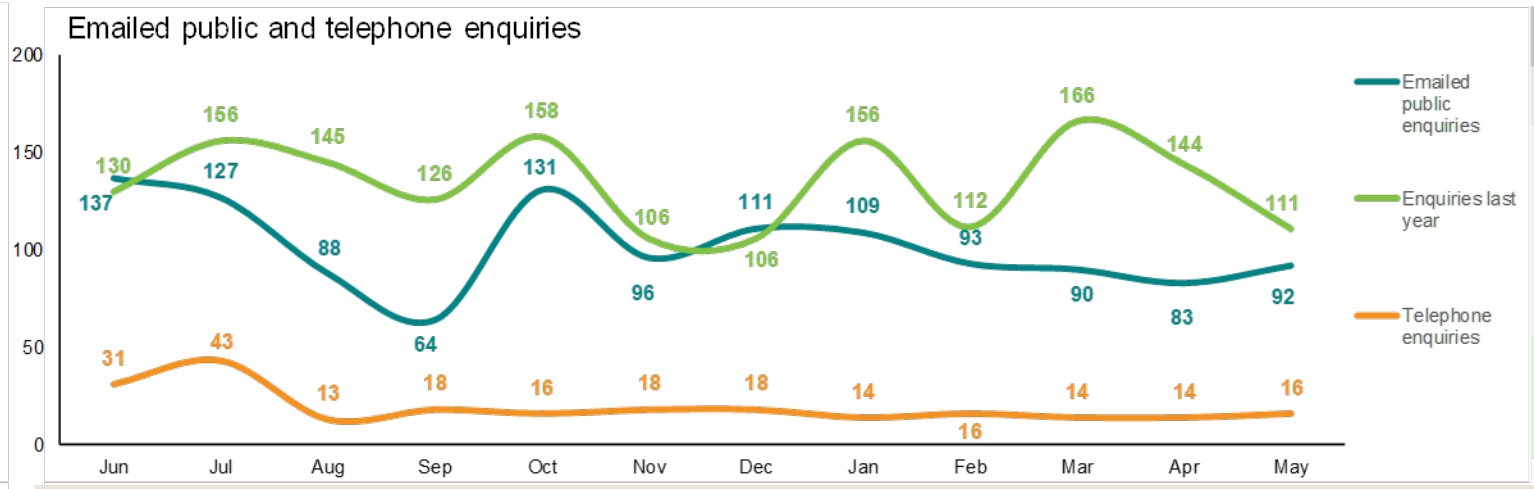
Target:
45 days or less

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	
Email and telephone enquiries	
Target: **not defined**	

The enquiries team received 92 enquiries in May which is higher than the number of enquiries we received in April. 16 calls were received in May. Themes included medical queries and concerns (2), Complaints (2), Donation (2), Chasing email response (2) and Other (5). Out of the 16 calls received, 13 were categorised as Straightforward and 3 were categorised as Challenging.

Human Fertilisation & Embryology Authority

Finance Report

Two months to 31 May 2026

Tom Skrinar
Director of Finance, Planning and Technology
1 July 2026

www.hfea.gov.uk

Summary financial position as of 31 May 2026

	Year-to-date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	1,299	1,264	(35)	9,235	9,233	(2)
Expenditure	1,470	1,461	(9)	9,173	9,233	60
Surplus / (Deficit)	(171)	(197)	26	62	0	62

KPIs
Bank balance: £2.6m (target £1.52m)
Debts 60 days old 32% (target <25%) (excluding 3 clinics is 10%)

Two months into the new financial year, we are posting a year-to-date deficit of £171k which is represented by a small surplus of income against budget of £35k offset by an overspend on expenditure of £9k. Details of significant variances are shown on the following pages.

The forecast for the year is showing a surplus against budget of £62k. At this point, we have not conducted a detail review of plans for the remainder of the financial year thus most cost lines are forecast to budget. A detailed review will be undertaken in early July when the first quarters figures will be presented.

2026/27 Income – YTD 31 May 2026

	Actual £000's	Budget £000's	Variance £000's	Variance %ge	Full year Budget £000's	Full year Forecast £000's	Variance £000's
INCOME							
DHSC Funding	33	33	0	0%	1,074	1,067	7
Licence fees	1,252	1,231	21	2%	8,064	8,075	(11)
Other	14	0	14		95	93	2
Total income	**1,299**	**1,264**	35	3%	**9,233**	**9,235**	(2)

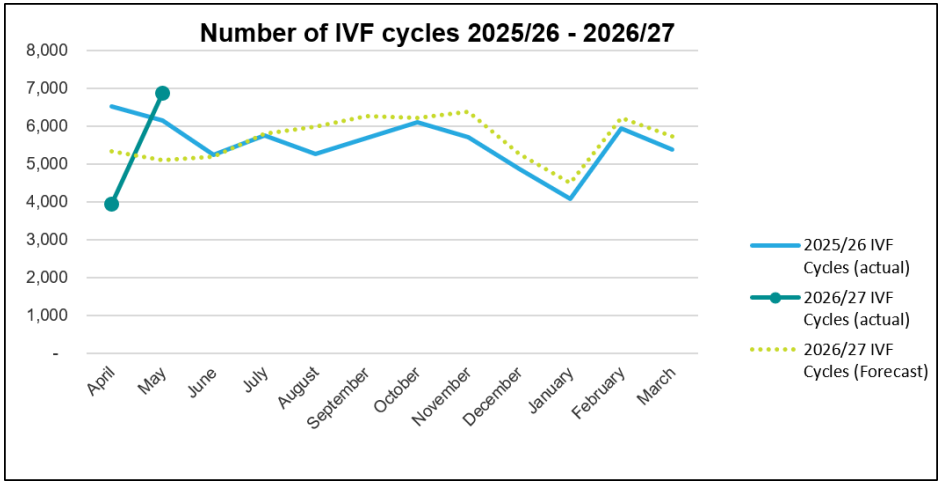
Income

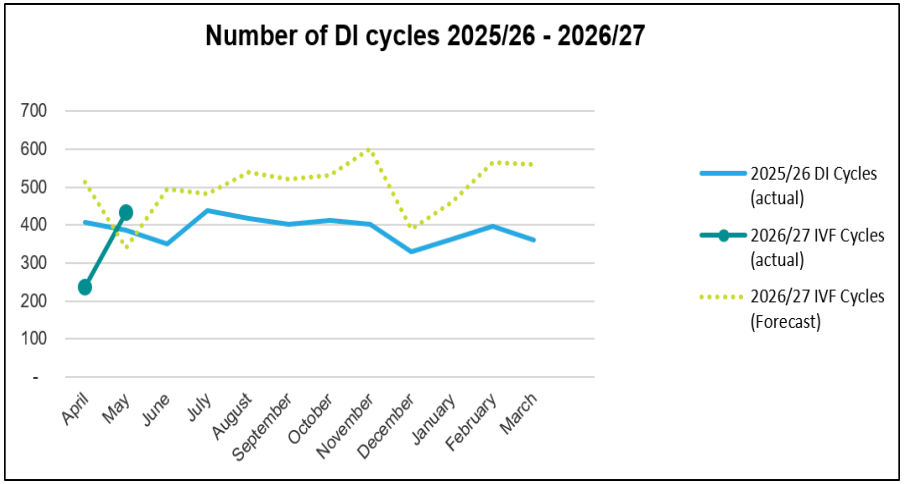
DHSC Funding is our grant in aid (GIA) both cash and non-cash, the latter being a notional sum to cover depreciation and amortisation of our assets. Year-to-date we are on budget. The £7k forecast short-fall is due to a reduction in our non-cash due to age of assets being depreciated.

Licence fees are the IVF, DI treatment fees plus invoices for renewal, storage and research fees. The increase against budget is due to the IVF/DI fees ending the month £11k over budget in addition to the invoices for renewal, storage and research fees which exceeded the budget by £10k.

Other income is purely bank interest on our current account which collects our licence fees. We do not and cannot earn interest on the account to which we draw down our grant in aid.

2026/27 Income - YTD Actual vs Budget





IVF / DI Activity for the two months ended 31 May 2026

The above graphs show the volumes of IVF and DI cycles, comparing activity for the 2026/27 and 2025/26 financial years as of May 2026

IVF cycles were extremely low in April which was the result of some clinics missing the submission deadline. In May, IVF cycles were 6,877 compared to 6,161 in 2025/26. Year-to-date, we are slightly below (364 cycles) compared to 2025/26.

DI cycles for the two months to end of May are 15.5% down on the same period last year. This could a pattern which we will be unable to confirm until later in the year.

We continue to monitor both IVF and DI cycles as any significant decline impacts on income and our ability stay within our budgeted envelope.

Human Fertilisation & Embryology Authority

2026/27 Expenditure YTD 31 May 2026

	Actual £000's	Budget £000's	Variance £000's	Variance %ge	Full year Budget £000's	Full year Forecast £000's	Variance £000's
EXPENDITURE							
Salaries and wages	1,051	1,115	(64)	-6%	6,708	6,647	61
Other Staff costs	22	20	2	9%	328	328	0
Other costs	37	4	33	933%	302	302	0
Project costs	116	110	6	5%	274	274	0
Estates incl non-cash costs	88	60	28	47%	487	480	7
IT costs	105	114	(9)	-8%	706	710	(4)
Legal and Professional	51	38	13	34%	428	432	(4)
Total Expenditure	**1,470**	**1,461**	**9**	1%	**9,233**	**9,173**	60

Variances above £5k

Salaries and wages – are £64k below budget which is impacted by the vacancies currently being recruited to within the IT team.

Other costs – is showing that it is over budget by £33k, however, a majority of the cost lines have budgets that start in June. For Q2, a re-profiling of the budget will take place ensuring we can identify when actual costs will be incurred.

Human Fertilisation & Embryology Authority

2025/26 Expenditure continued

- **Estates (incl non-cash) costs** – are over budget by £28k. This is represented by other accommodation costs (service charges and rates) that are budgeted quarterly, therefore the negative variance should reduce by the end of the quarter. The non-cash costs are expected to come in below budget as these costs are based upon the number of assets (laptops) we have deployed over the year.
- **IT Costs –** are under budget by £9k which relates mainly to support and consultancy costs where the use of external IT consultants was lower then expected. Based on the detailed review of costs, we expect these costs to remain close to budget.
- **Legal and Professional** – is over budget by £13k with £5k relating to Legal spend with the balance relating to Audit Fees specifically for DSPT work conducted over the last period c£10k. However, due to profiling this cost is expected to come within budget unless further audits are required. The balance relates to small underspends within other categories of legal spend.
- **Forecast** – a review of forecast costs will be conducted at the end of quarter one, where teams will confirm their plans for the remainder of the year and the associated costs.

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Human Fertilisation & Embryology Authority

Register Research Panel annual report to Authority

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment
Meeting:	Authority
Agenda item:	8
Meeting date:	1 July 2026
Author:	Amanda Evans, Head of Research and Intelligence Elena Corujo-Simon, Senior Research Manager
Annexes	Annex A – Active Register Research Panel approved projects Annex B – Publication list for approved Register Research Panel projects Annex C – Publication list for anonymised register data and other anonymous HFEA data

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note this report
Resource implications:	Medium
Implementation date:	2026-27
Communication(s):	Through regular updates to researchers, clinics, stakeholders and patients via our website, social media and newsletters.
Organisational risk:	Low

1. Introduction

1.1. The HFEA holds a Register of all patients, partners, donors, treatments and children born as a result of these treatments. It is believed to be the longest running database of assisted reproduction treatment in the world holding 35 years of data.

1.2. The Human Fertilisation and Embryology Act 1990, as amended ('the Act') and the Disclosure of Information for Research Purposes Regulations 2010 ('the 2010 Regulations') provide that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register. Continuing to increase the availability and benefit of our data for patients, clinics and researchers is a key aim of the current HFEA strategy. We want to continue to engage with researchers to improve access to relevant and valuable data on our Register to that end.

1.3. The Authority has delegated to the Register Research Panel (RRP) the power to authorise access to Register data for the purposes of medical or non-medical research. The panel is required to report annually to the Authority and this paper provides that annual report.

1.4. The RRP is one of many ways in which Register data is made available. Most people seeking to access Register data do not require identifiable information. To ensure we gain the most value from the Register, we proactively publish information tailored to relevant audiences such as researchers, healthcare professionals and the public. For example, this is done through publications, anonymised registers and the HFEA dashboard. We also respond to freedom of information requests (FOIs), data enquiries and parliamentary questions (PQs).

1.5. We regularly publish **data research reports** which receive wide media coverage. Fertility Trends is our annual statistical release and is the main point of reference for all data-related enquiries received throughout the year. It is published as an HTML report, with supporting underlying data tables. Fertility treatment 2024: trends and figures was published in June 2026. The publication included changes to birth rates measures in line with recent changes to our **Choose a Fertility Clinic** measures, reporting a combined birth rate for fresh and frozen embryo transfers per embryo transferred as the main headline statistic. It also included improvements to how we display data with three interactive figures.

1.6. In 2024, we launched our **award-winning** **HFEA dashboard** as a new tool to better enable public access to a wider breadth of data in a simplified and customisable format. Since release, the dashboard has been updated annually alongside Fertility Trends to include a new year of data, as well as updated to add improvements or include further data. This year, updates included providing additional age bands on select pages and changes to our IVF birth rates measures as detailed in 1.5. Visits to the HFEA dashboard averaged 5,000 a month, reaching over 60,000 visits from June 2025 to May 2026.

1.7. Both data research reports and the HFEA dashboard are used in scientific and medical research – widely cited in peer-reviewed publications and used in presentations at various conferences. The 'Fertility treatment: trends and figures' reports from 2019-2023 alone have been cited in at least 25 papers in the last two years, and the HFEA dashboard has been cited in several publications since it launched in 2024.

1.8. With large-scale internal changes to the way our data is stored and being used, we are additionally preparing a data strategy to align objectives across the HFEA in how we want to be

using data. This is in draft stages with relevant HFEA staff and expected to be discussed with Authority members in the Autumn.

1.9. Section 2 of this paper provides an overview of Register Research Panel activity undertaken since the previous RRP update (June 2025 to May 2026). Section 3 covers activities in improving engagement with researchers and section 4 outlines work carried out in providing further information in freely available anonymised formats.

2. Register Research Panel activity in 2025-26

2.1. The role of the RRP is to decide whether to grant or refuse requests to access Register data for specific research purposes. The RRP is chaired by a Director and has membership from staff with research, information governance, data register, clinical and policy expertise.

2.2. Since the introduction of the 2010 Regulations, the RRP has approved 27 project applications: 13 projects are currently active, one conditionally approved, two were consolidated, and 12 have been completed. A list of the currently active projects is available in Annex A.

2.3. The main output from RRP approved projects is typically publication of the research results in peer-reviewed academic journals. Between 1 June 2025 and 31 May 2026, there were two new peer-reviewed academic articles published from RRP approved research projects (see Annex B), and four published using anonymised data (see Annex C). There have been 28 peer-reviewed academic articles published from RRP approved research projects and 36 from anonymous HFEA data sources such as the anonymised register, since 2010.

2.4. Between 1 June 2025 and 31 May 2026, the RRP met on two occasions to consider two new project applications and one project change request to obtain more recent data. Both these new project applications were initially approved with conditions, and one of them is now fully approved. Additionally, the project reported as conditionally approved last year (May 2025) received final approval. Five projects were also approved for renewal. A list of the projects approved in the last year can be found in 2.9-2.11.

2.5. Updates to the following documentation were completed as part of the wider work to improve the information provided to and received from researchers: the RRP standard operating procedure, application form, project change request form, the data specification sheet as well as the RRP standing orders. To improve communication of RRP work on an ongoing basis to Authority, updates have been included since March 2026 within Committee Chairs' reports alongside updates from other HFEA committees and panels.

2.6. The **data research webpage** has also had continued updates to provide more information for researchers on how to apply to access data with monthly visits averaging around 1,800, to a total of almost 21,000 in the year.

2.7. Upcoming updates will include finalising a new decision tree for use by the panel that improves clarity in legislation used for RRP projects, which can require a combination of the 2010 Regulations and the Act.

2.8. The number of research enquiries has increased since last year, which is likely to be related to research engagement activities outlined in section 3, especially since most enquiries are from new research groups with whom the HFEA has not worked with before. However, the number of new applications has not increased as it can depend on researchers receiving funding to proceed, clarification from third parties on feasibility of complex linkages, or obtaining a UK-based collaborator if based abroad. These issues are common to other organisations we have

spoken to and explain the difference between the number of enquiries and the projects submitted to the RRP. While Register data is becoming more widely known, there remains more potential to improve patient care through increased high-quality research through increased awareness of the HFEA Register data and improving ease of accessing data (see Section 3).

2.9. In May 2024, we updated the Authority on the recommended updates to the regulations on disclosure for research that had been submitted to the Department of Health and Social Care (DHSC). The proposal included changes in three main areas: cost recovery, research following egg, sperm and embryo donation, and child consent. We received a response from DHSC in 2025 which included confirmation on where legislative change is required. We have reviewed the response and have followed up on our communication with DHSC with a new brief to seek further clarification on some aspects and we continue to raise the need for updates to legislation to enable long-term follow-up studies for children born and enable cost recovery.

Projects approved in 2025-26

2.10. **In frozen embryo transfer cycles, is the pregnancy potential of the embryo associated with the number of days the embryo spends in the in vitro culture before freezing?** (University of Manchester) The aim of this project is to determine whether, in frozen cycles, transferring a faster developing embryo, day 4 blastocyst, will result in a better pregnancy success rate.

2.11. **Disability data collection in IVF** (University of Stirling). The aim of this project is to understand how data on disability is collected in people having IVF treatment to improve monitoring of this characteristic and care in this population.

2.12. Development of a predictive cumulative live-birth model for donor-oocyte recipients using HFEA registry data (University of Bristol) – Conditionally approval. The aim of this project is to develop a model that predicts cumulative live birth in donor-egg IVF cycles.

3. Research engagement activities

3.1. As part of our strategic aim to increase the visibility of our data for research, we have engaged with the Health Data Research (HDR) UK Gateway to host a link to the HFEA data research website on their online platform. This enables researchers to more readily find out about HFEA data and view common variables of interest to researchers.

3.2. The HFEA Data Research Update Newsletter continues to provide a platform for updating research audiences on areas relevant to them. There have been eight editions so far, which included information on new HFEA publications and meetings, upcoming events, researcher spotlights and highlights of RRP projects and their publications. There are over 270 subscribers currently with a high open rate of around 55%. One of the researcher spotlights was additionally expanded on in an HFEA blog to highlight how patient data is enabling research.

3.3. We continue to promote use of the data research webpage and visits to the HFEA dashboard as an accessible source of information for researchers in our engagement activities, with both having high levels of views as detailed in 2.6 and 1.6 respectively.

3.4. The project enquiry form on the data research webpage continues to be successful in streamlining contact with new researchers. Since the introduction of this form in July 2024, 34 research groups from a wide range of research areas have enquired via the form. From June

2025 to May 2026, we received 15 requests and met with seven researchers. The form has aided communication with researchers around understanding feasibility of projects using data held and in tracking interest.

3.5. Following completion of data validation in January 2026, summary-level data submissions to international registries such as the **European IVF Monitoring (EIM)** and **International Committee Monitoring Assisted Reproductive Technologies (ICMART)** have recommenced. These registries provide valuable information on global changes and comparisons, with top level findings presented at academic meetings and published in journals. The HFEA attended the EIM annual meeting to discuss the UK register and presented on how the HFEA register is being used at the **ART Registers in the World congress** alongside a wide range of other world IVF data registries.

3.6. To support research relating to HFEA strategic aims, the Research and Intelligence team have also worked with various research teams through collaboration or by assisting on Stakeholder Advisory Groups such as **'Reproductive Borders and Bordering Reproduction'** at Kings College London. We have additionally been contributing to considerations in improving reproductive health data led by the **National Institute for Health and Care Research**. One research collaboration is currently in submission with academic journals on Ethnic disparities in the success of in vitro fertilization (IVF) treatment using anonymised HFEA register data and will be presented in a poster session at the upcoming ESHRE conference.

3.7. Lastly, we have presented data from our publications and the HFEA dashboard at conferences and meetings to highlight Register data available to researchers. Our recent publications and the HFEA dashboard were presented at the European Society of Human Reproduction and Embryology Conference 2025, the Royal Statistical Society international conference 2025 and Fertility 2026.

4. Anonymous Register data

4.1. The *Anonymised Register* data can be used for research without having to apply for approval, allowing researchers to access a large and rich dataset that does not contain any identifiable information. A new **anonymised register enquiry form** was introduced in January 2026 to collect some information to improve our understanding of how it is being used – such as their location, project aims and occupation. 36 individuals from a wide range of research areas have requested access to the datasets. The information has helped us understand that more than half of the requests originate from universities abroad, and that there is a large interest in creating new predictive models to study success rates.

4.2. We are continuing to review our publicly available datasets to ensure consistency with our other publications. We plan to update the anonymised registers in Winter 2026/27, including a review of what data is included to ensure it meets both researcher needs and government data access strategies. Following the example from other organisations, we are considering the creation of synthetic datasets to facilitate preliminary research while maintaining real-world data safety. We are planning to engage with researchers within this financial year to ensure this option meets their needs and can be used for research.

4.3. Additionally, we are talking to other data organisations with similar datasets to understand their current practices. Many of these organisations (UKHSA, CPRD, NHS England, Pioneer Hub) are using or developing their own Trusted Research Environment platforms (TREs) to allow

researchers access to datasets. This is widely regarded as best practice for providing access to data in a safe and secure manner; however, these can have significant cost implications that the HFEA will need to consider before any implementation.

4.4. In the 2025-26 financial year, the Research and Intelligence team responded to data-related enquiries in the form of 64 FOIs, 53 data enquiries and 27 PQs. While these requests have historically often required preparation of bespoke data, many are now answered by the HFEA dashboard or our publications. Requests that are not answerable by already published sources are often specific and more complex queries. Management of FOI requests will be led by the Information Governance team from July 2026 following recent internal re-organisation.

5. Summary

5.1. The Authority are asked to note the following:

- The activities of the RRP over the last year as outlined in section 2.
- Research engagement activity carried out to improve awareness of the HFEA Register and its value for research in section 3.
- Plans to review the anonymised register as noted in section 4, particularly noting considerations for potential use of Trusted Research Environments and synthetic datasets.

Annex A

Active Register Research Panel approved projects

Year of approval	Research Establishment	Chief Investigator	Title
2026	University of Stirling	Joanne Leitch and Catherine Best	Disability data collection in IVF
2025	London School of Economics	Matthias Doepke	The effect of government funding on IVF (in-vitro fertilisation) demand: Evidence from regional data in the UK
2025	University of Oxford	Moscho Michalopoulou and Nerys Astbury	Association of the body mass index of women undergoing in vitro fertilisation, with pregnancy, live birth, and pregnancy loss rates, and number of eggs collected: a population-based study of the Human Fertilisation and Embryology Authority database
2025	University of Manchester	Daniel Brison	In frozen embryo transfer cycles, is the pregnancy potential of the embryo associated with the number of days the embryo spends in *in-vitro* culture before freezing?
2023	University College London	Alastair Sutcliffe	General Health Outcomes in Subfertile Men: a UK register-based cohort study
2023	University of Aberdeen	Edwin Amalraj Raja	The impact of duration of freezing of IVF embryos on pregnancy and perinatal outcomes – analysis of U.K. national data
2020	University of Manchester	Stephen Roberts	Effects of Assisted Reproductive Technology (ART) on long-term Birth Weight trends: A National Cohort Study
2020	South London and Maudsley NHS Trust	Robert Stewart	Associations between Assisted Reproductive Technologies and Women's Mental Health: an investigation using clinical data linkage
2018	University of Edinburgh	Tom Clemens	Environmental determinants of IVF treatment
2017	University College London	Alastair Sutcliffe	Educational outcomes in children born after assisted reproductive technology: a population based linkage study
2016	University of Oxford	Claire Carson	Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England (PEARL)
2012	University of Aberdeen	David J. McLernon	Update IVF prediction model
2012	University College London	Alastair Sutcliffe	General Health and Hospital Admissions in Children Born after ART: A Population Based Linkage Study

Note: this table does not include one project which has conditional approval.

Annex B

Publication list - Approved Register Research Panel projects

Published since last Authority update (June 2025-May 2026)

1. Roberts, S.A., Brison D.R., Harper, J., Kondowe, F., & Vail, A. (2026) PGT-A is associated with reduced live birth rates in routine practice: evidence from the UK National ART register. Reproductive BioMedicine Online
2. Song, H., Clemens, T., Doherty, R.M., Stocker, J., & Bhattacharya, S. (2025) Assessing ambient air pollution's effects on birth outcomes: a Scottish IVF cohort study (2010-2018) Environmental Health 24 (54)

Published prior to last Authority update (before June 2025)

3. Purkayastha M, Sutcliffe A, Brison DR, Nelson S.M., Lawlor D., & Roberts. S.A. (2024) Perinatal health in a cohort of children conceived after assisted reproduction in the UK: a population-based record-linkage study. BMJ Open(14).
4. Williams, C.L., Bunch, K.J., Stiller, C., Murphy, M.F.G., Botting, B.J., Davies, M.C., Luke, B., Lupo, P.J., Sutcliffe, A.G. (2024) Langerhans cell histiocytosis in children born after assisted reproductive technology**.** *Reproductive BioMedicine Online*, 49(6):104379. https://doi.org/10.1016/j.rbmo.2024.104379
5. Sutcliffe, A.G., Purkayastha, M., Brison, D.R., Nelson, S.M., Roberts, S.A., Lawlor, D.A. (2023). General health in a cohort of children conceived after assisted reproductive technology in the United Kingdom: a population-based record-linkage study. *American journal of obstetrics and gynecology.* 228(1), 82-e1. https://doi.org/10.1016/j.ajog.2022.07.032
6. Hua, X., Rivero-Arias, O., Quigley, M. A., Kurinczuk, J. J., & Carson, C. (2023). Long-term healthcare utilization and costs of babies born after assisted reproductive technologies (ART): a record linkage study with 10-years' follow-up in England**.** *Human Reproduction*, *38*(12), 2507–2515. https://doi.org/10.1093/humrep/dead198
7. Ratna, M. B., Bhattacharya, S., & McLernon, D. J. (2023). External validation of models for predicting cumulative live birth over multiple complete cycles of IVF treatment. *Human Reproduction*, *38*(10), 1998–2010. https://doi.org/10.1093/humrep/dead165
8. Raja, E.A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2023). A comparison of perinatal outcomes following fresh blastocyst or cleavage stage embryo transfer in singletons and twins and between singleton siblings**.** *Human Reproduction Open*, *2023*(2): hoad003. https://doi.org/10.1093/hropen/hoad003
9. Kondowe, F. J. M., Clayton, P., Gittins, M., D'Souza, S. W., Brison, D. R., & Roberts, S. A. (2023). Growth of twins conceived using assisted reproductive treatments up to 5 years old: a national growth cohort**.** *Human Reproduction*, *38*(4), 751-761. https://doi.org/10.1093/humrep/dead018
10. McLernon, D. J., Raja, E. A., Toner, J. P., Baker, V. L., Doody, K. J., Seifer, D. B., Sparks, A. E., Wantman, E., Lin, P. C., Bhattacharya, S., & van Voorhis, B. J. (2022). Predicting personalized cumulative live birth following in vitro fertilization. *Fertility and Sterility*, 117(2):326-338 https://doi.org/10.1016/j.fertnstert.2021.09.015
11. Raja, E.A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2022). Comparison of perinatal outcomes after frozen or fresh embryo transfer: separate analyses of singleton, twin, and sibling live births from a linked national in vitro fertilization registry. *Fertility and Sterility*, 118(2), 323–334. https://doi.org/10.1016/j.fertnstert.2022.05.010

12. Ratna, M. B., Bhattacharya, S., van Geloven, N., & McLernon, D. J. (2022). Predicting cumulative live birth for couples beginning their second complete cycle of in vitro fertilization treatment. *Human Reproduction*, 37(9), 2075–2086. https://doi.org/10.1093/humrep/deac152
13. Sharpe, A., Mascarenhas, M., & Balen, A. (2022). Ethnic variation in the live birth rate and perinatal outcomes following frozen embryo transfer: an analysis of the HFEA database from 2000 to 2016. *Human Fertility*, 25(3), 583–592. https://doi.org/10.1080/14647273.2021.1913291
14. Bhattacharya, S., Maheshwari, A., Ratna, M. B., van Eekelen, R., Mol, B. W., & McLernon, D. J. (2021). Prioritising IVF treatment in the post COVID 19 era: a predictive modelling study based on UK national data. *Human Reproduction*, 36(3). https://doi.org/10.1093/humrep/deaa339
15. Purkayastha, M., Roberts, S. A., Gardiner, J., Brison, D. R., Nelson, S. M., Lawlor, D., Luke, B., & Sutcliffe, A. (2021). Cohort profile: A national, population-based cohort of children born after assisted conception in the UK (1992-2009): Methodology and birthweight analysis. *BMJ Open* 11:e050931. https://doi.org/10.1136/bmjopen-2021-050931
16. Castillo, C. M., Harper, J., Roberts, S. A., O'Neill, H. C., Johnstone, E. D., & Brison, D. R. (2020). The impact of selected embryo culture conditions on ART treatment cycle outcomes: a UK national study. *Human Reproduction Open*, *2020*(1):hoz031.
17. Cameron, N. J., Bhattacharya, S., & McLernon, D. J. (2020). Cumulative live birth rates following blastocyst- versus cleavage-stage embryo transfer in the first complete cycle of IVF: a population-based retrospective cohort study. *Human Reproduction*, 35(10):2365–2374. https://doi.org/10.1093/humrep/deaa186
18. van Eekelen, R., van Geloven, N., van Wely, M., Bhattacharya, S., van der Veen, F., Eijkemans, M. J., & McLernon, D. J. (2019). IVF for unexplained subfertility; whom should we treat? *Human Reproduction*, 34(7):1249–1259. https://doi.org/10.1093/humrep/dez072
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21. Williams, C. L., Jones, M. E., Swerdlow, A. J., Botting, B. J., Davies, M. C., Jacobs, I., Bunch, K. J., Murphy, M. F. G., & Sutcliffe, A. G. (2018). Risks of ovarian, breast, and corpus uteri cancer in women treated with assisted reproductive technology in Great Britain, 1991-2010: data linkage study including 2.2 million person years of observation. *BMJ (Online)*, 362: k2644 https://doi.org/10.1136/bmj.k2644
22. Cameron, N. J., Bhattacharya, S., Bhattacharya, S., & McLernon, D. J. (2017). Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women. *Human Reproduction*, 32(11):2287-2297. https://doi.org/10.1093/humrep/dex293
23. Maalouf, W., Maalouf, W., Campbell, B., & Jayaprakasan, K. (2017). Effect of ethnicity on live birth rates after in vitro fertilisation/intracytoplasmic sperm injection treatment: analysis of UK national database. *BJOG: An International Journal of Obstetrics and Gynaecology*, 124(6):904-910. https://doi.org/10.1111/1471-0528.14241
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Annex C

Publication list - Anonymised Register data and other anonymous HFEA data

Published since last Authority update (June 2025-May 2026)

1. Long A., & Franklin D.N. (2026) Predictors of success for human assisted reproduction. *Heliyon* 12 (1)
2. Borji A., Haick H., Pohn B., Graf A., Zakall J., Ragib Shahriar Islam S.M., Kronreif G., Kovatchki D., Strohmer H., & Hatamikia S (2025) An integrated optimization and deep learning pipeline for predicting live birth success in IVF using feature optimization and transformer-based models. *Computer Methods and Programs in Biomedicine 271*
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4. Zhang, Y., Jia, Q., Liu, Y., Guan, Y. (2025) Insemination methods for embryos transferred in frozen-thawed embryo transfer cycles do not impact reproductive outcomes in couples with non-male factor infertility. *Scientific Reports,* 15 (13630).

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SoHO Regulations update

Details about this paper

Area(s) of strategy this paper relates to:	To effectively regulate a changing fertility sector
Meeting:	Authority
Agenda item:	8
Meeting date:	1 July 2026
Author:	Annabel Salisbury, Regulatory Policy Manager
Annexes	Annex 1: Alignment of the SoHO Regulation with HFEA law reform proposals Annex 2: Changes made by the SoHO Regulation to consider as possible changes to UK law

Output from this paper

For information or decision?	For information and for decision
Recommendation:	The Authority is asked to consider whether the HFEA should only press for changes to UK law where the SoHO Regulation aligns with existing HFEA law reform proposals, or whether to press for additional changes in light of the SoHO Regulation
Resource implications:	Staff resources as planned in the current business plan
Implementation date:	Ongoing
Communication(s):	With DHSC: stakeholder roundtables (scheduled for the end of July), SoHO Regulations working group meetings and regular meetings with sponsor team With the sector: direct communications (via email and virtual meetings) with PRs of clinics in Northern Ireland and updates in Clinic Focus where needed
Organisational risk:	Low

1. Introduction

1.1. The Regulation on standards of quality and safety for substances of human origin intended for human application ('the SoHO Regulation') will come into force in August 2027. The Regulation covers gametes and embryos, as well as other substances of human origin (SoHO) outside of our remit. Following the UK's exit from the European Union and as per the terms of the Windsor Framework, the SoHO Regulation will apply to Northern Ireland (NI) only and not to Great Britain (GB). As the UK-wide regulator of fertility treatment and the Competent Authority for NI, we have a responsibility to comply with these Regulations as they relate to fertility treatment and to ensure that centres in NI do the same. At present there are three HFEA licensed fertility clinics in NI.

1.2. This paper first summarises the effect of EU exit on the regulatory system in NI (section 2). The main effects of the SoHO Regulation on clinics in NI and the HFEA are then set out in section 3, and impact of the SoHO Regulation on divergence between NI and GB is in section 4.

1.3. DHSC are leading a consultation process to identify any possible changes to UK law in light of the SoHO Regulation. If any changes are adopted, this would more closely align GB and NI. This paper (section 5) asks the Authority to agree whether the HFEA should take the position to only press for changes to UK law where the SoHO Regulation aligns with existing HFEA law reform proposals, or whether to press for any additional changes in light of the SoHO Regulation.

2. Background

2.1. NI remains aligned to some EU laws and, per the terms of the 2023 Windsor Framework, this includes EU legislation on health. This means that in effect two regulatory regimes apply to NI – **both** UK **and** EU law.

2.2. When the UK left the EU, we implemented some separate processes for NI and GB such as separate Standard Licence Conditions (SLCs), three separate General Directions, and some guidance in the Code of Practice that is marked as applicable to NI or GB only.

2.3. At the time of EU exit, it was noted that divergence between NI and GB may increase over time, and the SoHO Regulation presents the first significant divergence since then. This divergence arises because the SoHO Regulation replaces the 2004 European Tissues and Cells Directive (EUTCD) which was incorporated into UK law in 2007. The SoHO Regulation permits countries to apply stricter national standards than those required by the Regulation, meaning that we will need to apply whichever is stricter of the SoHO Regulation or UK law in NI. The changes required by the SoHO Regulation do not affect GB at this time.

3. Impact of the SoHO Regulation on clinics in Northern Ireland and the HFEA

3.1. In general, we aim to keep practice as consistent as possible UK-wide to avoid any unnecessary regulatory burden for NI clinics. We also aim to apply the SoHO Regulation proportionally considering that there are only three NI clinics. Most processes in NI will not be affected by the

SoHO Regulation. However, the SoHO Regulation does require some changes, which will result in updated SLCs for NI to be agreed by the Authority in November 2026, and updates to approximately five General Directions and other guidance. Because this is a technical update, no new patient information is planned.

3.2. Main changes for clinics in NI

3.2.1 **Expanded scope:** the SoHO Regulation captures a broader range of activities than the Act (eg, donor registration). This means that some organisations that do not fall within the scope of the Act are captured under the SoHO Regulation - for example, a satellite centre taking consent from donors. However, the oversight activities the HFEA needs to carry out for these centres are less stringent - for example, they do not need to be inspected. In NI at present, there a small number such centres meeting this definition. We will oversee these centres through their third-party agreements with licensed clinics.

3.2.2 **New requirements relating to patient protection:** the SoHO Regulation includes an overarching responsibility for SoHO entities to protect the health of patients, donors, and offspring born from fertility treatment, including protections relating to their dignity. In addition, clinics must not use SoHO in treatment without proven benefit and clinics should not advertise particular SoHO using misleading information. The SoHO Regulation covers many types of SoHO and these provisions are better suited to, for example, blood products rather than the types of add-ons generally used in fertility treatment. This is because most add-ons used in fertility treatment are, for example, a treatment or test applied to the patient rather than SoHO. More work is needed to assess what these powers would look like in practice for the HFEA.

3.2.3 **Changes to the authorised processes system:** the SoHO Regulation introduces a system to authorise prepared SoHO ('SoHO Preparations'), equivalent to our existing system for authorising novel processes. This includes a greater focus on the effectiveness of any novel treatment.

3.2.4 **New requirements relating to protection of donors and of children born from fertility treatment**: the SoHO Regulation requires that clinics must respect national limits on the number of donor-conceived offspring from a single donor when exporting, that advertisements for donors cannot refer to compensation, that egg donors must be monitored after donation, and ensure that egg donors are not donating too frequently based on a donor's health.

3.2.5 **New roles of responsibility:** Clinics in NI will need to appoint a physician and a releasing officer. Both roles require suitable qualifications and have specific responsibilities (in a similar way to a PR).

3.2.6 **Alignment with EU-wide standards:** Clinics in NI will be expected to align with technical guidelines published by the European Centre for Disease Prevention and Control (ECDC) and European Directorate for the Quality of Medicines & HealthCare (EDQM) and we will inspect them on this basis. Clinics in NI will also need to align with decisions made by a body called the SoHO Coordination Board (SCB), responsible for consistent application of the Regulation across the EU.

3.2.7 **New EU digital platform including data reporting requirements:** Clinics, regulators and governments will be required to share, submit and record information on the 'EU SoHO Platform'. We do not yet have access to the platform, however we will need to incorporate updating the platform into various processes including authorised processes and licensing. The

most significant change is that some activity data will need to be submitted to the EU SoHO Platform, either by clinics or by the HFEA.

3.3. Five of these changes in the SoHO Regulations - set out in Annex A - align with existing HFEA policy positions as set out in our law reform proposals relating to patient protection and innovation, either directly or in terms of broad principles.

3.4. Main changes for the HFEA

3.5. The SoHO Regulations will require changes across a number of different areas including inspection, incident reporting, licensing, traceability and import processes. Each change is relatively small but taken together will require a moderate amount of resource across the HFEA for implementation. This will involve, for example, updating SOPs, decision trees and internal training documents.

3.6. Implementation of the SoHO Regulation poses different challenges to previous EU exit work. Firstly, because the UK is not an EU member state, we are not included in regular EU-level discussions regarding implementation (which are taken at the SCB, see paragraph 3.2.6). In addition, there is less overall resource (both for DHSC and the HFEA) to implement these changes when compared to EU exit. The implementation of several aspects of the SoHO Regulation would benefit from further clarification and we are continuing to raise questions with the DHSC. This means that it is difficult to plan for and define the exact changes that are needed. There continues to be a risk that, if and when clarification is received, it may be different to our interpretation of the SoHO Regulation. This has implications for clinics in NI and for internal resource planning.

4. Divergence between NI and GB

4.1. As set out in section 2, the SoHO Regulation increases divergence between NI and GB. Moreover, that divergence is likely to increase over time, mainly via three mechanisms:

- **Implementing Acts:** the SoHO Regulation sets out that there will be more legislation in future to add detail to the SoHO Regulation eg, in relation to data submission
- **The SoHO Coordination Board (SCB):** as set out in paragraph 3.2.6, the SCB exists to co-ordinate implementation of the SoHO Regulation across the EU and in doing so they will make decisions affecting NI.
- **Technical standards:** the SoHO Regulation emphasises compliance with European Directorate for the Quality of Medicines & HealthCare (EDQM) and European Centre for Disease Prevention and Control (ECDC) guidelines. This means that NI clinics should refer to these EU-wide technical guidelines in relation to, for example, their quality-management system and patient and donor screening.

4.2. Divergence between GB, NI and the EU presents a challenge for the HFEA as a UK-wide regulator; operating two significantly different regulatory systems could be confusing for the sector and for patients, and involve disproportionate resource for the HFEA given the small size of the sector in NI. In addition, it is generally beneficial to minimise divergence where this would directly affect patients - for example, regarding ease of movement between GB and NI and import and export from GB to the EU.

5. For decision: possible changes to also apply to GB

5.1. DHSC consulted on whether the UK legislative framework for SoHO should be updated in light of the SoHO Regulation through a call for evidence that closed in June. The next stage is stakeholder roundtables due to take place in late July. At present, DHSC are exploring whether UK law is sufficient in the following areas within our remit:

- Movement of material (between GB and NI and for import / export)
- Incident reporting
- Future proofing and innovation
- Patient, donor and offspring protection
- Data reporting

5.2. The changes required by the SoHO Regulation present an opportunity to highlight to DHSC where changes to UK law would be beneficial. In relation to the issues in paragraph 5.1, the SoHO Regulation aligns with existing HFEA policy with respect to five of the HFEA proposals for law reform relating to patient safety and innovation (see Annex A for details). Our response to the DHSC call for evidence was based on the existing HFEA law reform proposals and highlighted the areas where HFEA law reform proposals and the SoHO Regulation are aligned.

5.3. The SoHO Regulation will apply some stricter standards in NI including standards relating to the protection of donors and offspring born from fertility treatment that go beyond our proposals for law reform. While UK law offers sufficient protection for offspring and donors, some of these stricter standards in SoHO Regulation would be beneficial if they were also applied to GB. One benefit of changing UK law to align with EU/NI is that, as set out in paragraph 4.2, divergence between GB and NI can be challenging. However, the possible benefits of alignment should be balanced with the need to avoid placing requirements on GB clinics without proven benefit. The planned stakeholder roundtables provide an opportunity to explore those arguments.

5.4. It is important to note that even if there are changes that would be beneficial to adopt in GB, we should be realistic about the possibility of changes to UK law. The SoHO Regulation comes into effect in August 2027 and there is little time for significant changes to the law before then. Given the uncertainty about whether any of the recommendations we might make will be implemented, we also need to consider how much HFEA resources are put to this.

5.5. Now that we have had the opportunity to look at the SoHO Regulation in more detail, there are some aspects that could be beneficial to adopt in NI (see Annex B), in addition to the changes that align with our existing law reform proposals (Annex A).

5.6. The Authority are asked to discuss the following two options:

5.6.1 **Option 1:** Only recommend changes to UK law that align with existing HFEA law reform proposals, as set out in Annex A.

Pros	Cons
• Presents a focused and consistent message to DHSC in line with the existing HFEA policy • The HFEA proposals for law reform were the result of extensive research including public consultation and stakeholder	• The SoHO Regulations had not been published when the proposals were agreed and, taking the SoHO Regulation into account, it may be beneficial to align GB and NI on other areas • By only focusing on existing proposals, we are not able to consider any issues that may

research. As such, they represent our highest priority issues	have arisen since the proposals were published in 2023

5.6.2 **Option 2:** Recommend **one or more** of the changes (a-h) to UK law set out in Annex B, in addition to existing HFEA law reform proposals.

5.7. For decision: should we press for changes to UK law only in line with existing HFEA law reform proposals or advocate for additional changes to align with the SoHO Regulation?

Recommendation: option 2, with specific recommendations for changes indicated in Annex B.

6. Next steps

6.1. The key dates for this work are as follows:

- **July 2026: DHSC stakeholder roundtables**
- **November 2026: Authority sign-off on updated SLCs and General Directions**
- **December 2026:** Begin re-licensing exercise for the three NI clinics
- **April 2027:** Publish all guidance and other materials for NI clinics
- **7 August 2027: SoHO Regulation applies**

6.2. The Authority will be kept up to date on any upcoming changes to UK law and timescales following the consultation process.

Annex A: Alignment of the SoHO Regulation with HFEA law reform proposals

This table sets out where the SoHO Regulation aligns either directly or in terms of principle with the HFEA law reform proposals. We would recommend that any changes to UK law take into account the HFEA's specific proposals for law reform.

HFEA Theme	HFEA Proposal		SoHO Regulation requirement
Patient protection & safety	**1**	The HFEA should have greater freedom to decide the regularity and form of inspections	The SoHO Regulation sets out that there must be an on-site inspection every four years (Art 27(9)). This is less strict than UK law which sets out that clinics must be inspected on-site every two years. While HFEA law reform proposals do not set out a specific recommended inspection schedule, if this was applied to GB then it would allow the HFEA greater freedom than under present UK law even if it not the degree of freedom we have been pressing for.
	5	The Act should be revised to include an overarching focus on patient protection[1]	The SoHO Regulation includes an overarching responsibility for SoHO entities to protect the health of patients and offspring born from fertility treatment by identifying and minimising risk (Art 57), including protections relating to the dignity of patients and offspring (Art 58(9)), and donors (Art 52(1)). If this were incorporated into UK law, this would mean patient protection is an explicit principle in the Act which aligns with the HFEA law reform proposal.

[1] Note that a broad definition of 'patient' is used here that includes donors and future children resulting from treatment (see 'Law Reform activity' in Human Fertilisation and Embryology Authority (HFEA). Modernising fertility law)

HFEA Theme	HFEA Proposal		SoHO Regulation requirement
	6	The Act should be revised to accommodate developments in the way fertility services are provided	The SoHO Regulation sets out that SoHO preparations should not be applied without proven benefit (Art 58(12a)) and clinics should not advertise or promote particular SoHO using information that is misleading (Art 58(12c)). The SoHO Regulation covers a range of SoHO and this provision explicitly addresses SoHO that is processed and used in treatment (eg, blood products). This means that this provision is not particularly well-suited for the types of add-ons generally used in fertility treatment (eg, tests applied to the patient). More work is needed to assess what these powers would look like in practice for the HFEA, however this aligns with the principle of this law reform proposal. If DHSC considered changing the law in this area, we would recommend that they consider the HFEA's specific proposals for law reform which take into account the unique requirements of the fertility sector.
			As set out in paragraph 3.2.1, the SoHO Regulation has a broader scope than the Act. As noted in the modernising fertility law report, one of the issues motivating this proposal is the fact that services are increasingly offered online and as such are not within the scope of the Act. There is at present a lack of clarity about whether the SoHO Regulation captures online-only services and, if so, what this scope looks like in practice. We have asked DHSC about this. However, if online services are captured then the SoHO Regulation aligns with this proposal for law reform.

HFEA Theme	HFEA Proposal		SoHO Regulation requirement
Scientific developments & innovation	**14**	The Act should explicitly give the HFEA greater discretion to support innovation in treatment and research	The SoHO Regulation includes a system for authorising SoHO preparations *(*ie, SoHO that have been subject to processing) that is similar to our authorised processes system. However, the system in the SoHO Regulation is better adapted to support innovation in treatment and research in the following ways that align with this proposal: • Structured risk-based authorisation process so that novel treatments can develop. • Novel SoHO preparations must be reviewed for whether they influence "quality, safety and *effectiveness*" (Art 20(1)) with effectiveness defined as whether or not that SoHO achieves the intended outcome (Art 3(39)). Currently under UK law novel processes can only be approved if they do not render the cells clinically ineffective or harmful to the recipient. This does not address whether the process is effective in achieving its purported effect and it is not encouraging of innovation. • Authorisation is granted on a centre-by-centre basis, which would allow greater discretion to authorise SoHO preparations on a trial / pilot basis.

HFEA Theme	HFEA Proposal		SoHO Regulation requirement
	15	The Act should be amended to 'future proof' it, so that it is better able to accommodate future scientific developments and new technologies	The SoHO Regulation includes the following 'future proofing' measures however these changes cannot easily transpose into UK law because we are not an EU member state. While UK law would benefit from changes to 'future proof' it, we would recommend doing so in line with the principles in the modernising fertility law report that are both more ambitious and better suited specifically to the UK. The SoHO Regulation changes are: • Where the regulatory status of a SoHO is unclear, member states can seek an opinion from the SoHO Coordination Board (SCB). This means the regulatory scope can respond to developments over time. • Technical requirements are set out in EDQM guidance which will be updated over time to respond to future developments. • Information about new technologies can be shared between Member States (Art 20(3)). This would support information gathering about emerging technologies and therapies that may fall within the scope of other regulators.

Annex B: Changes made by the SoHO Regulation to consider as possible changes to UK law

Theme		SoHO Regulation requirement	UK law	Pros of adopting as UK law	Cons of adopting as UK law	Recommendation
Offspring protection	a	As part of the novel process application clinics must submit a risk benefit analysis, including a documented process to identify risks to offspring (Art 39(2)(c)(v)).	UK law only requires consideration of harm to the recipient. In practice, it is part of our documented process to consider risks to offspring born from medically assisted reproduction alongside the recipient, but this isn't embedded in the UK legal framework.	• Provides legal basis for our practical consideration of any harm to offspring • Could be incorporated alongside wider recommendations about novel process authorisations, as set out in Annex A • Would align GB with NI and, if the 'test' for novel process authorisation is aligned, more likely that the same treatments would be approved and offered UK-wide	• Because harm to any offspring born is already considered in standard practice, not clear that a change to the law is required	**Would be beneficial to adopt in UK law.** **Recommend to DHSC that this is implemented in UK law**, alongside the change in line with proposal 14 (see Annex A).
	b	Recipients of donor gametes must be tested to identify risks of passing on "potentially life-threatening, disabling or incapacitating genetic conditions", **according to family history**, so that donors can be matched (Art 58(3b(ii))).	Clinics are required to test patients for conditions based on their medical and travel history (SLC T50(d)) however this is in relation to safe storage of their gametes or embryos to prevent cross-contamination, rather than for donor matching. UK law doesn't require that clinics	• Because this is directly linked to family history, testing would be appropriately limited • May prevent certain genetic conditions arising	• Additional resource for clinics to provide testing which will likely include a cost implication for patients • A potential consequence of testing donor recipients so that they can be matched with donors is that it may encourage expanded carrier screening (ECS)	**Lack of evidence that this would be beneficial to adopt in UK law at present.** This could be explored to include as UK-wide Code of Practice guidance in future if it is effective in NI and the EU.

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			proactively offer genetic testing.		of donors. UK guidelines on gamete and embryo donation set out that ECS is not recommended. On this basis, it may be more appropriate to see if this is effective in NI and the EU before changing any practice in GB	
	c	National limits on the number of donor conceived offspring from a single donor must be 'respected' when exporting to that country (Art 58(10)).	No comparable provision in UK law. Clinics must adhere to General Direction 0006 (either for GB or NI) to export. This includes that material cannot be exported if it could not lawfully be used in licensed treatment services in the UK, however this would not prevent export on the basis of any family limit in the third country.	• There is ongoing interest in international limits on the number of donor conceived offspring from a single donor. While this proposal does not introduce an international donor limit (which would be challenging to agree or implement), it goes some way to addressing concerns about large numbers of donor-conceived offspring internationally by giving additional responsibilities to clinics and donor banks • Keeps pace with general direction in relation to international movement of donated material – for example, UK guidelines on gamete and embryo	• GB does not export a significant amount of donated material thus it isn't clear that legal change would have great practical benefit. It may be more proportionate to include instead as Code of Practice guidance • Additional resource would be required for GB clinics to monitor national limits when exporting	**May be beneficial to adopt in UK law.** **Recommend that this is explored further with DHSC.**

Theme		SoHO Regulation requirement	UK law	Pros of adopting as UK law	Cons of adopting as UK law	Recommendation
				donation recommend phasing out use of donors from regions where information regarding family limits is not available		
	d	Clinics must make **all reasonable efforts to encourage** recipients of donated reproductive SoHO to report back any serious genetic conditions in any offspring born as a result of donation (Art 44(2) & Art 58(15(b)).	This is not a direct requirement of UK law. A comparable provision can be found in SLC T118; clinics are required to report all incidents to the HFEA and this would include donor-conceived offspring developing a serious genetic condition. Because of this requirement, clinics already monitor and report any offspring born with a serious genetic condition.	• This is a fairly limited requirement relating to information provision and would be relatively straightforward to implement and inspect • Recipients may be more likely to return to the clinic should any offspring born develop a serious genetic condition, which may benefit donors and other individuals conceived from the same donor	• In practice, clinics will already encourage recipients to return as part of the incident reporting process. A mandatory requirement *may* not be necessary and Code of Practice guidance may be proportionate	**May be beneficial to adopt in UK law.** **Recommend that this is explored further with DHSC.**
Donor protection	e	As part of the novel process application clinics must submit a risk benefit analysis, including a documented process to identify risks to donors (Art 39(2)(c)(v)).	UK law only requires consideration of harm to the recipient	• While in practice SCAAC are likely to consider any harm to donors, this would provide a legal basis to ensure that harm to donors is considered • Could be incorporated alongside wider recommendations about novel process		**Would be beneficial to adopt in UK law.** **Recommend to DHSC that this is implemented in UK law**, alongside the change in line with proposal 14 (see Annex A).

Theme		SoHO Regulation requirement	UK law	Pros of adopting as UK law	Cons of adopting as UK law	Recommendation
				authorisations, as set out in Annex A • Would align GB with NI and, if the 'test' for novel process authorisation is aligned, more likely that the same treatments would be approved and offered UK-wide		
	f	Advertisements for donors must not refer to compensation (Art 54(4)).	Advertising aimed at recruiting donors should not refer to the possibility of financial gain however it may refer to permitted compensation (Code of Practice 13.1). However, our powers in this area are limited and advertisements for donors are regulated by the Advertising Standards Authority (ASA).	• Would eliminate risk of anyone coming forward to donate for financial gain	• Code of Practice guidance sets out that only compensation rather than financial gain can be mentioned • Advertising is not within the HFEA's remit and another regulator such as the ASA would be better placed to recommend changes in this area	**May be beneficial to adopt in UK law.** **Recommend that this is explored further with DHSC.**
	g	Clinics must verify via establishing registries that donors are not donating more frequently than would be safe, where frequent donations may harm the donor (Art 53(1)(i)).	No comparable provision in UK law. NHS Scotland allows donors to donate a maximum of three times.	• May prevent donors from donating too frequently than would be safe. Although the data does not show that donors donate more frequently than would be safe (see next column), this change would eliminate that risk	• Lack of evidence that egg donors donate more frequently than would be safe; data from the Register shows that from 1991 to 2022, on average egg donors underwent 1.4 donation cycles, and fewer than 1% (0.7%) of these donors have undergone	**May be beneficial to adopt in UK law.** **Recommend that this is explored further with DHSC.**

Theme		SoHO Regulation requirement	UK law	Pros of adopting as UK law	Cons of adopting as UK law	Recommendation
				• More work could be done on how to implement this efficiently if it were applied UK-wide eg, whether this could be combined with the system to monitor the 10-family limit	more than 5 egg donation cycles since 1991[2]	
	h	Requires that SoHO donors are monitored after donation where donation involves a surgical procedure and/or where donors are treated with prescribed medication to facilitate SoHO donation – this includes egg donation (Art 53(3)).	There is no specific law in relation to follow-up of donors however clinics are required to report severe and critical cases of OHSS which are then reviewed by HFEA clinical governance. Clinics should also follow Code of Practice guidance: • Clinics should have documented processes that include follow-up to manage any complications of donation including OHSS and maintain relationships with local hospitals who may treat any patients experiencing OHSS for appropriate data	• Could support understanding of long-term effects of donation • While the confidentiality provisions of the Act would make this challenging (see next column), we would recommend to DHSC that this is incorporated alongside proposal 12 of the modernising fertility law report - that the Act should be updated to require automatic record-sharing between clinics and the NHS central records systems as the default position. More work would be needed to understand how this would work in practice – for example, how long	• We do not have concerns about under-reporting of severe and critical OHSS • This would be challenging to implement given the strict confidentiality provisions of the Act whereby fertility clinics must rely on building relationships and data sharing agreements with their local hospitals to understand the number of OHSS cases amongst their patients. This is inadequate as not all patients with OHSS will attend a local hospital that has a data sharing agreement with their clinic	**May be beneficial to adopt in UK law.** **Recommend that this is explored further with DHSC**, to be implemented alongside proposal 12 of the modernising fertility law report to address data sharing issues

[2] HFEA Scientific and Clinical Advances Advisory Committee (SCAAC). Minutes 9th June 2025. p9.

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			sharing (Code of Practice, 15.1), and • provide information about the possibility of developing OHSS and who to contact if symptoms develop (Code of Practice, 4.9) This is checked on inspection.	monitoring would continue		