Authority meeting

Date: 23 September 2026 – 12.45pm – 4.00pm

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. Department of Health and Social Care (DHSC) Sponsor Team Report (verbal) (5) For information	1.05pm
5. Committee Chairs' reports (20) For information	1.10pm
6. Performance Report (30) For information	1.30pm
7. Embryo testing guidance (30) For decision	2.00pm
Comfort break (10)	2.30pm
8. Future of data presentation on HFEA website (30) For decision	2.40pm
9. Choose a Fertility Clinic (CaFC) September publication (30) For decision	3.10pm
10. Update on upcoming donation work (verbal) (20) For information	3.40pm
11. Any other business (verbal) (5)	4.00pm
12. Close	

Minutes of Authority meeting held 1 July 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:	23 September 2026
Author:	Alison Margrave, Board Governance Manager
Annex	1 July 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 1 July 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 1 July 2026 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Tim Child (online) Frances Flinter Tom Fowler Zeynep Gurtin Alex Kafetz	Alison McTavish Geeta Nargund (online for items 1-5) Rosamund Scott Catharine Seddon Anya Sizer Stephen Troup (online) Christine Watson
Apologies	Graham James	
Observers	Emma Heslington, Department of Health and Social Care (DHSC)	
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) Amanda Evans (Head of Research and Intelligence) (item 8 only) Elena Corujo-Simon (Senior Research Manager) (item 8 only) Joanne Anton (Head of Policy) Annabel Salisbury (Regulatory Policy Manager) Sophie Tuhey (Head of Planning and Governance) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members

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

1. Welcome, apologies and declarations of interest

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

1.2. The Chair welcomed Emma Heslington from the Department of Health and Social Care (DHSC) to the meeting.

1.3. 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.

1.4. Declarations of interest were made by:

- Steve Troup (consultancy work within the fertility sector)
- 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 and NED for Care Quality Commission (CQC))
- Geeta Nargund (appointed as a Board Member of The Parliamentary Office of Science and Technology (POST))

2. Previous minutes and matters arising

2.1. The Chair introduced the minutes from the meeting held on 20 May 2026 and thanked those members who had contributed to the minutes.

2.2. The minutes of the meeting held on 20 May 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.

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, noting that it had been a busy period since the last Authority meeting.

3.2. The Chair informed members that she had attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting which was held in early June.

3.3. The Chair informed members that she had been involved in the shortlisting and interview process for the new Authority members (one lay and one professional). Recommendations have been made regarding appointable candidates and are awaiting Ministerial approval.

3.4. Members were informed that the advert for the Chair position would be published week commencing 6 July and were encouraged to share the advert.

3.5. The Chair informed members that she and the Chief Executive had attended the annual accountability meeting; this was a productive meeting and the HFEA is held in relatively high esteem by DHSC. Discussions had been held on the HFEA's law reform proposals and how these could be taken forward.

3.6. The Chair highlighted the HFEA all-staff event held in late June, noting its value in bringing colleagues together for team-building.

3.7. Concluding, the Chair informed members that together with senior executives she had attended a meeting with the MHRA AI Commission.

3.8. The Chief Executive informed members that he had attend the Audit and Governance Committee meeting held in June and that this meeting had considered the year-end reports from the Government Internal Audit Agenda and the Annual Report and Accounts from the National Audit Office.

3.9. The Chief Executive thanked the Chair and member, Anya Sizer, for attending the all-staff event and provided further insight in the work around refreshing the organisational values. Anya Sizer stated that it was a privilege to attend this event and reinforced what a unique organisation the HFEA is with dedicated, good staff.

3.10. The Chief Executive informed members that he had attended the ALB Chairs and Chief Executives meeting with discussions being held on shared services.

Decision

3.11. 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 paper before the Authority includes a summary from the April and May meetings.

4.3. The most recent SAC meeting was held earlier this week and had been chaired by Tim Child, this meeting will be reported on at the September Authority Meeting.

4.4. The SAC Chair spoke of the comprehensive paperwork that the committee receives for each meeting with a report from Genetic Alliance representing patient's viewpoints. Together this allows the committee to make well informed decisions.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC met on 16 June. They had received the annual opinion rating from GIAA, which was 'moderate'. Following discussions GIAA had agreed to revise the direction of travel rating to reflect the improved way of working and progress made on closing off audit recommendations.

4.6. The AGC held a frank discussion with GIAA on what might make the internal audit provision better value, but the HFEA confirmed it will be going out to tender for this service.

4.7. The AGC noted that only historic DSPT audit recommendations are outstanding, with all other audit recommendations closed. The AGC will consider the outstanding recommendations later in the year.

4.8. The AGC Chair informed the Authority that the meeting had received a comprehensive report on the Phoenix Programme, noting that the go-live date had been extended by six weeks and a lessons learnt exercise is already being complied.

4.9. AGC had discussed the revised Strategic Risk Register and asked that the risk of not taking up opportunities arising from AI be its own risk in a future revision rather than being a sub-risk. The AGC had also asked the Executive to capture the risk around the growth of the unregulated sectors and the mitigations which the HFEA had put in place, especially regarding communications.

4.10. The AGC held a detailed discussion on the draft Annual Report and Accounts and agreed to recommend to the Authority that the Accounting Officer be authorised to sign these. The AGC Chair commented that the audit report from KPMG was extremely positive with just one audit recommendation. The AGC Chair praised the HFEA team for this achievement and their hard work.

4.11. Closing, the AGC Chair stated that the bi-annual HR update report was extremely positive and noted that the time that the HFEA takes to fill vacancies is much shorter than the public sector average.

4.12. In response to a question, the Chief Executive explained that there was great public and media interest in sperm donation taking place outside of licensed clinics. He explained the difficulties and frustration in tackling unregulated donations and the reluctance of the police and social

media platforms to enforce the law. He reiterated that sperm donation outside of licensed clinics is illegal under the HFE Act.

4.13. The AGC Deputy Chair spoke of the transparent reporting by the IT team on the Phoenix Programme and the assurance and degree of confidence this provided to the committee.

4.14. The Chief Executive reminded the Authority that there are two elements to the Phoenix Programme, the first being the movement of the HFEA's records from the old CM system to SharePoint and the second element moving Epicentre to a different platform. He cautioned that end-to-end testing of the second element may encounter unknow problems but he would keep the AGC appraised.

4.15. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed members that SCAAC had held its virtual meeting on 3 June and the meeting papers are available on the HFEA website.

4.16. SCAAC had discussed emerging technologies in embryo and gamete testing, including genetic testing of sperm, microfluidic device – based sperm selection and AI driven sperm selection.

4.17. SCAAC had discussed the impact of microbiome on fertility and fertility treatment outcomes. SCAAC had last considered this topic in June 2025 and the more recent discussion looked at the research which emphasises the complex, multi-factorial nature of the relationship between microbial composition in the female reproductive tract and reproductive success.

4.18. SCAAC had discussed two add-on ratings and agreed that microbiome testing should be rated 'grey' due to lack of evidence and sperm DNA fragmentation testing should be rated 'red' due to safety concerns of harm from surgical procedure.

4.19. SCAAC had reviewed an application for authorised use of in vitro maturation for oocytes and agreed that this did not fit within the scope of the existing authorised process and therefore a new process application was required.

4.20. The SCAAC Chair reminded members that the HFEA will host its annual horizon scanning meeting next week at ESHRE 2026 and feedback on this will be brought to the Authority in September.

4.21. A member commented how reassuring the work of SCAAC is for patients, especially with regard to the review of add-ons, they questioned how patients could access this important work and whether the HFEA promotes this work to patient organisations.

4.22. The SCAAC Chair responded that the information on treatment add-ons on the HFEA website is written for non-professionals. SCAAC decisions regarding treatment add-ons is very transparent with all papers, including the decision tree and meeting minutes, being published on the HFEA website.

4.23. The Chair informed members that the HFEA would be hosting a session on the past, present and future of fertility regulation at ESHRE 2026.

4.24. The Chair referred to a recent article in Nature regarding base editing of embryos and spoke of developments in the fertility landscape and how important the work of the HFEA is.

4.25. The SCAAC Chair responded that Kathy Niakan had previously presented to SCAAC on this subject and the committee has a watching brief on this subject.

4.26. 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.

Decision

4.27. Members noted the Committee Chairs' reports.

5. Performance Report

5.1. The Chief Executive introduced the performance report and commented that whilst it is too early in the year to see trends, performance in May 2026 was good with ten KPIs rated Green, three Neutral, four Amber and two Red.

5.2. The Chief Executive informed members that the sickness absence KPI remains Green with no long-term absence.

5.3. Continuing, the Chief Executive said that whilst the turnover indicator was slightly above the threshold at 16.5% it was manageable and followed the cycle of natural movement of staff moving on for career progression and promotion, which as a small organisation the HFEA is limited in offering.

Strategy and Corporate Affairs

5.4. The Director of Strategy and Corporate Affairs referred to the upcoming ESHRE 2026 and reiterated the HFEA's activities at this event.

5.5. The Director of Strategy and Corporate Affairs noted the British Fertility Society (BFS) Study Week, which is being held in September, which includes a joint BFS/HFEA day.

5.6. Members were informed of parliamentary activity including the debate in the House of Lords on the adequacy of the law on the regulation of fertility treatment, led by Baroness Deech and supported by Baroness Nargund. Several of the HFEA's law reform proposals were quoted in this debate.

5.7. The Director of Strategy and Corporate Affairs referred to the BBC Wales programme on unregulated sperm donation and the associated press articles this generated. The updated FAQs relating to unregulated sperm donation on the HFEA's website achieves an average 100 view per day, but when the programme aired this peaked at 1,000 views a day.

5.8. The Director of Strategy and Corporate Affairs informed members that the Fertility treatment 2024: trends and figures report was published recently and the dashboard updated accordingly. She thanked the staff who were involved in the production of this report. The report had not received as much coverage as previously years but had some coverage in the media and good take up on social media, as well as views on the HFEA website.

5.9. Continuing, the Director of Strategy and Corporate Affairs informed members that the team is working on the embryo testing guidelines and the state of the sector report. In response to a question, she confirmed that the embryo testing guidelines will be coming to the September Authority meeting.

5.10. Several members congratulated the Director of Strategy and Corporate Affairs for her participation in the BBC Wales programme. The Director of Strategy and Corporate commented

that the law is very clear and that the only legal way to donate sperm is as at a HFEA licenced clinic.

Compliance and Information

5.11. The Director of Compliance and Information informed members that the inspection KPIs have started well for the year.

5.12. Regarding the post inspection feedback survey, a new process was started in December 2025 to increase completion. The process is now managed by the business support team and awareness has been raised through clinic focus and leaflets being handed out during inspection close out meetings. In the past six months there has been an increase in returns and the sector will be encouraged to keep providing feedback.

5.13. The Director of Compliance and Information informed members that the feedback from these surveys is discussed at the monthly inspectors meeting and actions taken as required.

5.14. The Director of Compliance and Information informed members that both the OTR KPIs were rated 'red' and this was due to planned annual leave of the OTR team.

5.15. The Director of Compliance and Information stated that the current OTR targets are no longer relevant, as the waiting list has decreased significantly and most of the OTRs on the waiting list are being actively worked on. A review of the KPIs is currently in progress and it is anticipated that these will focus on waiting times.

5.16. Members were informed that whilst the average waiting time for applications has decreased to around a month in May 2026, this can fluctuate as more complex OTRs are closed.

5.17. The Director of Compliance and Information stated the register audit schedule had been set for the financial year and 12 clinics had been selected for inspection. The Director of Compliance and Information explained that those clinics with the highest error rates are shortlisted for audit and explained the other factors used to choose which clinics should be audited.

Finance, Planning and Technology

5.18. The Director of Finance, Planning and Technology informed members that the Planning and Governance team had been preparing for new member recruitment, including updating the required induction documents.

5.19. The Director of Finance, Planning and Technology stated that there has been an increase in the number of corporate complaints and data requests recently and the team has been logging and responding to these. The team will continue to monitor volumes and keep the relevant policies and processes under review.

5.20. Members were informed that the recruitment of two key IT roles is underway and these roles are part of the HFEA's IT plan and will bring additional expertise and resilience to the team.

5.21. The Director of Finance, Planning and Technology informed members that this year's DSPT audit had been completed and there had been several important improvements delivered this year, but a few key actions remain outstanding. These are a priority and will be addressed once Phoenix has been completed and the additional IT resources recruited.

5.22. The focus for the Finance Team has been the preparation of the Annual Report and Accounts which will be discussed at a later agenda item.

5.23. At the May 2026 Authority the pre-audit deficit for 2025-26 of £299,000 was reported. During the audit there were several adjustments put through the accounts, which changed this position. In particular, significant revisions to estimated income relating to three clinics that have enduring gaps in their PRISM data submissions had to be made.

5.24. These changes moved the HFEA's deficit to £875,000, although the accounts show a deficit of around two million because they do not include Grant-in-Aid in the bottom line. The Director of Finance, Planning and Technology informed members that discussions had been held with the Department about this changing position, who were supportive of decisions relating to income recognition and are able to absorb this additional deficit.

5.25. Regarding 2026-27 spend it is too early in the year to get any indications of divergence from the budget but a full review of year-end forecast will be undertaken at the end of Q1.

5.26. In response to a question, the Director of Finance, Planning and Technology confirmed that the volume of corporate complaints and information requests has increased. He noted that in some cases these requests are interconnected, with the same individual progressing through several processes. For example, a clinical complaint may develop into a corporate complaint and then result in a data protection or information request, increasing the overall workload associated with a single case.

5.27. The Chief Executive noted that no clear trends had been identified in the nature of complaints received. Members were reminded that, as a public body, the HFEA must comply with statutory requirements for the retention and processing of information. The Chief Executive advised that, should the volume of requests continue to increase, it may be necessary to review existing policies to ensure requests can be managed efficiently without placing additional pressure on staff resources. It was also noted that public bodies operate within agreed staffing levels and cannot exceed their authorised headcount.

5.28. The Head of Planning and Governance clarified that the HFEA has two complaints policies. The Clinical Complaints Policy covers complaints about fertility treatment at a HFEA licensed clinic; the Corporate Complaints Policy covers complaints about the work of the HFEA and the way in which we have exercised our statutory duties (this includes data protection complaints).

5.29. The Head of Planning and Governance confirmed that an increasing number of corporate complaints and information requests appear to have used generative AI to frame and articulate their complaint or request.

5.30. A member spoke of the opportunity that complaints provide for learning and maximising learning opportunities for the organisation. They commented that the advent of AI means that people feel more empowered to complain and take action.

5.31. The Chief Executive responded that when the HFEA has made an error they are open and honest with sharing that with the complainant.

Decision

5.32. Members noted the performance report.

6. Annual Report and Accounts

6.1. The Director of Finance, Planning and Technology stated that AGC recommended that the Chief Executive, as Accounting Office, sign off the Annual Governance Statement at its meeting on 16 June. AGC also recommend the Annual Report and Accounts for approval by the Authority.

6.2. Due to the extremely tight deadline for certification and publication of the HFEA's Annual Report and Accounts approval from the Authority had been sought out of committee, via email. He thanked members for responding so promptly to this email and unanimous approval had been given on 19 June 2026.

6.3. The accounts were certified on 29 June 2026 and were laid in Parliament on 30 June. The Director of Finance, Planning and Technology thanked the HFEA's Finance Team for their work in preparing the Accounts and Annual Report.

Decision

6.4. Members noted the verbal report and that the HFEA's Annual Report and Accounts had been approved out of committee, via email, and successfully laid in Parliament.

7. Strategic Risk Register and Risk Appetite Statement

7.1. The Risk and Business Planning Manager introduced this agenda item and reminded members that the Authority reviews the Strategic Risk Register (SRR) twice a year, with detailed consideration of the SRR being undertaken by the AGC. The AGC had discussed the SRR at its June meeting.

7.2. The Risk and Business Planning Manager informed the members that the AGC reviewed the Risk Appetite Statement in both February and June 2026, with minor amendments presented for the Authority's approval.

7.3. The AGC Chair informed members that the AGC had recommended to the Executive that the sub-risk around the benefits from both new systems and AI not being realised should be its own risk in the next iteration of the SRR.

7.4. The Deputy AGC Chair spoke of the mitigations which the HFEA undertakes regarding the unregulated sector and how these had been articulated in the SRR.

7.5. In response to a question the Chief Executive confirmed that the risk regarding reputational risk had not been removed, but duplication throughout the SRR had been removed.

Decision

7.6. The Authority approved:

- the updated Strategic Risk Register
- the updated Risk Appetite Statement.

8. Register Research Panel (RRP) Annual Report

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

8.2. The Head of Research and Intelligence introduced the paper and reminded members that the HFE (Disclosure of Information for Research Purposes) Regulations 2010 allow the disclosure of

information for research purposes, and that the Authority has delegated authorisation for this to the Register Research Panel (RRP).

8.3. The Head of Research and Intelligence updated the recent Fertility treatment 2024: trends and figures publication and updates to the HFEA dashboard. The next planned publication using HFEA register data is a report on egg freezing in fertility treatment.

8.4. The Senior Research Manager informed the Authority of recently approved RRP projects and peer-reviewed papers using both RRP-approved datasets and the anonymised register.

8.5. The Senior Research Manager spoke of the activities undertaken to increase the visibility of the HFEA's data for research including the HFEA Data Research Update Newsletter which now has over 270 subscribers with a high 55% open rate.

8.6. The Senior Research Manager informed members that as part of the HFEA's strategic aim to increase the visibility of its data for research, the HFEA had engaged with the Health Data Research (HDR) UK Gateway to host a link to the HFEA data research website on their online platform.

8.7. The Senior Research Manager informed members of the new ways that had been set up to engage with researchers and find out information about who wants HFEA data, where they are from and how they want to use the data. An anonymised dataset enquiry form was launched in January 2026 to address this.

8.8. The Senior Research Manager commented that the team are looking at new options for the anonymised resources. This has included discussions with other data organisations with similar datasets to understand their current practices. Many of these organisations such as UK Biobank, UKHSA and NHS England are using or developing synthetic datasets and Trusted Research Environment platforms (TREs) to allow researchers access to datasets.

8.9. TREs are viewed as best practice for providing access to data in a safe and secure manner but the Senior Research Managers cautioned that these have significant cost implications that the HFEA will need to consider before any implementation.

8.10. A member questioned whether funding for TREs had been discussed with the DHSC as it aligns with the Government's policies regarding data. The Head of Research and Intelligence responded that more work needs to be done on the options available to the HFEA but then we could raise with the Department.

8.11. A member spoke of the research being conducted by private organisations and questioned whether any applications had been made to use the HFEA's data. The Director of Strategy and Corporate Affairs responded that applications from private companies had been received by the RRP and she referred to the 2010 regulations which govern how and to whom this data can be released. The Head of Research and Intelligence commented that applications from private organisations would be welcomed, but under the 2010 regulations they must be UK based.

8.12. A member questioned whether the list of publications, annexed to the paper, is shared wider with the sector such as via Clinic Focus as it may benefit resident doctors who are looking for projects and might not be aware of the rich source of data that the HFEA holds. The Head of Research and Intelligence responded that there had been articles in Clinic Focus previously and the HFEA attends several Conferences to promote the use of HFEA data.

8.13. Members discussed the growth and interest in life sciences and the Government's innovation agenda and how the HFEA's data could help stimulate the Government's growth agenda. The Chief Executive cautioned that the 2010 regulations sets out what the HFEA can charge for making its data available and the cost doesn't cover the cost of the work. He would not want to create a demand which cannot be met from current resources.

8.14. A member spoke in support TREs and provided their own personal experience in developing one and highlighted some of the challenges encountered during the project. He cautioned the amount of time required to implement a TREs and that the HFEA might want to consider using an established one which aligns with the HFEA's principles.

8.15. A member questioned whether the patient organisation groups get updates on the research projects carried out using the HFEA's data.

8.16. The Chair drew the discussion to a close and thanked the Head of Research and Intelligence and the Senior Research Manger for their comprehensive paper and informative presentation on the use of the HFEA's data.

Decision

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

9. SoHO Regulations update

9.1. The Regulatory Policy Manager introduced the paper and informed members that 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.

9.2. The Regulation covers gametes and embryos, as well as other substances of human origin (SoHO) which are outside of the HFEA's 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).

9.3. As the UK-wide regulator of fertility treatment and the Competent Authority for NI, the HFEA has 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.

9.4. The Regulatory Policy Manager spoke of the impact of the SoHO Regulation on clinics in NI and the HFEA. She stated that it is the HFEA's wish to avoid any unnecessary regulatory burden for NI clinics and she explained the main changes for clinics in NI

9.5. The Regulatory Policy Manager commented that the SoHO Regulation increases divergence between NI and GB, unless any changes are made to UK law. The DHSC were currently considering this issue.

9.6. The Regulatory Policy Manager explained the two options in the paper:

- **Option one**: Only recommend changes to UK law that align with existing HFEA law reform proposals, as set out in annex A of the paper.
- **Option two**: Recommend one or more of the changes (a-h) to UK law set out in Annex B of the paper, in addition to existing HFEA law reform proposals.

9.7. The Regulatory Policy Manager explained the next steps leading up to the SoHO Regulation implementation date of 7 August 2027.

9.8. In response to a question the Director of Strategy and Corporate Affairs commented that it would not be possible to implement the HFEA's proposals for law reform via the implementation of the SoHO Regulation.

9.9. Members were supportive of option two. In response to a question the Chief Executive confirmed that work and other priorities would not be dropped to implement the SoHO Regulation and it does not weaken the HFEA's proposals for law reform.

Decision

9.10. The Authority unanimously agreed to recommend option two: recommend one or more of the changes (a-h) to UK law set out in Annex B of the paper, in addition to existing HFEA law reform proposals.

Action

9.11. Executive to implement option two regarding SoHO Regulation.

10. Any other business

10.1. A member informed the Authority that he had attended the first NHS IVF Clinics Conference and provided an overview of the presentations and discussions. He commented that it was a very worthwhile conference and he asked that the HFEA be invited to attend or speak at the next one.

10.2. The Chair thanked everyone for their active participation in the meeting and for the high quality of papers before the Authority.

10.3. 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 23 September. Details of this meeting, including how to request to observe, is posted on the HFEA website. The Chair wished everyone a good summer break.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 23 September 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:	23 September 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
20/05/2026 Item 6.28	Executive to implement the Authority's decisions regarding Embryo Testing	Head of Policy	September 2026		An update and near final draft of the guidance on embryo testing will be brought to the Authority in September 2026.
01/07/2026 Item 9.11	Executive to implement option two regarding SoHO Regulation.	Regulatory Policy Manager	August 2027		DHSC stakeholder roundtables were delayed until mid-September 2026. An update will be brought to the Authority in January 2027.

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:	23 September 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 July 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:

    - 6 July – attended the SCAAC horizon scanning meeting at ESHRE
    - 8 July – Chaired the HFEA event 'Past, present and future regulating a changing fertility sector' at ESHRE
    - 15 July – met with the Fertilis group of private sector clinics (together with Chief Executive)
    - 22 July – attended ALB Chief Executives and Chairs transition update (together with Chief Executive)
    - 12 August – met the DHSC Permanent Secretary to discuss the HFEA strategic objectives for 26/27 (together with Chief Executive)
    - 10 September – attended ALB Chair and Chief Executive meeting
    - 15 September – Chaired the Renumeration Committee meeting

2.2 Chief Executive

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

    - 6 July – as above
    - 8 July – spoke at HFEA event at ESHRE
    - 15 July – as above
    - 22 July – as above and the same afternoon attended the Health and Social Care Regulators Forum
    - 12 August – as above
    - 26 August – met with Michael Henry, CEO CARE group
    - 10 September – as above
    - 15 September – 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:	5
Meeting date:	23 September 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:			
23 July	Serious incident investigation report	Care Fertility Nottingham	Noted. No regulatory action required – licence continued
	Serious incident investigation report	Manchester Fertility	Noted. No regulatory action required – licence continued
	Executive update – Renewal inspection report	St Jude's Women's Hospital	Approved – 2 year licence
	Variation of PR	Bridge Clinic	Approved – licence varied
	New research licence application	Avenues	Adjourned pending further information
10 September	Focused inspection	Bridge Clinic	Minutes not yet approved
Other comments:			
Executive Licensing Panel:			
24 June	Renewal inspection report	IVI London (Wimpole Street)	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Semovo Leeds	Approved – 4 year licence
	Renewal inspection report	St Mary's Hospital	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Chelsea & Westminster Hospital	Approved – 4 year licence (and ITE certificate)
	Interim research inspection report	The Babraham Institute	Approved – licence continued
	Variation of research premises	Guys Hospital	Approved – licence varied
	Import of oocytes from UAE	IVI London (Wimpole Street)	Approved
7 July	Research renewal inspection report	Centre for Reproductive Medicine, Coventry	Approved – 3 year licence

Date	Items considered	Centres	Outcomes
	Research renewal inspection report	Hartshorne and Genesis Group	Approved – 3 year licence
	Research renewal inspection report	Mechanochemical Cell Biology	Approved – 3 year licence
	Research interim inspection report	Cardiff University School of Biosciences	Approved – licence continued
	Import of oocytes from Lebanon	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
21 July	Renewal inspection report	Care Fertility Liverpool	Approved – 4 year licence (and ITE certificate)
	Research interim inspection report	Hull & East Riding Fertility	Approved – licence continued
	Variation of PR	Royal Surrey Hospital NHS Foundation Trust	Approved – licence varied
	Variation of premises	TFP Simply Fertility	Approved – licence varied
	Import of oocytes from Abu Dhabi	IVF London	Approved
4 August	Renewal inspection report and variation of SLC T52	Glasgow Royal Infirmary	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report and variation of SLC T52	The Gateshead Fertility Unit	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report and variation of SLC T52	Herts and Essex Fertility Centre	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	Bristol Centre for Reproductive Medicine	Approved – 4 year licence (and ITE certificate)
	PTT for proteasome-associated autoinflammatory syndrome 6 (PRAAS6) OMIM #620796	Guys Hospital	Approved
18 August	Renewal inspection report	Aberdeen Fertility Centre	Approved – 4 year licence (and ITE certificate)
1 September	Renewal inspection report	The James Cook University Hospital	Adjourned pending further information
	Renewal inspection report	Care Fertility Sheffield	Approved – 4 year licence (and ITE certificate)
	Variation of PR	CREATE Fertility, London Wimbledon	Approved – licence varied
	Variation of PR	CREATE Fertility Bristol	Approved – licence varied
	Variation of PR	CREATE Fertility, Leeds	Approved – licence varied

Date	Items considered	Centres	Outcomes
	PTT for Diamond Blackfan Anaemia Type 7 9DBA7) OMIM #612562	The Evewell West London	Approved
Other comments:	None.		

Licensing Officer decisions:

19 June	Variation of Licence Holder	Royal Surrey Hospital NHS Foundation Trust	Approved
9 July	Variation of Licence Holder	Wales Fertility Institute - Neath	Approved
	Variation of Licence Holder	Complete Fertility Centre Southampton	Approved
6 August	Variation of Licence Holder	The Fertility Home	Approved
10 August	Variation of Licence Holder	Wales Fertility Institute - Cardiff	Approved
13 August	Variation of Licence Holder	St Mary's Hospital	Approved
26 August	Voluntary revocation of licence	Care Fertility Tamworth	Approved
June 2026	4 x ITE import certificates	Various	All granted
July 2026	19 x ITE import certificates	Various	All granted
August	17 x ITE import certificates	Various	All granted
Other comments:	None.		

Statutory Approvals Committee:

29 June	Branchiootic syndrome 3 (BOS3) OMIM #608389	Glasgow Royal Infirmary	Approved
	Deafness, autosomal dominant 15/52, OMIM #602459	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved – applicant family only
	Fabry disease (sex testing), OMIM #301500	TFP Oxford Fertility	Approved
	Cardiac-urogenital syndrome (CUGS), OMIM #618280	Guys Hospital	Approved

Date	Items considered	Centres	Outcomes
	Import of oocytes from Ukraine	Herts and Essex Fertility Centre	Approved
	Export of embryo to USA	TFP Boston Place	Adjourned
	Import of embryos from Australia	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
	Import of embryos from USA	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Approved
27 July	Proteasome-Associated Autoinflammatory Syndrome 6 (PRAAS6), OMIM #620796	Guys Hospital	Approved
	Intellectual Developmental Disorder with Microcephaly and Pontine and Cerebellar Hypoplasia (MICPCH), OMIM #300749	Guys Hospital	Approved
	Ethylmalonic Encephalopathy (EE), OMIM #602473	Care Fertility Nottingham	Approved
	SIX2-related disorder, No OMIM number	CREATE Fertility Leeds	Approved
	Peripheral neuropathy recessive with or without impaired intellectual development (PNRIID), OMIM #618124	Guys Hospital	Approved
	Short stature, facial dysmorphism, and skeletal anomalies with or without cardiac anomalies 1 (SSFCS1), OMIM #617877	The Lister Fertility Clinic	Approved
	Import of embryos from Cayman Islands	Avenues	Approved
	Import of sperm from Australia	Wolfson Fertility Centre	Approved
26 August	Neurodevelopmental disorder with hearing loss, seizures, and brain abnormalities (NEDHSB), OMIM #616577	The Centre for Reproductive and Genetic Health t/a CRGH Portland	Minutes not yet approved
	Cardiomyopathy, Dilated 3C (CMD3C), OMIM #301163	The Lister Fertility Clinic	Minutes not yet approved

Date	Items considered	Centres	Outcomes
	Joubert syndrome-37 (JBTS37), OMIM #619185	TFP Oxford Fertility	Minutes not yet approved
	Epidermolytic Hyperkeratosis 2A, Autosomal Dominant (EHK2A), OMIM #620150	Guys Hospital	Minutes not yet approved
	Import of sperm from Denmark	Care Fertility London	Minutes not yet approved
	Import of embryos from USA	The Lister Fertility Clinic	Minutes not yet approved
	Export of sperm to Spain	Care Fertility Woking	Minutes not yet approved
Other comments:	At June's meeting SAC received a paper summarising the outcomes of the PGT-M list audit, which assessed whether there were any new or emerging treatments which would alter the severity of any condition(s) on the approved list for testing. No conditions were recommended for removal from the list as a result of new or emerging treatments.		
	When considering PGT-M applications, the Committee frequently considers not only the specific condition applied for, but also other similar conditions. In such cases, more than one condition may be authorised for testing.		

Audit and Governance Committee (AGC):

AGC has not met since the last report to Authority.

Scientific and Clinical Advances Advisory Committee (SCAAC):

SCAAC has not met since the last report to Authority.

Register Research Panel (RRP):

RRP has not met since the last report to Authority.

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 August 2026

Evgenia Savchyna
Corporate Performance Officer
23/09/2026

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:	23/09/2026
Agenda item:	Item 6
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 August 2026 was good, with twelve KPIs rated Green, two Neutral, two Amber and two rated Red.
- Compliance KPI performance was variable. The ‘Inspection reports to PR’ KPI was rated Red as two out of six reports missed the target. All reports were submitted to committee on time, resulting in the ‘Inspections reports to committee’ KPI being rated Green. The ‘End to end licensing’ KPI was rated Amber due to one report being significantly delayed because of its complexity.
- The PGT-M KPI returned to Green in August, with an average processing time of 57 working days. Nine applications were received in August 2026.
- Licensing KPIs were all rated Green, reflecting the consistently excellent performance.
- Eight FOI requests were due and completed within the statutory deadline. No PQs were due in August.
- Changes to the way the social media management platform tracks engagement have affected the reported engagement figures. The team is investigating the impact of these changes.
- Both HR KPIs, the ‘Staff sickness absence’ and the ‘Turnover’ were in Green in August.
- The ‘Debt over 60 days’ KPI was just above the target at 27%. The other two Finance KPIs were rated Green.

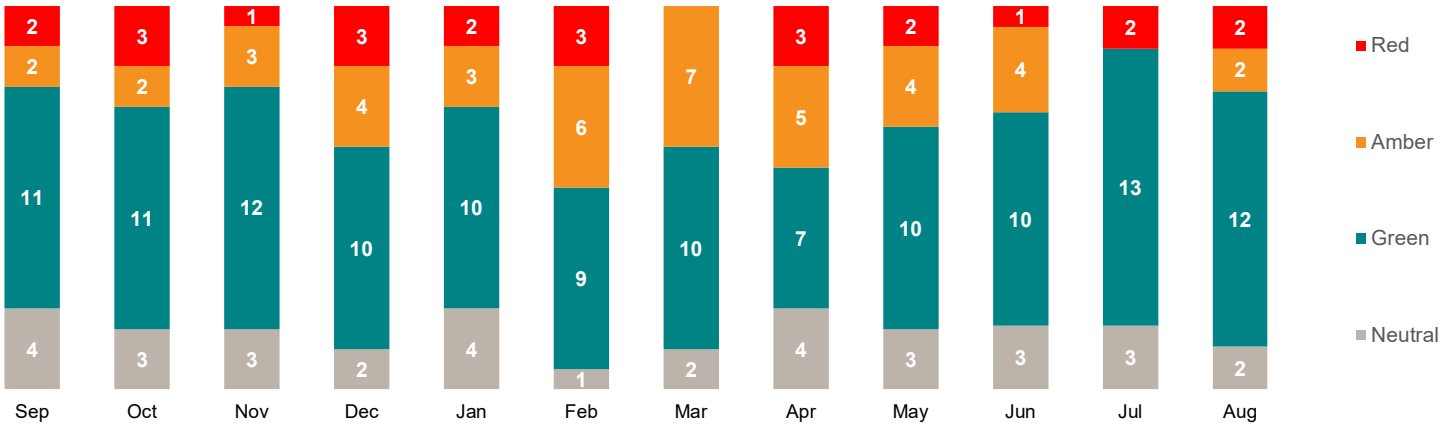
KPI reviews:

- The OTR review commenced in May 2026 and was completed in July 2026. As a result of the review, a new ‘OTR waiting time’ KPI, with a target of 60 days, has been introduced, and the ‘OTRs closed in month’ KPI has been removed. This change reflects the fact that the previous OTR targets (‘the OTR waiting list reduced by 40 OTRs’ and ‘156 OTRs closed per month’) are no longer appropriate, as the waiting list has reduced significantly and the majority of OTRs currently on the waiting list are actively being worked on.
- The current OTR waiting list comprises 280 applications. The waiting time for applications sent out in August was 83 days. This is above the current target of 60 days due to delays in receiving responses from clinics and other data issues.

Key performance indicators

Human Fertilisation & Embryology Authority

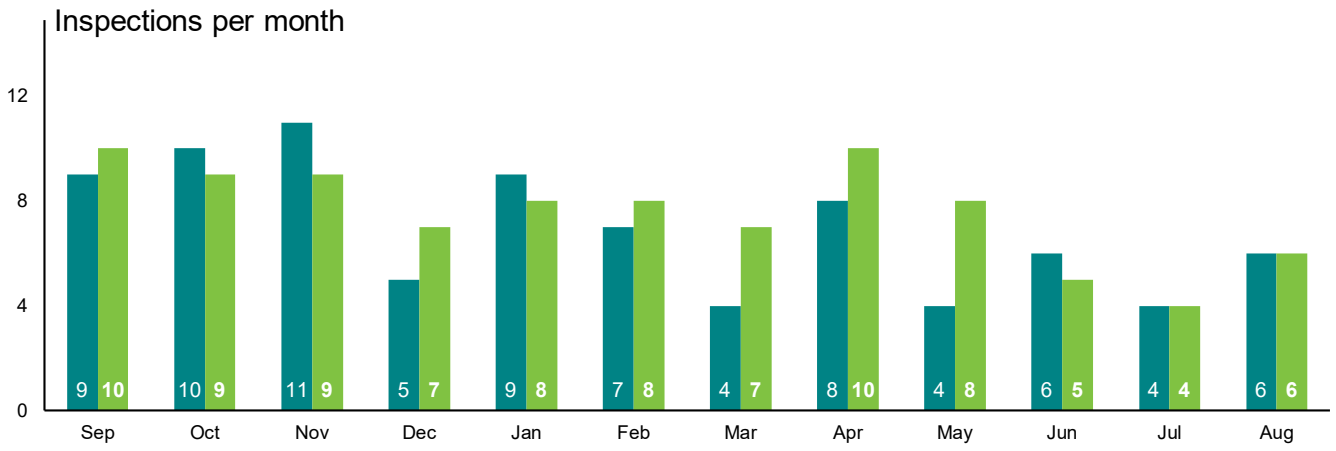
RAG status over last 12 months



RAG status over last 12 months

18 KPIs in total for each month starting from June 2026

For August, the 2 red indicators are in these teams**: Compliance - 1** ('Inspection reports to PR'), and **Information - 1** ('OTR waiting time').



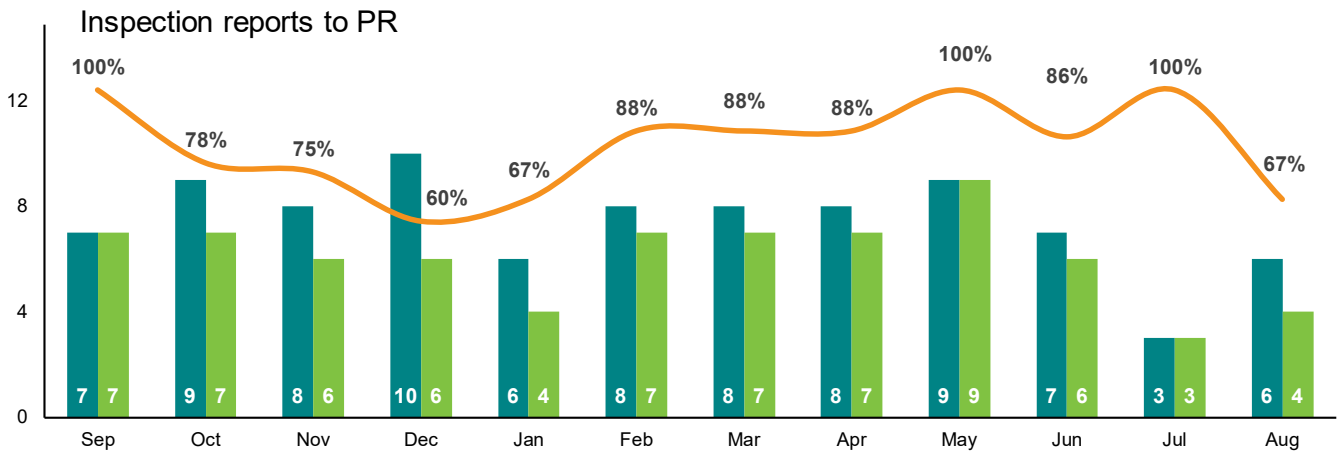
Status: **N/A**

Compliance

Inspections delivery

Target: **not defined**

Six inspections were planned and delivered in August 2026.



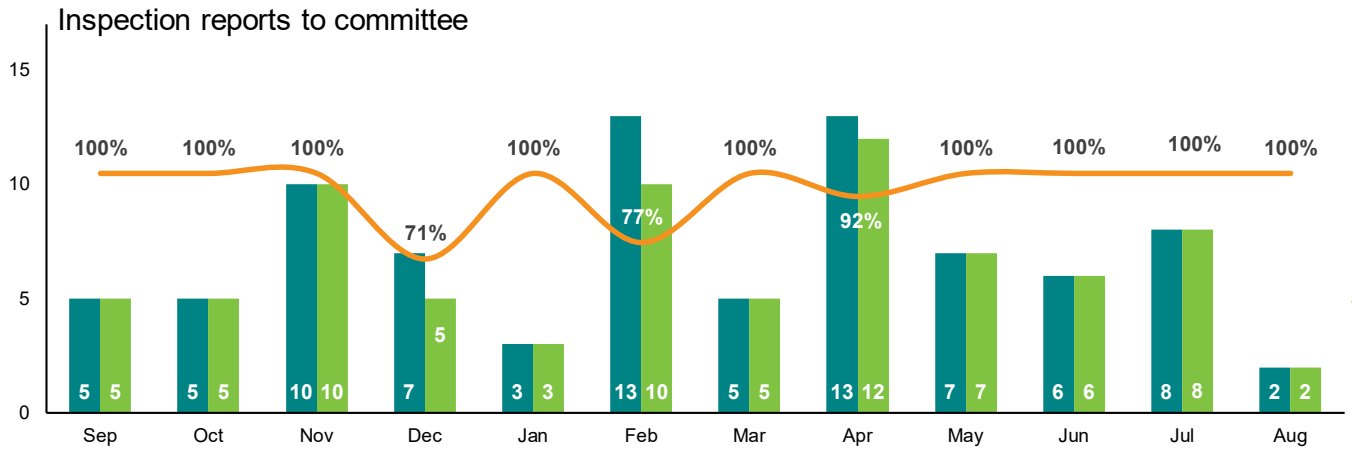
Status: **Red**

Compliance

Inspection reports sent to PR

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

Two out of six reports were delayed (31 wd and 35 wd) due to their complexity.



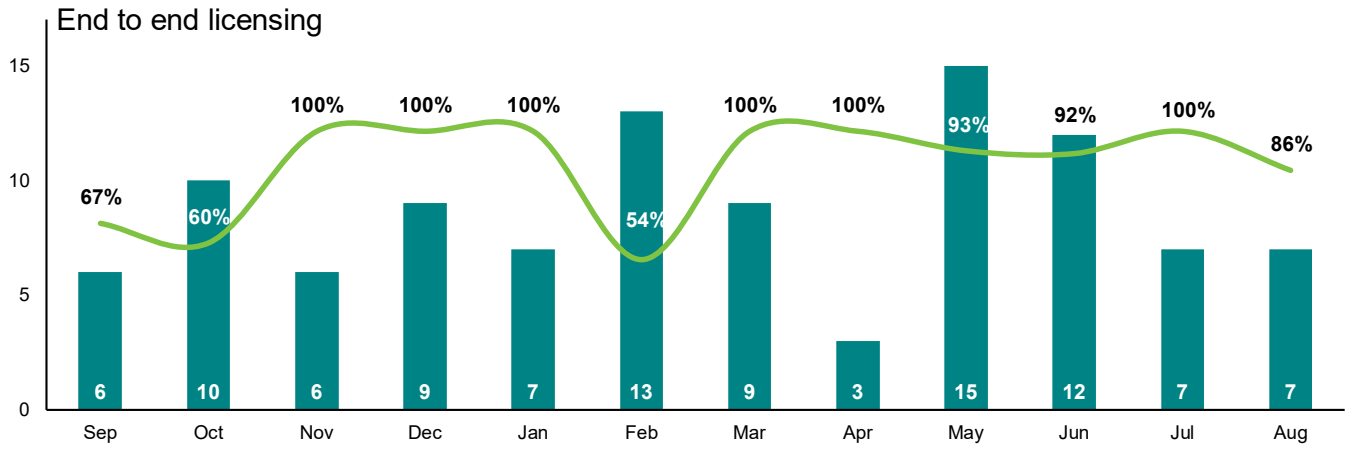
Status: **Green**

Compliance

Inspection reports sent to relevant licensing committee

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

All reports sent within KPI.



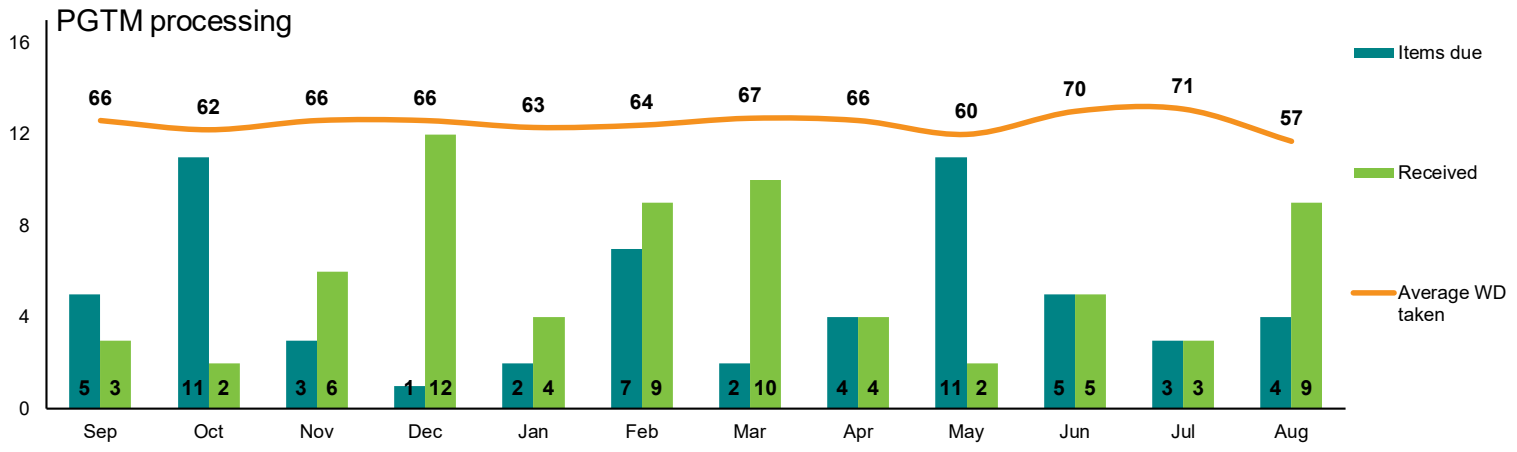
Status: **Amber**

Compliance

End to end licensing process

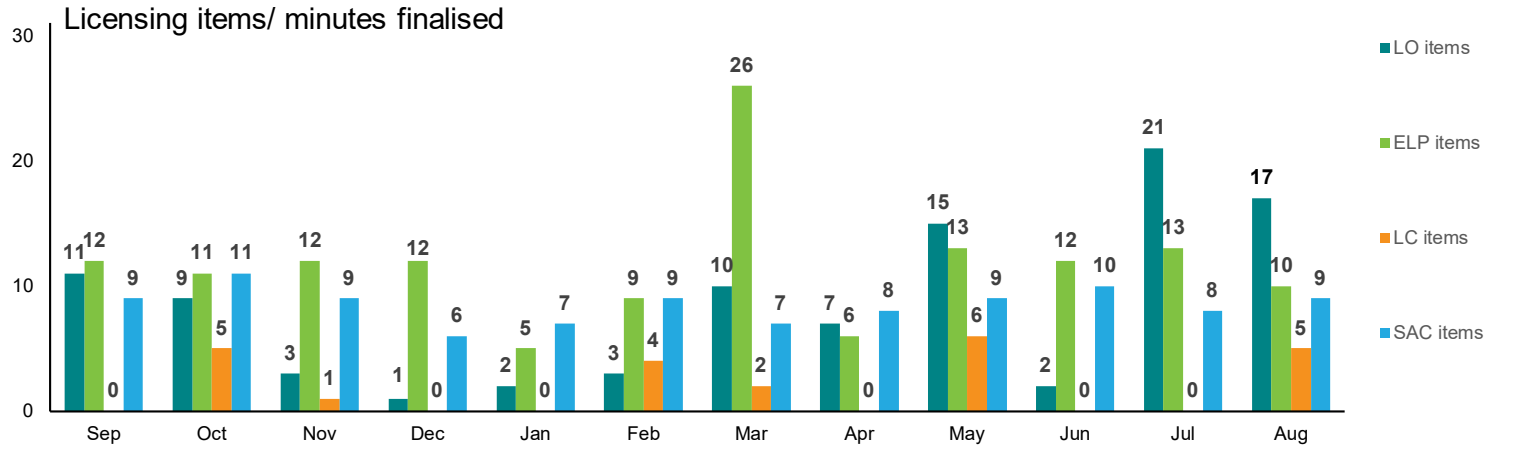
Target: **100% items completed within 80 working days**

One of the seven reports was not completed on time (324 wd) due to the complexity and the required post-inspection actions.



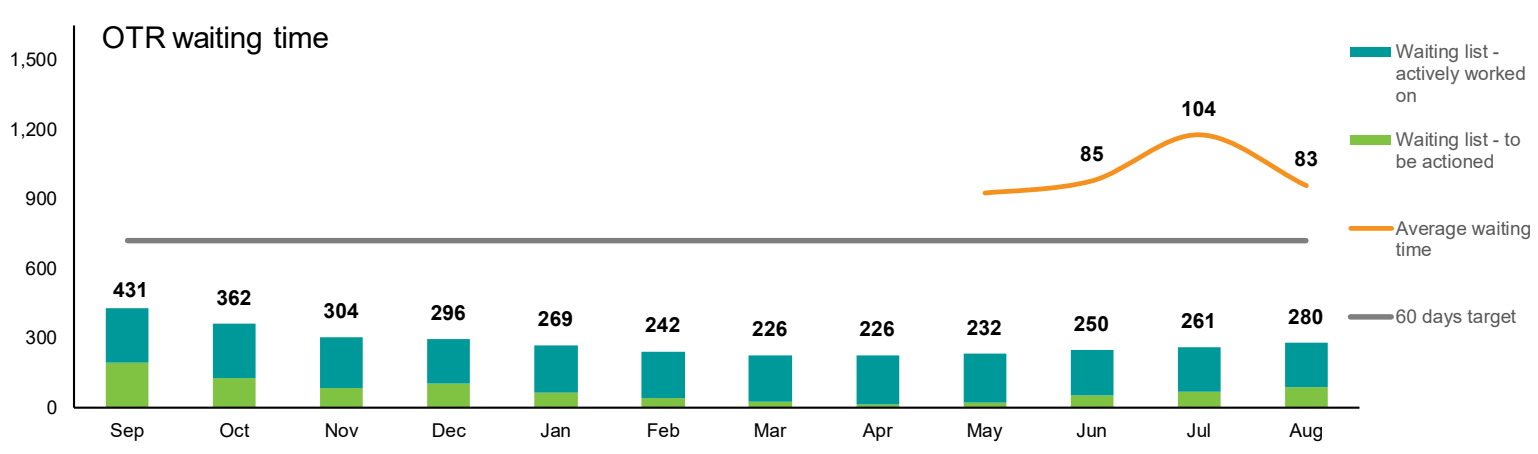
Status:	Green
Compliance	
PGTM processing efficiency	
Target: **average time within 60 working days**	

All PGTMs were processed within KPI.



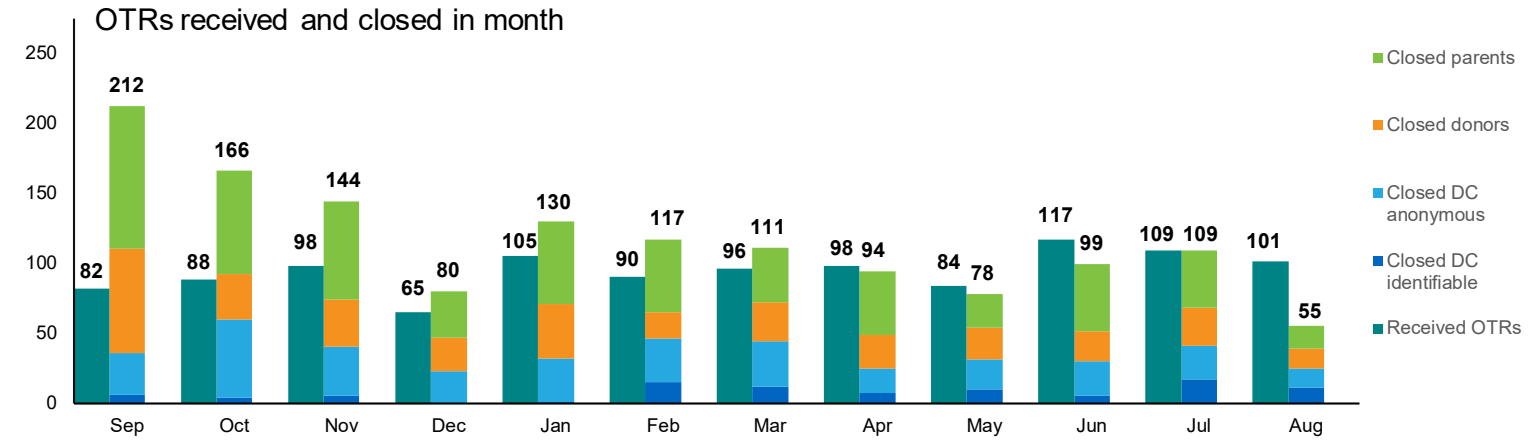
LO:	Green
ELP:	Green
LC:	Green
SAC:	Green
Licensing	
Licensing efficiency	
Targets: **LO - 5 WD ELP - 10 WD LC - 15 WD SAC - 20 WD**	

LO items continue to be high due to ITE certificates. Otherwise, a standard month for the committees.



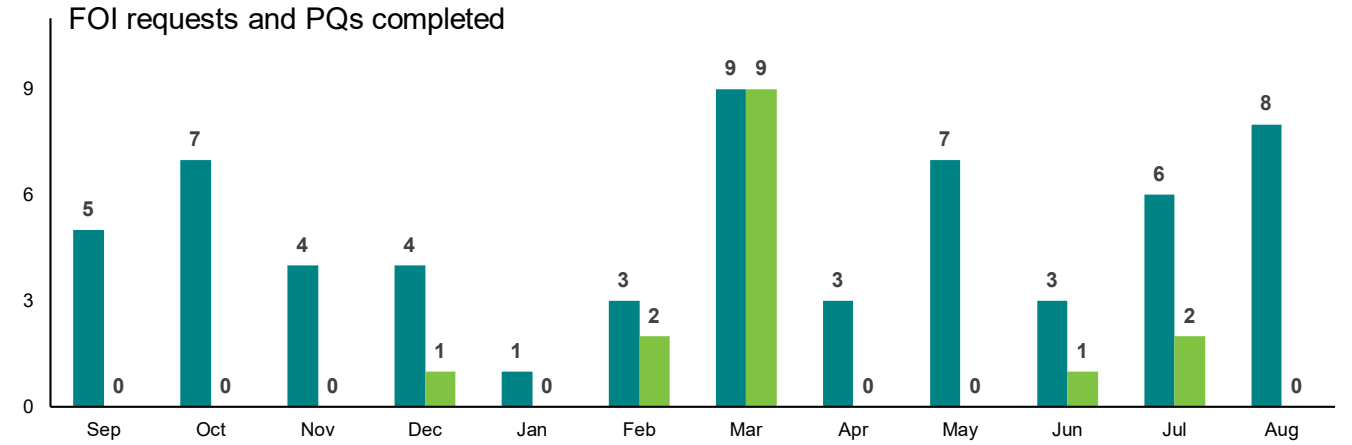
Status:	Red
OTR	
Average waiting time	
Target: 60 days	

OTRs in the waiting list: **Donor OTRs - 68; DC identifiable - 39; DC anonymous - 74; Parents - 99.**
Waiting list increased by 21 because fewer OTRs were processed in August due to annual leave and sickness leave.



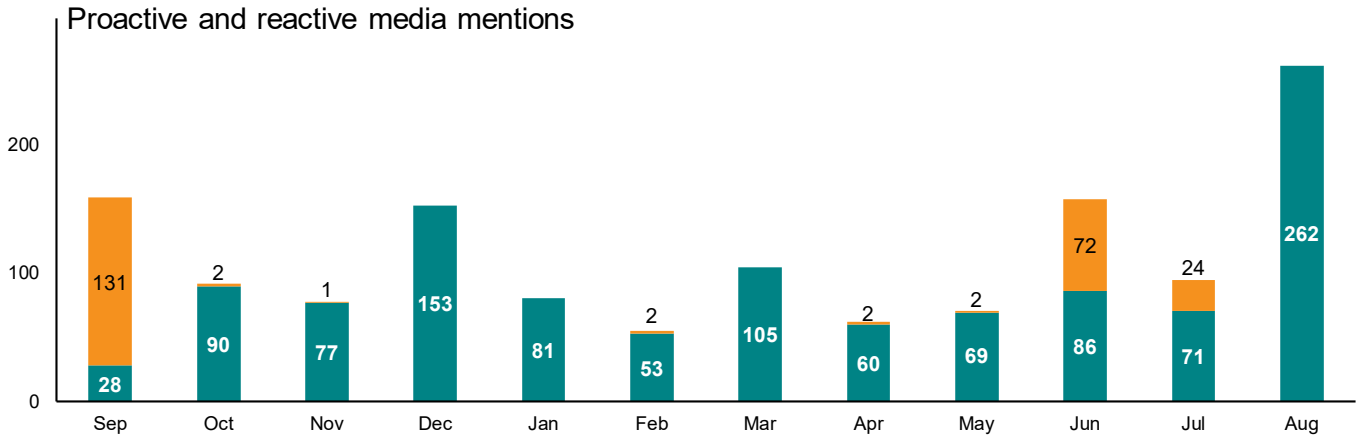
Status:	N/A
OTR	
OTRs received and closed in month	
Target: N/A	

OTRs sent out: **Donor OTRs - 14; DC identifiable - 11; DC anonymous - 14; Parents -16.**
Team closed fewer OTRs in August 2026 due to annual leave and sickness leave in the team. We received a similar number of OTRs as the last 2 months. A slightly smaller number of OTRs are held up by data issues and clinic non-responses.



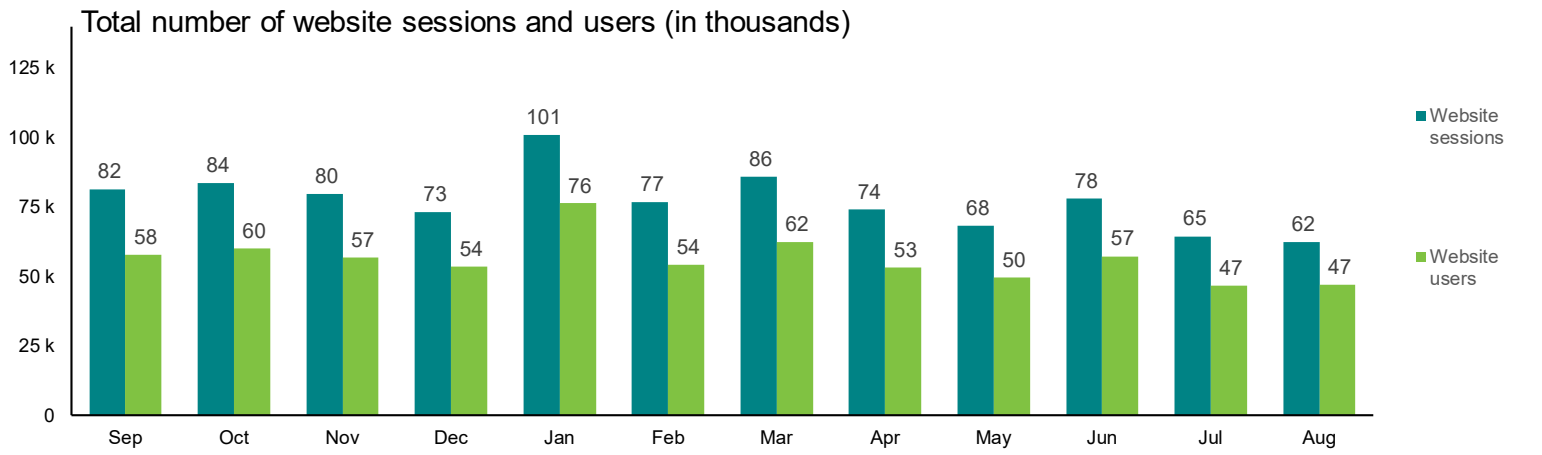
FOI:	Green
PQ:	Neutral
IG	
FOI and PQ completed	
Targets: **FOI - 20 WD PQ - set by DHSC**	

Eight FOIs due were completed within the statutory deadline. FOI requests topics covered donation, surrogacy, information on NHS funded cycles, immersive learning and training, the adoption of the UK Government's anti-Muslim hostility definition, financial spend and transparency information, vehicle information, and of the Code of Practice.



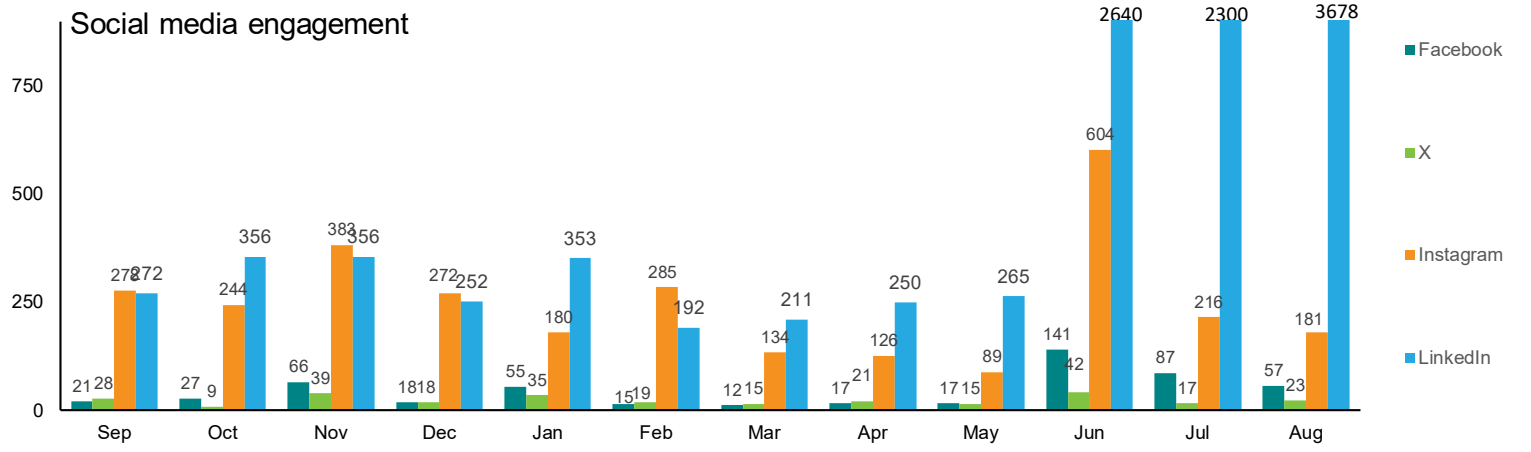
Status:	N/A
Comms	
Total media mentions (proactive and reactive split from April 2024)	
Target: **not defined**	

We received 262 pieces of coverage, all reactive. Themes included egg freezing, treatment abroad, and surrogacy. Coverage was largely driven by a story on treatment abroad, which led to the UK government issuing a warning to people having fertility treatment overseas and directing them to our advice page on the website; as well as by US congresswoman Alexandria Ocasio-Cortez revealing that she had frozen her eggs.



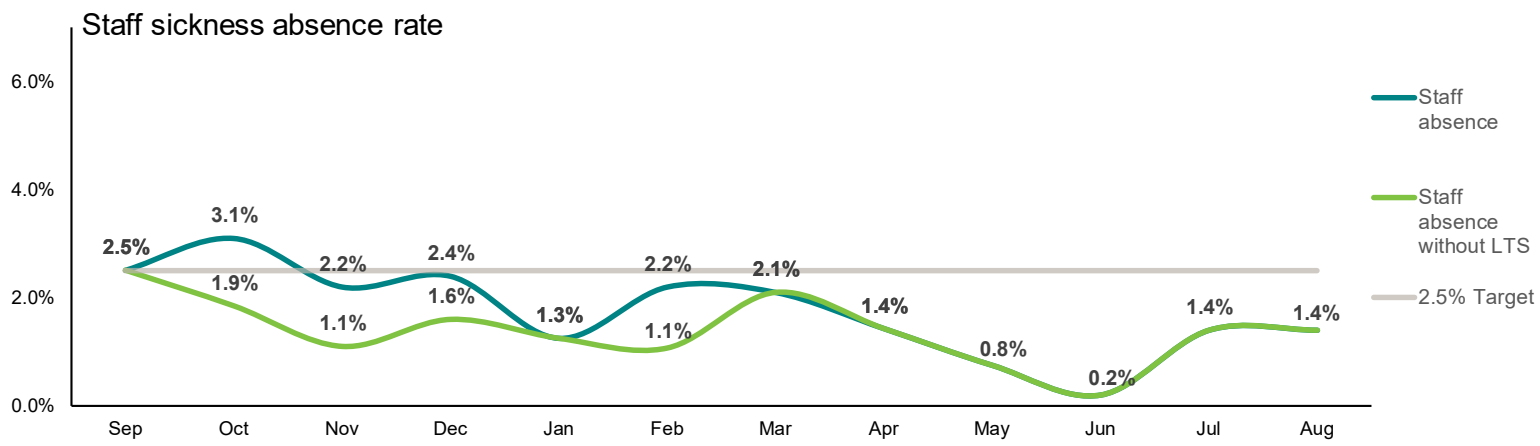
Status:	N/A
Comms	
Total number of website sessions and users (Internal traffic excluded from October 2023)	
Target: not defined	

The website's performance is generally consistent with overall trends. No significant changes to the top three pages observed.



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

Engagement varied across all channels with LinkedIn continuing to grow. The fertility treatment abroad content performed well across all social media platforms.



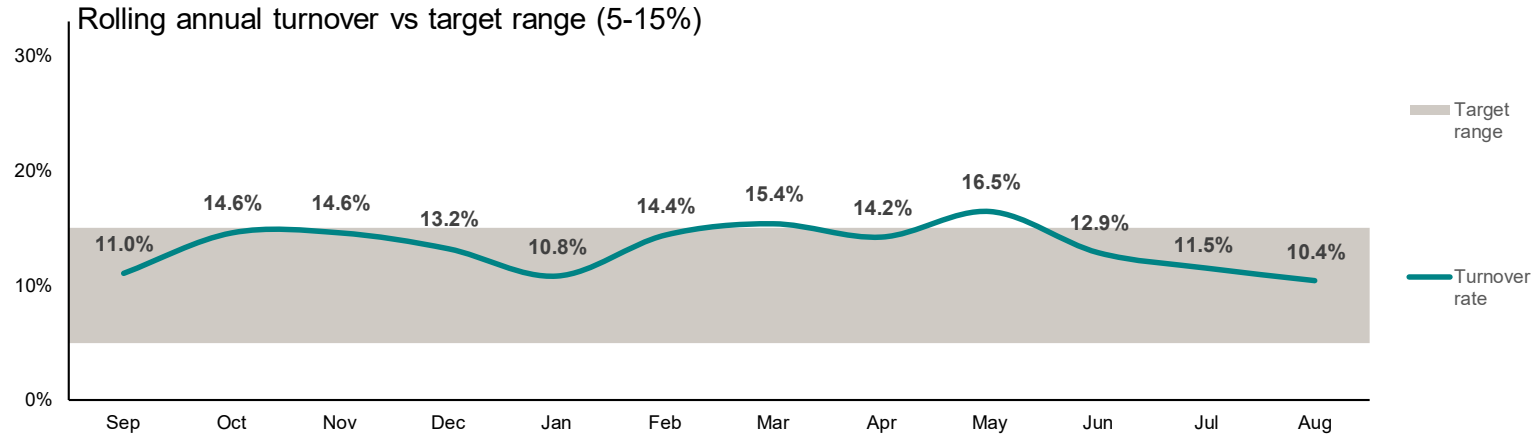
Status: **Green**

HR

Sickness

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

Sickness absence levels remain within a tolerable level.



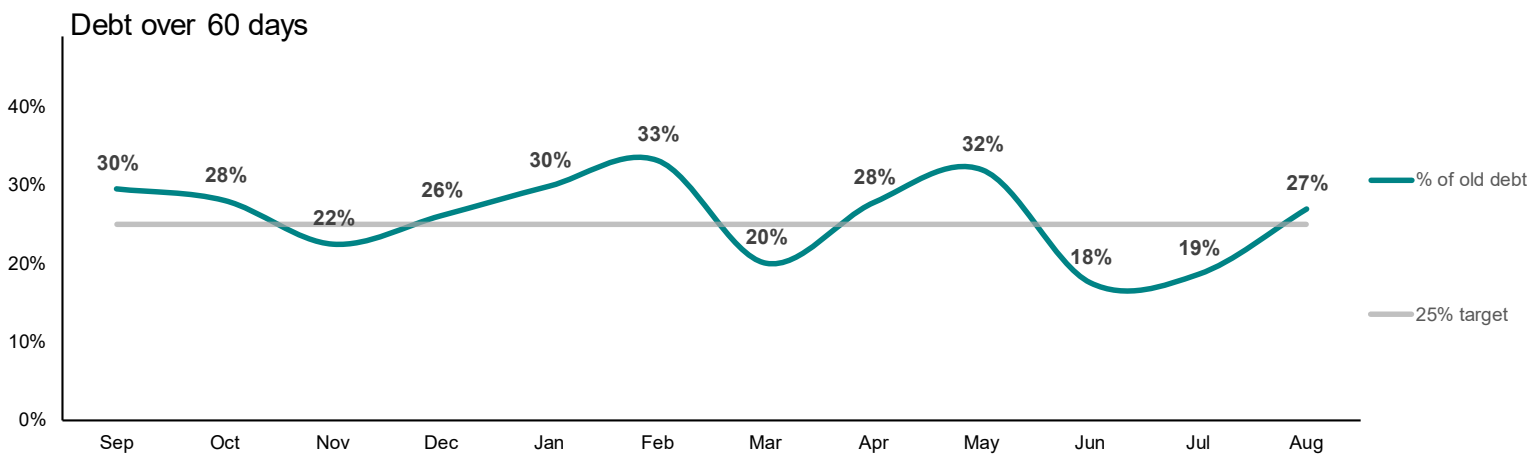
Status: **Green**

HR

Turnover

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

We had one leaver in August 2026.
Supplementary HR data: **Headcount - 89, Budgeted posts - 85, Vacant posts -1, Starters - 0, Leavers - 1.**



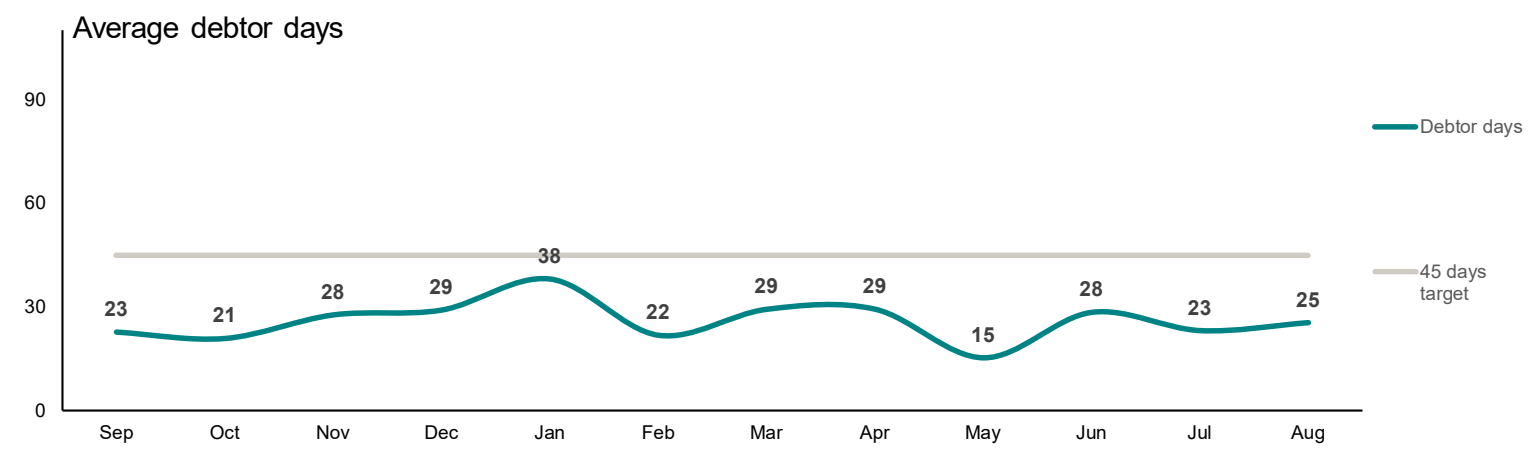
Status: **Amber**

Finance

Debt collection

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

Excluding estimated clinics 60+ days debt is £71,425.76, which represents 12.9% of total debt.



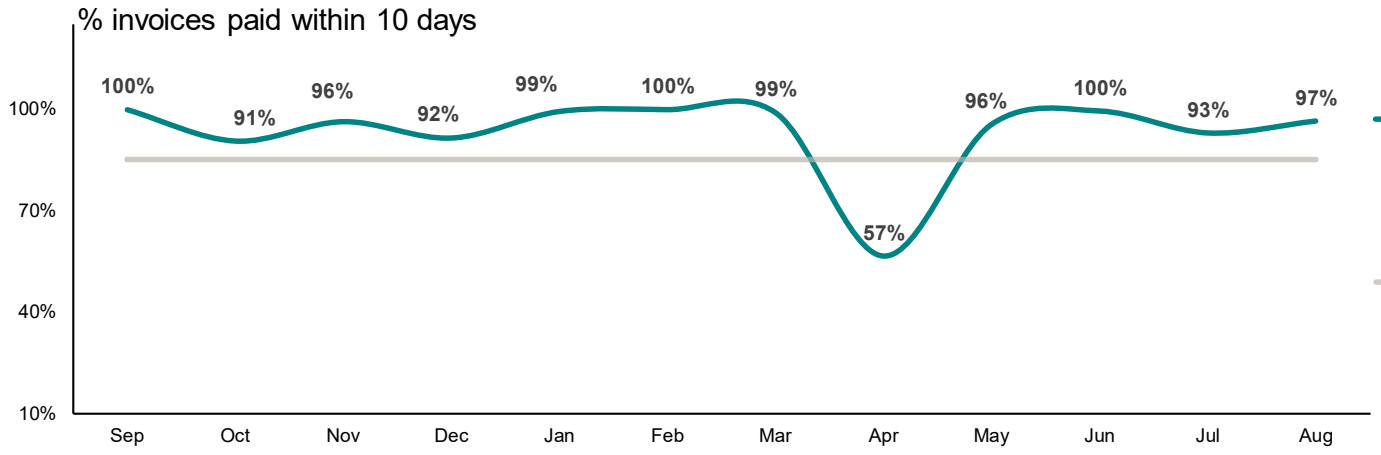
Status: **Green**

Finance

Debtor days

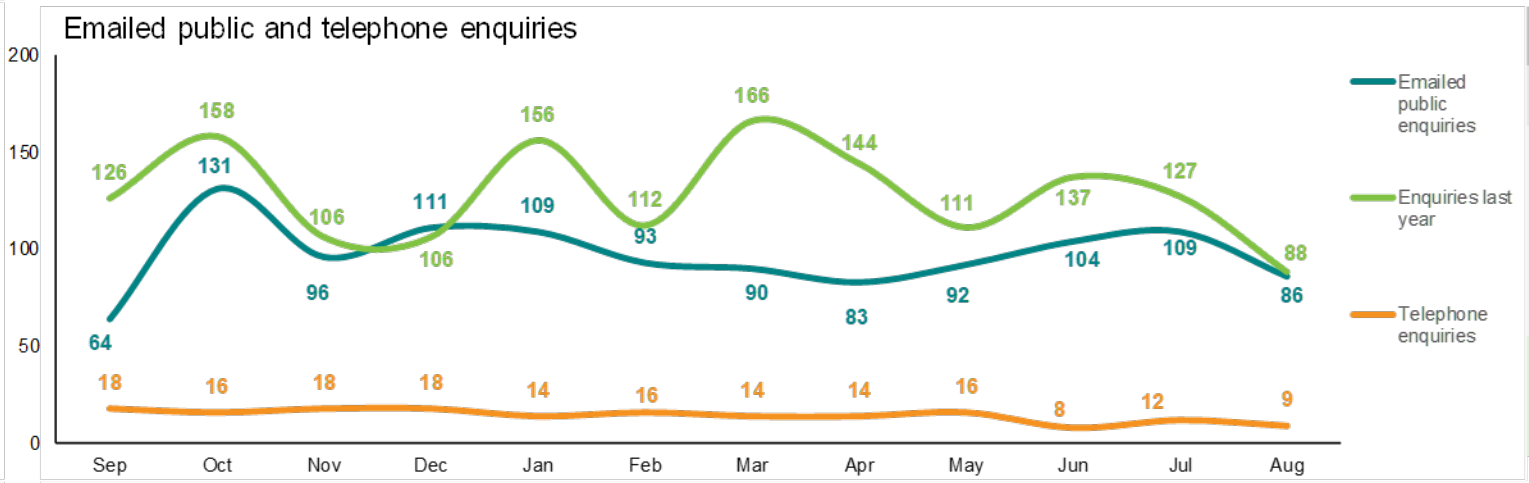
Target:
45 days or less

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**	

86 email and 9 telephone enquiries were received in August 2026, slightly lower than in July 2026. Calls included enquiries about medical queries and concerns (2), Opening The Register (2), beginning treatment (1) and donation (1). All 9 calls were categorised as Straightforward.

Human Fertilisation & Embryology Authority

Finance Report

Five months to 31 August 2026

Tom Skrinar
Director of Finance, Planning and Technology
23 September 2026

www.hfea.gov.uk

Summary financial position as of 31 August 2026

	Year-to-date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	**3,713**	**3,571**	**(142)**	**9,318**	**9,233**	**85**
Expenditure	**3,687**	**3,842**	**155**	**9,229**	**9,233**	**(4)**
Surplus / (Deficit)	**26**	**(271)**	**297**	**89**	**0**	**89**

KPIs

Bank balance: £2.7m (target £1.52m)

Debts 60 days old 26.9% (target <25%) (excluding 3 clinics is 12.9%)

Our year-to-date position (as of 31 August) is a surplus of £26k and a variance against budget of £297k. The positive variance is driven by positive movement in income and underspends within our expenditure. Key variances are explained overleaf.

The forecast for the year is showing a surplus against budget of £89k up by 43.5% (or £27k) from the last reporting period which was month two (May). June's figures were unavailable to report at July's Authority.

We undertook a review in July and where appropriate, changes were made to the forecast. A further review will be undertaken in early October which will reflect any additional changes shared by the various teams.

2026/27 Income – YTD 31 August 2026

	Actual £000's	Budget £000's	Variance £000's	Variance %ge	Full year Forecast £000's	Full year Budget £000's	Variance £000's
INCOME							
DHSC Funding	476	300	176	59%	1,217	1,074	143
Licence fees	3,201	3,247	(46)	-1%	8,010	8,064	(54)
Other	36	24	12	50%	91	95	(4)
Total income	**3,713**	**3,571**	142	4%	**9,318**	**9,233**	84

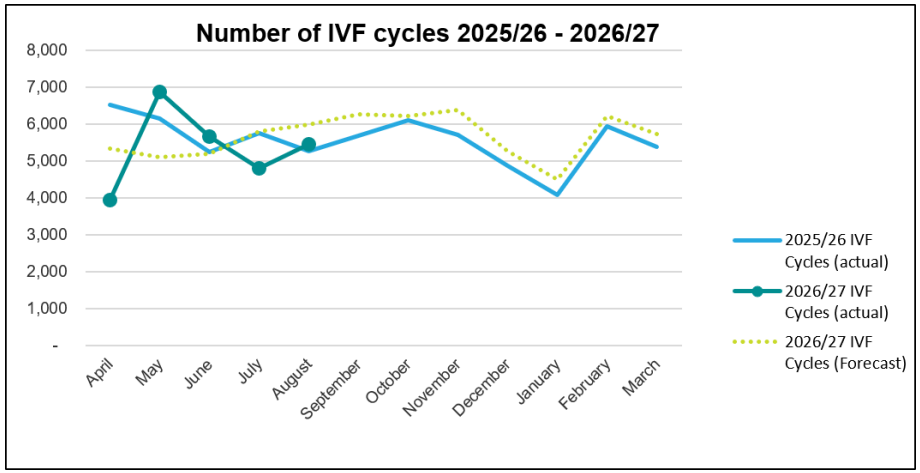
Income

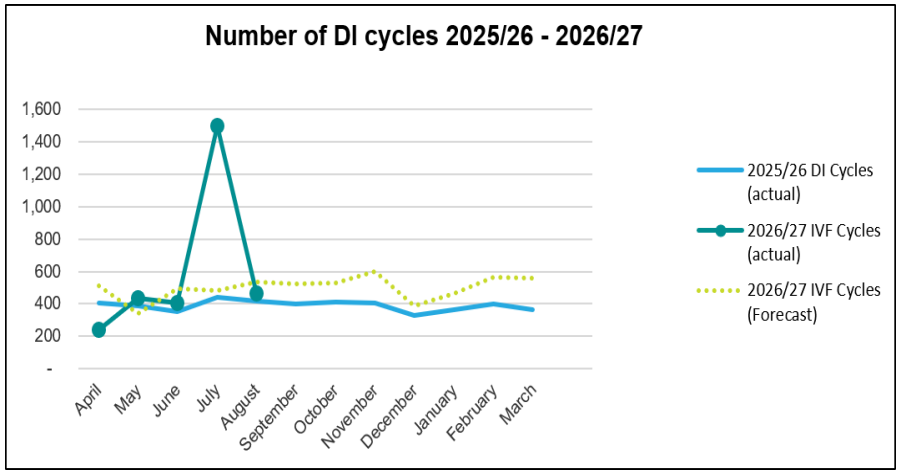
DHSC Funding is our grant in aid (GIA) both cash and non-cash, the latter being a notional sum to cover depreciation and amortisation of our assets. Year-to-date shows a positive variance of £176k which includes an additional £150k drawn down to cover additional costs for the Phoenix project whose end date has been extended due to unforeseen issues that have recently arisen. The balance (£26k) is due to profiling of the budget.

Licence fees are the IVF, DI treatment fees plus invoices for renewal, storage and research fees. The short-fall of £46k contains a short-fall in IVF fees due to a change made to PRISM/billing coding which resulted in clinics being charged incorrectly, with the result being refunds of c£69k. This has been offset by more income from other fees.

Other income is 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 August 2026

The above graphs show the volumes of IVF and DI cycles, comparing activity for the 2026/27 and 2025/26 financial years; year-to-date as of August 2026

YTD IVF cycles are 2,243 lower than the previous year and will have been impacted by the issue around the change of coding to our billing system. Against forecasted cycles, actual cycles are lower by 656 c£70k.

DI cycles similarly are down against last year by 22% (184) and 15.5% (123) against forecast. This is despite the spike seen in July. The reasons for these shortfalls are not known. It is possible that clinics are changing the profile of income generation to activity that we do not charge for. This could also apply to IVF cycles.

Continuous monitoring of both types of cycle will continue till early Q4 2026/27.

2026/27 Expenditure YTD 31 August 2026

	Actual £000's	Budget £000's	Variance £000's	Variance %ge	Full year Forecast £000's	Full year Budget £000's	Variance £000's
EXPENDITURE							
Salaries and wages	2,604	2,790	**(187)**	-7%	6,465	6,708	(242)
Other Staff costs	91	101	(10)	-10%	326	328	(2)
Other costs	101	58	43	74%	276	302	(26)
Project costs	286	274	12	4%	434	274	160
Estates incl non-cash costs	222	182	41	22%	496	487	9
IT costs	289	290	**(1)**	0%	783	706	77
Legal and Professional	94	145	(51)	-35%	448	428	20
Total Expenditure	**3,687**	**3,841**	**(154)**	-4%	**9,228**	**9,233**	4
Surplus/(Deficit)	**26**	(270)	296		89	0	(89)

Variances

Salaries and wages – are £187k below budget of which a large proportion is related to the vacancies currently being recruited to within the IT team. As of today, one of the posts has been successfully filled with a start-date of mid-September. These savings will likely be offset by increased contingent labour and IT service costs.

Other Staff costs – are below budget by £10k which is largely due to staff training costs which are £8k under budget year-to-date.

Human Fertilisation & Embryology Authority

2025/26 Expenditure continued

- **Other costs** – are £43k over budget. The main culprits are a late charge for Q4 25/26 for PGT applications (Genetic Alliance) these are difficult to budget for; Donor Conceived Register accrual is higher than budget which will be investigated by the end of Q2. There are other smaller variances across the directorates.
- **Project costs** – are over budget by £12k which relate solely to the Phoenix project whose end date has been extended to ensure migration of data to a new SharePoint is completed which also impacts on implementing Dynamics (our Licensing and inspections systems).
- **Estates (incl non-cash) costs** – are over budget by £41k. This is represented by accommodation costs (service charges, rent and rates) that are budgeted quarterly but are yet to be invoiced. The accruals for the above are based on estimates which are currently higher than budget.
- **IT Costs –** are more or less on budget year-to-date. We do expect there to be an increase in Azure costs which will impact form quarter three.
- **Legal and Professional** – is under budget by £51k of which the majority relates to legal (£50k). This budget we tend to leave unaltered as it is difficult to predict when the next case could arise. The balance is within our internal and external audit fees
- **Forecast** – The forecast currently includes increases in our IT costs (Azure and Dynamics), Phoenix Program costs (although additional GIA has been allocated). In early October a further review of all expenditure will be undertaken.

Embryo Testing

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment
Meeting:	Authority
Agenda item:	7
Meeting date:	23 September 2026
Author:	Dina Halai, Head of Regulatory Policy, Scientific (job-share) Rachel Cooper, Head of Legal Rachel Cutting, Director of Compliance and Information
Annexes	Annex A: Wording on genetic testing in the **Human Fertilisation and Embryology (HFE) Act 1990 (as amended)**, standard licence conditions and code of practice Annex B (as separate file): Embryo testing guidance - DRAFT

Output from this paper

For information or decision?	For decision
For decision:	Members are asked to: • Review the draft guidance on embryo testing and provide any final comments (substance not style) Following this meeting, sign-off of the final draft guidance on embryo testing has been delegated to Authority members Frances Flinter, Tim Child and Rosamund Scott (see Minutes of the Authority meeting on 20th May 2026).
Resource implications:	Within budget - resource will be required to implement from the Policy, Compliance, Licencing and Legal and Communications
Implementation date:	Autumn 2026
Communication(s):	To be decided post Authority discussion
Organisational risk:	Low/**Medium**/High

1. Background

1.1. The **Human Fertilisation and Embryology (HFE) Act 1990 (as amended)** (the "1990 Act") prohibits embryo testing except for one of the purposes permitted in the Act (the "Permitted Purposes"; see Annex A for exact wording in the Act).

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

1.3. The methodologies for carrying out genetic testing have advanced significantly since the law was passed. Sophisticated testing now routinely generate data which goes beyond simple binary results for which the testing was originally sought. These developments raise the question of what information may lawfully be obtained from permitted testing and used for selection of embryos, ie although the reason for testing may be lawful, there is a question about whether receipt of some of the information generated from the test is legally permitted.

1.4. This mismatch between what is lawful in the UK and advances in the information that can be derived from particular tests does mean that where those advances are in the best interest of the patient, and supported by robust evidence, the law could now be seen as restrictive in preventing potentially relevant tests from being undertaken. However, the HFEA has a duty to promote compliance with the Act as it stands, and to ensure testing is carried out lawfully, by, for example, providing clinics with guidance, and inspecting clinic activities.

1.5. The Authority considered the current practice and emerging issues relating to embryo testing in September 2025 (as set out in detail within the **meeting paper** and **minutes** of that meeting) and agreed that the advancements in methodologies and variation in clinic practices suggested that guidance for the sector clarifying the law is needed. A further discussion was had at the **May 2026 meeting**, at which next steps were agreed for this work.

1.6. This paper provides an update on progress made since, including stakeholder views, and requests that the Authority review the draft guidance on embryo testing (Annex B) and offer final comments.

1.7. Following this meeting, sign-off of the final draft guidance on embryo testing has been delegated to Authority members Frances Flinter, Tim Child and Rosamund Scott (see Minutes of the Authority meeting on 20th May 2026).

2. Drafting of the guidance on embryo testing

2.1. The draft guidance can be found at Annex B.

2.2. To recap: the intended purpose of the proposed guidance on embryo testing is to:

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

2.3. Points to note about the draft guidance:

- Some Authority members have already contributed to the drafting.
- We have avoided referring to the type of test (eg PGT-A, PGT-M etc) and instead refer to the Permitted Purposes in the 1990 Act where possible. This is because the varied understanding within the sector of the purposes for which embryo testing is permitted seems to be exacerbated by the use of terminology focused on specific tests rather than focusing on the purpose of the testing as set out in the legislation.
- We have avoided being overly prescriptive on which tests are and are not allowed but given some examples to pre-empt queries we may receive in the future. The onus is on the clinic to think about the Permitted Purposes and whether any test they are considering would satisfy those purposes. This also future proofs the guidance given the pace of advances in types and methods of testing.

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

3.1. Since 1(b) refers to 'any other' abnormality, the HFEA has the power to authorise testing for other HFEA-approved abnormalities for which there is not a particular risk. At the **May 2026 meeting**, the Authority agreed 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.

3.2. Since the May meeting and in response to suggestions made by Authority members at that meeting, the Executive has carried out further policy work to consider the circumstances in which additional genetic information could legally be obtained by engaging with experts (a Professor of Reproductive Genetics and a Consultant Genetic Counsellor) and the UK National Screening Committee.

3.3. Through this engagement, it has become clear that there are currently no circumstances in which 'any other' abnormality for which there is not a particular risk may also be the subject of testing under 1(b) in practice.

3.4. In summary, the UK National Screening Committee (UK NSC) have advised that:

- In the absence of a shared carrier status or relevant family history, the probability of an embryo being affected by another genetic condition is very low and certainly no higher than the general population.
- In the absence of a relevant family history, the presence of a genetic variant does not reliably predict if, or how, a condition will present. Thus, in the context of testing for 'any other' abnormality, we cannot be confident that the significant risk criterion set out in the Act will be met. Further evidence would be needed to support this assumption.

  See annex B within the draft guidance for full advice received from the UK National Screening Committee.

3.5. The guidance has been drafted to reflect the advice received from the UK National Screening Committee. We have included that the HFEA will review this part of the guidance again should new evidence emerge.

4. Stakeholder review

4.1. Feedback was gathered from various (13 responded) stakeholders (Persons Responsible at clinics with licences for embryo testing, commercial companies providing genetic testing, and professional bodies) on the understandability and clarity of the guidance.

4.2. The results reinforced the need for greater clarity for the sector on embryo testing, as set out in this guidance. Stakeholder feedback has been incorporated into the draft guidance, including requests for further detail on the management of incidental findings, the types of testing permitted under 1(a) and 1(e) and the expertise that should be involved in determining the appropriateness of testing.

5. Impact of this guidance

5.1. As a reminder, the guidance is being introduced *not* because the law has changed but in response to the advances in testing technology in recent years which raise the question of what information may lawfully be obtained and used for selection of embryos.

5.2. It is important to remember that there has been no broad parliamentary discussion of the intent of this Act since it was amended in 2008, so we do not know the views of parliament on what embryo testing would be allowed now.

5.3. As noted above, this guidance:

- Clarifies the existing law regarding embryo testing and approvals required;
- provides licensed clinics with information on what the HFEA expects from clinics when carrying out embryo testing in accordance with the law for each permitted purpose; and
- clarifies where additional genetic information can and cannot be obtained and used in clinical decision making.

5.4. This is the first time we have set out specific guidance on embryo testing and clinics may now realise that some embryo testing practices that they have assumed are within the law, are not. As a result, our guidance may require a change in existing processes within clinics that have a licence to offer embryo testing. Furthermore, patients may be upset as to why they cannot proceed with a particular pathway anymore.

5.5. In particular, the following clarifications in the guidance are likely to have an impact on current clinic practices, and potentially on patient expectations:

- Recording reason for testing – through this guidance, the HFEA will now explicitly require clinics to record the reason for testing within patient records before embryo testing is requested. This will not require the creation of a new form but does require the recording of the necessary information within patient records which may be subject to HFEA inspection in the usual way.
- Third-party agreements with testing companies – clinics may need to update these agreements to make clear the scope of lawful testing under the Act as clarified in the new guidance and state that the information that is being sought must be in accordance with the Permitted Purposes and no other information should be analysed and included in the genetics report sent back to the clinic. These agreements are subject to HFEA inspection in the usual way.
- Given that the assessment of 'seriousness' is reserved in law to the HFEA, the umbrella "chromosomal rearrangements (various)" approval will be removed from 1 January 2027, refer to **Clinic Focus - July 2026** for further detail. A clinic will need to obtain the approvals needed to test for specific chromosomal abnormalities under 1 (b), or consider whether testing for the chromosomal abnormality can take place under 1(a).

5.6. We smooth the implementation of the guidance by considering drop-in Q&A sessions or a webinar for relevant clinic staff to attend and ask questions. See section 6.3 for further comms planned.

6. Next steps

6.1. As stated above, following this meeting, sign-off of the final draft guidance on embryo testing has been delegated to Authority members Frances Flinter, Tim Child and Rosamund Scott (see Minutes of the Authority meeting on 20th May 2026).

6.2. As agreed at the **May 2026 meeting**, consequential changes to the Code of Practice, the Standard Licence Conditions, General Directions, and other ancillary documents, where required will be signed off by the Authority Chair.

6.3. Once final and published, we will communicate about the new embryo testing guidance with centres, patients and stakeholders, as appropriate. This will likely include (but not be limited to):

- Publication of the embryo testing guidance to the Clinic Portal
- Updates to our website so that patients are aware of what testing they could have access to
- A Clinic Focus article
- Drop-in Q&A sessions or a webinar for relevant clinic staff to attend and ask questions about the guidance
- Updates at a SCAAC meeting and various stakeholder meetings eg Patient Organisation Stakeholder Group (POSG), Professional Stakeholder Group (PSG), Licensed Centres Panel

Further policy work

6.4. We are keen to publish a first version of this guidance this autumn, which already contains a substantial amount of clarification for the sector. We will need to revisit this guidance periodically as the field continues to evolve and have identified the following areas where further work is needed with information to be incorporated into future iterations of this guidance. Some of that work may require stakeholder engagement before Authority decision.

6.5. The information provided in the draft guidance regarding testing under Permitted Purpose 1(c) (sex selection for the purpose of avoiding a serious genetic condition) is correct. However, further policy work is planned to consider the range of scenarios that may arise when applying 1(c) testing in practice. As part of this work, additional detail may be developed to help minimise the unnecessary exclusion/discarding of healthy carrier embryos.

6.6. Carrier status – Identifying the carrier status of an unaffected embryo is not within the scope of testing for a permitted purpose because there is not a significant risk that the child born from a carrier embryo will have or develop the serious disability, illness or medical condition. The legislation is focused on the welfare of the child who would actually be born rather than the reduction in the long-term burden of genetic disease ie to remove disease from that family/wider society. We know that many clinics currently do receive information on unaffected carriers, and therefore this is a key issue that we need to do further policy work on. We will bring this back to the Authority for a future discussion.

6.7. As presented at previous Authority meetings, the HFEA has taken the position 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. This means that patients do not have a legal right to the

embryo's full sequence of raw genetic data under the UK's data protection laws, nor an automatic right to request that the embryo’s DNA or DNA sequence is exported outside the UK for further testing or analysis which would not be lawful in the UK. We understand that the Information Commissioner’s Office are looking into this and await their decision.

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

Section 13, 1990 Act: Conditions for treatment

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

to this Act….

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

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition,

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

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

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

(b) a gender-related serious illness, or

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

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

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

(a) it affects only one sex, or

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

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

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

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

[1] Licences for treatment

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

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

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

(ii) a gender-related serious illness, or

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

establishing the **sex** of the embryo,

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

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

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

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

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

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

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

(a) it affects only one sex, or

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

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

Paragraph 1ZB - Sex selection

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

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

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

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

(b) a gender-related serious illness, or

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

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

(a) it affects only one sex, or

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

Human Fertilisation & Embryology Authority

Guidance on testing embryos – DRAFT

[Publication/go live date - TBD]

1. Purpose of this guidance

1.1. This guidance:

- Clarifies the law regarding embryo testing and approvals required;
- provides licensed clinics with information on what the HFEA expects from clinics when carrying out embryo testing in accordance with the law for each permitted purpose; and
- clarifies where additional genetic information can and cannot be obtained and used in clinical decision making.

2. The law

2.1. The Human Fertilisation and Embryology Act 1990 (the '1990 Act') prohibits embryo testing except for one of the purposes permitted in the Act (the "Permitted Purposes). Exact wording on Permitted Purposes for genetic testing in the 1990 Act is as follows:

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

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

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

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

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

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

(ii) a gender-related serious illness, or

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

*establishing the **sex** of the embryo,*

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

or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

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

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

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

*(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), **that there is a significant risk that a person with the abnormality will have or develop a serious** physical or mental disability, a serious illness or any other serious medical condition.*

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

(a) it affects only one sex, or

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

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

2.2. We acknowledge that there may be value in testing, analysis and use of genetic data for a patient that the law currently does not allow, for example quality control testing. Whilst the HFEA has acknowledged that the Act is outdated in particular ways and has put forward proposals on how and why certain aspects of the law should be updated, it considers that the current law permits embryo testing to be undertaken in a clinically appropriate, safe and ethical manner.

2.3. In this guidance, we have avoided using terminology focused on specific tests (eg PGT-A, PGT-M etc) and instead refer to the Permitted Purposes in the 1990 Act as this will help guide which abnormalities can be tested for under each of the Permitted Purposes.

3. The implications of the law

Relationship between this guidance and the Code of Practice / other developments

3.1. This guidance should be read alongside the HFEA Code of Practice. Where this guidance is inconsistent with the Code of Practice, we expect clinics to follow this guidance as it reflects the HFEA's interpretation of the law in the context of modern testing practices and capabilities until the next update of the Code of Practice.

3.2. We also expect clinics to adhere to the agreement between the HFEA and other professional and patient bodies (the 19th October 2023 consensus statement) which states that treatment add-ons, which can include some embryo tests, that have no strong evidence of their safety and/or effectiveness should only be offered in a research setting.

General points

3.3. **Embryo Testing Licence**: 'Testing embryos' is a licensable activity: clinics must have a licence to perform testing. You can find out more about applying for a clinic licence here: Applying for a clinic licence | HFEA. 'Testing embryos' includes the application of any process that produces information about embryos' genes, chromosomes or mitochondria; this includes non-invasive methodologies.

3.4. **Information Received**: Once a clinic has the relevant licence, **embryo testing is allowed for one (or more) of the Permitted Purposes and the information obtained from the test(s), received by the clinic and acted upon by the clinic must be limited to the information permitted under that/those purpose(s).** For example, testing under 1(a) can only seek information about an abnormality which may impact the capacity to result in a live birth; testing under 1(a) cannot seek information about an abnormality that presents a significant risk that the child will have or develop a serious condition; this testing is only permissible under 1(b) ie when the embryo is known to be at particular risk of inheriting a serious condition.

3.5. **Embryo Selection**: It is unlawful to select an embryo for transfer unless this is based on information derived from one of the Permitted Purposes. Embryos can only be selected for transfer based on information from testing that meets a specified purpose in law. Prohibitions on testing embryos in the UK cannot lawfully be circumvented by arranging for the analysis to be carried out in another jurisdiction and then using the results in the UK to select embryos for transfer. If a UK-based clinic were to act on a patient's preference based on testing that would not be lawful in the UK as laid out in Licence Condition T88, eg preimplantation genetic testing involving polygenic scores, (PGT-P, see **HFEA blog on PGT-P)** then it would be acting unlawfully and would be subjected to regulatory action.

3.6. **Third-Party Agreements**: Third-party agreements with testing companies should make clear the scope of lawful testing under the Act and state that the information that is being sought must be in accordance with the Permitted Purposes and the scope of the patient's consent. **No other information should be analysed and included in the genetics report sent back to the clinic**. These agreements are subject to HFEA inspection in the usual way.

3.7. **Records:** The onus is on the Person Responsible to justify why a test is being requested and to understand whether the test is compliant with the law and satisfies one of the Permitted Purposes. Records of the reasons for testing and consent forms are subject to HFEA inspection in the usual way.

3.8. Clinics must adhere to **Standard Licence Conditions T21 and T86-90**, summarised as follows:

- If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must be accredited to conduct the relevant test(s) by UKAS, the national accreditation body for the UK, or another accreditation body recognised as issuing accreditation to an equivalent standard.
- Embryos that are known to have a genetic abnormality which presents a significant risk that the child will have a serious condition must not be preferred to those that are not known to have such an abnormality;

- Clinics must ensure that embryo testing is only requested for genetic conditions that are expressly authorised by the Authority;
- It is unlawful to transfer to a woman an embryo that has been subject to a test that supplies genetic information about the embryo unless the test has been expressly authorised by the Authority;
- It is unlawful to use any information derived from tests on an embryo to select embryos of a particular sex for social reasons.

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

Additional findings

3.10. Additional findings are those that are proactively sought, ie a decision has been made to look for or adjust filters in order to identify these findings.

3.11. Analysis of multiple abnormalities is permitted under 1(a) only where there is evidence to support that each abnormality may reduce the capacity to result in a live birth.

3.12. Analysis of multiple abnormalities is permitted under 1(b) only for **approved** conditions and only if the precondition of a 'particular risk' is first satisfied in relation to each abnormality.

3.13. The law states that additional findings ie 'any other' abnormality for which there is not a particular risk may also be the subject of testing under 1(b), but only where:

- the precondition of a 'particular risk' to the embryo is first established in relation to an initial abnormality; and
- where 'any other' abnormality likewise presents a **significant risk** that the child will have or develop a serious condition.

However, advice received from the UK National Screening Committee is that there are currently no circumstances in which 'any other' abnormality may also be the subject of testing under 1(b) in addition to the initial abnormality for which there is a particular risk. This is because there are currently no circumstances in which there would be prior reason to believe that an embryo is at significant risk of 'any other' approved abnormality, for which there is not a particular risk. Clinics must follow the UK National Screening Committees advice.

Refer to section 5 on 'Testing under (1b): Testing for an abnormality that presents a significant risk that the child will have or develop a serious condition' for further detail and Annex B for advice received from the UK National Screening Committee which explains this position.

3.14. Additional findings cannot be looked for under any Permitted Purpose:

- 1(a) – can only identify an abnormality (or abnormalities) that may affect capacity to result in a live birth.
- 1(b) – refer to paragraph 3.10 and section 5 on 'Testing under (1b): Testing for an abnormality that presents a significant risk that the child will have or develop a serious condition' for further

detail and Annex B for advice received from the UK National Screening Committee which explains this position.

- 1(c) – can only establish the sex of the embryo.
- 1(d) – can only establish whether the tissue of any resulting child would be compatible with that of the sibling.
- 1(e) - can only establish whether the embryo is one of those whose creation was brought about by using the gametes of particular persons.

3.15. Compliance with the above points ensures testing is lawful and avoids unlawful data analysis. It also avoids the risk of detecting findings of uncertain significance, and those about which the patients have neither received counselling nor given consent.

Incidental findings

3.16. Incidental findings are defined as findings that are genuinely accidentally and unavoidably identified. Unlike additional findings, incidental findings are not sought for and should be rare.

3.17. Persons Responsible should satisfy themselves that appropriate filters have been placed to avoid the analysis of information that is not being sought and that goes beyond the Permitted Purpose within which testing is taking place. If filters are adjusted to obtain more information, this would amount to seeking additional findings, because a proactive step would have been taken to identify and analyse more information.

3.18. If an incidental finding meets one of the Permitted Purposes, a clinic can report it back to the patient. For example, when testing for aneuploidy under 1(a), you may detect a segmental aneuploidy or a microdeletion; such findings may only be reported back under 1(a) if there is evidence that each abnormality could affect an embryos capacity to result in a live birth. Alternatively, a finding may be reported under 1(b) if the relevant abnormality is on the approved PGT-M list.

3.19. 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.

3.20. An incidental finding that does not meet one of the Permitted Purposes must not be reported back to the patient.

3.21. Compliance with the above points ensures testing is lawful and avoids unnecessary data analysis. It also avoids the risk of incidental findings about which the patients have neither received counselling nor given consent, and information about incidental findings of uncertain significance.

Staff to be involved in embryo testing

3.22. A clinical geneticist should be involved in deciding whether a particular patient should receive treatment involving embryo testing.

3.23. The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists.

3.24. It should maintain close contact with the primary care physician and the referring clinician.

3.25. Clinics must adhere to Standard Licence Condition T12, as follows:

- Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.

Patient information, consent and rights

3.26. In keeping with the law and the regulatory principle that patients must have provided relevant consent, clinics must obtain the patients' written informed consent to the specific permitted test before carrying out any embryo testing.

3.27. Centres should ensure that the scope, limitations, accuracy, implications, risks and benefits of any test offered, and the meaning of the test results, are explained to all patients being offered embryo testing, and this should happen before the test is requested and carried out.

3.28. The clinic should ensure that people seeking treatment have access to clinical geneticists, genetic counsellors and infertility counsellors before and after testing.

3.29. Treatment should include patient support following embryo testing.

3.30. 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. This means that patients do not have a legal right to the embryo's full sequence of raw genetic data under the UK's data protection laws, nor an automatic right to request that the embryo's DNA or DNA sequence is exported outside the UK for further testing or analysis that would not be lawful in the UK.

Non-invasive methodologies

3.31. As outlined above, a licence for 'Testing embryos' is needed for the application of any process that produces genetic information about an embryo; this includes non-invasive methodologies, for example non-invasive ploidy testing.

3.32. Clinics must adhere to Standard Licence Condition T91:

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

3.33. Should you wish to submit an application for a process which does not currently exist on the **authorised processes list**, please contact your Clinic Inspector.

4. Testing under (1a): Testing for an abnormality which may affect capacity to result in a live birth

Applicable permitted purpose as stated in the Act

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

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

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

Approvals required from the HFEA

4.1. A licence to 'test embryos'. You can find out more about applying for a clinic licence here: Applying for a clinic licence | HFEA.

4.2. The HFEA requires clinics to record the following information in patient records before embryo testing under 1(a) is requested:

- Purpose of testing;
- For each abnormality, the supporting evidence which indicates that the gene, chromosome or mitochondrion abnormality being tested for may affect capacity to result in a live birth; and
- Date on which the test is requested.

This may be subject to HFEA inspection in the usual way.

Implications of the law

4.3. Testing for chromosome, gene or mitochondrion abnormalities that reduce the capacity to result in a live birth is permitted under 1(a) only where there is evidence to support this. It is up to the Person Responsible to ensure there is evidence to support testing for abnormalities under 1(a). The Act does not impose an evidential threshold; clinics should make their own assessment of the evidence and be confident that it is sufficiently robust to be able to warrant testing for this purpose.

4.4. Analysis of multiple abnormalities is permitted under 1(a) only where there is evidence to support that each abnormality may reduce the capacity to result in a live birth. In this case, information on multiple abnormalities would not be additional findings; they are individual findings.

4.5. Testing for an abnormality that impairs implantation, increases the risk of miscarriage or otherwise reduces the likelihood of a live birth is permitted under 1(a). Testing for abnormalities that do not reduce the likelihood of a live birth is not permitted under 1(a).

4.6. If a familial chromosome abnormality is known to increase the risk of miscarriage, then testing for that abnormality is permitted under 1(a). Testing for an abnormality that can affect an

[1] Licences for treatment

embryo's capacity to result in a live birth *and* cause a serious medical condition is permitted under 1(a) and testing for such an abnormality does not require approval from the SAC.

The HFEA's position on some new testing methods

4.7. It is up to Persons Responsible to satisfy themselves that the specific test meets the Permitted Purpose given the evidence available at the time of testing.

4.8. Current evidence suggests that Pronuclear confirmation can be permitted for testing under 1(a) as it tests for an abnormality which may affect capacity to result in a live birth.

4.9. Current evidence suggests that the use of Mitoscore is not permitted for testing under 1(a) and is therefore unlawful. If the evidence advances and suggests that embryos with low mito-levels are more likely to miscarry, testing for levels below that level could fall under 1(a).

4.10. Pre-implantation genetic testing for polygenic disease (PGT-P) does not meet a permitted purpose for testing as it does not identify a specific abnormality. Furthermore, there is no evidence that PGT-P can effectively be used to reduce miscarriage rates. See **HFEA blog on PGT-P**.

5. Testing under (1b): Testing for an abnormality that presents a significant risk that the child will have or develop a serious condition

Permitted purpose as stated in the Act

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

(1) A licence under paragraph 1[2] cannot authorise the testing of an embryo, except for one or more of the following purposes—

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

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

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

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

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

Approvals required from the HFEA

[2] Licences for treatment

5.1. A licence to 'test embryos'. You can find out more about applying for a clinic licence here: **Applying for a clinic licence | HFEA**.

5.2. The HFEA, through SAC as a delegated body, needs to be satisfied that there is a significant risk that the abnormality being tested for will lead to a condition that is sufficiently serious (refer to **Statutory Approvals Committee (SAC) Decision Trees** for detail). Once a condition has been considered sufficiently serious, it is added to the **approved PGT-M list** which means it has been HFEA-approved for use by any centre licensed to test embryos.

5.3. Learn more about the **HFEA's PGT-M application process**.

5.4. "Chromosomal rearrangements (various)" were previously approved as a group, allowing testing under 1(b) for various different chromosomal abnormalities without the need for individual approvals. Given that the assessment of 'seriousness' is reserved in law to the HFEA, the umbrella "chromosomal rearrangements (various)" approval will be removed from 1 January 2027: refer to **Clinic Focus - July 2026** for further detail. A clinic should obtain the approvals needed to test for specific chromosomal abnormalities under 1 (b) or consider whether testing for the chromosomal abnormality can take place under 1(a).

5.5. If a familial chromosome abnormality is known to increase the risk of miscarriage, then testing for that abnormality is permitted under 1(a). Testing for an abnormality that can affect an embryo's capacity to result in a live birth *and* cause a serious medical condition is permitted under 1(a). Refer to section 4 on 'Testing under (1a): Testing for an abnormality which may affect capacity to result in a live birth' for further detail on approvals required for testing under 1(a).

5.6. Testing under 1(b) for an X-linked variant may automatically reveal the sex of the embryo; in this circumstance revealing information to patients about the sex of the embryo may be unavoidable; however clinics should continue selecting for embryos according to the risk they carry of developing the SAC-approved serious condition. A retrospective SAC application for testing under Permitted Purpose 1(c) is not required in this instance since the purpose of the testing was not to establish the sex of the embryo but to test for an abnormality that presents a significant risk that the child will have or develop a serious condition.

Implications of the law

The precondition of a particular risk of a serious condition must first be satisfied

5.7. Testing under 1(b) can only be carried out for **approved** conditions and only if the precondition of a particular risk of a serious condition is first satisfied.

5.8. When considering whether or not there is a particular risk that an embryo may have an abnormality, the SAC will take into account whether the abnormality is heritable and if so, what the mode of inheritance is. A 'particular risk' is higher than the risk in the general population.

5.9. It is important to note that, before the embryo(s) of a given patient are tested for an **approved** condition under 1(b), the Person Responsible will need to be satisfied that the statutory test is met in respect of that patient, ie the requirements that:

- there is a particular risk that the embryo(s) may have the relevant abnormality; and

- in turn, that that abnormality presents a significant risk that the resulting child will have or develop a serious condition;
- note that, while a parent may carry an abnormality, this does not necessarily mean that there is a significant risk that the resulting child will have or develop a serious condition as a consequence, which is a precondition for the particular risk element for testing to be lawful in each case under 1(b).

Relevant staff should be involved when considering embryo testing, as described elsewhere in the guidance.

5.10. Within patient records, there should be reference to why the patient meets the statutory requirements for testing under 1(b); this should include the particular risk of a serious condition, eg the family history and the mode of inheritance. Records of any testing decisions within patient records are subject to HFEA inspection in the usual way.

Testing for 'any other' abnormality

5.11. It is unlawful for clinics to seek to conduct what would amount to population screening for other conditions using 1(b), even if those conditions are on the **approved PGT-M list**.

5.12. Whilst in law additional findings ie 'any other' abnormality for which there is not a particular risk may also be the subject of testing under 1(b), the UK National Screening Committee (UK NSC) has advised that:

- In the absence of a shared carrier status or relevant family history, the probability of an embryo being affected by another genetic condition is very low and certainly no higher than the general population.
- In the absence of a relevant family history, the presence of a genetic variant does not reliably predict if, or how, a condition will present. Thus, in the context of testing for 'any other' abnormality, we cannot be confident that the significant risk criterion set out in the Act will be met. Further evidence would be needed to support this assumption.

See annex B for advice received from the UK National Screening Committee.

5.13. **Therefore, based on advice received from the UK National Screening Committee, there are currently no circumstances in which 'any other' abnormality may also be the subject of testing under 1(b) in addition to the initial abnormality for which there is a particular risk. This is because there are currently no circumstances in which there would be prior reason to believe that an embryo is at significant risk of 'any other' approved abnormality, for which there is not a particular risk. Clinics must follow the UK National Screening Committees advice.**

5.14. We will review this part of the guidance again should new evidence emerge.

The HFEA's position on some new testing methods

5.15. PGT-P: does not meet a permitted purpose for testing as it does not identify a specific abnormality, therefore is unlawful. See **HFEA blog on PGT-P**.

6. Testing under (1c): Testing to establish the sex of the embryo

Permitted purpose as stated in the Act

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

(1) A licence under paragraph 1[3] cannot authorise the testing of an embryo, except for one or more of the following purposes—

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

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

(ii) a gender-related serious illness, or

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

*establishing the **sex** of the embryo*

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

(a)it affects only one sex, or

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

Approvals required from the HFEA

6.1. A licence to 'test embryos'. You can find out more about applying for a clinic licence here: **Applying for a clinic licence | HFEA**.

6.2. The HFEA, through SAC as a delegated body, needs to be satisfied that the serious condition affects only one sex or affects one sex significantly more than the other (refer to **Statutory Approvals Committee (SAC) Decision Trees** for detail). Once a condition has been approved for sex testing, it is added to the **approved PGT-M list** for use by any centre licensed to test embryos.

6.3. Learn more about the **HFEA's sex testing application process**.

Implications of the law

6.4. Where a condition is on the **approved PGT-M list** but not specifically approved for sex testing, sex testing is not permitted.

6.5. Testing under 1(c) can only be requested if the precondition of a particular risk of a serious gender-related condition is first satisfied.

6.6. It is important to note that, before a patient's embryo(s) are tested under 1(c), the Person Responsible will need to satisfy themself that the statutory test is met in respect of that patient;

[3] Licences for treatment

ie the requirement of a 'particular risk' of the approved abnormality is a necessary pre-condition for testing to be lawful in each case under 1(c).

6.7. Within patient records, there should be reference to why the patient meets the statutory requirements for testing under 1(c); this should include the particular risk of a serious gender-related condition. Records of any testing decisions within patient records are subject to HFEA inspection in the usual way.

6.8. Any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it must not be used to select embryos of a particular sex for social reasons.

7. Testing under (1d): Testing for the purposes of preimplantation tissue typing

The Act

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

(1) A licence under paragraph 1[4] cannot authorise the testing of an embryo, except for one or more of the following purposes—

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

Approvals required from the HFEA

7.1. A licence to 'test embryos'. You can find out more about applying for a clinic licence here: Applying for a clinic licence | HFEA.

7.2. Preimplantation tissue typing (PTT) requires approval from the HFEA on a case-by-case basis for specific patients.

7.3. Learn more about the HFEA's PTT application process.

Implications of the law

7.4. The Person Responsible will need to be satisfied that the statutory test is met.

[4] Licences for treatment

7.5. Within patient records, there should be reference to why the patient meets the statutory requirements for testing under 1(d). Records of any testing decisions are subject to HFEA inspection in the usual way.

8. Testing under (1e): Testing in a case where uncertainty has arisen

The Act

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

(1) A licence under paragraph 1[5] cannot authorise the testing of an embryo, except for one or more of the following purposes—

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

Approvals required from the HFEA

8.1. A licence to 'test embryos'. You can find out more about applying for a clinic licence here: **Applying for a clinic licence | HFEA**.

8.2. The HFEA requires clinics to record the following information in patient records before embryo testing is requested when testing under 1(e):

- Reason for testing, that is the uncertainty that has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons eg where a labelling, or witnessing, or traceability error has occurred and a risk assessment has determined uncertainty; and
- Date on which the test has been requested.

This may be the subject to HFEA inspection in the usual way.

Implications of the law

8.3. For the use of this test to be lawful, there must be uncertainty about whose gametes were used to create the embryo. The Person Responsible will need to be satisfied that this statutory test is met.

8.4. If testing for an abnormality that satisfies a permitted purpose raises uncertainty about the genetic relation of the embryos being tested, then testing under 1(e) is permitted to establish which of those embryos have been created using the gametes of the parent(s)/donor(s).

[5] Licences for treatment

8.5. Clinics must adhere to General Directions 0011 on reporting adverse incidents and near misses and report to the HFEA any type of gamete or embryo misidentification or mix-up as a serious adverse event; that is, all testing under 1(e).

8.6. Quality control testing of embryos is not permitted as a matter of course and cannot be carried out on all embryos unless uncertainty has arisen.

The HFEA's position on some testing methods

8.7. Parental QC – permitted only where there is uncertainty about whose gametes were used to create the embryo.

8.8. Sibling QC – although the intention of such testing may be to act in the patient's interests by confirming that all embryos within a tested cohort are full genetic siblings, it does not fall within a Permitted Purpose and is therefore unlawful. This is because sibling QC does not determine whether the embryos were created using gametes of particular persons. Moreover, testing under 1(e) is permitted only where there is uncertainty, not as a routine measure.

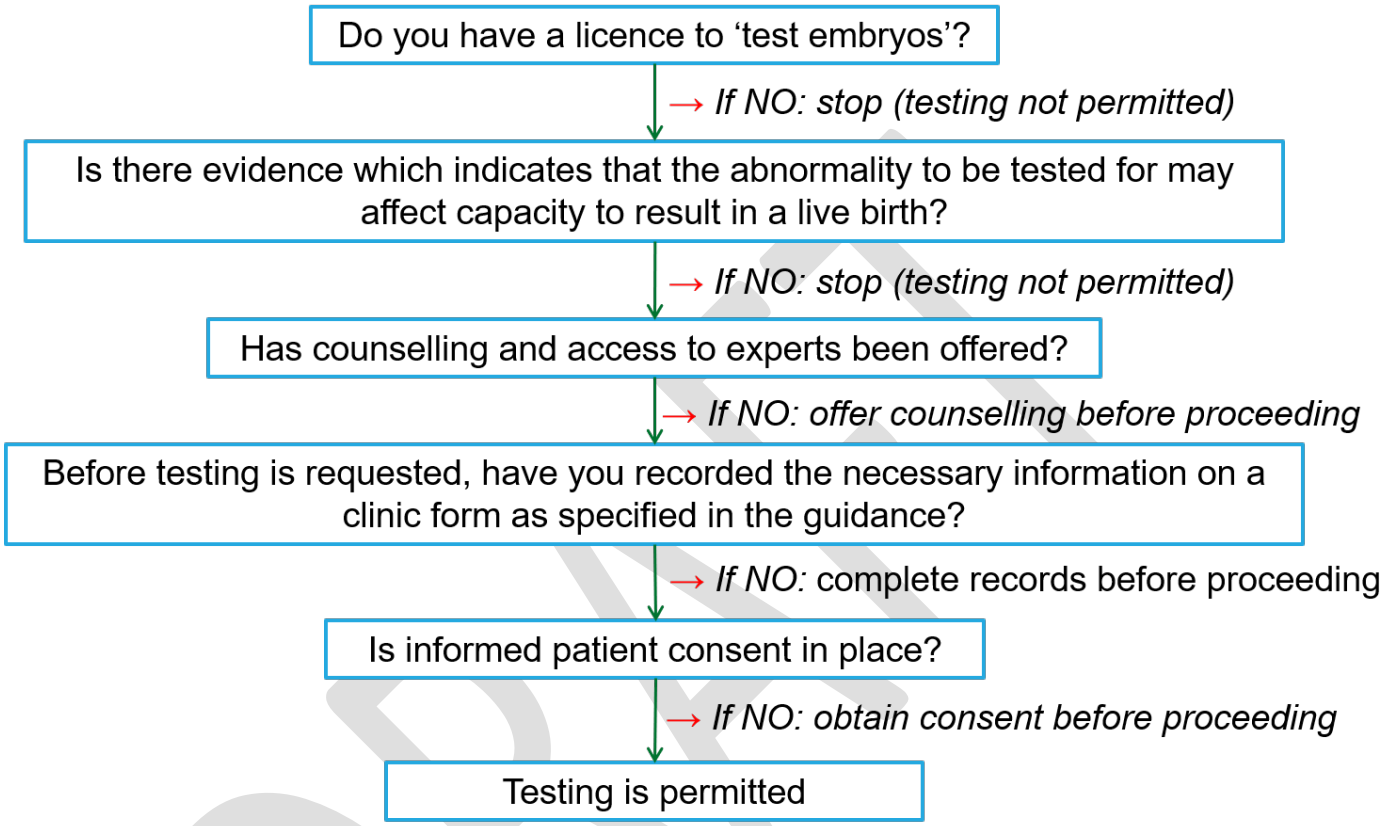
Version/revision control

Version	Changes	Updated by	Approved by	Release date	Review date
0.1	Draft for a briefing meeting with the Authority	Dina Halai, Rachel Cutting	Peter Thompson		
0.2	Updates made following May 2026 Authority meeting	Dina Halai, Rachel Cutting, Rachel Cooper, Frances Flinter, Rosamund Scott, Tim Child			
0.3	Updates made following stakeholder engagement	Dina Halai, Rachel Cutting, Rachel Cooper, Frances Flinter, Rosamund Scott, Clare Ettinghausen, Peter Thompson		Circulated as draft as part of September 2026 Authority meeting papers	

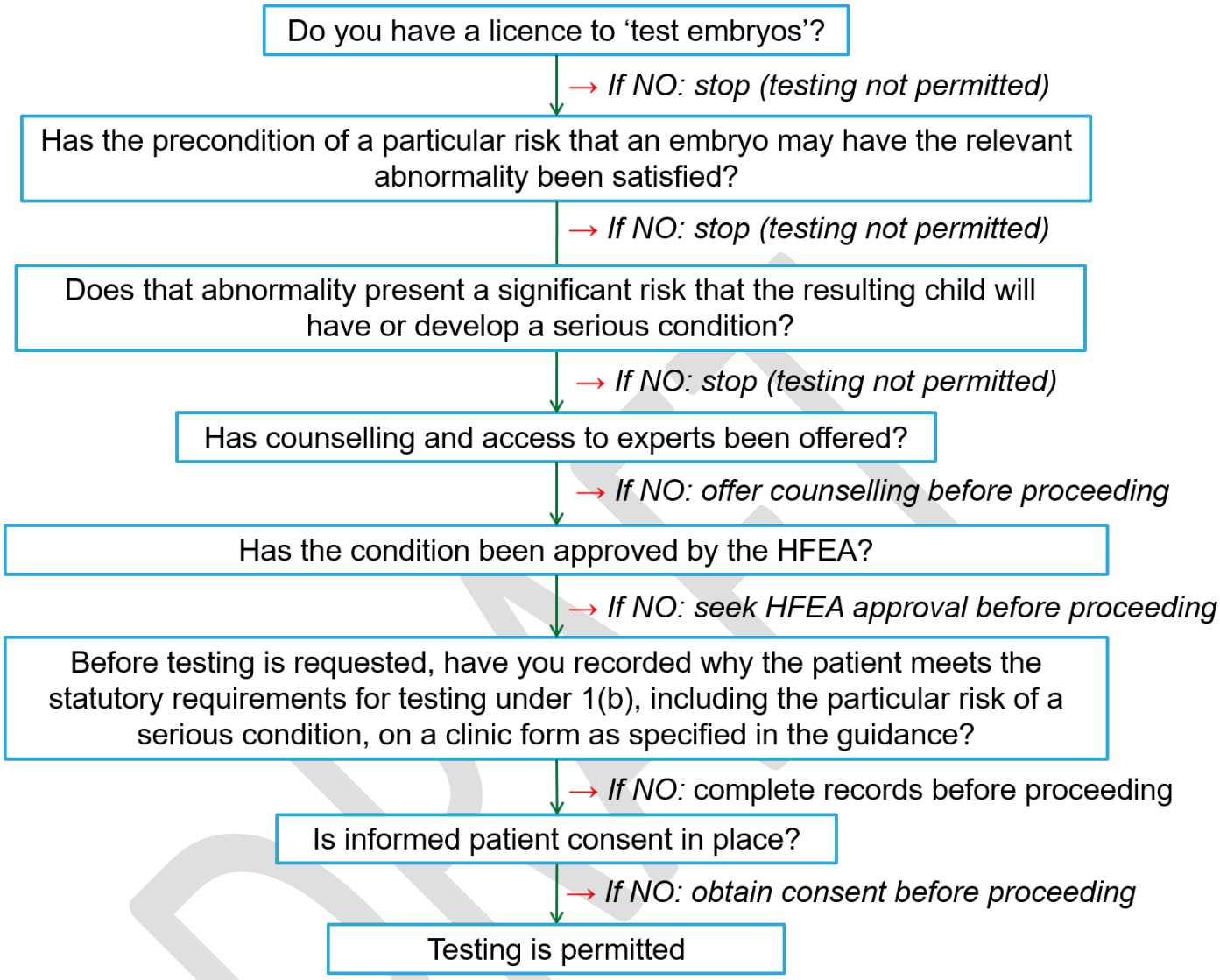
Annex A: Flowcharts

N.B. Clinics should refer to the above guidance on embryo testing for detail.

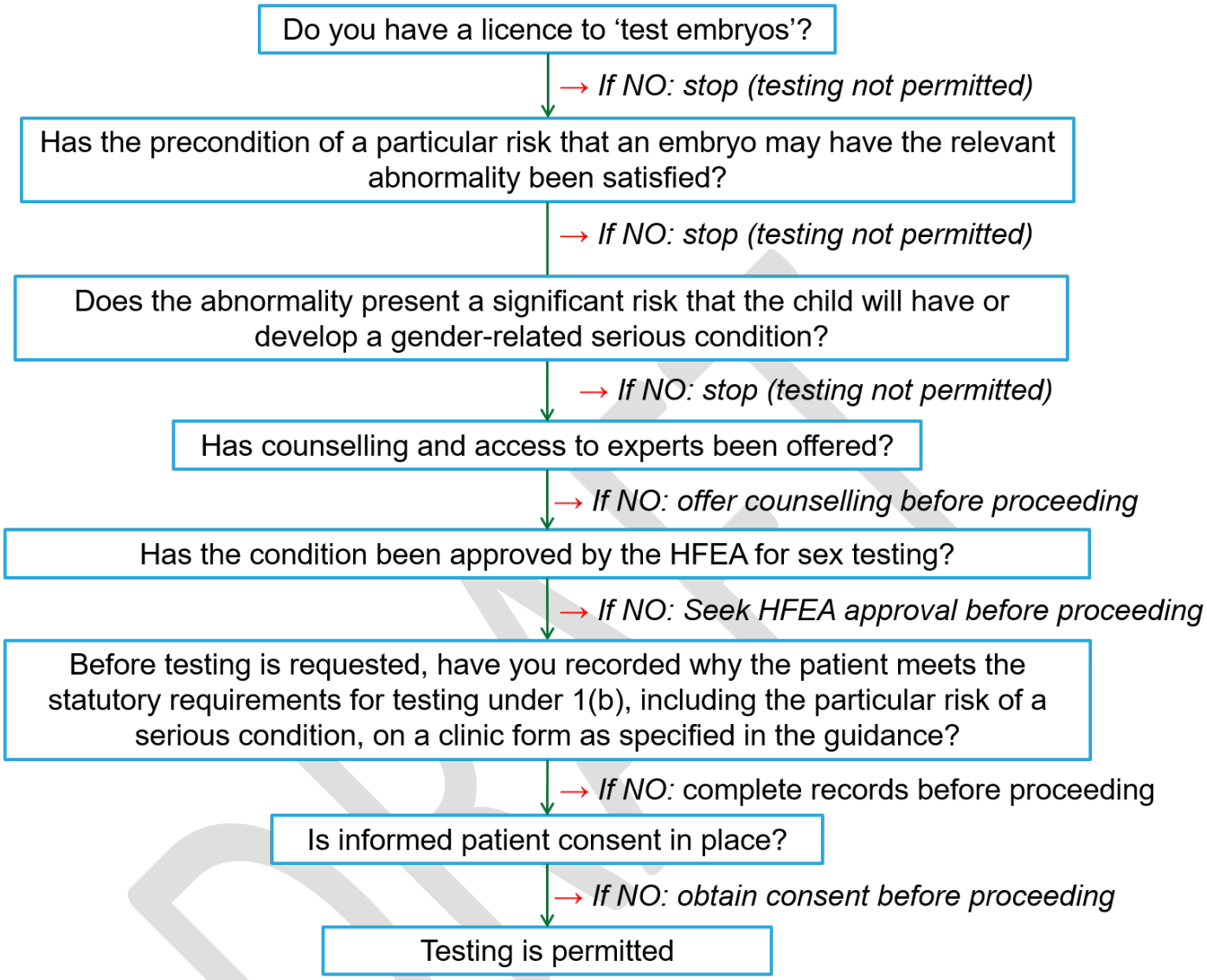
Flowchart for testing under 1(a)



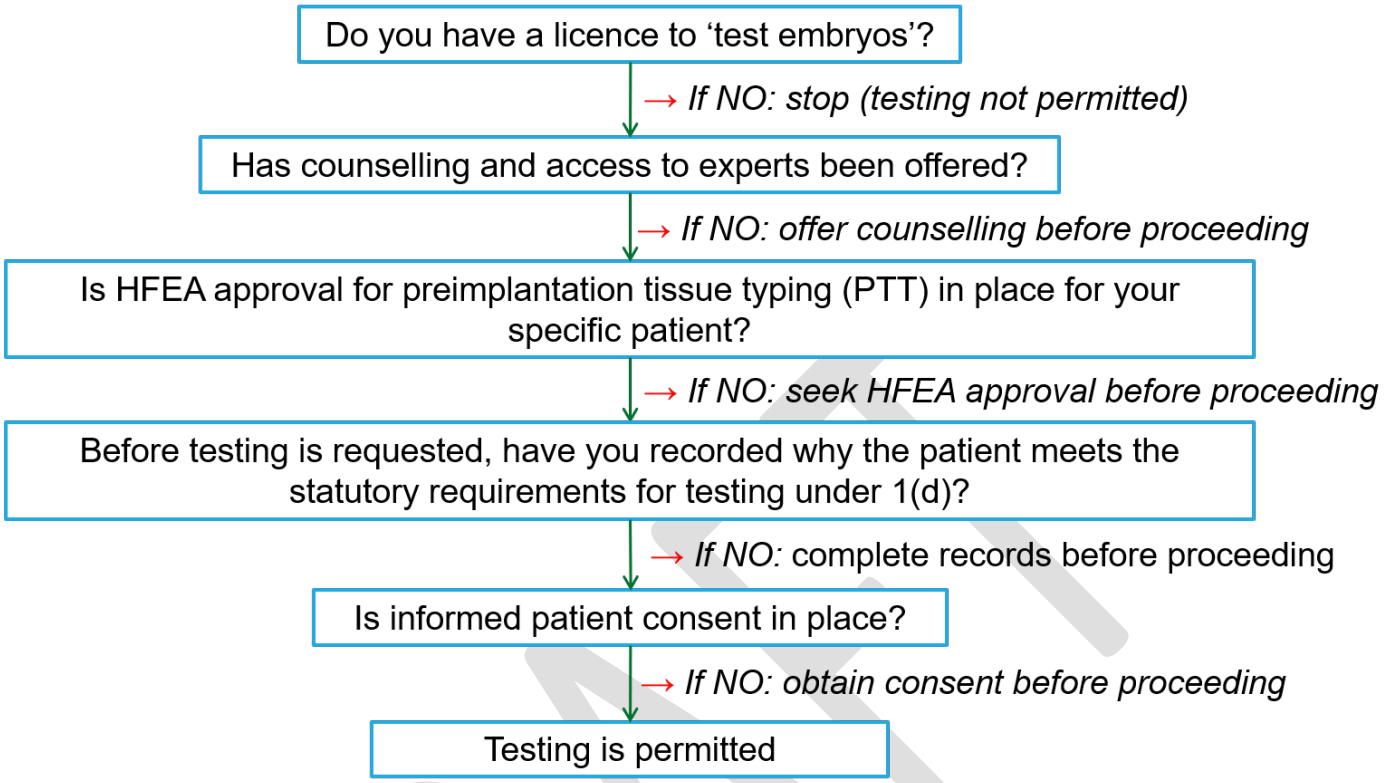
Flowchart for testing under 1(b)



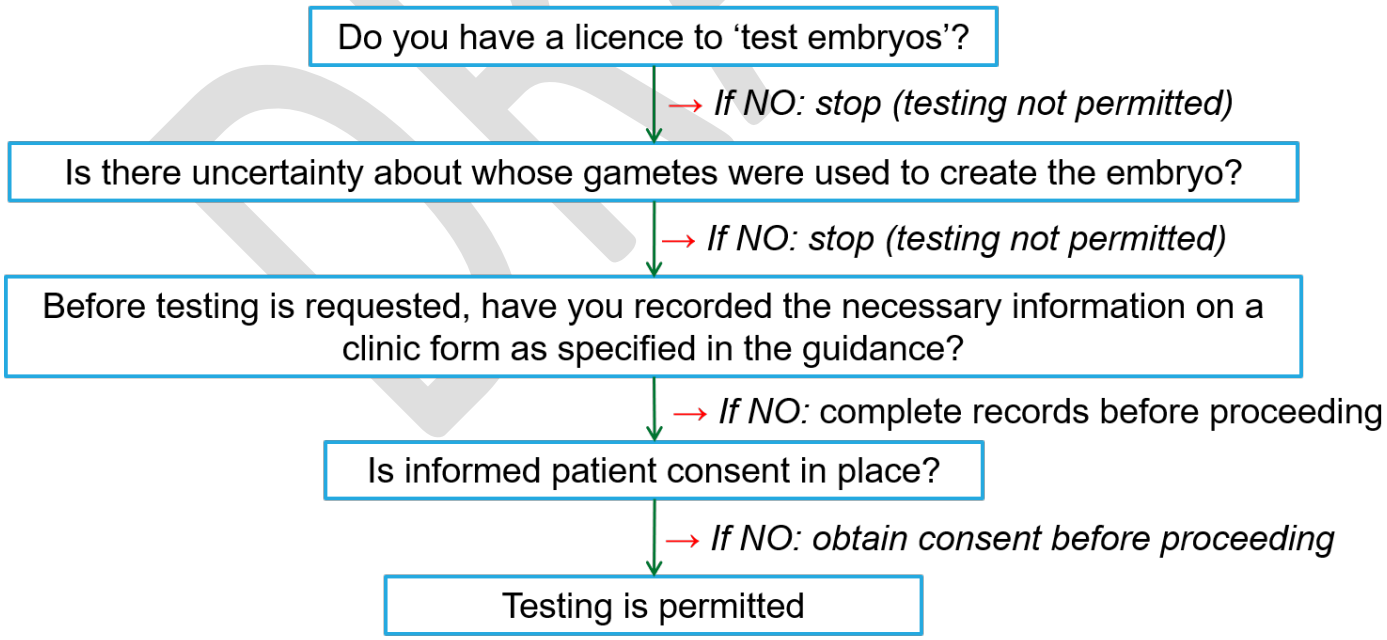
Flowchart for testing under 1(c)



Flowchart for testing under 1(d)



Flowchart for testing under 1(e)



Annex B: Advice from the UK National Screening Committee on additional genetic information being obtained and used in clinical decision-making when testing under 1(b)

UK National Screening Committee

UK National Screening Committee
Southside, 39 Victoria Street
London, SW1H 0EU
T +44 (0)20 3682 0923
www.gov.uk/uk-nsc

Dina Halai
Human Fertilisation and Embryology Authority
2nd floor
2 Redman Place
London
E20 1JQ

01 July 2026

via email

Dear Dina,

Re: Pre-implantation genetic testing of embryos — HFEA request for UK NSC guidance

Thank you for your email on the 09 June and subsequent meeting with several members of the UK National Screening Committee (UK NSC) regarding pre-implantation genetic testing of embryos.

As discussed, we have reviewed the query submitted and acknowledge the complex and increasing pressure the Human Fertilisation and Embryology Authority (HFEA) face on this issue.

The UK NSC has discussed this and provides some thoughts for HFEA's further consideration.

Testing/ Screening
There are important considerations in determining appropriate boundaries for testing embryos for additional conditions under section 1(b). It appears that the suggestion to test for more conditions could easily and inadvertently become a screening programme for which there is no evidence.

A key issue is the distinction between targeted testing for a specific genetic abnormality where a known particular risk exists, and broader testing for additional conditions in the absence of such a priori risk, which begins to resemble screening rather than risk-based testing. The intent of section 1(b), as we understand it, is to address a defined inherited risk where one or both members of a couple has a known risk (particular risk as defined in section 1(b)). Expanding testing beyond these parameters would move this from being a targeted, risk- based testing approach towards a form of general embryo screening, which is not underpinned by the same evidential, ethical or policy requirements. In the absence of a shared carrier status or relevant family history, the probability of an embryo being affected

by another genetic condition is very low and certainly no higher than the general population.

Concern regarding clinical validity and predictive value of testing in the absence of a particular risk
There are significant limitations in the clinical validity and predictive value of many genetic findings when identified outside a known (particular) risk context. In the absence of a relevant family history, the presence of a genetic variant does not reliably predict if, or how, a condition will present. Thus, in the context of the proposed expansion of testing to conditions other than the one initially eligible for testing under section 1(b) we cannot be confident that the significant risk criterion set out in the Act, (that the presence of the genetic variant in the embryo will result in a person with a serious mental or physical disability or medical illness) will be met. Further evidence would be needed to support this assumption. Therefore, there is a potential risk of embryos being discarded based on a finding of a genetic variant which may never result in serious clinical disease. This harm needs to be weighed against any potential benefit of identifying a clinically significant abnormality.

Equity/ Fairness amongst groups
The proposed expanded testing is not being offered to all persons undergoing IVF, only to those who are eligible for the initial testing under section 1(b). Others having IVF for reasons of infertility or where embryos are tested for aneuploidy under section 1(a) are not eligible to be offered the expanded testing. This raises a question of fairness across all groups undergoing IVF in terms of access to this expanded testing. While this selective approach is the only one legally permissible under the Act (on our reading of section 1(b)), there is a moral question of fairness to be addressed in justifying this approach.

Risk of increased tolerance for discarding embryos based solely on genetic testing
The broadening of embryo testing in this way may result in, or even normalise, discarding of embryos based on a genetic test where there is significant uncertainty about its clinical relevance. Unlike in neonatal genetic testing there is no opportunity for confirmatory testing or opportunity to treat the condition. This is a sensitive and complex area that would require further ethical, legal and public consideration.

Consent
There are practical and ethical challenges in securing valid informed consent as the scope of testing expands. Achieving meaningful consent would require detailed, condition-specific genetic counselling for each additional condition, which may not be feasible at scale and may undermine the validity of consent.

Commercial pressure
There are also concerns that expansion of embryo testing may be driven, in part, by commercial pressures, rather than by a strong evidence base, with potential

implications for patient expectations and decision-making particularly where the significance and predictive value of findings are uncertain. This is an area which the UK NSC is continuously contending with in light of commercial companies offering screening for a variety of conditions in the absence of evidence and treatment, perpetuating that more is better. As private screening is not well regulated but is becoming more accessible, the risk is that the demand of such offers overtake the evidence base leading individuals who engage with private screening, then seeking follow up of clinical advice and clarification through the national health service and the UK NSC.

Summary
The UK NSC would advise against expanding testing to conditions without a particular inherited risk and in the absence of robust evidence.
The UK NSC is concerned about the ethical implications such an offer would generate. Further consideration is needed to fully understand the implications of such an offer and to avoid testing becoming screening. It wold be advisable that public information, engagement and guidance issued by experts is sought to strengthen HFEA's position.

Yours sincerely,

Dr Graham Shortland
Vice Chair, UK National Screening Committee

Prof Anne Mackie
Director of Programmes, UK National Screening Committee

Annex C: Wording on genetic testing in the HFE Act 1990 (as amended), standard licence conditions and code of practice

Section 13, 1990 Act: Conditions for treatment

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

to this Act….

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

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition,

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

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

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

(b) a gender-related serious illness, or

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

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

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

(a) it affects only one sex, or

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

Schedule 2, 1990 Act

Para 1ZA – Embryo Testing

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

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

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

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

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

(ii) a gender-related serious illness, or

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

establishing the **sex** of the embryo,

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

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

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

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

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), **that there is a significant risk that a person with the abnormality will have or develop a serious** physical or mental disability, a serious illness or any other serious medical condition.

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

(a) it affects only one sex, or

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

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

<u>Paragraph 1ZB - Sex selection</u>

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

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

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

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

(b) a gender-related serious illness, or

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

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

(a) it affects only one sex, or

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

Extracts from the Code of Practice:

1.1. Prohibitions on embryo selection are as follows:

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

[1] Licences for treatment

Future of data presentation on the HFEA website

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:	8
Meeting date:	23 September 2026
Author:	Clare Ettinghausen, Director of Strategy & Corporate Affairs
Annexes	Annex A: Data on the HFEA website Annex B: Annex B Current and mock-up of future landing page for accessing HFEA data

Output from this paper	
For information or decision?	For decision
Recommendation:	The Authority is asked to decide: • the principles of data presentation on the HFEA website • Should HFEA data be moved to be published in a single source or single source of access where possible? • Should the HFEA continue to publish only verified data or in future publish unverified data? • Should the HFEA provide raw data for external use. Should this be under licence or with widespread use of AI tools, an unnecessary step that will quickly become outdated? • Should the inspection ratings be reviewed as part of the wider discussion on risk-based inspection? Should the patient ratings be continued?
Resource implications:	To be resourced by HFEA staff
Implementation date:	Ongoing into the next business year
Communication(s):	Ongoing
Organisational risk:	Low

1. Introduction

1.1. The Human Fertilisation and Embryology Authority (HFEA) is required by the Human Fertilisation and Embryology Act 1990 (the HFE Act) to ensure every licensed fertility clinic in the United Kingdom (UK) submits treatment and outcome information. The HFEA holds information on fertility treatments, patients, partners, donors and children born as a result of these treatments in the UK on a secure database known as 'The Register', which is believed to be the longest running database of its kind in the world. We use this data to improve patient care and support researchers to conduct research, while ensuring very strong protection of patient, donor and offspring confidentiality.

1.2. We have collected data on all IVF and donor insemination treatments performed in the UK since 1 August 1991. In recent years this has represented around 100,000 cycles of treatment and storage per year.

1.3. We publish a subset of this data in various ways on the HFEA website as part of our statutory responsibilities under section 8 of the HFE Act to provide information. This is primarily through the national level data on the **HFEA dashboard**, **research reports** and clinic level data on **Choose a Fertility Clinic**. Cycle-level data can be made available to researchers through application to the **Register Research Panel**. Annex A shows examples of this. We also regularly provide data on specific issues via **Freedom of Information** requests or **parliamentary questions**.

1.4. During the discussions on updates to Choose a Fertility Clinic (CaFC) during 2025 the Authority agreed that the range of data published on the HFEA website for patients and the public should be reviewed to see if there could be better ways of presenting this data.

1.5. An early discussion of this took place in **January 2026** and again in **March 2026** and the key points from these discussions are set out in section 2 below.

1.6. The aim of this paper is for the Authority to make decisions on key aspects of this work so that it can be progressed over the next business year.

1.7. This paper re-caps the previous discussions with the Authority on these issues; section 3 summarises activities since March 2026; section 4 outlines the principles and section 5 lists the issues for decision; and section 6 proposes next steps.

2. Previous discussions with the Authority

2.1. The Authority discussed issues relating to how data was presented on the HFEA website in **January 2026** and the following points were discussed. This was an early discussion and does not represent HFEA policy positions.

Publishing of data

- Consideration should be given to potential advantages of making the full data set available to reputable organisations and the HFEA being seen as an authoritative source of information and stimulating research.
- Consider the possibility of providing the full data through APIs, so organisations which have their own patient facing websites in the fertility sector could provide CaFC data.

- It was stressed that it is very important for the HFEA to have accurate data for the Register, but that CaFC data only needs to be accurate to a percentage. If all clinics were submitting at the level of the best quality data submission, then the data could be publishable in near real time. The more clinics that can improve the quality of their data submission, the gap between entry of data and publication can be closed. There is a need to balance between fine detail accuracy and timeliness of data submission and the potential ability to provide patients with current data rather than historical data.
- It was noted that if the next publication is Summer 2026, we will be presenting pregnancy outcomes some 8 months after the last data publication and patients may like the option of more frequent data updates.

HFEA explanations of data and principles

- The viewing stats for the full CaFC were high and it reflected the need for this information and that the HFEA was seen as an authoritative source of data although it was noted that very few users go down to detailed individual clinics' statistics.
- In considering the future presentation of data on the HFEA website and whether verified or unverified data could be used, it was important not to mislead users and there may potentially be commercial sensitivity of unverified data.
- Suggested principles which could be used when considering the wider question of how HFEA provides its data could be clarity, fairness and user friendliness.

2.2. The Authority then discussed this in **March 2026** when the following points were made. This was again a wide-ranging discussion and does not represent HFEA policy positions.:

Usefulness of HFEA data and verification

- The data HFEA provides is a useful resource that is available to everyone, and it should continue to be easily accessible to both patients and researchers.
- Working with the different users of the HFEA's data, including patient groups, so that a wide range of views can be taken into consideration when planning changes to the presentation of HFEA's data. Healthcare workers, including commissioners, should be included in the group of users and their requirements for data and how they will use it should be taken into consideration.
- Consideration of verified versus unverified data noting the benefit of providing up-to-date information for patients. Clinics must ensure the data they have submitted is correct for CaFC, it could be possible in the future to move away from the large piece of verification work if clinics continued to improve their data submission.
- However, it was also considered that unverified data should be used carefully, and reasonable caveats would be required that would need to be worded in lay terms for the public.
- Other members were more enthusiastic about unverified data if it meant that the available data could be more recent.

Accessing HFEA data

- Consider how people are accessing information, with the younger generation moving away from fact-based websites to influencer generated content. Any changes to the presentation of HFEA's data must ensure that it is applicable to the next generation including the growth of AI and how this could affect and change data presentation in the future.

- Given this, we should consider how much time, effort and resources should be allocated to future data presentation when the true effect of AI has not yet been realised.

Data submission and interpretation

- The Chief Executive spoke about the possibility of building incentives into data submission, so that the data that clinics submit the first time, is accurate and useable.
- The interpretation of the data which the HFEA undertakes and the quality of the reports which the HFEA produces such as the fertility sector 2024/25 and fertility treatment trends and figures 2023 was considered valuable.

Patient and inspection ratings

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

3. Activity since last discussed by Authority

3.1. Since the Authority last discussed this in March, further internal consideration of data presentation has taken place to refine the principles below and issues for decision.

3.2. As CaFC publication has been undertaken, the planned launch of inspection dashboards and publication of Fertility Trends in June 2026 have given further opportunities to consider both the principles and the issues set out below.

3.3. Following the Authority meeting in March, we have also had outline discussions with the HFEA stakeholder groups (**Patient Organisation Stakeholder Group, Professional Organisation Stakeholder Group and Licensed Centres Panel**).

3.4. We set out the background to this discussion from the decisions the Authority made on CaFC onwards; we outlined the different sources for publishing data on our website showed some examples of data presentation elsewhere including the **RCOG elective recovery dashboard**; fertility data from the **US based SART data**; and the Australian fertility clinics **success rates website**. These had previously been shown in a presentation at the Authority meeting in March 2026.

3.5. An indication of the ambitions and principles that would apply to future presentation of data was discussed and then a series of questions was asked of the groups:

- Should HFEA data be available in a single source? What would be gained/lost by this?
- Is it more important to have up to date unverified data OR older verified data? Data is two years old – does this matter?
- Is it more important to make as much data freely and easily available than using our interpretations? Is there value in HFEA explanations
- Are inspection and patient ratings still relevant in an environment where there are numerous ratings available?

3.6. We received similar feedback on these questions from the stakeholder groups as received by the Authority. This is summarised as:

- All groups felt it important to have HFEA data as an impartial trusted source of data.

- For patients (and for clinic staff to discuss with patients) having more statistics at the outset can be confusing. Many want to start with 'top level' and work through options rather than be presented with lots of different options at the start.
- The groups did not express a strong view about publishing verified or unverified data.
- The patient and professional stakeholder groups agreed with the Authority that the current patient feedback mechanism adds little of importance. However, some LCP members felt that as it was current (refreshed annually) it was better than other systems (such as google reviews) where reviews stay up forever. They felt that the feedback mechanism was good but flawed and those flaws could be fixed - for example, it was raised that if there were multiple vexatious reviews on CaFC then these could be removed by the HFEA.
- Most thought the current inspection ratings were not understood or helpful and should be changed. (NB is this part of wider regulatory policy work on looking at risk-based inspections.)
- Although participants were unsure about a single source of data, it was helpful to have an agreed set of definitions and a single point of access to HFEA data.

4. Principles for data presentation

4.1. The Authority briefly discussed some example principles in March 2026. The draft principles below assume that any future data presentations fit with wider government and health service principles and an underlying ambition to ensure that there should be a single point of access (if not a single source of information) and consistent metrics (data sources) used.

- **Transparent and accessible** - to publish as much information as possible with the data we hold within the boundaries of the law, freely available in the most accessible way.
- **Useful and usable** – the aim of any data presentation should be to ensure data is relevant to the users' needs, for example, to help patients and the public to understand different treatment types and outcomes and draw comparisons between clinics.

5. Issues for decision

Should HFEA data be available in a single source of access?

5.1. The current different types of data presentation reflect that the same statistics are shown in different ways, depending on the use and audience.

5.2. A single source of data for public consumption could be in a much larger dashboard that has both national and clinic level data in one place. At present, this data is in several different places on the HFEA website and not easy to switch from one to another. There is therefore merit in considering whether this data should be available in a single source so that all users enter the data at the same point. However, different users have different needs and to accommodate all users via one source (e.g. a dashboard) might mean it becomes overly complex.

5.3. An emerging view is that a single source of data may be problematic and separating national fertility data from clinic level data continues to be helpful. Therefore, as long as the source of

the information is the same starting point (the Register) then multiple outputs may be more appropriate to meet different user's needs.

5.4. Work being undertaken by the Head of Information to clarify all HFEA metrics and definitions will support this work while allowing flexibility of presenting the same set of data in different contexts based on user requirements if needed.

5.5. A single source of access to data may be the best way of resolving this. This is shown in rough below at Annex B.

5.6. The example **here** shows a single source of access to data but with different outputs, depending on what the user wants to view.

5.7. **For decision: should HFEA data be published in a single source or single source of access where possible?**

Newer verified data or older unverified data?

5.8. At present we mainly publish verified data which means that data is old before we publish it as we wait for outcome information from the treatments submitted by licensed clinics then validate and process the data received. Data verification involves data quality checks that verify treatment, pregnancy and birth outcome data with licensed clinics and delays data publication. Some fertility data sets are published as both preliminary and final such as those from the US based **SART**. ONS births data is provided up to the end of the previous year.

5.9. At present clinics report data to us via PRISM, that is then verified on a periodic basis. Should we decide not to run the verification process, automate the process or run it more regulatory then we would have more current data to publish.

5.10. Some LCP members felt that although it would be helpful to patients to publish more recent clinic level data, the benefit would be outweighed by publishing unverified data which could change over time.

5.11. One of the benefits of PRISM has been that the 'error rate' of data inputted by clinics directly to PRISM has reduced to the extent that clinic level performance data need not be verified before publication. Data submitted by third party systems (currently 73% of clinics) is not yet at the same low error rate as PRISM but the quality of data submission is generally improving. Taken together, this suggests that the value of verification is likely to diminish over time, or at least the risk of verification changing published data significantly should diminish.

5.12. Moreover, other data sets change over time and there will be more up to date data on inspection dashboards that will be reported in inspection reports from later this year. It may be that publishing unverified data has a consequence of incentivising clinics to provide more timely, good quality data first time. If inspection dashboards are part of the information gathered to further develop risk-based inspection and regulation, then it might be asked why we would withhold this information from the public.

5.13. Against that, the current system, with most data published being two years old is accepted and understood and that may be an argument for keeping with the present system for now at least.

5.14. A consequence of the next CaFC update (planned for September 2026) is that data related publications are now out of step. The CaFC September 2026 update has treatments for 2025 and births for 2024. Fertility Trends and the HFEA dashboard has data only going up to 2024, so treatment data by clinic will now be out of step.

5.15. The Authority may want to consider whether a decision below is implemented over time in line with any changes to CaFC to move away from the current intensive and lengthy verification process.

5.16. For decision: Should we continue to publish only verified data or move to publish unverified data?

Value of HFEA data explanations

5.17. A key aspect of our current data output - primarily through Fertility Trends - is that the data is accompanied by a commentary or explanation of the data to enable patients, and the public to better understand the information presented. This requires care and attention, and it could be argued that it would be better to only provide raw numbers without explanation.

5.18. The benefits of issuing reusable published datasets are that we could provide more data in this way and that would be helpful in terms of transparency and require less resource. Alternatively, it could be argued that having HFEA explanations helps understanding and is important for public trust in these important data sets.

5.19. A further consideration is the publication of data sets in a format that enables the creation of 'league tables'. This was discussed previously at various Authority meetings (most recently in May 2021) when the Authority re-affirmed the assumptions below.

5.20. It was previously agreed that clinic data should not be provided in a format that creates league tables for the following key reasons: clinics treat different categories of patients so comparisons are not possible and therefore patients should be encouraged to look at more than success rates; success rates themselves may not vary much from one year to next; many patients have little choice of which clinic to use; how would patients of a clinic at the lower end feel?

5.21. However, with the widespread use of AI tools now to collect HFEA data and information from other websites, creating comparison or league tables is very simple, with or without the publishing of the 'raw data' from the HFEA and there are several websites already publishing this information using HFEA data.

5.22. One alternative that has been previously mentioned by the Authority is to enable permission to use to HFEA data only under specified terms and conditions – SART for example, has a form if non-patients wish to use the data; and the National Institute for Clinical Excellence (NICE) has an open content licence.

5.23. **For decision – should the HFEA provide the raw data for external use. Should this be under licence or with widespread use of AI tools, an unnecessary step that will quickly become outdated?**

Are inspection and patient ratings still relevant?

5.24. Current CaFC pages have inspection and patient ratings. These have been commented on in various discussions with different viewpoints aired.

5.25. For **inspection ratings** it is generally felt that they are not widely understood and the length of a licence (the sole determinant of the current rating) is not a good tool for comparing clinics. Part of the wider work we are undertaking on risk-based inspection is looking at how clinics can be assessed and if the Authority want to review what is included in an inspection rating, then this is the relevant piece of work to consider any further inspector (HFEA) ratings.

5.26. **Patient ratings** have mixed feedback. In an environment where there are numerous ratings available, the small number of ratings most clinics receive is not indicative of the level of patient care. In inspection reports, the ratings are always noted, together with the centre's own patient feedback, which nearly always has a much higher response rate.

5.27. Over several years, we have encouraged clinics to increase the numbers of patients providing reviews on CaFC as well as publicising the mechanism ourselves. Neither route has dramatically increased the number of responses, although there is a large disparity between the clinics that have a large number of responses and those who have few or none.

5.28. An advantage of the CaFC ratings are they are reset annually, unlike for example, reviews on google that stay indefinitely. Secondly, they are a mechanism for patients to provide feedback that is seen directly by inspectors and can be broached with the clinic on inspection.

5.29. However, the reviews are not verified and some clinics have suffered from repeat identical reviews that are clearly intended to lower a clinic's overall rating. There was also a historical attempt for a bot to access the ratings.

5.30. In order to have an improved patient ratings system, for example, to add in a user verification process, would require development and other resources.

5.31. **For decision: should the inspection ratings be reviewed as part of the wider discussion on risk-based inspection? Should the patient ratings be continued?**

6. Next steps

6.1. Following the Authority meeting, we will work to implement the Authority decisions and outline a timetable for this work in the business plans for the remainder of the current 2025-2028 HFEA strategy.

6.2. Where decisions are made to change how we present data, we will develop example pages with the input of the Patient Engagement Forum as well as members of our patient and professional stakeholder groups and Licensed Centres Panel.

6.3. As this work progresses, we will keep the Authority updated and bring back significant developments and/or further items for decision.

7. Authority decision

7.1. The Authority decisions below will enable a piece work to progress in line with the decision to design how data on our website could be shown in the future. These decisions are not in relation to the current CaFC system.

7.2. The Authority is asked to discuss and agree or amend the principles set out above

- **Transparent and accessible** - to publish as much information as possible with the data we hold within the boundaries of the law, freely available in the most accessible way.
- **Useful and usable** – the aim of any data presentation should be to ensure data is relevant to the users' needs, for example, to help patients and the public to understand different treatment types and outcomes and draw comparisons between clinics.

7.3. The Authority is asked to discuss and decide on the following issues:

- Should HFEA data be moved to be published in a single source or single source of access where possible?
- Should the HFEA continue to publish only verified data or in future publish unverified data?
- Should the HFEA provide raw data for external use. Should this be under licence or with widespread use of AI tools, an unnecessary step that will quickly become outdated?
- Should the inspection ratings be reviewed as part of the wider discussion on risk-based inspection? Should the patient ratings be continued?

Annex A Data on the HFEA website

1. Choose a Fertility Clinic

Clinic level data for all HFEA licensed clinics

Most used area of the HFEA website with most users not accessing the more detailed statistics.

Clinic homepage statistics

Births per egg collection procedure (including fresh and frozen transfers and PGT-A but excluding donor eggs) (ages under 38, 38 and over or all)

Births per embryo transferred (including fresh and frozen transfers excluding PGT-A and donor eggs) (ages under 38, 38 and over or all)

Multiple birth rate (ages under 38, 38 and over or all)

More detailed statistics

2. HFEA dashboard

Customisable data from 1991 onwards

Well-used and quoted but we don't know who users are

HFEA dashboard

All cycles – Information on the number of treatment cycles and the number of patients, split by different treatment types.

IVF and ICSI cycles – Information on the number of In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) cycles and live births.

Donor insemination - Information on the number of Donor Inseminations (DI) cycles and live births.

IVF birth and pregnancy rates – Information on IVF and ICSI birth and pregnancy rates per embryo transferred and per cycle.

DI birth and pregnancy rates – Information on DI birth and pregnancy rates per cycle.

Sperm and egg donors – Information on the number of people becoming egg and sperm donors.

Funding – Information on the number and percentage of NHS and privately funded treatments.

Egg freeze and thaw – Information on the number of patients freezing and thawing eggs, and the average age when these cycles occur.

Multiple births – Information on the multiple birth and multiple embryo transfer rate.

3. HFEA data publications

Official statistics - source for all public information (beyond FOIs/PQs)

Fertility Trends

Covers main data points, birth rates, number of patients, multiple births, NHS funding etc

Includes underlying data set with tables not published anywhere else e.g.

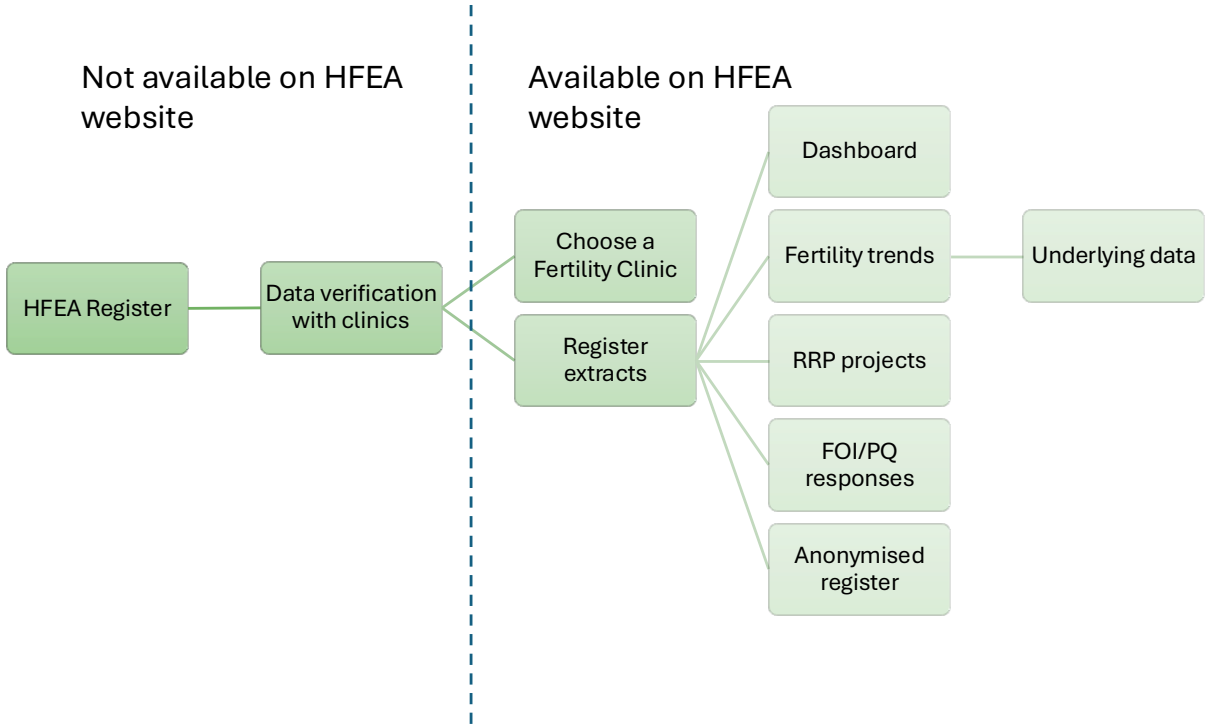
4. FOIs/PQs

As far as possible, responses to data queries in FOIs and PQs use published data. However, this is not always possible.

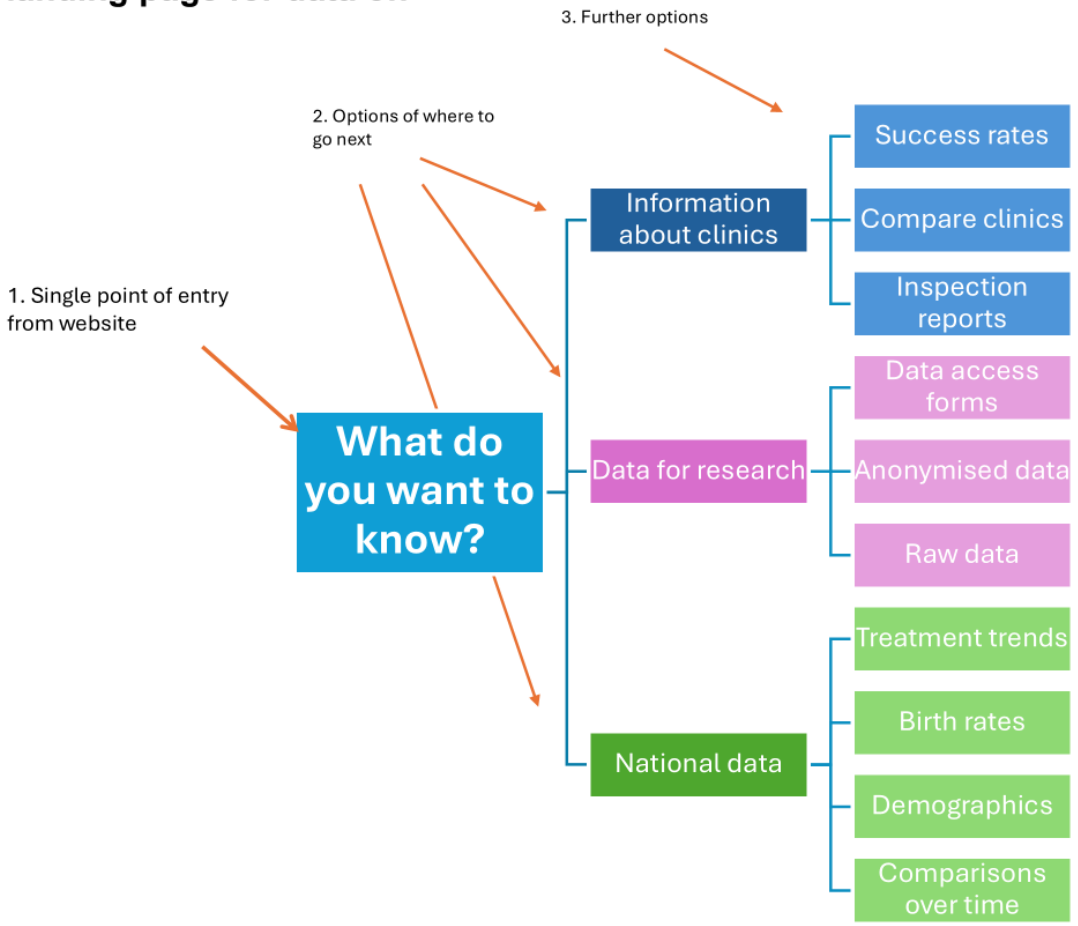
Statutory duty to collect data from clinics and provide information to the public			
Data output	**Customisable**	**Verified?**	**Available to all?**
Clinic level outcome data on Choose a Fertility Clinic	Yes – via website	Verified data with 2-year time lag	Yes
National register data on HFEA dashboard	Yes – via website	Verified data with 2-year time lag	Yes
Annual reports looking at trends in register data and deep dives	No – via website	Verified data with 2-year time lag	Yes
Data set for projects approved via the Register Research Panel	No	Verified datasets generally provided. specifically for each project	Published papers as a result of research but datasets no.
Anonymised Register	Yes - excel	Yes	Yes

Annex B Current and mock-up of future landing page for accessing HFEA data

Current display of data on HFEA website



Potential future landing page for data on HFEA website



Choose a Fertility Clinic – publication September 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:	9
Meeting date:	23 September 2026
Author:	Clare Ettinghausen, Director of Strategy & Corporate Affairs; Rachel Cutting, Director of Compliance & Information

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked: 1. For those clinics in the categories that have submitted partial or full data to the HFEA and/or have not signed it off (or expressed a wish that it is not published), their data is published on the HFEA website with a caveat if there are concerns about the number reported or lack of sign off. Only where a clinic has submitted insufficient data to calculate reasonably reliable headline statistics would no data be published – in such cases there would be compliance issues that can be advanced separately; 2. If data is subsequently submitted, then it will be added to CaFC in due course – therefore the incentive to publish is linked with step 4 below. 3. That future CaFC updates are published in line with decisions made above. 4. That future consideration will be given to how we can publish data error submissions, timeliness and error rates as a way of highlighting good practice.
Resource implications:	To be resourced by HFEA staff
Implementation date:	September 2026

Communication(s):	As set out in section 6
Organisational risk:	Low/Medium

1. Background

1.1. The Authority have discussed Choose a Fertility Clinic (CaFC) several times in recent years: in May 2025, July 2025, November 2025 and January 2026.

1.2. Those discussions related to the main profile page statistics and publication of the first full CaFC in January 2026 following the migration of the HFEA's Register data to a new database and the introduction of the new data submission system, PRISM.

1.3. The Authority agreed in January 2026 that following publication of the first full CaFC through PRISM, verification for the next CaFC update should start on 1 March 2026. This would cover treatments for 2025 and live births for 2024.

1.4. That process began and 95 licensed clinics were sent verification totals for checking with a deadline of end of May 2026. A few clinics requested individual extensions to the end of June which were granted.

1.5. The vast majority of clinics have submitted and verified their data as required, but there are a small number of clinics who have failed to comply with the requirements of data submission and verification in General Direction 0005.

1.6. As a result of this, the CaFC data update has been delayed until after this Authority meeting to allow for a discussion on the position the Authority wishes to take on publishing the data of those clinics that fall into this category. The decision will set out the way forward on, at least until any wider changes to the way we publish data are implemented.

1.7. This paper sets out the background to the current CaFC update; the situation in relation to the very small number of clinics that have not signed off their data and compliance with General Direction 0005 (GD0005); proposed next steps for those clinics that did not complete data submission and/or verification by the final deadline of 31 August 2026 and how to address similar issues going forward within the present CaFC system. The decisions sought are set out in section 5.

2. Current situation

2.1. For the CaFC publication in January 2026, if a clinic had not completed submission and verification of their data, we did not publish it, as agreed by the Authority in November 2025. The minutes of that meeting state:

For those clinics who will not meet the full CaFC publication deadline for this year, the Authority agreed that no information should be displayed.

2.2. This was followed by a Chief Executive's letter in January 2026 to all PRs that said:

For the small number of clinics that did not meet the full CaFC publication deadline, no data will be shown on the main profile page, old data will be removed, and there will be an explanation for why there is no data for that clinic. Once the appropriate data has been received and verified, it will be displayed on CaFC.

2.3. Because of the move to PRISM and updated Register, these clinics did not catch up with their submissions by the deadline. Data was published later for those clinics who caught up with data submission as set out in the Chief Executive letter.

2.4. This year, five years post-PRISM launch, there is a different situation as there are some clinics that have either not submitted all or some data or have not signed off their data. The PRISM programme manager has engaged with PRs to request and assist with submission and sign off

of data over the past several months and escalated to inspectors and the Director of Compliance and Information as required.

2.5. The issues with these clinics fall into different categories as set out below:

- Those that are still entering data as part of their catch up. Live births entered first, so current reported figures may be overstated (for this update, 2 clinics).
- Those that have entered all data for all years, but haven't responded to requests to confirm sign off (1 clinic).
- Those that have not entered any live births for 2024 and no treatments for 2025. So currently reporting 0% success rates and the clinic is not responding to any communications (1 clinic).
- Those where data entanglement from a closed clinic is preventing them reporting full data for current clinics, but there is sufficient data to calculate a success rate that we think is broadly accurate despite missing data (2 clinics).
- Those where data has been submitted for 2024, but where there are some missing early outcomes for 2025 so the pregnancy rate may be under reported. PR has expressly not given permission to publish. (For clarity, PRs have no such right of veto) (1 clinic).

3. Compliance with General Direction 0005

3.1. The rules regarding data submission are set out in General Direction 0005: Clinics are required to submit data within the timeframes specified, must correct errors within four weeks of submission and the PR must sign-off to verify that the data submitted is complete and accurate.

3.2. In the situation described in the paragraphs above, the clinic/PR has not met the requirements of General Direction 0005.

3.3. As the Authority will be aware, the HFEA has a statutory duty as set out in section 8 of the Human Fertilisation and Embryology Act 1990 (HFE Act) to provide information. This is primarily via our website, and the most used area of the website are the CaFC pages that enable patients and the public to view impartial and standardised clinic success rates.

3.4. In January 2026 when some clinics' data was published later than others, a caveat was put on their CaFC page that stated:

This clinic has not completed or signed off its data so it cannot be shown. This page will be updated when the data sign off process is complete.

3.5. The Authority agreed in November 2025 that as the previously published data dated back to 2018, it would be misleading for patients and therefore should be removed.

3.6. For this CaFC update, clinics have had time to catch up with data submission and if they are not ready to sign-off their data, or will not do that, then they are not compliant with GD0005.

3.7. This will be noted as a non-compliance in their next inspection report.

3.8. As regards CaFC we propose publishing data for those clinics set out above that has been submitted explained either as incomplete or not signed off by the PR. That is, where the data that has been submitted is sufficient to not be misleading to the public then we will publish it even where it has not been signed off by the PR. Or if there is so little data that publication would be meaningless, then no data will be published, and this would be explained.

3.9. As clinics are required to tell us when a treatment has been registered, publication should incentivise the reporting of early outcomes (pregnancies) and births and prompt timely sign-off by PRs in future. The proposed policy also has the merit of not acting as a disincentive for the large majority of clinics who have been diligent in providing their data and signing it off by the deadline.

3.10. In future we could consider publishing data error submissions, timeliness and error rates as a way of highlighting good practice on data submission in line with our statutory duty to provide information as set out above.

4. Future CaFC updates

4.1. When the PRISM programme first launched, the assumption was that data quality would be much improved and in time a full verification exercise would not be needed prior to CaFC publication. It was therefore envisaged that more regular CaFC updates would be published following the first full post-PRISM update in January 2026.

4.2. The clinics that are submitting data directly to PRISM have a very low error rate of 0.6%. (This accounts for 27% of all PRISM submissions).

4.3. Clinics submitting via an API have a higher error rate (depending on suppliers of between 2.0% and 8.3%) which accounts for 73% of all PRISM submissions.

4.4. Verification is time consuming for clinics and the HFEA alike. Going forward, we need to incentivise timely, accurate first-time data submission. To that end, we propose publishing a set of publication dates for future CaFC updates and ensuring clinics are aware of these. Once those dates are set, it will be the responsibility of clinics to ensure they have accurate data submitted to meet the deadlines we set. The HFEA will no longer chase clinics multiple times, although support will be offered if there are technical issues through the Register team.

4.5. Any decision by the Authority regarding caveats or other notes published with CaFC will be reflected in future CaFC publications using our current system.

4.6. To note that there is a separate ongoing discussion with the Authority about the future of data presentation on the HFEA website, which may in the longer term have an impact on how CaFC data is displayed (e.g. if it is moved to a dashboard) and may have an impact on future publication timelines. This would also be clearly communicated with licensed clinics in a timely manner as this work progresses.

5. For decision

5.1. The Authority is asked to consider the issues set out in the paper and decide whether to continue the policy established for the January 2026 update to CaFC, or whether to move to a general policy of publication. If the latter, then specifically:

1. For those clinics in the categories that have submitted partial or full data to the HFEA and/or have not signed it off (or expressed a wish that it is not published), their data is published on the HFEA website with a caveat if there are concerns about the number reported or lack of sign off. Only where a clinic has submitted insufficient data to calculate reasonably reliable headline statistics would no data be published – in such cases there would be compliance issues that can be advanced separately;
2. If data is subsequently submitted, then it will be added to CaFC in due course – therefore the incentive to publish is linked with step 4 below.
3. That future CaFC updates are published in line with decisions made above.
4. That future consideration will be given to how we can publish data error submissions, timeliness and error rates as a way of highlighting good practice.

6. Next steps

6.1. A Chief Executive's letter will be issued to all PRs following the Authority meeting to set out the decision.

6.2. A note will also go in the September edition of Clinic Focus to set out that publication has taken place, how many clinics have been included, and outline the Authority decision in relation to CaFC data publication for those clinics who are in the categories set out above.

6.3. Following the Authority decision, the remaining clinics' data will either be published or the existing data will remain with the appropriate explanations.

6.4. As set out in paragraph 3.7, any clinic who has not met the publication deadline will have this noted as a non-compliance at the next inspection.

6.5. In future years full CaFC submission deadlines will be published in advance and if these deadlines are not met then inspectors will be informed when a clinic does not comply with GD0005 so this can be noted as a non-compliance at the following inspection.

Human Fertilisation & Embryology Authority

Update on donation work

Authority meeting- 23rd September 2026

Donation: priorities for 2026/27

- Addressing the impact of the international donor sperm market
- Operational handling of OTR issues when dealing with Register discrepancies
- Donor restrictions, warnings and safeguarding mechanisms and managing new genetic information
- Ongoing engagement around unregulated sperm donation

Human Fertilisation & Embryology Authority

Stakeholder roundtable- addressing the impact of the international donor sperm market

- Bring together key stakeholders to explore the impacts of the international donor sperm market and large international donor sibling groups
- Consider the potential benefits/risks of different policy approaches
- Identify areas of consensus and agree any next steps for the HFEA and others

Human Fertilisation & Embryology Authority