

# **Authority meeting**

Date: 9 July 2025 - 1.30pm - 4.00pm

**Venue: 2 Redman Place** 

Agenda item Time	
Welcome, apologies and declarations of interest (5)	1.30pm
2. Minutes of the meeting held on 12 March 2025 (5) For decision	1.35pm
Chair and Chief Executive's report (15)     For information	1.40pm
Committee Chairs' reports (20)     For information	1.55pm
5. Performance Report (30) For information	2.15pm
6. Annual Report and Accounts (10) For decision	2.45pm
7. Strategic Risk Register (10) For decision	2.55pm
Comfort break (5)	3.05pm
8. Register Research Panel Annual Report (30) For information	3.10pm
Choose a Fertility Clinic focused consultation (25)     For information	3. 40pm
10. Any other business (verbal) (5)	
11. Close	



# Minutes of Authority meeting held on 21 May 2025

Details:	
Area(s) of strategy this	Regulating a changing environment
paper relates to:	Supporting scientific and medical innovation
Agenda item	2
Meeting date	9 July 2025
Author	Alison Margrave, Board Governance Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 21 May 2025 as a true record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	Low

# Minutes of the Authority meeting on 21 May 2025 held at 2 Redman Place, London

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Geeta Nargund Catharine Seddon Rosamund Scott Anya Sizer Stephen Troup Christine Watson
Apologies	Steve Pugh, Department of Health and Social Care (DHSC) (online)	
Observers		
Staff in attendance	Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Rachel Cutting (Director of Compliance & Information) Tom Skrinar (Director of Finance & Resources) Sophie Tuhey (Head of Planning and Governance) Kevin Hudson (PRISM Programme Manager) (item 6) Luke Reader (Phoenix Programme Manager) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

#### **Members**

There were 14 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 meeting.
- **1.2.** The Chair also welcomed observers and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. The recording would be made available on the HFEA website to allow members of the public to view it.
- **1.3.** Declarations of interest were made by:
  - Geeta Nargund (clinician at a licensed clinic)
  - Anya Sizer (freelance advisory work within the fertility sector)
  - Stephen Troup (consultancy work within the fertility sector)
  - Tim Child (consultancy work within the fertility sector overseas)

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

**2.1.** The minutes of the meeting held on 12 March 2025 were agreed as a true record of the meeting and could be signed by the Chair.

#### Matters arising

- **2.2.** The Chair introduced the report and informed members that the items had been actioned as detailed in the report.
- **2.3.** Members noted the matters arising report.

## 3. Chair and Chief Executive's report

- **3.1.** The Chair gave an overview of her engagement with key stakeholders and her attendance at decision-making committees of the Authority.
- **3.2.** The Chair informed members that together with the Chief Executive they attended meetings with Baroness Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health, and the HFEA's sponsor minister, in March and April. The meetings were primarily to discuss the HFEA's proposals for law reform. The Chair informed members that Baroness Merron had thanked the HFEA for the work that it does, which is held in high regard.
- **3.3.** The Chair informed members that she had sat on the interview panel to appoint a new member to the Scientific and Clinical Advances Advisory Committee (SCAAC).
- **3.4.** The Chair thanked all the members for their participation in the year end appraisal process, these have now all been completed and will be submitted to the Department well in advance of the required deadline. She provided details of her appraisal, and the positive comments received about the work that the HFEA does.
- **3.5.** The Chair informed members that she was working with the Board Governance Manager to refresh the periodic board effectiveness review, and this would be brought to the Authority away day in November.
- **3.6.** The Chief Executive referred to the Authority's discussion on Stem Cell Based Embryo Models (SCBEM) in January and informed members that he had attended a number of events discussing the possible stages for establishing a regulatory framework for SCBEM.
- **3.7.** The Chief Executive informed members that he had participated in the International Network for Delivery of Regulation (INDR) Roundtable conference 'Shaping the future of regulation' at Wolfson College in Oxford. The Chief Executive spoke about striking the balance between a robust regulatory framework whilst also supporting innovation.
- **3.8.** The Chief Executive informed members that the Irish Parliament had recently passed the Health (Assisted Human Reproduction) Bill 2023, which included measures for the establishment of a regulatory body similar to the HFEA. Continuing, the Chief Executive said that he had recently spoken at workshop on this and related topics at Maynooth University.
- 3.9. The Chief Executive referred to the Places for Growth update provided by the Government and stated that at the moment there is no information regarding whether ALBs will be affected. The Chief Executive stated that 50% of the HFEA's workforce is already located outside London and the current office lease is in place until 2030. The Chief Executive undertook to keep the Authority and staff updated on the potential impact on the HFEA.

#### Decision

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

# 4. Committee Chairs' reports

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

- **4.2.** The Statutory Approvals Committee (SAC) Chair (Frances Flinter) referred to the summary of the monthly committee meetings contained in the paper and the range of conditions considered. The committee were turning around applications quickly and she expressed thanks to both the committee members and the staff for their work. The SAC Chair commented on the excellent review and advice received from the external SAC Advisors.
- 4.3. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had held two exceptional meetings in April. The first meeting was to discuss proposals to impair the value of PRISM as currently included on the HFEA's balance sheet. The second meeting was to consider the recommendations to publish an Interim Choose a Fertility Clinic (CaFC) in May using the headline metrics proposed and suggested caveats; and verify the Full CaFC in one exercise, combing 2023 and 2024 data. The next AGC meeting is being held on 17 June.
- **4.4.** The Licence Committee Chair (Graham James) reminded members that the paper before them includes not only the decisions taken by the Licence Committee, but also the work of the Executive Licensing Panel and the Licensing Officer. The Licence Committee deals with the complex issues, and he remarked that it was pleasing to see the improvements made by clinics and this was reflected in the granting of their licences.
- **4.5.** The Chair thanked all Committee Chairs for the reports and expressed sincere thanks to the committee members and the staff who service the various committees for their hard work. The Chair stated that committee papers and minutes are published on the HFEA website.

#### Decision

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

# 5. Annual Performance report 2024-2025

- **5.1.** The Chair commented that the annual review of performance allows the Authority to review the performance over the past 12 months.
- **5.2.** The Chief Executive introduced the annual performance report for 2024-2025 and reminded members of the Key Performance Indicators (KPIs) which are used to measure performance.
- **5.3.** The Chief Executive stated that the HFEA's performance across all 19 KPIs had been consistently strong and improving throughout the year; where there was a particular drop it had only been temporary and for a valid reason. In March 2025, 13 indicators rated Green, three Amber, three Neutral and none were Red. The Chief Executive expressed his thanks to the staff for their continued hard work for the organisation.
- **5.4.** The Chief Executive referred to the HR KPIs and commented that staff sickness was generally below the 2.5% target.
- **5.5.** The staff turnover KPI is currently at 4% which is the lowest it has been for the past year. Given the pressures on public sector, this is a good result and the recent HR survey indicates that the HFEA staff are motivated and enjoy working for the HFEA.
- **5.6.** The Chair commented that at the last Chair and CEO DHSC ALB meeting she had attended it was clear that the HFEA's high staff engagement score and low turnover were not reflected

across all ALBs. She thanked the Chief Executive and leadership team for their skill and dedication in leading the HFEA.

#### Compliance and Information

- 5.7. The Director of Compliance and Information commented that the performance report shows a positive year and good performance with KPIs being met. As mentioned by the Chief Executive when there has been a delay in the inspection and licensing KPIs this is due to genuine reasons such as further engagement with PRs or the Compliance & Enforcement policy requiring management reviews.
- **5.8.** The inspection schedule has been planned for the forthcoming year, and it is a very busy schedule. Even with the busy inspection schedule the inspectors are engaging well with the Pheonix project.
- **5.9.** The Director of Compliance and Information stated that over the last twelve months 1,726 people had received information from the Opening the Register (OTR) service.
- **5.10.** The OTR team is fully staffed, and all are trained on the systems which has helped to reduce the waiting list to its lowest level, which is currently 738.
- **5.11.** The Director of Compliance and Information stated that the current average waiting time for OTR applications is just over eight months. There is currently a workstream to finish a lot of the oldest OTRs, which have been held up due to data complexities or clinic issues. When these are closed it is anticipated that the waiting time will reduce further.
- **5.12.** The Director of Compliance and Information informed members that over the past year the Register Team and IT Development Team had worked in close partnership to reduce the backlog of support tickets in PRISM. This collaborative work has brought the volume of outstanding queries down from over 1,000 in August 2024 to below 100 by 2 May 2025. This means that the team can now shift its focus from backlog clearance to efficient daily ticket handling, which is beneficial for the sector.
- **5.13.** The Chair commented that whilst the reduction in the OTR waiting list is encouraging an eightmonth delay is still a considerable wait time and asked whether it would be possible to report in a future meeting what the forward trajectory for reducing this wait time might be.
- **5.14.** The Director of Compliance and Information responded that a clear trajectory on the waiting list reduction time would be possible towards the end of the calendar year.

#### Strategy and Corporate Affairs

- **5.15.** The Director of Strategy and Corporate Affairs thanked several members for speaking on behalf of the HFEA at The Fertility Show and the British Infertility Counselling Association (BICA) Annual Conference.
- 5.16. The Director of Strategy and Corporate Affairs stated that performance has been good across the strategy and corporate affairs KPIs for the past year. Information requests were dealt within the required timeframes and these included enquiries, Freedom of Information requests and responding to Parliamentary questions.
- **5.17.** Proactive media enquiries were largely focused around the publication of reports such as the National Patient Survey, Family formations in fertility treatment and State of the fertility sector. The Director of Strategy and Corporate Affairs reported that there were over 260 pieces media for

- the National Patient Survey even though it was published on the same day at the Government's Spring statement.
- **5.18.** It was reported that social media engagement is increasing with continued growth for Instagram and LinkedIn. There has been an increase of 80,000 users for the HFEA's website, which correlates with the results of the patient survey that the HFEA's website is seen as a reliable source of information about treatment.
- 5.19. The Director of Strategy and Corporate Affairs referred to the Licensing KPIs and stated that over 200 individual items have been considered by Executive Licensing Panel, Licensing Committee and Statutory Approvals Committee. The volume of work in managing these items was explained and thanks were given to the Licensing Team, especially the Committee Officers for their work in supporting the committees.
- **5.20.** Members were informed that in addition to the items mentioned above the Licensing Officer had considered over 200 items and the work of the Licensing Team in managing these was acknowledged.
- **5.21.** The work of the Policy Team in leading on the scientific development work, patient protection safety items, proposed law reform and implementation of the changes in law relating to screening in fertility treatment was acknowledged.
- **5.22.** The Director of Strategy and Corporate Affairs informed members that since the last Authority meeting the Professional Stakeholder Group (PSG), and the Patient Organisation Stakeholder Group (POSG) had met. The next round of stakeholder meetings will be in the Autumn.
- **5.23.** The Chair acknowledged the media coverage obtained and commented that the work of the Authority is very relevant.

#### Finance, Planning and Technology

- **5.24.** The Director of Finance, Planning and Technology informed members that the new Head of Planning and Governance has settled well into the team. The team has been finalising the business plan and ensuring that teams across the HFEA have service delivery plans in place for 2025-26.
- **5.25.** A new Strategic Risk Register is being prepared to reflect the new strategy, which was recently adopted, and this will be presented to the AGC in June.
- **5.26.** The Governance team has been working on annual tasks such as updating biographies and declared conflicts of interest on the website and ensuring members have completed their mandatory training. Advance work is also taking place with the Licensing team for the recruitment of external members to committees that will be required in the next couple of years.
- **5.27.** The Director of Finance, Planning and Technology stated that the IT team has been very busy with a number of complex tasks, including supporting the IT development project, which will be discussed under agenda item seven.
- **5.28.** Members were informed that a penetration test on the HFEA's website will be carried out before the end of the month. The team is working with an external consultant to help strengthen its approach to business continuity and a test exercise is planned for the all-staff event in July.
- **5.29.** The Director of Finance, Planning and Technology informed members of the work that the IT and Information Governance teams have undertaken to support the new Cyber Assessment

- Framework (CAF) aligned DSPT requirements. This audit commenced that week and the HFEA must submit its formal return by 30 June. It is anticipated that this year's assessment will be tough and the HFEA will need to build on the recommendations arising from the audit. The CAF will be discussed with the AGC during their June meeting.
- **5.30.** The Director of Finance, Planning and Technology stated that it had been a busy time for the small finance team in preparing to finalise the year's accounts with the auditors. Members were reminded about the issues relating to duplicate activity returns submitted to PRISM in error by clinics over the past few years. The Finance and PRISM teams are working closely with the NAO to ensure that they have the evidence they need to confirm that the refunds are all present and correct. The current, pre-audit financial position for 2024/25 is a surplus of £133k, although there are likely to be some accounting and other changes as the audit position is finalised.
- **5.31.** Regarding the 2025/26 finances the main cost to be managed is the IT project. For the HFEA this is a high-cost project and whilst there is some contingency available the HFEA needs to manage costs and prioritise any additional investments as the project progresses.
- **5.32.** A member commented that with the recent high profile cyber attacks which had taken place it was reassuring to see the lessons learnt exercise and mitigations which the HFEA had put in place.
- **5.33.** A member congratulated the team for the outstanding good performance across all the KPIs and questioned, whether in the in spirit of continuous improvement more periodic reviews of the KPIs is needed to ensure that the organisation is being stretched. The Chief Executive stated that the leadership team will reflect on this challenge.

#### Decision

**5.34.** Members noted the annual performance report 2024-2025 and recorded thanks to the staff for their continued good work.

# 6. Choose a Fertility Clinic: next steps

- **6.1.** The Chair introduced this agenda item and stated that the Authority has a duty to provide information, and the Choose a Fertility Clinic (CaFC) function provides verified information on all UK licensed fertility clinics. CaFC incorporates both how the HFEA inspectors rate the clinics and how patients rate the clinic.
- **6.2.** Due to the migration of the HFEA's register data to a new database and the introduction of the new data submission system, PRISM, CaFC has not been updated with new data for some time and the Authority had previously agreed that a suitable caveat should accompany the data.
- **6.3.** The data in CaFC will be updated in two stages during the current year, the Interim CaFC will provide headline success metrics for birth rates for 2022. The Full CaFC which will conclude later in the year will provide both headline success metrics and detailed statistics on pregnancies to 2024 and birth rates to 2023.
- **6.4.** The Chief Executive introduced the paper and stated that the CaFC function provides a suite of information which provides patients with a starting point to measure success and orientate information. Each clinic has a dedicated website page with the following information (as relevant):
  - how HFEA inspectors rate the clinic

- how patients rate the clinic
- pregnancy and birth rates from different fertility treatments
- multiple birth rates
- waiting times for donated eggs, sperm or embryos (clinic inputted)
- details of the treatments offered, staffing and facilities at each clinic (clinic inputted)
- 6.5. The Chief Executive informed members that the work on the Interim CaFC began in mid-February, with clinics being issued with a calculation sheet that they were asked to verify. The Interim CaFC will be based on publishing three headline rates (the 'composite' headline rate, the 'fresh only' headline rate and the multiple birth rate). This will also include caveats that various practices can affect success rates such as the proportion of donor egg treatments or PGT-A cycles carried out by clinics. In addition, for clinics where the number of donor egg treatments and/or PGT-A cycles is above the national average, a note will be added advising patients that this can make it more difficult to compare that clinic's rate against the UK average and those of other individual clinics.
- **6.6.** The Chief Executive spoke of the work required for the Full CaFC and that clinics will be asked to verify 2023 birth rates and 2024 pregnancies in one single sign off sheet that will be issued to clinics in June.
- **6.7.** The Chief Executive informed members that there have been regular communications with clinics about the updating of CaFC, including a short survey which was described in the letter dated 7 May to PRs.
- **6.8.** The Chief Executive informed members that the headline metrics for CaFC were agreed in 2016-17 and that since then the balance of treatment activity in the sector and multiple birth practices have both changed significantly.
- **6.9.** The Director of Compliance and Information spoke of the changes within the sector noting that the balance of fresh and frozen cycles has changed. In 2012 20% of IVF cycles used frozen embryos and in 2022 that had increased to around 45% of cycles.
- **6.10.** The Director of Compliance and Information stated that due to the success of the One at a Time campaign, elective single embryo transfer has become commonplace in the sector with multiple births decreasing from 17% in 2012 to around 4% today.
- **6.11.** Members were informed that the use of donor treatments has increased from 11% in 2012 to around 16% of IVF cycles in 2022. The use of donor eggs to increase the likelihood of success was discussed.
- **6.12.** The Director of Compliance and Information explained how the growth in the number of cycles which use PGT-A, sometimes alongside 'batching cycles' may elevate the rate based on per embryo transferred and risks undermining the effectiveness of births per embryo transferred as a fair measure of clinic performance.
- **6.13.** Whilst fresh or frozen cycles with own eggs is still the most common treatment, the Director of Compliance and Information commented that the HFEA's current headline metrics could be reviewed to inform patient choice.
- **6.14.** The Chief Executive spoke about the short, focused consultation which would be undertaken with regard to the headline metrics used and then the longer-term work which could be undertaken in

- 2026 to review the HFEA's different information sources and consider whether they can be brought together in a more unified or different way.
- **6.15.** Members discussed the importance of having an authoritative source of data to help inform choice and how patients find it useful to compare clinic data in the same way. Members noted the work being undertaken to ensure CaFC was updated.
- **6.16.** Patients' reasons for sourcing this data were discussed and it was stressed that the HFEA data is not a predictive model and cannot answer patients' question of what their chances of having a baby are.
- **6.17.** Members discussed the increased use of PGT-A even though this is rated red as an add-on on the HFEA's website for most patients. Given the increase in use of PGT-A members discussed the benefits of considering publishing data on cycles started rather than embryos transferred.
- **6.18.** Members discussed the importance of the decrease in multiple births and how the One at a Time campaign had impacted behaviour within the sector. Given that multiple births are the single greatest health risk of fertility treatment members did not want to see a change in behaviour and an increase in multiple births if this metric was no longer published.
- **6.19.** A member spoke about The Society for Assisted Reproductive Technology (SART) in the United States of America and the way that they report birth outcome date from its member clinics. The use of their five-headline metrics was explained.
- **6.20.** Members discussed that the metrics used need to be a fair measure of clinic performance and that they need to be the most useful ones to inform patients and the public. The ability of PRISM being able to provide cumulative success rates was seen as a benefit for patients.
- **6.21.** A member spoke about how patients are accessing data and the increasing use of the NHS appwas highlighted as a shift in how the public access health information.
- **6.22.** Members felt that a consultation on the metrics used as detailed in paragraph 3.5 of the report before the Authority, and a longer term look at how this information might be presented was timely. Members noted the focused nature of the proposed consultation on headline metrics, involving clinic staff, stakeholder groups and the patient engagement forum. Some members raised the desirability of ensuring a wide range of voices are heard such as patients from diverse ethnic and socio-economic backgrounds. The option of having a free text response in the consultation was raised, while recognising that this might not be possible in the focused consultation and may form part of the wider work scheduled for 2026 and beyond.

#### Decision

#### **6.23.** Members noted:

- the progress made on updating CaFC this year and the work planned to the end of 2025.
- the merits of undertaking a wider review, beginning in 2026, of how the HFEA various data sources might be unified or presented differently in future.

## 7. Phoenix Programme

**7.1.** The Chair introduced the agenda item and spoke of the importance of having robust IT infrastructure that supports the work of the Authority.

- **7.2.** The Director of Finance, Planning and Technology introduced the paper and explained that the over-riding aim of the Phoenix programme is to replace aging systems with modern, cloud-based solutions that will be resilient and efficient, and provide the HFEA with options to innovate more easily, for example through the use of AI.
- **7.3.** The Director of Finance, Planning and Technology explained the scoping and procurement process undertaken and the involvement of the DHSC commercial team in managing the procurement process. Following the tender process Ceox were awarded the contract which covers the replacement of the three systems and 12 months of initial support.
- 7.4. The Director of Finance, Planning and Technology spoke of the governance structure and risk management of the Phoenix Programme and how the HFEA has continued to engage with other organisations to learn from their experiences in implementing major IT change programmes and risk. He stated that the Care Quality Commission (CQC) have published a lessons-learned report into their own IT Transformation Project which had significant challenges: Independent IT review: executive summary Care Quality Commission. The Director of Finance, Planning and Technology explained the pro-active approach the HFEA had taken to minimise the risk areas highlighted in the CQC report.
- **7.5.** The Director of Finance, Planning and Technology explained the reporting structure with a monthly Programme Board meeting, a monthly verbal report to the Corporate Management Group (CMG), a weekly update email issued to all relevant HFEA and Ceox staff and quarterly written report to the Audit and Governance Committee (AGC).
- 7.6. The Director of Finance, Planning and Technology concluded his presentation by stating this is a complex and challenging change programme, but it has a significant opportunity for success. He spoke of the clear focus from senior managers and the positive engagement of staff generally. As the programme progress the programme team will focus on maintaining this positive level of engagement to ensure that the HFEA can foster the right mix of pragmatism and innovation to deliver the IT improvements.
- **7.7.** Members congratulated the HFEA for a clear paper which sets out the programme in detail, members were pleased to see the lessons learnt from other ALB IT projects and the steps that the HFEA had put in place to ensure success of their project.
- **7.8.** Members were appreciative of the clear governance and reporting for this project and noted that the AGC will have oversight of the programme on behalf of the Authority.
- **7.9.** In response to a question the Phoenix Programme Manager confirmed that there could be further benefits realised through the programme such as SharePoint supporting a much better search function than the current CM system; replacing Epicentre will mean that it will be easier and quicker for the HFEA to train new staff on the system.
- **7.10.** In response to a question the Phoenix Programme Manager confirmed that the level of cyber security will be increased by using industry-standard platforms such as Microsoft Dynamics.
- **7.11.** The Chair drew the discussions to a conclusion stating that this was a wonderful start to the project which will greatly improve the HFEA's use of data. The Chair stated that monitoring oversight of this project was delegated to the AGC who will ensure that the Authority is informed of any slippages to the project timeline.

#### **7.12.** Members noted:

- the case for change to replace historic HFEA IT systems
- the funding and commercial decisions that led to the appointment of the HFEA's IT development partner
- progress and timescales for the project, including governance and risk management.
- 7.13. Members agreed that oversight of the programme would be carried out by the AGC

### 8. Any other business

- **8.1.** The Director of Strategy and Corporate Affairs informed members that the Law Commission had published a letter from Baroness Merron which stated that the Government is unable to prioritise surrogacy reform and do not intend to put forward these legislative proposals at the current time. The HFEA had a place holder in its Business Plan since 2023 for any work arising from surrogacy reform. Members noted the release of this place holder for the HFEA Business Plan.
- **8.2.** The Chair thanked everyone for their active participation in the meeting, there being no further items of any other business the Chair closed the meeting and reminded members that the next Authority meeting will be held on 9 July 2025.

#### Chair's signature

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

Signature

Chair: Julia Chain Date: 9 July 2025



# 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:	9 July 2025
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

# **Output from this paper**

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

#### 1. Introduction

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

#### 2. Activities

#### 2.1 Chair activities

- The Chair has continued to engage with the decision-making functions of the Authority and with key
  external stakeholders:
  - 27 May Peter and I met our sponsor team at DHSC for our annual accountability meeting
  - 27 May Peter and I met representatives from the Fertilis Group of clinics
  - 9 June attended the SCAAC meeting, also on the same day participated the shortlisting for the external adviser vacancy

#### 2.2 Chief Executive

- The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:
  - 22 May meeting with the Regulatory Horizon Council to discuss their work on IVGs
  - 27 May attended the DHSC/HFEA annual accountability meeting
  - 27 May met representatives of the Fertilis Group
  - 9 June attended the SCAAC meeting
  - 17 June attended the AGC meeting



# **Committee Chairs' reports**

Details about this paper		
Area(s) of strategy this paper relates to:	Regulating a changing environment	
Meeting:	Authority	
Agenda item:	4	
Meeting date:	9 July 2025	
Author:	Caroline Pringle, Head of Licensing	
Annexes	-	
Output from this pap	er	
For information or decision?	For information and decision	
Recommendation:	The Authority is invited to note this report, and Chairs are invited to comment on their committees.	
	The Authority is asked to approve the change of wording to the definition of a treatment add-on, on the recommendation of SCAAC.	
Resource implications:	In budget	
Implementation date:	Ongoing	
Communication(s):	This information will be published on our website.	
Organisational risk:	Low	

**Date** 

**Outcomes** 

# 1. Committee reports

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

**Centres** 

### 2. Recent committee items considered

Items considered

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

Licence Co	mmittee:		
8 May	Executive update to renewal report for licensing decision	Guys Hospital	Approved – 3 year licence
	Executive update to renewal report for licencing decision	NewLife Fertility	Approved – 3 year licence
16 June	Focused interim inspection	Homerton Fertility Centre	Approved – licence continued
Other comments:	Licence Committee will next meet on 17 July 2025.		
Executive L	icensing Panel:		
13 May	Renewal inspection report	Care Fertility Bath	Approved – 4 year licence (and ITE certificate)
	Renewal inspection report	London Sperm Bank (LSB), London Bridge	Approved – 4 year licence (and ITE certificate)
	Variation of PR and variation of SLC T52 without application	Bourn Hall Wickford	Approved – licence (and ITE certificate) varied
28 May	Renewal inspection report	Hull & East Riding Fertility	Approved – 4 year licence (and ITE certificate)
	Interim research inspection report	MRC Human Genetics Unit	Approved – licence continued
	Interim inspection report and variation of SLC T52 without application	Harley Street Fertility Clinic	Approved – licence continued and varied
	Interim inspection report and variation of SLC T52 without application	TFP Simply Fertility	Approved – licence continued and varied
	Variation of PR	St Mary's Hospital	Approved – licence varied
	Variation of PR	<b>University of Manchester</b>	Approved – licence varied

Date	Items considered	Centres	Outcomes
	Variation of PR	Maternal and Fetal Health Research Centre, St Mary's	Approved – licence varied
11 June	Renewal inspection report	Ninewells Hospital	Approved – 4 year licence (and ITE certificate)
	Research interim inspection report	Centre for Reproductive Medicine, Coventry	Approved – licence continued
	Research interim inspection report and variation of premises	Hartshorne and Genesis Group	Approved – licence continued and varied
	Research interim inspection report	Mechanochemical Cell Biology	Approved – licence continued
	Interim inspection report	Agora Clinic Brighton	Approved – licence continued
	Interim inspection report and variation of SLC T52 without application	TFP Belfast Fertility	Approved – licence continued and varied
	Variation of LH and variation of SLC T52 without application	Edinburgh Fertility Centre	Approved – licence varied
	Variation of PR and variation of SLC T52 without application	Care Fertility Leeds	Approved – licence (and ITE certificate) varied
24 June	Initial inspection report	Semovo Sheffield	Minutes not yet approved
	Renewal inspection	Jessop Fertility	Minutes not yet approved
	Interim inspection report and variation of SLC T52 without application	Gloucestershire Hospitals NHS Trust	Minutes not yet approved
	Interim inspection report and variation of SLC T52 without application	Care Fertility Northampton	Minutes not yet approved
	Variation of PR	TFP Simply Fertility	Minutes not yet approved
	Variation of PR, LH, and SLC T52 without application	The James Cook University Hospital	Minutes not yet approved
	Variation of PR and LH	<b>Hull &amp; East Riding Fertility</b>	Minutes not yet approved
Other comments:	None.		
Licensing C	Officer decisions:		
May	12 ITE import certificates	Various	All granted

Date	Items considered	Centres	Outcomes
Other comments:	None		
Statutory A	pprovals Committee:		
29 April	PGT-M: Metaphyseal Chondrodysplasia, Schmid Type (MCDS), OMIM #156500	Guys Hospital	Approved
	PGT-M: Autoimmune Lymphoproliferative Syndrome, Type IA (ALPS1A), OMIM #601859	Care Fertility Nottingham	Approved
	PGT-M: Dyggve-Melchior- Clausen Disease (DMC), OMIM #223800	Guys Hospital	Approved
	PGT-M: Medical sex selection in addition to Breast Ovarian Cancer Familial Susceptibility (BRCA2 and BRCA1), OMIM numbers: *113705, *600185 and #612555	Care Fertility Nottingham	Adjourned pending further information
	Special directions for import of sperm from the USA	Care Fertility London	Approved
	Special directions for export of sperm to Spain	<b>Care Fertility Manchester</b>	Approved
27 May	Mitochondrial donation: M0035 - to avoid Pure Mitochondrial Myopathy, caused by the m.5650G>A pathogenic variant within the MT-TA gene, OMIM *590000	Newcastle Fertility Centre at Life	Approved
	Mitochondrial donation: M0035 - to avoid a fatal, neonatal-onset hypertrophic cardiomyopathy and metabolic acidosis, caused by the m.1638T>C pathogenic variant within the <i>MT-TV</i> gene, OMIM *590105	Newcastle Fertility Centre at Life	Adjourned pending further information
	PGT-M: CHEK2 mutation and increased risk of breast cancer, OMIM *604373	TFP Oxford Fertility	Approved
	PGT-M: Congenital Heart Defects and Skeletal	Care Fertility Nottingham	Approved
			Page 18 of 61

Date	Items considered	Centres	Outcomes
	Malformations Syndrome, OMIM #617602		
	Ectodermal Dysplasia 11A, Hypohidrotic/Hair/Tooth Type, Autosomal Dominant, OMIM #614940	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Approved
	Spinocerebellar Ataxia, Autosomal Recessive, with Axonal Neuropathy 3, OMIM #618387	TFP Boston Place Fertility	Approved
	17-Beta Hydroxysteroid Dehydrogenase III Deficiency, OMIM #264300	Fertility Exeter	Approved
	Special direction for import of embryos from Canada	Regional Fertility Centre, Belfast	Approved
	Special direction for import of embryos from Canada	TFP Wessex Fertility	Approved
23 June	PGT-M: Intellectual Development Disorder with or without Peripheral Neuropathy, OMIM #619844	Guys Hospital	Minutes not yet approved
	PGT-M: Leukoencephalopathy with Brainstem and Spinal Cord Involvement and Lactate Elevation, OMIM #611105	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Minutes not yet approved
	PGT-M: Deafness, Autosomal Dominant 11, OMIM #601317 (Patient-specific licence)	Care Fertility Nottingham	Minutes not yet approved
	PGT-M: Hypotonia— Cystinuria Syndrome, OMIM #606407	TFP Oxford Fertility	Minutes not yet approved
	PGT-M: Medical sex selection in addition to Breast Ovarian Cancer Familial Susceptibility (BRCA2 and BRCA1), OMIM numbers: *113705, *600185 and #612555	Care Fertility Nottingham	Minutes not yet approved
	Special directions for import of embryos from USA	<b>Bourn Hall Clinic Norwich</b>	Minutes not yet approved
	Special direction for import of embryos from Spain	Chelsea & Westminster Hospital	Minutes not yet approved

Date	Items considered	Centres	Outcomes
	Special direction for import of embryos from Czech Republic	The Fertility & Gynaecology Academy	Minutes not yet approved
Other comments:	When considering PGT-M applications, the Committee frequently considers not only the specific condition applied for, but also other similar conditions. In such cases, more than one condition may be authorised for testing.		

# **Audit and Governance Committee:**

17 June 2025	Main agenda items:
	Internal audit – results and annual opinion
	Progress with current internal audit recommendations
	Annual report and accounts – including the governance statement
	External audit completion report
	HFEA's Information and Governance Security Risk Management
	Resilience, business continuity management and cyber security
	Information assurance and security (SIRO report)
	Risk update – strategic risk register and horizon scanning
	Digital projects – PRISM and Phoenix
	Human resource strategy
	Estates

# **Scientific and Clinical Advances Advisory Committee:**

Date	Items considered	Outcomes
9 June	The agenda and papers for this meeting are published on the <b>SCAAC webpage</b> .	The SCAAC Chair will report on this meeting verbally.
	Items considered included:	Key takeaways are as follows:
	Relevant public health developments and research findings	Under this item, members considered two recent papers on the use of intracytoplasmic sperm injection (ICSI) in patients without severe male factor infertility, including the recent <u>randomised clinical trial</u> by Berntsen et al. (2025). As highlighted on the HFEA <u>webpage</u> , good practice guidelines published by the <u>British Fertility Society</u> and recommendations published by the <u>European Society of Human Reproductive Medicine</u> do not recommend using ICSI over standard IVF treatment in these circumstances.  In addition, the SCAAC discussed the recent guidance from the Medicines and
		guidance from the Medicines and Healthcare products Regulatory Agency

(MHRA) considering the use of GLP-1 agonist drugs like semaglutide (brand name Ozempic). Licenced centres will have received an alert about this on 5 June 2025 highlighting MHRA advice against using these medicines while trying to conceive. To ensure that patients are aware of this guidance, the SCAAC recommended that patient-facing information on the use of GLP-1 medicines when trying to conceive is made available via the HFEA website. This will reflect the guidance issued by the MHRA.

Application for treatment add-on: platelet-rich plasma (PRP)

The committee considered an application to add platelet-rich plasma (PRP) for intrauterine and intraovarian infusion/injection to <u>our rated treatment</u> add-on list.

Given there is limited evidence regarding the effectiveness and risks of these treatments, the SCAAC members considered that both intrauterine and intraovarian PRP treatment met the criteria eligible for an HFEA treatment add-on rating.

Impact of the microbiome on fertility and fertility treatment outcomes

Members reviewed research developments, including research on both the male and female reproductive tract microbiome and infertility, alongside relevant research on the gut microbiome, and interventions targeted to improve fertility treatment outcomes by altering the microbiome.

In light of an increasing number of clinics offering microbiome testing as an adjunct to fertility treatment, members proposed that these tests should be considered as treatment add-ons\*.

Health outcomes for ART patients (including gestational surrogates and egg donors)

The SCAAC discussed research findings related to risk factors associated with different types of ART, including treatment using donated gametes, egg donation, and undergoing ART as a gestational surrogate. Members were joined by external expert Professor Alistair Sutcliffe from University College London, a paediatrician and researcher.

The SCAAC recommended that information on the HFEA website relating to donation,

surrogacy and pre-conception health be reviewed and where necessary updated in line with the research discussed.

\*For decision:

In <u>July 2022</u>, the Authority agreed the definition of treatment add-ons that the HFEA will provide information on; the agreed definition covers treatments and does not include tests. At its June 2025 meeting, the SCAAC agreed that often tests are being offered to patients with the claim that they will increase the chances of having a baby, but this is often not backed by the evidence, and therefore unbiased and evidence-based information on some tests would be useful for patients. In order for microbiome and other pre-treatment testing (for example, <u>sperm DNA fragmentation testing</u>) to meet the definition of an add-on, the SCAAC have made a recommendation to ask the Authority to consider amending the definition of treatment add-ons to include tests, as set out below (new proposed wording underlined):

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

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

This change will have modest resource implications for the Executive, which include:

- updating the definitions of add-ons on the <u>patient-</u> and <u>clinic-facing</u> webpages;
- communicating the change as appropriate with the sector; and
- updating the decision tree used by the SCAAC to determine if a treatment or test qualifies for inclusion in our rated information.

Going forward, there will likely be an increase in the workload and budgetary requirements as follows:

- an increase in the number of add-ons applications to be drafted for SCAACs
  consideration for tests to be included (though we will need to be mindful that we focus
  on add-ons which are widely available for use and that patients could benefit from
  information on);
- an increase in the number of literature searches for each new add-on;
- commissioning an external expert to review the quality and conclusions of the research for each new add-on;
- SCAAC time to review new add-ons applications, consider which populations/outcomes to allocate ratings for, and then to allocate ratings to them; and
- the work involved in the regular (5-yearly) review of our rated information which continues to grow.

### 3. Recommendation

- **3.1.** The Authority is invited to note this report. The information will be updated on the HFEA website.
- **3.2.** The Authority is also asked to approve the change of wording to the definition of a treatment add-on that the HFEA will provide information on, on the recommendation of SCAAC.
- **3.3.** Comments are invited, particularly from the committee Chairs.



# Monthly performance report

Performance up to May 2025

# **Evgenia Savchyna**

Corporate Performance Officer 09/07/2025

www.hfea.gov.uk



# About this paper

## **Details about this paper**

Area(s) of strategy this paper relates to:

Whole strategy

Meeting:

Authority

Meeting date:

09/07/2025

Agenda item:

Item 5

Author:

Contents

Evgenia Savchyna, Corporate

Performance Officer

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

The Corporate Management Group (CMG) reviews performance in advance of each Authority meeting, and their comments are incorporated into this

Authority paper.

Communication(s):

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



# Management summary

- Performance across KPIs in May 2025 was variable, with twelve KPIs rated Green, three Neutral, and four rated Red.
- The 'Inspection reports to PR' KPI was rated Red. However, 'Inspection reports to committee' and 'End-to-End Licensing' KPIs met their targets and were Green.
- A record number of PGT-M applications (16) were received in May, with 6 PGT-Ms due. All applications due in May were processed within target with an average processing time of 52 days.
- May was a steady month for the Licensing team, with no LC items due.
- The OTR waiting list has been steadily decreasing since January 2025. In May, the OTR team reduced the waiting list by 66 applications, resulting in the 'OTR waiting list change KPI' being rated Green. The 'OTRs closed in month' KPI was also rated Green, with 171 OTRs processed. A higher number of OTRs were received this months for no known reason.
- A slightly lower number of email enquiries were received in May compared to March and April, while telephone enquiries remained steady. Themes of both types of enquiries varied.
- Both FOIs and PQs were completed within their targets.
- In May, there was more reactive media coverage due to a BBC piece about the use of polygenic testing in IVF.
- Long term sickness will reduce as ill health retirement was approved for one employee.
- Three high value invoices were delayed, resulting the '% of invoices paid within 10 days' KPI turning Red. The 'Debt Collection' KPI was also rated Red due to year-end invoices paid in May 2025.

#### **KPI reviews**

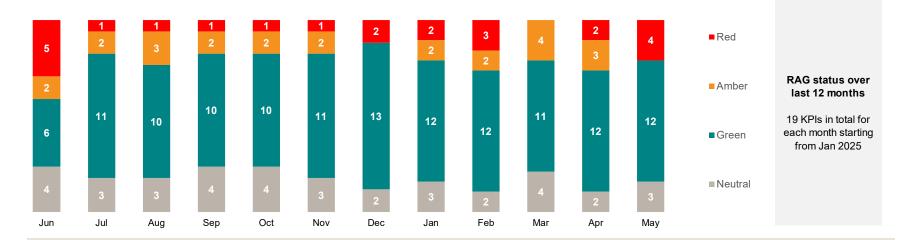
- Three team KPI reviews were completed in May and early June: Intelligence, Comms, and HR as part of the annual review process.
- The reviews included a data validation check for the previous three months reporting and a full review of the current KPIs and a discussion with the team to ascertain if any KPIs should be changed and/ or new KPIs introduced.
- Following these reviews, none of the KPIs for these teams were changed.



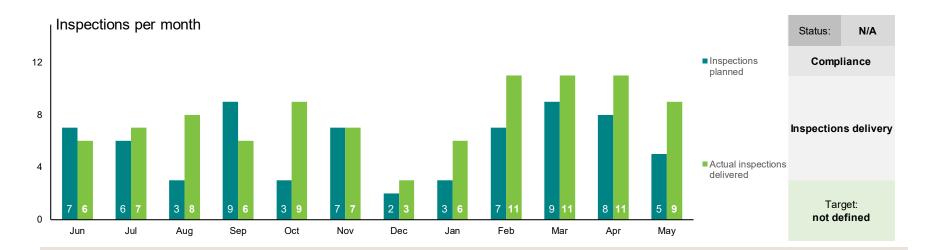
# Key performance indicators



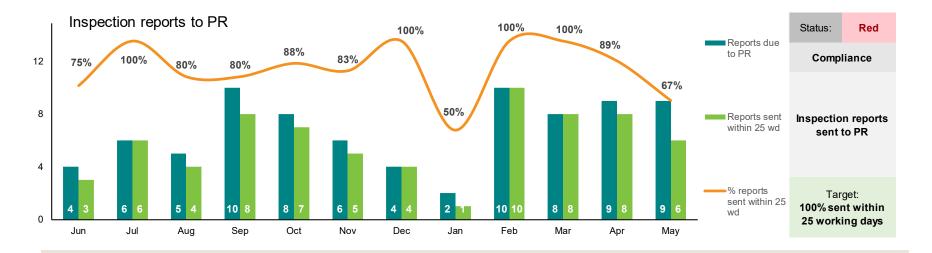
#### RAG status over last 12 months



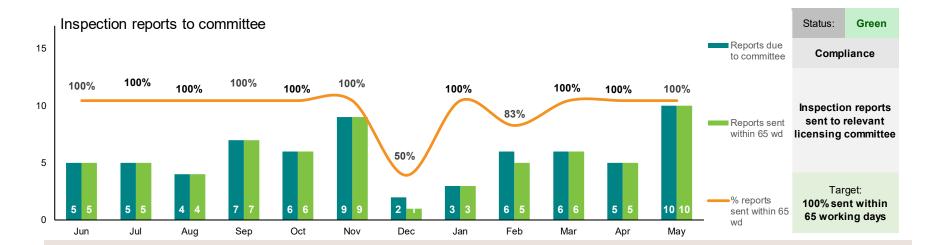
In May 2025, the 4 red indicators were in Compliance ('Inspection reports to PR'), HR ('Sickness rate') and Finance ('Debt Collection within 40 days' and '% invoices paid within 10 days').



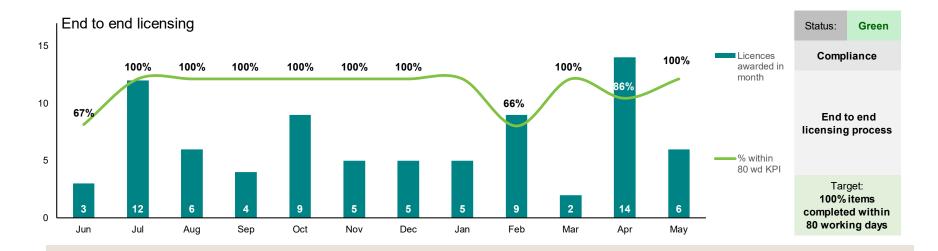
Four more inspections were delivered than planned due to additional inspections added (a variation of premises, an initial inspection and inspection rescheduling).



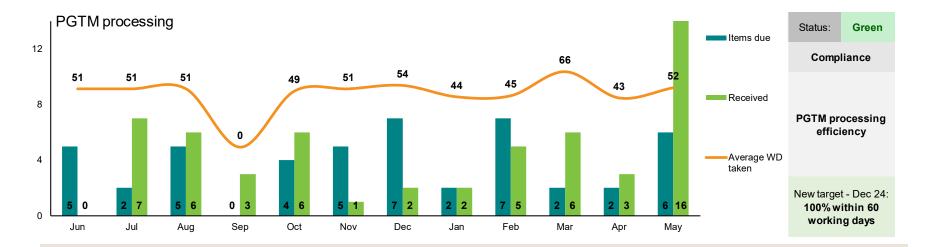
Three reports were delayed due to the requirement of extensive QA.



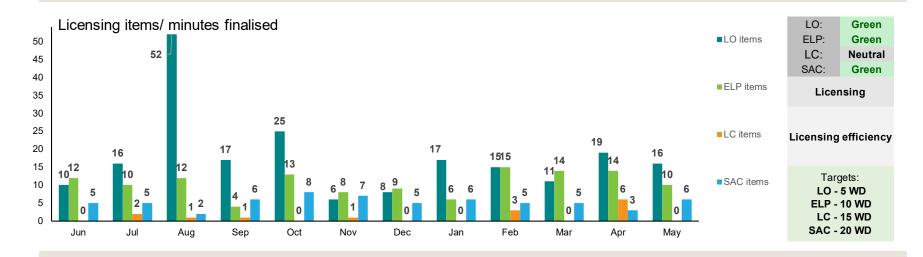
All reports sent to committee within target.



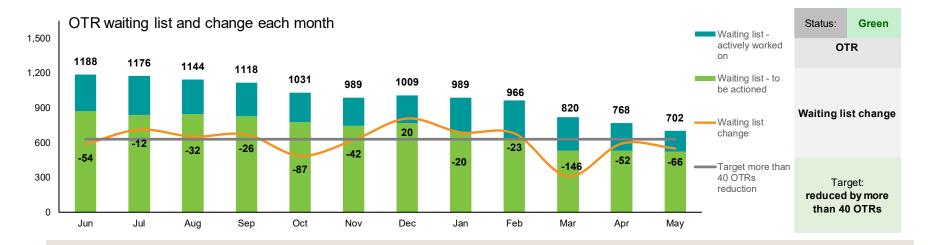
All inspection reports were completed within the 80 working day turnaround time.



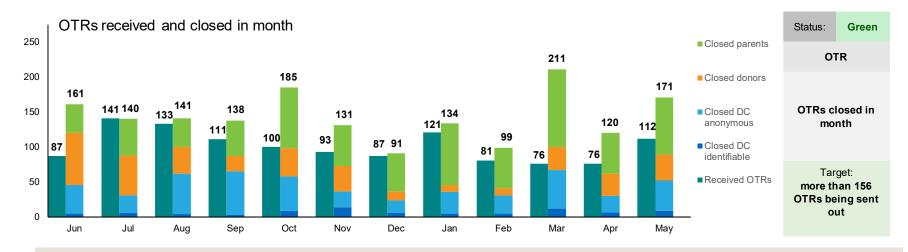
The target has been achieved, with applications processed in an average of 52 days. A record number of 16 PGT-M applications were received in May.



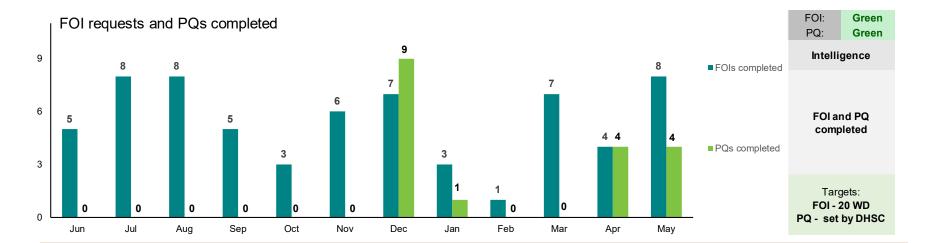
All LO items were ITE certificates but otherwise a standard month in terms of numbers. LO, ELP and SAC targets have all been met.



Supplementary data of OTRs in the waiting list: **Donor OTRs - 182; DC identifiable - 52; DC anonymous - 163; Parents - 305.** Although a higher number of OTRs were received, processing a very high number of OTRs meant a reduction in the waiting list.

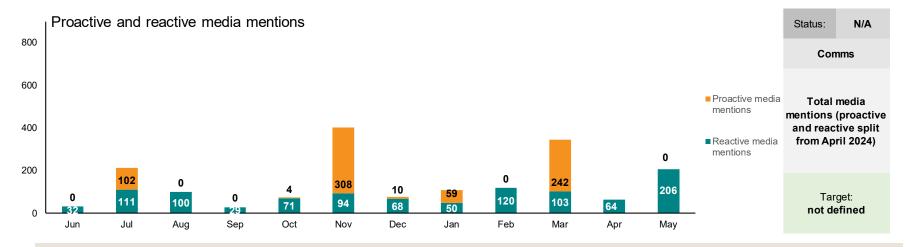


OTRs sent out supplementary data: **Donor OTRs - 37; DC identifiable - 9; DC anonymous - 43; Parents - 82.**A higher number or OTRs received for no known reason. A higher number of identifiable OTRs were received; we are trying to process them as soon as they come in. The waiting time continues to go down but is still at an average of 8 months due to outliers that are our oldest OTRs.

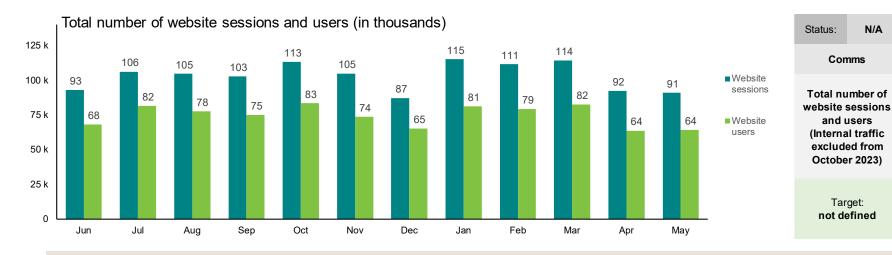


FOIs detail: 5x HR/Finance, 2x Donation, 1x Fertility trends.

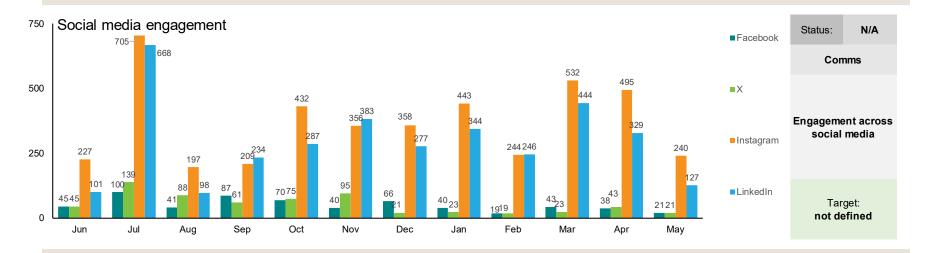
PQs detail: 3x Donation, 1x Fertility trends.



In May, coverage themes included unregulated donation, solo motherhood, IVF and polygenic testing. A 'Tech Now' (BBC) piece about the use of polygenic testing in IVF (broadcast on 23 May) has since been repeated across all of the BBC's regional channels, 111 times since it aired, which explains the higher levels of coverage we secured in May.

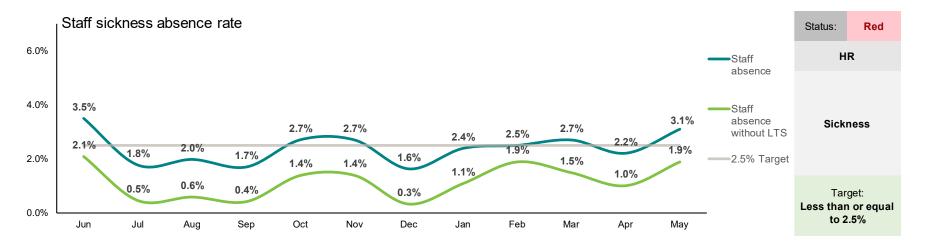


The website saw fewer sessions and users, likely due to the ongoing work on the Umbraco upgrade (our hosting platform) and frequent reboots, causing periods of unavailability. A spike in views for the CaFC pages was observed on 12 and 30 May with 2.4k and 2.9k views, respectively.

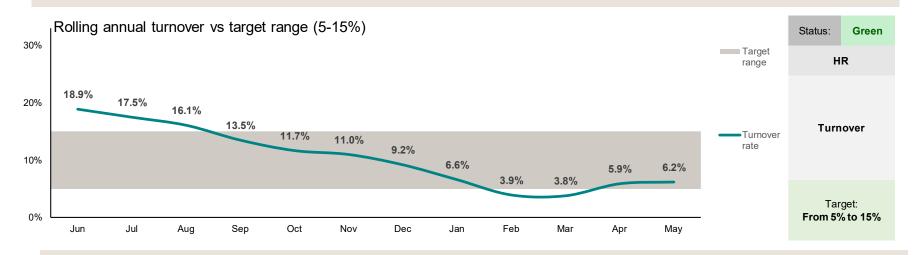


Engagement during May was lower than previous months. There were also fewer awareness events to promote in May, and more time spent preparing for the Fertility Trends 2023 publication.

N/A

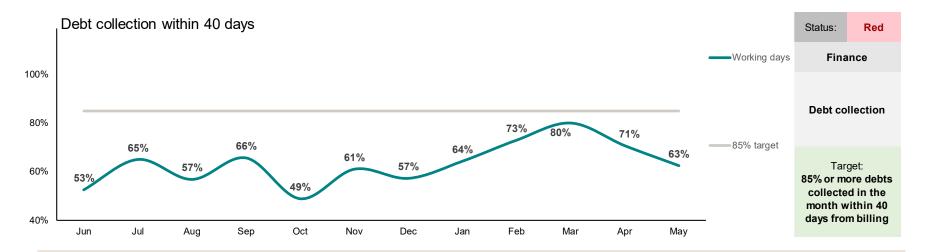


We are expecting that we are in the final two months of reporting LTS as ill health retirement has been approved for the employee.

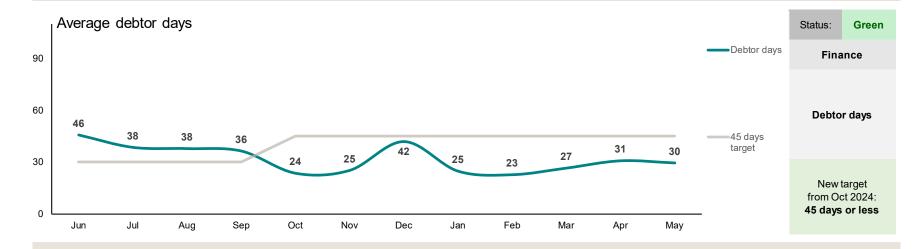


We continue to carry a vacancy in the IT team, along with a vacant Inspector post. Two other vacancies have been appointed to and will be filled in July (Policy Manager and Licensing Manager).

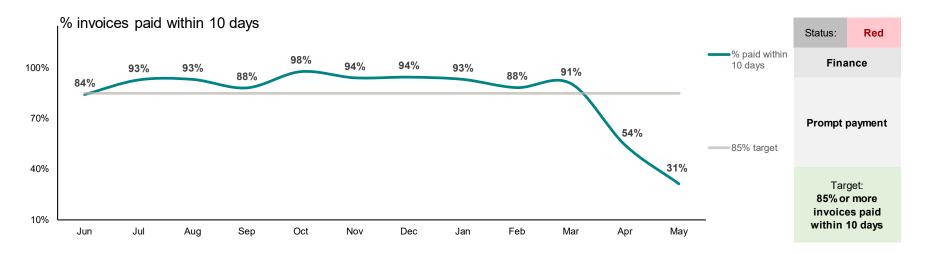
Supplementary HR data: Headcount - 83, Budgeted posts - 84, Vacant posts - 4, Starters - 0, Leavers - 1.



Due to year end, a lot of March and April invoices were paid at the end of May. Therefore, a large number exceeded 45 days. Overall payments were high.



The target has been met.



Three high value invoices were delayed for payment whilst awaiting approval. Excluding these three invoices, we paid 90% within 10 days.



The themes of enquiries varied, and no recurring themes were identified by the team. 20 phone calls were received in May. Themes included Other (5), Complaints (3), Beginning treatment (3), Medical queries and concerns (2) and Opening The Register (2).



# Finance Report

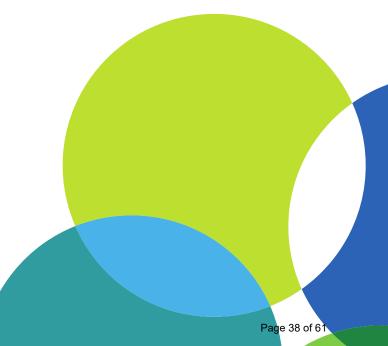
Period to May 2025

### **Tom Skrinar**

Director of Finance, Planning and Technology 09/07

/25

www.hfea.gov.uk



# Summary financial position as of 31 May 2025

Туре	Actual YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s
Income	1,244	1,300	(56)
Expenditure	(1,438)	(1,322)	(116)
Total Surplus/(Deficit) pre-audit	(194)	(22)	(172)

We are only two months into the new financial year and the position is a deficit against budget of (£172k). At the end of June, we will conduct a detailed review of plans for the remaining nine months of the year.

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



# 2025/26 Income - Year to date 31 May 25

Year end	YTD Actual	YTD Budget	Variance
	£'000s	£'000s	£'000s
Income			
DHSC Funding	-	-	-
DHSC Funding – non-cash	39	38	1
Licence Fees	1,186	1,235	(49)
Other income	19	27	(8)
Total	1,244	1,300	(56)

### **INCOME**

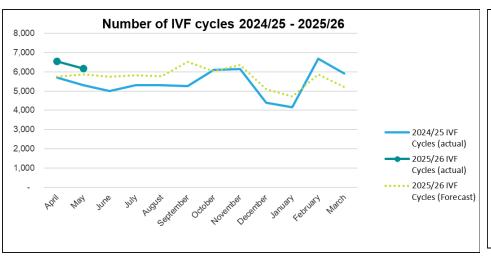
Year to date, our total income is under budget by 4.3%. The key factors affecting this variance are:

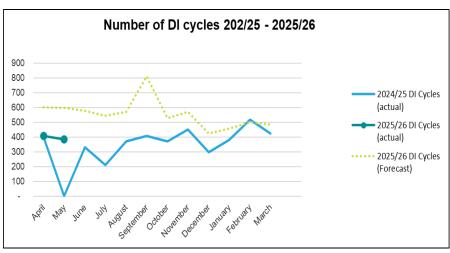
- Grant in aid (GIA) we have not drawn down any of our cash allocation, this will be done in June.
- Licence fees IVF/DI activity are below budget by (£49k) which is represented by IVF cycles which are 7% above budget and DI 33% are below budget.

Other income – is interest received on our bank balance which is (£8k) below budget. This position is likely to change throughout the year as we collect licence fee income.



# 2024/25 Income - YTD Actual vs Budget





### **IVF / DI Activity**

The above graphs depict the volumes of IVF and DI cycles, comparing activity for the 2024/25 and 2025/26 financial years as of M02 (May). It is too early to ascertain what cycle activity will look like for the year. A forecast exercise will be undertaken in July

Currently IVF activity actual vs budget year to date are 12,691 and 11,875 respectively. Our DI volumes are 794 and 1,179.

At the end of Q1, an analysis of cycles including any refunds will be undertaken which will feed into our forecast.



# 2025/26 Expenditure YTD May 2025

As of March-25	YTD Actual	YTD Budget	Variance
	£'000s	£'000s	£'000s
Expenditure			
Salaries/Wages	985	1,012	(27)
Other Staff costs	27	26	1
Other costs	65	18	47
Project Costs	120	123	(3)
Facilities (estates) costs	102	61	41
IT Costs	88	71	17
Legal and Professional	51	11	40
Total	1,438	1,322	116

### **Key Variances**

Variances may be subject to profiling issues which will be reviewed at the end of the quarter.

Salaries/wages – are under budget by £27k; the main area is within salaries with a small variance on contract staff

**Other costs** – are over budget by £47k. Significant areas of overspend are within Donor Information costs which include Q4 24/25 charges (£27k). This will be investigated and corrected at the end of Q2. The balance is due to profiling of costs which are currently quarterly.

**Facilities (estates) costs** – are over budget year to date due to an accrual for the increase in rent, in addition rates and service charge costs (£12k) which we normally profile quarterly. The balance includes costs of staff attending the office (remote worker) which are difficult to profile (£21k) over budget. The remainder are small items.







# Register Research Panel annual report to Authority

Details	about	this	pap	er
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Area(s) of strategy this paper Supporting scientific and medical innovation relates to:

Meeting: Authority

Agenda item: 8

Meeting date: 9 July 2025

Author: Amanda Evans, Head of Research and Intelligence

Kazuyo Machiyama, Senior Research Manager

Annexes Annex A – Active Register Research Panel approved projects

Annex B – Publication list for approved Register Research Panel projects

Annex C – Publication list for anonymised register data and other

anonymous HFEA data

# **Output from this paper**

For information or decision?	For information
Recommendation:	The Authority is asked to note this report
Resource implications:	Medium
Implementation date:	2024-25
Communication(s):	Through updates to researchers, clinics, stakeholders and patients via our website and social media
Organisational risk:	Low

### 1. Introduction

- **1.1.** The HFEA holds a Register of all patients, partners, donors, treatments and children born as a result of these treatments. It is believed to be the longest running database of assisted reproduction treatment in the world holding over 30 years of data.
- 1.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (2010 Regulations) provide that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register. Continuing to increase the availability of data for research is a key aim of the current strategy. We want to continue to engage with researchers to improve access to relevant and valuable data on our Register to that end.
- **1.3.** The Authority has delegated to the Register Research Panel (RRP) the power to authorise access to Register data for the purposes of medical or non-medical research. The panel is required to report annually to the Authority and this paper provides that annual report.
- 1.4. The RRP is one of many ways in which Register data is made available. Most people seeking to access Register data do not wish to access identifiable information. To enable researchers, healthcare professionals and the public to undertake research using Register data, we proactively release as much data as possible through publications, anonymised registers and the HFEA dashboard. We also respond to freedom of information requests (FOIs), enquiries and parliamentary questions (PQs).
- 1.5. We regularly publish <u>data research reports</u> which receive wide media coverage. Fertility Trends is our annual statistical release and is the main point of reference for all data-related enquiries received throughout the year. It is published as an HTML report, with supporting underlying data tables. Fertility treatment 2023: trends and figures was published in June 2025. Due to delays in data validation with clinics following the launch of PRISM, all data releases have included preliminary data for 2020-23. We also published the <u>Family formations in fertility treatment 2022</u> report in November 2024.
- 1.6. In March 2025, we published our third edition of the <u>National Patient Survey</u>. The survey explored patient experience of fertility treatment in the UK has changed over the last decade, including satisfaction of treatment which remains high, as well as waiting times and treatment add-on use. We received over 1,500 responses and will continue to use the responses to inform our future work.
- In 2024, we launched our <u>award-winning HFEA dashboard</u> as a new tool to better enable public access to a wider breadth of data in a simplified and customisable format. Since release, the dashboard has been updated annually alongside Fertility Trends to include a new year of data, as well as updated to add improvements or include further data. Recent examples of updates include adding a new page on donor insemination (DI) pregnancy and birth rates, and adding filters to enable users to view reciprocal IVF data.
- 1.8. Section 2 of this paper provides an overview of Register Research Panel activity undertaken since the previous RRP update (May 2024 to June 2025). Section 3 covers activities in improving engagement with researchers and section 4 outlines work carried out in providing further information in freely available anonymised formats.

# 2. Register Research Panel activity in 2024-25

- **2.1.** The role of the RRP is to decide whether to grant or refuse requests to access Register data for specific research purposes. The RRP is chaired by a Director and has membership from staff with research, information governance, data register, clinical and policy expertise.
- **2.2.** Since the introduction of the 2010 Regulations, the RRP has approved 26 project applications: 11 projects are currently active, two are conditionally approved, two were consolidated, and 11 have been completed. A list of the currently active projects is available in Annex A.
- 2.3. The main output from RRP approved projects is typically publication of the research results in peer-reviewed academic journals. Between 1 May 2024 and 31 May 2025, there was one new peer-reviewed academic article published from RRP approved research projects (see Annex B), and six published using anonymised data (see Annex C). There have been 26 peer-reviewed academic articles published from RRP approved research projects and 32 from anonymous HFEA data sources such as the anonymised register, since 2010.
- **2.4.** Between 1 May 2024 and 31 May 2025, the RRP met on six occasions to consider four project applications and one project change request. Of these new project applications, one was rejected, two were approved (with conditions), and one required further clarification before being approved at second consideration. Five projects were also approved for renewal. A list of the projects approved in the last year can be found below.
- **2.5.** Updates to the following documentation were completed as part of the wider work to improve the information provided to and received from researchers: the RRP standard operating procedure, application form, project renewal request form, and the data specification sheet. The data research webpage has also had continued updates to provide more information for researchers on how to apply to access data.
- **2.6.** Upcoming updates will include ensuring clarity in legislation used for RRP projects, which can require a combination of the 2010 Regulations and the Human Fertilisation and Embryology Act 2008. This will be amended where required.
- 2.7. The number of research enquiries, new applications and approved projects have increased since last year, which is likely to be related to research engagement activities outlined in section 3. While Register data is becoming more widely known, there remains more potential to improve patient care through increased high-quality research through increased awareness of the HFEA Register data and improving ease of accessing data.
- 2.8. In May 2024, we updated the Authority on the recommended updates to the regulations on disclosure for research that had been submitted to the Department of Health and Social Care (DHSC). The proposal included changes in three main areas: cost recovery, research following egg, sperm and embryo donation, and child consent. We have received a response from DHSC which includes confirmation on where legislative change is required. We have reviewed the response provided and will be seeking further clarification on some aspects. In the interim, we are outlining ways in which we can continue to improve data access within our current legislative framework, including in reviewing requirements around how consent is applied. We will continue to raise aspects of the legislation that remain prohibitive to ensuring high quality research can be carried out using our data.

# **Projects approved in 2024-25**

2.9. The effect of government funding on IVF demand: Evidence from regional data in the UK (London School of Economics). This project aims to estimate how demand for IVF changes in relation to NHS funding availability.

- 2.10. Association of the body mass index of women undergoing in vitro fertilisation, with pregnancy, live birth, and pregnancy loss rates, and number of eggs collected: a population-based study of the Human Fertilisation and Embryology Authority database (University of Oxford). This project aims to analyse any relationship between IVF patients' BMI in the UK and treatment outcomes. The research will also analyse whether this varies by funding type, age or ethnicity.
- 2.11. How does the duration of in-vitro culture affect the health and pregnancy potential of the human embryo? (University of Manchester) Conditional approval. The aim of this project is to determine whether transferring a faster developing embryo, day 4 blastocyst, results in improved pregnancy success, with reduced pregnancy complications and adverse neonatal outcomes.

# 3. Research engagement activities

- 3.1. As part of our strategic aim to increase the availability and benefit of our data, we have introduced new ways of reaching researchers with information relevant to them through a data research newsletter and a webinar, and introduced a new enquiry form to streamline how researchers can contact us with new project proposals. We have additionally continued to present our publications and dashboard at academic conferences to highlight data available.
- **3.2.** The <u>HFEA Data Research Update Newsletter</u> was launched in July 2024 to provide a platform for updating research audiences on areas relevant to them. There have been four editions so far, which included information on new HFEA publications and meetings, upcoming events, and highlights of RRP projects and their publications. There are over 240 subscribers currently with a high open rate of around 60%.
- 3.3. The HFEA hosted the first webinar titled 'Accessing the UK fertility national register for research' in February 2025. This webinar provided an introduction to the HFEA, an overview of data we hold on our register and how to access it, and finished with a Q&A session. 180 people signed up for the webinar and 82 people attended the session live. The full recording has been made available on the HFEA YouTube channel and the data research webpage. 77% of those who provided post-webinar feedback reported a 'very good' overall experience. Attendee feedback highlighted interest in hearing about examples of successful applications and existing research projects in future webinars. Monthly visits to the data research webpage nearly doubled in February with the webinar, to around 3,500.
- 3.4. A <u>project enquiry form</u> was introduced on the data research webpage in July 2024 to streamline interest in data access from new researchers. Since the introduction of this form, 18 research groups from a wide range of research areas have enquired via the form. The form has aided communication with researchers around understanding feasibility of projects using data held and in tracking interest.
- 3.5. To support research relating to HFEA strategic aims, the Research and Intelligence team have also worked with various research teams through collaboration or by assisting on Stakeholder Advisory Groups. One collaboration resulted in a publication this year in Human Reproduction on the <a href="effectiveness and safety of consecutive single embryo transfer compared to double embryo transfer">effectiveness and safety of consecutive single embryo transfer compared to double embryo transfer</a> using anonymised HFEA register data.
- **3.6.** Lastly, we have presented data from our publications and the HFEA dashboard at conferences and meetings to highlight Register data available to researchers. The HFEA dashboard was

presented at the Royal Statistical Society international conference 2025, as well as data meetings in government such as Public Digital's Data Bites and DataConnect24. Our recent publications were presented at Fertility Conference 2025, European Society of Human Reproduction and Embryology Conference 2025, and the International Symposium on Medically Assisted Reproduction: Health, Social and Demographics Aspects.

# 4. Accessing anonymous Register data

- **4.1.** The Anonymised Register data can be used for research without having to apply for approval, allowing researchers to access a large and rich dataset that does not contain any identifiable information. Following large-scale data migration work (as part of the PRISM programme) which has led to improvements in data quality, we are currently reviewing our publicly available datasets to ensure consistency with our other publications. It is planned to update the anonymised registers following data validation completion in Winter 2025/26, including a review of what data is included to ensure it meets researcher needs.
- **4.2.** In the 2024-25 financial year, the Research and Intelligence team responded to data-related enquiries in the form of 67 FOIs, 48 intelligence enquiries and 10 PQs, as well as numerous data requests through our press office and general enquiries inboxes. While these requests have historically often required preparation of bespoke data, many are now answered by the HFEA dashboard estimated to answer around a third of data requests. Requests that are not answerable by the dashboard are often specific and more complex queries.

### **Annex A**

# **Active Register Research Panel approved projects**

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

Note: this table does not include two projects which hold conditional approvals, and so have not yet been fully authorised yet.

### Annex B

# **Publication list - Approved Register Research Panel projects**

### Published since last Authority update (May 2024-June 2024)

 Williams, C.L., Bunch, K.J., Stiller, C., Murphy, M.F.G., Botting, B.J., Davies, M.C., Luke, B., Lupo, P.J., Sutcliffe, A.G. (2024) Langerhans cell histiocytosis in children born after assisted reproductive technology. *Reproductive BioMedicine Online*, 49(6):104379. https://doi.org/10.1016/j.rbmo.2024.104379

### Published prior to last Authority update (before May 2024)

- Sutcliffe, A.G., Purkayastha, M., Brison, D.R., Nelson, S.M., Roberts, S.A., Lawlor, D.A. (2023). General health in a cohort of children conceived after assisted reproductive technology in the United Kingdom: a population-based record-linkage study. *American journal of obstetrics and* gynecology. 228(1), 82-e1. https://doi.org/10.1016/j.ajog.2022.07.032
- 3. Hua, X., Rivero-Arias, O., Quigley, M. A., Kurinczuk, J. J., & Carson, C. (2023). Long-term healthcare utilization and costs of babies born after assisted reproductive technologies (ART): a record linkage study with 10-years' follow-up in England. *Human Reproduction*, 38(12), 2507–2515. https://doi.org/10.1093/humrep/dead198
- Ratna, M. B., Bhattacharya, S., & McLernon, D. J. (2023). External validation of models for predicting cumulative live birth over multiple complete cycles of IVF treatment. *Human Reproduction*, 38(10), 1998–2010. https://doi.org/10.1093/humrep/dead165
- Raja, E.A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2023). A comparison of perinatal outcomes following fresh blastocyst or cleavage stage embryo transfer in singletons and twins and between singleton siblings. *Human Reproduction Open*, 2023(2): hoad003. https://doi.org/10.1093/hropen/hoad003
- 6. Kondowe, F. J. M., Clayton, P., Gittins, M., D'Souza, S. W., Brison, D. R., & Roberts, S. A. (2023). Growth of twins conceived using assisted reproductive treatments up to 5 years old: a national growth cohort. *Human Reproduction*, *38*(4), 751-761. https://doi.org/10.1093/humrep/dead018
- 7. McLernon, D. J., Raja, E. A., Toner, J. P., Baker, V. L., Doody, K. J., Seifer, D. B., Sparks, A. E., Wantman, E., Lin, P. C., Bhattacharya, S., & van Voorhis, B. J. (2022). Predicting personalized cumulative live birth following in vitro fertilization. *Fertility and Sterility*, 117(2):326-338 https://doi.org/10.1016/j.fertnstert.2021.09.015
- 8. Raja, E.A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2022). Comparison of perinatal outcomes after frozen or fresh embryo transfer: separate analyses of singleton, twin, and sibling live births from a linked national in vitro fertilization registry. *Fertility and Sterility*, 118(2), 323–334. https://doi.org/10.1016/j.fertnstert.2022.05.010
- 9. Ratna, M. B., Bhattacharya, S., van Geloven, N., & McLernon, D. J. (2022). Predicting cumulative live birth for couples beginning their second complete cycle of in vitro fertilization treatment. *Human Reproduction*, 37(9), 2075–2086. https://doi.org/10.1093/humrep/deac152
- 10. Sharpe, A., Mascarenhas, M., & Balen, A. (2022). Ethnic variation in the live birth rate and perinatal outcomes following frozen embryo transfer: an analysis of the HFEA database from 2000 to 2016. *Human Fertility*, 25(3), 583–592. https://doi.org/10.1080/14647273.2021.1913291
- 11. Sutcliffe, A. G., Purkayastha, M., Brison, D. R., Nelson, S. M., Roberts, S. A., & Lawlor, D. A. (2022). General health in a cohort of children conceived after assisted reproductive technology in the United Kingdom: a population-based record-linkage study. *American Journal of Obstetrics and Gynecology*, 228(1):82e1-82e17. https://doi.org/10.1016/j.ajog.2022.07.032
- 12. Bhattacharya, S., Maheshwari, A., Ratna, M. B., van Eekelen, R., Mol, B. W., & McLernon, D. J. (2021). Prioritising IVF treatment in the post COVID 19 era: a predictive modelling study based on UK national data. *Human Reproduction*, 36(3). https://doi.org/10.1093/humrep/deaa339
- Purkayastha, M., Roberts, S. A., Gardiner, J., Brison, D. R., Nelson, S. M., Lawlor, D., Luke, B., & Sutcliffe, A. (2021). Cohort profile: A national, population-based cohort of children born after assisted conception in the UK (1992-2009): Methodology and birthweight analysis. *BMJ Open* 11:e050931. https://doi.org/10.1136/bmjopen-2021-050931
- 14. Castillo, C. M., Harper, J., Roberts, S. A., O'Neill, H. C., Johnstone, E. D., & Brison, D. R. (2020). The impact of selected embryo culture conditions on ART treatment cycle outcomes: a UK national study. *Human Reproduction Open*, 2020(1):hoz031.
- 15. Cameron, N. J., Bhattacharya, S., & McLernon, D. J. (2020). Cumulative live birth rates following blastocyst- versus cleavage-stage embryo transfer in the first complete cycle of IVF: a population-

- based retrospective cohort study. *Human Reproduction*, 35(10):2365–2374. https://doi.org/10.1093/humrep/deaa186
- 16. van Eekelen, R., van Geloven, N., van Wely, M., Bhattacharya, S., van der Veen, F., Eijkemans, M. J., & McLernon, D. J. (2019). IVF for unexplained subfertility; whom should we treat? *Human Reproduction*, 34(7):1249–1259. https://doi.org/10.1093/humrep/dez072
- 17. Hann, M., Roberts, S. A., D'Souza, S. W., Clayton, P., Macklon, N., & Brison, D. R. (2018). The growth of assisted reproductive treatment-conceived children from birth to 5 years: a national cohort study. *BMC Medicine*, 16(224). https://doi.org/10.1186/s12916-018-1203-7
- Williams, C. L., Bunch, K. J., Murphy, M. F. G., Stiller, C. A., Botting, B. J., Wallace, W. H., Davies, M. C., & Sutcliffe, A. G. (2018). Cancer risk in children born after donor ART. *Human Reproduction*, 33(1):120-146. https://doi.org/10.1093/humrep/dex333
- Williams, C. L., Jones, M. E., Swerdlow, A. J., Botting, B. J., Davies, M. C., Jacobs, I., Bunch, K. J., Murphy, M. F. G., & Sutcliffe, A. G. (2018). Risks of ovarian, breast, and corpus uteri cancer in women treated with assisted reproductive technology in Great Britain, 1991-2010: data linkage study including 2.2 million person years of observation. *BMJ (Online)*, 362: k2644 https://doi.org/10.1136/bmj.k2644
- Cameron, N. J., Bhattacharya, S., Bhattacharya, S., & McLernon, D. J. (2017). Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women. *Human Reproduction*, 32(11):2287-2297. https://doi.org/10.1093/humrep/dex293
- 21. Maalouf, W., Maalouf, W., Campbell, B., & Jayaprakasan, K. (2017). Effect of ethnicity on live birth rates after in vitro fertilisation/intracytoplasmic sperm injection treatment: analysis of UK national database. *BJOG: An International Journal of Obstetrics and Gynaecology*, 124(6):904-910. https://doi.org/10.1111/1471-0528.14241
- 22. McLernon, D. J., Maheshwari, A., Lee, A. J., & Bhattacharya, S. (2016). Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women. *Human Reproduction*, 31(3):572-581. https://doi.org/10.1093/humrep/dev336
- 23. McLernon, D. J., Steyerberg, E. W., te Velde, E. R., Lee, A. J., & Bhattacharya, S. (2016). Predicting the chances of a live birth after one or more complete cycles of in vitro fertilisation: population based study of linked cycle data from 113 873 women. *BMJ (Online)*, 355:i5735. https://doi.org/10.1136/bmj.i5735
- 24. Smith, A. D. A. C., Tilling, K., Nelson, S. M., & Lawlor, D. A. (2015). Live-birth rate associated with repeat in vitro fertilization treatment cycles. *JAMA Journal of the American Medical Association*, 314(24):2654-2662. https://doi.org/10.1001/jama.2015.17296
- 25. Lawlor, D. A., & Nelson, S. M. (2012). Effect of age on decisions about the numbers of embryos to transfer in assisted conception: A prospective study. *The Lancet*, *379*(9815):521-527. https://doi.org/10.1016/S0140-6736(11)61267-1
- 26. Nelson, S. M., & Lawlor, D. A. (2011). Predicting live birth, preterm delivery, and low birth weight in infants born from in vitro fertilisation: A prospective study of 144,018 treatment cycles. *PLoS Medicine*, 8(1):e1000386. https://doi.org/10.1371/journal.pmed.1000386

### **Annex C**

# Publication list - Anonymised Register data and other anonymous HFEA data

### Published since last Authority update (May 2024-June 2024)

 Kondowe, F.J.M., Gittins, M., Clayton, P., Brison, D.R., & Roberts, S.A. (2025) Bias due to nonconsent in assisted reproductive treatment cohort studies: consent for disclosure to non-contact research in the Human Fertilisation and Embryology Authority register. *Human Reproduction*. 40(5), 946–955 https://doi.org/10.1093/humrep/deaf045

- Datta, A.K., Nargund, G., Wilding, M. Dobson, S., Campbell, S. (2025) Embryo utilisation rate and transferable embryo to oocyte ratio correlate positively with livebirth rate but negatively with oocyte number: analysis of 14,156 fresh IVF/ICSI cycles. *Journal of Ovarian Research* 18(112) https://doi.org/10.1186/s13048-025-01693-4
- 3. Tighe, J., Broughton, S., Roberts, R., Kasaven, L. S., Cutting, R., Bridges, E., Ng, A., Evans, A., Theodorou, E., Nagi, J.B., Jones, B.P. (2025) Effectiveness and safety of consecutive single embryo transfer compared to double embryo transfer: results from the UK HFEA registry. *Human Reproduction* 40(5) 885-894. https://doi.org/10.1093/humrep/deaf028
- Zhang, Y., Jia, Q., Liu, Y., Guan, Y. (2025) Insemination methods for embryos transferred in frozen-thawed embryo transfer cycles do not impact reproductive outcomes in couples with nonmale factor infertility. Scientific Reports 15(1) 13630. https://doi.org/10.1038/s41598-025-97051-x
- 5. Datta, A.K., Campbell, S., Diaz-Fernandez, R., Nargund, G. (2024) Live birth rates are influenced by an interaction between male and female partners' age: analysis of 59951 fresh IVF/ICSI cycles with and without male infertility. *Human Reproduction*. deae198. https://doi:10.1093/humrep/deae198.
- 6. Paffoni, A., Vitagliano, A., Corti, L. *et al.* (2024) Intracytoplasmic sperm injection versus conventional in vitro insemination in couples with non-male infertility factor in the 'real-world' setting: analysis of the HFEA registry | Journal of Translational Medicine. *Journal of Translational Medicine* 22(687). https://doi.org/10.1186/s12967-024-05515-x

### Published prior to last Authority update (before May 2024)

- 7. Allen, C., McLernon, D., Bhattacharya, S., & Maheshwari, A. (2023). Early pregnancy outcomes of IVF cycles using donor versus partner sperm: analysis of 1 376 454 cycles recorded by the Human Fertilisation and Embryology Authority (1991–2016). *Human Reproduction*, 38(6):1191-1201. https://doi.org/10.1093/humrep/dead057
- 8. Bambaranda, B. G. I. K., Bomiriya, R., Mehlawat, P., & Choudhary, M. (2022). Association of extended culture to blastocyst and pre-malignant gestational trophoblastic disease risk following IVF/ICSI-assisted reproduction cycles: an analysis of large UK national database. *Journal of Assisted Reproduction and Genetics*, 39(10). https://doi.org/10.1007/s10815-022-02583-0
- 9. Shen, L., Zhang, Y., Chen, W., & Yin, X. (2022). The Application of Artificial Intelligence in Predicting Embryo Transfer Outcome of Recurrent Implantation Failure. *Frontiers in Physiology*, 13. https://doi.org/10.3389/fphys.2022.885661
- Zhang, Y., Shen, L., Yin, X., & Chen, W. (2022). Live-Birth Prediction of Natural-Cycle In Vitro Fertilization Using 57,558 Linked Cycle Records: A Machine Learning Perspective. Frontiers in Endocrinology, 13. https://doi.org/10.3389/fendo.2022.838087
- Lewin, J., Lukaszewski, T., Sangster, P., Williamson, E., McEleny, K., Al Wattar, B. H., & Yasmin, E. (2022). Reproductive outcomes following surgical sperm retrieval in couples with male factor subfertility: A 10-year retrospective national cohort. *Fertility and Sterility*. https://doi.org/10.1016/j.fertnstert.2022.12.041
- 12. Allen, C. P., McLernon, D. J., Bhattahcharya, S., & Maheshwari, A. (2022). Perinatal outcomes of 221,709 singleton and twin pregnancies after the use of donor versus partner sperm. *Fertility and Sterility*, *118*(5), 948–958. https://doi.org/10.1016/j.fertnstert.2022.08.015
- Henderson, I., Lacey, L., Akhtar, M. A., & Quenby, S. (2022). Ethnic group and reason for ART failure: analysis of HFEA registry data from 2017-2018. Fertility and Sterility. https://doi.org/10.1016/j.fertnstert.2022.11.005
- 14. Roberts, S. A., Wilkinson, J., Vail, A., & Brison, D. R. (2022). Does PGT-A improve assisted reproduction treatment success rates: what can the UK Register data tell us? *Journal of Assisted Reproduction and Genetics*. https://doi.org/10.1007/s10815-022-02612-y
- 15. Mascarenhas, M., Mehlawat, H., Kirubakaran, R., Bhandari, H., & Choudhary, M. (2021). Live birth and perinatal outcomes using cryopreserved oocytes: an analysis of the Human Fertilisation and

- Embryology Authority database from 2000 to 2016 using three clinical models. *Human Reproduction (Oxford, England)*, 36(5). https://doi.org/10.1093/humrep/deaa343
- 16. Goyal, A., Kuchana, M., & Ayyagari, K. P. R. (2020). Machine learning predicts live-birth occurrence before in-vitro fertilization treatment. *Scientific Reports*, *10*(1). https://doi.org/10.1038/s41598-020-76928-z
- 17. Kamath, M. S., Antonisamy, B., & Sunkara, S. K. (2020). Zygotic splitting following embryo biopsy: a cohort study of 207 697 single-embryo transfers following IVF treatment. *BJOG: An International Journal of Obstetrics and Gynaecology*, 127(5). https://doi.org/10.1111/1471-0528.16045
- 18. Supramaniam, P. R., Granne, I., Ohuma, E. O., Lim, L. N., McVeigh, E., Venkatakrishnan, R., Becker, C. M., & Mittal, M. (2020). ICSI does not improve reproductive outcomes in autologous ovarian response cycles with non-male factor subfertility. *Human Reproduction*, *35*(3). https://doi.org/10.1093/humrep/dez301
- 19. Marconi, N., Raja, E. A., Bhattacharya, S., & Maheshwari, A. (2019). Perinatal outcomes in singleton live births after fresh blastocyst-stage embryo transfer: a retrospective analysis of 67 147 IVF/ICSI cycles. *Human Reproduction*, 34(9), 1716–1725. https://doi.org/10.1093/humrep/dez133
- 20. Supramaniam, P. R., Mittal, M., Ohuma, E. O., Lim, L. N., McVeigh, E., Granne, I., & Becker, C. M. (2019). Secondary sex ratio in assisted reproduction: an analysis of 1 376 454 treatment cycles performed in the UK. *Human Reproduction Open*, 2019(4). https://doi.org/10.1093/hropen/hoz020
- Henderson, I., Lacey, L., Akhtar, M. A., & Quenby, S. (2022). Ethnic group and reason for ART failure: analysis of HFEA registry data from 2017-2018. Fertility and Sterility. https://doi.org/10.1016/j.fertnstert.2022.11.005
- 22. Sharpe, A., Avery, P., & Choudhary, M. (2018). Reproductive outcome following pre-implantation genetic diagnosis (PGD) in the UK. *Human Fertility*, 21(2). https://doi.org/10.1080/14647273.2017.1336259
- 23. Kamath, M. S., Antonisamy, B., Mascarenhas, M., & Sunkara, S. K. (2017). High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births. *Reproductive BioMedicine Online*, *35*(3). https://doi.org/10.1016/j.rbmo.2017.06.013
- 24. Sunkara, S. K., Antonisamy, B., Selliah, H. Y., & Kamath, M. S. (2017). Perinatal outcomes after gestational surrogacy versus autologous IVF: analysis of national data. *Reproductive BioMedicine Online*, 35(6). https://doi.org/10.1016/j.rbmo.2017.08.024
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- 26. Ghuman, N. K., Mair, E., Pearce, K., & Choudhary, M. (2016). Does age of the sperm donor influence live birth outcome in assisted reproduction? *Human Reproduction*, 31(3). https://doi.org/10.1093/humrep/dev331
- 27. Maheshwari, A., Raja, E. A., & Bhattacharya, S. (2016). Obstetric and perinatal outcomes after either fresh or thawed frozen embryo transfer: an analysis of 112,432 singleton pregnancies recorded in the Human Fertilisation and Embryology Authority anonymized dataset. *Fertility and Sterility*, 106(7). https://doi.org/10.1016/j.fertnstert.2016.08.047
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- 29. Sunkara, S. K., Khalaf, Y., Maheshwari, A., Seed, P., & Coomarasamy, A. (2014). Association between response to ovarian stimulation and miscarriage following IVF: An analysis of 124 351 IVF pregnancies. *Human Reproduction*, 29(6). https://doi.org/10.1093/humrep/deu053
- 30. Maalouf, W. E., Mincheva, M. N., Campbell, B. K., & Hardy, I. C. W. (2014). Effects of assisted reproductive technologies on human sex ratio at birth. *Fertility and Sterility*, *101*(5), 1321–1325. https://doi.org/10.1016/j.fertnstert.2014.01.041

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# Choose a Fertility Clinic – focused consultation 2025

**Details about this paper** 

Communication(s):

Organisational risk:

•	•		
Area(s) of strategy this paper relates to:	Regulating a changing environment / Supporting scientific and medical innovation		
Meeting:	Authority		
Agenda item:	7		
Meeting date:	9 July 2025		
Author:	Clare Ettinghausen, Director of Strategy & Corporate Affairs		
Annexes	Annex A Screenshot of current CaFC page		
	Annex B Outline of CaFC survey		
For information or decision?  Recommendation:	For decision  The Authority is asked to discuss and approve:      That a focused consultation as set out in section 4 is published over the summer with a read out of the responses coming to Authority for discussion and decision over the full CaFC publication in Autumn 2025.		
	<ul> <li>That we should seek views on the four metrics set out at paragraph 4.3.</li> <li>That in line with the Authority's decision in March 2025 to maintain the current multiple birth rate of 10% but to change how it is reporte at inspection to report by exception - the multiple birth rate for every clinic is removed from the headline rate on CaFC and only reported by exception where the rate is above 10%.</li> </ul>		
Resource implications:	To be resourced by HFEA staff		
Implementation date:	Summer 2025		

As set out in section 3

Low

# 1. Background

- **1.1.** The Authority last discussed Choose a Fertility Clinic (CaFC) in <u>May 2025</u>. At that meeting, the background to CaFC was set out including updates to the headline metrics (data) which were then published as an <u>'interim CaFC' in May 2025</u>.
- 1.2. The Authority noted that by the end of 2025, CaFC will be updated with detailed data to the end of 2023 (births) and 2024 (pregnancies) and the metrics used in this publication would be decided following a focused consultation with the sector and patient groups on the most appropriate metrics for the upcoming 'full' CaFC publication.
- 1.3. It was also noted in the May 2025 meeting that following the publication of the full CaFC at the end of 2025, the information programme that begun with PRISM will be complete.
- 1.4. The Authority agreed that following the publication of the full CaFC later in 2025, we should review the different information sources held on the HFEA website and consider whether they can be brought together in a more unified or different way.
- **1.5.** This paper outlines *only* the planned focused consultation on the headline metrics for the full CaFC publication in late 2025.
- 1.6. Section 2 is a reminder of how the balance of treatment activity has changed over time; section 3 outlines how the focused consultation will be carried out; section 4 gives an overview of the focused consultation and if multiple births should be shown on the front page; section 5 gives next steps and in section 6, the Authority are asked for decision to go forward with the focused consultation.

# 2. Metrics and changes over time

- 2.1. In this paper we use the term 'headline metrics' to cover the metrics on the clinic profile page in CaFC (namely the single metric at the top of the page and the current three metrics further down the page). See Annex A for screenshots showing this.
- **2.2.** To recap: the following summary was set out in the May 2025 Authority paper:
- **2.3.** The headline metrics for CaFC were agreed in 2016-17. The metrics were:
  - Birth per embryo transferred this is based on the number of births (counted as a single birth event) divided by the total number of embryos transferred, for fresh cycles with the patient's own eggs.
  - Births per egg collection based on the number of births (counted as a single birth event) divided by the total number of egg collections over a 12-month period and following their usage over a maximum of 24 months.
  - Multiple births based on the total number of multiple birth events divided by the total number of birth events.
- 2.4. The decision to adopt these metrics followed a period of consultation and beta testing (see also paragraph 3.1). It reflected Authority policy concerns including that metrics should assist in the reduction of multiple births. The balance of treatment activity in the sector and multiple birth practices have both changed significantly since then. In summary:
  - The balance of fresh and frozen cycles has changed 20% of IVF cycles in 2012 used frozen embryos, in 2022 that had increased to around 45% of cycles. Moreover, we have observed that many large clinics now undertake significantly less than 40% of fresh treatments in their overall mix of treatments provided. In such circumstances a headline metric based solely on fresh transfers risks providing an unrepresentative picture of individual clinic performance.

- Multiple births have decreased from 17% in 2012 to around 4% today.
- The use of donor treatments has increased from 11% in 2012 to around 16% of IVF cycles in 2022. Typically, where donor eggs are younger than the age of the patient it increases the likelihood of success.
- The growth in the number of cycles which use PGT-A, sometimes alongside 'batching cycles' both these developments, either separately or together, can impact on the accuracy of the birth per embryo transferred metric. This is because: first, the metric doesn't take into account where the patient has undergone egg collection and testing and shows no 'normal' embryos and therefore an embryo transfer doesn't occur; second, when cycles are 'batched' the patient undergoes multiple cycles with PGT-A from which an embryo is selected; third it doesn't reflect the multiple cycles undertaken to achieve an embryo transfer (NB. batching is also undertaken without PGT-A and again this wouldn't reflect the number of cycles undertaken to reach embryo transfer). In sum, PGT-A and batching may therefore elevate the rate based on per embryo transfer and risks undermining the effectiveness of births per embryo transferred as a fair measure of clinic performance.

### **2.5.** It was also noted that:

- While the predominant fertility treatment in the UK is still fresh or frozen transfer with own eggs, the growth in donor eggs and the use of PGT-A, especially when combined with batching cycles, raise questions as to whether our current headline metrics are the most useful ones to inform patient choice now or in the future.
- for the 'interim' CaFC we decided to present two headline metrics: birth per embryo transferred (measured two ways: a 'consolidated' rate involving all transfers (including frozen, donor and PGT-A etc.) and a 'fresh' rate, based on fresh transfers of own eggs as used since 2017) and multiple births.

### 3. Focused consultation

- 3.1. The Authority agreed in the May 2025 meeting that a focused consultation should be carried out to review the headline metrics published for the full CaFC. (It is important to note the previous consultation on metrics in 2016/17 was part of a much larger exercise seeking views on our new website and other elements; there is therefore no need to undertake a similar scale consultation.)
- **3.2.** It was noted that the HFEA data is not a predictive model for individual patients' chances of success.
- **3.3.** Members noted the increase in use of PGT-A and potential benefits of publishing data on cycles started rather than embryos transferred. Members also noted the important health benefits of the decrease in multiple births and that they did not want to see a change in behaviour and increase in multiple births as a result of any changes in published metrics.
- **3.4.** Members noted that the metrics used need to be a fair measure of clinic performance and the most useful ones to inform patients and the public.
- **3.5.** The focused survey will be available in an online format to ensure it is easy to complete via phone or laptop/computer, and accessible versions will be supplied on request.
- **3.6.** To gain views from HFEA licensed centre staff, professional and patient organisations, and patients we will do the following:
  - Send the consultation to every HFEA licensed centre directly to the Person Responsible
  - Publicise the consultation for clinic staff to respond to via Clinic Focus
  - Send directly to the <u>Professional and Patient Organisation Stakeholder groups</u>
  - Share directly with the HFEA Patient Engagement Forum.

- We may also publicise on HFEA social media channels
- **3.7.** Depending on the scale of response, this may impact how much analysis can be carried out before the Authority next discuss this in the Autumn.
- 3.8. The survey will be open for at least six weeks, with the exact launch date to be agreed following design and user testing of the survey over the next few weeks. The results will be shared with the Authority for further discussion and decision over the full CaFC publication in the Autumn.

### 4. Consultation overview

- **4.1.** As noted above, the consultation will have a small number of questions currently looking *only* at the metrics published on each clinic's CaFC profile page. An indication of the areas to be covered is set out in Annex B.
- **4.2.** Respondents will be asked to identify how they are responding (e.g. patient, professional (clinic staff), on behalf of a professional body etc.) and there will be background information to explain the context of the survey as set out in section 2 above.
- **4.3.** Respondents will be asked to rank their preferences from four metrics: births per cycle/births per egg collection/births per embryo transfer and births per embryo transferred with an explanation of the differences. Our starting point is that a limited number of metrics is most straightforward to understand. There are currently three as shown in Annex A.
- **4.4.** Respondents will also be asked whether they prefer a rate that amalgamates (combines) different treatments (i.e. one that includes fresh transfer/frozen transfers/own/donor eggs/PGT-A cycles) or a rate drawn only from various sub-sets of treatments.

### Multiple births rate

- **4.5.** As set out in paragraph 2.3 above, the current headline metrics on CaFC include a multiple birth rate.
- **4.6.** The Authority last discussed multiple births in <u>March 2025</u> when it was noted that the national average multiple birth rate is now below 3.5% and 92% of clinics with over 150 IVF cycles are below the 10% rate. The <u>Authority agreed</u> at the meeting that the current multiple birth rate of 10% should be maintained, but that reporting at inspection and in the following inspection reports should only be *by exception* when a clinic is above the 10% rate.
- **4.7.** Given this, it would follow that we would only report on multiple births by exception on CaFC rather than for every clinic.
- 4.8. The Authority is asked if the multiple birth rate for every clinic should be removed from the headline rate on CaFC and only reported by exception where the rate is above 10% and therefore not included in the consultation.

# 5. Next steps

- 5.1. Should the Authority agree with the plan set out in section 3 above, then the consultation will proceed. A working group made up of HFEA staff will analyse the results and report back to the Authority. We would also provide the results to those groups set out at 3.6 above and in Clinic Focus.
- **5.2.** We will then seek to publish the full CaFC with metrics as determined by the Authority following feedback from the consultation later in 2025.

### 6. For decision

## **6.1.** The Authority is asked to agree the following:

- That a focused consultation as set out in section 4 above is published over the summer with a read out of the responses coming to Authority for discussion and decision over the full CaFC publication in Autumn 2025.
- That we should seek views on the four metrics set out at paragraph 4.3.
- That in line with the Authority's decision in March 2025 to maintain the current multiple birth rate of 10% but to change how it is reported at inspection to report by exception the multiple birth rate for every clinic is removed from the headline rate on CaFC and only reported by exception where the rate is above 10% and therefore not included in the consultation.

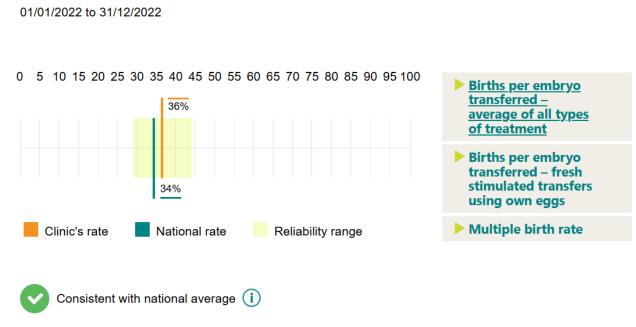
# **Annex A Screenshots of CaFC profile page**



#### Current individual clinic interim CafC data

The three data points below could be reduced or be changed following consultation

# Births per embryo transferred - average of all types of treatment



## **Annex B Outline of CaFC survey**

### Introductory text

The survey link will take users to a HFEA webpage containing background information as summarised in paragraph 2.4 above. All information will be written in as lay language as possible.

The survey will consist of 10 questions at most starting with administrative details such as whether a person is replying individually or on behalf of an organisation/group/clinic.

#### Clinic's CaFC profile statistics

These questions will ask respondents to rank which statistic they prefer as the main one from births per cycle/births per egg collection/births per embryo transfer/births per embryo transferred. It will be set out that all of these rates can be shown by different age groupings.

A description of each rate will explain when it 'counts' from and how the rate is calculated and whether a cumulative rate can be shown.

### Questions on the different ways the statistics could be presented

These questions ask about the different ways the statistics could be presented, for example, by including or excluding different treatment types such as fresh or frozen treatments, or own or donor eggs, or PGT-A cycles.

It also asks whether there should be one combined statistic for all treatments that could be split by age.