Human Fertilisation & Embryology Authority

Authority meeting

Date: 22 January 2025 – 12.45pm – 4.00pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of the meeting held on 20 November 2024 and matters arising (5) For decision	12.50pm
3. Chair and Chief Executive's report (10) For information	12.55pm
4. Committee Chairs' reports (15) For information	1.05pm
5. Performance Report (25) For information	1.20pm
6. Strategic Risk Register (15) For information	1.45pm
7. Strategy 2025-2028 (15) For decision	2.00pm
Comfort break – 10 minutes	2.15pm
8. Modernising fertility law – Stem cell-based embryo models (45) For decision	2.25pm
9. Modernising fertility law – IVGs (45) For decision	3.10pm
10. Any other business (verbal) (5)	3.45pm
11. Close	

Minutes of Authority meeting held on 20 November 2024

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	22 January 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 20 November 2024 as a true record of the meeting.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Minutes of the Authority meeting on 20 November 2024

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Catharine Seddon Christine Watson Geeta Nargund Rosamund Scott Anya Sizer Stephen Troup
Apologies	Steve Pugh, Department of Health and Social Care (DHSC)	
Observers	Adrian Thompson, Board Apprentice Farhia Yusuf (DHSC)	
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) Paula Robinson (Head of Planning and Governance) Rebecca Taylor (Scientific Policy Manager) Anna Coundley (Policy Manager) Anna Wilkinson (Policy Manager) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members
There were 14 members at the meeting – 9 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, A warm welcome was extended to the four new members, who commenced their appointment with the HFEA in October.

1.2. The Chair informed the meeting that apologies had been received from Steve Pugh from the Department of Health and Social Care.

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

1.4. Declarations of interest were made by:

- Tim Child (Clinician working at IVF company and consultant to a fertility company)
- Geeta Nargund (Clinician at a licensed clinic and licence holder)
- Anya Sizer (Fertility consultant and trustee of The Fertility Alliance)
- Stephen Troup (Consultancy work within the fertility sector)

2. Minutes of the last meeting and matters arising

2.1. The minutes of the meeting held on 25 September 2024 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

2.2. Members were advised that the matters arising item regarding communicating licensing, regulatory activity and incident information had been actioned as detailed in the Committee Chairs' reports paper presented to the meeting.

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. She informed members that she had chaired a meeting of the remuneration committee which had agreed to recommend a pay increase for staff in line with Government recommendations. The Chair said that this recommendation had been agreed by DHSC.

3.2. The Chair informed members that, together with the Chief Executive, she had attended the DHSC ALB Senior Leaders meeting where DHSC had shared the government's health mission and proposed plans.

3.3. The Chair spoke about the Conference hosted at Girton College, Cambridge, to mark the 100th anniversary of the birth of Mary Warnock, and expressed her thanks to the team at Girton College for hosting this event. The Chair outlined the programme with its focus on past, present and future developments and the range of speakers on this topic.

3.4. The Chair informed members that she would be attending and speaking at the Fertility Conference 2025 in January.

3.5. The Chief Executive spoke about the meeting held in early November with the Regulatory Innovation Office and the recently published Government innovation white paper.

3.6. The Chief Executive stated that he will be speaking at the Progress Educational Trust (PET) Conference held in early December.

3.7. Members were informed that the Director of Finance & Resources, Tom Skrinar, will be employed full time by the HFEA in the New Year. Currently this position is shared with the Human Tissue Authority (HTA) but following discussions with DHSC and HTA it was agreed to end this shared agreement. The Chief Executive stated that Tom's remit will be expanded to include IT and Planning and Governance and the relevant staff teams had been informed of the impending changes.

Decision

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

Effective Governance

3.9. The Chief Executive introduced the paper and spoke to the proposal to amend article 1.6 of Annex D of the standing orders to allow for seven members of the Licence Committee, rather than six.

3.10. Members were reminded that they had received the required notice of motion in advance of this meeting, regarding the intention to amend the standing orders by a formal vote.

Decision

3.11. The members unanimously voted in favour of the changes to the standing orders.

Action

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

4. Committee Chairs' reports

4.1. The Chair introduced the report in its new format, following the decisions made by the Authority in September regarding communicating licensing, regulatory activity and incident information. The Chair invited Committee Chairs to add any other comments to the presented report.

4.2. The Licence Committee Chair (Graham James) stated that the newly appointed Authority members observed the recent Licence Committee meeting as part of their induction process. The committee had completed its committee effectiveness review. He welcomed the new format of the Committee Chair's report which reflected the decisions made at the last meeting regarding transparency of information.

4.3. The Statutory Approvals Committee (SAC) Deputy Chair (Geeta Nargund) provided further information about the PGT-M applications and special directions considered by the committee and stated that one PGT-M application had been refused due to insufficient data being available. The SAC Deputy Chair congratulated the committee staff for the excellent papers submitted to the committee.

4.4. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave a brief overview of the remit of the committee for the benefit of the new members. Further context on the Data Security and Protection Toolkit (DSPT) 'limited assurance' audit was provided to members, noting that DSPT was designed for NHS Trusts and is not proportionate for small ALBs. The committee has asked the executive to review outstanding audit recommendations and propose those that they intend to accept at risk. Further information was provided on digital projects including the intention to publish Choose a Fertility Clinic (CaFC) data in 2025, governmental functional standards and the deep dive discussion on internal incidents and near misses. Members were reminded that they had received an invitation to the assurance mapping training being held on 6 December.

4.5. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed the authority that SCAAC had met on 7 October and had received an update from the Newcastle Fertility Centre on their mitochondrial donation work. The committee had also discussed stem-cell based embryo models (SCBEMs), in vitro derived gametes and scientific considerations relevant to the 14-day rule. The committee chair also gave SCAAC a brief overview of the annual horizon scanning meeting which was held at the European Society of Human Reproductive Medicine (ESHRE) Conference.

4.6. The Chair thanked all Committee Chairs for the reports and stated that committee papers and minutes are published on the HFEA website.

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and for the benefit of the new Authority members stated that the Key Performance Indicators (KPIs) which had been agreed previously with the Authority measure various operational aspects of the business conducted by the HFEA.

5.2. The Chief Executive informed members that the report includes data up to the end of October. Performance continues to be good across the KPI indicators with ten green, two amber, one red and four neutral indicators.

5.3. The Chief Executive referred to the HR KPIs contained in the paper and informed members that staff turnover remains green, staying below the 15% target and is continuing its downwards trend. The Chief Executive spoke of the small size of the organisation, lack of promotion and public pay constraints which can affect staff turnover.

5.4. Whilst staff sickness slightly exceeds the 2.5% target, the Chief Executive remarked that this was due to seasonal viruses common at this time of the year.

5.5. The Chief Executive informed members that the staff survey had closed a couple of weeks ago and a response rate of 87% had been achieved. The question regarding whether staff members were happy working for the HFEA had received a positive response of nearly 90%. He expressed his thanks and gratitude to all staff for their work and contribution to the HFEA.

5.6. The Chair, on behalf of the Authority, expressed thanks to the Chief Executive and other member of the Senior Management Team for the happy and positive working culture they have created at the HFEA.

Compliance and Information

5.7. The Director of Compliance and Information stated that the new members of the inspection team are continuing to integrate well into the team and that there has been a significant, sustained improvement in the KPIs. Thanks were expressed to the whole team for this work.

5.8. Members were informed that the DSPT is now aligned to the cyber assessment framework (CAF) which has increased demands on the staff involved. A scoping exercise has been finalised and roles and responsibilities have been assigned. It was noted that the audit support documentation has not yet been published.

5.9. The Director of Compliance and Information informed members that the scoping of the application pen testing requirements is being undertaken with the supplier and is likely to start in the New Year.

5.10. The new Business Continuity plan has been finalised and disseminated amongst HFEA staff and plans are being made for the next business continuity exercise.

5.11. Members were informed that 20 bids for the Epicentre and CM (document management system) replacement had been received and these were now being independently reviewed by the bid assessment panel. It is anticipated that the tender will be awarded in late December with the project starting in the new calendar year.

5.12. The Director of Compliance and Information stated that the new Opening the Register (OTR) systems are now providing real benefit with 138 cases closed in September and 185 in October. Over the past six months 936 applications had been processed.

5.13. OTR applications remain steady with approximately 100 received each month, meaning that inroads have been made to the waiting list which has been reduced by 30% since its peak.

5.14. For applications closed in the last 6 months the wait time was 8.6 months and for those closed in the past month the average wait time had been reduced to 5.4 months.

5.15. Members were informed that OTR applications relating to post 2005 identifiable donors remain low with an average of 3 a month. In addition, there is a steady and small number of pre 2005 donors removing their anonymity and post 2005 updating their details.

5.16. A member questioned whether it was possible to develop a KPI to monitor special direction applications. The Director of Compliance and Information undertook to discuss this suggestion with the relevant teams.

5.17. A member congratulated the inspection team for the work and the positive results which are being achieved.

5.18. The Chair asked whether it would be possible to develop a KPI for OTR applications now that a good inroad had been made to the waiting list. The Director of Compliance and Information stated that this would be possible in the future as the Dynamics case manager system allows staff to split and differentiate applications, but further work is first required to reduce the waiting list, especially with regard to complex applications.

Strategy and Corporate Affairs

5.19. The Director of Strategy and Corporate Affairs spoke about the recent changes in law relating to screening in fertility treatment meaning that enhanced screening is no longer necessary for couples having reciprocal IVF, and people who are HIV+ with an undetectable viral load can now donate their gametes for use in treatment as 'known donors'.

5.20. Members were informed of the very good response rate across all groups, for the national patient survey which closed recently. Recruitment is now underway for new members for the Patient Engagement Forum (PEF).

5.21. The Director of Strategy and Corporate Affairs informed members that the annual State of the fertility sector report was published in October and the Family formations in fertility treatment report is due to be published shortly.

5.22. Members were informed that both stakeholder group meetings were held in October and groups discussed the HFEA's proposed new strategy and were able to feed ideas into this process.

5.23. The Governance Team and wider HFEA team had been involved in the induction process of the four new Authority members and thanks were given to all who had organised this.

5.24. The Director of Strategy and Corporate Affairs spoke of applications to the Register Research Panel (RRP); in response to a question, she explained the process for reviewing such applications and the strict criteria they must meet. Members were reminded that the HFEA now publishes a Data Research newsletter and an annual update on the will come to the Authority during 2025.

5.25. Members were updated on activities around National Fertility Awareness Week including webinars run for civil servants.

5.26. The Director of Strategy and Corporate Affairs informed members that the Head of Planning and Governance, Paula Robinson, will retire next year and explained how the team will be structured in the future. Members expressed their sincere thanks to the Head of Planning and Governance for all her work, especially in developing the new strategy.

Finance

5.27. The Director of Finance and Resources informed members that a detailed review of the forecasting for the remaining period had been completed and that a small underspend of £60,000 is being forecast, before taking into account any accounting adjustments such as potential provisions reversals.

5.28. Members were informed that due to the procurement process for the Epicentre replacement taking longer than first anticipated it will be necessary to return a proportion of the Grant-in-Aid (GIA) to the department and reapply for the same funds next year (and that there were no guarantees currently that this request would be agreed by the Department).

5.29. Members were informed of the work that is being undertaken by the Finance Team to reduce the historic debt.

5.30. A member questioned whether the budget would be out of step due to income being 8% down but treatment fees being higher for the same period. The Director of Finance and Resources responded that discussions are currently taking place with the National Audit Office (NAO) with regard to the level of provision required for duplicate invoices.

5.31. The Chief Executive reminded members that 95% of the HFEA's income comes from billable activities and stated that the duplicate invoices arose from the change from the old system to the new PRISM system and a few centres entering duplicate data. Members were reminded that the new system has a number of checks and balances which ensures that this issue should not arise again.

5.32. A member questioned whether there was any concern from PRs about the lack of stakeholder events this year. The Chief Executive responded that when events are held there needs to be real value for all attendees and given pressures on both the sector and the HFEA this year it was not deemed viable to arrange PR events.

5.33. A member suggested that due to changes in PRs and licence holders it may be worth canvassing what events would be welcomed. The Director of Strategy and Corporate Affairs commented that there are now fewer PRs but that they often manage multiple clinics.

5.34. The Director of Compliance and Information reminded members of the various speaker engagements that HFEA staff had undertaken during the year and the range of different groups engaged with during the year.

5.35. The Chair drew the discussion to a conclusion stating that it had been an incredibly busy year for the HFEA and on behalf of the Authority expressed thanks to all staff for their efforts.

Decision

5.36. Members noted the performance report.

6. Strategy and Planning

6.1. The Chair introduced the agenda item reminding the Authority that they previously decided to extend the current strategy for an additional year, to the end of 2024.

6.2. The Head of Planning and Governance introduced the paper and spoke about how the proposed strategy was developed using input from various Authority workshops, staff members and stakeholder meetings and members of the patient engagement forum. The timeline for preparation and publication of the final strategy and corresponding business plan was explained.

6.3. The Head of Planning and Governance stated that a priority identified early in the planning phase was that the strategy should recognise the increasing complexity of the UK fertility landscape, and the challenges that presents, both for patients making difficult treatment choices, and for clinics and the HFEA.

6.4. The vision is to ensure a well-regulated fertility sector, which is trusted by patients and the wider public, with the information which the HFEA provides being useful and accessible and that biosciences that lead to innovations in treatment can flourish, within an ethical framework. This is encapsulated in the following vision statement:

Regulating for confidence:

- Safe treatment
- Right information
- Supported innovation

6.5. The Head of Planning and Governance spoke of the discussions around future challenges and priorities and how these helped to populate the columns in the tables contained in the strategy headed ‘we want’ and ‘we will’. These show the changes that the HFEA wants to see and explains at a high level how the HFEA will drive those changes. The corresponding business plans for each year of the strategy would set out the actions in more detail.

6.6. The proposed strategy has two main pillars of ‘regulating a changing environment’ and ‘supporting scientific and medical innovation’. The Head of Planning and Governance provided further information on proposed activities under both of these pillars.

6.7. The Head of Planning and Governance highlighted the range of stakeholder feedback received on the draft strategy and that overall, the feedback was very positive and supportive.

6.8. The Head of Planning and Governance spoke of how the strategy feeds into the business plans and for 2025/26 this is likely to include law reform; CaFC; the fees review; the Epicentre, content manager and portal project; patient survey outcomes and implementation; and supporting the Government’s ten-year health plan, once published.

6.9. The Head of Planning and Governance stated that the business plan for the coming year, and possibly beyond, would need to be flexible to allow for any reprioritisation which might be required for law reform discussions.

6.10. Members discussed the proposed strategy, noting that it had captured all their previous workshop discussions and articulated these into the vision and two main pillars of the strategy.

6.11. Members discussed how the HFEA can use its voice to not only highlight issues relating to the fertility sector but the wider women's health policy and 10-year health plan (once published). The HFEA's continued transparency and the visibility of its work was noted as very important.

6.12. Members discussed the issue raised regarding whether the Authority potentially has a role in regulating pricing, noting how complex this work could be. It was felt that the HFEA did not have the resources to consider this for the 2025-2028 strategy, but that it might be possible for the next period. Members discussed the generational change in attitude in spending money and behaviour of consumers and how this would affect pricing of goods and services.

6.13. Members discussed the importance of continuing to speak up for patients and highlighting the less represented groups, to ensure that all voices are heard.

6.14. Members discussed the potential of combining efforts with other health bodies and regulators to help influence and inform policy.

6.15. Member discussed the duty of providing the right information and how to continue to raise the HFEA's visibility with patients, noting that the landscape of how people access information is changing with a greater emphasis on the internet and social media.

6.16. Members discussed the impact of the law reform work, noting that the timetable for any changes is for Government to decide.

Decision

6.17. The Authority welcomed the direction of travel outlined in the draft strategy presented to the meeting.

6.18. It was agreed that regulating pricing should not be included in the 2025-2028 strategy, but that it may be appropriate to consider this for the next strategy.

Action

6.19. Authority members to send their views on the positioning of the vision statement within the document to the Head of Planning and Governance by close of business next day.

6.20. Head of Planning and Governance to further develop the strategy and business plan for the January 2025 Authority meeting.

7. Law Reform – Scientific developments

7.1. The Chief Executive spoke about the suite of proposals on law reform which the HFEA had published last year. Within these proposals were several items which required further work and therefore these two agenda items are brought to the meeting today for debate and decision.

7.2. The Chair spoke about the Warnock Report published in 1984 which identified the need for principles and limits to govern fertility treatment and human embryo research and recommended the creation of the HFEA. The Chair spoke about the developments within the sector and how the HFEA and the sector are operating within an Act which is 30 years old. The Chair spoke about the considerable work the HFEA undertook to develop the proposals for law reform.

7.3. The Chair stated that as an expert regulatory body, it is expected that the HFEA advises the Government on proposed changes to the law. The Chair stressed that the issue of embryo

research is not being re-opened but that the Authority needs to consider whether to recommend amending the time limit permitted for research.

7.4. The Scientific Policy Manager introduced the paper and informed members that one of the areas identified under the theme future scientific developments in the proposals published last year was the 14-day rule for embryo research and the paper before the Authority considers this item in detail and makes recommendations for change.

7.5. The Scientific Policy Manager highlight to members that a number of countries are considering extension to 28 days, such as Netherlands, Sweden and Norway. Members were informed that the Health Council of Netherlands (an advisory body) had recommended the change to 28 days in a report published in October 2023.

7.6. Members were informed that the Scientific and Clinical Advances Advisory Committee (SCAAC) considered the scientific and technical case for and against extending the 14-day rule at their meeting held in early October. A summary of SCAAC's discussions is shown at section four of the paper presented to the Authority Meeting.

7.7. The Scientific Policy Manager spoke of the case to revisit the 14-day rule noting that advances in embryo culture makes it possible to sustain embryos for longer and that previous concerns about sentience have been clarified. The opportunity to be able to research what is called the "black box" of embryo development from 14 to 28 days during which time miscarriages occur and congenital conditions begin to develop was highlighted.

7.8. Members were informed that advances arising from better understanding of early embryo development could also enable validation of stem cell-based embryo models (SCBEMs).

7.9. The Scientific Policy Manager outlined the case for keeping the status quo and the case for extending the 14-day rule as detailed in the paper presented to the Authority; clearly explaining both to members.

7.10. The Scientific Policy Manager highlighted the surveys and public dialogue already conducted regarding the ethical and moral considerations and public opinion of extending the 14-day time limit for embryo research.

7.11. The Chair of SCAAC spoke of the process and options which patients are given when considering donating embryos for research. He took the opportunity to summarise the outcomes of the SCAAC's discussion on this item for the Authority:

- The committee had agreed there was a case for extending the limit beyond 14 days.
- The majority of the committee agreed that if the time limit were to be extended there should be a new upper limit agreed, and whilst the committee did not make a recommendation on a new time limit, 28 days was the most widely discussed time period.
- The majority of the committee felt that the justification for extending the time limit should be considered on a case-by-case basis.

7.12. A number of members spoke in favour of extending the time limit to 28 days for the benefit of research, although this view was not unanimous. The potential benefits and positive impact for patients was highlighted, especially research into early pregnancy loss. A few members spoke strongly in favour of advancing such research.

7.13. In discussing the proposed time extension members noted that for research post 28 days material can be used which is obtained through early pregnancy loss or terminations. Members discussed the importance of having a defined upper time limit, for public confidence and researcher clarity.

7.14. Members discussed the ethical aspects of extending the time limit, noting the debate and public engagement during the creation of the Warnock Report. Members were informed that the Nuffield Council on Bioethics plan to look at ethical issues and public engagement around extension of the 14-day rule.

7.15. In response to a question the Director of Compliance and Information stated that embryo research is regulated by the HFEA and the purposes embryos can be used for is clearly set out in law, as described in section 2.6 in the paper before the Authority. A research application is scrutinised by the HFEA, both by the inspectors, peer review and those considering the approval of a licence. Following a licence being granted research premises are inspected in a similar way to a fertility clinic.

7.16. Continuing, the Director of Compliance and Information said that the HFEA Code of Practice makes it clear that we would expect patients give fully informed consent when donating their embryos to research following receipt of appropriate information from a designated person who is independent to the patient's treatment. A patient in a clinic should also have access to counselling when making decisions. Members were informed that the provision of information, offer of counselling and consent is all inspected against.

7.17. A number of members were reassured by the explanation and existing stringent processes the HFEA has in place for reviewing research applications.

7.18. Members discussed the principles of extending the time limit for research projects and came to the view that it should not be a blanket increase for all research projects, but that applications must set out the reasons for the extension and meet strict criteria. Any such applications must be considered on a case-by-case basis and should state the specific time limit beyond 14 days their research requires, which must be the minimum needed for the purposes of the research.

7.19. Members discussed the special status of the embryo as defined in the Act and that any research undertaken could provide significant results which may assist future patients. The principles around the protection, treatment and respect for embryo research from the original Warnock report would still be maintained.

7.20. Members discussed the scientific material and information which had been presented to them and the advice received from SCAAC.

Decision

7.21. The Authority agreed with a clear majority that there is now a case for recommending that the law is changed to extend the time limit on embryo research.

7.22. The Authority agreed that 28 days would be an appropriate new fixed upper limit.

7.23. The Authority agreed that if the new time limit is established for embryo research, those projects seeking to extend beyond 14 days would need to meet specific criteria.

Action

7.24. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

8. Law Reform – Patient protection and safety

8.1. The Policy Manager introduced the paper and informed members that this paper contains more detailed recommendations relating to the following law reform proposals:

- Proposal 3: The HFEA should have a broader and more proportionate range of regulatory enforcement powers.
- Proposal 4: The HFFEA should have the power to impose financial penalties.
- Proposal 5: The Act should be revised to include an over-arching focus on patient protection.
- Proposal 6: The Act should be revised to accommodate developments in the way fertility services are provided.

8.2. The Policy Manager informed members that the proposals contained within the papers have been developed following discussions with a number of other regulatory bodies, both inside and outside of the healthcare sector and with the Institute of Regulation. The work was also discussed at the September meeting of the Licensed Centres Panel.

8.3. The Policy Manager introduced the recommendation to have an expanded ladder of regulatory sanctions and commented that the benefits of such would be:

- To provide greater flexibility to take earlier, more targeted and proportionate action.
- To enable targeted, regulatory action that would better protect the patient and reduce the complete (temporary or permanent) closure of clinics, which is unlikely to be in patients' best interests.
- To provide a more agile regulatory system incorporating sanctions that are quicker to agree and implement, in addition to the more severe sanctions that the HFEA have.

8.4. The Policy Manager explained that the expanded ladder of regulatory sanctions would allow for greater flexibility to vary or suspend licences.

8.5. Members were informed that if the HFEA was given the legal power to issue written warnings it would, effectively, put the HFEA's current process on a statutory footing and provide a stronger incentive for PRs to address non-compliances. The Policy Manager stated that many other regulators such as the CQC, Gambling Commission and Ofcom use formal written warnings to address non-compliance.

8.6. The Policy Manager spoke about the proposal for the HFEA to be able to issue fixed penalty notices (FPNs) noting that many regulators such as CQC, The Pension's Regulator and The Gambling Commission have powers to issue financial penalties as a means of incentivising compliance.

8.7. The Chair of the Licence Committee spoke in favour of having a greater variety of regulatory sanctions available to address breaches of licence conditions. He highlighted the possible benefits that this could bring.

8.8. Members discussed the proposed expanded ladder of regulatory sanctions, noting that financial penalties must be applied consistently to both the private and public sector. Some members expressed concerns that fines might be passed onto patients. Members agreed that any new suite of tools would carry resource implications for the HFEA and should not be overly onerous to use.

8.9. The Policy Manager referred to proposal 5, that the Act should be revised to include an over-arching focus on patient protection, and informed members that last month the Patient Safety Commissioner published a set of patient safety principles. She commented that the HFEA's jurisdiction is confined to areas specifically set out in the Act and in the absence of any specific reference to patients in the Act, it is difficult for the HFEA to create enforceable regulatory policies to address patient protection issues.

8.10. Members were very supportive of the proposed approach, as detailed in the paper presented to the Authority, to introducing a patient protection principle to the legislation. Members discussed the possibility of adding a set of principles to the Act, as with the Mental Capacity Act and a number of members offered their support to the Policy Team in developing this idea further.

8.11. The Policy Manager referred to proposal 6, that the Act should be revised to accommodate developments in the way fertility services are provided. The Policy Manager explained that a range of activities marketed as fertility treatments now take place outside of HFEA licensed clinics in a variety of settings and the challenges this can cause for patients

8.12. Members discussed how the patient pathway has changed since the Act was first introduced, noting that the Act currently reflects a model where treatment happens at a licensed centre. Members were supportive of the greater patient protection these proposals could bring.

8.13. The Policy Manager explained that the proposal is to bring more activity under the HFEA's regulatory oversight by expanding the list of activities that the HFEA currently regulates and to regulate entities which provide those activities.

8.14. Members spoke of not adding to the burden of regulation unnecessarily and that regulation should be proportionate for the services being offered at the facility, noting that the Authority could adopt a graduated approach to the regulation and oversight of these service providers, depending on the type of activity being offered.

8.15. Members spoke about possible unintended consequences of expanding regulatory oversight, including the impact on HFEA's resources and the possible movement of some services abroad to circumvent the UK regulations.

Decision

8.16. The Authority agreed to an expanded ladder of regulatory sanctions; lowering the thresholds for placing conditions on a licence or suspending a licence and that the addition of formal written warnings and fines would better support the HFEA's regulatory and compliance activities.

8.17. The Authority agreed the proposed approach, as outlined in the paper, to introducing a patient protection principle to the legislation.

8.18. The Authority agreed the proposed approach to bringing more activity under HFEA regulatory oversight by expanding the list of activities that it currently regulates.

8.19. The Authority agreed with the general direction of travel to bring into the regulatory scope some of the service providers which are not currently being regulated.

Action

8.20. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

9. Any other business

9.1. The Chair thanked everyone for their active participation in the meeting which had considered a full and detailed agenda.

9.2. The Chair informed members that this would be Adrian Thompson's last meeting as his Boardroom Apprentice placement concludes at the end of December. On behalf of the Authority the Chair thanked Adrian for his time and hoped that he had found his placement useful.

9.3. Adrian Thompson thanked the HFEA for the opportunity to undertake his placement with the organisation and said that he had learnt a lot from his time with the Authority.

9.4. There being no further items of any other business the Chair extended season's greetings to all and reminded members that the next Authority meeting will be held on 22 January 2025.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 22 January 2025

Authority meeting

Matters Arising

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	2		
Meeting date	22 January 2025		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For discussion		
Recommendation	To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.		
Resource implications	To be updated and reviewed at each Authority meeting		
Implementation date	2024/25 business year		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
20 Nov 2024 item 3.12	Board Governance Manager to publish the revised standing orders.	Board Governance Manager	Nov 2024		Revised standing orders were published on the HFEA website Email sent to Authority members, Audit and Governance Committee members and the HFEA's auditors with link to revised standing orders. The standing orders have also been updated in the standard licensing pack.
20 Nov 2024 Item 6.19	Authority members to send their views on the positioning of the vision statement within the document to the Head of Planning and Governance by close of business next day.	Authority members	21 Nov 24		Many thanks to members for responding. The final draft of the strategy will be presented to the Authority.
20 Nov 2024 Item 6.20	Head of Planning and Governance to further develop the strategy and business plan for the January 2025 Authority meeting.	Head of Planning and Governance	Jan 2025		Sign-off of the strategy will be presented to the Authority.
20 Nov 2024 Item 7.23 and 8.20	The HFEA to continue to discuss with DHSC and Government the law reform proposals.	Senior Management Team	Ongoing		Ongoing discussions with DHSC and as part of our quarterly accountability meetings.

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:	22 January 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 November 2024.
- 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 November – attended all-staff event
    - 4 December – attended PET Conference
    - 8-11 January – spoke at Fertility 2025

2.2 Chief Executive

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

    - 27 November – attended all-staff event
    - 28 November – interviewed for the new Head of Planning and Governance
    - 4 December – spoke at PET Conference and gave an interview to the New York Times
    - 6 December – attended the Audit & Governance Committee
    - 8 January – gave an interview to Times Radio
    - 21 January – attended the Government 2025 IFG's annual conference

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Item number:	4
Meeting date:	22 January 2025
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

Output from this paper

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

1. Committee reports

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

2. Recent committee items considered

1.2 The table below sets out the recent items to each committee:

Date	Items considered	Centres	Outcomes
Licence Committee:			
31 October	Renewal inspection report	Guy's Hospital	Decision reserved
16 January	Renewal inspection report	NewLife Fertility Centre	Minutes not yet approved
	Renewal inspection report	The Fertility & Gynaecology Academy	Minutes not yet approved
	Variation of premises	Guys Hospital	Minutes not yet approved
Other comments:	None.		
Executive Licensing Panel:			
18 November	Interim inspection report	Manchester Fertility	Approved – continuation of licence
	Variation – Change of PR	Bridge Clinic	Approved – licence (and ITE certificate) varied
4 December	Renewal inspection report	Royal Surrey Hospital NHS Foundation Trust	Approved – 2-year licence
	Focused interim inspection report	Edinburgh Fertility Centre	Approved – continuation of licence
	Interim inspection report	Acorn Fertility	Approved – continuation of licence
	Variation – change of premises and PR	TFP Wessex Fertility	Approved – licence (and ITE certificate) varied
	Variation – change of premises	Care Fertility London	Approved – licence varied
	Interim inspection report – executive update	The James Cook University Hospital	Approved – continuation of licence
7 January	Initial inspection report	Roylance Stability Storage Limited ta ('trading as') Sampled	Minutes not yet approved
	Research renewal report	Wellcome Centre for Cell	Minutes not yet approved

Date	Items considered	Centres	Outcomes
		Biology	
	Interim inspection report	Sunderland Fertility Centre	Minutes not yet approved
	Interim inspection report	TFP Nurture Fertility Ltd	Minutes not yet approved
	Interim research inspection report	Institute of Reproductive and Developmental Biology	Minutes not yet approved
	Variation to add embryo testing	Centre for Reproductive Medicine, Coventry	Minutes not yet approved
21 January	Variation – change of PR	Leicester Fertility Centre	Minutes not yet approved
	Variation – change of LH	TFP Thames Valley Fertility	Minutes not yet approved
	Variation - change of LH	Andrology Unit, Hammersmith Hospital	Minutes not yet approved
	Variation – change of PR	Centre for Reproductive and Genetic Health City	Minutes not yet approved
	Variation of Licence to include new Standard Licence Condition T52	London Women's Clinic	Minutes not yet approved
	Variation of Licence to include new Standard Licence Condition T52	Agora Clinic Brighton	Minutes not yet approved
	Variation of Licence to include new Standard Licence Condition T52	Agora Clinic Eastbourne	Minutes not yet approved
Other comments:	None.		

Licensing Officer decisions:

November and December	14 x ITE import certificates	Various	All granted
	Change of centre name	CARE Fertility Plymouth	Approved - licence (and ITE certificate) varied
Other comments:	None		

Statutory Approvals Committee:

29 October	Mitochondrial donation:	Newcastle Fertility at Life	Approved

Date	Items considered	Centres	Outcomes
	M0033 - to avoid Leber Hereditary Optic Neuropathy (LHON), OMIM #535000 caused by mutation in MTND1, OMIM *516000		
	PGT-M: Developmental and Epileptic Encephalopathy 106 (DEE106), OMIM #620028	Care Fertility Nottingham	Approved with four additional conditions
	PGT-M: Neurodevelopmental Disorder with Involuntary Movements (NEDIM), OMIM #617493	Glasgow Royal Infirmary	Approved
	PGT-M: NR5A1 Related Sex Reversal (XX or XY) and Adrenal Insufficiency, OMIM *184757	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Approved
	PGT-M: Ichthyosis, Congenital, Autosomal Recessive 4A (ARCI4A), OMIM #601277	Care Fertility Leeds	Approved
	PGT-M: Beta-Ureidopropionase Deficiency (UPB1D), OMIM #613161	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Refused
	PGT-M: Weaver Syndrome (WVS), OMIM #277590	Guy's Hospital	Approved with two additional conditions
25 November	PGT-M: Brain Small Vessel Disease 2 (BSVD2), OMIM #614483	Edinburgh Fertility Centre	Approved with one additional condition
	PGT-M: Dyskeratosis Congenita, Autosomal Dominant 4, (DKCA4), OMIM #615190	TFP Oxford Fertility	Approved with five additional conditions
	Special direction for export of oocytes to Russia	Avenues	Granted
	Special direction for import of embryos from Hong Kong	TFP Wessex Fertility	Granted
	Special direction for export of embryos to Canada	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Granted
10 December	PGT-M: Intellectual Disability-	Aria Fertility	Minutes not yet approved

Date	Items considered	Centres	Outcomes
	Hypotonic Facies Syndrome, X-Linked, 1 (MRXHF1), OMIM #309580		
	PGT-M: Deafness, Autosomal Dominant 11 (DFNA11), OMIM #601317	Care Fertility Nottingham	Minutes not yet approved
	PGT-M: Macular Dystrophy, Patterned, 1 (MDPT1), OMIM #169150	TFP Oxford Fertility	Minutes not yet approved
	PGT-M: Split-Hand/Foot Malformation 4 (SHFM4), OMIM #605289	Guy's Hospital	Minutes not yet approved
	PGT-M: Pycnodysostosis, OMIM #265800	Guy's Hospital	Minutes not yet approved
	Special direction for export of sperm to US	TFP Oxford Fertility	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.		

Date	Items considered:	Outcomes:
Audit and Governance Committee:		
6 December	Papers can be found here Internal audit Progress with current audit recommendations External audit report – audit planning Risk update Digital projects – PRISM and Epicentre replacement Resilience, business continuity management and cyber security Human Resources bi-annual update 2024 Government functional standards	The Chair will report on this meeting verbally.
Other comments:	The Committee also conducted its annual review of effectiveness and received training on assurance mapping.	

Scientific and Clinical Advances Advisory Committee:	
The Committee's next meeting will be held on 3 February 2025.	
Other comments:	None.

3. Recommendation

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

1.4 Comments are invited, particularly from the committee Chairs.

Human Fertilisation & Embryology Authority

Monthly performance report

Performance up to December 2024

Evgenia Savchyna
Corporate Performance Officer
22/01/2025

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:	22/01/2025
Agenda item:	Item 5
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

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

Latest review and key trends

Latest review

- The attached report is for performance up to and including December 2024.
- There were thirteen Green, two Red, and two Neutral indicators.

Key trends

- The below table shows the red RAG statuses for the last three months.

October (1)	November (1)	December (2)
Debt collection within 40 days	Debt collection within 40 days	Debt collection within 40 days
		Inspection reports to committee within 65 working days

Human Fertilisation & Embryology Authority

Management summary

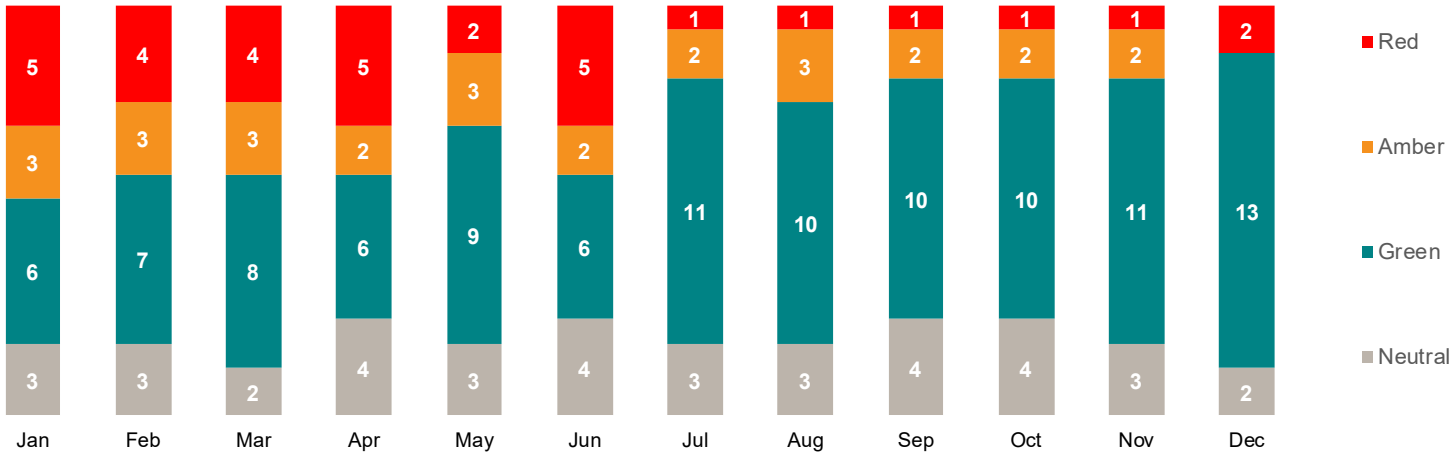
Management commentary

- Performance across KPI indicators remained consistently strong over the last six months with thirteen Green, two Red, and two Neutral indicators in December 2024.
- The Compliance team continues to perform well against their targets. Although the 'Inspection Reports to Committee' KPI was rated Red, this was due to just one report being delayed by four days. All other inspections KPI remained in Green.
- Following the Compliance KPI review, the PGT-M KPI target has been changed from 75 to 60 working days. The KPI remained in Green in December.
- December was a standard month for the Licensing team except for pressures for minutes due to the Christmas break.
- The OTR KPI is in progress and the team aims to finalise it in January 2025 and introduce the OTR KPIs based on the review's findings.
- The OTR waiting list slightly increased due to fewer OTRs being processed in December. This was a result of the team dealing with operational issues and identifiable OTRs that took longer to process, in addition to the Christmas break.
- The number of email enquiries remained the same as in November (106 enquiries). The number of phone enquiries was the lowest in December (17 calls only).
- Nine PQs and seven FOIs were completed and processed within targets in December.
- The 'Family Formations in Fertility Treatment 2022' report and the Chief Executive's speech at the PET conference on embryo research contributed to media coverage. The 'Donating your eggs' page saw a spike in views on 19 Dec reaching over 3K page views making it one of the top three pages of the month of December.
- Staff sickness was the lowest in December (1.6 %). HR will revisit the numbers in January 2025 to make sure that the figures were a reflection of the actual sickness in the reported period. Turnover was the lowest in December (9,2%) too.
- The Debt Collection KPI remains Red, primarily due to old debt. The targets for Average debtor days and percentage of invoices paid within 10 days have been met.

Key performance indicators

Human Fertilisation & Embryology Authority

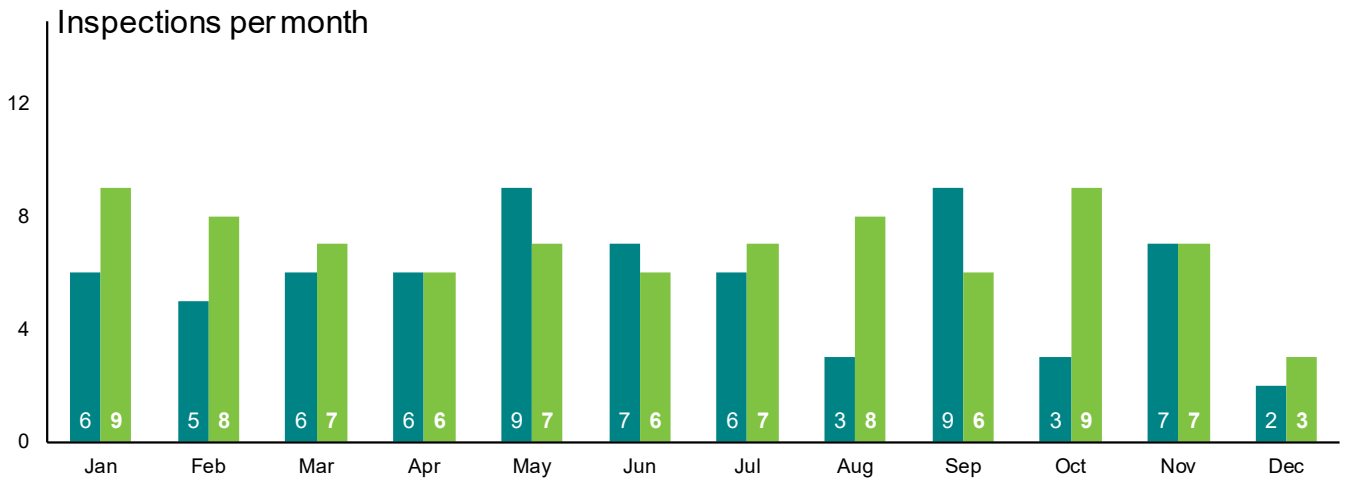
RAG status over last 12 months



RAG status over last 12 months

17 KPIs in total for each month

For December, the 2 red indicator are in these teams: Compliance (1) and Finance (1).



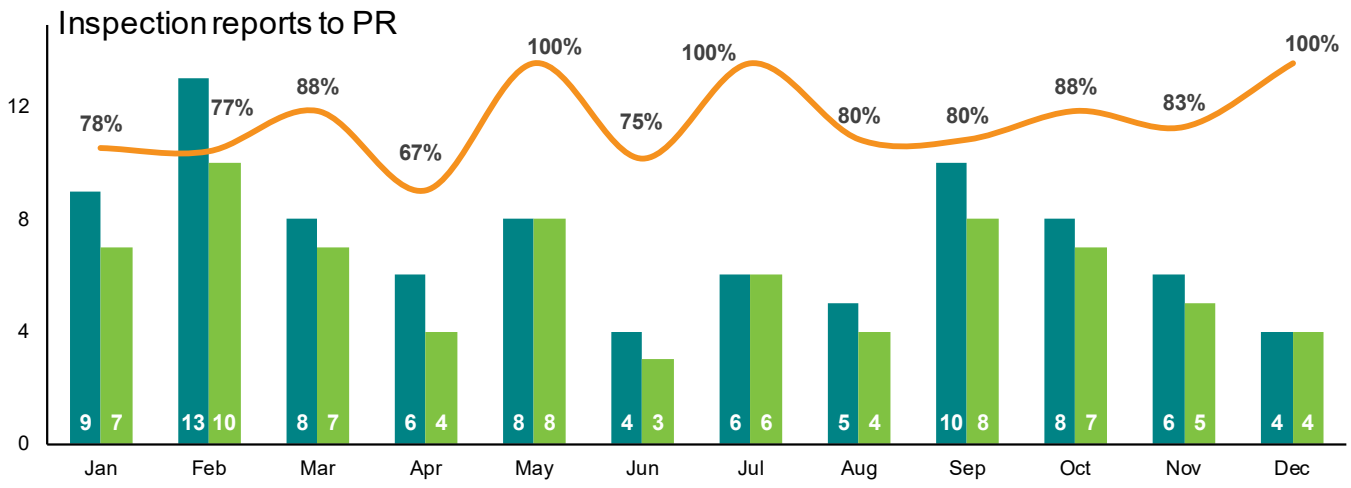
Status: **N/A**

Compliance

Inspections delivery

Target: **not defined**

Fewer inspections were planned for December 2024 due to the Christmas break. One additional inspection was added to the December plan.



Status: **Green**

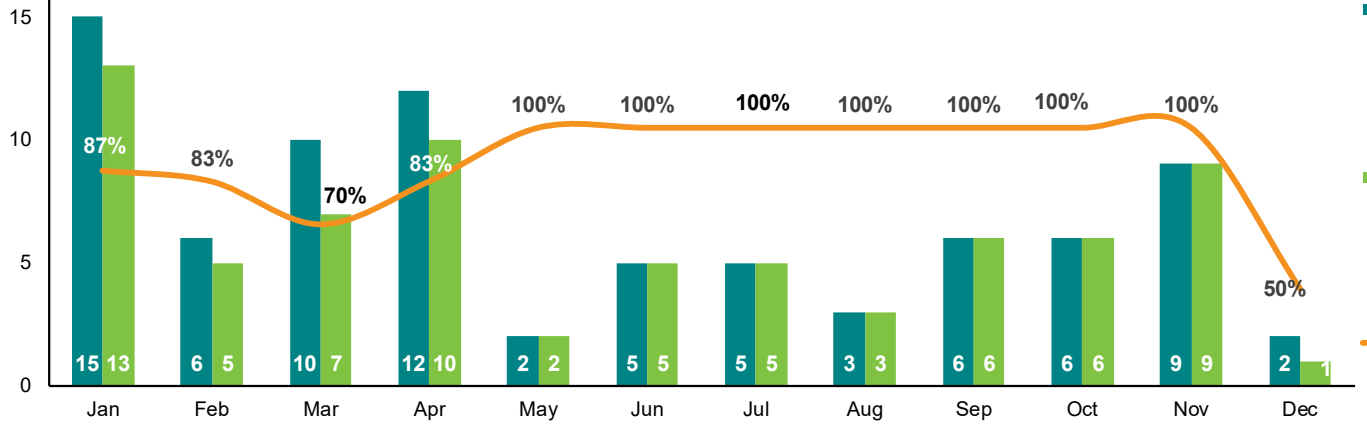
Compliance

Inspection reports sent to PR

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

All reports sent within KPI.

Inspection reports to committee



Status: **Red**

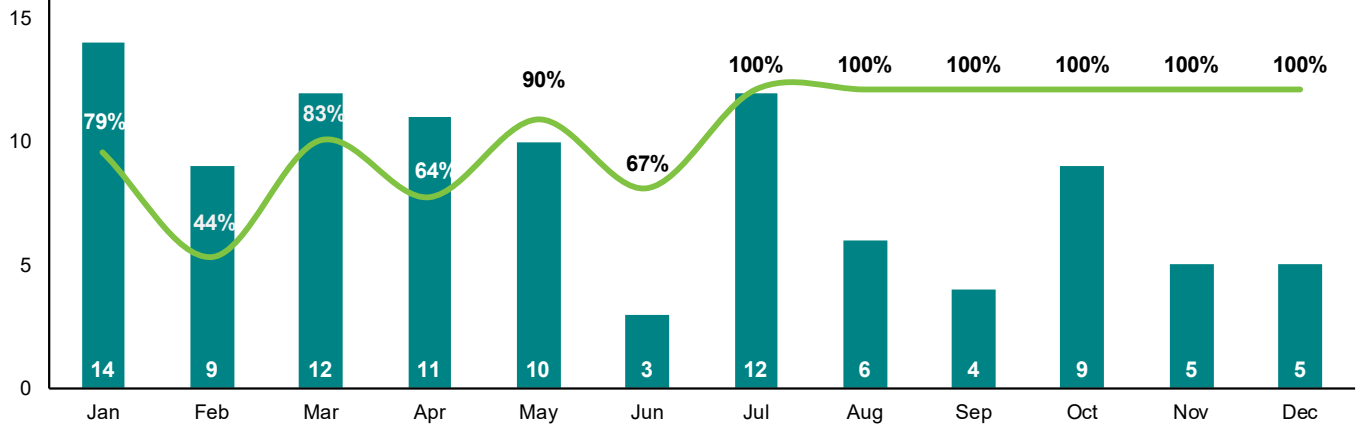
Compliance

Inspection reports sent to relevant licensing committee

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

One inpection report missed a KPI by 4 days due to post inspection actions.

End to end licensing



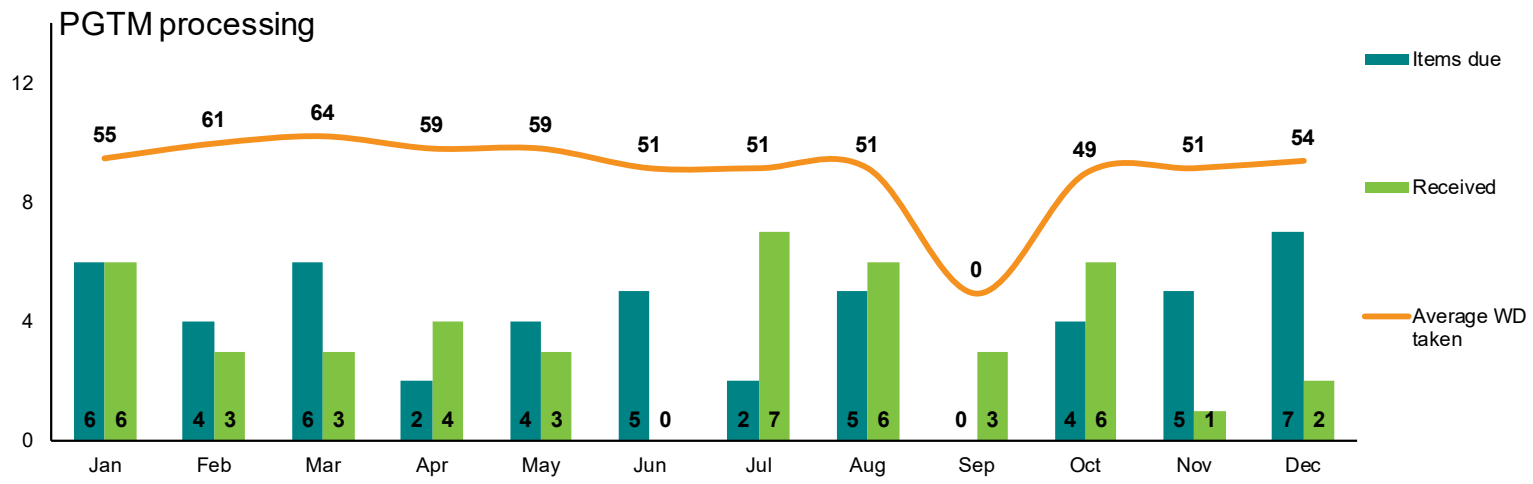
Status: **Green**

Compliance

End to end licensing process

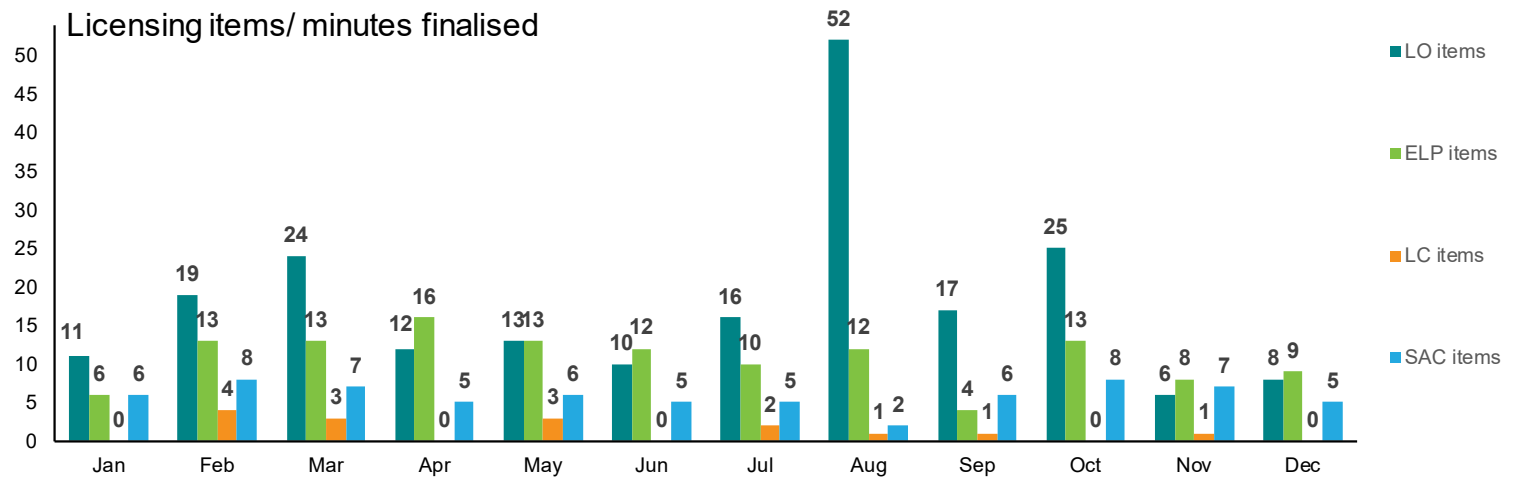
Target: **100% items completed within 80 working days**

All within KPI.



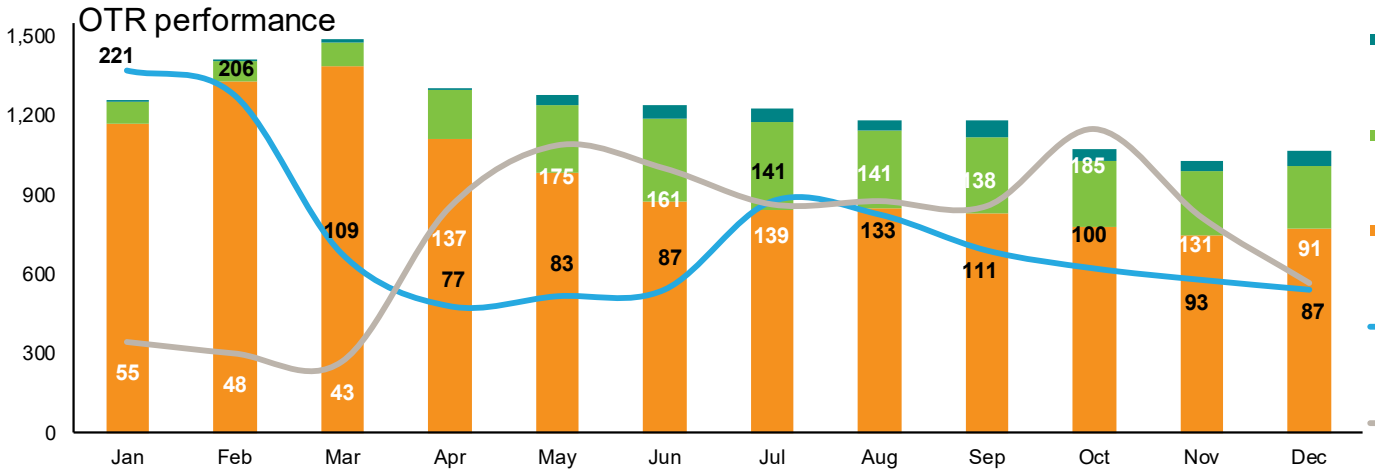
Status:	Green
Compliance	
PGTM processing efficiency	
New target - Dec 24: **100% within 60 working days**	

All PGTMs have been processed within KPI.



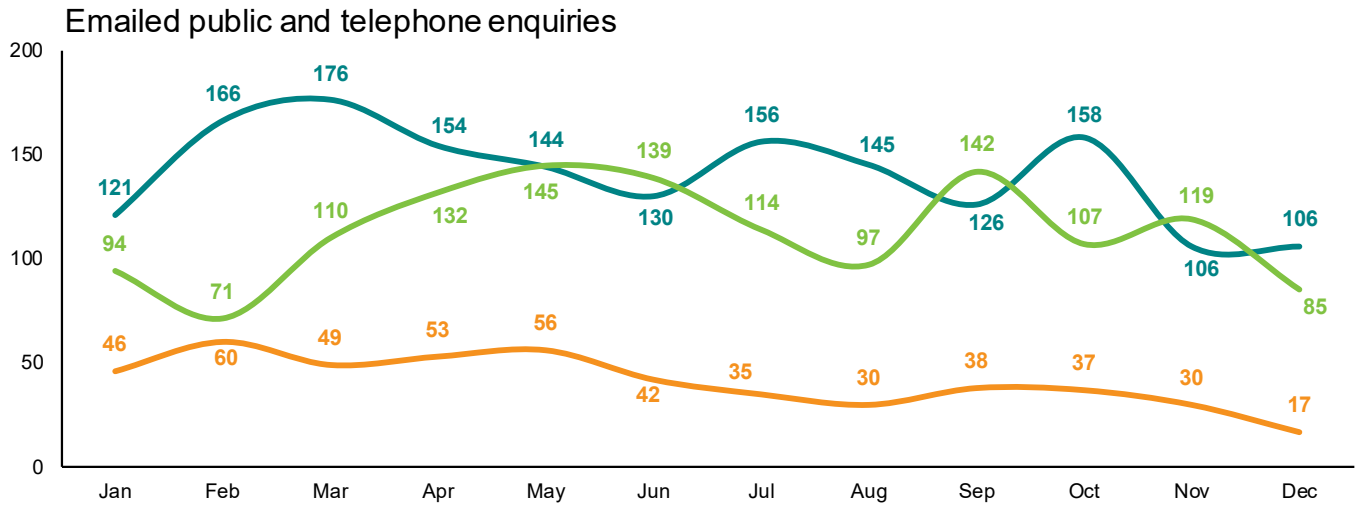
LO:	Green
ELP:	Green
LC:	Neutral
SAC:	Green
PlanGo	
Licensing efficiency	
Targets: **LO - 5 WD ELP - 10 WD LC - 15 WD SAC - 20 WD**	

Fairly standard month despite time pressures (especially for SAC minutes) owing to the Christmas break. The LO items this month were all ITE certificates.



Status:	N/A
Information	
OTR performance	
Target: to be developed	

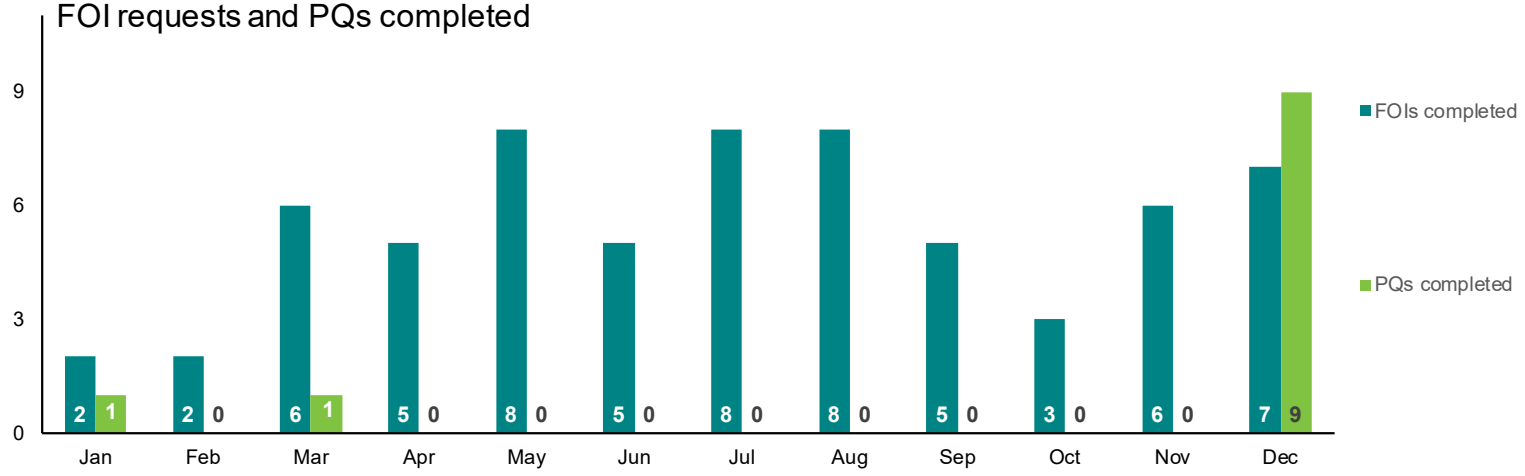
Significantly fewer OTRs processed this month due to resource needed to deal with operational issues, and all identifiable OTRs taking longer to process due to checking status with clinics. Waiting list slightly increased, due to above factors but also due to figures being taken after Christmas break (annual leave plus bank holidays mean OTRs can be received but would not be sent out).



Status:	N/A
Policy/Comms	
Emailed public and telephone enquiries	
Target: not defined	

We received the same number of enquiries that were received in November. We did receive a number of enquiries about Apricity as they announced shortly before Christmas that they would be ceasing all operations from 1 January 2025. Call themes: Beginning treatment (5), Other (4), Complaints (3), Donation (1), Legal parenthood (1), Funding (1) and Medical queries and concerns (1). 16 out 17 calls were straightforward and 1 call was challenging.

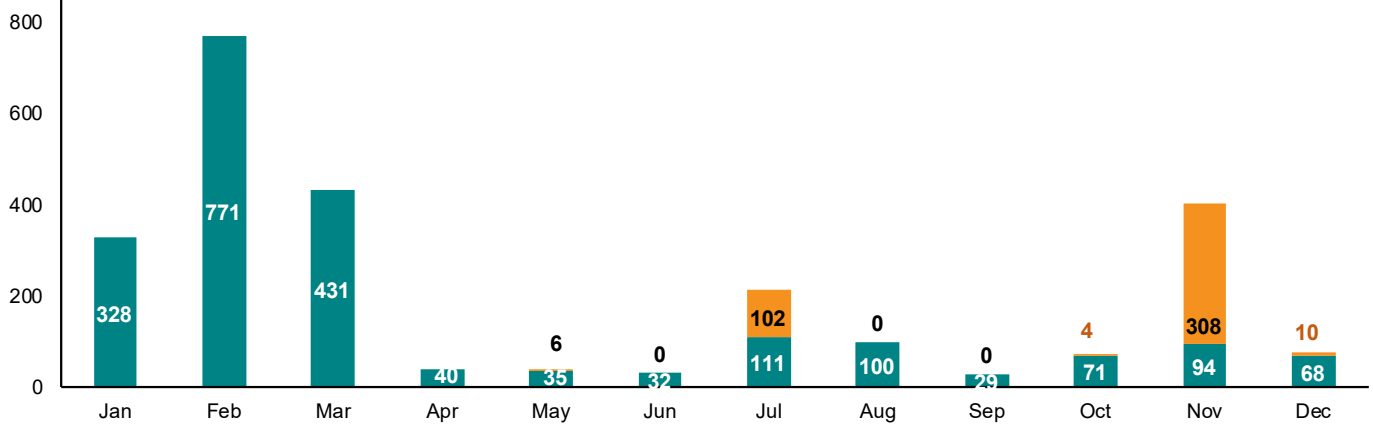
FOI requests and PQs completed



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

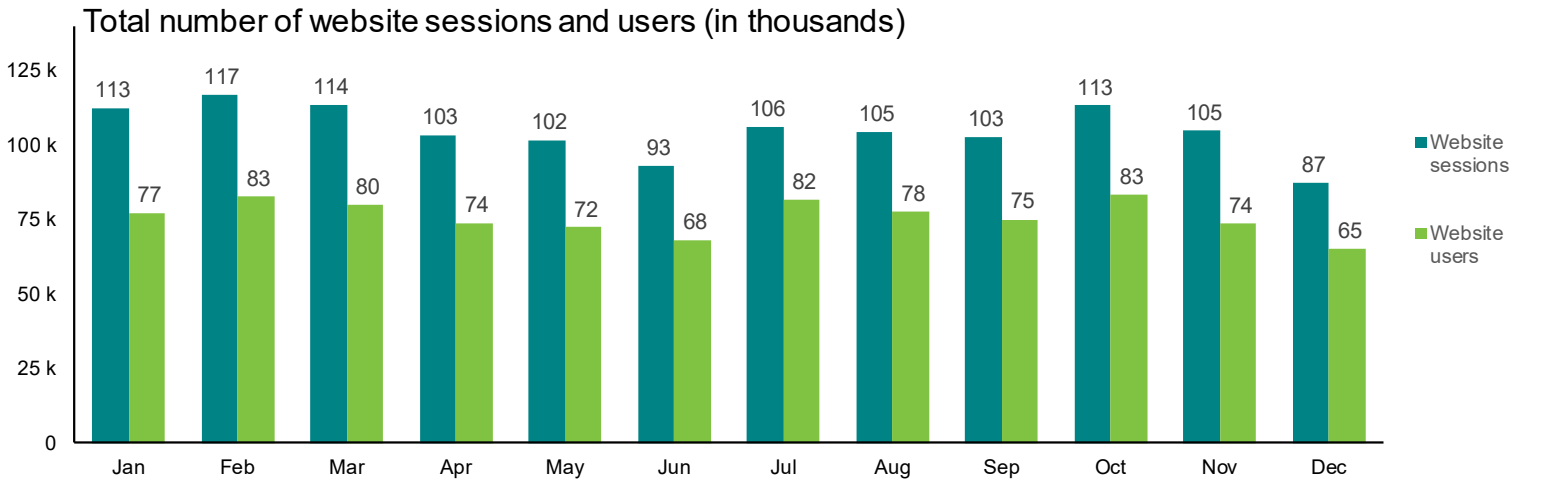
PQs were about egg donation and FOIs were about clinic success rates, cost of treatment, finance, embryo research, cumulative success rates, OTR, and IT.

Proactive and reactive media mentions



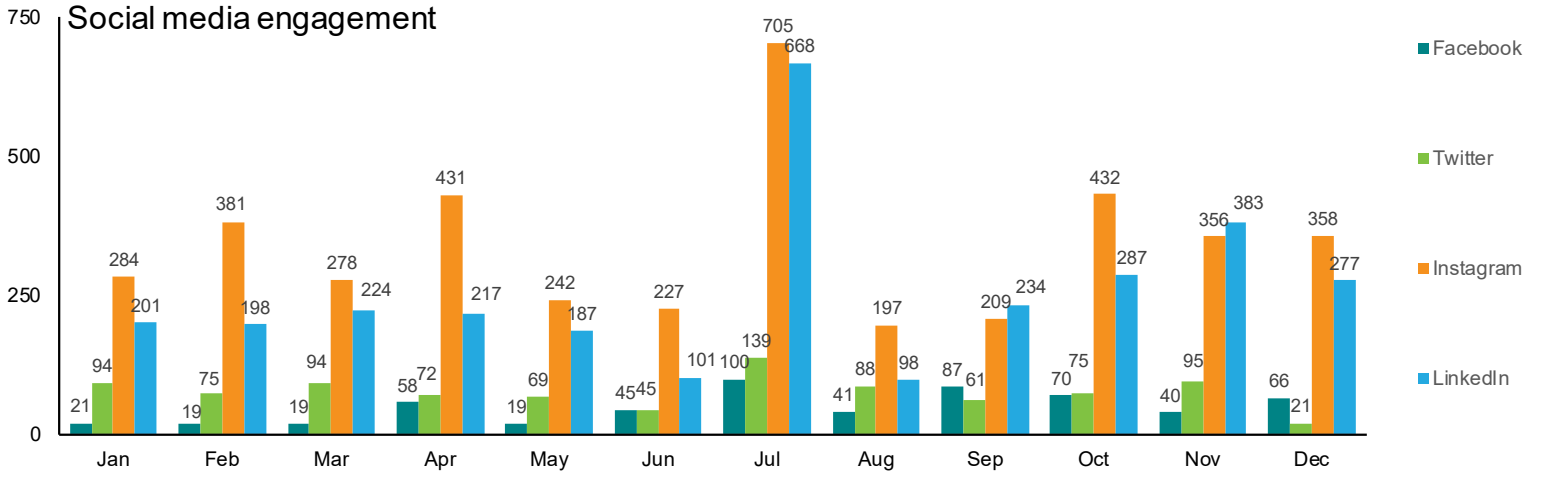
Status:	N/A
Comms	
Total media mentions (proactive and reactive split from April 2024)	
Target: **not defined**	

In December, the 'Family formations report' continued to receive coverage, as did the Chief Executive's speech to the PET conference on the special status of the human embryo. Other topics covered were single people having treatment, egg donation and unregulated sperm donation.



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

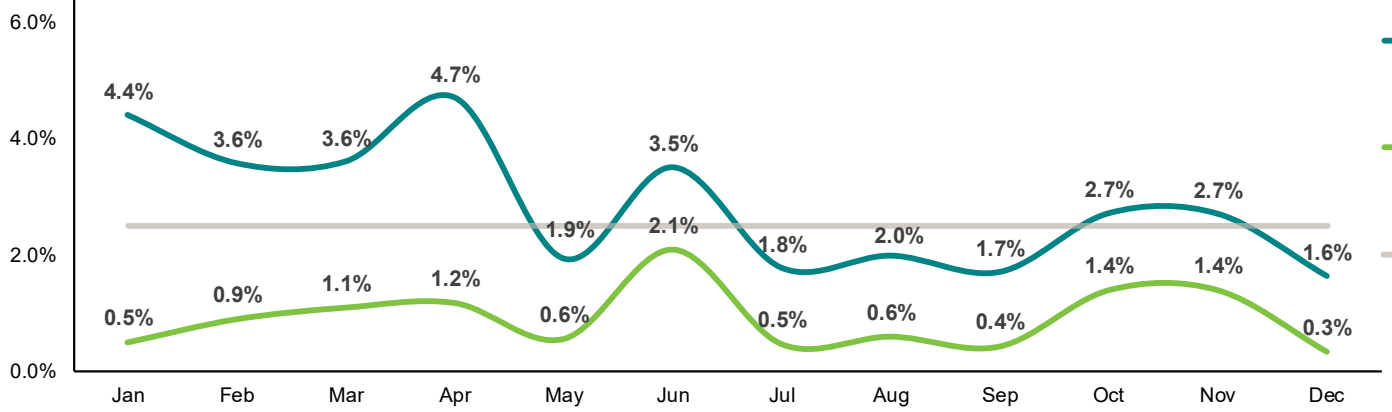
Overall website traffic was in line with trends of the festive period. The 'Donating your eggs' page saw a spike in views on 19 Dec 2024 reaching over 3k page views and making it one of the top three pages of the month.



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

Our channels saw high engagement in December, despite pausing all active content from 20 Dec 2024. The best performing post was 'How to support people going through fertility treatment during the festive period', with particularly strong engagement on Instagram and Facebook. Content also included Family Formations data, advice for single patients considering treatment, a blog from a solo mother and Grief Awareness week.

Staff sickness absence rate



Status: **Green**

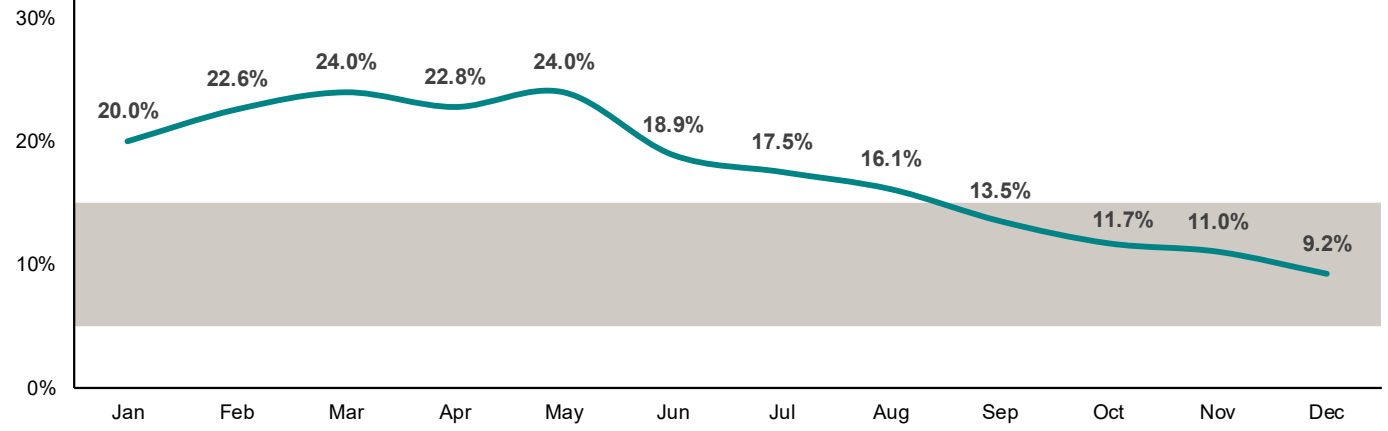
HR

Sickness

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

Sickness is very low for December. HR suspects not all is recorded so they will rerun the report next month which may result in a slight change.

Rolling annual turnover vs target range (5-15%)



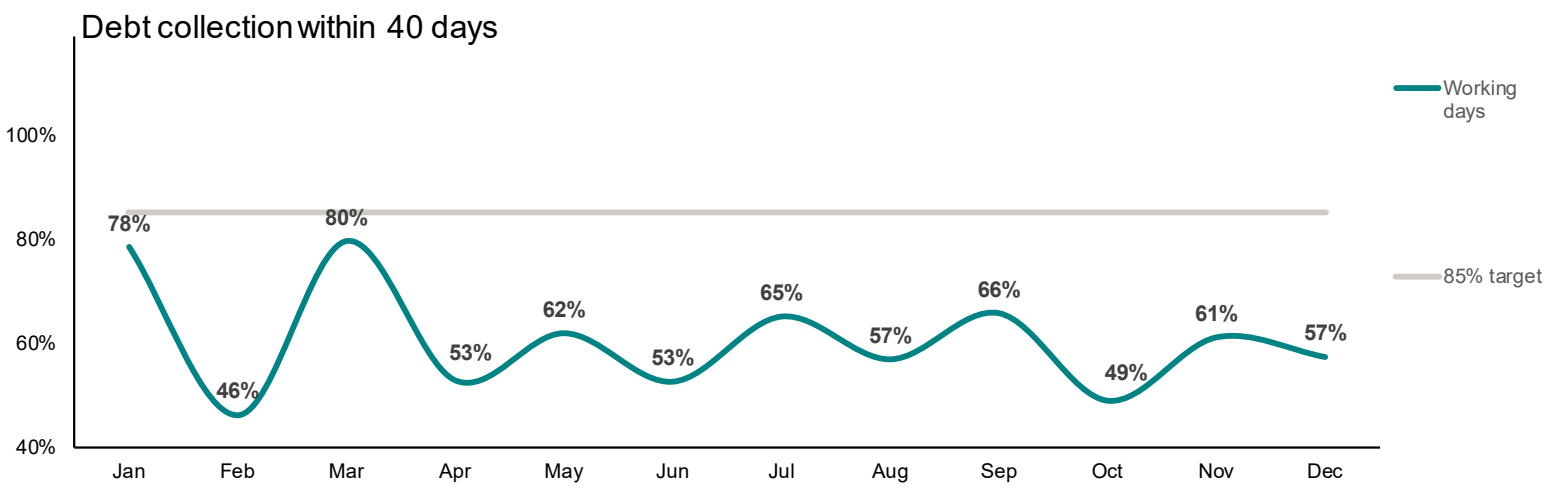
Status: **Green**

HR

Turnover

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

Our one leaver was planned, end of fixed term contract following an apprenticeship. Turnover is 7.96% otherwise.
Supplementary HR data: **Headcount - 78, Posts - 76, Vacant posts -1, Starters - 1, Leavers - 1.**



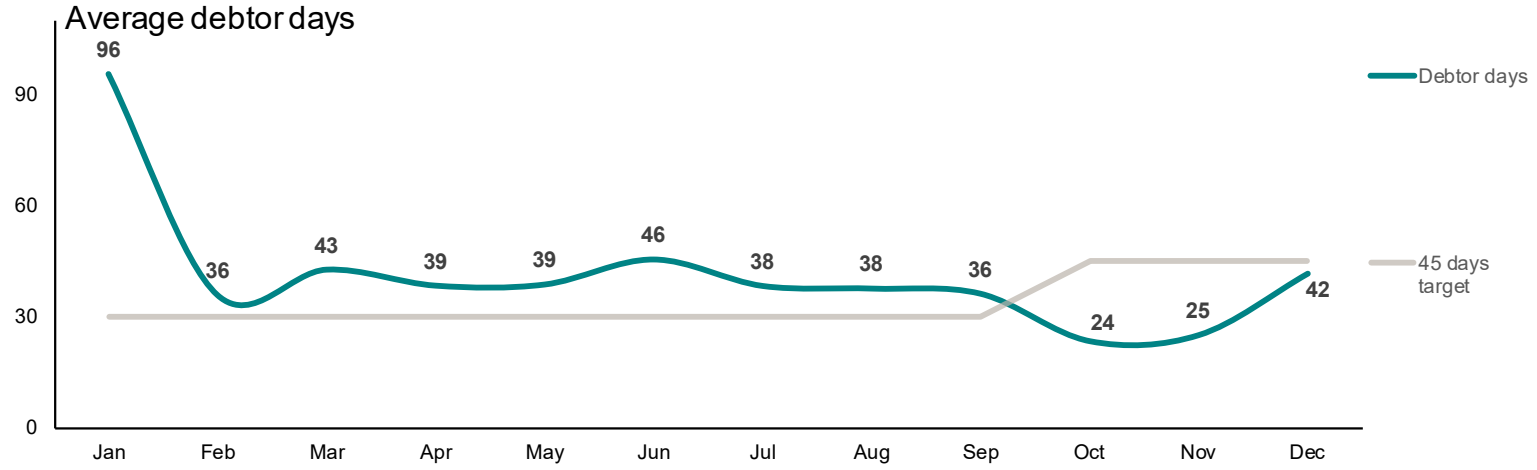
Status: **Red**

Finance

Debt collection

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

As above pressure is still being applied to older debt which impacts this KPI.



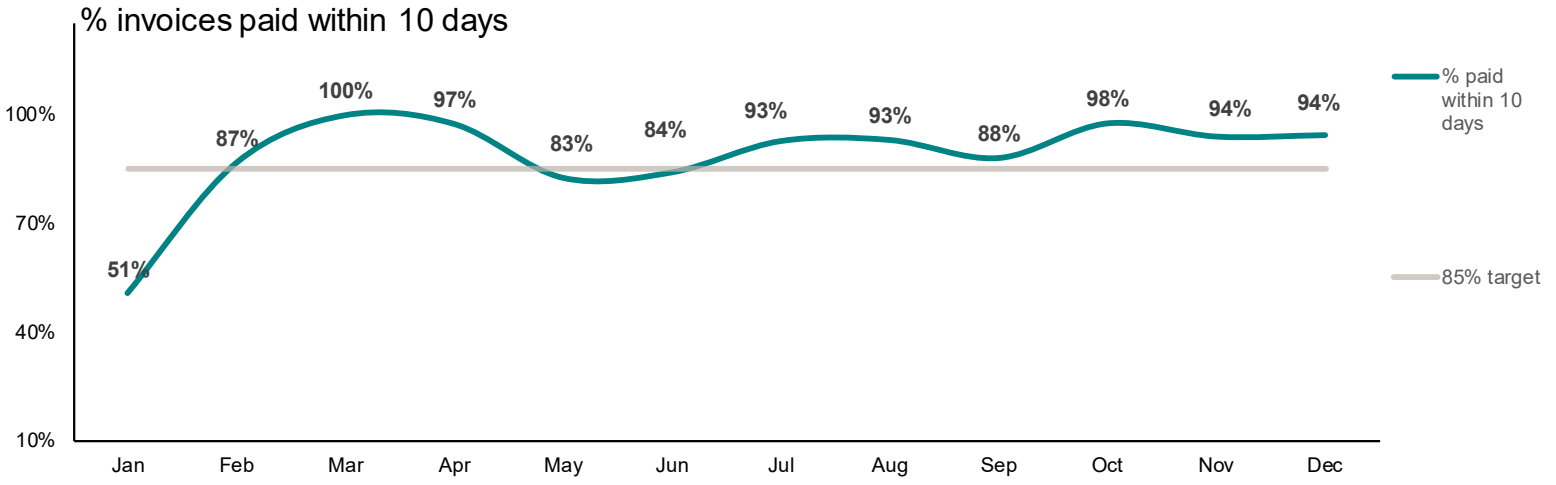
Status: **Green**

Finance

Debtor days

New target
from Oct 2024:
45 days or less

The target has been met.



Status: **Green**

Finance

Prompt payment

Target:
85% or more invoices paid within 10 days

The target has been met.

Human Fertilisation & Embryology Authority

Finance Report

Period to December 2024

Tom Skrinar
Director of Finance
07/01/2025

www.hfea.gov.uk

Summary financial position as at 31 December 2024

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Variance %	Full year Forecast £'000s	Full year Budget £'000s	Variance £'000s
Income	5,677	6,324	(647)	(10)	7,395	8,231	(836)
Expenditure	5,506	6,255	749	3	7,527	8,231	704
Total Surplus/(Deficit)	**171**	**69**	**102**		**(132)**	**0**	**(132)**

As of 31 December 2024, we are posting a net surplus of £171k and a surplus against the budget of £102k.

A breakdown of the components is detailed in the following slides.

In early January, we undertook a further review of plans and costs to the end of the financial year. The full year forecast reflects the information received from teams.

Human Fertilisation & Embryology Authority

2024/25 Income – YTD & Forecast Budget

As of October	YTD Actual	YTD Budget	Variance	Forecast	Full Year Budget	Variance
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Income						
DHSC Funding	484	809	(325)	642	1,078	(436)
Licence Fees	5,014	5,440	(426)	6,544	7,052	(508)
Other income	179	75	104	209	101	108
Total	**5,677**	**6,324**	**(647)**	**7,395**	**8,231**	**(836)**

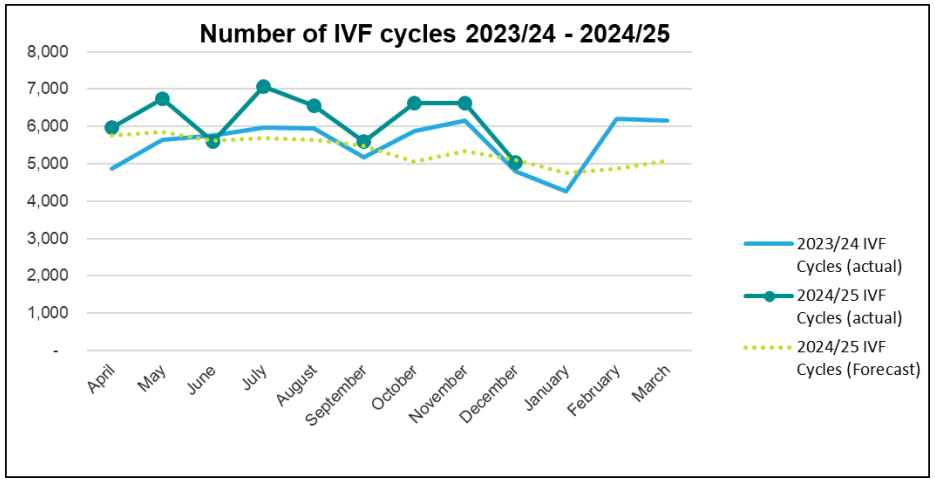
INCOME

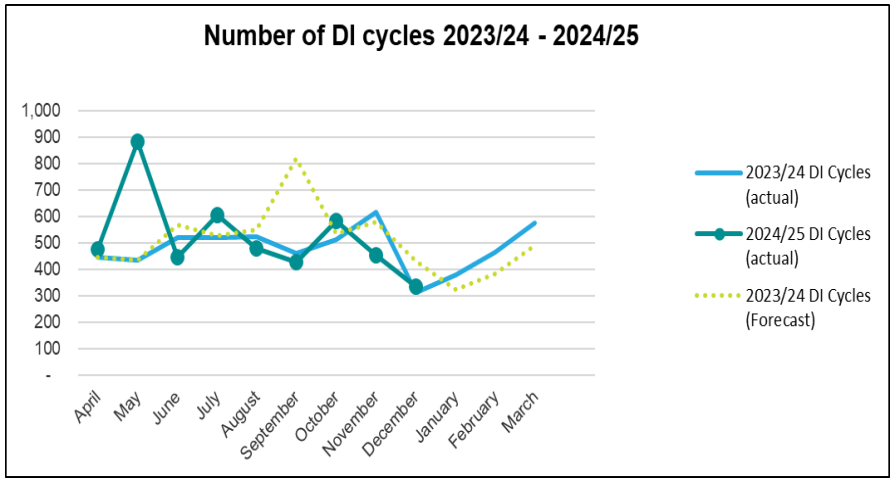
Year to date, our income is under budget by 10%. This shortfall is due to the IVF/DI activity which whilst is ahead by 11%/8% respectively on last year, continues to be impacted by corrections posted by clinics. Detailed analysis is necessary to ascertain income for 24/25 vs refunds which may relate to prior years. We have amended the forecast activity for quarter 4 as a prudent measure. This has resulted in a short-fall of Licence fee income against budget of £497k.

Grant in aid income is below budget as we have not drawn down all the additional, funding for the Epicentre project due to time-scales changing and the bulk of the work commencing in 25/26.

Human Fertilisation & Embryology Authority

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 2023/24 and 2024/25 financial years. The volumes of IVF include cycles that have been refunded which is somewhat misleading and therefore, a decision was taken to reduce activity in Q4 by 20-25% between January and March 2025.

A plan is in place to conduct a detailed analysis of our income and those corrections triggered by clinics in time for the year end audit. This work is necessary as this is one area that our auditors have highlighted as a significant risk. If we are able to identify the value of refunds and trace them back to the original charge this will provide the necessary assurance that the auditors require and that demonstrates a robust control. It will also enable us to factor risk into our planning going forward.

2024/25 Expenditure-YTD Actual vs Budget

As of October	YTD Actual	YTD Budget	Variance	Year Forecast	Year Budget	Variance
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Expenditure						
Salaries/Wages	4,152	4,164	(12)	5,605	5,552	53
Other Staff costs	172	158	14	227	210	17
Other costs	157	185	(28)	217	246	(29)
Project Costs	0	697	(697)	65	791	(726)
Facilities (estates) costs	419	369	50	537	492	45
IT Costs	379	440	(61)	559	587	(28)
Legal and Professional	226	242	(16)	317	353	(36)
Total	**5,505**	**6,255**	**750**	**7,527**	**8,231**	**704**

Salaries/wages – year to date are under budget by 0.3%, this is mainly on-costs (pension) where the budget assumed all staff are in the pension scheme.

Other Staff costs – are over budget by £14k. These costs are mainly represented by travel and subsistence for inspections, training, recruitment and staff welfare. Inspection Travel costs are £15k below budget and have been consistently under, these are offset by overspends within other areas and in particular Training (£27k) and Staff welfare (£13k). The balance is made up of small over/underspends within administration costs.

Other costs – are £28k below budget. Significant areas of underspend are within Strategy and Corporate Affairs directorate and cover costs such as Stakeholder events (£14k), Library & Subscriptions (6k); and Non-Authority Committee costs – Advisor fees (£10k). These are offset by smaller over/underspends across other directorates.

2024/25 Expenditure-YTD Actual vs Budget

- **Project costs -** significant underspend due to the Epicentre project in a cooling off period post contract award. It is expected that some costs will be incurred during quarter 4 but the bulk in 2025/26 and possibly beyond.
- **Facilities (estates) costs** – these are the accommodation costs for 2 Redman Place and non-cash costs which are depreciation of our computer equipment. We are overspending by £50k year to date due to the accounting treatment of our rent. By year end the overspend will reduce to a sum equal to unrecoverable VAT.
- **IT Costs –** are underspent by £61k which is due to reduced spend against support costs (where utilisation of Alscient our supplier of technical consultancy has reduced); reductions in our IT Subscriptions costs for Office 365 licences and the purchase of low value software, the former being due to the HFEA participating in a scheme with Microsoft where the price of licenses are reduced for the public sector.
- **Legal and Professional** – our legal spend year to date is showing an underspend of £31k. This is an area where spend could increase as there is at least one case pending.
- Offsetting this underspend is an overspend on both internal and external audit fees. The fees are increasing as the auditors increase their scope. In particular, the external audit fee increase reflects the work conducted around the duplication of cycles billed. It is expected that the fee for 25/26 be as high as 24/25.

2024/25 Expenditure-Forecast vs Budget

- **Forecast outturn** – We are forecasting an overspend of £132k before any adjustments such as release of contingencies or provisions. We have agreed with the department, that unused Grant in aid will be returned which has been factored into our forecast.
- We continue to monitor our income and those adjustments (credits) that our clinics continue to process as this will impact on our year end position. We are holding back a provision against our income which may either be increased or released in full or part at year end, dependent on the volume of credits at year end alongside the results of the detailed analysis being undertaken.

Human Fertilisation & Embryology Authority

Strategy and Planning

Details about this paper

Area(s) of strategy this paper relates to:	Strategy 2025-2028
Meeting:	Authority
Agenda item:	7
Meeting date:	22 January 2025
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex A: final draft strategy for 2025-2028

Output from this paper

For information or decision?	For decision
Recommendation:	Approve the 2025-2028 strategy.
Resource implications:	In budget
Implementation date:	April 2025-March 2028
Communication(s):	The strategy will be published on our website.
Organisational risk:	Low

1. Introduction

1.1. At the November 2024 Authority meeting, members commented on a draft of the strategy, and received additional information about feedback from our stakeholders, and an initial delivery plan.

1.2. The Authority is now asked to approve the final version of the strategy, with a view to publication in April 2025.

1.3. The business plan for 2025/26, which will deliver the first year of the strategy will be presented at the March Authority meeting.

2. Context

2.1. As set out in the paper to the November meeting, our strategy focuses on how we will approach the increasing complexity of the fertility landscape, and the significant developments taking place in scientific research.

2.2. Our goal is to ensure a well-regulated fertility sector, that is trusted by patients and the wider public, that the information we provide is useful and accessible, and that biosciences that lead to innovations in treatment can flourish, within an ethical framework.

2.3. Our vision is:

Regulating for confidence:

– Safe treatment

– Right information

– Supported innovation

2.4. Our main strategic themes are:

- Regulating a changing environment
  - Maintaining confidence in the sector and providing assurance for patients, and for clinic staff, researchers and scientists.
  - Enhancing our regulatory efficiency and tools.
  - Giving patients greater clarity and helping them to navigate an increasingly fragmented landscape.
  - Providing accurate and timely information to those making Opening the Register (OTR) requests.
  - Through our law reform work, continue to make the case for wider powers to cover new service provision models.
- Supporting scientific and medical innovation
  - Ensuring that new developments are safely regulated, and that barriers to entry for new treatments and technologies are proportionate.
  - Preparing for the ways in which Artificial Intelligence (AI) is likely to impact on, and benefit, patients, the sector and the HFEA.

– Through our law reform work, continue to make the case for wider powers to cover new developments that currently fall outside the regulatory framework.

2.5. Within each theme, we have also included an objective about using our authoritative voice as a regulator to highlight, with evidence from our data, the issues that matter to patients, such as equality of access to treatment or the regulation of new bioscience developments.

3. Changes since November

3.1. The draft strategy is attached at Annex A.

3.2. The Authority was broadly content with the draft presented at the last meeting. The main comments made in addition were as follows:

- Positioning of the vision statement was discussed – the majority wished to show the vision at the top of the first page, so this has been moved accordingly.
- It was agreed that making a case for the HFEA to have wider powers to include regulating pricing should not be included in the 2025-2028 strategy, but that it may be appropriate to consider this for the next strategy.
- Members also made several small editorial comments on parts of the text, which have been amended to address the points raised.

3.3. Since the November meeting, the introductory text and the section on challenges and priorities have also been finalised in line with comments and feedback.

3.4. Our goal of achieving law reform in the short to medium term remains central. For the time being, we do not know the possible timing of this. It is important to note that any announcement of a parliamentary timetable for this work would necessitate a fresh look at strategic priorities, since our focus would need to shift toward legislative change and implementation. We will therefore need to continue to retain some flexibility in the way we plan to deliver the strategy and our future business plans.

3.5. The business plan for 2025/26 (to follow in March) will provide an opportunity to reprioritise pieces of work in the event of law reform being announced. However, the precise decisions would depend in part on the timing of any such announcement. We will continue to work up our detailed operational plans over the coming weeks.

3.6. If the Government's new 10-year plan for health is published before the strategy, we will also ensure our strategy and business plan are appropriately aligned with it.

4. Recommendation and next steps

4.1. The Authority is asked to approve the strategy for 2025-2028, planned for publication in April 2025

4.2. If any final editorial changes are needed in response to events just before publication, we will communicate these to members by email in order to avoid delays between meetings.

Human Fertilisation & Embryology Authority

Our strategy

2025-2028

Our vision

We want to ensure a well-regulated fertility sector that is trusted by patients and the wider public, that we provide information that is helpful for patients in making treatment choices, and that biosciences that lead to innovations in treatment can flourish within an ethical framework.

Our vision is for:

Regulating for confidence:

- Safe treatment
- Right information
- Supported innovation

This vision recognises the changing UK fertility landscape, and the challenges this presents, both for patients making difficult treatment choices, and for clinics and the HFEA in ensuring the sector is well regulated and that treatment is safe and well evidenced.

2028 marks the 50th anniversary of the first baby born from IVF and the UK regulatory framework has played a key role in ensuring that fertility treatment in this country is safe and of a high quality. But we cannot be complacent.

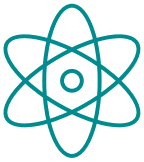
By 2028 the fertility sector we regulate will be very different from the one that existed when we were set-up in 1991. Many elements of advice are offered online, often from outside the UK, and the distinctions between fertility 'lifestyle advice' and medical advice are becoming increasingly blurred. Over time, more diagnostic tests will be informed by AI, and personalised genetic testing is likely to be more commonplace. Some patients may view these developments as positive, providing greater choice and convenience while others may feel unsure about where to go for advice and how to trust the different sources of information.

The next few years are also likely to see significant new developments in scientific research bringing the possibility of new treatment options. Research on embryo models and in vitro derived gametes is now moving fast. The UK has real strengths in bioscience and decisions need to be made on whether and how best to regulate such developments.

The HFEA will need to change and adapt to ensure it remains effective, since the regulatory regime was designed for a world where all treatment was provided in a physical licensed clinic. Online advice and diagnostic tests require a different kind of regulation, elements of which will require a change in the law. The HFEA has a statutory duty to provide information to help patients make informed choices about their treatment options, but we will need to go further. And while inspection will still have a vital role in ensuring high quality services, greater use of data can also inform regulatory action.

As the fertility sector changes over the coming years, we want patients who are seeking a longed-for family to continue to have safe, high-quality, fertility treatment. And we want clinics, researchers and the wider public to have confidence that our regulation can meet the demands of changing times.

Our ambitions for 2025-2028 are summarised across two themes, set out in the table below:

 **Theme 1: Regulating a changing environment**	 **Theme 2: Supporting scientific and medical innovation**
1. To effectively regulate a changing fertility sector.	5. To ensure the safe regulation of emerging new science and technology, under a clear ethical framework.
2. To continue to increase the availability and benefit of our data for patients, clinics and researchers.	6. To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA.
3. To ensure that the HFEA responds well to issues related to donation.	7. To influence and inform Government in relation to new developments and their regulation.
4. To make a difference on issues that matter to patients.	

Future challenges and priorities

Key challenges that have informed the Authority's consideration of strategic priorities include:

- The fertility sector is changing – it is increasingly commercial, increasingly technology driven and increasingly providing certain services online. This presents patients with new choices (and new dilemmas) which the existing regulatory model was not designed for.
- Access to fertility treatment – some people are delaying trying to start a family and if they have difficulty conceiving, they are finding it hard to access NHS services, while others are excluded from NHS funding.
- Donation is a growing issue for the HFEA and fertility sector, as more people access the HFEA register and interest grows.
- Scientific innovation is now pushing against what is currently lawful in the UK. Obstacles could threaten advances that could help patients and the UK's reputation in biosciences.
- The 1990 Human Fertilisation and Embryology Act is out of date in some respects and requires modernisation.

Following our public consultation in 2023[1] on reforming the HFE Act, we made a range of proposals that we believe would improve patient care and maintain the UK's position as a country where scientific and clinical innovation can flourish. In summary, we have recommended the following:

Patient safety and good practice: the Act should include an over-arching focus on patient protection, and the HFEA should have a broader and more proportionate range of regulatory enforcement powers.

Access to donor information: the Act should enable the removal of donor anonymity from birth, and clinics should be required to inform donors and recipients of the potential for donor identity to be discovered through, for example, DNA testing websites or social media.

Consent: the consent regime in the Act should be overhauled, with a requirement for automatic record-sharing between clinics and the NHS (with the option for patients to opt out).

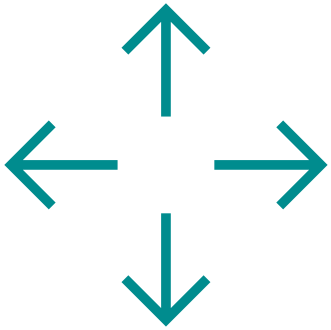
Scientific developments: there should be greater discretion to support innovation in treatment and research, and the Act should be future-proofed so that it is better able to accommodate future developments and new technologies.

It is important to recognise that if parliamentary time is made available to consider changes to the Act within the lifespan of this strategy, that this would require substantial support from the HFEA. If this occurs, we would reprioritise the objectives in this strategy.

In addition, the Government's 10-year plan for health is expected to be published shortly after this strategy, and we will work to ensure that our work aligns with that plan as needed.

[1] See Modernising fertility law | HFEA

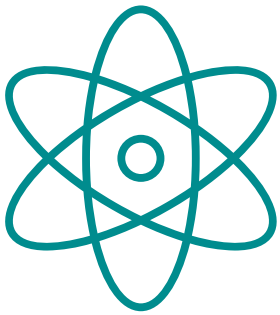
Regulating a changing environment



Objectives	We want	We will
1. To effectively regulate a changing fertility sector.	To maintain public confidence in the safety of the UK fertility sector.	Conduct our regulatory work with fertility clinics in an effective, efficient, consistent and transparent manner, publishing outcomes on our website and reducing the regulatory burden where possible. Provide assurance for patients that the UK fertility sector is well regulated, and provides high quality care, regardless of the choice of clinic. Implement the outcome of our fees review, to ensure the HFEA's regulatory activities continue to be adequately funded.
	To bring together our inspection and clinical governance information with other internal data sources to help us to regulate better.	Enhance our regulatory capability and tools. Make the inspection process more streamlined and efficient.
	Wider regulatory powers to allow us to act further in the patient's interest.	Through our law reform work, continue to make the case for enhanced regulatory powers to ensure effective patient protection and safety in all aspects of fertility treatment including those offered online.
2. To continue to increase the availability and benefit of our data for patients, clinics and researchers.	Patients and others to have confidence that they can access trusted, clear data when navigating the fertility service landscape.	Make improvements to the HFEA website to make more information more readily available. Improve the Choose a Fertility Clinic patient and inspection ratings system. Develop criteria and an HFEA 'trust mark' to help patients identify licensed and regulated sources of treatment. Improve the reach of our data so that patients can also have access via other online sources. Develop our internal systems to work towards a single source of information model for our data. Improve data availability for researchers.

3. To ensure that the HFEA responds well to issues related to donation.	To continue to provide accurate and timely information to those affected by donation and making Opening the Register (OTR) requests. To address the implications that arise in relation to the use of donors in treatment.	Continue to develop and monitor our systems to streamline and improve the efficiency of the OTR process. Produce effective communications and clear policy responses.
4. To make a difference on issues that matter to patients.	To speak up for patients on issues such as equality of access to fertility treatment in relation to family type, socio-economic status, ethnicity, or geographical location.	Continue to highlight issues relating to inequality of access to fertility treatment and use our data and publications to provide evidence. Use our authoritative voice and evidence to influence policy makers. Speak up for patients, using our data, expertise and our voice to influence and inform policymakers and legislators in relation to regulatory issues. Work collaboratively with stakeholders and other parts of the healthcare system with a shared interest, for example in relation to inequalities or legislative reforms, and wider Government initiatives on health priorities and women's health.

Supporting scientific and medical innovation



Objectives	We want	We will
5. To ensure the safe regulation of emerging new science and technology, under a clear ethical framework.	To ensure that the barriers to entry for new treatments and technologies are proportionate.	Lead policy formation and the development of regulatory criteria in response to new treatment advances and scientific developments.
	Establish whether new developments (for example new embryo models, artificial gametes) should be brought within a clear regulatory framework.	Work with stakeholders and the government towards ensuring emerging areas are safely regulated.
6. To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA.	Patients and clinic staff to be confident in AI tools as they are deployed.	Work with the sector, professional bodies and other regulatory bodies while ensuring that the way AI is deployed in clinics is patient-centred, evidence-based and safe. Develop our regulatory and inspection approach to take account of AI usage and consider how we can mitigate any risks effectively.
	The HFEA to make best use of developments in AI to make our work more efficient and effective.	Through our IT development activities, work towards a 'single view' model of our data so that we are able to make use of AI and automation to streamline certain administrative tasks.
7. To influence and inform Government in relation to new developments and their regulation.	A new legislative framework that allows the UK to maintain its reputation as a leading jurisdiction for fertility biosciences.	Speak up for patients, using our data and our voice to influence and inform policymakers and legislators in relation to new bioscience developments and their regulation. Work to ensure that changes to the Act are made in such a way as to build in some degree of 'future proofing', so that future new developments can be regulated effectively without requiring changes to the law on each occasion.

Law Reform: Scientific developments - stem cell-based embryo models

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	8
Meeting date:	22 January 2025
Author:	Dina Halai, Head of Regulatory Policy, Scientific (job-share)
Annexes	Annex A: HFE Act on embryos and embryo use

Output from this paper

For information or decision?	For decision
For decision:	Members are asked to consider: • Whether there is a case for recommending that SCBEMs are subject to some form of statutory regulation • Whether SCBEMs should be regulated on their own terms or as "live human embryos" • Whether to make it explicit that SCBEMs cannot be transferred to a human • Whether to introduce a fixed upper limit on embryo model culture time (informed by emerging consensus)
Resource implications:	Dependant on amendments to the Human Fertilisation and Embryology Act 1990 (as amended)
Implementation date:	N/A
Communication(s):	To feed into the HFEA's ongoing work and dialogue with Government on proposals for changes to the law.
Organisational risk:	**Low**/Medium/High

1. Introduction

1.1. The HFEA published a set of **proposals** for modernising the **Human Fertilisation and Embryology Act 1990 (the HFE Act)** in November 2023. This followed a substantial programme of work, including a series of Authority discussions and decision-making, meetings of a Legislative Reform Advisory Group, small, targeted expert roundtables and a public consultation.

1.2. One of the four areas where proposals were made was in future scientific developments and innovation. The recommendations made were:

- The Act should explicitly give the HFEA greater discretion to support innovation in treatment and research.
- The Act should be amended to 'future proof' it, so that it is better able to accommodate future scientific developments and new technologies.

1.3. The proposals went on to say that any revised regime should uphold the following principles:

- Public engagement and discussion before authorisation: Consideration of significant scientific advances and any changes in the regulation of those advances should be preceded by broad and meaningful public debate and engagement, as appropriate to the issues raised. It should be recognised that the views of scientific researchers are not the only important ones, and that the examination of ethical issues should form part of any additional future work.
- Have a clear but flexible framework to accommodate scientific developments in an ethical and safe way. This might include a clear legislative authorisation to adapt licence conditions for this purpose. It should also include continuous monitoring and a method for deauthorisation.
- Ongoing scrutiny of regulatory decisions: It is essential that any changes to the regulation of scientific developments is open to scrutiny. For example, if it was considered appropriate for the HFEA to permit developments and the use of innovative technologies, ongoing parliamentary scrutiny would be beneficial, so that the HFEA is not considered to be 'writing its own rules' on a range of matters. This could, for example, be through an amendment to the Act that requires regular updates by the HFEA to a relevant parliamentary select committee.
- Balance of different interests: Considering the balance of scientific and clinical innovation alongside the ethical, social, and philosophical issues in any new regime.

1.4. One of the areas identified under future scientific developments was the development of stem cell-based embryo models (SCBEMs). Despite their biological similarity to embryos, SCBEMs are not explicitly currently regulated by the HFE Act. Definition of embryos, eggs and sperm in the HFE Act can be found in annex A. This paper looks in more detail at this policy area and makes recommendations for change.

1.5. The Scientific and Clinical Advances Advisory Committee (SCAAC) considered the technical issues associated with SCBEMs at their October 2024 meeting (see **meeting papers)**. Members may find the detail in the SCAAC papers helpful in providing background to the policy discussion that follows.

1.6. The structure of this paper is as follows:

- Section 2 provides background on SCBEMs
- Section 3 looks at the international context
- Section 4 looks at the UK context and regulatory gaps identified
- Section 5 summarises the recommendations of the SCAAC
- Section 6 looks at the ethical considerations and public opinion
- Section 7 asks Authority members to consider several questions for decision.

2. Background

2.1. SCBEMs is an umbrella term for a variety of biological structures which can mimic different stages of early human embryo development and can be generated with varying degrees of completeness. SCBEMs can therefore have different features and uses in research. Efforts have been made to organise SCBEMs into categories based on ethically significant characteristics, however there is still debate that some models cannot straightforwardly be classified as one or the other. **The International Society for Stem Cell Research (ISSCR) guidance 2021** relies on a distinction between integrated (SCBEM's that contain the relevant embryonic and extra-embryonic structures and might realistically manifest the ability to undergo further integrated development if cultured for additional time in vitro) and non-integrated models (which experimentally recapitulate some, but not all aspects of the peri-implantation embryo).

2.2. In replicating the early developmental stages, SCBEMs open avenues for research which are otherwise constrained by technical ethical and legal limitations when using human embryos. These entities are becoming increasingly similar to *bona fide* human embryos, and research on SCBEMs could offer significant benefits, including improving our understanding of the early development of embryos. Another advantage of SCBEMs is that they have the potential to be scalable, which opens opportunities such as for toxicology testing.

2.3. SCBEMs are relatively new and, as yet, do not neatly fit existing regulatory structures in the UK nor in other jurisdictions. At present, SCBEMs are not explicitly referred to in legislation. The HFEA is responsible for the regulation of human embryo research; the amendments to the HFE Act in 2008 did not explicitly ban research on human SCBEMs, but the use of embryo models in fertility treatment is not allowed (prohibitions in connection with embryos can be found in Annex A).

2.4. Research in this field continues at pace and could in the future push against the boundaries of what is legally permitted in the UK. Given the similarity of SCBEMs to live human embryos, as well as their potential uses, and the lack of clarity about the legal position of research involving SCBEMs, it is timely to consider how they should be governed and whether it would be appropriate to future-proof the HFE Act in preparation for the possibility of SCBEMs becoming indistinguishable from live human embryos.

3. International regulatory and governance landscape

3.1. In 2021, the ISSCR (International Society for Stem Cell Research), a global non-profit independent organisation, issued **guidelines** supportive of SCBEM research and distinguishing current SCBEMs from embryos. It recommended that SCBEM research be subject to review,

approval and monitoring through a specialised oversight process to assess the scientific rationale and merit of the research and its ethical permissibility. The ISSCR guidelines state that, based on the current state of science, models should not be considered human embryos from either a biological or legal perspective. The ISSCR distinguishes three categories of research: those that do not raise ethical issues, those that require vigilance, and those that should be prohibited. In the ISSCR guidelines, both types of embryo models (integrated and non-integrated) are considered to suggest a gradation of ethical concerns. According to the ISSCR, research using integrated models must be approved by ethics committees, while research using non-integrated models need only be notified to the same committees. The ISSCR guidelines are currently under review.

3.2. At the European level, most countries refer to the ISSCR guidelines, especially countries where research on human embryos and embryonic stem cells is not regulated by law.

3.3. The Health Council in the Netherlands is, as far as we are aware, the only European country with proposals to revise legislation (the **Dutch Embryo Act 2002**) to set out the limits of culture time and define both embryos and SCBEMs. Following a request from the Ministry of Health and Welfare, the Health Council of the Netherlands established a temporary committee to look at embryo research. The **Committee recommended** that:

- integrated embryo models (designed to represent whole embryos) qualified for protection under the Dutch Embryo Act as their potential to become a person could not be ruled out.
- a 28-day culture limit for both embryo research and integrated SCBEMs that might one day have potential to develop into a human being. These models would be designated “non-conventional embryos”. The proposed Dutch approach has suggested that 28 days would balance utility in research and the point of limb bud development when some sections of society would see the SCBEM as becoming more human. It aligns with their support for extension of the 14-day rule for embryos to 28 days. As such, it would have benefits of consistency and clarity.

3.4. There has been a change of government in the Netherlands since the report was published and the new government has not given any indication that it wishes to consider or act on the report’s recommendations.

3.5. In 2023, in France the Conseil d’Orientation (an advisory body of the French Biomedicine Agency) set out an **opinion on the regulation of SCBEMs**. In common with the ISSCR, the Conseil supports a permissive position - i.e. that embryoids are cultured cells not embryos. No special framework should be provided, but the same rules should apply as for all research on cell lines. The Conseil has the view that even if non-human animal models acquire properties that make them impossible to distinguish from naturally conceived embryos, the human SCBEM can be distinguished from the human embryo. This is because SCBEMs originate from stem cells rather than fertilisation, and SCBEMs are at no point intended to serve the goal of procreation. The Conseil d’Orientation report also states that while integrated embryo models cannot currently acquire the ability to become a fetus, they may do so in future. The Conseil retains the view that SCBEMs should not be considered embryos, unlike the Dutch Health Council.

3.6. In Australia, some SCBEMs (see for more information: **Determining whether an embryo model is regulated by the ERLC | NHMRC**) are encompassed in their statutory definition of ‘embryo’ and as a result are subject to the same regulatory framework.

4. UK's regulatory and governance landscape

4.1. As noted in section 2 above, SCBEMs are not currently explicitly referred to in UK law. As things stand, the HFE Act is solely concerned with *bona fide* human embryos and there is broad consensus that SCBEMs are not currently embryos.

4.2. Nor is there any mechanism under the existing HFE Act to bring SCBEMs under regulatory oversight. While there is a power to allow the Secretary of State to amend the existing definition of live human embryo in the HFE Act (S1(6)[1], in our view this would not enable SCBEMs to be brought into the Act without reform.

4.3. This means that the existing constraints on human embryo research - where all research requires a license from the HFEA and research can only be carried out for specified purposes set out in the HFE Act (2008) - do not apply to SCBEMs

4.4. SCBEMs are, as their name indicates, derived from stem cells and there is of course a degree of oversight which applies to such cell lines. In summary, the HFE Acts governs derivation of human embryonic stem cells (hESCs) into embryonic stem (ES) cell lines and relevant HFEA embryo research requires licencees to deposit a sample of each cell line generated in the **UK Stem Cell Bank (UKSCB)**. The UKSCB then oversees research generating SCBEMs from hESCs.

4.5. The **Human Tissue Act 2004** in England and Wales and Northern Ireland and the **Human Tissue (Scotland) Act 2006** govern the use and storage of tissue and cells that come from the human body, which is relevant to skin, blood or other body cells reprogrammed into an embryonic-like pluripotent state. However, once the stem cell line is established, the Act ceases to apply. These types of cell lines can be deposited at the UKSCB but are not subject to the same level of oversight by the UKSCB Steering Committee.

4.6. Lastly, all research involving human tissue should have Research Ethics Committee (REC) approval, but this is not a legal requirement as stated in the **April 2010 Code of Practice for the use of Human Stem Cell Lines**.

4.7. There has been a number of different analyses of the policy dimensions of SCBEMs in the UK. In February 2024 a **briefing was published by the Parliamentary Office of Science and Technology** in which stakeholder suggestions towards effective oversight of SCBEMs include: (i) identifying similarities and differences between SCBEMs and human embryos, (ii) an independent oversight process involving experts and lay members, (iii) conducting public engagement to increase public understanding and identify concerns surrounding the technology.

4.8. In July 2024, a voluntary **Governance of Stem Cell-Based Embryo Models Code of Practice** for the UK ('the G-SCBEM Code') was produced by Cambridge Reproduction working in partnership with the Progress Educational Trust (PET). This code builds on the ISSCR guidelines and considered findings from a **public dialogue on the governance of research involving SCBEMs**. It sets out research principles including the requirement that SCBEMs are

[1] S1(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) "embryo", "eggs", "sperm" or "gametes" includes things specified in the regulations which would not otherwise fall within the definition.

researched for the minimum time necessary. The G-SCBEM Code also sets out that transferring SCBEMs into the uterus of a living person or other animal is not permitted. It does not, however, set an upper limit for how long SCBEMs can be kept in culture, instead it states that limits should be set on a case-by-case basis.

4.9. In compliance with ISSCR guidance, the G-SCBEM Code recommends that a review committee is established, and a register maintained. This register would record studies and make basic details available to the public as appropriate. The Oversight Committee, when it is formed, is intended to review applications, assess compliance with the G-SCBEM Code, and confirm culture time limits for each individual research project being reviewed. It is intended that the G-SCBEM Code will be revised periodically to take account of the latest developments.

4.10. Although the G-SCBEM code is voluntary it may be seen as a step to fill the regulatory gap. It outlines an approach that could increase confidence in research whilst retaining the flexibility needed to respond to developments. However, some warn of limited legitimacy – the worry is that it allows scientists to review and approve other scientists work - and the Oversight Committee is given extensive discretion under this proposal, even though the plan in time is that members be appointed through an impartial process. In addition, it is argued that a fixed upper limit on embryo model culture time is needed to strengthen the regulatory response, which could also help maintain public confidence in such research.

4.11. In November 2024, the Nuffield Council on Bioethics (NCOB) published a **report setting out a road map for current and future governance of the research using human SCBEMs**. Their proposed framework has three stages as follows:

- (1) Embed voluntary oversight via the G-SCBEM Code with the establishment of the proposed Oversight Committee and register to improve transparency and accountability, and to develop expertise in the review of SCBEMs. The Oversight Committee should set case-by-case limits to ensure that models are cultured to the minimum stage required, as proposed in the G-SCBEM Code. One objective during this period should be to learn about the potential risks, benefits, and capabilities of SCBEMs through public and stakeholder engagement.
- (2) Enable regulatory control by amending the HFE Act to set up a regulatory sandbox to make provision for the separate regulation of SCBEMs and put the SCBEM Oversight Committee on an independent statutory footing, as one of the possible sandbox exit strategies. The HFE Act should also be amended to prevent direct use of SCBEMs in assisted reproduction to produce pregnancy.
- (3) Settle a tailored and proportionate regulatory scheme for relevant SCBEMs as it becomes clearer how they will be used and categorised.

4.12. The NCOB report further recognises that there is merit in setting an overall upper culture limit for SCBEMs. This is because, as SCBEM research advances, some model types may increasingly share features with embryos. However, the report acknowledges that there is considerable uncertainty about how such a limit should be agreed. It also recognises that culture limits placed on SCBEMs that more closely resemble the embryo should not unnecessarily restrict important research on SCBEMs that do not resemble the complete embryo, such as models of a particular embryonic tissue.

5. SCAAC considerations of SCBEMs

5.1. The SCAAC last considered SCBEMs at its **October 2024 meeting** and agreed that most embryo model research does not seek to replicate the embryo in its entirety, but to mimic the function of a tissue or an aspect of development. The benefits and drawbacks of SCBEM research can be found within the papers and minutes of that SCAAC meeting. The SCAAC recommended that:

- SCBEMs and live human embryos are not the same, so if SCBEMs are to come under the HFE Act, their definition should be distinct from live human embryos and not overly prescriptive/restrictive.
- Over time, clearly defined upper limits on SCBEM research should be established without inadvertently prohibiting good research. Currently, a pragmatic time limit for embryo models would be difficult to agree as models vary widely and do not mimic the sequential stages of human embryo development.
- Prohibited activities such as transferring embryo models into a human or animal uterus, and not developing SCBEMs all the way to viability, should be made clear.
- Projects should be reviewed on a case-by-case basis, with the time limit for each individual project, below a set upper limit, being specified by a review committee.

6. Case for change and public opinion

6.1. Two public dialogues have been conducted in the UK.

6.2. A **public dialogue conducted by the Human Developmental Biology Initiative (HDBI)** with 70 members of the UK public was published in October 2023. Participants held a range of views on the ethical status of SCBEMs - from being the same as a human embryo, to being 'biological material' similar to DNA. The models were seen to offer benefits such as supplementing the scarce resource of human embryos, enabling learning about human development and in the future reducing or potentially replacing the need for human embryos in research. Many participants wanted to see these models regulated. They were concerned that without regulation, scientists could use models as alternatives to human embryos in ways that could harm society, such as using models for experiments for well beyond 14 days or even creating an alternative form of human life.

6.3. A **public dialogue led by Cambridge Reproduction and PET** with 38 of the 70 participants who took part in the aforementioned HDBI's public dialogue was published in April 2024. Findings included:

- Many participants concluded that embryo models are distinctly different from human embryos, or different enough that they do not pose the same moral concerns as human embryo research. However, some participants worried that more complete embryo models could become so like human embryos that it would not be possible to differentiate between the two. For these reasons, some participants want to see a robust, legislative approach to governance.
- Many participants see a voluntary code of practice as a short-term stepping stone to legislation in the medium to long term.
- Most participants believe time or physical development milestone limits on embryo model research are necessary for several reasons, including to ensure no harm is done to SCBEMs which may develop some form of sentience and physical resemblance to a human

embryo. There was no consensus about whether the same limits should be applied to all types of SCBEMs or whether limits should be considered on a case-by-case basis, or by placing embryo models in particular classes.
- Participants wanted to see more work done on classifying SCBEMs and determining how similar and different they are to human embryos.
- There was widespread agreement with prohibition on the use of SCBEMs for reproduction. The foundation of regulatory flexibility and high levels of public trust in the scientific development of emerging technologies form a strong backdrop to the development of a suitable regulatory response to SCBEMs. Governance should aim to promote scientifically robust and ethical research whilst reassuring the public that harms will be mitigated.

6.4. The NCOB report referred to in paragraphs 4.11 and 4.12 above recognises that ongoing and wider public engagement and dialogue, with representation from diverse groups, is needed to ensure that the governance of SCBEMs is informed by a meaningful understanding of public views, values and interests.

7. For decision

7.1. It is clear from the discussion above that SCBEMs are novel and do not fit the existing regulatory structures in the UK. They are not *bona fide* human embryos and there is a general view that it would be unhelpful if SCBEMs were regulated by the same rules as apply to human embryos. However, as SCBEMs become more like human embryos there is a case for some form of statutory regulatory oversight. That could be limited to a revision to the HFE Act to place clear prohibitions on the use of SCBEMs, or more positively to put in place a bespoke regulatory scheme that seeks to guide the development of SCBEM research more generally. If the latter, then any such scheme should be proportionate to the risks and opportunities involved.

7.2. The Authority is asked to consider:

- Whether there is a case for recommending that SCBEMs are subject to some form of statutory regulation
- Whether SCBEMs should be regulated on their own terms or as “live human embryos”
- Whether to make it explicit that SCBEMs cannot be transferred to a human
- Whether to introduce a fixed upper limit on embryo model culture time (informed by emerging consensus)

Annex A: HFE Act on embryos and embryo use

(1) In this Act (except in section 4A or in the term "human admixed embryo")—
*(a)embryo means a **live human embryo** and does not include a human admixed embryo (as defined by section 4A(6)), and*
(b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

(2) This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body; and in this Act—
*(a) references to embryos the creation of which was brought about in vitro (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation **or any other process by which the embryo was created began outside the human body whether or not it was completed there**, and*

(4) In this Act (except in section 4A)—
*(a) references to eggs are to **live human eggs, including cells of the female germ line at any stage of maturity**, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,*
*(b) references to sperm are **to live human sperm, including cells of the male germ line at any stage of maturity**, and*
(c) references to gametes are to be read accordingly.

A. Definition of "Permitted" Gametes/Embryos (s3ZA)

(2) A permitted egg is one—
*(a) which has been **produced by or extracted from the ovaries** of a woman, and*
(b) whose nuclear or mitochondrial DNA has not been altered.

(3) Permitted sperm are sperm—
*(a) which have been **produced by or extracted from the testes** of a man, and*
(b) whose nuclear or mitochondrial DNA has not been altered.

(4) An embryo is a permitted embryo if—
*(a) it has been **created by the fertilisation of a permitted egg by permitted sperm**,*
(b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and
(c) no cell has been added to it other than by division of the embryo's own cells.

***Prohibitions in connection with embryos**.*

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except—

(a) in pursuance of a licence, or

(b) in the case of

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo, in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or a third party agreement.]

(2) No person shall place in a woman—

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).]

(3) A licence cannot authorise—

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, [F29 or]

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, F30 ...

F30(d) . . . . . .

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with [F31the day on which the process of creating the embryo began], not counting any time during which the embryo is stored.

Law Reform: Scientific developments - in vitro gametes

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	9
Meeting date:	22 January 2025
Author:	Rebecca Taylor, Scientific Policy Manager
Annexes	Annex A: HFE Act on gametes

Output from this paper

For information or decision?	For decision
Recommendations:	Members are asked to consider: • Should in vitro gametes (IVGs) be subject to statutory regulation? • If statutory regulation is desirable, should secondary legislation be introduced in future to regulate IVGs for clinical use? • Whether it is necessary to make it explicit that IVGs cannot currently be transferred to a human? • Whether the Authority has a view on prohibiting the biologically dangerous or ethically complex clinical use of IVGs?
Resource implications:	Dependant on amendments to the Human Fertilisation and Embryology Act 1990 (as amended)
Implementation date:	NA
Communication(s):	To feed into the HFEA's ongoing work and dialogue with Government on proposals for changes to the law.
Organisational risk:	**Low**/Medium/High

1. Introduction

1.1. The HFEA published a set of **proposals for modernising the HFE Act** in November 2023. This followed a substantial programme of work, including a series of Authority discussions and decision-making, meetings of a Legislative Reform Advisory Group, small, targeted expert roundtables and a public consultation.

1.2. One of the four areas where proposals were made was in future scientific developments and innovation. The recommendations made were:

- The Act should explicitly give the HFEA greater discretion to support innovation in treatment and research.
- The Act should be amended to 'future proof' it, so that it is better able to accommodate future scientific developments and new technologies.

1.3. The proposals went on to say that any revised regime should uphold the following principles:

- Public engagement and discussion before authorisation: Consideration of significant scientific advances and any changes in the regulation of those advances should be preceded by broad and meaningful public debate and engagement, as appropriate to the issues raised. It should be recognised that the views of scientific researchers are not the only important ones, and that the examination of ethical issues should form part of any additional future work.
- Have a clear but flexible framework to accommodate scientific developments in an ethical and safe way. This might include a clear legislative authorisation to adapt licence conditions for this purpose. It should also include continuous monitoring and a method for deauthorisation.
- Ongoing scrutiny of regulatory decisions: It is essential that any changes to the regulation of scientific developments is open to scrutiny. For example, if it were considered appropriate for the HFEA to permit developments and the use of innovative technologies, ongoing parliamentary scrutiny would be beneficial, so that the HFEA is not considered to be 'writing its own rules' on a range of matters. This could, for example, be through an amendment to the Act that requires regular updates by the HFEA to a relevant parliamentary select committee.
- Balance of different interests: Considering the balance of scientific and clinical innovation alongside the ethical, social, and philosophical issues in any new regime.

1.4. One of the areas identified under future scientific developments was the regulation of in vitro gametes (IVGs). This paper looks in more detail at this policy area and makes recommendations for change.

1.1. The Scientific and Clinical Advances Advisory Committee (SCAAC) considered the likely future use and regulation of IVGs at their October 2024 meeting (see **meeting papers)**.

1.2. The structure of this paper is as follows:

- Section 2 provides a background on IVGs
- Section 3 looks at how the current HFE Act defines and regulates gametes
- Section 4 outlines the international context including public opinion
- Section 5 summarises the discussions undertaken and presents the recommendations made at the October 2024 SCAAC meeting

- Section 6 outlines the potential benefits and drawbacks of IVGs
- Section 7 looks at the case for regulation
- Section 8 asks Authority members to consider recommendations for decision.

2. Background

2.1. In vitro gametes (IVGs) are gametes (eggs or sperm) created in a laboratory (in vitro) by reprogramming other cells, such as embryonic stem cells or skin cells, to become functional egg and sperm cells. This process is known as in vitro gametogenesis. There are different approaches to generating gametes in vitro which can vary depending on the initial source of cells:

- Generating IVGs from immature germ cells retrieved from the gonads.
- Using embryonic stem cells or induced pluripotent stem cells (developed from somatic cells like skin cells) to generate IVGs – this requires inducing in vitro meiosis[1].
- Modified somatic cell nuclear transfer (SCNT) used for generating oocytes (eggs).
- Using stem cell based embryo models (SCBEMs) as an alternative source of germ cells.

2.2. In addition, there are currently animal studies investigating the transfer (transplantation) of partially matured in vitro derived gametes into ovaries or testes for further maturation in vivo, so the same approach may in future be taken with humans.

2.3. Despite many advances in research on IVGs, there is currently no agreement among scientists as to the likely timeframe for creating viable human in vitro gametes; some believe 2-3 years, while others think more like 10 years. Once IVGs can be created, they would need to be validated, and then tested for safety and efficacy. To date, reproductive in vitro gametogenesis has been achieved only in mice, but not yet in non-human primates.

2.4. IVGs represent a fundamental innovation in reproductive biology for both research and fertility treatment. IVGs have the potential to vastly increase the availability of human gametes (sperm and eggs) for research and, if proved safe, effective and publicly acceptable, to provide new fertility treatment options for men with low sperm counts and women with low ovarian reserve. This could greatly increase the supply of sperm, eggs and embryos and could reduce or remove the need for gamete and embryo donation for research and fertility treatment.

3. HFE Act and gametes

3.1. The original Human Fertilisation and Embryology Act 1990 (the HFE Act) defined gametes as “live human gametes”, “except otherwise stated”, a definition which does not explicitly apply to IVGs but does not explicitly exclude them either. See annex A for relevant provisions of HFE Act.

3.2. Provisions in the amended HFE Act 2008 permit the Secretary of State to introduce regulations which would allow for the definition of embryo, eggs, sperm and gametes to be amended to include things that would not otherwise fall within the definition. However, this would allow the

[1] Meiosis is the process of cell division in sexually reproducing organisms that reduces the number of chromosomes in gametes (eggs or sperm) so they are haploid (contain one set of chromosomes) and can then undergo fertilisation.

current definitions to be amended but would not allow for the creation of a separate new definition of IVGs distinct from traditionally derived gametes.

3.3. Under the current HFE Act (schedule 2, paragraph 6, licences for research) an embryo created in vitro using IVGs (sperm and eggs) could be used for research, but would require an embryo research licence from the HFEA.

3.4. However, in vitro derived gametes and embryos developed from IVGs could not be used for fertility treatment, as they do not meet the definition of "permitted gametes" or "permitted embryos" for the purposes of treatment. This prohibition arises because section 3 (2) requires that eggs or sperm permitted for treatment must be "produced by or extracted from the ovaries of a woman/testes of a man".

3.5. The current definition of gametes in the Act *could* be interpreted to include in vitro gametes and any embryo created in vitro using those gametes, which would allow research (under the current licencing regime), but not clinical use of IVGs.

4. International context

4.1. In many countries, there is interest in the use of IVGs for research and clinical use, and research is being undertaken in public universities and private research institutes in the UK, Japan, the USA, the Netherlands and Belgium among others. Despite the interest and research activity, only two countries have sought to legislate to cover the use of IVGs.

4.2. Netherlands – The Dutch Embryo Act was amended in 2021 to allow the development of "non viable" IVG embryos for research purposes. This would cover embryos created using stem cell derived gametes that have been genetically modified to ensure non-viability. This means that such IVG embryos do not meet the current legal definition of an embryo which is "a cell or cluster of cells with the potential to grow into a human being". The 2021 amendments do not address the use of IVGs for human reproduction.

4.3. Norway - IVG are not explicitly mentioned in Norwegian Biotechnology Act, but the wording of the relevant paragraphs means that assisted reproduction using IVG would not be explicitly prohibited. However, the use of IVG would be considered a new method and require approval from the Ministry of Health as well as ethical approval by Norwegian Biotechnology Advisory Board. IVG are allowed in research and fall under rules governing research involving embryonic stem cells.

4.4. According to the 2021 **International Society of Stem Cell Research (ISSCR) Guidelines for Stem Cell Research and Clinical Translation**, human IVGs (unfertilised and not generated into an embryo) fall under category 1b research, which is research permissible without review, but must be reported to designated body for monitoring. These guidelines are currently being updated.

Public Opinion

4.5. While there has not been any public engagement of scale on the topic of IVGs in the UK or elsewhere, there has been some research that shows tentative, cautious support.

4.6. Studies conducted in the UK, Belgium, Netherlands and Japan revealed:

- An overall positive public view of IVG use in research.
- A strong insistence on the need for appropriate regulation and oversight for IVG use.

- Higher acceptance of the use of IVG for reproduction by those with self-reported infertility, for example a Dutch study found such individuals expressed support for the concept of IVG fertility treatment as it uses the patient's own cells and is less invasive than traditional IVF, but concerns over safety and efficacy.

5. SCAAC consideration of IVGs

5.1. SCAAC considered the scientific and technical aspects of IVGs, including potential benefits and drawbacks, and noted:

- How to amend the definition of gamete in the HFE Act, taking scientific accuracy into account noting:
  - The term "live" is insufficient to distinguish human gametes from IVGs, as any cell in culture could be described as "live"; a more appropriate distinction could be having undergone meiosis in vivo.
  - Any changes to the definition of gamete must ensure that any research facility storing stem cells (not IVGs) would not inadvertently fall under HFEA licence requirements or unintentionally contravene the HFE Act.
- That IVGs (unlike SCBEMs) were ultimately aimed at fertility treatment use.
- That intended use could help define regulation, so IVGs fertilised for human reproduction with the aim of resulting in a live birth would meet the definition of an embryo, and those created for research use would be embryo models.
- That the term "artificial" for IVG was thought inappropriate; biologically "stem-cell derived" is the most accurate term.
- That source material is key for IVG, and research has shown that induced pluripotent stem cells appear to have more genetic mutations than embryonic stem cells, although recent research has started to overcome such problems.
- It will be critical to test the safety of IVGs for clinical application before that takes place, but that establishing when IVG technology is sufficiently advanced for translation from research to clinical application will be challenging. This will require evaluating when and how it will be possible to use an IVG to create a fertilised embryo for transfer into a human uterus.
- Evaluating and ensuring the long-term safety of IVGs is likely to require extending the 14-day rule to understand the longer-term outcomes of epigenetic correction and to validate the fertilised IVGs against conventional embryos post 14-days of culture
- Despite claims made by some research organisations, committee members did not expect IVG for clinical use to be feasible within the next 2-3 years.
- A member highlighted that the arguments in support of IVG technology are compelling, particularly the possiblity of significantly reducing the challenges many patients face in accessing fertility treatment (in terms of age, cost, and narrowing inequality). If successful, older patients could benefit from IVG technologies as they will extend the age at which women can procreate. There will also be less incentive for patients to freeze eggs or use donor eggs for treatment. IVGs could additionally be utilised by male same-sex couples, patients who have experienced premature infertility (such as cancer patients), or those with Klinefelter's syndrome and XXY.

- That it may be necessary to consider introducing age limits for IVG fertility treatment; there is currently no legally imposed age on fertility treatment in the UK; this is something for individual clinics to decide.
- That public engagement on IVGs would be valuable as public opinion has not currently been explored.

5.2. The Committee recommended:

- That the definition of "gamete" in the HFE Act should be updated to address the following:
  - Remove the statement that this covers germ cells at "any stage of maturity".
  - Give consideration to the use of the term "live" for the current definition of gametes within the Act.
  - Consider how to define embryos created from single or dual IVGs.

6. Benefits and drawbacks of IVGs

6.1. The **potential benefits of using IVGs in research** could include:

- Expanding understanding of developmental biology including identifying causes of infertility and congenital conditions arising during gamete development, fertilisation or early embryo development.
- Increasing the availability of oocytes and embryos for research (assuming successful fertilisation of IVGs to create embryos) enabling greater early-stage embryo research.
- Gametes derived from stem cells lines would be genetically isogenic (many gametes with the same genotype), which could aid research studies by minimising potentially confounding genetic differences.
- Using in vitro derived eggs and sperm and embryos to test the reprotoxicity of drugs on fertility and embryonic development.

6.2. The **potential drawbacks of using IVGs in research** could include:

- Insufficient reproducibility: IVGs do not develop in exactly same way as traditionally derived gametes so cannot replace them entirely and results from IVG research may not be reliable.

6.3. The **potential benefits of IVG clinical use** include:

- Enabling people to have a genetically related child they could not otherwise conceive for example same sex couples and heterosexual couples with one infertile partner.
- Eliminating the need for egg or sperm donors, which would remove or reduce the costs and other challenges associated with donation.
- Obviating the need for invasive and costly egg retrieval as part of IVF, which could reduce some of the risks involved in treatment, as well as making fertility treatment more affordable and accessible.
- Less invasive, less risky and more ethical fertility preservation, particularly for children and adolescent cancer patients
- Improved embryo screening and genome editing of in vitro gametes and in vitro derived embryos could reduce the risk of passing on serious genetic disease to offspring for people who are affected by or carry the genes for such conditions.

- Reducing age barriers to having children.
- Removing the need for people with serious health conditions to stop taking medication while trying to conceive/undergoing IVF.

6.4. The **potential drawbacks to using IVG clinical use** include:

- The potential for IVG to introduce germline genetic and epigenetic modifications that could be transmitted across generations (although there is research being undertaken to address this)
- The greater number of gametes and embryos being produced through IVG leading to expanded pre-implantation genetic testing (PGT). This could arise through patients wishing to further refine embryo selection without concerns about selection resulting in too few embryos to transfer. In jurisdictions where PGT-P targeting polygenic diseases is permitted or PGT-M (for monogenic conditions) is less strictly regulated than the UK, patients may seek to screen IVG derived embryos for many different conditions with a possible disability bias and/or tipping over into enhancement/selection of desirable traits (eugenics)[2].
- Possible ethical concerns about the destruction of large numbers of IVG derived embryos through expanded screening.
- Possible logistical challenges for clinics as they need to store higher numbers of IVG eggs and sperm and IVG derived embryos.
- The reduction in age barriers for parenthood creating new challenges such as higher risk pregnancies in older mothers, and children born to much older parents.
- An increase in the demand for gestational surrogates.
- The possibility of creating IVG derived embryos that are considered biologically dangerous such as “solo parenting” (egg and sperm from the same person), which would carry a greater risk of offspring with harmful genetic mutations (genetic defects) than first cousin or sibling reproduction[3].
- The possibility of using IVGs in to enable ethically and socially complex reproduction such as “multiplex parenting” (IVGs created from more than two parents). This could result in offspring genetically related to four parents, who would technically be the child’s genetic grandparents. It would also require restrictions to avoid close genetic mixing.[3]

7. The case for regulation

7.1. IVGs are neither explicitly covered nor explicitly excluded by the HFE Act, so as a result they could be interpreted as meeting the current definition of gametes. If so, then they would not in law be distinguished from traditionally derived gametes.

[2] In the UK this risk is constrained by the need to obtain a licence from the HFEA Statutory Approvals Committee (SAC) before pre-implantation genetic screening for monogenic diseases (PGT-M) can be offered. Currently, pre-implantation genetic screening for polygenic diseases (PGT-P) is not permitted in the UK.

[3] The HFEA Code of Practice point 11.17 prohibits clinics from performing fertility treatment that involves mixing gametes of close relatives who are genetically related.

7.2. There are different types of in vitro gametes depending on source material and methods used to create them. As the science develops further, it is likely become clearer how they could be regulated and differentiated (or not) from the current definition of permitted sperm/eggs.

7.3. Under the Act as it stands, IVGs could be considered gametes and used for research (under an HFEA research licence) but would be prohibited in fertility treatment because they do not meet the definition of "permitted gametes" in fertility treatment. However, IVGs are being developed with the aim of using them for fertility treatment in the future.

7.4. IVGs could in future be used for fertility treatment that is considered biologically dangerous such as "solo parenting".

8. For decision

The Authority is asked to consider the following in relation to the research and clinical use of in vitro derived gametes:

8.1. Whether there is a case for recommending that IVGs are subject to some form of statutory regulation?

8.2. If there is a case for statutory regulation of IVGs, should secondary legislation be introduced in future to regulate the clinical use of IVGs in human reproduction?

- As the science develops, any amendments to the Act via secondary legislation would need to consider the efficacy and safety of using IVGs in clinical practice to then determine whether IVGs should be regulated on their own terms or as "permitted gametes".

8.3. Whether it is necessary to make it explicit that IVGs cannot currently be transferred to a human? The secondary legislation could then allow for a future amendment to allow their use in treatment.

8.4. Whether the Authority has a view in relation to the pre-emptive prohibition of biologically dangerous use of IVGs for reproduction such as "solo parenting" and ethically and socially complex reproduction such as "multiplex parenting"?

Annex A

HFE Act on gametes and gamete use

The HFE Act (1990) defines gametes under

(4) References in this Act to gametes, eggs or sperm, except where otherwise stated, are to live human gametes, eggs or sperm but references below in this Act to gametes or eggs do not include eggs in the process of fertilisation. (1990)

Amendments to the HFE Act were made in 2008:

In this Act (except in section (4A)
(a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,
(b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and
(c) references to gametes are to be read accordingly.] (2008)

(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) "embryo", "eggs", "sperm" or "gametes" includes things specified in the regulations which would not otherwise fall within the definition.

(7) Regulations made by virtue of subsection (6) may not provide for anything containing any nuclear or mitochondrial DNA that is not human to be treated as an embryo or as eggs, sperm or gametes.]

Prohibitions on the use of Gametes are defined under the HFE Act as follows:

(1) No person shall—
(a) store any gametes, or
(b) in the course of providing treatment services for any woman, use the sperm of any man unless the services are being provided for the woman and the man together or use the eggs of any other woman, or
(c) mix gametes with the live gametes of any animal, except in pursuance of a licence.

(2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

(3) No person shall place sperm and eggs in a woman in any circumstances specified in regulations except in pursuance of a licence.

(4) Regulations made by virtue of subsection (3) above may provide that, in relation to licences only to place sperm and eggs in a woman in such circumstances, sections 12 to 22 of this Act shall have effect with such modifications as may be specified in the regulations.

(5) Activities regulated by this section or section 3 of this Act are referred to in this Act as "activities governed by this Act".

Section 4 Prohibitions in connection with gametes

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman—

(a) a human admixed embryo,

(b) any other embryo that is not a human embryo, or

(c) any gametes other than human gametes

Embryos for use in research may only be created under a research licence.

Schedule 2, point 6, paragraph 3

"Licences for research

3 (1) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of embryos in vitro, and

(b) keeping or using embryos,

for the purposes of a project of research specified in the licence.