Authority meeting

Date: 20 November 2024 –11.00am to 3.30pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	11.00am
2. Minutes of the meeting held on 25 September 2024 and matters arising (5) For decision	11.05am
3. Chair and Chief Executive's report (10) For information 3.1 Effective governance paper – changes to the Standing Orders For decision	11.10am
4. Committee Chairs' reports (15) For information	11.20am
5. Performance Report (25) For information	11.35am
6. Strategy and planning (45) For decision	12.00pm
Lunch break (12.45-1.15pm)	
7. Modernising fertility law – scientific developments (60) For decision	1.15pm
Comfort break (10 minutes)	
8. Modernising fertility law - Patient protection and safety (60) For decision	2.25pm
9. Any other business (verbal) (5)	3.25pm
10. Close	3.30pm

Minutes of Authority meeting held on 25 September 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	20 November 2024		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 25 September 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 25 September 2024

Members present	Alex Kafetz Graham James Alison McTavish Gudrun Moore	Geeta Nargund Catharine Seddon Christine Watson
Apologies	Julia Chain Tim Child Zeynep Gurtin Frances Flinter Jonathan Herring	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Steve Pugh (DHSC) 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) Alison Margrave (Board Governance Manager)	

Members

There were 7 members at the meeting – 5 lay and 2 professional members.

1. Welcome and declarations of interest

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

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

1.3. Declarations of interest were made by:

- Geeta Nargund (Clinician at a licensed clinic)
- Jason Kasraie (PR at a licensed clinic)

2. Minutes of the last meeting and matters arising

2.1. The Deputy Chair proposed that minute 7.18 be amended to:

"The Chair drew the discussion to a close noting that the principles for the review were agreed; that options B 'status quo plus (mixed activity driven)' and E 'banded flat annual fee' as presented in the paper were currently favoured by the Authority and warranted further development; and that if possible the decoupling of the HFEA's fee as a perceived 'treatment tax' levied on patients by clinics was welcomed."

2.2. With this amendment the minutes of the meeting held on 3 July 2024 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

2.3. Members were advised that the matters arising item had been actioned as detailed in the paper presented to the meeting.

2.4. Members noted the matters arising report.

3. Chair and Chief Executive's report

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

3.2. Members were informed that the Chair had attended and participated in the all-staff event held on 15 July at the HFEA's office and the Chief Executive spoke of the valuable experience in bringing all the HFEA staff together. He spoke about the stability of the workforce and generally high staff morale.

3.3. The Chief Executive informed members that together with the Chair and Director of Strategy and Corporate Affairs he had an introductory meeting with the HFEA's new sponsor minister, Baroness Merron, and that this was a very positive early meeting with open and enthusiastic dialogue. The HFEA had taken the opportunity to highlight the law reform work and the key challenges over the next 5 to 10 years.

3.4. Members were informed that the Chair had met with the Scottish Minister of Health, Jenni Minto MSP, on 17 September. The Chief Executive reminded members that the HFEA is a UK wide regulator and, although reports to the Westminster Government, positive continued relationships with the devolved administrations are welcome.

Decision

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

4. Committee Chairs' reports

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

4.2. The Licence Committee Chair (Graham James) gave an overview of recent meetings and informed members of the decision to lift a clinic suspension and the stimulating discussion regarding a licence for a research centre. On behalf of the committee, he thanked outgoing member, Gudrun Moore, for her expertise, warmth and humanity which she brought to the committee.

4.3. The Statutory Approvals Committee (SAC) Deputy Chair (Gudrun Moore) provided a brief overview of the three meetings which had been held since the Authority last met noting that they had approved most applications and special directions.

4.4. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the HFEA's Annual Accounts and Report were laid in Parliament on 25 July. Thanks were given to all staff involved in the production of the accounts. Members were informed that the next meeting of the AGC is being held virtually on 1 October and that a training session on assurance mapping would be held after the meeting on 6 December.

4.5. The Deputy Chair informed members that the Scientific and Clinical Advances Advisory Committee (SCAAC) next meeting is being held on 7 October and that a separate agenda item on the HFEA's horizon scanning function is being brought to this Authority meeting.

Decision

4.6. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and informed members that the report includes data up to the end of August. Performance continues to be good across the KPI indicators with ten green, three amber, one red and three neutral indicators. He expressed thanks to all the HFEA staff for their continued hard work.

5.2. The Chief Executive referred to the HR KPIs contained in the paper and the positive downwards trend in both sickness and turnover. Since May the turnover rate for staff has been moving towards target which has provided a period of stability for the organisation and a solid resource base to continue work and development.

5.3. The Deputy Chair commended the Chief Executive and the Senior Management Team for their leadership and support of HFEA staff which is evidenced via staff surveys.

Compliance and Information

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

5.5. Members were informed that following the recently published reports on CQC and Ofsted the HFEA had reflected on its own inspection regime's strengths and weaknesses. An opportunity had been identified to strengthen inspectors' training and specialised training had been arranged for later in the year. Members were informed this training would cover aspects such as handling difficult situations whilst on inspection; identifying those individuals who may be experiencing stress due to the inspection and how to handle these individuals calmly, confidently and with sensitivity/empathy to ensure they are properly supported during the inspection process.

5.6. The Director of Compliance and Information informed members that the Data Security Protection Toolkit (DSPT) is undergoing significant changes and will eventually be replaced by the Cyber Assessment Framework (CAF). Whilst the HFEA is still evaluating this change, it is likely that this will involve more work for the IT team.

5.7. Members were informed that the team is working through the recommendations arising from the infrastructure penetration test and that the application pen test will be scheduled imminently.

5.8. Members were informed that the tender process for the Epicentre replacement is currently open, with the team responding to clarification questions from prospective suppliers. The closing date

for receiving tenders is early October and it is anticipated that the contract will be awarded by the end of October following a scoring and shortlisting process.

5.9. The Opening the Register (OTR) team is now fully staffed and trained with the new case management system and were able to process over 800 applications in the last 6 months, which is more than were processed in the entirety of 2023.

5.10. Members were informed that currently there is a low number of OTR applications relating to post 2005 identifiable donors. This could be attributed to the number of children conceived with an anonymous donor after April 2005 and a gradual change in the culture of 'telling' after the law change, which will affect how many of those eligible to access donor information know that they are donor-conceived.

5.11. The Deputy Chair thanked the HFEA team for their reflection on its inspection process following the publication of the CQC and Ofsted reports. This clear commitment to continuous reflection and learning is very welcomed.

5.12. The Chief Executive spoke of the requirements for DSPT and the increased level of corporate reporting to Government, which for a small ALB are not proportionate to the organisation's resources. He cautioned that the Authority may need to address priorities in the future if requirements of corporate reporting increase still further.

5.13. A member spoke of the good progress which the HFEA had made with DSPT and cautioned that DSPT was designed for large organisations such as NHS bodies. The new standards should be appropriate for all organisations, no matter their size.

5.14. In response to a question regarding the number of planned and delivered inspections, the Director of Compliance and Information stated that some inspections may be pulled forward and gave some examples of why this might happen.

Strategy and Corporate Affairs

5.15. The Director of Strategy and Corporate Affairs remarked that the summer period had continued to be busy and referred to the number of licensing activities undertaken during this period.

5.16. Members were informed that the Fertility Trends report had been published and gained widespread coverage online, in print, TV and radio. The State of the Sector report would be published in October and an update on the Family Formation report later this year.

5.17. The Director of Strategy and Corporate Affairs spoke of the fieldwork being undertaken for the national patient survey, which is conducted every three years. The HFEA is keen to increase responses from Black and ethnic minority patients and Authority members were encouraged to promote the survey where possible.

5.18. Members were informed of the patient organisation and professional body stakeholder meetings which were taking place in the Autumn and how these will be used to inform and update people on the work of the HFEA and get views on areas such as the new HFEA strategy and the multiple birth rate.

5.19. The Director of Strategy and Corporate Affairs updated members on the continuing work regarding proposed law reform, noting that the November Authority meeting will receive papers on patient protection and safety, and scientific developments.

5.20. Members were informed that the SCAAC meeting in October will be discussing scientific developments, and the papers prepared for that meeting are of an extremely high calibre and would be available on the HFEA's website.

5.21. Members were informed that members of the senior management team had undertaken several speaking engagements at conferences and events including a joint training day at the British Fertility Society study week.

Finance

5.22. The Director of Finance and Resources informed members that the HFEA's annual report and accounts were laid in parliament on 25 July, and he expressed his thanks to the team for all their work in this regard.

5.23. The Director of Finance and Resources referred to the paper and stated that whilst the August data is showing a surplus of £30,000 a full review will be undertaken at the end of quarter two.

5.24. Members were appraised of the potential spend on IT investments and when this might happen.

5.25. The Director of Finance and Resources spoke on the debt KPIs and commented that these were being influenced by long-term debt, with a couple of clinics affecting the overall results. The Chief Executive commented that the HFEA does not have a structural problem in collecting debt but there are a few historical problems which the team are working to resolve.

Decision

5.26. Members noted the performance report.

6. HFEA's horizon scanning function

6.1. The Scientific Policy Manager introduced the paper and reminded members that the HFEA established its horizon scanning function in 2004 to identify developments in research and technology that could have an impact on the field of assisted reproduction or embryo research.

6.2. Members were informed that horizon scanning is an annual cycle that feeds into the HFEA's strategic business planning, the Scientific and Clinical Advances Advisory Committee's (SCAAC) workplan and the Authority's consideration of scientific and ethical issues and standards.

6.3. Through this horizon scanning function the HFEA can build knowledge, build relationships in the sector and then use that knowledge to help shape its current and future work.

6.4. The Scientific Policy Manager explained how horizon scanning topics are identified through annual literature reviews, attendance at conferences, the annual HFEA horizon scanning meeting held at the European Society for Human Reproduction and Embryology (ESHRE) Conference and when papers are brought to the HFEA's attention by SCAAC members.

6.5. In February 2024 SCAAC had prioritised 14 topics for their 2024/25 workplan into high (10), medium (2) and low (2) priority categories. Further information was provided on several of the high priority topics and how these were considered by SCAAC.

6.6. The Scientific Policy Manager showed the range of topics which had been discussed at the horizon scanning meetings from 2019 to 2023 and spoke about how the HFEA's focus changed as these topics advanced and developed. New topics can arise as a result of new research or

technology. Stem cell based embryo models was a new horizon scanning topic in 2021 and now in 2024 they are being considered from a regulatory perspective.

6.7. Continuing, the Scientific Policy Manager spoke about how the different horizon scanning activities feed into each other and gave the example of AI, which was first raised at a horizon scanning meeting in 2018, made a high priority topic in 2019 and then became part of the HFEA's organisation strategy in 2020. At first the HFEA was monitoring AI regarding its use in fertility treatment but since 2023 this has developed to also include AI in regulation.

6.8. The Scientific Policy Manager spoke of the annual HFEA horizon scanning meeting which is held at the ESHRE annual conference. This year's meeting had discussed early embryo genetic screening with PGT-P; organoids; AI in the IVF lab and ovarian rejuvenation.

6.9. The Deputy Chair thanked the Scientific Policy Manager for the interesting presentation and commented that as the Authority needs to carefully balance scientific developments with ethical debate, the horizon scanning work is extremely useful in helping to find this balance.

6.10. A member spoke of the important topics being discussed by the October SCAAC meeting some of which will be brought to the November Authority meeting for discussion and decision. The member spoke of the scientific developments being made in the fertility sector and how the Authority might respond to them.

6.11. The Director of Strategy and Corporate Affairs reminded members that SCAAC brings together expertise within the field and its role is to advise to the Authority. The papers for the SCAAC meeting will be published on the HFEA website shortly after the meeting. There has been public dialogue on the 14-day rule and the Nuffield Council of Bioethics will be publishing a report on embryo models in November.

6.12. In response to a question on topic prioritisation and the SCAAC workplan, the Scientific Policy Manager explained that those topics which are a high priority come more frequently for discussion at SCAAC meetings.

6.13. A member referred to the slide which had shown what topics had been discussed at horizon scanning meetings since 2019 and commented that this shows the changing importance of these topics over time.

6.14. The Chief Executive commented on how the horizon scanning function allows the HFEA to monitor topics and develop work streams as the individual topics develop momentum. The horizon scanning function allows the HFEA to put priorities around where it focuses its attention on items which are developing.

6.15. A member commented that topics which are discussed under horizon scanning are not just scientific topics, but also those which are patient centred.

6.16. Members reflected how quickly the sector is changing and the increasing pace of change. They felt that the HFEA's horizon scanning function was crucial to ensure that the HFEA was front and centre in keeping up with such developments and that as an Authority it could continue to balance the ethnical needs of research and a patient focus.

6.17. The Deputy Chair drew the discussion to a close thanking all members for their active participation on this important topic.

6.18. The Authority noted the report.

7. State of the Fertility Sector report

7.1. The Director of Compliance and Information told members that the State of the Fertility Sector report for 2023/24 would be published shortly and she took this opportunity to provide an overview to members.

7.2. This report summarises the HFEA's regulatory work for the period 1 April 2023 to 31 March 2024 and covers the 135 centres which were licensed by the HFEA to provide fertility treatment, storage and/or research. The report is compiled from information gathered from inspections and from other sources including the HFEA's register of fertility treatments, incident reports and patient feedback mechanisms.

7.3. Members were informed that all grades of non-compliance had increased from the previous year, but this is in line with the higher number of inspections carried out. Members were reminded that information regarding the types of non-compliances are given to licensed centres via the quarterly clinical governance updates, which allows centres to reflect against their own practice and identify any improvements.

7.4. Members were informed that total incidents reduced by 8% compared to the previous financial year. In response to a question the Director of Compliance and Information commented that incidents area way of learning for the sector but that it was important to remember that 99% of treatment and storage cycles are completed without incident.

7.5. The grading of incidents was explained, and members were informed that Grade A incidents are the most serious and are rare occurrences. The Director of Compliance and Information spoke of how these incidents are dealt with by the inspection team and how the inspectors put in place enhanced regulatory oversight to ensure risks are mitigated.

7.6. The Director of Compliance and Information stated that the effectiveness of regulation has been under the spotlight recently with the publication of independent reports on the CQC and Ofsted. Both reports were critical of aspects of the inspection regime used in each organisation and this has led the HFEA to review its own inspection regime.

7.7. The Director of Compliance and Information summarised the findings of that review. The HFEA maintains a robust regulatory oversight of the sector with licensed premises being inspected every 2 years as required by law. If the HFEA had any concerns then inspections would be more frequent, and the centre would be closely monitored.

7.8. Members were informed that all HFEA inspectors have direct scientific or clinical expertise relating to the fertility sector.

7.9. Members were also reminded that the HFEA inspection methodology underwent a major overhaul in 2021/22 and the HFEA believes it provides a robust mechanism for how we regulate the sector. Feedback from clinics also suggested that the HFEA inspections promote improvement. However, as part of its continuous cycle of improvement and growth the HFEA review had identified a number of improvements in areas such as IT systems and inspector training.

7.10. In response to a question about publishing trend information the Chief Executive spoke about the importance of building a culture of openness and reporting. He reiterated that 99% of cycles are completed without incident.

7.11. In response to a question the Director of Compliance and Information informed members that the details of non-compliance are provided in the Quartey Clinical Governance update.

7.12. A member referred to the NHS patient safety incident response framework (PSIRF) and questioned how this relates to the reporting of incidents to the HFEA. The Director of Compliance and Information responded that it is a mandatory requirement under the HFE Act for all clinics to report incidents to the HFEA. Discussions had also been held with NHS England (NHSE) to ensure that centres were not overburdened with reporting functions. The Director of Strategy and Corporate Affairs suggested that a future article in Clinic Focus could explain this.

7.13. The Deputy Chair drew the discussion to a close and welcomed the publication of this report which is an important element of HFEA's accountability and transparency and underpins the HFEA's strategic aim of 'best care'.

8. Communicating licensing, regulatory activity and incident information

8.1. The Director of Strategy and Corporate Affairs introduced the paper and spoke of the HFEA's ambition to increase the transparency of the information it holds, noting that most of the information which the HFEA publishes is written for governance/licensing purposes rather than for patients.

8.2. The Director of Strategy and Corporate Affairs explained the HFEA's current position regarding publishing information relating to licensing, compliance and incidents. Some shortcomings of the established position had been exposed in the last year in light of some licensing decisions. The reactive statement regarding Guy's and St Thomas ACU and the proactive statement on the Homerton Fertility Centre were discussed.

8.3. The risks and benefits of publishing more information which is shown in Annex A of the paper presented to the Authority was discussed. It was noted that the CQC routinely publishes its press notices on the outcomes of their inspections, reviews and ratings, and posts these on social media.

8.4. The Director of Strategy and Corporate Affairs spoke to the proposed changes regarding publishing of licensing decisions and the revised Committee Chair's report which would come to each Authority meeting and be published on the HFEA website.

8.5. Continuing, the Director of Strategy and Corporate Affairs spoke of how clinic level incident information is currently published in the annual State of the Sector report and the quarterly clinical governance report. This governance report gives an overview of non-compliances found on inspections and through incident investigations so that learning can be shared with HFEA licensed centres via the monthly Clinic Focus newsletter. Members were informed that the HFEA has faced criticism from journalists that this information is difficult to find on the HFEA website.

8.6. Members were informed of how NHSE publishes incident information via 'never event' and other reports and the information which these reports contain at provider level. The HFEA is now proposing that details of incidents by type and grade by clinic should be published as part of the underlying data set with the annual State of the Sector report.

8.7. A member spoke of the need to continue to nurture the culture of reporting, and any changes should be framed to ensure that this culture is still supported and encouraged.

8.8. A member welcomed the increased information which would be provided on licensing decisions as they felt that many people didn't realise the steps, processes and support which the HFEA undertakes with the licensed centres. The member also advocated for using language in incident reporting that could be understood by patients rather than just professionals. Stakeholder groups could perhaps be used to assist with this.

8.9. Members were supportive of increasing the transparency of the information which the HFEA holds, noting that this may have a resource implication if it leads to a greater number of freedom of information requests and enquiries.

8.10. Members discussed best practice in other regulatory organisations, noting that many of them publish information across all media outlets at the same time, including social media. Members cautioned that any social media posts must adhere to the information contained in the official press release and not be an edited version of that.

8.11. In response to a question the Chief Executive confirmed the HFEA's intention is to make information more readily available on the HFEA's website and that it was important to reach the general public on whatever platform they seek information, be it websites or social media. The Chief Executive also commented that the recommendations brought forward to this meeting will set out the HFEA's current direction of travel and these can be amended, if required, over time.

8.12. In response to a question regarding digitally excluded people the Chief Executive commented that Ofcom data shows that the age range of people looking for fertility treatment would generally have internet access and mobile phones.

8.13. Members questioned whether it would be possible to distinguish between those centres that have been refused a licence for administrative reasons, rather than because they were deemed to offer unsuitable or unacceptable services or facilities.

Decision

8.14. The Authority unanimously agreed the following recommendations:

- When a licence committee suspends or revokes a clinic licence, or adds additional conditions, a summary of the decision should be publicised through a news release; social media posts; and information on the clinic's CaFC pages. This includes removing the rating for the duration of the suspension to avoid causing confusion for patients. This would always follow the PR and Licence Holder being notified about the decision.
- Where a suspension takes place with immediate effect then this should be publicly communicated before the minutes are published.
- Information about licensing decisions should be made more easily publicly available through Authority papers and separately on the HFEA website.
- Details of incidents by type (e.g. administrative, clinical, laboratory) and grade by clinic should be published as part of the underlying data set with the annual State of the Sector report.

Action

8.15. The Executive to implement the decisions regarding communicating licensing, regulatory activity and incident information.

9. Any other business

9.1. The Deputy Chair thanked all for their active participation in the meeting. As this was the last meeting for Jason Kasraie, Gudrun Moore and Jonathan Herring she expressed the Authority's appreciation for the rich and diverse experience and perspective they brought to all discussions and for their dedicated work over several years on many of the HFEA committees.

9.2. The Deputy Chair reminded members that they had been sent information about the conference at Girton College, University of Cambridge on 30 October to mark Mary Warnock's 100th birthday.

9.3. There being no further items of any other business the Deputy Chair reminded members that the next Authority meeting will be held on 20 November 2024 with a Board strategy session being held on the afternoon of 19 November.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 20 November 2024

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	20 November 2024		
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
25 September 2024 Item 8	The Executive to implement the decisions regarding communicating licensing, regulatory active and incident information.	Director of Strategy and Corporate Affairs	Ongoing/ December 2024		• All PRs received a letter from the Chief Executive outlining changes 27/09/24. • Clinic Focus article published explaining changes in September 2024 edition. • Incident information published in the underlying data of State of the Sector report 01/10/24. • Decisions outlined to Professional and Patient Organisation Stakeholder groups in October 2024. • Decisions relating to publishing information following LC meetings will be incorporated into amended SOPs to be approved at future CMG. • Committee updates with centre information will follow from November 2024/January 2025 Authority meeting and will be published on the HFEA website as well.

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:	20 November 2024
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

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

1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meeting in September 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:

    - 1 October – attended the Audit & Governance Committee meeting
    - 7 October – attended the Scientific and Clinical Advances Advisory Committee Meeting (with Chief Executive)
    - 10 October – attended the DHSC ALB senior leaders meeting for all Chairs and Chief Executives (with Chief Executive)
    - 16 October – chaired the Renumeration Committee Meeting
    - 30 October – hosted a conference at Girton College to mark Mary Warnock's 100th birthday celebration

2.2 Chief Executive

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

    - 1 October – attended the Audit & Governance Committee meeting
    - 2 October – gave a talk to students at Mayfield School, Dagenham on behalf of Speakers for Schools
    - 7 October – attended the Scientific and Clinical Advances Advisory Committee meeting
    - 10 October – attended the DHSC ALB senior leaders meeting for all Chairs and Chief Executives
    - 16 October – attended the Remuneration Committee meeting
    - 17 October – visit to Kings Fertility Clinic
    - 4 November – met with representatives of the Regulatory Innovation Office and Regulatory Horizons Council

Effective governance

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
Agenda item:	3.1
Meeting date:	20 November 2024
Author:	Alison Margrave, Board Governance Manager
Annexes	

Output from this paper

For information or decision?	For decision
Recommendation:	Agree the proposed changes to Standing Orders, effective 21 November 2024 (vote required).
Resource implications:	In budget
Implementation date:	21 November 2024
Communication(s):	The Standing Orders are published on our website and on the staff intranet (Hub). They are also included in the standard licensing pack, which will be updated.
Organisational risk:	Low

1. Introduction

1.1. As a public body, the HFEA is committed to adopting best practice in corporate governance and adhering to Government functional standard GovS 001.

1.2. The HFEA has a number of committees established under the Standing Orders which are made in accordance with our powers under the HFE Act.

1.3. High-quality decision-making processes are essential to maintain the integrity of the HFEA as a regulator and licensing body and trust in the conduct of operational activities as it applies to everyone affected by fertility treatment including licensed centres, patients and the wider public.

1.4. An effective governance paper incorporating the reviews of committee effectiveness and any associated changes to Standing Orders is brought to the Authority in March of each year. However proposed changes to the Standing Orders can be brought forward to the Authority at any time.

1.5. In light of the appointment in October 2024 of four new Authority Members, the composition of the HFEA's various committees has been discussed with the Chair, members, and the Committee Chairs. It was agreed to propose to the Authority an amendment to the maximum number of members on the Licence Committee, for improved resilience.

1.6. In accordance with the Standing Orders, Authority members received the required 'notice of motion' in advance of this meeting, regarding the intention to amend the Standing Orders by a formal vote at the November Authority Meeting.

2. Proposed changes to the Standing Orders

2.1. It is proposed to amend article 1.6 of Annex D of the Standing Orders to allow for seven members of the Licence Committee, rather than six. The proposed amendment is shown below (colour legend used: yellow highlight is text to be deleted and green highlight is text to be added):

> 1.6. The Licence Committee shall consist of no more than ~~six~~ seven members including a Chair and Deputy Chair, appointed by the Chair of the Authority. In the absence of the Committee Chair, the Deputy Chair or other person nominated by the Chair of the HFEA may act as Committee Chair.

2.2. The reason for this proposed change is to increase the resilience of the committee and to help the HFEA maintain quoracy.

3. Recommendations

3.1. The Authority is asked to approve, by a majority vote, the revised Standing Orders to come into effect from 21 November 2024.

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:	20 November 2024
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):	As agreed at the September 2024 Authority meeting.
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	Minutes not yet approved.
Other comments:	None.		
Executive Licensing Panel:			
17 September	Research renewal inspection report (Research project R0173)	Centre for Human Reproductive Science	Approved – 3-year licence (standard for research licences)
	Interim inspection report	Care Fertility Sheffield	Approved – continuation of licence
	Executive update and licence variation	The Fertility & Gynaecology Academy	Approved – continuation and variation of licence to include amended Standard Licence Conditions in effect following amendments in 2022.
30 September	Interim inspection report	The Gateshead Fertility Unit	Approved – continuation of licence
	Interim inspection report	Complete Fertility Centre Southampton	Approved – continuation of licence
	Interim inspection report	The Lister Fertility Clinic	Approved – continuation of licence
	Variation - change of PR	Regional Fertility Centre, Belfast	Approved – licence (and ITE certificate) varied
15 October	Research renewal inspection reports x 3 (Research project R0026)	St Mary's Hospital	Approved – 3-year licence
		Maternal and Fetal Health Research Centre, St Mary's Hospital	Approved – 3-year licence
		University of Manchester	Approved – 3-year licence

Date	Items considered	Centres	Outcomes
	Interim inspection report	Concept Fertility	Approved – continuation of licence
	Research interim inspection report (Research project R0204)	Centre for Reproductive Health	Approved – continuation of licence
	Interim inspection report	Assisted Reproduction Unit (ARU), University Hospital of Hartlepool	Approved – continuation of licence
4 November	Research renewal inspection report (Research project R0067)	Hull & East Riding Fertility	Approved – 3-year licence
	Interim inspection report	Care Fertility Leeds	Approved – continuation of licence
	Interim inspection report	CREATE Fertility, Birmingham	Approved – continuation of licence
	Interim inspection report	Salisbury Fertility Centre	Approved – continuation of licence
	Variation – change of PR	Wales Fertility Institute – Neath	Approved – licence (and ITE certificate) varied
	Variation – change of PR	Wales Fertility Institute, Cardiff	Approved – licence (and ITE certificate) varied
18 November	Interim inspection report	Manchester Fertility	Minutes not yet approved
	Variation – Change of PR	Bridge Clinic	Minutes not yet approved
Other comments:	None.		

Licensing Officer decisions:

September and October	29 ITE import certificates	Various	All granted
19 September	Voluntary Revocation	The Gurdon Institute	Approved – licence revoked
19 September	Variation – change of LH	CREATE Fertility, Birmingham	Approved – licence varied
19 September	Variation – change of LH	CREATE Fertility, Manchester	Approved – licence varied
19 September	Variation – change of LH	CREATE Fertility, Leeds	Approved – licence varied
19 September	Variation – change of LH	IVI London (Wimpole	Approved – licence varied

Date	Items considered	Centres	Outcomes
		Street)	
1 October	Variation – change of LH	Aberdeen Fertility Centre	Approved – licence varied
9 October	Variation – change of LH	CREATE Fertility Bristol	Approved – licence varied
28 October	Voluntary Revocation	London Egg Bank	Approved – licence revoked (and ITE cancelled)
Other comments:	Four of the 29 ITE import certificates were due to a change of centre address for Born, Denmark.		
Statutory Approvals Committee:			
30 September	PGT-M: Cerebral Cavernous Malformations 2 (CCM2), OMIM #603284	TFP Oxford Fertility	Condition authorised.
	PGT-M: Wilms Tumour 1 (WT1), OMIM #194070	Birmingham Women's Hospital	Two conditions authorised.
	PGT-M: Ulnar-Mammary Syndrome (UMS), OMIM #181450	Birmingham Women's Hospital	Condition authorised.
	PGT-M: Triosephosphate Isomerase Deficiency (TPID), OMIM #615512	Guy's Hospital	Condition authorised.
	PGT-M: Cardiomyopathy, Familial Hypertrophic, 2 (CMH2), OMIM #115195	Guy's Hospital	Eight conditions authorised.
	PGT-M: Glass Syndrome (GLASS), OMIM #612313	The Lister Fertility Clinic	Condition authorised.
	Special Directions for import of eggs from Chile	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Special directions granted.
	Special Directions for import of embryos from Malaysia	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Special directions granted.
29 October	Mitochondrial donation: M0033 - to avoid Leber Hereditary Optic Neuropathy (LHON), OMIM #535000 caused by mutation in MTND1, OMIM *516000	Newcastle Fertility at Life	Minutes not yet approved.

Date	Items considered	Centres	Outcomes
	PGT-M: Developmental and Epileptic Encephalopathy 106 (DEE106), OMIM #620028	Care Fertility Nottingham	Minutes not yet approved.
	PGT-M: Neurodevelopmental Disorder with Involuntary Movements (NEDIM), OMIM #617493	Glasgow Royal Infirmary	Minutes not yet 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	Minutes not yet approved.
	PGT-M: Ichthyosis, Congenital, Autosomal Recessive 4A (ARCI4A), OMIM #601277	Care Fertility Leeds	Minutes not yet approved.
	PGT-M: Beta-Ureidopropionase Deficiency (UPB1D), OMIM #613161	The Centre for Reproductive and Genetic Health Trading as CRGH Portland	Minutes not yet approved.
	PGT-M: Weaver Syndrome (WVS), OMIM #277590	Guy's Hospital	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:		
1 October	Papers can be found here. Internal audit Progress with current audit recommendations External audit report Risk update Deep dive discussion: near misses Digital projects – PRISM and Epicentre replacement Resilience, business continuity management and cyber security Fraud risk assessment Reserves policy Government functional standards	The Chair will report on this meeting verbally.
Other	None.	

Date	Items considered:	Outcomes:
comments:		

Scientific and Clinical Advances Advisory Committee:

7 October	The agenda is **here** and the papers are **here**.	
	Mitochondrial donation	The Committee considered research progress in established methods for mitochondrial donation therapies and their use to improve oocyte quality and rescuing developmental competence, as well as emerging alternative approaches to mitochondrial correction. The team at the Newcastle Fertility Centre at Life gave an update on their mitochondrial donation work. The Committee noted that protocols, patient selection and clinical outcomes continue to improve and no concerns were raised in response to the update.
	Stem-cell based embryo models (SCBEMs)	The Committee discussed scientific research developments related to SCBEMs as part of HFEA's ongoing work on modernising fertility law and the proposals on future scientific developments and innovation submitted to the Department of Health and Social Care late in 2023. The Committee considered and advised on SCBEM research applications and limits on SCBEM research, to support the development of recommendations on incorporating SCBEMs into any revisions of the HFE Act.
	In vitro derived gametes	As part of the HFEA's work on proposals to amend the HFE Act to accommodate new 'categories' of cells, the Committee also discussed research progress for in-vitro gametes (IVGs), their current and future use in research and fertility treatment, and how the HFE Act definition of a gamete could be updated to cover IVGs in fertility research and treatment.
	Scientific considerations relevant to the	The Committee discussed the scientific rationale for maintaining or extending the 14-

Date	Items considered:	Outcomes:
	14-day rule	day rule including potential benefits and drawbacks of any extension focusing on the scientific and technical aspects. These considerations will inform the HFEA's ongoing work on modernising fertility law.
Other comments:	The Chair gave a brief summary on the HFEA's annual Horizon Scanning Meeting held in July 2024 during the European Society of Human Reproductive Medicine (ESHRE) conference. This summary covered the topics presented by experts in the field: genetic screening of the early embryo, the promise of organoids, future uses of AI in the IVF lab, and emerging strategies in ovarian rejuvenation.	

3. Recommendation

1.3 The Authority is invited to note this report, which has been revised in line with discussions about transparency at the September 2024 meeting. 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 October 2024

Evgenia Savchyna
Corporate Performance Officer
20/11/2024

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:	20/11/24
Agenda item:	Item 7
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 October 2024.
- There were ten Green, two Amber, one Red, and four Neutral indicators.

Key trends

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

July (1)	August (1)	September (1)
Debt collection within 40 days	Debt collection within 40 days	Debt collection within 40 days

Human Fertilisation & Embryology Authority

Management summary

Management commentary

- Performance across KPI indicators remained consistently strong over the last four months with ten Green, two Amber, one Red, and four Neutral in October.
- The inspections team continues to perform well against their targets, with only the Inspection reports to PR KPI as Amber. The end-to-end licencing KPI has been Green for the last four months, and the Inspection reports to committee KPI has been Green for the last six months.
- All PGT-M applications have been processed within KPI with an average of 49 working days taken to process the items.
- The OTR waiting list has been shrunk by 85 applications due to the highest number of applications sent out and the lower number of applications received. The OTR KPI review is scheduled to commence in November 2024.
- The number of email enquiries has risen back to the levels seen in July, with a notable increase in questions related to screening requirements. As a result, we are considering adding more information about the screening requirements to the website.
- Three FOIs completed were related to donation (x2) and gamete movement. No PQs due this month.
- We had four proactive media mentions this month. Notably, the annual State of the Sector report received good press attention, as did information about donor compensation, which was followed by a spike in website views related to the recent changes in donor compensation.
- On social media, we posted about Black History Month, the Patient Engagement Forum, and law changes related to Reciprocal IVF and donation from known donors who are HIV+ with an undetectable viral load.
- Turnover remains in Green, staying below the 15% target and continuing its downward trend. However, staff sickness slightly exceeds the 2.5% target, largely due to seasonal viruses.
- As the result of the Finance KPI review, the Debtor Days KPI's target has been extended from 30 to 45 days.

Summary financial position as at 31 October 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	4,507	4,880	(373)	(8)	7,710	8,231	(521)
Expenditure	4,086	4,670	584	12.5	7,650	8,231	581
Total Surplus/(Deficit)	**421**	**210**	**211**		**60**	**0**	**60**

For the seven months ended 31 October 2024, we have net surplus of £421k, over against budget, a surplus of £211k.

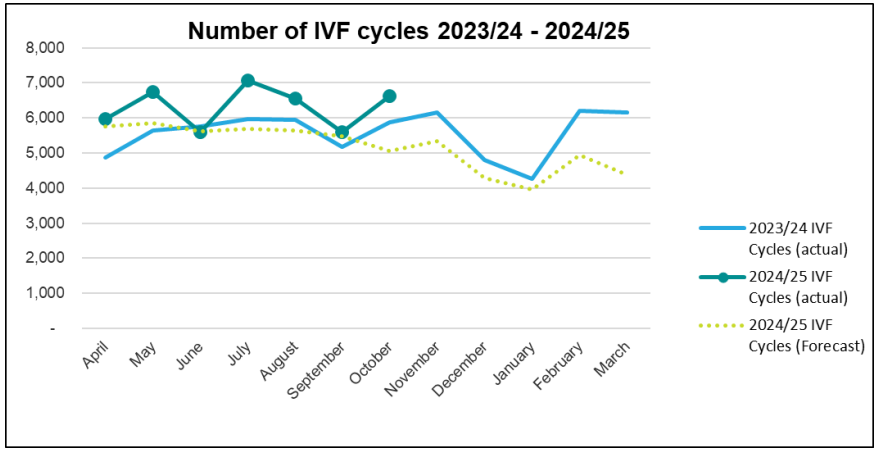
A breakdown of the components is detailed on the following slides.

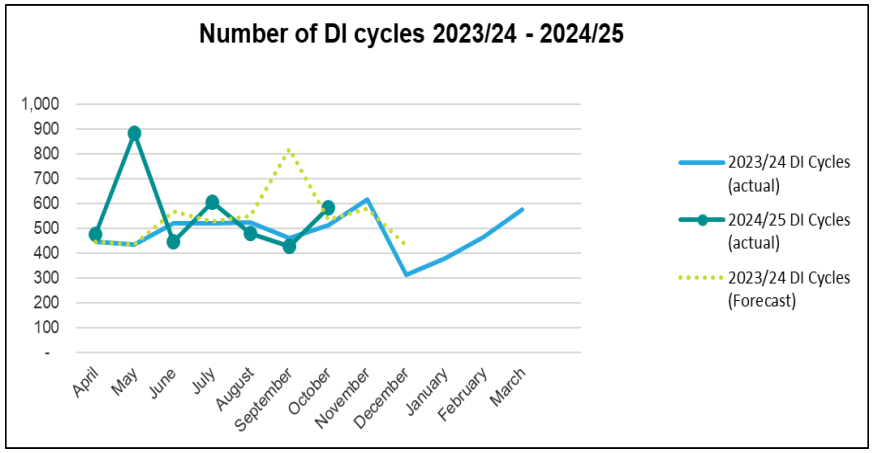
A detailed review of financial plans for the remainder of the year was undertaken early in October. The full year forecast reflects all changes shared by teams and currently results in a small underspend of £60k.

Human Fertilisation & Embryology Authority

2024/25 Income - YTD Actual vs Budget

As of October	YTD Actual	YTD Budget	Variance	Var
	£'000s	£'000s	£'000s	%
Income				
DHSC Funding	445	558	(113)	(20)
Licence Fees	3,922	4,271	(349)	(8)
Other income	140	51	89	175
Total	**4,507**	**4,880**	**(373)**	**(8)**





INCOME

As of month, 7 (October), our income is tracking below budget by £373k (or 8%). We have drawn down most of our core GIA with a view to returning £618k to the Department due to the tender process for the replacement of Epicentre taking longer than planned. We expect the Department to make these funds available in 25/26.

Treatment fees

IVF fees are 13% higher than the same period in 2023/24 and DI are 14% higher than the same period. IVF activity is still being impacted by refunds/corrections that clinics process directly through PRISM. Work is ongoing to quantify what impact the refunds are having.

Human Fertilisation & Embryology Authority

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	3,005	3,135	130	5,387	5,381	(6)
Other Staff costs	120	115	(5)	239	211	(27)
Other costs	180	623	443	687	1,207	520
Facilities (estates) costs	291	276	(15)	518	492	(26)
IT Costs	284	337	53	506	587	81
Legal and Professional	206	184	(22)	313	353	39
Total	**4,086**	**4,670**	**584**	**7,650**	**8,231**	**581**

Salaries/wages – year to date are under budget by 4%, this is mainly on-costs (pension) where the budget assumed all staff are in the pension scheme. We are also carrying a vacancy at Manager level.

Other Staff costs – are slightly below budget. These costs are represented by travel and subsistence for inspections, training, recruitment and staff welfare. Travel costs are £13k below budget and are offset by overspends within Training (£15k) and Staff welfare (£9k). The balance is made up of small over/underspends within administration costs.

Other costs – are £433k (71%) below budget. The budget includes funds set aside for project of £395k largely for the Epicentre project which currently has no spend to date. The balance is represented by underspends within Authority and committee costs (£26k); Strategy and Corporate Affairs and Compliance and Information directorates (£22k). Main areas are within Stakeholder events where the team has advised no events are scheduled for this year; library and subscriptions, media Monitoring, and discretionary.

Human Fertilisation & Embryology Authority

2024/25 Expenditure-YTD Actual vs Budget

- **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 £15k year to date due to the accounting treatment of rent. By year end the overspend will reduce.
- **IT Costs –** are underspent by £53k which is due to reduced support costs (where utilisation of Alscient our supplier of technical consultancy has reduced); reductions in our IT Subscriptions costs for O365 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 a small overspend of £8k which is represented by the cost of seconded staff (which has come to an end) where the actual time charged was higher than budgeted due to additional advice being needed.
- In addition to this small overspend, our audit fees are above budget which is represented by the external audit fees (£9k) being agreed after the budget was set and an increase in internal audit fees (£5k) due to the inclusion of VAT not budgeted for.

2024/25 Expenditure-Forecast vs Budget

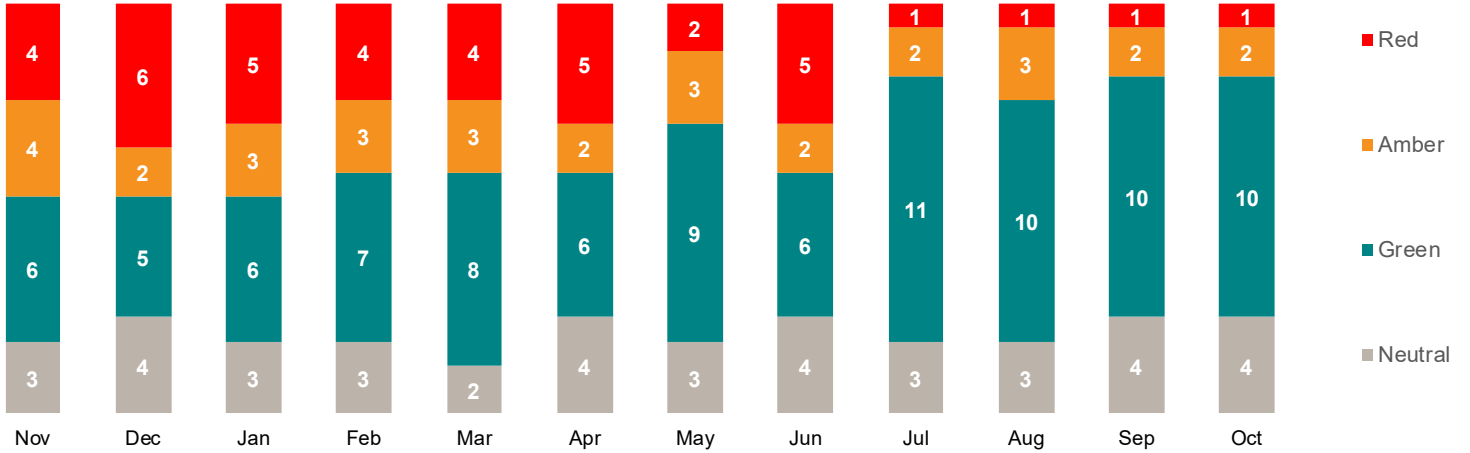
- **Forecast outturn** – We are forecasting a small underspend of £60k before any adjustments such as release of contingencies or provisions. We have agreed with the department, that unused Grant in aid will be returned which has been factored into our forecast.
- We continue to monitor our income and 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 be released in full or part at year end, dependent on the volume of credits which again could impact positively on our outturn.

Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

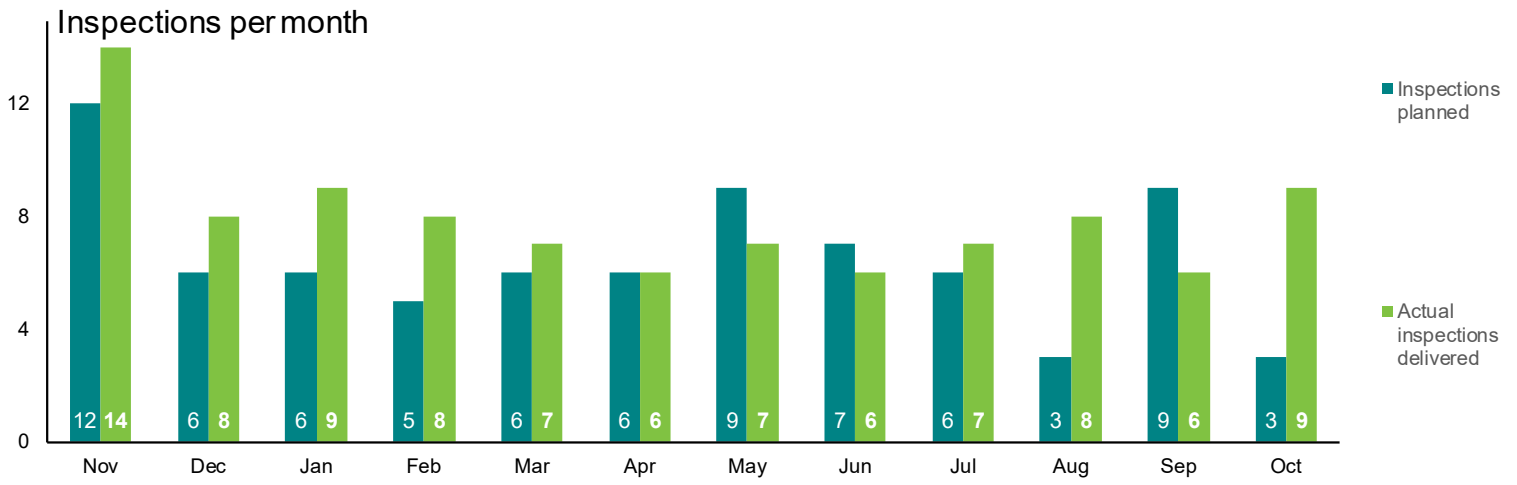
RAG status over last 12 months



RAG status over last 12 months

17 KPIs in total for each month

For October, the 1 red indicator is in Finance (1).



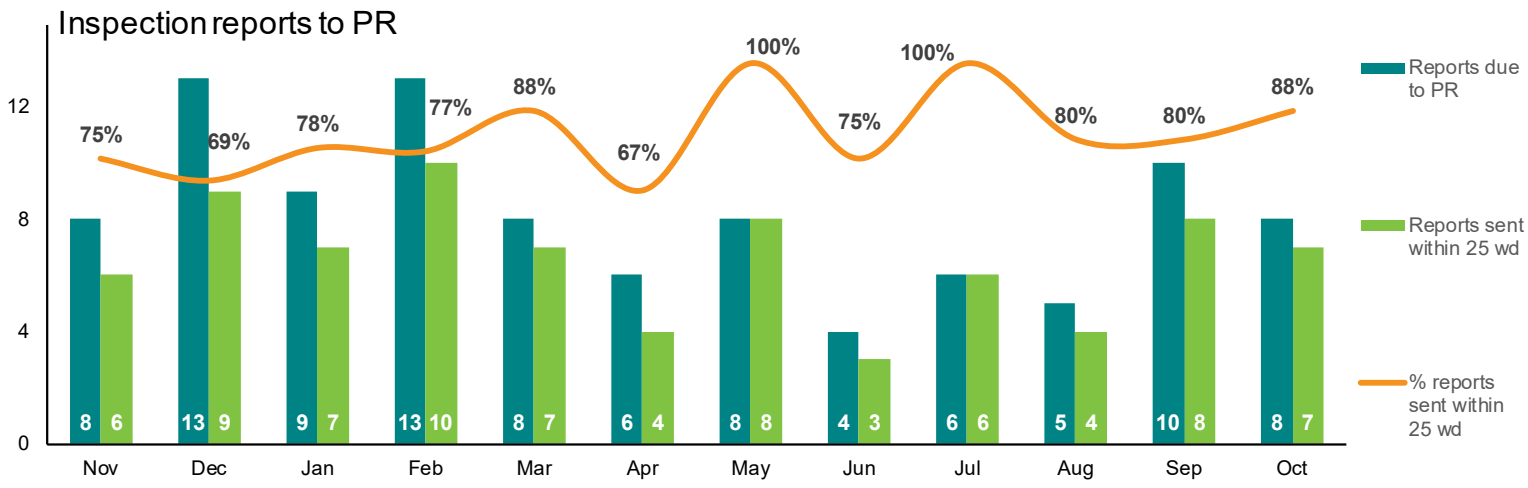
Status: **N/A**

Compliance

Inspections delivery

Target: **not defined**

In October, we conducted six more inspections than initially planned. Three of these were rescheduled from November, and one from December, in order to balance inspectors' workload. Additionally, two inspections were rolled over from September due to inspector availability.



Status: **Amber**

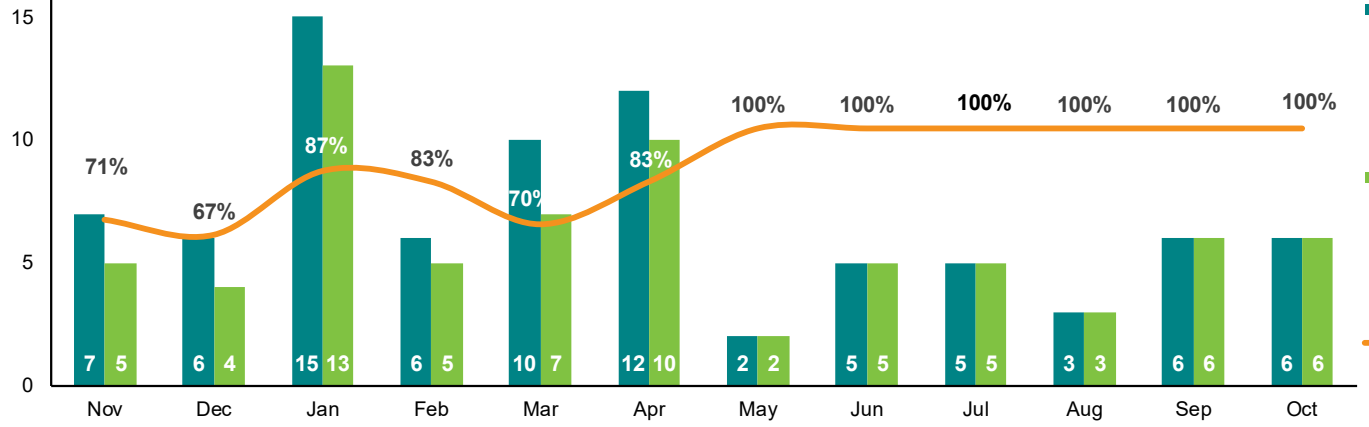
Compliance

Inspection reports sent to PR

New target - Dec 23: **100% sent within 25 working days**

One report was delayed (40 wd) due to increased oversight.

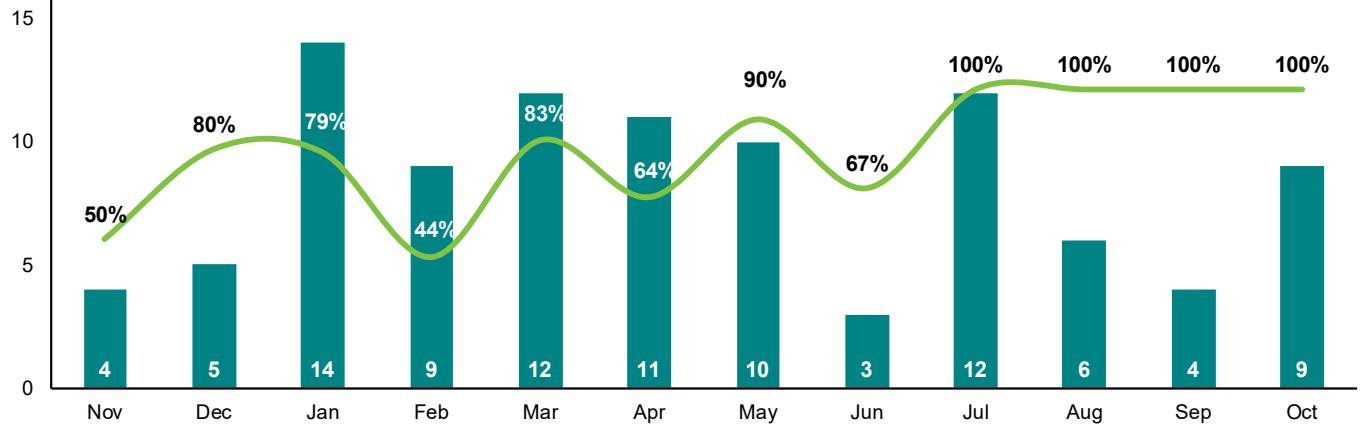
Inspection reports to committee



Status:	Green
Compliance	
Inspection reports sent to relevant licensing committee	
New target - Dec 23: **100% sent within 65 working days**	

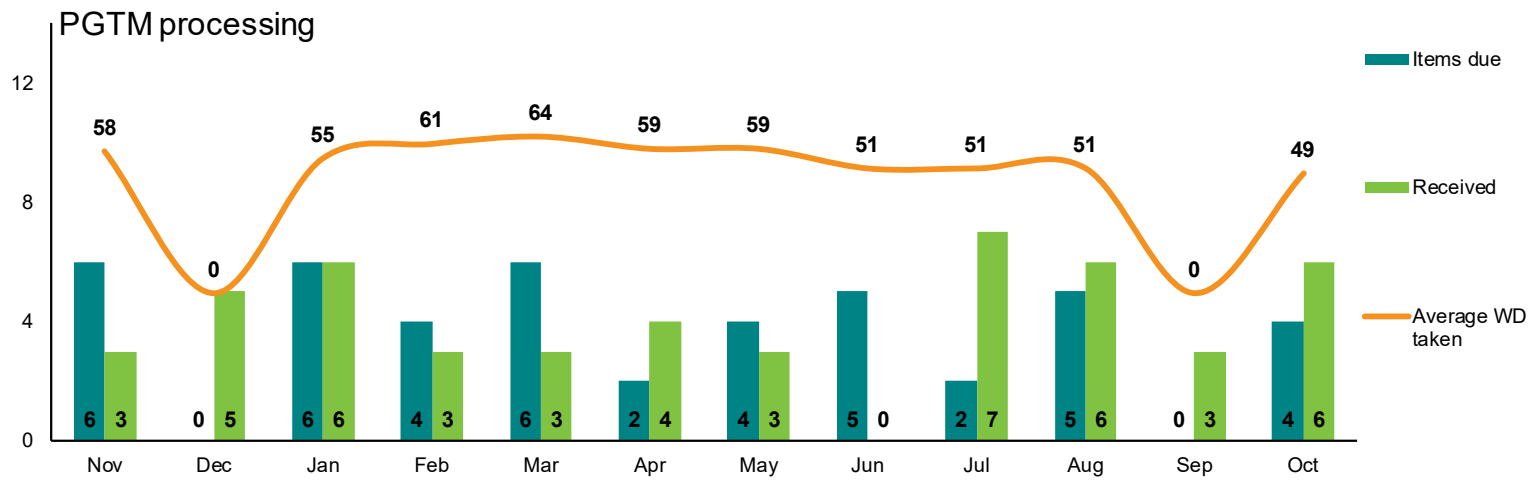
All reports sent within KPI.

End to end licensing



Status:	Green
Compliance	
End to end licensing process	
New target - Dec 23: **100% items completed within 80 working days**	

All licences within KPI.



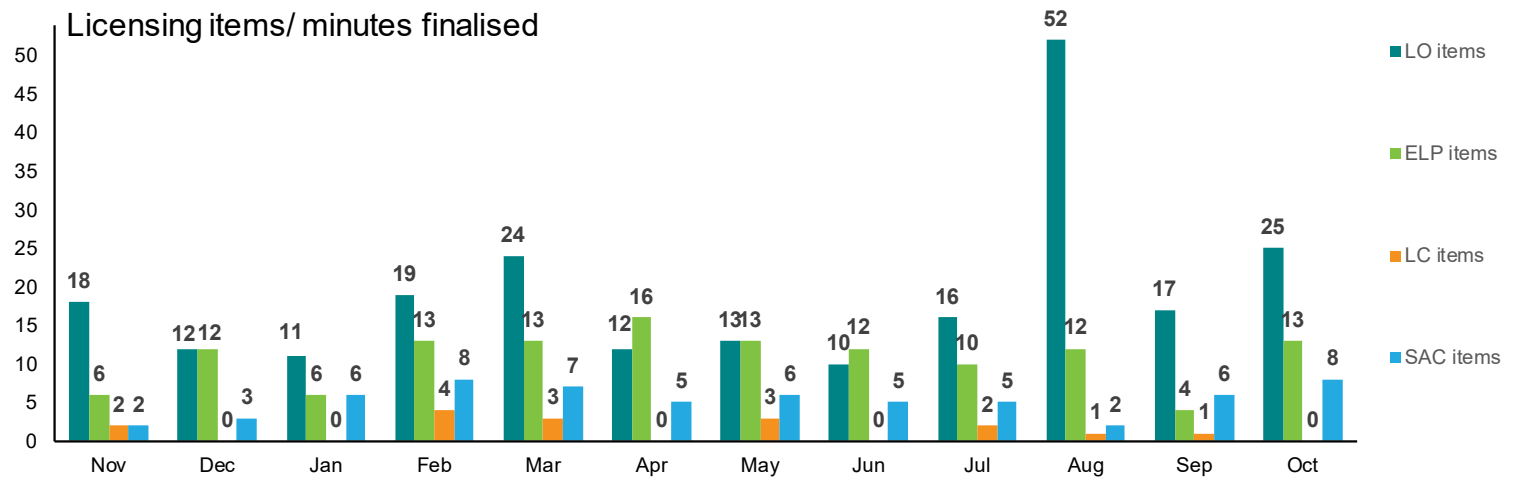
Status: Green

Compliance

PGTM processing efficiency

Target:
100% within 75 working days

All PGTMs have been processed within KPI.



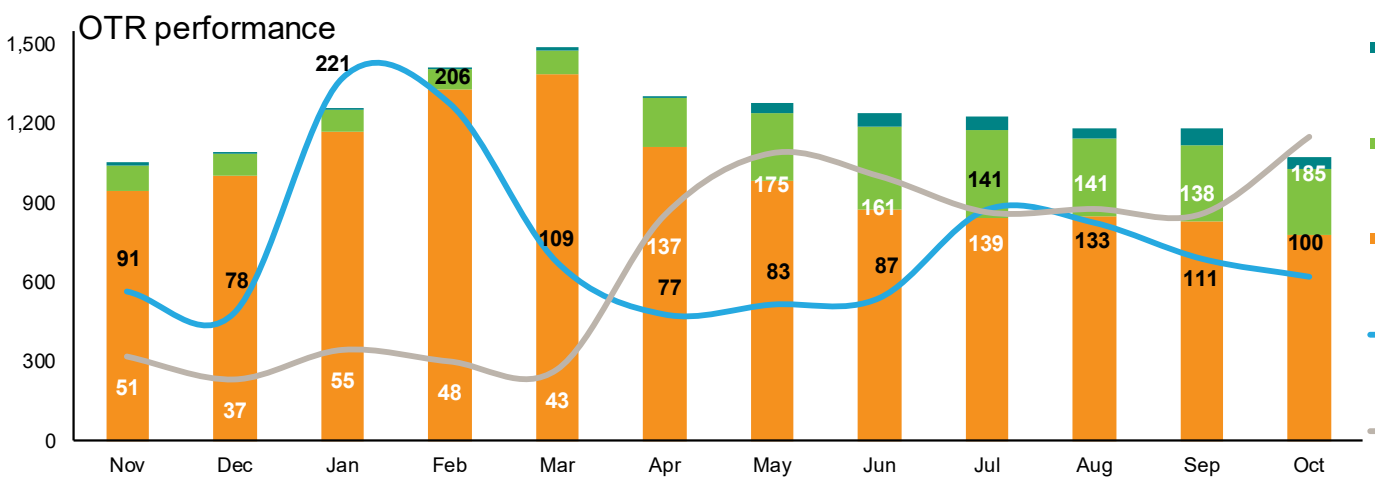
LO: Green
ELP: Green
LC: Neutral
SAC: Green

PlanGo

Licensing efficiency

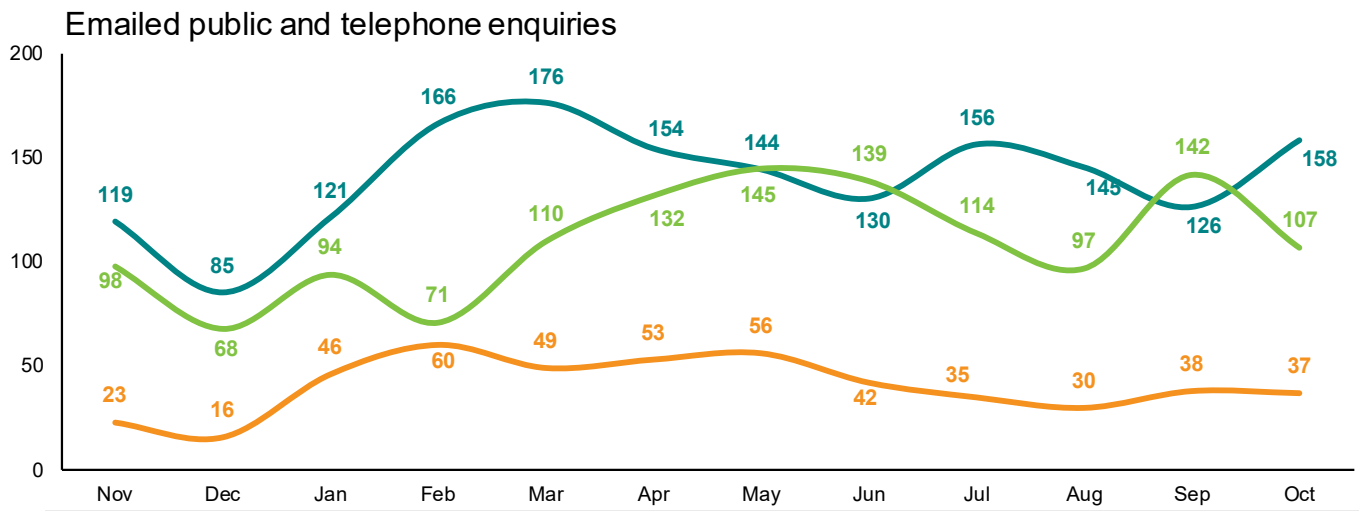
Targets:
LO - 5 WD
ELP - 10 WD
LC - 15 WD
SAC - 20 WD

We processed two voluntary revocations through the LO which are rare items - as such, noteworthy that there have been two in the same month.



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

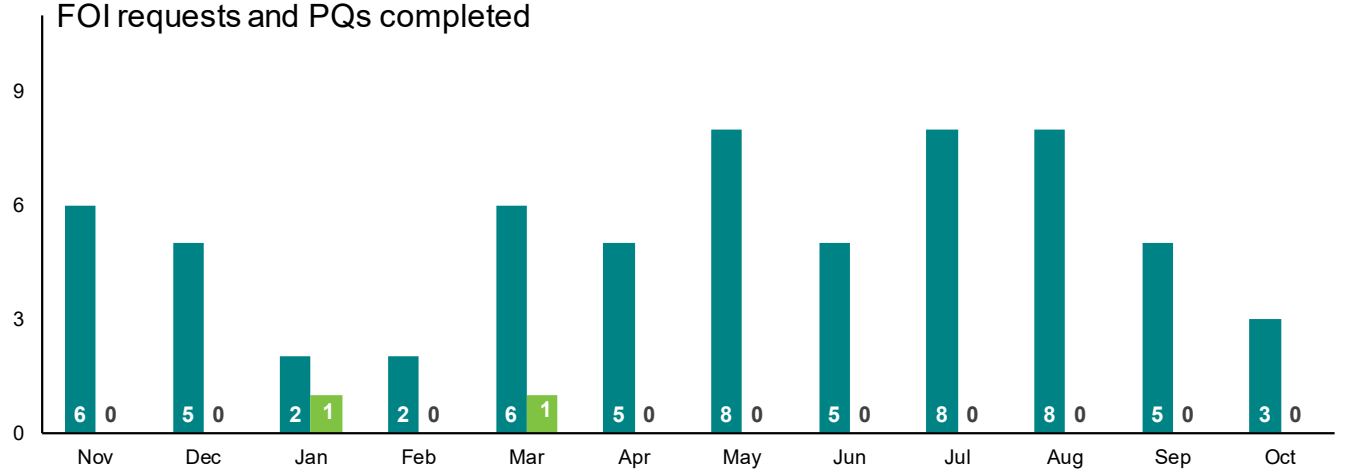
Record high number of OTRs were sent out with 185 receiving information. Only 100 received so the waiting list was shrunk by 85 applications. Continued high number of DSL applications.



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

There has been an increase of 32 enquiries compared to September, along with a rise in number of enquiries about screening requirements. We are reviewing the screening information we provide on our website to consider whether we should add more information to address some of these questions. Call themes: Treatment (7), Other (5), OTR (5), Marketing (4) and Donation (3). 3 calls were categorised as challenging.

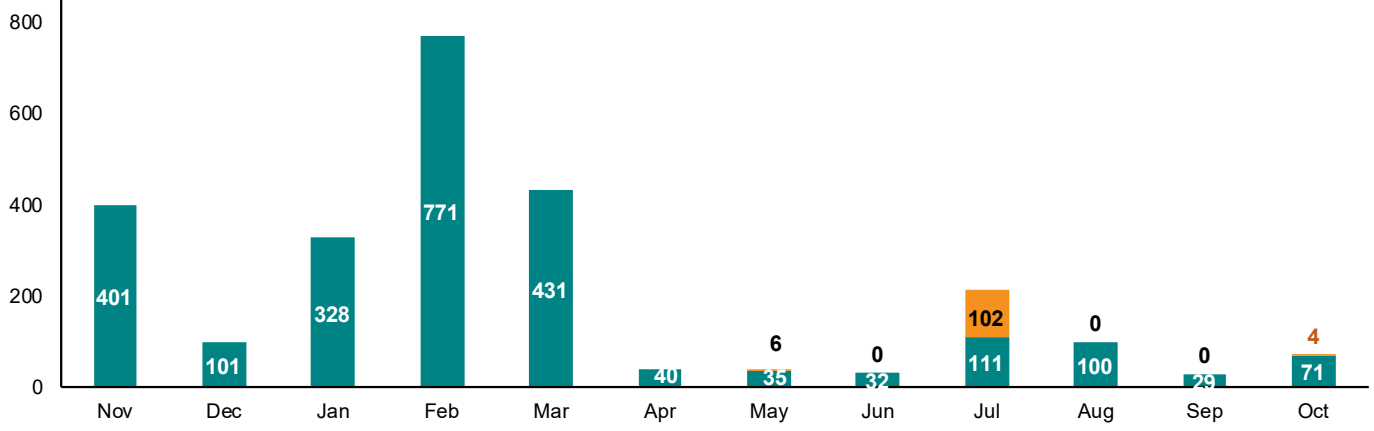
FOI requests and PQs completed



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

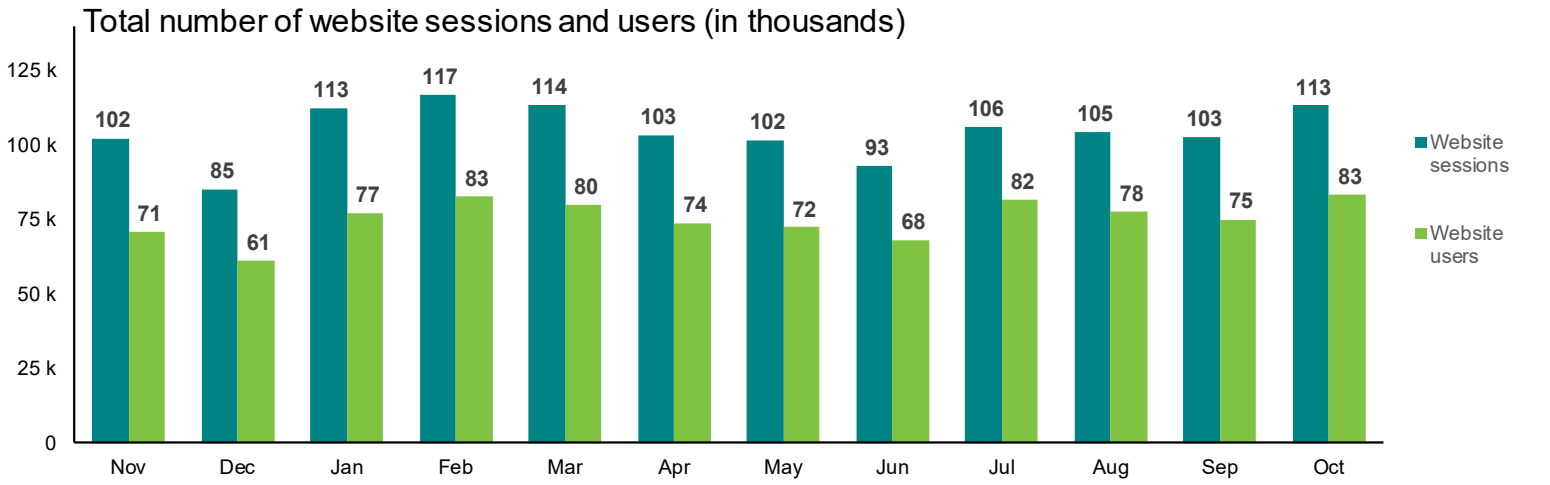
FOIs were turned around within KPI timescales. FOI topics were related to donation (x2) and gamete movement.

Proactive and reactive media mentions



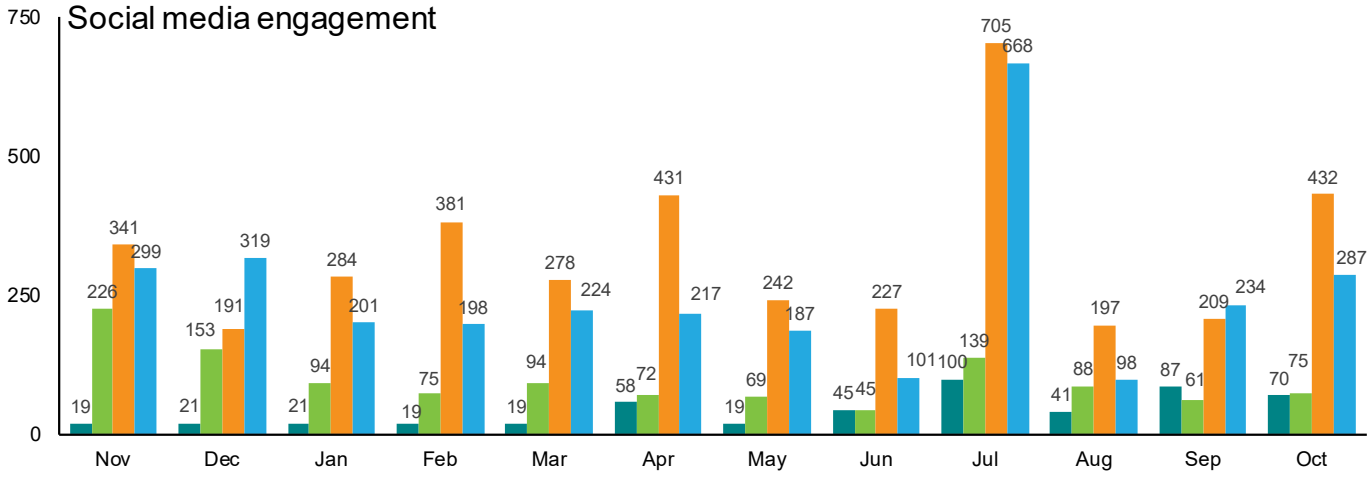
Status:	N/A
Comms	
Total media mentions (proactive and reactive split from April 2024)	
Target: **not defined**	

In October, we published our annual state of the sector report which received some press attention - this report is usually doesn't receive much press attention as it reports on clinical activity rather than patient data. October also saw an increase in donor compensation which received lots of press attention throughout the month.



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

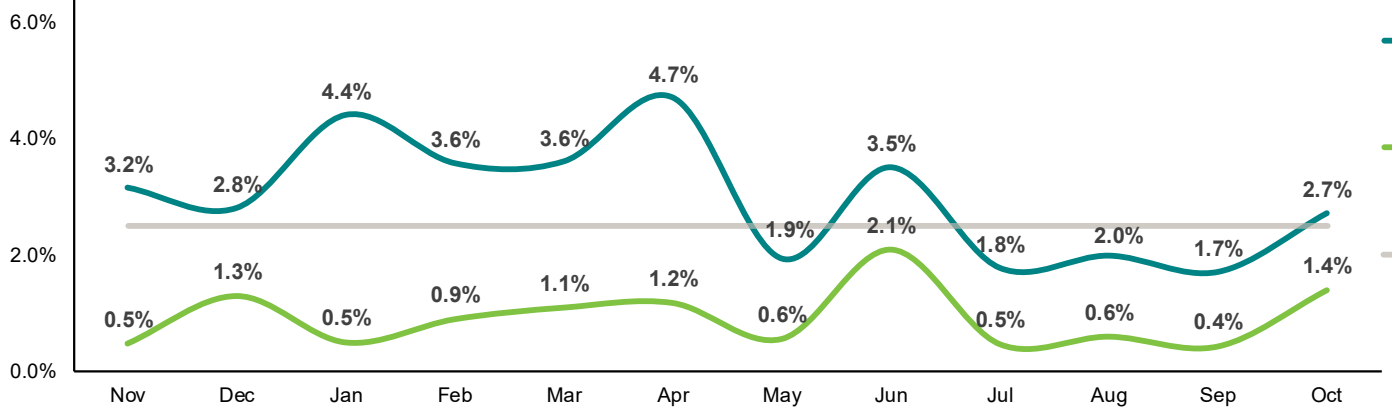
Website sessions and users saw a spike in views relating to donor compensation changes. No significant changes in website's top three pages are observed.



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

Our channels saw high engagement. Content was based around Black History Month and recruitment to our Patient Engagement Forum. We also posted about our egg donation factsheet and Julia Chain's statement regarding screening law changes. Engagement was higher on Instagram, LinkedIn and X than last month, this is likely due to new content relating to donor compensation changes.

Staff sickness absence rate



Status: **Amber**

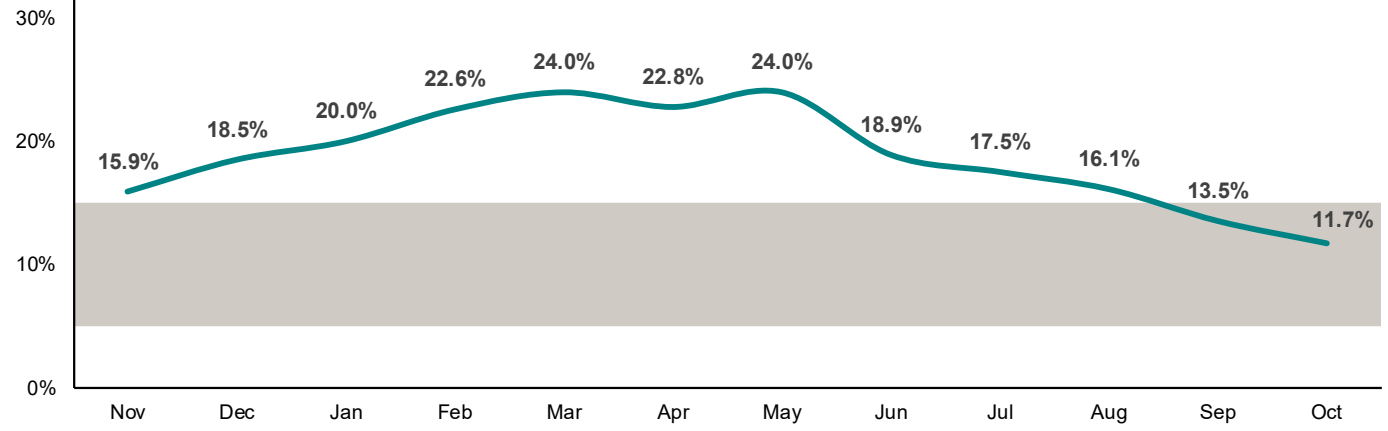
HR

Sickness

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

Sickness is slightly higher this month with expected seasonal viruses.

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



Status: **Green**

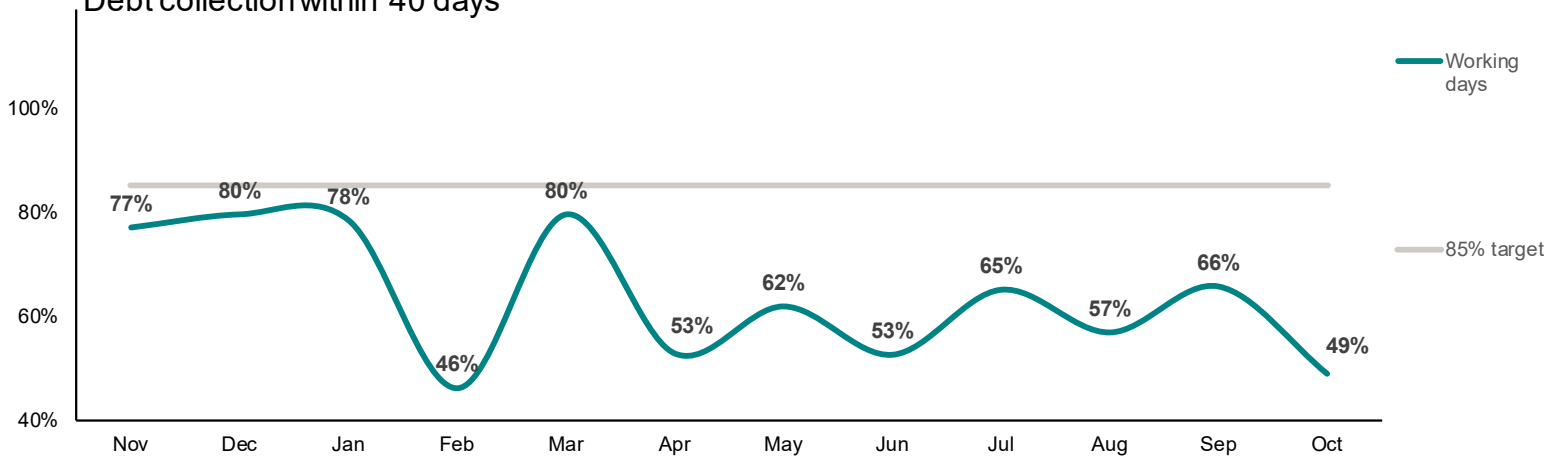
HR

Turnover

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

Turnover remains low, with no resignations pending.
Supplementary HR data: **Headcount - 78, Posts - 76, Vacant posts -0, Starters - 0, Leavers - 0.**

Debt collection within 40 days



Status: **Red**

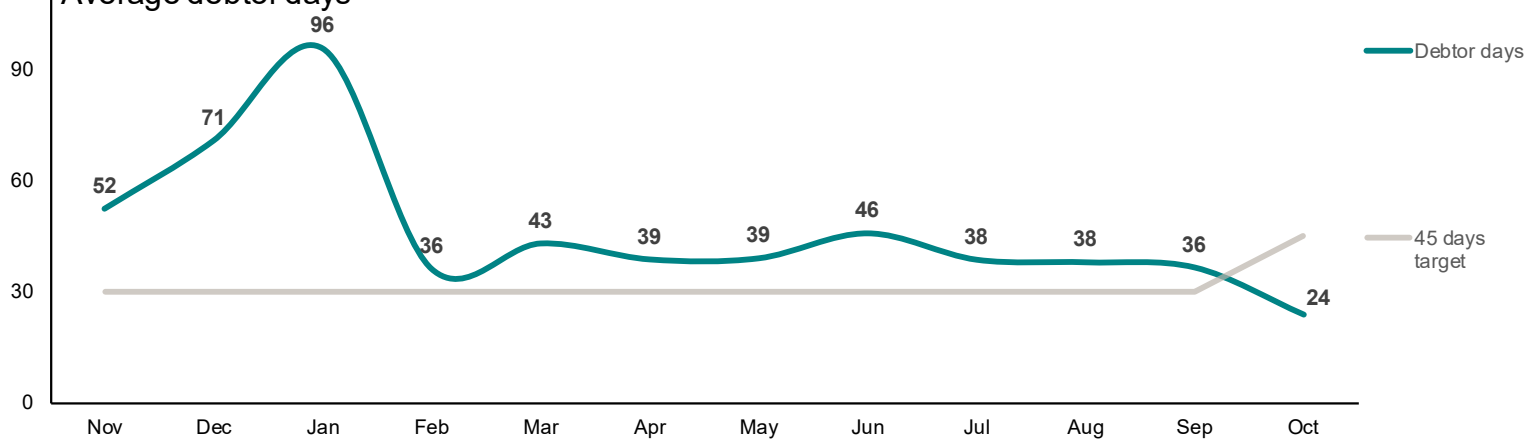
Finance

Debt collection

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

Significant effort applied to chasing the older debt has resulted in over £300k of aged debt being paid in the month.

Average debtor days



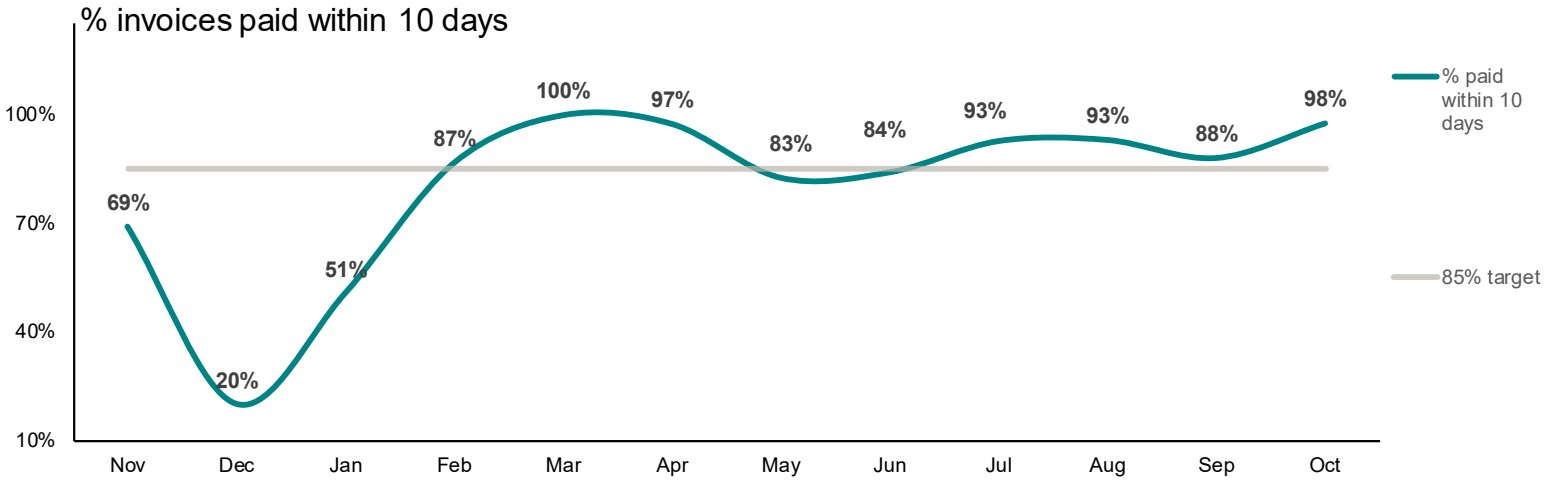
Status: **Green**

Finance

Debtor days

New target from Oct 2024:
45 days or less

The target has been increased to 45 days following the Finance KPI review.



Status:	Green
Finance	
Prompt payment	
Target: **85% or more invoices paid within 10 days**	

The target has been met.

Strategy and Planning

Details about this paper

Area(s) of strategy this paper relates to:	Strategy 2025-2028
Meeting:	Authority
Agenda item:	6
Meeting date:	20 November 2024
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex A: Draft strategy for 2025-2028 Annex B: Outline three-year plan, including business plan content for 2025/26

Output from this paper

For information or decision?	For decision
Recommendation:	Comment on the draft strategy and stakeholder feedback, with a view to approving a final version of the strategy in January 2025. Comment on the draft outline three-year plan for delivery. Year one of this plan will form the basis for the business plan for 2025/26.
Resource implications:	In budget
Implementation date:	April 2025-March 2028
Communication(s):	The strategy and each year's business plan will be published on our website.
Organisational risk:	Low

1. Introduction

1.1. Following earlier Authority discussions and feedback from our stakeholder groups, this paper presents:

- A draft of the new HFEA strategy for 2025-2028
- Feedback from our stakeholder groups
- Initial delivery plans.

2. Context

2.1. Our strategy is important, since it guides all of our work and informs the delivery of our statutory functions. The Authority has dedicated significant workshop time to discussing the environmental context in which we operate, anticipated changes in the sector, science and society, and the Authority's vision for the next three years.

2.2. Our vision and objectives focus on the increasing complexity of the fertility landscape, and what this will mean for patients, clinics, and the HFEA as a regulator. For example, we know that some aspects of care and advice are increasingly being offered online, and that over time more diagnostic tests will be informed by AI. The next few years will also see some significant developments in scientific research. Decisions will need to be made on how best to regulate such developments, and some of these changes will require a change in the law. We will also want to go further in providing information that helps patients to make difficult treatment decisions.

2.3. 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.

2.4. Our vision is:

Regulating for confidence:

– Safe treatment

– Right information

– Supported innovation

3. The draft strategy

3.1. The draft strategy is attached at Annex A. The Authority's views on the draft are now invited.

3.2. The following should be noted:

- Members' comments on an earlier version have been incorporated into this draft, with the exception of one suggestion to move the vision statement to the beginning of the 'Our vision' section. Members' views on the best positioning for the vision statement (before or after the contextual paragraphs) are invited.
- The introductory text and the section on challenges and priorities will be finalised at a later stage, once the objectives and associated actions have been agreed.

- The text may need to be updated following the Authority's decisions on recommendations from the Scientific and Clinical Advances Advisory Committee. These recommendations will be considered at today's meeting, and at the January 2025 meeting.
- The 'trust mark' idea was originally expressed in two different places, so this has been merged into one line to avoid duplication.
- Design work will be done between January and April, so this is not the final design.
- We are working towards a goal of achieving law reform in the short to medium term and the potential timetable should become clearer over the next few months. If this comes to fruition, then the strategic work of the organisation – other than 'business as usual' – will shift toward legislative change. If it becomes clear that this ambition is more likely to be delivered in the longer term, then law reform will remain a key strategic objective as set out below.

3.3. The strategy falls into two main themes:

- 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.
  - Developing a 'trust mark' to indicate which sources of data are regulated and/or verifiable.
  - Through our law reform work, continue to make the case for wider powers to cover new service provision models.
  - Make improvements to our information provision and the reach of our data.
  - Providing accurate and timely information to those making Opening the Register (OTR) requests.
- Supporting scientific and medical innovation
  - Ensuring that new developments are safely regulated, and that barriers to entry for new treatments and technologies are proportionate.
  - Through our law reform work, continue to make the case for wider powers to cover new developments that currently fall outside the regulatory framework.
  - Preparing for the ways in which Artificial Intelligence (AI) is likely to impact on, and benefit, patients, the sector and the HFEA.

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

3.5. The new government has recently begun a consultation on a new 10-year plan for health for publication in Spring 2025. This will form part of the context for our new strategy 2025-28 and we will work to ensure that our final draft is aligned where relevant.

4. Feedback from stakeholders

4.1. Feedback has been sought through meetings of our main stakeholder groups. In addition, the attached draft has been sent for comment to members of our Patient Engagement Forum.

4.2. Stakeholders were supportive of the proposals in the strategy. Alongside positive comments, there were some matters for the HFEA to consider in relation to the way we implement certain things, but there were no comments disagreeing with the direction set out in the strategy.

Licensed Centres Panel

4.3. The feedback was largely positive, and the members present supported the overall direction of the strategy. They believe we are addressing the right things.

4.4. There was one main note of caution, that we take care about how we implement some elements of the strategy so that the impact on clinics is well understood and managed. These concerns related not only to the strategy but to other matters such as our planned work on improving the transparency of our regulatory information.

4.5. There was support for the inclusion of AI in the strategy, and recognition that this is evolving fast.

4.6. The group were keen on us using our voice to enrich the narrative around the way the UK deals, as a country, with issues such as equality of access. There was interest in the trust mark idea, with some questions about how this would work in practice (and this would obviously need to be thought through when doing the work).

Patient Organisations Stakeholder Group

4.7. Again, the group were supportive of the ideas within the strategy.

4.8. There was a similar question about, and support for, the development of a trust mark.

4.9. Some useful ideas were raised about future presentation of data on Choose a Fertility Clinic (CaFC).

4.10. Questions were asked about the timeline for law reform.

4.11. One issue was raised for possible inclusion, either in the strategy or a future business plan:

- A member recalled an earlier discussion about the Authority potentially having a role in regulating pricing. At present we do not have any financial powers. Although this hasn't formed part of our proposals on legislative reform to date, is this worthy of further discussion?

Professional Stakeholder Group

4.12. The main point of discussion was the ten-family limit, and whether there was more the HFEA could do, in collaboration with bodies including the Association of Reproductive and Clinical Scientists (ARCS), about the international position on this.

4.13. There were no particular comments on the strategy itself, and no objections to the overview presented.

Patient Engagement Forum

4.14. Feedback is also being sought from members of the Patient Engagement Forum, and any comments received will be relayed to the Authority verbally at the meeting.

5. Planning for delivery

5.1. As is our usual practice, the Corporate Management Group held its annual business planning meeting in September. We took this opportunity to give early consideration to the delivery of the strategy across three years. In addition, we considered other activities for next year's business plan. A further planning meeting will be held in late January 2025.

5.2. CMG's initial thoughts on planning for the next three years, including an outline of all activities (strategic and statutory) for the 2025/26 business plan are set out in Annex B. This work is still at a preliminary stage at present.

6. Recommendations

6.1. The Authority is asked to:

- Comment on the draft strategy and vision (see Annex A), with a view to a final version being submitted to the January 2025 Authority meeting for sign-off.
- Comment on the optimum positioning for the vision statement within the 'Our vision' section (see paragraph 3.2 above).
- Discuss the stakeholder feedback received to date, in particular the additional item raised for consideration in paragraph 4.11:
  - A member also recalled an earlier discussion about the Authority potentially having a role in regulating pricing. At present we do not have any financial powers. Although this hasn't formed part of our proposals on legislative reform to date, is this worthy of further discussion?
- Comment on the outline three-year delivery plan, noting that further work is planned on this after the January 2025 Authority meeting.
- Approve the draft list of activities for the 2025/26 business plan (see Annex B), so that drafting can begin before the January Authority meeting. Further operational planning will follow.

Annex A

Human Fertilisation & Embryology Authority

Our strategy

2025-2028

Our vision

Our 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 IVF and the UK is one of the safest places in the world to have fertility treatment. The regulatory framework has played a key role in making that happen. 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.

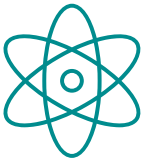
With that context in mind, we want to ensure a well-regulated sector that is trusted by patients and the wider public, that we provide information that is helpful for patients in making treatment choices, and that biosciences that lead to innovations in treatment can flourish within an ethical framework.

Our vision is therefore for:

Regulating for confidence:

- Safe treatment
- Right information
- Supported innovation

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

 **Theme 1: Regulating a changing environment**	 **Theme 2: Scientific developments and medical innovation**
[Drafting Note (DN): Table will contain the final wordings of the objectives, once all agreed]	

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 – people are delaying trying to start a family and if they have difficulty conceiving, they are finding it difficult to access NHS advice and tests.
- 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 on reforming the HFE Act in 2023[1], 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.

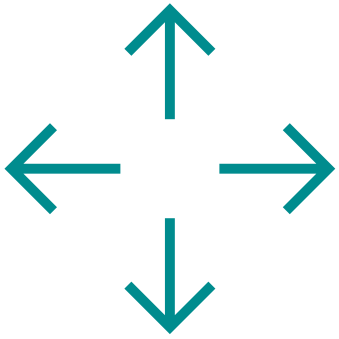
Consent: the consent regime in the Act should be overhauled, with a requirement for automatic record-sharing between clinics and the NHS (with the option for patients to opt out).

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 HFEA staff. If this occurs, it is likely that we would need to reprioritise the objectives in this strategy.

[1] See Modernising fertility law | HFEA

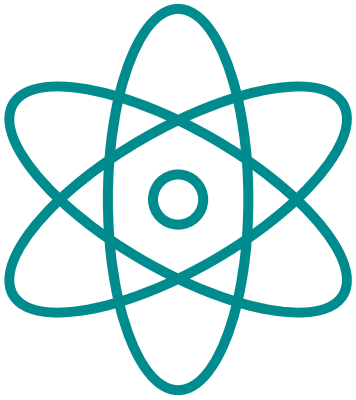
Regulating a changing environment



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 centres in an effective, efficient, consistent and transparent manner, publishing outcomes on our website. 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 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 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.

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.
	Certainty as to whether new developments that currently fall outside regulation (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	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.

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.

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Annex B – Outline delivery plan

1. Introduction

1.1. This annex outlines:

- Our annual recurring 'business as usual' which is built into all business plans
- Continuing work beginning in 2024/25 and new known work for 2025/26
- An initial three-year outline plan for delivering the strategy

1.2. Further detailed work will be done on the three-year plan, and the business plan for 2025/26, between the November Authority meeting and the publication of the new strategy for 2025-2028, in April 2025. In particular, the Corporate Management Group (CMG) will meet again after the January 2025 Authority meeting, by which time the strategy will be in its final design phase.

1.3. Next year's business plan will contain the business as usual (see section 2 below), the items of work that either continue from this business year, or which we know will start next year (see section 3 below), and the activities scheduled for year one of the strategy (see section 4 below). As ever, it will be important that we prioritise and schedule items in a manageable way.

2. Business as usual

2.1. The table below details our statutory recurring activities, which are built into every business plan:

Business as usual activities
Regulatory activities:
Inspection and audit
Incidents and events/complaints
Collaborating with other regulators
Licensing/PGT-M etc.
Governance and licensing tools
Legal information and advice
Managing our data assets:
Maintaining the Register and related data submission and analytical systems
Choose a Fertility Clinic update (i.e. to become BAU after the current verification exercise is complete)
Opening the Register requests

Information for researchers
Policy work and guidance:
Code of Practice and guidance updates as necessary
Horizon scanning and the Scientific and Clinical Advances Advisory Committee
Communications activities:
Communications channels and media
Website information provision
Regular data publications
Maintaining compliance with accessibility requirements
Stakeholder engagement
Information management and IT services:
Records management and information governance
Managing Freedom of Information, Parliamentary Questions and other information requests
Holding our data securely
Cyber security and associated IT work
Data Security and Protection Toolkit (DSPT) compliance
Other corporate business:
Managing complaints about the HFEA
Recruiting and retaining staff

3. Continuing and new work for 2025/26

3.1. The table below details the work we know will be ongoing from the current business plan, or will start in 2025/26:

Work continuing from 2024/25 or starting in 2025/26
Law reform
CaFC verification and publication post-PRISM
OTR and donation focus (subject to Authority discussion)
Multiple births target implementation work subject to Authority decision in January/March 2025
Completion of the PGT-M list audit
Potentially, updates to our finance systems (SAGE and WAP)
Fees review

Delivery of a new document management system and a replacement for our centres database, Epicentre. – It's important to note that this will be a significant 18-month project with a number of team interdependencies – work beginning in January 2025	
Upgrading our website software and security	
Work as needed relating to the EUTCD	
Patient survey outcomes and implementation	
Supporting the Government's ten-year health plan (to be published spring 2025)	

4. Strategy delivery

4.1. The table below sets out the work needed to fulfil the strategy. This is in the preliminary stages of development and will require a more detailed review by CMG once the strategy is finalised at the January 2025 Authority, and as we develop the business plan for 2025/26. It's important to note that the potential packages of work have not yet been scoped in any detail.

4.2. We should also bear in mind that if the Department of Health and Social Care (DHSC) decides that the Act may receive Parliamentary time at some stage during this three-year strategic period, the related workload would require deprioritisation of some non-Act related priorities until the implementation of the new legislation has been completed. Amendments to the Act are impactful in terms of resources and will require input from our staff. If this eventuality occurs, it will require assessment and reprioritisation of the remainder of the strategy at that time.

4.3. The shaded column below indicates which items are to be included in the business plan for 2025/26. Drafting of the business plan will begin shortly.

Strategy delivery – April 2025 – March 2028

Strategy objective (draft wording)	Activities	Business plans		
		2025/26	2026/27	2027/28
1. To effectively regulate a changing fertility sector. Maintaining public confidence in safety	Continuing to perform our regulatory duties to a high standard, publishing outcomes, and making improvements where we can.	✓	✓	✓
	Review of the inspection report (post-Epicentre delivery)	-	✓	✓
	Fees review	✓	-	-
1. To effectively regulate a changing fertility sector.	Further work on dashboards to increase the efficiency of the inspection process, following this year's project to produce an inspectorate dashboard.	✓	✓	-

Strategy objective (draft wording)	Activities	Business plans		
		2025/26	2026/27	2027/28
Bringing together our inspection and clinical governance information and other data sources to help us regulate better				
1. To effectively regulate a changing fertility sector. Wider powers to allow us to act further in the patient's interest	Pending any wider powers, to continue with our duty to protect patients through our regulatory activities.	✓	✓	TBC
	Continue to make the case for law reform.	✓	TBC	TBC
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 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 (with terms and conditions applying to the provider of the data).	-	✓	✓
	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 provide accurate and timely information to those affected by donation and making Opening the Register (OTR) requests.	Continue to develop and monitor our systems to streamline and improve the efficiency of the OTR process.	✓	✓	-

Strategy objective (draft wording)	Activities	Business plans		
		2025/26	2026/27	2027/28
3. To ensure that the HFEA responds well to issues related to donation. To address the implications that arise in relation to the use of donors in treatment.	Produce effective communications and clear policy responses when these are required.	✓	✓	✓
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 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.	✓	✓	✓
5. To ensure the safe regulation of emerging new science and technology under a clear ethical framework. Certainty as to whether new developments that currently fall outside regulation (for example new embryo models, artificial gametes) should be brought within a clear regulatory framework.	Lead policy formation and the development of regulatory criteria in response to new treatment advances and scientific developments.	✓	✓	✓
	Work with stakeholders and the government towards ensuring emerging areas are safely regulated.	✓	✓	✓

Strategy objective (draft wording)	Activities	Business plans		
		2025/26	2026/27	2027/28
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 to ensure that the way AI is used in clinics is evidence-based and safe.	✓	-	-
	Develop our regulatory and inspection approach to take account of AI usage and mitigate risks effectively.	✓	✓	✓
6. To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA. The HFEA to make best use of developments in AI to make our work more efficient and effective.	Following our planned re-platforming of certain internal IT services in 2025/26 and 2026/27, to work towards a 'single view' model of our data and to scope the benefits, opportunities and risks of using AI and automation to improve our efficiency.	✓	✓	✓
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 expertise 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 'futureproofing', so that future, as yet unknown, developments can be regulated effectively without requiring changes to the law on each occasion.	✓	✓	✓

Law Reform: Scientific developments - 14-day rule on embryo research

Details about this paper

Area(s) of strategy this paper relates to:	Shaping
Meeting:	Authority
Agenda item:	7
Paper number:	HFEA (20/11/2024) 007
Meeting date:	20 November 2024
Author:	Rebecca Taylor, Scientific Policy Manager
Annexes	Annex 1: Timeline of embryo development and research and the proposed regulation

Output from this paper

For information or decision?	For decision
For decision:	Members are asked to consider: • Whether the 14-day rule on embryo research should be extended. • If so, what new time limit would be appropriate? • If a new time limit is established, should any application for embryo research beyond 14 days have to meet specific criteria?
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 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 14-day rule for embryo research. This paper looks in more detail at this area and makes recommendations for change.

1.5. The Scientific and Clinical Advances Advisory Committee (SCAAC) considered the scientific and technical case for and against extending the 14-day rule at their October 2024 meeting (see **meeting papers)**.

1.6. The structure of this paper is as follows. Section 2 provides a background to the 14-day rule; section 3 looks at the international context; section 4 summarises the arguments discussed at the October 2024 SCAAC meeting along with recommendations from the Committee, and outlines the broader ethical concerns and considerations including public opinion on the 14-day rule. Sections 5 and 6 look at the broad arguments for and against any extension and section 7 asks Authority members to consider several questions for decision.

2. Background

2.1. The 14-day time limit for embryo research originated from recommendations in the 1984 Warnock Committee report in the UK, with similar recommendations being made in other countries.

2.2. The Warnock Committee sought to strike a balance between allowing potentially valuable medical research and addressing the moral, legal, ethical and social concerns raised by embryo research. 14-days set a clear limit that corresponded to embryo development and could be identified through biological markers, namely the emergence of the primitive streak (precursor of brain and spinal cord). It is also the last moment an embryo can split into twins, thus the start of individual development.

2.3. The Warnock Committee also established three principles in relation to regulating human embryo research:

- The subject of the human embryo is one about which people have strong feelings and views, and these must be respected.
- There would never be agreement on the ethical status of the human embryo, so a degree of compromise would be necessary in order for there to be any legislation at all.
- However imperfect, some legislation would be better than none.

2.4. Discussion in the UK Parliament in 1988 noted that while the Warnock Committee had proposed a 14-day time limit for embryo research, the Royal College of Obstetricians and Gynaecologists (RCOG) suggested 28 days, but the latter was not subsequently adopted. The discussions in parliament reflected the view that there should be an upper limit, and that the relevant statutory licensing authority should determine, where beneath that limit, embryo research can be authorised.

2.5. The Warnock report recommendations, including the time limit for culturing human embryos, were then incorporated into legislation in 1990 through the Human Fertilisation and Embryology Act 1990 (the HFE Act) which states in sub-section 3:

"(3) A license cannot authorise –
(a) keeping or using of an embryo after the appearance of the primitive streak."

And further stipulates:

"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 [the day on which the process of creating the embryo began], not counting any time during which the embryo is stored."

2.6. Any research using human embryos or human admixed embryos requires a research licence from the HFEA. The Authority can grant a licence if the research can be considered necessary and desirable to achieve at least one of the following principal purposes defined in the HFE Act (2008):

- (a) increasing knowledge about serious disease or other serious medical conditions,
- (b) developing treatments for serious disease or other serious medical conditions,
- (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

- (d) promoting advances in the treatment of infertility,
- (e) increasing knowledge about the causes of miscarriage,
- (f) developing more effective techniques of contraception,
- (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
- (h) increasing knowledge about the development of embryos.

2.7. The HFEA website contains **summaries of approved research projects** using donated embryos.

2.8. The 14-day rule was subsequently adopted in many other jurisdictions including Australia, Belgium, Canada, China, France, India, Japan, The Netherlands, Norway, South Korea, Spain, Sweden and Taiwan.

2.9. When the 14-day limit was first recommended in 1984, it was only possible to culture embryos up to 7 days. However, by 2016, researchers in the US and UK were able to sustain embryos in vitro until 13 days, before destroying them in order to comply with the 14-day rule.

2.10. In developing proposals to modernise the HFE Act, a public consultation was undertaken, which generated responses to the idea of extending the 14-day rule including:

- Concern that research after 14 days would involve embryos whose central nervous system, heart and brain are beginning to develop, raising the question of sentience.
  NB: As outlined elsewhere in this paper, scientific research has now established that embryos are not sentient at this stage of development.
- Support for extending the 14-day rule to address gaps in scientific knowledge and better understand miscarriages, infertility and developmental conditions.
- That should any extension be considered, it must be subject to strict conditions including a clearly identifiable time limit and prohibitions on some forms of research, to ensure research remains safe and ethical.
- That any changes to the 14-day rule in the HFE Act must be subject to appropriate parliamentary and public scrutiny.

3. International discussions on 14-day rule

3.1. In recent years, following advances in embryo culture methods, many scientists in the human biology field would like to undertake research beyond the current internationally accepted 14-day limit. This has been shown in many **peer reviewed journal articles** and also in **media coverage**. Studying human embryonic development beyond 14 days would enable us to learn more about the 14-28 day period, which is when many miscarriages occur and congenital conditions begin. This had led some countries to explore the idea of extending the 14-day limit.

3.2. Following a request from the Dutch Ministry of Health and Welfare, the Health Council of the Netherlands, an Advisory Body, examined the desirability of extending the 14-day rule and how to establish a developmental limit for embryo like structures (ELS) in October 2023 **recommended**:

- Extending the time limit on human embryo research to 28 days and also applying it to stem-cell based embryo models (SCBEMs)
- Case-by-case approval from the Central Committee on Research involving Human Subjects (CCMO) required for any research project going beyond 14 days.

There has been a change of government in the Netherlands since the report was published and the new government have not acted on these recommendations.

3.3. In a May 2024 statement, the Norwegian Biotechnology Advisory Board **published details of discussions** (only in Norwegian) on the 14-day rule:

- Nine of the Board's 15 members believe current 14-day limit should be extended up to and including day 28 and a case-by-case exemption should be established to allow research beyond 28 days for special cases
- Five members want to keep the current 14-day time limit, of which three would support a case-by-case dispensation up to day 28.

3.4. The Swedish National Council on Medical Ethics (SMER) issued **a letter** in April 2024 on the need for an updated regulatory framework for research on early human development addressing both human embryo research and embryo models. Among other recommendations, the SMER recommended that the Swedish government looks into "an extension of the time permitted for research on human embryos" in order to "enable research in an important period of embryo development where much remains unknown".

3.5. Chinese researchers have suggested **in a peer reviewed article** that China's Ethical Guidelines should be amended to set a new time limit for embryo research beyond 14 days. No formal proposals have yet been developed.

3.6. In 2021, the International Society for Stem Cell Research (ISSCR) published updated **guidance** for stem cell research and clinical translation, which proposed changes to the 14-day rule. ISSCR guidance establishes categories of research:

- Category 1A – permissible without review
- Category 1B - permissible without review, but must be reported to designated body to monitor research in case issues arise
- Category 2 – permissible after review and approval through specialised scientific and ethical review
- Category 3a – prohibited despite scientific rationale as currently unsafe
- Category 3b – prohibited due to lack of scientific justification, being unsafe and/or considered unethical

Until 2021, research involving human embryos up to 14 days fell under category 2 (permissible with review), while research beyond 14 days fell under category 3b (prohibited). In recommendation 2.2.2.1, ISSCR proposed moving embryo research beyond 14 days to category 2 as follows:

"*Should broad public support be achieved within a jurisdiction, and if local policies and regulations permit, a specialized scientific and ethical oversight process could weigh whether the scientific objectives necessitate and justify the time in culture beyond 14 days, ensuring that only a minimal number of embryos are used to achieve the research objectives*."

3.7. The ISSCR is currently updating its guidelines on stem cell and embryo research.

4. SCAAC considerations of the 14-day rule

4.1. At its October 2024 meeting, the SCAAC considered the 14-day rule on embryo research, including the arguments for keeping and extending the time limit, focusing on the scientific and technical aspects.

4.2. The SCAAC agreed that:

- There is a case to be made for extending the 14-day rule however did not agree on any specific future upper limit, although 28 days was most commonly mentioned in discussions and noted to be subject to international consideration. Determining small incremental increases through secondary legislation may be favourable as the research evolves.
- It is important to define an upper time limit for embryo research, that should be clearly justified whether by reference to principles, developmental stages, cultural norms, or the benefits that might come from allowing research up to a new extended limit.
- Members supported the suggestion that projects should be reviewed on a case-by-case basis, with the time limit for each individual project being specified by a review committee.

4.3. In discussing this matter, SCAAC members also noted a number of points including:

- The possible benefits of allowing embryo culture beyond could include:
  - The ability to investigate late onset pregnancy complications, such as pre-eclampsia, still birth, and growth restrictions which are thought to have origins in early-stage embryo development, when the placenta is beginning to form.
  - The ability to study early organ development (organogenesis), which is thought to be the time frame within which the origins of many congenital defects arise, including those related to neural tube closure and cardiac disorders.
  - The ability to test and improve the safety of established techniques including mitochondrial donation.

- There is currently no alternative way to study the so-called ‘black box’ period of embryo development, which is between 14-28 days, other than using human embryos. However, when SCBEMs and IVGs can be validated, it may be possible to use them in research covering this stage of development. Validation of SCBEMs beyond 28 days can be done against material from miscarriages or terminations.
- At present embryos and embryo models are not equivalent and research using both structures is more nuanced. Seeking to reduce or replace embryo research through the use of embryo models, would need careful consideration given their current limitations.

- In relation to any new upper time limit on embryo research:
  - Any new proposed time limits on embryo research may be linked to known milestones in early pregnancy such as when pregnancy is first detected (around 5 or 6 weeks), up to 6 weeks when early miscarriages commonly occur, or at 6/7 weeks when foetal heart scans can be performed.
  - The idea of a 28-day limit was discussed recognising that this is being considered in other jurisdictions. There is also a clear biological (morphological) marker. However, as embryos have not yet been cultured in vitro beyond 14 days, it is not known whether this biomarker would arise the same way as it does in vivo.

  - A member highlighted a further reason which favoured a 28-day limit is that there is some tissue from abortions and miscarriages available as a valid alternative after 28 days.
  - A member highlighted that while 28 days may be an appropriate new upper limit, it may take time until it is technically possible to culture to that boundary.
- Despite recognising the potential research benefits, a member challenged whether it was premature to revisit the 14-day rule at this time, indicating that more research could still be done on human embryos and other animal models (including non-human primate models) to extend knowledge and benchmark normal embryo development prior to 14-days.

5. The case for keeping the status quo

5.1. The case for keeping the status quo and retaining the 14-day rule in embryo research should be considered. This includes questions about the reliability of embryo culture, the 7-14 day discoveries that could still be generated and the use of SCBEMs.

Scientific considerations

5.2. It has been argued that most embryo research discoveries have been made within the 7-day pre-implantation period, and research on 7-14 day old embryos has not yet been fully explored, so may offer further discoveries. That there may be more to learn from 7-14 day stage of embryo development may limit discoveries generated from 14-28 day research.

5.3. The reliability of culturing embryos in-vitro beyond 14 days is not yet absolutely certain. Although cells of the majority of embryonic and extraembryonic lineages found have been detected in *in vitro* embryos cultured to 12/13 days, some disparities *in vivo* in the clustering of cell types have been observed. Discrepancies might be due to the appearance of transient and intermediate cell lineages, the possible presence of aberrant cells, or *in vitro* culture methods not reliably replicating the post-implantation womb.

5.4. It is not yet known how reliably extended *in-vitro* culture could replicate the post implantation environment of the womb. Currently research on ectogenesis (artificial wombs) shows the most promise in relation to third trimester research, namely supporting pre-term infants in place of an incubator. This research was outlined in a recent HFEA **literature review on ectogenesis**.

5.5. The development of research using SCBEMs opens the door to reducing or replacing human embryo research. Researchers are already using embryo models to better understand implantation and early post-implantation development. *In vitro* models are becoming increasingly sophisticated and able to match *in vivo* tissue physiology. This is increasing understanding of the molecules and signalling pathways involved in implantation, and may in future enable the development of *in vitro* models of disease and subsequently the identification of new pharmaceutical treatments.

5.6. In a 2023 opinion on SCBEMs, the Conseil d'Orientation (advisory body of French Biomedicine Agency) said there should be no extension of the 14-day rule for human embryo research because of proposals to allow research on integrated embryo models such as blastoids until the equivalent of 28 days post fertilisation.

Ethical and moral considerations and public opinion

5.7. Because embryos have the potential to become human beings, embryo research has always been understood as raising important ethical and moral concerns. These include different views

around when human life is considered to begin and therefore be worthy of protection, and what kind of protection and safeguards are appropriate, which can lead to an opposition to any human embryo research, or in some cases IVF as a whole.

5.8. The ethical and moral concerns relating to embryo research are reflected in the way embryo research is regulated in the UK. The regulatory framework set up after the Warnock report recognised the special status of the human embryo and the need to regulate research strictly and with clarity. Embryo research requires an HFEA licence, which is assessed on a case-by-case basis and is not granted unless the research is necessary and desirable to generate insights in one of a number of research areas, and cannot be undertaken other than with human embryos (see 2.5 for more detail). The current 14-day time limit has become easy to understand for the public and for researchers to comply with.

5.9. Respondents to the HFEA consultation who did not support any change to the 14-day rule raised the following points:

- That research after 14 days would involve embryos whose central nervous system, heart and brain are beginning to develop, raising the question of sentience.
- That any extension beyond 14 days would lead to a "slippery slope" with an ever-extending time limit approaching viability.

5.10. A **public dialogue on embryo research** specifically addressing possible extension of the 14-day rule was undertaken by the Human Developmental Biology Initiative (HDBI) and UKRI Sciencewise. The initiative involved a representative group of 70 people from across the UK. A minority of those questioned expressed concerns about human embryo research (some of whom were unsure, some of whom were opposed) to changing the 14-day rule, views included:

- That they opposed all forms of embryo research
- Uncertainty in relation to the benefits that may arise from such research
- Concern about developmental milestones including when the embryo might feel pain
- The importance of donors having a say over how long research can happen on embryos donated for research

Other considerations

5.11. A challenge remains for those who would like SCBEMs to replace or reduce the need for human embryo research, which is the current need to use human embryos to validate those models.

6. The case for extending the 14-day rule

6.1. The case for extending the 14-day rule on embryo research is outlined below. This includes the potential for valuable scientific discoveries to be made, international discussions and recommendations, and the risk of the UK falling behind as a leading nation for life sciences.

Scientific considerations

6.2. Introduction of the 14-day rule in embryo research has enabled many important research discoveries including, but not limited to:

- Improvements in IVF and other ART success rates, which has benefitted many fertility patients. **HFEA data** shows that in 1991 the pregnancy rate for IVF patients aged 18-34 undergoing fresh transfer was only 11% per embryo transferred, in 2022 it was 42%.

- Genetic testing of embryos, for example **pre implantation genetic screening for monogenic disorders (PGT-M)** in the UK allows parents with serious inherited conditions to avoid passing those conditions on to their children.
- **Mitochondrial donation treatment** (sometimes called mitochondrial replacement therapy) – the UK was the first country to approve this treatment which enables parents with serious mitochondrial disease to avoid passing on that disease to their children.
- Derivation of human embryonic stem cells - scientists can now use human embryonic stem cells to help model diseases, test new drugs and advance research in regenerative medicine including **developing stem cell based therapies**.
- Understanding of human embryogenesis including key molecular factors controlling how cell lineages are formed, morphology, timing and biophysical features of embryo development and insights into the establishment of epigenetic patterns and how they can be disrupted by different in vitro culture conditions.

6.3. While 7-14 day research has not been exhausted as yet, many valuable discoveries have been made (see above). In addition, research conducted post 14 days would be investigating different stages of embryo development.

6.4. The 14-28 day period of early human development is sometimes referred to as a “black box” due to the limited research that has so far been possible. Days 14-28 are when embryological defects leading to miscarriage and disease tend to occur, in particular during organogenesis (post 21 days) when the embryo is most sensitive to teratogens, and heart and neural tube development begins.

6.5. While initial studies culturing embryos to 12/13 days showed some discrepancies compared to in vivo embryos, there has now been improvements in culture technology, for example those using 3D approaches. Further information can be found in an HFEA literature review on the 14-day rule in the **October SCAAC papers** (pages 67-84).

6.6. In addition, non-human primate embryos have now been successfully cultured to 20 days and beyond, encompassing primitive streak formation, germ cell development and early neurulation. It is reasonable to assume that similar culture conditions could allow human embryos to be successfully sustained longer than 14 days.

6.7. Studying early embryo development post 14 days could:

- Advance our knowledge of embryogenesis in particular the gastrulation phase when neural plate and neural tubes, major organs and body axes are established.
- Help identify the developmental origins that contribute to common, severe pregnancy complications such as pre-eclampsia, growth restriction, stillbirth etc. Although these complications are usually identified at a later stage it is thought they might arise earlier on (between days 14 and 42) due to errors in placental formation. This research could reveal new biomarkers, which could be translated into early screening for pregnancy women and close monitoring/intervention for those at risk.
- Examine how the complex signals of the intrauterine environment affect embryo development and subsequent early pregnancy loss.
- Understand the origins of defects such as neural tube mis-folding, heart defects, skeletal abnormalities, and certain types of cancer.
- Provide a scientific foundation for preventing birth defects and teratogenesis.
- Improve understanding of epigenetic programming that occurs during this stage of development that could impact disease progression in later life.

6.8. While some research is possible after 28 days on tissues from aborted or miscarried embryos, this does not enable the study of placental development. A 28-day time limit would therefore bridge the gap between the current 14-day embryo research time limit and research using tissues from abortions or miscarriages post 28 days.

6.9. Advances arising from better understanding of early embryo development could also enable:

- Validation of stem cell-based embryo models (SCBEMs).
- Refinement of the way pluripotent stem cell differentiation mimics embryogenesis.
- Identification of benchmarks for the safety and efficacy of human genome editing (CRISPR), mitochondrial replacement therapy (MRT), and in-vitro derived gametes (IVGs).

6.10. SCBEMs are derived from pluripotent stem cells such as human embryonic stem cells (taken from human embryos) or induced pluripotent stem cells. While the resulting embryo models can recapitulate some features of early embryonic development *in vitro*, they are not yet able to replace embryonic stem cells in their entirety.

6.11. Researchers are currently developing organised from SCBEMs which could in future be used for research such as drug development.

6.12. While SCBEMs may in future be used in some research currently using human embryos, they will not remove the need for human embryo research.

6.13. Ensuring that SCBEMs accurately replicate embryonic development beyond 14 days will require validation with human embryos cultured beyond 14 days.

Ethical and moral considerations and public opinion

6.14. A 2022 **Ipsos/PET survey** found that when the public was asked their views on embryo research, more members of the public expressed support for it than opposed it:

- 41% supported embryo research (27% tend to support, 14% strongly support)
- 18% oppose embryo research (10% tend to oppose, 8% strongly oppose)
- 24% neither support nor oppose
- 13% don't know and 3% would not answer

6.15. The HDBI/UKRI Sciencewise **public dialogue** found that a majority of participants supported some form of extending the 14-day rule on embryo research but wanted to be sure that:

- Embryo research would continue to be robustly regulated;
- That research would have the potential to generate insights such as improving IVF success rates, reducing multiple miscarriages, and better understanding, preventing and treating serious conditions;
- That the public would have the opportunity to participate in any discussions on amending the 14-day rule.

In addition the dialogue found that for some participants:

- Embryo research at 28 days posed no significant new ethical considerations than embryo research up to 14 days.
- A new upper limit of 28 days was seen as benefitting from having a clear biological marker (closing of the neural tube).

6.16. Respondents to the HFEA consultation who expressed support for possible extension of the 14-day rule noted:

- Their support was in the context of such research being able to address gaps in scientific knowledge and better understand miscarriages, infertility and developmental conditions.
- That should any extension be considered, it must be subject to strict conditions including a clearly identifiable time limit and prohibitions on some forms of research, to ensure research remains safe and ethical.
- That any changes to the 14-day rule in legislation must be subject to appropriate parliamentary and public scrutiny.

6.17. In relation to concerns about possible sentience (including ability to feel pain) and awareness of embryos beyond 14 days, recent scientific developments have confirmed that this is not possible at this 14-28 day stage of embryo development:

- Specific studies have shown that the cells within embryos at 17 and 28 days cannot be considered as a central nervous system, heart or brain, but are instead the first precursor cells that will go on to form these tissues.
- Synchronised impulses of neurons in the peripheral nervous system cannot be detected until around 20 weeks.

Other considerations

6.18. Part of the case for extending the 14-day rule in a safe and ethical way is that it can contribute to the UK's reputation as a leading nation for enabling scientific innovation including well-regulated embryo research.

6.19. The new government's industrial strategy announced in October 2024, identified life sciences as one of eight growth-driving sectors to be prioritised based on both existing and emerging strengths.

6.20. Given that other countries are already considering allowing embryo research beyond 14 days (see section 3), it is important that the UK is not left behind. Failure to act in a timely manner could result in UK based researchers seeking to move abroad to undertake the research or the UK struggling to attract leading researchers and investment in the developmental biology field.

7. For decision

7.1. The Authority is asked to consider:

- If there is now a case for recommending that the law is changed to extend the time limit on embryo research?
- If so, would 28 days be an appropriate new fixed upper limit?
- If a new time limit is established, should it apply to all embryo research projects or should projects seeking to go beyond 14 days have to meet specific criteria?

Should a new upper time limit for embryo research be adopted in future, the Executive has assumed that the current system of requiring all projects to obtain a research licence would remain in place. If necessary, the research licence procedure could be modified to include additional criteria for projects seeking to go beyond 14 days.

Annex 1 – Timeline of embryo development and research and the proposed regulation

Up to 14 days

Development:

Zygote forms, undergoes cell division

Day 3 - morula, Day 6 - blastocyst

6-10 days - pre-embryo attaches to uterine wall (implantation)

From 14 days – primitive streak forms, gastrulation (different cell layers, start of organ formation) starts

Research discoveries to date:

Improvements in IVF success rates

Genetic testing of embryos

Mitochondrial replacement therapy

Derivation of human embryonic stem cells.

Understanding of human embryogenesis, including:

- key molecular factors controlling cell lineage formation

- morphology, timing and biophysical features of embryo development

- establishment of epigenetic patterns and their disruption by different in vitro culture conditions

Regulation:

Embryo culture allowed for up to 14 days or appearance of primitive streak (if earlier) for all licenced embryo research.

Licences granted for up to 3 years, providing research is being carried out to meet at least one research purpose, as outlined in the Act.

Between 15-28 days

Development:

Implantation completes

Gastrulation (mesoderm, endoderm and ectoderm cells develop) continues

Mid week 3 – primitive heart tube forms

Organogenesis begins

Limb buds and sensory placodes become visible

Heart tube starts to pump blood

Neurulation begins – formation of neural tube from ectoderm cells

Research discoveries to date:

While very little research has yet been undertaken on this stage, there are some discoveries including:

- Which genes are active and in which human embryo cell types

- Which cell types have not formed, e.g. neural cells have not formed by 17 days

- That there are differences in human signalling pathway usage compared to other species.

Regulation:

HFEA approval required to culture embryos beyond 14 days, to a maximum of 28 days.

Should new time limit apply to all embryo research projects or should projects seeking to go beyond 14 days have to meet specific criteria?

28+ days

Regulation:

28 days set as upper limit in legislation.

Embryo culture prohibited beyond 28 days in UK.

Aborted or miscarried embryos can be used for research beyond 28 days.

Law reform: patient protection and safety

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	8
Meeting date:	20 November 2024
Author:	Anna Wilkinson, Policy Manager Anna Coundley, Policy Manager
Annexes	Annex A: Current ladder of sanctions and example of a potential new ladder of sanctions Annex B Traditional patient pathway vs. modern patient pathway Annex C: Legal definitions and further detail relating to proposal 6

Output from this paper

For information or decision?	For decision
Recommendation:	To make decisions on the more detailed approaches to the law reform proposals on patient protection and safety)
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:	Medium

1. Background

1.1. The primary legislation governing the regulation of fertility treatment and embryo research in the UK is the Human Fertilisation and Embryology Act 1990 (as amended). Although the Act was updated in 2008, in large part it remains as written over 30 years ago. Developments in the structure of the fertility sector, clinical and scientific developments, and in popular attitudes towards fertility treatment, mean modernisation is needed.

1.2. 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].

1.3. The HFEA made 15 proposals in total, organised under four themes. One of the themes was on patient protection and safety. The proposals under this theme were that:

1. The HFEA should have greater freedom to decide the regularity and form of inspections.
2. There should be the possibility of appointing Deputy PRs and PRs with a broader range of qualifications or experience.
3. **The HFEA should have a broader and more proportionate range of regulatory enforcement powers.**
4. **The HFEA should have the power to impose financial penalties.**
5. **The Act should be revised to include an over-arching focus on patient protection.**
6. **The Act should be revised to accommodate developments in the way fertility services are provided.**
7. The appeals process in the Act (and associated Regulations) should be amended to allow for challenges to licensing decisions to be resolved in a more efficient and proportionate way.

1.4. At the time of publication, we recognised that some of the proposals required further refinement. This paper does that in relation to proposals 3, 4, 5 and 6 (in bold above) and builds upon the significant amount of work already carried out. Proposals 1, 2 and 7 provide the broader context but do not require further work at this stage.

1.5. The arguments advanced in this paper 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, a review of legislation governing other regulators, and a literature review on the efficacy of different regulatory powers. Our work was also discussed at the September meeting of the Licensed Centres Panel.

1.6. The structure of the paper is as follows. Section 2 considers how a broader range of powers, including financial penalties (proposals 3 and 4) could be used. Section 3 sets out what an over-arching focus on patient protection might look like (proposal 5) and Section 4 sets out options for revising the Act to accommodate developments in the way fertility services are provided (proposal 6).

1.7. Any decision to modernise the HFE Act is of course for the Government. This paper focuses on options that can only be achieved by a change in the law. If we hear from Government that law change is unlikely in the near future, the Authority may wish to consider interim means of partially addressing some of the challenges highlighted in this paper.

[1] See the **paper** and **minutes** from the Authority meeting on 13 September 2023 .

2. Proposals 3 and 4: The HFEA should have a broader and more proportionate range of regulatory enforcement powers, including the power to impose financial penalties

2.1. Proposals 3 and 4 of our recommendations for changes to the Act argue that the HFEA should have a broader and more proportionate range of regulatory enforcement powers, including the power to impose financial penalties. A common way of thinking about regulatory powers is the idea of an escalating 'ladder of sanctions'. As a general principle the objective is to achieve compliance with the most proportionate sanction. However, at present, the HFEA has a limited range of sanctions and a very high bar for any regulatory action.

2.2. In summary, the key challenges with our current regulatory sanctions are that:

- The HFEA must show that the requirements for revoking a licence (the most serious available sanction) are met before we can impose alternative sanctions, such as conditions or a temporary suspension. This is a very high bar for any regulatory action, with the result that non-compliant services might continue to operate while not meeting the required standards for longer than they should, increasing the risks to patients.
- We lack intermediate powers to encourage compliance, which again risks the persistence of non-compliant services for longer than necessary.
- We cannot issue financial penalties: in many areas of non-compliance, variation, suspension or revocation of a licence would be disproportionate and would negatively impact on patients. Many regulators have powers to issue financial penalties which might be more effective.

An expanded ladder of regulatory sanctions

2.3. The limited nature of our available sanctions is illustrated in Annex A, by a side-by-side comparison of our current ladder of regulatory sanctions (Diagram 1) and a potential expanded ladder (Diagram 2). The key point is the absence of sanctions at the bottom of the current ladder (other than informal advice). Diagram 2 illustrates a wider range of sanctions of escalating severity, such as formal warnings and financial penalties.

2.4. The benefits of such an expanded ladder of sanctions are:

- 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 a clinic, 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 we already have.

2.5. Sanctions could be used in isolation or in combination with other sanctions (such as fines or action on a licence).

Changes to current powers: Greater flexibility to vary or suspend licences

2.6. Even if our ladder of sanctions were revised, there is also a case for changing the tests that apply to the regulatory sanctions we already have. Currently the grounds for varying, suspending and revoking a licence are identical (although the standard of proof is different in respect of suspension – see paragraph 2.8). This significantly restricts the circumstances in which licence conditions and suspension action can be taken. Lowering the thresholds in respect of varying and suspending a licence would allow us to take action to restrict non-compliant clinics' practice before the point at which compliance is so poor that revocation is

warranted. The ability to vary a licence at a lower threshold than is currently possible would allow for quicker targeted interventions in particular areas of practice with minimal disruption to patients having treatment in other areas. For example, if a clinic is not following the law on the use of donor gametes this area of practice could be halted immediately, without the need to establish that the bar for revocation has been met, whilst other patients' treatment can continue.

2.7. Suspending a licence should also be possible at a lower threshold, and at an earlier stage than is currently possible, before practice becomes so poor revocation would be justified. This could prevent dangerously poor practice before it arises by allowing suspension at an earlier stage.

2.8. Whilst the grounds for varying, suspending and revoking licences are the same, as noted above currently the standard of proof for suspending a licence is lower than that for varying or revoking a licence.[2] A licence can also be suspended with immediate effect, even if the suspension is challenged. Enabling a licence to also be varied with this lower standard of proof for a short period, and with immediate effect, thereby more quickly imposing conditions relating to particular areas of practice, would effectively create a 'prohibition order' that could be used to very quickly halt unsafe practice. This would be useful in cases where even a short-term continuation of clinic activities in a certain area could pose patient safety issues.

New powers: Written warnings

2.9. Many other regulators (such as the CQC, Gambling Commission and Ofcom) use formal written warnings to address non-compliances. Written warnings are communications in response to lower-level non-compliance(s) that serve to warn about the possibility of enforcement action if a non-compliance is not remedied. They might include information on which part of law, regulation or Licence Condition(s) has been breached, how the clinic failed to comply, a warning about further action and a timescale within which the licensed clinic must correct the non-compliance.

2.10. Our current compliance processes already include steps in which information about possible future regulatory action (effectively, informal warnings) are communicated to clinics following inspections: Inspector recommendations and forewarnings of possible future regulatory action on a licence are circulated as part of the inspection process to PRs prior to Licencing Committee or Executive Licencing Panel meetings.

2.11. A legal power to issue written warnings would effectively put our current process on a statutory footing and provide a stronger incentive for PRs to address non-compliances. Written warnings could be an early and fast statutory action to address less severe areas of non-compliance (for example failure to conduct audits according to the prescribed schedule within the QMS) and have the potential to reduce the need for more severe sanctions (i.e. a fine, or licence variation, suspension, or revocation) at a later point. This power could also be combined with a power to take account of written warnings when making decisions about action on a licence. The failure to respond appropriately to written warnings could therefore also constitute useful evidence of the need to issue more severe enforcement, where necessary.

2.12. The force of any written warning would likely be strengthened by proactively publicising information about their use. This would align with the decisions taken at the **September 2024 Authority meeting** to more proactively communicate decisions about enforcement action and increase regulatory transparency.

New powers: Fixed penalty notices (FPNs)

2.13. Many regulators (for example, CQC, The Pension's Regulator and The Gambling Commission) have powers to issue financial penalties as a means of deterring non-compliance. Financial

[2] This is to ensure that practice can more quickly be (temporarily) halted where there is the possibility of unsafe practice.

penalties can be issued alone or alongside other sanctions, where appropriate, as a form of proportionate enforcement action.

2.14. Through our discussions with other regulators we have found two broad approaches to issuing financial penalties: (A) Models in which very large financial penalties, often in hundreds of thousands or millions of pounds, are issued on a case-by-case basis, as used by the Information Commissioner, Ofcom and others for very serious breaches of guidance and the law; and (B) fixed penalty notices (FPNs) which are fines of specific, typically lower, relative value assigned to particular types of non-compliance, according to a fining schedule.

2.15. As a licensing body the HFEA already has a range of sanctions for severe non-compliances (licence variation, suspension and revocation). There might, therefore, be an argument that we have relatively little need to levy such large fines when we can in effect take away a clinic's licence to operate. Equally, there is an argument that in a competitive market, increasingly with private equity funding, the power to levy a large fine might in some cases be an effective tool to address serious non-compliances. The Authority will want to take a view as to whether a power to levy such large fines would be helpful.

2.16. FPNs of low to moderate value have a more obvious use in the modern fertility market. They could be issued for specific, easy-to-identify forms of non-compliance, such as failure to submit data on time, error rates in PRISM consistently above a specified percentage, or breach of guidance on donor compensation. They could also be issued alongside more severe sanctions, such as imposing licence conditions for more serious forms of non-compliance. They could be issued according to a predetermined schedule of FPNs assigned to risk levels or types of non-compliance[3] to ensure a consistent approach that would reduce uncertainty for clinics. The force of a FPN could potentially be strengthened by use of other sanctions alongside them e.g. licence conditions.

2.17. FPNs could also be indexed to clinic size in some manner recognising the differential impact on a fine depending on turnover or financial stability[4] (though this approach would be complex to administer and present challenges in terms of the fairness of the same non-compliance attracting a different fine). As we progress with discussions on these points through the legislative process, the detail of any approach would need to be developed carefully taking account of clarity, transparency, consistency and capacity to incentivise compliance.

Recommendation

2.18. The Authority is asked to consider:

- The approach to an expanded ladder of regulatory sanctions.
- Lowering the thresholds for placing conditions on a licence or suspending a licence.
- How formal written warnings and fines could better support our regulatory and compliance activity.

3. Proposal 5: The Act should be revised to include an over-arching focus on patient protection

3.1. Proposal 5 of our recommendations for changes to the Act argues that the Act should be revised to include an over-arching focus on patient protection. Further, that patient protection

[3] For example, the CQC issue a £4000 fine for carrying on a regulated activity without being registered.

[4] For example, the CQC issues differently sized fines for the same non-compliance that take account of an organisation's staff count to make them more effective on larger, well-resourced organisations.

should be an explicitly stated principle of the Act, with a requirement that HFEA decision-making and compliance by licensed clinics should have reference to it. To be clear: the special status of the embryo would remain a guiding principle; patient protection would be an additional requirement.

3.2. When it agreed its recommendations in November last year, the Authority took the view that the absence of any specific statutory reference to patients in the Act was out of step with modern healthcare and made it harder for the HFEA to take proportionate action where patient protection or safety was at risk. Last month, the Patient Safety Commissioner published a set of **Patient Safety Principles**, describing them as a 'guide for leaders at all levels on how to design and deliver safer care for patients and reduce avoidable harm, in a just and learning culture'. 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.

3.3. This is exemplified by two key aspects of patient protection and safety: multiple births and treatment add-ons. Although we have significantly reduced the incidence of multiple births by working with professional and patient groups, it is difficult for us to enforce policies to tackle the small number of clinics who have high multiple birth rates. Similarly, in respect of unproven treatment add-ons, whilst we can recommend that the benefits and risks are discussed with each patient with reference to the HFEA add-ons rating system, we have struggled to implement enforceable policies in this area.

3.4. Existing limitations of the Act means the HFEA relies heavily on our Code of Practice as a regulatory tool to encourage good practice on patient protection concerns. However, enforcing compliance with guidance in the Code can be difficult when it is not traceable back to Licence Conditions, or the Act.

What a patient protection principle could look like

3.5. We believe that this regulatory gap could be addressed by inserting an overarching legal principle to protect patients into a revised Act. This should not be read as proposed legal drafting but such a principle might read as follows: "*In exercising functions in relation to this Act, the Authority and the services that it licences, must where appropriate have regard to the protection of patients (including so far as relevant, health and safety, patient autonomy, fairness, safety and effectiveness of existing and new treatments and technology, provision of accurate and evidence based information, processes for obtaining informed consent, the quality of the experience undergone by patients*)."

3.6. This approach could help us better address a range of important policy issues, including:

- Health and safety – multiple births.
- Safety and effectiveness of existing and new treatment and technologies – treatment add-ons.
- Provision of accurate and evidence-based information – costed treatment plans, information about success rates, the offer and marketing of treatment add-ons.
- Informed consent – ensuring patients have sufficient information and time to give informed consent.
- Quality of experience – complaints, issues around after care and follow-up.

3.7. The Act could also be amended to include a broad definition of what we mean by 'patient.' Unlike in most areas of healthcare, 'patient' in the context of the fertility sector is not straightforward and can include several different people. The person undergoing embryo transfer or insemination is obviously the patient, yet their partners, gamete providers, gamete and embryo donors, surrogates and intended parents accessing surrogacy are also relevant here.

3.8. A patient protection principle could also sit within a new statutory set of overarching principles that would underpin the purposes or statutory objectives of the HFEA. Several other regulators have a set of statutory objectives, for example, legislation governing Ofwat creates a set of objectives and requires Ofwat to use its powers in the manner in which it considers is best calculated to achieve the stated objectives. Something similar could be useful for the HFEA.

3.9. A revised Act could continue to express the existing consideration of the special status of the embryo, and welfare of the child while introducing a new principle covering patient protection. This approach could provide the Authority with additional legal footing to address concerns relating to patient protection and safety. As noted above, a focus on the needs and protection of patients would bring us in step with other healthcare regulators.

Recommendations

3.10. The Authority is asked to consider:

- The proposed approach to introducing a patient protection principle.

4. Proposal 6: Revising the Act to accommodate developments in the way fertility services are provided

4.1. Proposal 6 of our recommendations for changes to the Act refers to 'bringing all related UK services, whether offered in physical premises or online, within a broad definition of regulated fertility services.'

Modern context of fertility treatment

4.2. To recap, the modern fertility sector is changing, with new online services appearing regularly. In line with developments in some other parts of the healthcare sector, the typical UK fertility patient pathway has become more fragmented, with an increasing shift towards aspects of treatment taking place outside of a UK licensed clinic, in a range of online settings. In some contexts, more activities are taking place outside of the licensed clinic than in it. The differences between the traditional and modern fertility patient pathway are set out in diagrammatic form at Annex B.

4.3. Online services may provide various aspects of the patient pathway, such as pre-treatment information, counselling, tests, scans, screening (sometimes at the patient's home), welfare of the child assessments, and practical assistance through mobile apps. Some also offer concierge services that help with accommodation and transport for international patients, fertility finance plans and insurance providers that may partner with licensed clinics, and fertility coaching services that guide patients through emotional and practical aspects of their journey. They may partner with licensed UK clinics or overseas facilities for physical treatments like egg collection and embryo transfer. The boundaries between these offerings are not always clear, and multiple services may be packaged together.

4.4. The existing regulatory framework reflects the traditional patient pathway where all or most treatment takes place under one roof, at a licensed fertility clinic. For some patients, now only egg collection and embryo transfer take place in the licensed clinic. This presents several regulatory issues. Important aspects of the patient pathway, for example pre-treatment information provision, the welfare of the child assessment and taking consent, are taking place outside of a licensed clinic, for example at an online satellite centre. Under such an arrangement, a licensed clinic's PR is ultimately responsible for ensuring that each of the required elements is completed correctly. However, in practice, this can be challenging for the

PR, especially if they oversee multiple satellite centres. It also means that regulatory oversight rests on another licensed person's assessment rather than independent oversight as originally envisioned by Parliament.

4.5. For the patient, it may be unclear whether an unlicensed online service is regulated by the HFEA or not, or where the physical treatment will be provided. Patients can be under the false impression that a service provider, which, for example, has taken their consent, is regulated by the HFEA. This is particularly problematic in cases where a patient wishes to make a complaint about an aspect of their treatment and are not clear who they should complain to.

4.6. Finally, online services may present success rates on their website in a confusing or misleading way. For example, an unregulated online service may present the success rates of the fertility clinic they partner with (where the embryo transfer takes place), but to patients it may appear to be the success rate of patients using that particular online service.

Expanding the list of activities that we regulate

4.7. To effectively tackle the regulatory challenges highlighted above, the HFEA needs to have closer regulatory oversight over activities currently being carried out by unlicensed service providers to ensure that patients can have confidence in their whole fertility treatment journey. We set out two different ways to achieve this below, but first we explain the common approach both options are based on: to add to the existing list of 'licence activities' specified in the Act an additional category of 'important activities' which we consider should have closer regulatory oversight, regardless of the context in which they are being provided.

4.8. To provide background, certain activities ('licence activities') can only be carried out by licensed clinics (or, for some activities, where there is a third-party agreement with a licensed clinic). These are activities which could affect the quality or safety of the gametes or embryo. Annex C provides more detail on what is currently covered by licence activities, satellite and third-party premises and agreements.

4.9. In addition to these 'licence activities,' clinics must ensure other requirements are fulfilled, including several related to steps in the patient pathway. For example, clinics must consider the welfare of the child when providing treatment. The same applies to consent—where clinics must keep records of consent that comply with the requirements in Schedule 3 of the Act. These examples are not classed as 'licence activities', but the legislation makes it clear that we regulate them as part of the licensed clinic's obligations. Such activities take place in licensed clinics but are increasingly taking place in satellite centres (with or without a third-party agreement) with less oversight from the PR or the HFEA.

4.10. We propose that we have closer regulatory oversight over some activities taking place outside of licensed clinics (under third-party/satellite arrangements) by introducing additional 'important activities' to the list of licence activities already specified in the Act (i.e. formalise in the Act the status of certain activities which we consider important aspects of the patient pathway). This could include adding activities relating to:

- Pre-treatment Information provision
- Screening
- Taking consent
- Welfare of the child
- Offer of counselling
- Aspects of post-treatment patient journey, for example, monitoring for Ovarian Hyperstimulation Syndrome (OHSS).

4.11. This regulatory approach would provide greater reassurance to patients that important aspects of their patient pathway have the necessary regulatory oversight, whether or not they receive this service at the licensed clinic or by another provider.

4.12. The two options set out below are based on this common approach. The first option constitutes a simplification and strengthening of the framework already in place. The second option represents a more significant change to the remit of the HFEA's regulation.

Option 1: Extend the list of activities for which a licensed clinic must have a third-party agreement in place

4.13. This option builds on the existing legal framework by extending the list of activities which would require a third-party agreement between the licensed fertility clinic and the service provider. This list would reflect the activities that are increasingly taking place outside of a UK licensed clinic in the modern patient pathway, such as those outlined at 4.10 above.

4.14. This would mean:

- All providers of 'important activities' would be either licensed clinic or have a third-party agreement with a licensed clinic.
- Satellite centres (which currently may or may not have a third-party agreement in place, depending on the nature of the services they provide) would be removed from our regulatory framework (as any organisation engaging in any 'important activity,' would be legally required to have a third-party agreement in place).
- Any other organisations which are currently neither satellite centres, nor have a third-party agreement with a licensed clinic, would require a third-party agreement with a licensed clinic to provide important activities.

4.15. This option would require more organisations to have a third-party agreement with licensed clinics (rather than just those undertaking activities that could impact the safety of gametes/embryos), thereby extending our reach (in terms of power to inspect) to providers of fertility services we currently do not directly regulate, such as 'online clinics' which provide information, screening, counselling etc. as part of the patient pathway. It could mean an increased HFEA oversight of a patient's pathway, encouraging continuity of care even where several parts of the pathway may be provided by different providers.

4.16. However, this option in isolation would be limited in what it could achieve. PRs of licensed clinics would still bear legal responsibility for the operations of third-party premises and, without the HFEA directly inspecting third parties, the situation would be unlikely to significantly improve. Even if the HFEA were to inspect the third party, it would have no powers to sanction them directly and any failings would be non-compliances by the PR of the licensed clinic. The increasing involvement of private equity investors in the fertility sector, potentially reduces the influence a PR has. With all that in mind, reforming the Act in this way when PRs already face challenges in exercising influence over satellite centres, may be insufficient. Furthermore, requiring third party agreement with HFEA licensed clinics could provide a false sense of reassurance to patients, while oversight by the PR (and as a result, also by the HFEA) may be limited.

Option 2: Extend the list of activities which require an HFEA licence and regulate entities which provide those activities

4.17. Option 2 would be a more significant departure from the status quo but would better meet the ambition in the law reform proposals. It would involve reimagining and simplifying the current legal and regulatory framework by extending the list of activities which would require an HFEA licence. It would allow the HEFA to regulate any entity which provided those activities (such as those listed at 4.10) and would cover organisations both physical and virtual, as well as individuals.

4.18. All activities which can currently be carried out by a licensed clinic, third-party premises or satellite centre could be included in this list of important activities, in addition to additional

activities which we consider should be regulated. 'Satellite', 'transport' and 'third-party' premises and agreements would no longer be necessary.

4.19. This would mean the HFEA could directly inspect and take regulatory action against any entity, including online clinics and other online services, if they carry out the important activities as part of a patient's pathway. This option would:

- Bring more organisations under the HFEA's direct regulation and inspection regime, where these organisations conduct 'important activities' in the patient pathway.
- Provide greater HFEA oversight of organisations already within the HFEA's view, but which currently rely on the PR's oversight which may be more (for third-party premises) or less (for satellite centres without a third-party agreement) formalised.

4.20. The Authority could adopt a graduated approach to the regulation and oversight of these service providers, depending on the type of activity being offered. For example, it may not be appropriate to regulate all service providers in exactly the same way. The principle of minimal intervention requires that regulation is used only where needed.[5] This 'graduated approach' would reduce unnecessary burdens on service providers and on the HFEA.

4.21. For example, the Authority might consider it necessary to have closer regulatory oversight of providers who carry out certain 'important activities' and develop an inspection process that aligns with that risk, with more light touch oversight (such as a more desk-top approach) for others who provide activities posing less direct risk, such as provision of information to patients. We could consider a 'concentric ring' model of regulation whereby we would have wide oversight, but with increasing intensity (i.e. stricter regulatory requirements) as the activity became riskier. We could also require different levels of information and compliance from providers who are carrying out a limited part of the patient journey, as opposed to the same level of regulatory oversight we provide on matters of quality and safety.

Recommendations

4.22. The Authority is asked to:

- Consider the proposed approach to bringing more activity under HFEA regulatory oversight by expanding the list of activities that we currently regulate, and
- Second, agree the proposed approach set out in Option 2, which is to extend the list of activities which require an HFEA licence and regulate entities which provide those activities.

[5] Government guidance sets out how policymakers and regulators should ensure their work is proportionate, for example in rule-making and minimising burdens on small businesses (the Better Regulation Framework) and how regulators intervene (the Regulators' Code). Interventions should not be disproportionate to the issue or scale of harm that they are seeking to address and should take into account the interests of regulated entities and of citizens or service users.

Annex A: Current ladder of sanctions and example of a potential new ladder of sanctions

Diagram 1 sets out the HFEA's current 'ladder of sanctions'. Diagram 2 shows what an expanded 'ladder of sanctions' with an increased range of powers including written warnings and financial penalties could look like.

Diagram 1 - Current ladder of sanctions

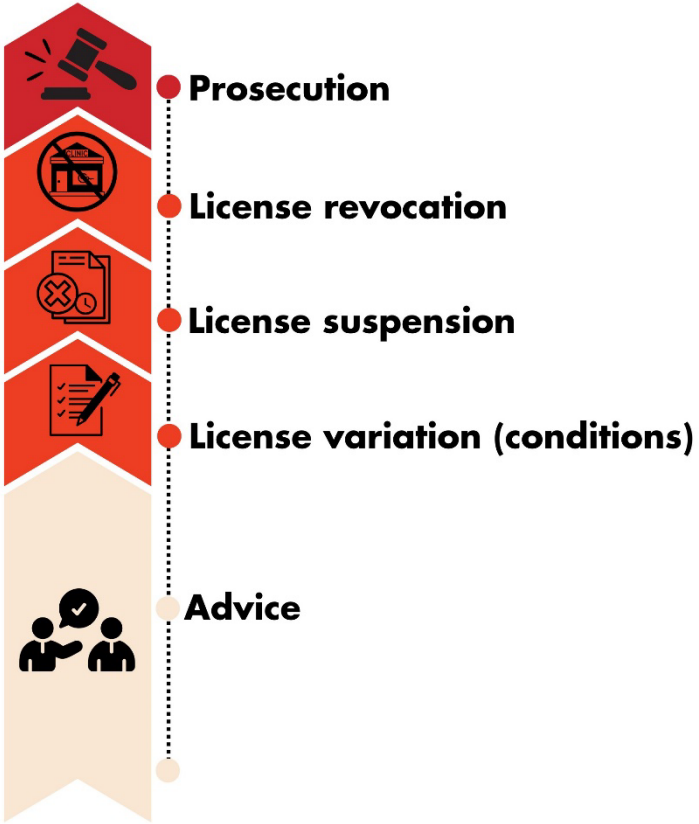


Diagram 2 - Example of a potential new ladder of sanctions

Annex B: Traditional patient pathway vs. modern patient pathway

Diagram 3 sets out the ‘traditional’ patient pathway. Diagram 4 sets out the ‘modern’ fertility pathway.

Diagram 3 - Traditional patient pathway

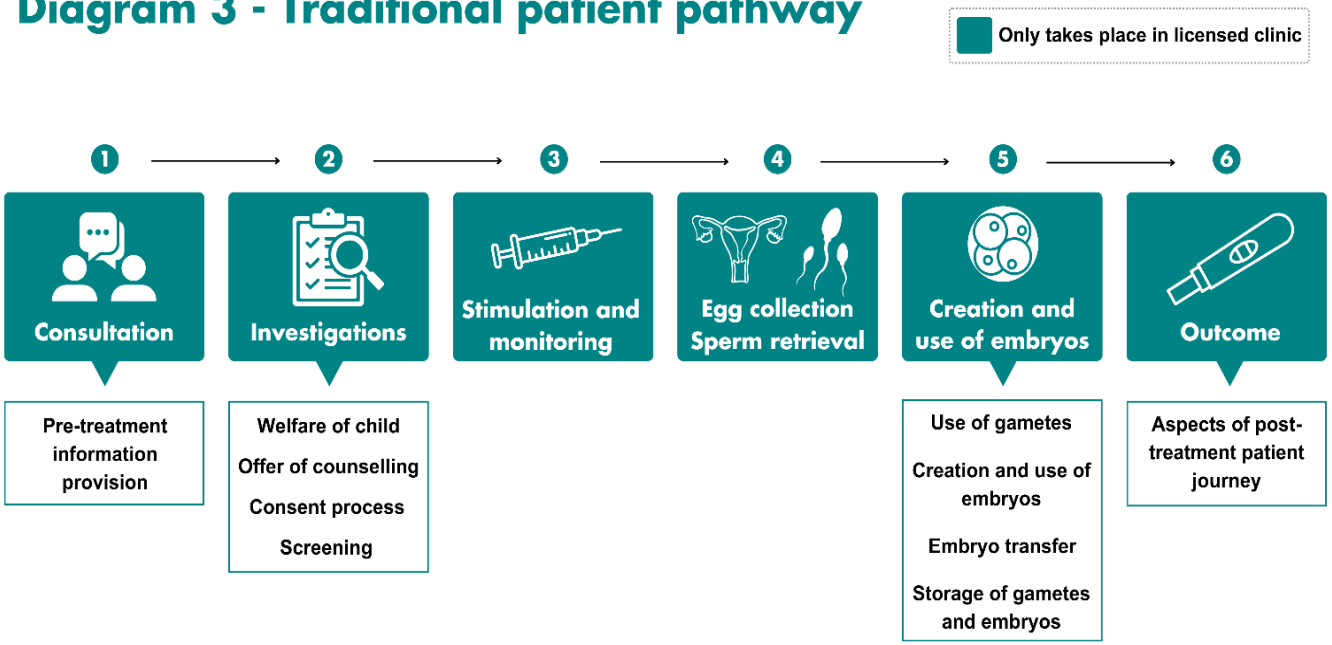
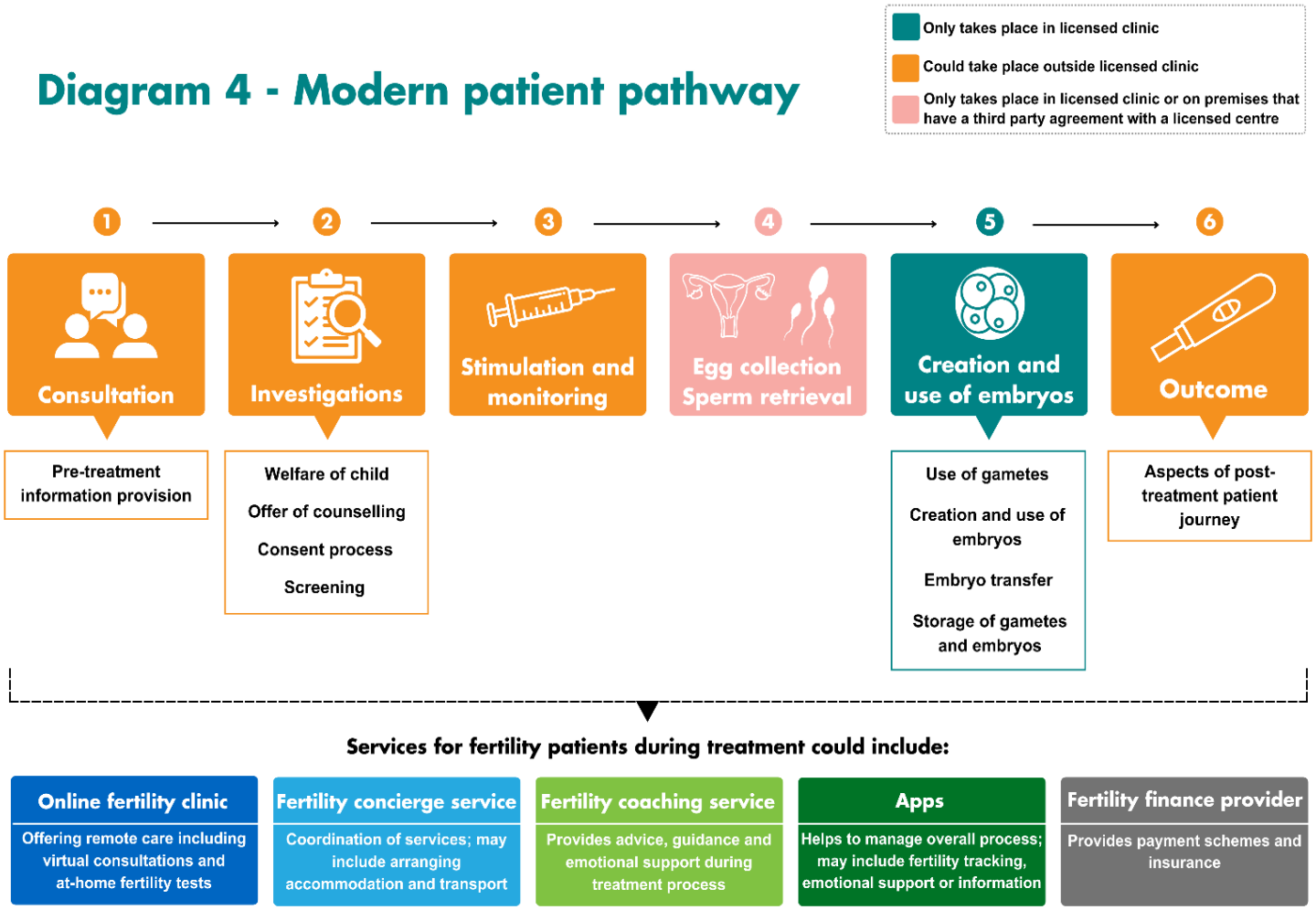


Diagram 4 - Modern patient pathway



Annex C – Legal definitions and further details relating to proposal 6: Revising the Act to accommodate developments in the way fertility services are provided

Licence activities (also known as **'licensed' or 'licensable' activities**)**:** These are activities that can only be carried out with a licence or by an organisation that has a third-party agreement (defined below) with a licensed clinic. They include, for example, the procuring, keeping, processing, distribution, use and storage of gametes; the creation, procuring, keeping testing, processing, distribution of embryos; placing embryos inside a woman and the use of embryos in training.

Third party agreements (**'TPA's**)**:** Some activities, such as procuring, testing, processing and distribution of gametes, can only be carried out either by a licensed clinic or a person/organisation which has a Third-Party Agreement ("TPA") with a licensed clinic. In addition, TPAs are required between the licensed clinic and any person who provides goods or service to that clinic which could affect the quality or safety of the gametes or embryo. The TPA must specify the terms of the relationship and responsibilities between the parties and have detailed procedures that need to be followed. It is ultimately the responsibility of the PR of the licensed clinic to ensure that the conditions of the TPA are complied with (s17(1)(f)).

Relevant third-party premises: The HFEA has powers to enter and inspect relevant third-party premises (essentially premises which provide a service for which a TPA is required) and can even revoke a clinic's licence if it ceases to be satisfied that the third-party premises are suitable for the activities entrusted to that party (s18(2)). The HFEA does not use this power and has, to date, relied on PRs and inspections of licensed clinics to ensure compliance by third-party suppliers.

Unregulated Satellite Centres: Activities that are outsourced by a licensed clinic and take place on different premises are often referred to as satellite services. However, encompasses providers with third-party agreements (as defined in the Act - see above) as well as completely unregulated external organisations. These could cover other activities which are part of the patient journey, which could be carried out by external organisations and for which the HFEA has no regulatory oversight and no legal power to inspect. These may include the provision of information, obtaining consent and even some quasi-medical services, such as drug therapy, assessment and monitoring. Under General Direction 0010, these centres require a written agreement with the licensed clinic. However, unless they are carrying out an activity for which a TPA is required under the Act the HFEA has no regulatory oversight. Instead, it can only regulate these providers indirectly, through the licensed clinic. It is the responsibility of the PR of the licensed clinic to assess the satellite service in terms of compliance.