Authority meeting

Date: 20 March 2024 –1.00pm to 4.00pm

Venue: HFEA Office, 2nd Floor 2 Redman Place, London E20 1JQ

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	1.00pm
2. Minutes of the meetings held on 24 January 2024 and matters arising (5) For decision	1.05pm
3. Chair and Chief Executive's report (15) For information	1.10pm
4. Committee Chairs' reports (20) For information	1.25pm
5. Performance Report (30) For information	1.45pm
6. Opening the Register (15) For information	2.15pm
Break	
7. Authorised Process Review (20) For decision	2.40pm
8. Effective Governance (15) For decision	3.00pm
9. Donor compensation (30) For decision	3.15pm
10. Any Other Business (5)	3.45pm
11. Close	3.50pm

Minutes of Authority meeting held on 24 January 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 March 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 24 January 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 24 January 2024

Members present	Julia Chain Tim Child Zeynep Gurtin Jonathan Herring Graham James Alex Kafetz	Alison McTavish Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Frances Flinter Alison Marsden	Steve Pugh DHSC Amanda Davies DHSC
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Farhia Yusuf (Department of Health and Social Care – DHSC) Kath Bainbridge (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar	Paula Robinson Anna Wilkinson Shabbir Qureshi Alison Margrave

Members
There were 11 members at the meeting – 8 lay and 3 professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, HFEA staff and DHSC colleagues present. The Chair welcomed Jason Kasraie, in his role as Special Adviser to the Authority and Adrian Thompson, who has joined the Authority for a year as a Boardroom Apprentice.

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

1.3. Declarations of interest were made by:

- Geeta Nargund (Clinician at a licensed clinic)

2. Minutes of the last meeting and matters arising

2.1. A member proposed that the last sentence of minute 5.12 be amended and it was agreed that the Chief Executive would consult with the Chair on the amended wording.

2.2. With this amendment members agreed that the minutes of the meeting held on 15 November 2023 were a true record and could be signed by the Chair.

Matters arising

2.3. Members were advised that the matters arising items had either been actioned as detailed in the paper presented to the meeting or that an update would be presented to members under the Directors' report in agenda item 5.

3. Chair and Chief Executive's report

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

3.2. The Chair informed the Authority about her attendance at the PET Conference in December 2023 and Fertility 2024 which was held in Edinburgh in January. On both occasions she spoke about the law reform proposals, these were well received by participants and there was overall support for change. Members who had attended these events agreed that HFEA's presence was very well received.

3.3. The Chair informed the Authority that together with the Director of Strategy & Corporate Affairs she had attended the Women's Health Summit, where the Parliamentary Under Secretary of State had set out the government's priorities for the Women's Health Strategy in 2024.

3.4. The Chair referred to the proposed minor updates to GD 0007 which were circulated to members for approval via correspondence in early January. Members had agreed to these changes and the updated General Direction 0007 will come into force on 19 February 2024.

3.5. The Chair informed members that she would be undertaking visits to clinics in 2024 and would be meeting the Scottish minister in May 2024.

3.6. The Chief Executive provided an update on the key external activities contained in the paper presented to the Authority.

3.7. The Chief Executive spoke about the DHSC Audit and Risk Committee meeting which he attended with the Audit & Governance Committee Chair and Director of Finance & Resources. This had been a productive meeting and HFEA had been able to frame its key risks to the DHSC Committee.

3.8. The Chief Executive spoke about the all-staff event held in December and the positivity around this event. The results of the annual staff survey had been presented and he provided details of the key findings many of which scored more favourably than the average for the public sector or NHS.

Decision

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

4. Committee Chairs' reports

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

4.2. In the absence of the Licence Committee Chair (Alison Marsden), the Deputy Chair of the committee (Graham James) gave an overview of recent meetings and said there had been several cases of notable compliance improvements which had been pleasing to note.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further insight to the work of the committee. He explained that when an application for a PGT-M condition is received the Executive will consider whether there are similar conditions which could be licensed at the same time. He stated that a number of applications for conditions which also include deafness had been received and the committee had asked the Executive and peer reviewers to undertake a full review of autosomal recessive deafness conditions.

4.4. The Scientific and Clinical Advances Advisory Committee Chair (Tim Child), informed the Authority that the next meeting will be held in early February. He reported that three members and an external adviser had visited Newcastle Fertility Centre at Life in December to hear first hand about their mitochondrial donation programme.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an update on the work of the committee highlighting the discussion on the risk register and strategy, she gave assurance to the Authority that there is appropriate mitigations in place. She informed Authority that the committee had agreed a new timetable for the Choose a Fertility Clinic (CaFC) update, which will allow for three years of verified data to be used and the committee felt that this would be in the best interests of patients. She provided further updates on the mitigations in place to enable the Authority to identify fake OTR websites, the HR bi-annual report including the staff survey and the committee's annual review of effectiveness. After the formal meeting members participated in a training session on good governance, which had been well received.

4.6. The Chair spoke about the importance of the work undertaken by the various committees and expressed her thanks to the Chairs and all members for their commitment to this work.

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and stated that of the 17 KPIs, four are red, three amber, seven green and three neutral. Regarding the HR KPIs, he reiterated that as a small organisation any long-term sick leave will have a negative impact on this KPI and as reported earlier these are distinct cases unrelated to stress or workload. In response to a question, he stated that if the long-term sickness rate was removed the actual sickness rate would be 0.48%.

5.2. PRISM activity levels continue to be stable with an average error rate of just 3.4%. The 32 clinics with an error rate above 4% will continue to receive a targeted approach to address this.

5.3. The Chief Executive informed members that eight clinics have volunteered to be pilots for the 10 family limit alerts, and it is anticipated that this pilot will start in February. In response to a question, he confirmed that the limit is applicable only to use in the UK, regardless of the source of donation. He reiterated that HFEA does not have jurisdiction outside the UK.

5.4. In December 2023 the Audit & Governance Committee agreed a new timetable for the Choose a Fertility Clinic (CaFC) update. Verification with clinics will commence in January 2024 and run until Summer 2024 with the process of sign-off and publication starting in Autumn 2024.

Compliance and Information

5.5. The Director of Compliance and Information informed members that as a small team, the compliance team was being impacted by long-term absence. Whilst this puts additional pressure on the inspection team it has not resulted in a clinic not being able to have a licence renewed.

5.6. The Fuller Independent Inquiry phase one report raised some wider concerns about regulation and the compliance team had reviewed each recommendation to see if there is any learning which could be relevant to the HFEA. For example, a point raised was that the HTA appears to view inspections in isolation. On review the HFEA, when preparing for an inspection, considers non compliances from previous inspections as well as other issues such as incidents, complaints and whistleblowing. As these are all taken into account it was considered the HFEA do not view inspections on isolation.

5.7. A member commented that the recommendations contained within the Fuller Independent Inquiry phase one report were also being considered by regulators outside the health sector, especially regarding getting assurance rather than being reassured. The Director of Compliance and Information agreed and commented on the process which the HFEA uses to assure itself, by collecting desk-based evidence before an inspection.

5.8. The Director of Compliance and Information stated that there had been staff turnover again in the OTR Team, but these vacancies had been successfully recruited to. The case management system is working well and should be beneficial in helping to manage and categorise the waiting list.

5.9. Members were informed that the baseline assessment for the Data Security and Protection Toolkit has started and will be completed by end of February and that the audit on business continuity will commence this quarter. The business case for the Epicentre replacement has been presented to the Department and meetings have been held with the DHSC procurement team.

Strategy and Corporate Affairs

5.10. The Director of Strategy and Corporate Affairs spoke about the high workload being successfully managed by the Licensing Team.

5.11. The report on Ethnic Diversity in fertility treatment was published in December, and she highlighted key disparities identified in the report. To further this work the HFEA, British Fertility Society, Fertility Network UK and the Royal College of Obstetricians and Gynaecologists agreed a call to action to reduce disparities in access to and outcomes for Black, Asian and ethnic minority patients. Members were informed that the Royal College of General Practitioners had now joined this call for action.

5.12. A member congratulated the HFEA team for this excellent report and the media attention it has received.

5.13. The Director of Strategy and Corporate Affairs informed members that a soft launch of the dashboard had taken place, and that these are ground breaking and probably the first of their kind in the world. She encouraged members to use and promote the dashboard.

5.14. Members were informed that the HFEA's first Instagram Live was held on 16 January and this had received positive feedback, thanks were given to the staff involved in organising it. Updates

were provided on other media engagements especially around the topics of egg freezing, funding and donation.

5.15. Members were informed that it is now possible to exclude internal traffic from the HFEA's website sessions data, so as to provide a 'top 3' most viewed web pages.

5.16. Members were informed that work continues on OTR communications, add-ons, Code of Practice, consent forms, law reform and the next fertility trends report.

Finance

5.17. The Director of Finance and Resources referred to the paper and stated that as previously reported the HFEA is currently operating with a deficit of £138k which can be attributed to increases in IT costs, the unplanned non-consolidated bonus for staff which was agreed by the Government but needed to be met out of the HFEA's current budget and a reduction of Grant in Aid (GIA) of £100k. He stated that the Department is aware of the deficit and has not requested any corrective action.

5.18. Members were informed that the proposals for fee increases were with HM Treasury for approval.

5.19. The GIA bid for a replacement for epicentre had been submitted although the Director of Finance and Resources expressed some concern as to when a response might be received. In response to a question, he stated that if the bid was unsuccessful then an additional fee increase could be considered to fund this project, although this is not the HFEA's preferred option. The Chief Executive spoke about the wider pressures on the Department and that he would keep the members informed of any progress.

Decision

5.20. Members noted the performance report.

6. Draft Business Plan 2024-2025

6.1. The Chair introduced this item reminding members that every year the HFEA is required to set a Business Plan for the coming financial year. Resources continue to be tight and therefore the Authority needs to decide what the priorities should be.

6.2. The Risk and Business Planning Manager introduced the paper and explained the planning cycle to produce the Business Plan, including submission to the Department for approval. Once approval is received from the Department the final business plan will be published on the HFEA website.

6.3. In addition to the HFEA's statutory work the Risk and Business Planning Manager spoke about the main priorities for 2024-2025 as detailed in the paper presented to the Authority. In response to a question, he confirmed that they were not listed in order of priority.

6.4. In response to a question the Director of Strategy and Corporate Affairs confirmed that the team will continue to develop further aspects of the law reform proposals, especially focussing on patient safety and protection, and scientific developments. Members were reminded of the good engagement received on the public consultation undertaken by the HFEA, which will be useful for the work going forward.

6.5. A member questioned what the scale of the fee review work would be, noting that the HFEA has fixed expenditure but a variable income stream.

6.6. The Chief Executive responded that the review would look at what model or regime could be used to ensure that the cost of regulation is fairly apportioned without being administratively cumbersome to implement. Consideration of models used by other regulators will be undertaken and then analytical work to ensure that required levels of revenue will be achieved to run the organisation.

6.7. In response to a question the Director of Strategy and Corporate Affairs spoke about prioritising work to actively look at the potential impact of AI on the fertility sector and on new scientific developments such as synthetic gametes and embryo-like models.

6.8. Members were informed about proposed further development of dashboards to enable greater use of HFEA's data and how this could be used in the future to support compliance activities.

Decision

6.9. Members approved the main section of the business plan for 2024-2025, noting that it will be further developed over the next two to three months.

7. Opening the Register - update

7.1. The Director of Compliance and Information presented the update on Opening the Register (OTR) reminding members that there were three main workstreams.

7.2. The new IT system for managing applications went live at the beginning of August and the OTR team has provided positive feedback regarding ease of use and efficiency.

7.3. The testing of the OTR RITA reports is now complete and these have been in use since 22 January. The SOP will now be updated to include these new procedures.

7.4. Continuing, the Director of Compliance and Information stated that a separate report on the future of support services is before the Authority for consideration later in the agenda.

7.5. The Director of Strategy and Corporate Affairs spoke of the success of the #WhoIsMyDonor campaign and the need to slow down some activity to avoid overloading the team. The second phase of activity has now commenced including activities such as Instagram live Q&A session and new web content.

7.6. Members were informed that several risks had been downgraded due to successful activities such as webinars for clinic staff and engagement in FAQ on the clinic portal.

7.7. Continuing, the Director of Strategy and Corporate Affairs informed the Authority that the three workstreams were ending at the end of the financial year and after this date will be considered as business as usual. The Executive are therefore proposing that the March 2024 OTR report will be the last and after this date any updates will be provided via the Performance Report.

Decision

7.8. Members noted the update on OTR and agreed that after March 2024 future OTR reports will be included in the Performance Report.

8. Future of OTR Support Services

8.1. The Chair introduced this agenda item reminding members that they received an information paper in November 2023 and the paper before them now requires a decision to be made about the OTR support services.

8.2. The Policy Manager introduced the paper and provided a recap of the current provision of support services which are in place until September 2024.

8.3. It was noted that the HFEA has no statutory responsibility to provide this service and given the pressures on the HFEA's core budget it was no longer sustainable to provide this service. Any future model of support needs to be financially sustainable.

8.4. The Policy Manager spoke about the methodology of the review including international comparison, funding options, stakeholder roundtable meetings, survey and costing analysis. The results of the review are now brought to the Authority for a decision on the way forward.

8.5. The proposed options were then discussed, and members congratulated the team for the quality of the paper presented to them.

8.6. Much of the discussion focused on option four to end the funding for a commissioned support service and improve and expand information and signposting. The HFEA is already seen as a credible source of high-quality information and could collaborate with other organisations to help to improve and strengthen website signposting. Members discussed whether a support App could be developed or a user generated forum moderated by the HFEA.

8.7. The Director of Compliance and Information stated that the HFEA website is a good starting place and that this should be utilised fully first and further developments could be considered over time. Any future development work not included in the paper presented to the Authority would need to be costed.

8.8. The Director of Strategy and Corporate Affairs spoke against the idea of moderating social media, such as forums as it is not within the HFEA's remit and additional resourcing with specific skills would be required.

8.9. Continuing, Members discussed options four and five to end funding for a commissioned support service and bring the letterbox service in-house. Members questioned the uptake for the letterbox service and if it was brought in-house the need to future proof it, perhaps by having a one-year trial.

8.10. Members questioned whether it was possible to obtain data from the Hewitt Centre as to the number of letter-box users and why they had used this service rather than alternative ones. Members were cautious about increasing the HFEA's workload when the demand for this service might not be present.

8.11. The Chair drew the discussion to an end noting that options one, two and three were not supported by the Authority. Members were then asked to decide on options four and five.

Decision

8.12. Members agreed to proceed with option four as presented in the paper to end funding for a commissioned support service effective September 2024 and improve and expand information and signposting.

8.13. Members agreed that further information regarding the letterbox service (option five) should be sought and brought to the Authority for decision via correspondence.

Action

8.14. Executive to proceed with option four to end funding for a commissioned support service effective September 2024 and improve and expand information and signposting.

8.15. Executive to gather further information from the Hewitt Centre on the letterbox service and circulate this to members for decision via correspondence.

9. Public Body Review 2023

9.1. The Chair introduced this item reminding members that the Public Bodies Review programme was announced in April 2022 and that the HFEA was the second Arm's Length Bodies (ALB) of the Department of Health and Social Care (DHSC) to be reviewed with the final report being published in November 2023. This meeting was the first opportunity for the report to be discussed since publication.

9.2. The Chief Executive informed members that the Cabinet Office guidance sets out the process that departments are expected to follow then conducting public body reviews. ALBs are scrutinised against four main quadrants of accountability, efficacy, efficiency and governance.

9.3. The HFEA completed a self-assessment exercise and the Review decided that the primary focus would be on accountability, efficacy and efficiency, as well as looking at the adequacy of the legal framework given the focus of law reform work at the time of the review. The review considered the HFEA to have good governance arrangements so this was not a focus for the review.

9.4. The Chief Executive highlighted the following quotes from the report:

- "HFEA performs important functions. It regulates a discrete and specialised area of medical practice and scientific research, which can raise sensitive clinical, legal and ethical issues."
- "HFEA has a small, highly experienced and capable executive management team to support its chair and members. The effectiveness of HFEA is dependent upon the breadth of skills and experience its members bring as well as the quality of support they receive from the management team."

9.5. The Chief Executive informed members that the central conclusion of the review was that the HFEA should remain an executive non-departmental public body.

9.6. The Director of Strategy and Corporate Affairs informed members that of the 19 recommendations arising from the review, five of these were applicable to the Department.

9.7. The Director of Strategy and Corporate Affairs presented each recommendation applicable to the HFEA, the Executive's response and proposed timing. She informed members that the Executive

would report progress against each recommendation via the quarterly accountability meetings held with the Department.

9.8. A member questioned whether the HFEA should be more ambitious about using the data from PRISM regarding recommendation eight of the review. The Director of Compliance and Information responded that the HFEA is bound by current legislation, which states that an inspection must be conducted within a two year period. The HFEA would like to use the data to influence the type and frequency of inspection, and this would be considered alongside the proposed law reform proposals.

9.9. Those professional members who use the Code of Practice spoke in favour of retaining the current format of the code and did not see the benefit of a shorter, slimmed down version as presented in recommendation nine.

9.10. Members noted that whilst recommendation 15 refers to working with NHSE, the HFEA regulates UK wide. Members discussed whether the HFEA could be a catalyst for change within wider health priorities and that the disparities highlighted by the ethnic diversity report should be reinforced in the HFEA's response to this recommendation and further closer working with NHSE on related issues should be encouraged.

9.11. A member suggested that the HFEA, and especially the Authority members, could develop a relationship with Geonomics England.

9.12. The Chair drew the discussion to a close and thanked the Executive for the work they completed for this review, in an already busy work environment. The Chair also thanked those Authority members who were interviewed by the Public Body Review team.

Decision

9.13. The members noted the recommendations arising from the Public Body Review and the HFEA's response to each as detailed in the paper presented to the Authority and amendments to the actions as agreed.

10. Any other business

10.1. The Chair thanked all for their active participation in the meeting.

10.2. There being no further items of any other business the Chair reminded members that the next meeting will be held on 20 March 2024, in person, at the HFEA's offices at 2 Redman Place.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 20 March 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 March 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	2023/24 business year		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Action	Date added	Assigned to	Target date	Revised date	Progress to date
6.16 The Director of Finance and Resources to seek approval from HM Treasury and implement the decisions regarding the 2024/25 budget.	15 Nov 2023	Director of Finance and Resources	Jan 2024		DHSC and HMT approved in January 2024 the budget and fee increase agreed with the Authority in November. We await approval from DHSC for additional GIA funding to cover urgent IT investments in 2024/25, which may necessitate a further fee increase in 2024/25 if it is not granted. This situation has been communicated to the sector.
8.14 Executive to proceed with option four to end funding for a commissioned support service effective September 2024 and improve and expand information and signposting.	24 Jan 2024	Senior Management Team	Sept 2024		This will now be delivered over the next few months with a focus on improving information on website and signposting to relevant support organisations.
8.15 Executive to gather further information from the Hewitt Centre on the letterbox service and circulate this to members for decision via correspondence.	24 Jan 2024	Regulatory Policy Manager	March 2024		Information circulated to Authority Members in February 2024. This action is now complete and can be removed.

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 March 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 meetings in January 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:

    - 5 February – attended Scientific Clinical Advances Advisory Committee meeting.
    - 21/22 February – conducted the interviews for new Members to SCAAC (together with Tim Child and Christine Watson)
    - 27 February – observed the Statutory Approvals Committee meeting.
    - 28 February – attended the shortlisting meeting to appoint new Authority Members (the interviews are due to take place at the end of March
    - 29 February – attended the Surrogacy Network meeting.
    - 5 March – attended the Audit and Risk Committee meeting.

2.2 Chief Executive

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

    - 25 January – attended ALB Senior Leaders Meeting for Chief Executives
    - 31 January – attended the Nuffield Council on Bioethics Strategy Launch
    - 5 February – attended Scientific Clinical Advances Advisory Committee meeting. On the same day also participated in the Sciencewise roundtable on 20 years of public dialogue
    - 20 February – attended the ACE Annual Conference
    - 28 February – interviewed for the Senior Legal Adviser post (together with the Director of Finance and the Head of HR). Also that evening attended the 20th Anniversary of FNUK (together with the Director of Strategy and Corporate Affairs)
    - 5 March – attended the Audit and Risk Committee meeting.

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 March 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):	None
Organisational risk:	Low

1. Committee reports

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

2. Recent committee items considered

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

Meetings held	Items considered	Outcomes
Licence Committee:		
15 January	4 interim inspections	All approved
7 March	1 Renewal 2 Executive updates	Minutes not yet approved Suspension notice and Special Directions issued to one clinic, pending the completion of the minutes.
Other comments:	The Committee also conducted its annual review of effectiveness at the March meeting.	
Executive Licensing Panel:		
22 January	1 Initial 2 Renewals 2 Interims 1 Variation of licensed premises 1 Change of centre name	All approved
6 February	3 Renewals 3 Interims	All approved
20 February	2 Renewals 1 Interim 2 Variations of licensed premises 1 Variation of activities	All approved
4 March	1 Initial 2 Renewals 1 Interim 1 Change of Licence Holder 1 Removal of condition on licence 1 Executive update	All approved
19 March	1 Initial 4 Renewals 1 Variation of licensed premises 2 Interims	Minutes not yet approved
Other comments:	None.	

Meetings held	Items considered	Outcomes
Licensing Officer decisions:		
January - February	30 ITE import certificates 4 Changes of LH	All granted
Other comments:	None.	
Statutory Approvals Committee:		
29 January	5 PGT-M 3 Special Directions for import/export	All granted
27 February	4 PGT-Ms 1 review of autosomal deafness conditions 3 Special Directions for import/export	Minutes not yet approved
Other comments:	The committee also received an item for information about the authorised processes project and conducted its annual review of effectiveness at the January meeting.	
Audit and Governance Committee:		
5 March	The main items considered were: Internal audit and progress with audit recommendations External audit planning Risk update: • Strategic Risk Register • Discussion on deep dive list and horizon scanning Deep dive discussion on the use of Debt and Commercial Government Functional Standards Digital projects / PRISM update Resilience, business continuity and cyber security Accounting policies Government Functional Standards	
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
5 February	The committee performed its annual prioritisation of topics identified through the horizon scanning process and reviewed its workplan for 2024/25.	The SCAAC prioritised 14 topics, including a new high priority topic – 'Testicular tissue transplantation to

Meetings held	Items considered	Outcomes
		restore fertility in males'. The committee agreed that the review of treatment add-ons ratings will take place every five years, with continued monitoring of findings between reviews and ad-hoc review if required.
	The mitochondrial donation programme	The Chair gave an update following a visit to Newcastle Fertility Centre in December 2023. The team at Newcastle will be invited back to a future meeting of SCAAC to give an update.
	Impact of long-term cryopreservation of gametes and embryos	SCAAC determined that there is currently not enough evidence to determine the impact of long-term storage on viability of embryos, if any. The HFEA website will be updated to reflect this.
	Heritable genome editing	The committee determined that it is still unsafe to proceed with heritable genome editing for clinical practice. Future discussions of the committee will focus on technical advances and feasibility of techniques for germline editing.
	Artificial intelligence (AI), robotics and automation	The Executive should continue to clarify where AI technologies are being applied in assisted reproduction and emphasised the importance of validating systems before they are offered in practice.
Other comments:	The committee conducted its annual review of committee effectiveness led by the Chair and a summary of feedback was recorded. The Chair also gave a brief summary of the committee's feedback on a paper circulated to the committee between meetings by email, detailing the proposed revisions to the Authorised processes list and decision tree for authorising, reviewing and deauthorising processes. SCAAC made recommendations concerning the Authorised processes list and supported	

Meetings held	Items considered	Outcomes
	the proposal to divert the decision-making powers relating to Authorised processes from SAC to SCAAC (via change in Standing Orders), pending Authority's approval on 20 March 2024.	

3. Recommendation

3.1 The Authority is invited to note this report. Comments are invited, particularly from the committee Chairs.

Human Fertilisation & Embryology Authority

Monthly performance report

Performance up to January 2024

Evgenia Savchyna
Corporate Performance Officer
20/03/2024

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	Item 6
Meeting date:	20/03/2024
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

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

Human Fertilisation & Embryology Authority

Latest review and key trends

Latest review

- The attached report is for performance up to and including January 2024.
- There were six Green, three Amber, five Red, and three Neutral indicators.

Key trends

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

November (4)	December (6)	January (5)
End to end licensing within 70 working days	Inspection reports to PR within 25 working days	End to end licensing within 80 working days
Staff sickness rate below 2.5%	Reports to Committee within 65 working days	Staff sickness rate below 2.5%
Average debtor days	End to end licensing within 80 working days	Turnover within 5% to 15% range
Invoices paid within 10 working days	Turnover within 5% to 15% range	Average debtor days within 30 working days
	Average debtor days within 30 working days	Invoices paid within 10 working days
	Invoices paid within 10 working days	

Human Fertilisation & Embryology Authority

Management summary

IT and register performance reporting

- PRISM: 561K units from 104 clinics. Error rate is 3.5%. There remain 32 clinics with errors greater than 4%.
- 10 Family Limit: We have 8 clinics that have volunteered to be pilots for 10 family limit alerts. We anticipate starting the pilot in February.
- CaFC: In December Clinic Focus, we set out the rough timetable for CaFC with a sign-off and publication in Autumn 2024.

Management commentary

- Performance has been variable across KPI indicators with six Green, three Amber, five Red, and three Neutral indicators.
- The Inspection KPIs continue to be affected by long-term absence within the team, however, 'Inspections report to PR' and 'Inspections reports to committee' KPIs show a positive trend.
- Media coverage and the airing of the ITV series 'Born from the same stranger' contributed to the substantial increase in the number of OTRs received which were more than three times the average. More OTRs were actioned in January compared to December 2023.
- Following the ITV series, there has been an increase in both email and phone enquiries. The key themes were donation, opening the register, starting a treatment and choosing a fertility clinic.
- The trend for the largest increase in followers on LinkedIn continues, with 283 new followers. The visible increase in followers on Instagram, with 137 new followers, may be attributed to the banner on our website linking our account ahead of the Instagram live with Rachel Cutting: 'Releasing Donor Information'. HFEA dashboards were launched which led to good engagement across all channels.
- Staff sickness was higher than in the last two months which is mainly associated with long-term sickness.
- A large percentage of the debt balance relates to a small number of clinics that have been withholding payment. We are still focussing on the older outstanding invoices.

Summary financial position

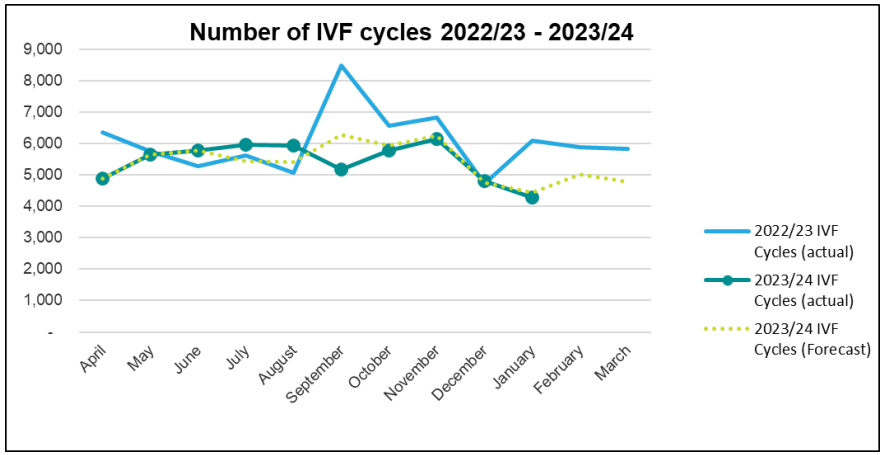
Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2023/2024 £'000s	Budget for 2023/24 £'000s	Variance Budget vs Forecast £'000s
Income	5,993	5,932	(61)	7,079	7,260	181
Expenditure	5,892	5,880	(12)	7,217	7,257	40
Total Surplus/(Deficit)	**101**	**52**	**49**	**(138)**	**3**	**(141)**

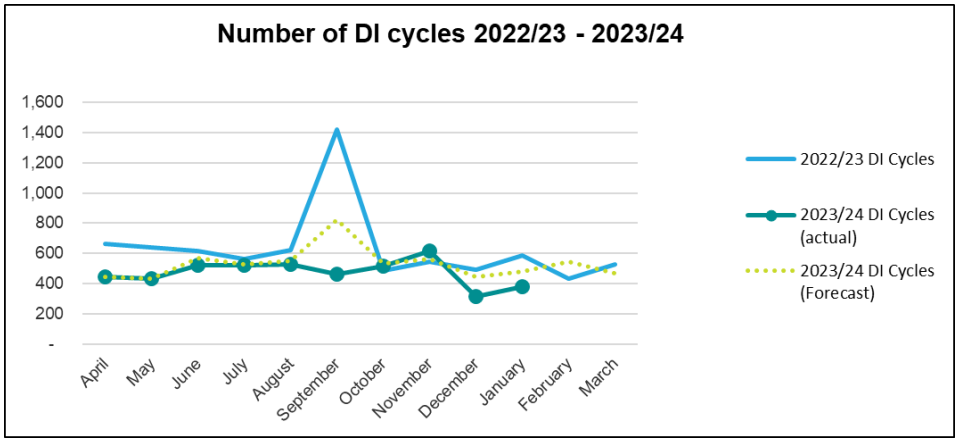
Commentary on financial performance to 31 January 2024

Year to date, we have a surplus against budget of £49k. This has been impacted by increases within our income (namely bank interest), reductions in spend against key areas such as salaries, Facilities and Other costs. Further detail is within the main commentary.

Our current forecast position is a deficit against budget of £141k which is likely to change as we approach the year end where various accounting adjustments are likely to be made as we move through the audit.

Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2022/23 IVF Cycles (actual)	60,783	5,166,555	72,493	6,161,905
2023/24 IVF Cycles (actual)	54,352	4,619,920	64,153	5,453,005
Variance	(6,431)	(546,635)	(8,340)	(708,900)

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2022/23 DI Cycles	6,627	248,513	7,589	284,588
2023/24 DI Cycles	4,732	177,450	5,746	215,488
Variance	(1,895)	(71,063)	(1,843)	(69,100)

Year to date, our IVF income is down against the same period last year by 10.6% or 6,431 cycles.
We are seeing volumes increase very slowly with February 2024's volumes coming in c6% higher than February 2023.
There are only 3 clinics who continue to be billed based upon 2020/21 volumes.

Similarly, DI volumes continue to increase at a very slow pace. Year to date, volumes are 28.6% (1,895) below budget. February volumes are coming in 1% higher than the same month in 2023.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

	Year to Date (Jan-24)			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income						
Grant-in-aid	811	744	(67)	951	991	40
Non-cash (Ring-fenced RDEL)	194	194	-	232	232	-
Grant-in-aid - PCSPS contribution	50	75	25	-	100	100
Licence Fees	4,761	4,838	75	5,697	5,829	132
Interest received	122	26	(95)	130	35	(95)
Seconded and other income	55	55	0	69	73	5
Total Income	5,993	5,932	(61)	**7,079**	**7,260**	**181**
Revenue Costs						
Salaries (excluding Authority)	4,227	4,286	59	5,094	5,145	51
Staff Travel & Subsistence	75	45	(30)	124	100	(24)
Other Staff Costs	132	80	(52)	116	66	(50)
Authority & Other Committees costs	160	203	42	197	235	38
Facilities Costs incl non-cash	366	463	96	462	610	148
IT Costs	465	244	(220)	544	312	(232)
Legal / Professional Fees	325	368	43	460	521	61
Other Costs	109	166	57	187	223	36
Other Project Costs	33	25	(8)	33	48	15
Total Revenue Costs	**5,892**	**5,880**	**(12)**	**7,217**	**7,260**	**43**
TOTAL Surplus / (Deficit)	**101**	**52**	**49**	**(138)**	**0**	**(138)**

Income.

At the end of M10 (January) our total income is 1% (£61k) above budget a reduction of 3% from Q2 (September). Our Treatment fee income is slightly under budget by less than 0.02% (£77k) year to date. Volumes of IVF/DI remain slow in their increase rate. Volumes were down for the month of January, compared to the same period in 2022/23 (IVF LY 6,088 vs CY 4,266) and DI (LY 588 vs CY 379). It is currently unclear as to what is affecting volumes this financial year. Interest received continues to positively impact our income and currently exceeds budget by 3.7%

Expenditure (by exception)

Year to date, expenditure is over budget by £12k.

Salaries - are under budget by £59k overall. The majority of this underspend comes from employer pension contributions (£106k) which are offset by overspends with Contingent Labour and Shared services (£68k).

Staff Travel & Subsistence - are over budget by £30k (up 10k from September) which is largely Inspection costs which have increased in line with the number being undertaken and the impact of increases in travel prices. The profile of this budget is different from the actual spend, contributing to this variance.

Other Staff cost - are over budget by £52k which relate to overspends of £28k each within Staff Training and Payroll & Pension Processing costs. The latter includes an unexpected cost for MyCSP (Pension Administrator) charging for reviewing changes to pension reports HFEA submits (£23k).

Authority & Other Committees costs - are under budget mainly due to expenditure of Advisor Fees being below budget, plus a reversal of an accrual of £21k relating to Appeals.

Facilities Costs - are under budget by £97k which largely relates to adjustments we make in accounting for the lease of 2RP.

IT Costs - are over budget by £221k which was foreseen at the time the budget was set. Our Office 365 Licence costs have increased significantly from last year c100% and are currently overspending against budget by £98k, added to this are overspends within Consultancy and Support costs of £127k. The significant variance is due to the initial budget being set at 50% below previous years.

Legal / Professional - are under budget by £43k of which £46k relates directly to the legal spend with the balance (overspend) against Internal and External Audit Fees. A further review of legal spend in February is expected to see a small increase in the underspend where our legal team will confirm there are no cases in the pipeline for March.

Other costs and Other Project costs - in total are under budget by £49k. We are underspending against other costs by £57k as costs for Donor Conceived Register (DCR) had not been accrued which will be rectified in February's accounts. The overspend against Project costs of £8k is due to coding of legal costs that were unbudgeted.

Forecast

The current forecast is a deficit of £138k for the year and against budget. This includes significant increases in our IT spend and the slow increase in income contributing to this position.

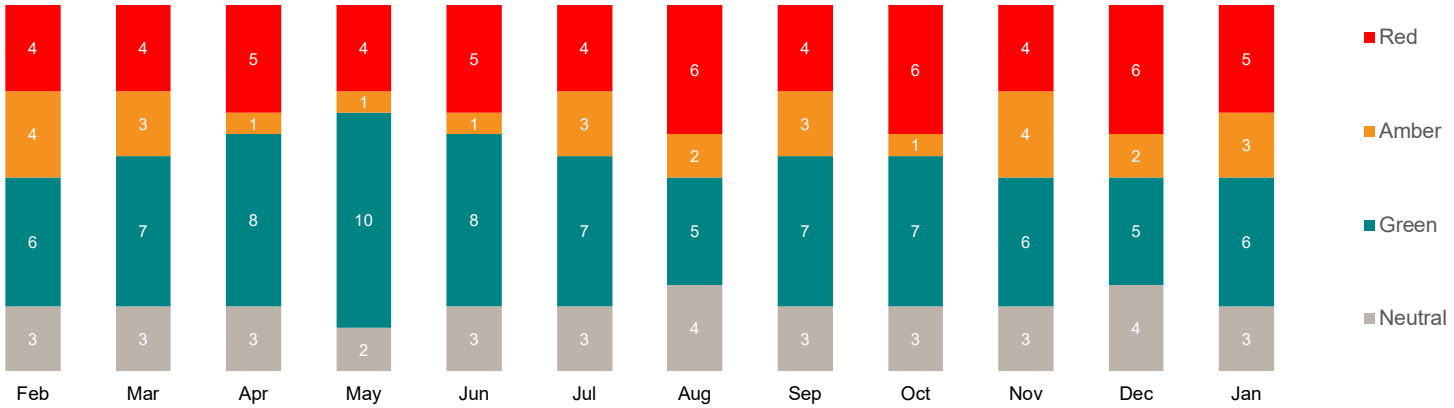
There are also one or two possible cost pressures around our Licences for the Document Management System (DCMS) which could increase the deficit by a further c£32k. It is expected that further information will be available and thus amend our forecast in February.

Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

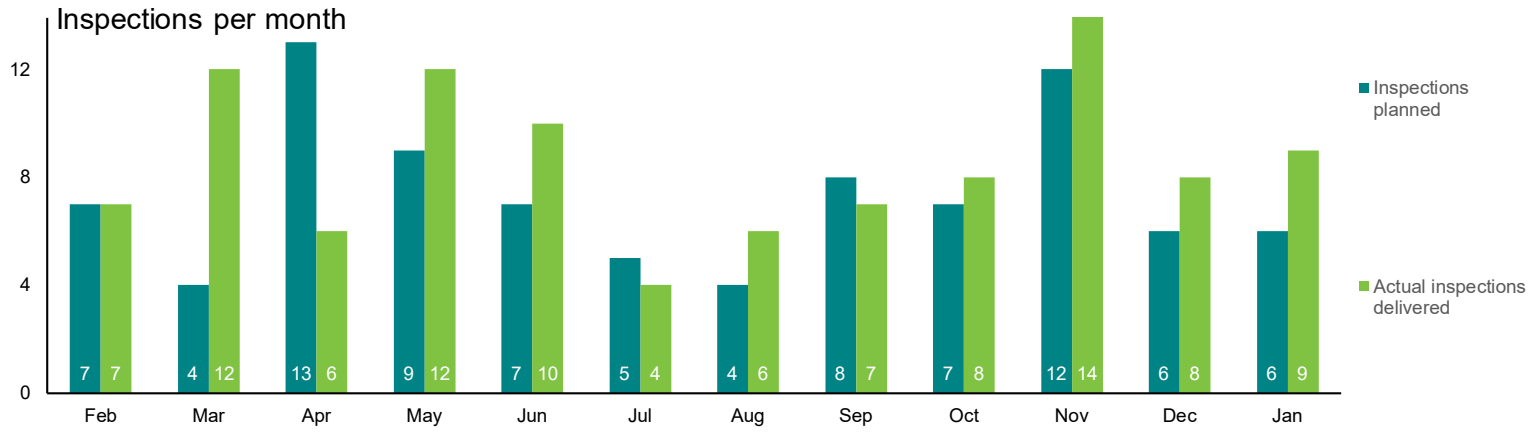
RAG status over last 12 months



RAG status over last 12 months

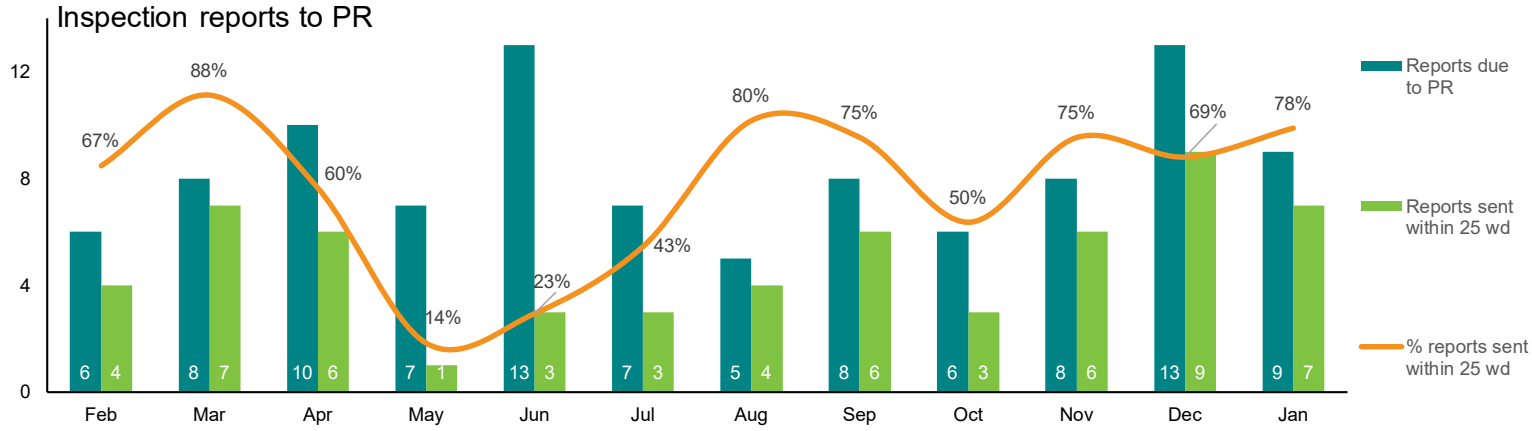
17 KPIs in total for each month

For January, the **5 red** indicators are in these teams: **Compliance - 1, Finance - 2, HR - 2**.



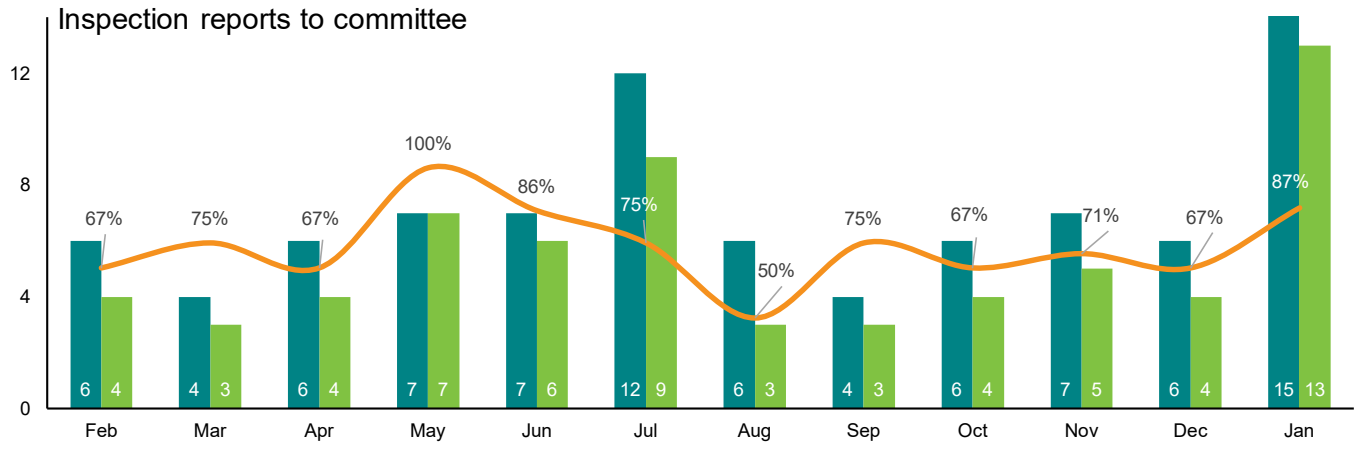
Status:	N/A
Compliance	
Inspections delivery	
Target: **not defined**	

Despite workload and long-term absence, the team still delivered scheduled inspections in addition to extra visits including rescheduled inspections, one initial and one additional change of premises inspection. In addition to the scheduled numbers, unannounced clinic visits were conducted due to regulatory concerns raised.



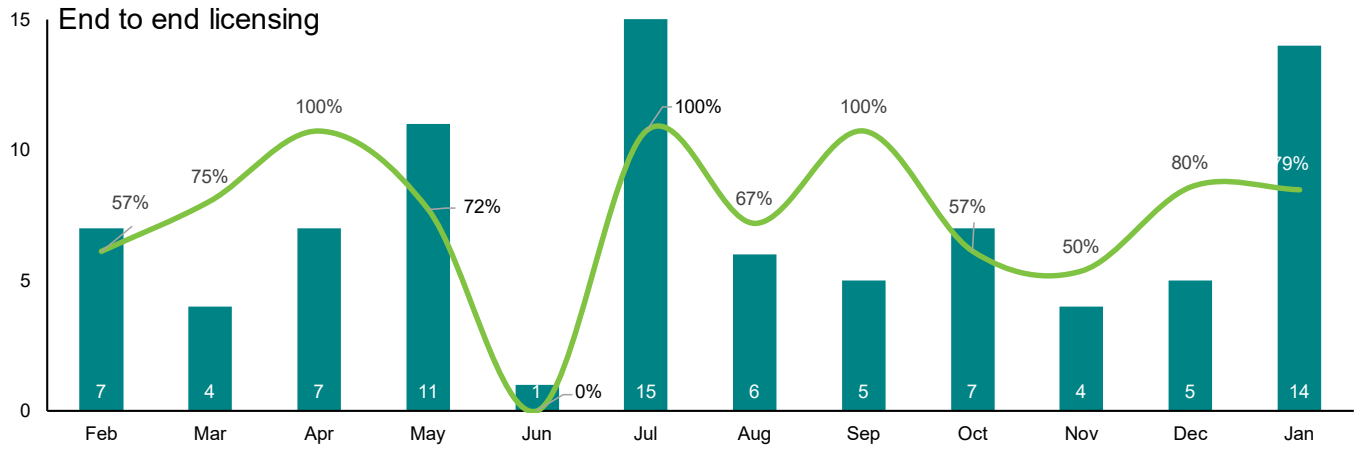
Status:	Amber
Compliance	
Inspection reports sent to PR	
New target from Dec: **100% sent within 25 working days**	

One report not sent to PR yet due staff workload.
Another report delayed as inspector in the process of being trained and their reports require approval from senior before proceeding.



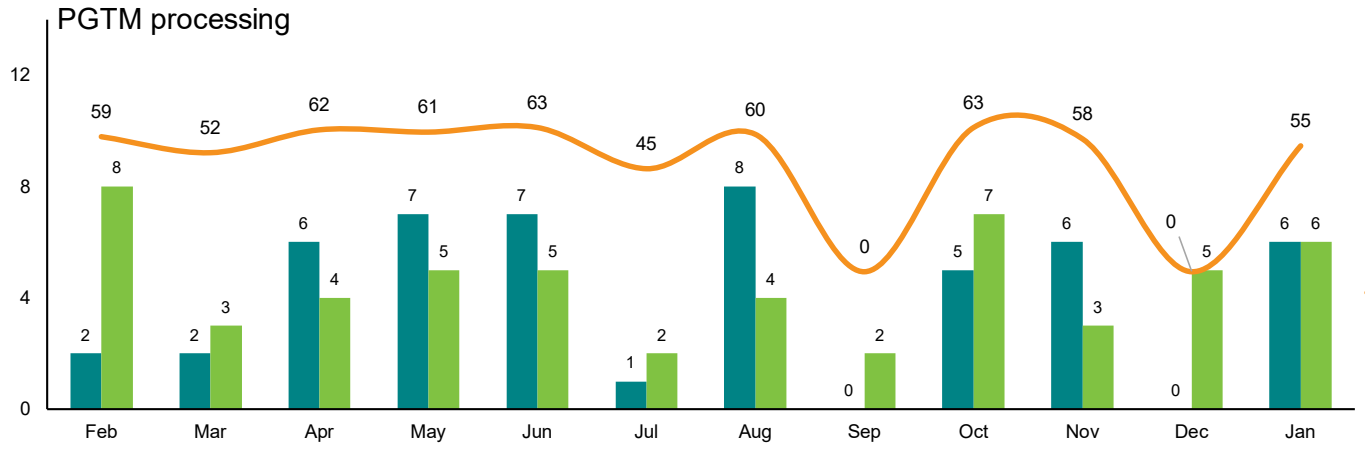
Status:	Amber
Compliance	
Inspection reports sent to relevant licensing committee	
New target from Dec: **100% sent within 65 working days**	

Two reports not sent to committee yet due to staff workload.



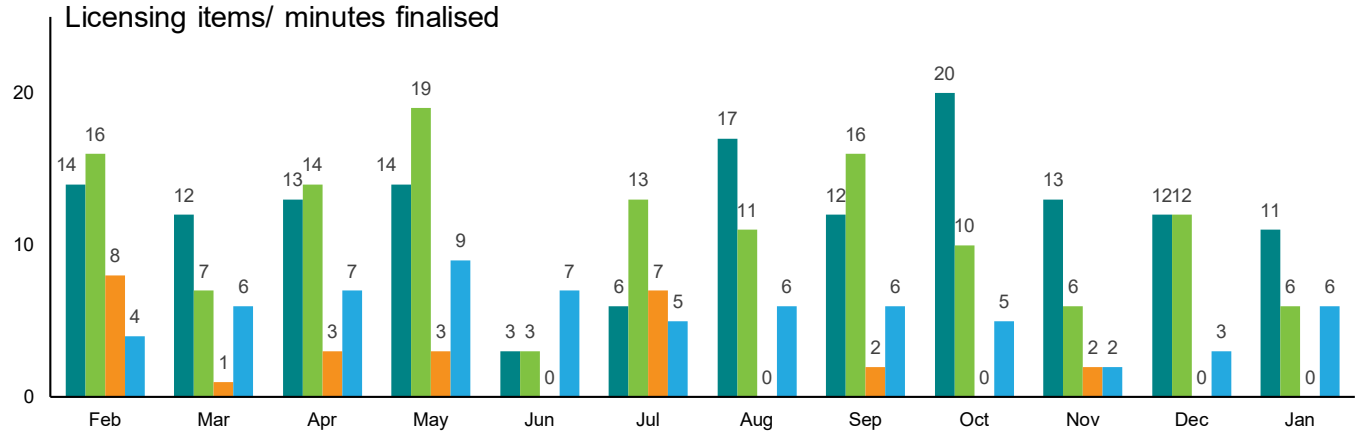
Status:	Red
Compliance	
End to end licensing process	
New target - Dec: **100% items completed within 80 working days**	

Three reports delayed for a variety of reasons (additional meetings with PR, reallocation of inspections and PR availability, and staff absence/workload).



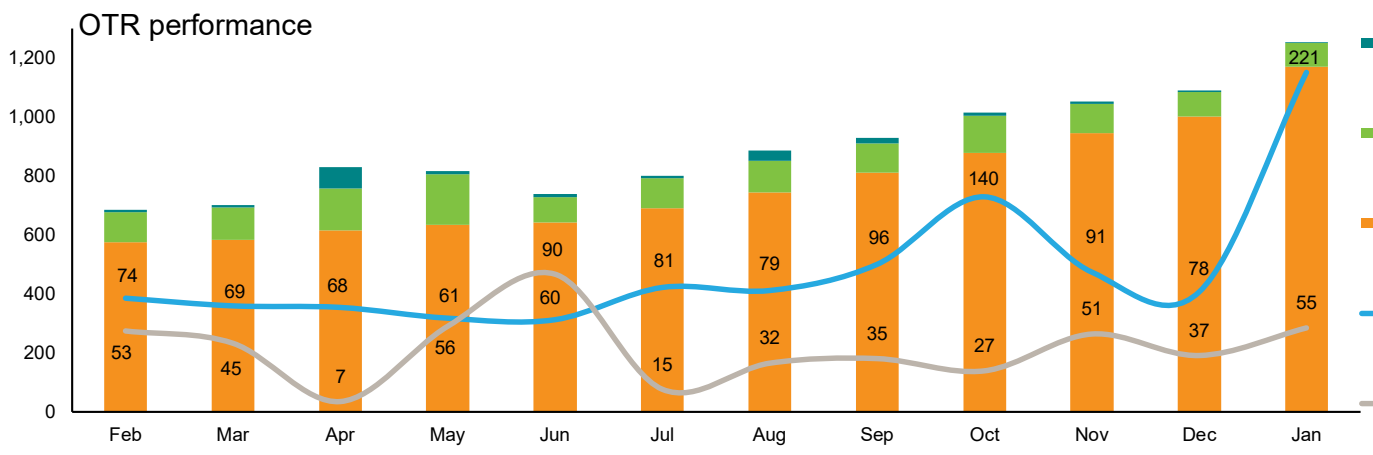
Status:	Green
Compliance	
PGTM processing efficiency	
Target: **100% within 75 working days**	

All PGTMs have been processed within KPI.



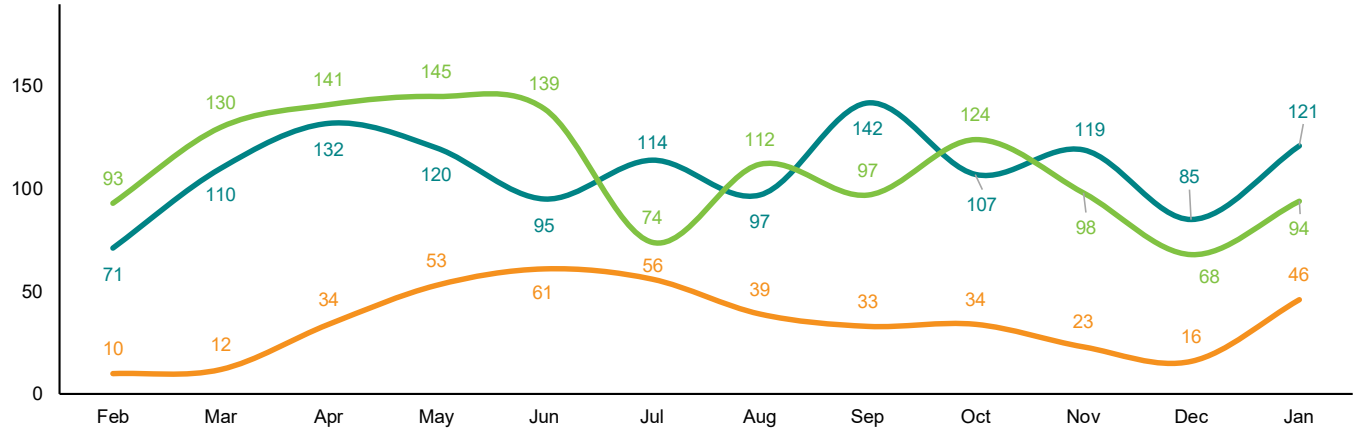
LO:	Green
ELP	Green
LC	Neutral
SAC	Green
PlanGo	
Licensing efficiency	
Targets: **LO - 5 WD; ELP - 10 WD: LC - 15 WD; SAC - 20 WD.**	

A regular month for licensing items. The relatively long gap between the last 2023 ELP meeting and the first of 2024 means only minutes for one meeting were due for sign off in January (normally two feed into this data each month).



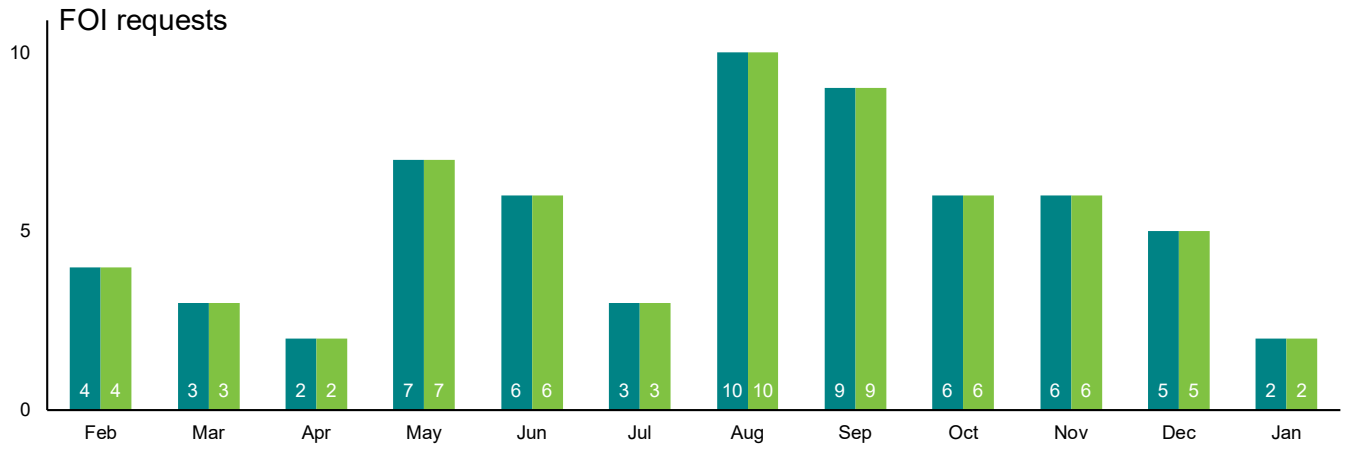
Status:	N/A
Information	
OTR performance	
Target: **to be developed**	

Exremely high number of OTRs received - recent media coverage and documentary a contributing factor.



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

We received an influx in emails following the airing of Born From The Same Stranger on ITV. **Themes**: Donation (18), Complaints (10), Starting treatment/CaFC (8), Import/export (5), data request/success rates (5), and Other (31). We have seen an increase in calls relating to donation following the airing of the programme. **Call themes:** OTR (15), Starting treatment/CaFC (10), Funding (2), and Other (14).



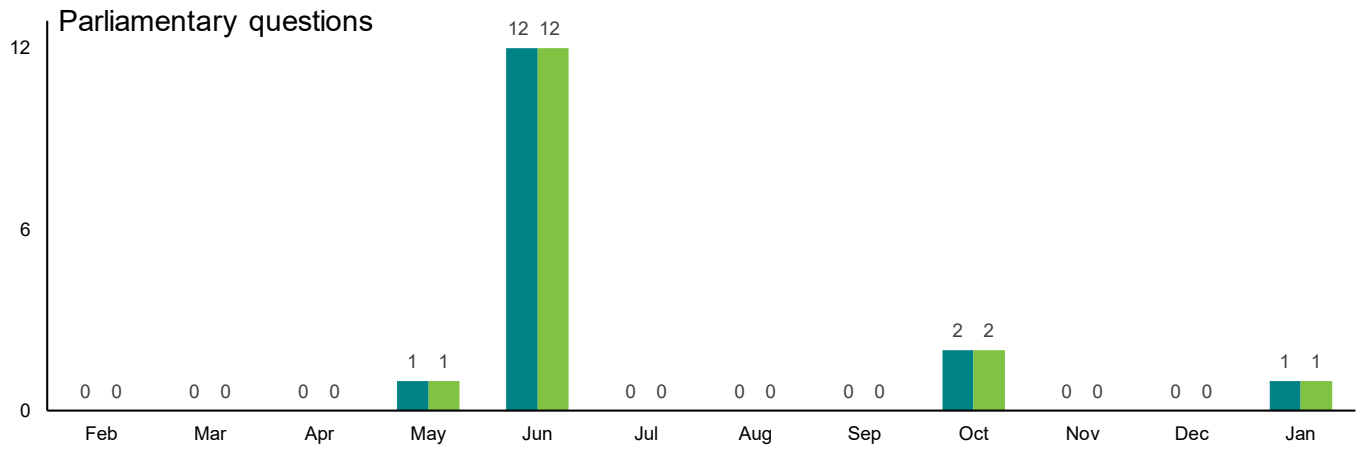
Status: **Green**

Intelligence

FOI responses

Target: **100% within 20 working days**

The FOIs due in January were about clinic level data and fertility trends.



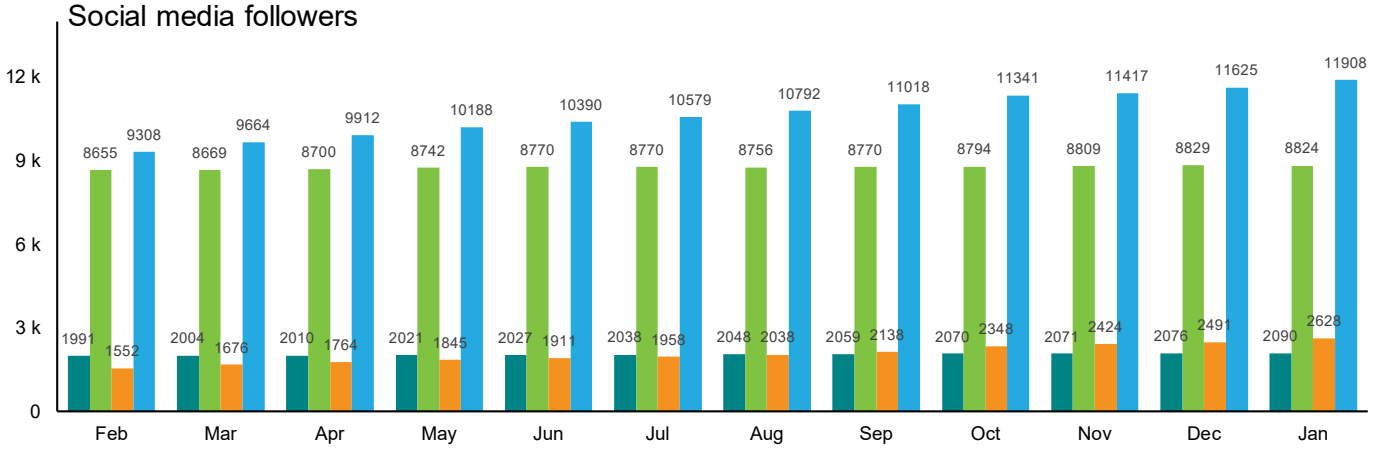
Status: **Green**

Intelligence

PQs responses

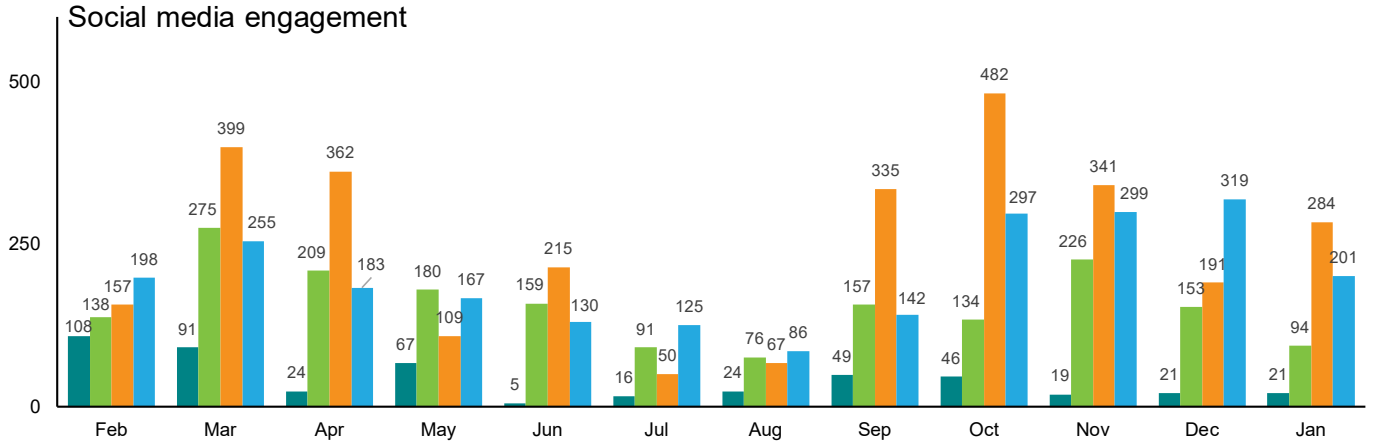
Target: **100% within deadlines set**

The PQ received was about clinic licences.



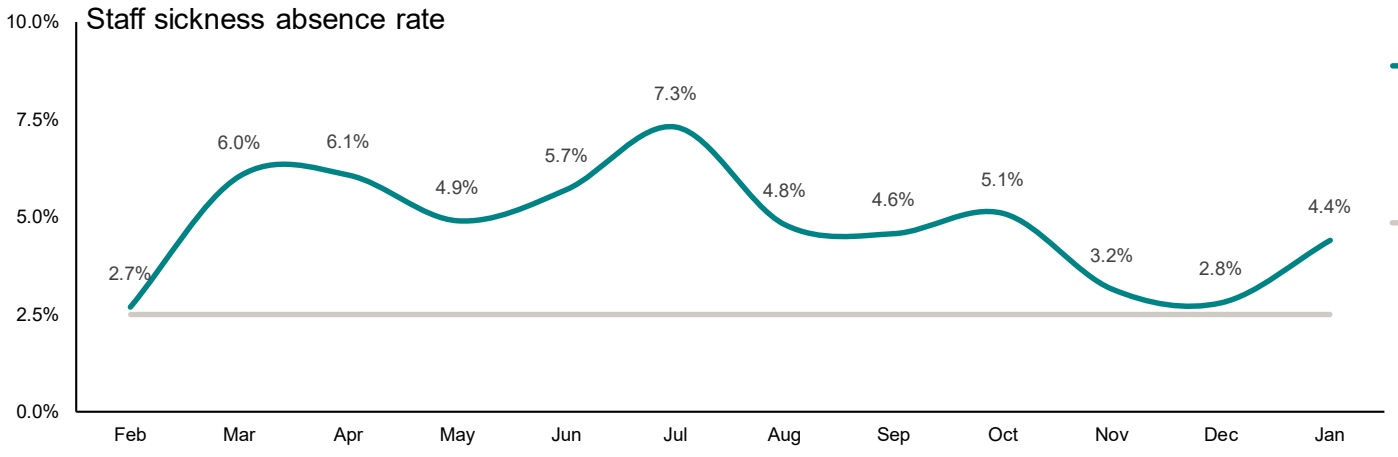
Status:	N/A
Comms	
Total number of followers across social media	
Target: **not defined**	

There was a considerable increase in followers on LinkedIn and Instagram, a steady increase on Facebook and a slight decrease on Twitter. The increase on Instagram could be attributed to the banner on our website linking to our account ahead of the Instagram live: Releasing Donor Information.



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

In January, we posted a variety of content. The Instagram live performed well with 44 people joining to watch Rachel Cutting answer #WhoIsMyDonor questions. This month also saw the hard launch of the HFEA dashboard, with good engagement across all channels. Other content included Fertility 2024, a blog from an IVF patient, Time to Talk day, egg freezing and posts to support the new ITV series Born from the Same Stranger.



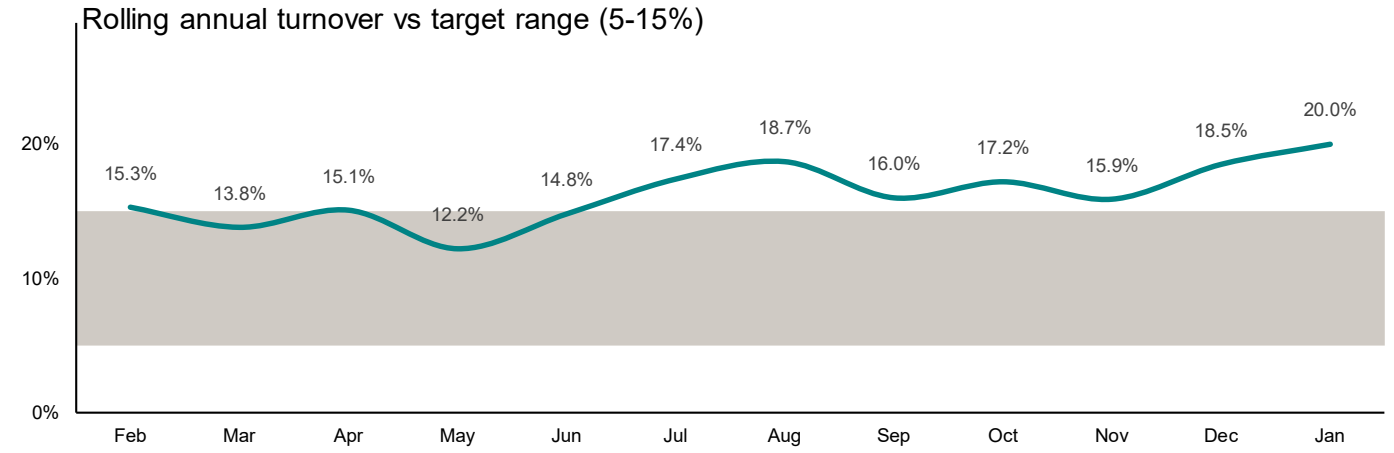
Status: **Red**

HR

Sickness

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

Although staff sickness is above target, if we take out LTS the underlying rate is just 0.5%.



Status: **Red**

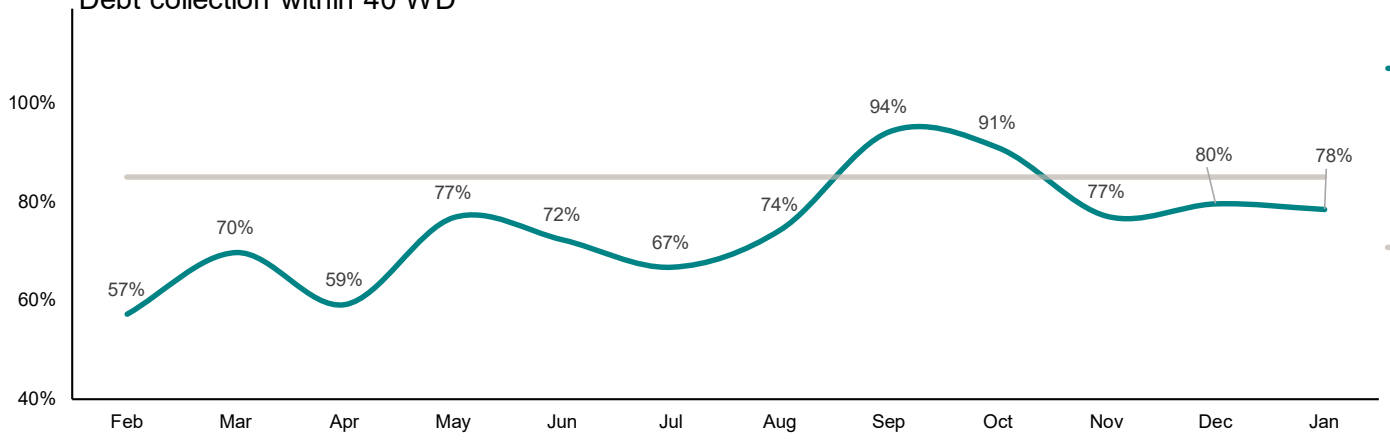
HR

Turnover

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

There were two leavers in January. One returning to education and one for personal reasons.
Supplementary HR data: **Headcount - 74, Posts - 76, Starters - 2, Leavers - 2.**

Debt collection within 40 WD



Status: **Amber**

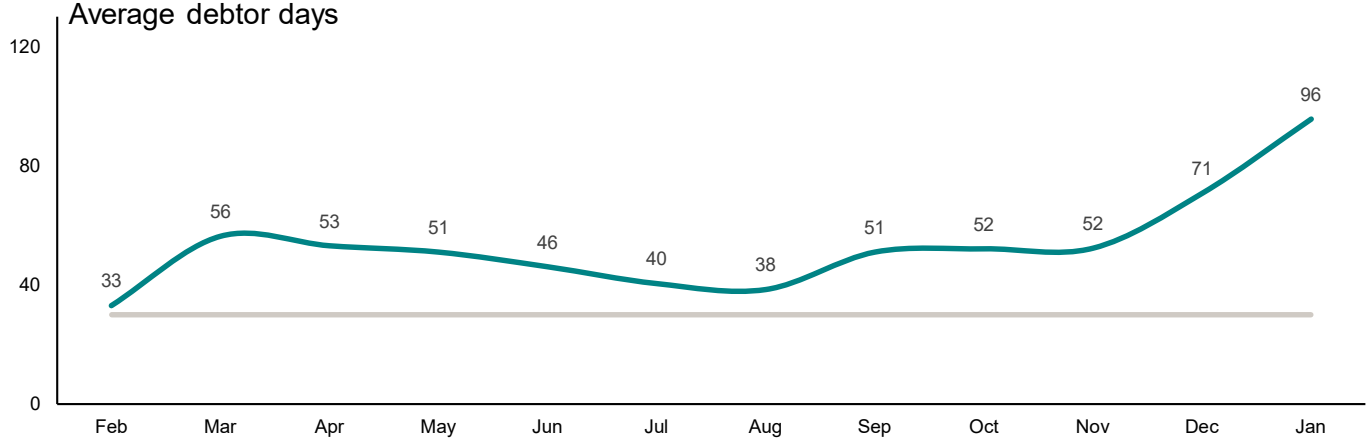
Finance

Debt collection

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

Debt recovery of current invoices remains steady. We are still focussing on the older outstanding invoices.

Average debtor days



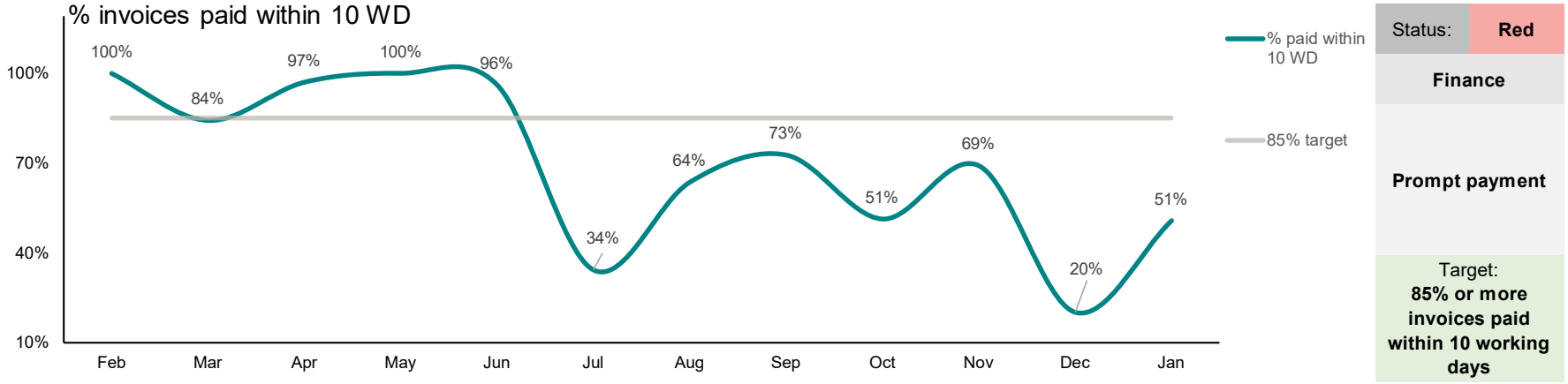
Status: **Red**

Finance

Debtor days

Target: **30 working days or less**

A large percentage of the debt balance relates to a small number of clinics that have been withholding payment. We have resolved the issues regarding several of these clinics and we have received payment towards some of this old debt in February.



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

84% of invoices were paid within 10 days. The small number of invoice paid late were for significant values (Rent invoices totaling £156k) and that has distorted the KPI.

Human Fertilisation & Embryology Authority

Opening the Register – update

Rachel Cutting and Clare Ettinghausen

20 March 2024

HFEA activity during 2023/24

Three workstreams

OTR service	Future of support service	Communications
Ensuring our staffing levels and team structure are appropriate for the demand and systems are effective in processing applications	To report back to the Authority on next steps for a multi-layered support service	To ensure patients, clinic and public communications are timely, informative and relevant throughout 2023 and beyond

Human Fertilisation & Embryology Authority

OTR service

Workstream update

- New IT system for managing applications went live beginning of August (earlier than scheduled). Positive feedback received regarding use from the OTR team in terms of ease and efficiency

- Testing of the OTR RITA reports is complete. They have been in use for active OTRs for a number of weeks and the performance is good.

- The SOPs will be updated to document the above procedure.

Human Fertilisation & Embryology Authority

Future of support service

Workstream update

- Members agreed at the January meeting to improve and expand all the HFEA's information and signposting for donor conceived people and donors. This work will be conducted throughout 2024.

- Members also agreed that a decision on the future of the OTR Letterbox service should be taken by email following further information. Options circulated to members in February.

- Members agreed via email that the Letterbox service should not be brought in-house and that we should issue information and advice to donor conceived people on making initial contact with their donor.

Human Fertilisation & Embryology Authority

Communications

Workstream update

- Following the release of the ITV docu-series *Born From the Same Stranger*, one of the documentary teams that the HFEA had spoken to, there was a large increase in OTR applications, which have risen since our #whoismydonor campaign launched in September 2023.
- As a result, in February, CMG agreed to convert content from that campaign to ongoing BAU to space it further over the months to come.
- A successful Instagram live Q&A took place in January targeting DCIs and donors.
- New web content is reviewed so that anything new will also work well with outputs required following Authority decision on support services.
- More than a three-fold increase in views of all website pages relating to donation (474,000 from 19 Sept 2023- 3 March 2024 compared with 145,000 in the same period the previous year).
- More than 940 views of our FAQs for clinics.

Human Fertilisation & Embryology Authority

Remaining risks

1. Capacity of HFEA resource to meet OTR demands
   - Mitigating actions include increasing staff resources, using a new operating system to improve efficiencies, reviewing how incoming requests are handled to prioritise when needed and support in handling enquiries from other members of staff.
2. Reputational risks remain
   - Addressed through managing expectations where possible of time taken to process applications, acknowledging that over the next few months, we will have better oversight of the efficiencies gained from new systems etc
3. Legal limits of what information we can provide
   - Addressed by always being clear in our communications what information we hold and who can access it.

Human Fertilisation & Embryology Authority

Next Steps

- Final completion of work under each workstream by end of business year.
- As set out, aspects being taken forward through BAU activity.
- Development of information on support for website over the next few months.
- Further monitoring of OTR through performance reporting.

Human Fertilisation & Embryology Authority

Authorised processes review: current list and decision tree

Area(s) of strategy this paper relates to:	The best care / Shaping the future
Meeting:	Authority
Agenda item:	7
Paper number:	HFEA (20/03/2024) 007
Meeting date:	20 March 2024
Author:	Mina Mincheva, Policy Manager
Annexes	Annex A: Current application process to authorise a process which does not appear on the Authorised processes list Annex B: Current Authorised processes list Annex C: Proposed updated Authorised processes list

Output from this paper

For information or recommendation?	For decision
Recommendation:	The Authority is asked to discuss and approve: • the proposed updates to the Authorised processes (AP) list • the proposal to divert the decision-making powers relating to AP from Statutory Approvals Committee (SAC) to the Scientific and Clinical Advances Advisory Committee (SCAAC) via change in Standing Orders • the development of a new decision tree and accompanying guidance for decisions relevant to AP • that the Chair can sign off changes to General Direction (GD) 0008, on behalf of the Authority
Resource implications:	Within budget
Implementation date:	After March 2024 Authority meeting (if approved)
Communication(s):	Actioned as appropriate based on the Authority's decisions
Organisational risk:	Low

1. Introduction

1.1. Since the incorporation of the European Tissues and Cells Directive (EUTCD) into the HFE Act in 2007, the HFEA has a statutory responsibility to have an approval process for processes that fall within its regulatory remit which may affect the quality of tissues and cells. The **authorised processes** (AP) list describes the processes clinics can use to carry out the licensable activities set out in the HFE 1990 Act. The list has been designed to encompass high-level processes, focusing on processes more broadly rather than on different methodologies used to perform them. Fertility clinics that hold an HFEA licence are permitted to undertake the appropriate AP as part of their clinical practice, in accordance with the licence they hold.

1.2. Since its introduction in **May 2011** the AP list and application process for authorising a new process have largely remained unchanged and unreviewed, and with 12 years of scientific developments there is a need to review the current list. The proposed updates to the AP list aim to:

- bring the list in line with up-to-date practice and terminology;
- ensure the list is clear and consistent; and
- future proof the list such that small modifications to procedures/techniques fall under the umbrella term.

1.3. If a centre wishes to use a process which does not appear on the AP list, they need to apply to the HFEA for the process to be authorised before they can use it. If authorised, the process is added to the AP list and can become permitted for any licensed clinic to use (unless a condition is placed on the authorisation, for example to be used in the applying centre only). For further details of the current application process see Annex A. Applications to add new process to the AP list are infrequent; the last process was approved in **June 2015** (in **June 2020**, the Scientific and Clinical Advances Advisory Committee – SCAAC - discussed a variation in its use which was not approved).

1.4. This paper sets out:

- The proposed updates to the AP list so that it continues to be in line with clinical and scientific advancements.
- The proposed way forward for the decision-making process and considering applications for new processes.

2. Proposed updates to the AP list

2.1. The AP list is a key piece of information for clinics to operate within the conditions of their licence (as required by **SLC** T6). The current **AP** list is comprised of two parts:

- Authorised processes – processes that have been authorised for use in appropriately licensed centres.
- Prohibited processes – processes that are prohibited for use in clinical practice.

2.2. The proposed updated list (Annex C) is based on feedback received from the SCAAC, the Statutory Approvals Committee (SAC), the Professional Stakeholders Group (PSG), the Licensed Centres Panel (LCP), and inspectors.

Modified terminology

- References to 'vitrification' or 'freezing' have been changed to cryopreservation in the revised list (Annex C). The term 'cryopreservation' is now the preferred terminology to use since this is an umbrella term that captures both vitrification and slow freezing.
- 'Morphological grading' (line 35 of Annex B) has been merged with 'Non-invasive assessments', (line 38 of Annex B) and renamed 'Embryo grading (including non-invasive assessments, see T91 for limitations)' to encompass the broad range of embryo grading techniques in use, including but not limited to assessing embryo morphology and non-invasive assessments (line 38 of Annex C).
- The terminology has been changed from 'woman' to 'person' (line 41 of Annex C).

Additions to the list

- 'Culture of sperm' has been added to the revised AP list under the activity 'Keeping gametes'.
- 'Testicular tissue collection' has been added to the revised AP list under the activity 'Procuring gametes'.
- 'Grading of gametes' has been added under the activity 'Processing gametes'.
- PGT-SR was added to the revised AP list, as a process under the activity 'Testing embryos'.
- 'Supply of sperm from a licensed centre to unlicensed premises in thawed or thawing state for home insemination' has been added under the activity 'Distribution of gametes'.
- The licensable activity 'Gamete testing' has been added to the list and 'Genetic testing associated with polar body biopsy', has been added under this activity.
- 'Biopsy' has been added under the activity 'Processing embryos'.

Other amendments

- Line 21, 22 and 23 of Annex B refer to freezing of pronucleate embryos, early cleavage embryos and blastocysts, respectively. These references have been removed from the revised list as they are encompassed by 'Cryopreservation of embryos' more broadly. Respectively, 'Cryopreservation of embryos' has been amended to 'Cryopreservation of embryos (including at the pronucleate and blastocyst stage)' to reflect this change (see line 26 of Annex C).
- At line 46 of Annex C, 'thawing/re-warming' is specified, to make this consistent with thawing/re-warming as used elsewhere in the list.
- 'Polar body biopsy' has been moved from 'Testing embryos' to 'Processing gametes'.
- The wording of the explanatory footnote for 'Egg activation using Calcium ionophore' has been updated and 'or in accordance with professional guidelines' has been added.
- References to procedural variations in how 'Assisted hatching' is performed (ie mechanical, chemical, laser) has been removed to keep the AP list consistently focused on processes and not methodologies (see line 37 and 47 in Annex C).
- Key information about AP such as restrictions, guidance notes, etc has been listed under the relevant AP (lines 14, 17, 24, 25, 38 in Annex C).

2.3. The Executive asks the Authority to approve the proposed updated AP list.

3. Roles of SCAAC and SAC in considering the AP list and new processes

Current decision-making process

3.1. Currently, the Authority has delegated the authorisation of processes to SAC, who are advised on the matter by SCAAC (Annex A). The role of the SCAAC is to review new process applications and advise the SAC on the following:

- evidence to suggest the process is not safe; and
- evidence to suggest that the process is not effective.

3.2. SAC then determine if the process is suitable for use by considering whether the process is safe and effective. This disparity between the recommendation given by SCAAC (is there evidence the process is **not** effective or is **not** safe) and the decision taken by SAC (is there evidence the process **is** effective or **is** safe) means that the advice from SCAAC may not be directly relevant to the decision made by SAC.

3.3. Furthermore, the test applied does not reflect the test required by law as detailed further below.

Suggested revision to the decision-making process

3.4. Ideally, SCAAC and SAC should consider the evidence under the same legal test. This could however result in SAC automatically approving what SCAAC have already recommended, making it therefore more appropriate for any decisions on the authorisation of processes be made by a single Committee.

3.5. As the SCAAC consists of professionals with varied clinical and scientific expertise (for details refer to Annex A (5) in Standing Orders from April 2023), members are well placed to consider and decide upon the authorisation of processes. Diverting the decision-making power relating to AP from SAC to SCAAC – ie the change from a two-committee process to a one-committee process – should allow for a more practical and streamlined application process, making best use of the expertise of the SCAAC members.

3.6. The Executive asks the Authority to approve delegation of powers to SCAAC to make decision relevant to authorised processes. This would include delegating powers to SCAAC to:

- determine applications for new processes to be authorised in licensed activities
- regularly review the AP list
- reconsider authorised processes
- impose conditions in respect of any authorised process
- prohibit, reject or deauthorise a process
- suspend an authorised process.

Suggested changes to Standing Orders

3.7. The SCAAC and SAC have been consulted and support the proposal to move the AP decision-making powers to SCAAC from SAC (via change in Standing Orders).

3.8. If the Authority agrees with this proposal, the Standing Orders and terms of reference for SAC and SCAAC (Annex A, sections 3 and 5) should be modified accordingly. The proposed changes to Annex A, sections 3 and 5 of Standing Orders are laid out in agenda item 8, Effective Governance paper. Briefly, the main changes for the Authority to consider refer to:

- Section 3: Amending 'Purpose of the Committee' section to reflect the removal of the decision-making power relating to AP from SAC. Similarly, under 'Delegated powers and functions of SAC' section - removal of delegated decision-making power relating to AP (sub-section 3.2 f). Accordingly, amendment of wording in sub-section 3.10.
- Section 5: Amending 'Purpose of the Committee' section to reflect the addition of decision-making power to SCAAC relating to AP.
- Section 5: Addition of a paragraph under 'Functions of SCAAC' section that refers to the new delegated power to SCAAC to make decisions relating to AP.
- Section 5: Under 'Meetings of SCAAC' section addition of three paragraphs referring to:
    - the possibility for SCAAC to convene additional meeting(s) (aside from the official three meetings per year) when discussion on an item (or items) cannot be delayed until next meeting.
    - clarifying the voting process relating to AP.
    - the possibility for the Chair to request a legal adviser to be in attendance for decisions relating to AP.

3.9. Although the Executive is proposing that SCAAC be given decision-making powers relating to AP, we suggest that the name of the Committee remains unaltered as the Committee's role remains largely advisory.

3.10. The Executive asks the Authority to approve the proposed changes to Standing Orders – specifically Annex A, section 3 and section 5 – diverting of decision-making powers to SCAAC from SAC for the purpose of APs only (detailed out in agenda item 8).

4. Updating the decision tree

4.1. If the Authority agrees to the proposed delegation of power to SCAAC, a new robust process will be developed which will include an improved legal test to accurately reflect the actual wording of the statutory test as set out in the Third Directive (ie that **the process must not render the tissues and cells clinically ineffective or harmful to the recipient**). An updated decision tree with explanatory notes and guidance for all decisions relating to AP will also be produced to assist the SCAAC with decision making. This will help to make future decision making accurate and legally defensible.

4.2. These are the proposed overarching principles for updating the decision tree:

- Mirroring the statutory test as set out in the Third Directive (see 4.1.), the legal test in the new decision tree can be split in two stages:
    - Stage 1: Does the process render the tissues and cells clinically ineffective?
    - Stage 2: Does the process render the tissues and cells harmful to the recipient?
- When considering an application for a new process, if it passes the two-stage legal test, the decision-making Committee can place requirements for mandatory continuous reporting, the length of time and conditions of which will be developed and agreed on with the decision-making Committee.

- When considering an application for a new process, if the process does not pass either or both of the two stages due to insufficient evidence, authorisation is refused and the application is rejected.
- On reconsideration of an authorised process, at the end of its initial default period of mandatory continuous reporting, if it passes the legal test for approval, the decision-making Committee could approve it on a permanent basis (with appropriate conditions if required) or subject it to a further review period if more evidence is still needed before it can be fully approved.
- When considering an application for a new process, if the process does not pass either or both the two stages because there is evidence that the process renders the cells/tissues inefficient and/or the process is harmful, authorisation is refused and the process is added to the 'prohibited processes' part of the AP list.
- The decision tree will also include a process to reconsider an AP if there are concerns with an option for deauthorisation.

4.3. Once a new process has been authorised, it will be flagged on the AP list as 'authorised (subject to default period of mandatory reporting)'. If other clinics want to carry out this process, they will need to inform the HFEA before doing so. We anticipate enforcing this through adding a requirement in GD 0008 for clinics to report the proposed use of an authorised process which is under default period of mandatory reporting to the HFEA.

4.4. The Executive asks the Authority to approve the overarching principles for the update of the decision tree as set out in 4.2.

4.5. Should the Authority approve the proposed delegation of power to SCAAC, the Executive proposes to work with SCAAC to develop the new decision tree and guidance.

4.6. Provided that the Authority approves the overarching principles of the decision tree, the Executive asks the Authority if they are satisfied that the approval of the final documents for the updated decision tree, process and accompanying guidance can be made by SCAAC.

4.7. The Executive asks the Authority to approve that the Chair does final sign-off of draft changes to GD 0008 and Chair's letter on behalf of the Authority, outside of an Authority meeting.

5. Next steps

5.1. If approved by the Authority the AP list will be updated on the website and communication to the sector will be actioned as appropriate.

5.2. If the Authority agrees to delegate sole responsibility for AP to SCAAC, a new decision tree and guidance will be developed by the Executive in collaboration with SCAAC, with final agreement and approval by SCAAC.

5.3. GD 0008 will be updated and signed off by the Chair on behalf of the Authority.

6. For decision

6.1. The Authority is asked to discuss and approve:

- the proposed updates to the AP list.
- the proposal to divert the decision-making powers relating to AP from SAC to SCAAC via change in Standing Orders.

- the development of a new decision tree and accompanying guidance for decisions relevant to AP.
- that the Chair can sign off changes to GD 0008, on behalf of the Authority.

Annex A - Current application process to authorise a process which does not appear on the AP list

If a centre wishes to use a process which does not appear on the AP list, they need to apply to the HFEA to authorise the process for use.

The Authority has delegated the authorisation of new processes to the Statutory Approvals Committee (SAC) (as per Annex A, paragraph 3.2 (f) of HFEA standing orders), who are advised on the matter by Scientific and Clinical Advances Advisory Committee (SCAAC) (as per Annex A, paragraph 5.2 (a) of HFEA standing orders).

The role of the SCAAC, as outlined in the current decision tree, is to review the process applications and advise SAC on whether the process is suitable for carrying out the licensed activity, specifically:

- evidence to suggest the process is not safe; and
- evidence to suggest that the process is not effective.
-

The SAC then uses the evidence provided within the application and the expert advice provided by the SCAAC to consider the following:

- Is the process suitable for use to carry out a licensed activity?
- Is the process safe?
- Is the process effective?

The SAC can then make a number of decisions including:

- Refuse authorisation.
- Adjourn decision in order to seek further information.
- Authorise for use at all centres.
- Authorise with conditions, for example process to be used at named centres only.
- Refer to the Authority for final decision.

On approval, the process is labelled as ‘recently approved’ for the first two years and centres must inform the HFEA if they would like to use the process in their clinic.

At the end of the two years all centres using the process should submit an outcome report to the HFEA for consideration at SCAAC. If the findings of the outcome report raise concerns over the safety or effectiveness of the process, then SCAAC can make a recommendation to SAC to de-authorise the process and remove the process from the list of authorised processes.

Annex B – Current AP list

Licensed activity	Line no.	Authorised processes
Procuring gametes	1	Egg collection
	2	Surgical sperm collection
	3	Ovarian tissue collection
Keeping gametes	4	Culture of eggs
Processing gametes	5	Semen preparation (including the use of reagents to increase sperm motility)
	6	Egg preparation
	7	In vitro maturation
	8	Thawing/re-warming gametes
	9	Egg activation using Calcium Ionophore (only in suitable patients* - see below for further guidance)
Distribution of gametes	10	Transfer of sperm between centres
	11	Transfer of eggs between centres
Use of gametes	12	IUI
	13	GIFT
	14	IVF
	15	ICSI
Storage of gametes	16	Freezing of eggs
	17	Freezing of sperm
	18	Vitrification of eggs
	19	Freezing of testicular tissue (not for transplantation purposes unless a HTA licence is in place)
	20	Freezing of ovarian tissue (not for transplantation purposes unless a HTA licence is in place)
Storage of embryos	21	Freezing of pronucleate embryos
	22	Freezing of early cleavage embryos
	23	Freezing of blastocysts
	24	Vitrification of embryos
	25	Vitrification of blastocysts

Creation of embryos	**26**	IVF
	27	ICSI
Procuring embryos	**28**	Lavage
Keeping embryos	**29**	Culture system
Testing embryos	**30**	PGT-M
	31	PGT-A
	32	Polar body biopsy
Processing embryos	**33**	Culture
	34	Assisted hatching (mechanical, chemical, laser)
	35	Morphological grading
	36	Manipulation
	37	Thawing/re-warming of blastocysts and embryos
	38	Non-invasive assessments
	39	Intrauterine culture of gametes and embryos (including insertion and removal of device, followed by transfer of embryo(s) to the same woman)'
Distribution of embryos	**40**	Transfer of embryos between centres
Placing permitted embryo in a woman	**41**	Embryo transfer
Using embryos in training	**42**	Embryo biopsy
	43	Blastocyst biopsy
	44	Cryopreservation and thawing techniques
	45	Vitrification
	46	Assisted hatching (mechanical, chemical, laser)
	47	Embryo handling and manipulation
	48	Assessment of embryos

*The HFEA's Scientific and Clinical Advances Advisory Committee considered the use of Calcium Ionophore as an egg activation technique and highlighted the theoretical risks relating to embryo viability (eg, premature activation and triploid embryos). Given the theoretical risks of using Calcium Ionophore, centres using it are expected to do so only in selected patients, such as those with PLCz deficiency. Centres are expected to document their rationale for using Calcium Ionophore for individual cases. As with all treatments and processes, centres should ensure that patients are fully informed about the efficacy and potential risks and that validation is carried out.

Annex C – Revised AP list

Licensed activity	Line no.	Authorised processes
Procuring gametes	**1**	Egg collection
	2	Surgical sperm collection
	3	Ovarian tissue collection
	4	Testicular tissue collection
Keeping gametes	**5**	Culture of eggs
	6	Culture of sperm
Processing gametes	**7**	Semen preparation (including the use of reagents to increase sperm motility)
	8	Egg preparation
	9	Grading of gametes
	10	In vitro maturation
	11	Cryopreservation of gametes
	12	Thawing/re-warming gametes
	13	Polar body biopsy
	14	Egg activation using Calcium Ionophore (only in selected patients or in accordance with professional guidelines* - see below for further guidance)
Distribution of gametes	**15**	Transfer of sperm between centres
	16	Transfer of eggs between centres
	17	Supply of sperm from a licensed centre to unlicensed premises in thawed or thawing state for home insemination As per the Code of Practice this should only be done in **exceptional circumstances.**
Use of gametes	**18**	IUI
	19	GIFT
	20	IVF
	21	ICSI
Storage of gametes	**22**	Cryopreservation of eggs
	23	Cryopreservation of sperm
	24	Cryopreservation of testicular tissue (HTA licence may be required depending

		on the reasons for storage and intended use)
	25	Cryopreservation of ovarian tissue (HTA licence may be required depending on the reasons for storage and intended use)
Storage of embryos	**26**	Cryopreservation of embryos (including at the pronucleate and blastocyst stage)
Creation of embryos	**27**	IVF
	28	ICSI
Procuring embryos	**29**	Lavage
Keeping embryos	**30**	Culture system
Testing gametes	**31**	Genetic testing associated with polar body biopsy
Testing embryos	**32**	PGT-M
	33	PGT-A
	34	PGT-SR
Processing embryos	**35**	Culture
	36	Biopsy
	37	Assisted hatching
	38	Embryo grading (including non-invasive assessments, see T91 for limitations)
	39	Manipulation
	40	Thawing/re-warming of blastocysts and embryos
	41	Intrauterine culture of gametes and embryos (including insertion and removal of device, followed by transfer of embryo(s) to the same person)
Distribution of embryos	**42**	Transfer of embryos between centres
Placing permitted embryo in a woman	**43**	Embryo transfer
Using embryos in training	**44**	Embryo biopsy
	45	Blastocyst biopsy
	46	Cryopreservation and thawing/re-warming techniques
	47	Assisted hatching
	48	Embryo handling and manipulation
	49	Assessment of embryos

*The HFEA's Scientific and Clinical Advances Advisory Committee considered the use of Calcium Ionophore as an egg activation technique and highlighted the theoretical risks relating to embryo viability (eg, premature activation and triploid embryos). Given the theoretical risks of Calcium Ionophore activation, centres using it are expected to do so only in selected patients, such as those with PLCz deficiency, or in accordance with professional guidelines. Centres are expected to document their rationale for using Calcium Ionophore for individual cases. As with all treatments and processes, centres should ensure that patients are fully informed about the efficacy and potential risks and that validation is carried out.

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:	8
Meeting date:	20 March 2024
Author:	Alison Margrave, Board Governance Manager
Annexes	Annex A: Proposed changes to the Standing Orders Annex B: Authorised processes changes to the Standing Orders

Output from this paper

For information or decision?	For decision
Recommendation:	Agree the proposed changes to Standing Orders, effective 1 April 2024 (vote required). Note the annual reviews of committee effectiveness and the action points for each committee.
Resource implications:	In budget
Implementation date:	1 April 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 and which are made in accordance with the powers of 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. This paper is intended to provide assurance over the structures established by the Authority, effectiveness of committees, decisions taken, and that activities of the HFEA are aligned with its statutory duties, responsibilities and objectives.

1.5. It also provides members with updates and recommendations related to the governance of the Authority. The HFEA is committed to an annual review of its governance arrangements consisting of a review of each committee's effectiveness and of the Standing Orders.

1.6. In accordance with the Standing Orders, Authority members received notification and motion regarding the intention to amend the Standing Orders at the March Authority Meeting.

2. Annual review of committee effectiveness

2.1. On an annual basis all committees are required to review their own effectiveness using a standard template. Between September 2023 and March 2024 this exercise was conducted by the Licence Committee, Executive Licensing Panel, Statutory Approvals Committee, the Scientific and Clinical Advances Advisory Committee and the Register Research Panel.

2.2. The Audit and Governance Committee used the specific effectiveness tool for Audit Committees produced by the National Audit Office (NAO) and carried out a 360 review whereby feedback was received not just from committee members, but also the Senior Management Team and the Internal and External Auditors.

2.3. All Authority members sit on at least one committee which means that they all participated in the review of their respective committee(s).

2.4. It is reassuring that all committees stated that the meetings and papers were well prepared and that they had sufficient information necessary to take decisions.

2.5. Generally, the feedback from committees has been positive. There are a number of recommendations for improvement and the table below summarises the feedback from each committee and possible actions which the committee/Executive could take.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or Executive)
Audit and Governance Committee (AGC)	Consider whether/when to recruit a second external member. Discuss membership resilience and diversity with the Authority Chair, as	Chair to review with Head of Planning and Governance. AGC Chair to discuss with Authority Chair once new Authority members are appointed.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or Executive)
	and when Authority membership changes.	
	To continue to build assurance mapping into the 'deep dive' papers on risk topics. To consider 'assurance' as a training topic for December 2024.	This is in place for action by all deep dive authors. The Executive to source suitable training for the committee.
	To work with the internal auditors to agree manageable actions following each audit and to prioritise and report on agreed actions, particularly those that are overdue.	Executive to implement during audit meetings.
	To amend the terms of reference in the Standing Orders to change the quorum to two (as an interim measure).	Proposed changes to the Standing Orders are brought to the Authority in this paper. If approved will be reviewed next year.
Licence Committee (LC)	A review of processes and procedures could be undertaken, including the role of inspectors in supporting decision-making at meetings.	Licensing team to discuss with senior management team how best to take forward.
	Consideration of timing of reporting of Grade A incidents in cases where there is a history of non-compliances at the clinic.	Compliance team to take into consideration in scheduling.
	Refreshing training to be done as joint training with new members, when appointed.	Licensing team to arrange once new members appointed.
	Induction and training to incorporate more explanation about the different role and functions of the LC, the ELP and the inspectorate.	
	Balance size and complexity of agendas where feasible to do so.	Compliance team to bear in mind when scheduling items.
	Terminology in papers to state 'inspectorate' rather than 'executive' when that is what is meant.	Compliance and Licensing teams to note this terminology change in future papers, minutes, etc.
	Consider using the informal Authority workshops to brief other members.	For discussion with Authority Chair.

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or Executive)
	Consider how best to highlight current issues to the sector so as to encourage learning and public understanding.	For discussion with the Director of Strategy and Communications.
Executive Licensing Panel (ELP)	May be beneficial to have an annual meeting with the Chair of Licence Committee. Review membership in Spring 2024 to ensure enough members. New members to participate in a clinic visit as part of their induction. To amend article 1.9 of their terms of reference in the Standing Orders to reflect that members of the panel shall attend training and update sessions when needed.	To be discussed with the Licence Committee Chair. Chair to review and take forward. When new members are appointed the committee secretary to arrange with the Compliance team as part of their induction. Proposed changes to the Standing Orders are brought to the Authority in this paper.
Statutory Approvals Committee	Chair's briefing, including page references for all items to be shared with all members in advance of meeting. This will make the papers and surrounding discussions easier to follow during meetings. Continue to discuss future membership, quoracy and members' time commitments with the Chair of the Authority. To remove authorisation of 'novel processes' from SAC, and to give this delegation to SCAAC instead, with new processes around it.	Committee Secretary to implement this. Members will be encouraged to state page number of the pack when discussing an agenda item. To be reviewed when new Authority members are appointed. Proposed changes to the Standing Orders have been brought to the March Authority meeting in the Authorised Processes paper and this paper.
Scientific and Clinical Advances Advisory Committee	Clarity around the process of prioritising issues and improved visibility of the committee workplan for the upcoming year. Could meet more frequently or extend the duration of the meetings to avoid the need to carry over work (increased workload during 2023).	Circulate the updated workplan for the committee and the functions of the SCAAC (from Standing orders) as part of the matters arising paper at every meeting. Be mindful about the workload of SCAAC members who sit on other committees of the HFEA when planning SCAAC work. Consider convening smaller working groups of the

Committee	Conclusions and Recommendations	Suggested actions (for the committee itself and/or Executive)
		SCAAC, or seeking advice by email as required.
	Members of the Authority could be invited to observe SCAAC meetings.	Consider extending invitations to more Authority members.
	Membership of the SCAAC needs to be reflective of the sector in terms of those representing NHS and private clinics.	To keep in mind with current recruitment of three new expert advisors to the SCAAC.
	Continue to communicate the work of the SCAAC with the sector and allow the sector to feed into the work of the SCAAC.	The Executive now publish Clinic Focus articles following each SCAAC meeting, highlighting the topics discussed and any relevant outcomes. Representatives of the sector can raise issues/concerns to be considered by the SCAAC at relevant engagement meetings (such as via the professional stakeholder group) or with their inspectors and this is considered by the Executive.
	To remove authorisation of 'novel processes' from SAC, and to give this delegation to SCAAC instead, with new processes around it.	Proposed changes to the Standing Orders have been brought to the March Authority meeting in the Authorised Processes paper and this paper.
Register Research Panel	Would be beneficial to the Panel to have additional support when discussing areas such as data security, which the members are not experts in.	Possible development of an IT checklist for IT security requirements.
	Would be beneficial to gain feedback from researchers on how they find the RRP application process, with the intention that improvements to webpage/guidance can be made.	Potential survey/meeting of RRP researchers about process.
	Review membership of the Panel to ensure right skill set.	Look to appoint additional Policy Panel member and a member with a strong understanding of the Register.
Remuneration committee	Formal review not undertaken due to infrequency of meetings.	

3. Review of the Standing Orders

3.1. A review of the Standing Orders has been undertaken, including any recommendations arising from the results of the committee effectiveness review. The proposed changes to the Standing Orders are shown at Annex A. If members would like to see a full tracked changes copy of the Standing Orders, they may request this from the Board Governance Manager.

3.2. Annex A includes:

- The proposed **changes to the Standing Orders highlighted in the preceding agenda item "Authorised processes**"; for clarity these changes are also shown in Annex B. If the Authority has agreed to the proposed changes, this will entail removing the approval of the use of novel processes from the terms of reference of the Statutory Approvals Committee and delegating this process instead to the Scientific and Clinical Advance Advisory Committee. In the event that the Authority does not agree to the proposals on authorised processes when considering that item, the related material will be withdrawn from the set of proposed changes to Standing Orders during the meeting, prior to a vote.
- A proposed **change to article 1.9 of the protocol for the conduct of meetings of the Authority's Executive Licensing Panel**. This change reflects that members of the panel shall attending training and update sessions when needed.
- A proposed **change from the Audit & Governance Committee to amend the quorum for their meetings from three to two**. The committee are proposing this as an interim measure and if approved this change will be reviewed next year.
- Proposed **changes to the Membership of the Statutory Approvals Committee**, removing the requirement that the Committee Chair and Deputy be lay Authority members and giving the committee the power to co-opt additional members if a particular expertise is needed.
- Proposed **changes to the leadership paragraph of the seven principles underpinning public life, page 63 of the Standing Orders**. This is to reflect the changes made by the Government since the last review of our Standing Orders. These principles can be view on the Government website: the Seven Principles of Public Life

3.3. We have also taken this opportunity to update certain terminology throughout the Standing Orders, namely altering 'Department of Health' to 'Department of Health and Social Care'.

3.4. As detailed in Article 3.1 of the Standing Orders any proposed changes to the Standing Orders require a majority vote by the Authority.

3.5. The Authority is asked to review and approve the proposed change(s) to the Standing Orders as set out in Annex A. If approved the new Standing Orders would come into effect on 1 April 2024.

4. Recommendations

4.1. The Authority is asked to:

- Approve, by a majority vote, the revised Standing Orders to come into effect from 1 April 2024.
- Note the feedback from the annual reviews of committee effectiveness and the action points for each committee.

Annex A

Standing Orders – proposed changes

Page 5 (article 1) – replace “Department of Health” with “Department of Health and Social Care”.

Page 5 (article 3) – replace “Department of Health” with “Department of Health and Social Care”.

Page 10 (article 2.1) – replace “Secretary of State for Health” with “Secretary of State for Health and Social Care”.

Page 12 (article 3.3.1l) – replace “Secretary of State for Health” with “Secretary of State for Health and Social Care”.

Page 14 (article 4.13) – replace “Department of Health” with “Department of Health and Social Care”.

Page 17 (article 4.12.1) – replace “Department of Health” with “Department of Health and Social Care”.

Page 19 (article 5.1.1 i) - replace " Department of Health” with “Department of Health and Social Care”.

Page 19 (article 5.1.1 m) – replace “Department of Health” with “Department of Health and Social Care”.

Page 24 (article 7.2.4) – replace “Department of Health” with “Department of Health and Social Care”.

Page 31 (**article 2.10)** – replace “three” with “two”.

Page 32 (article 2.12 e) – replace “Department of Health” with “Department of Health and Social Care”.

Page 33 (article 3.1) – add “and” between treatment and to; and delete “and to authorise the use of novel processes in licensed activities” so that it now reads “The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing, to authorise the use of mitochondrial donation treatment and to issue special directions for the import/export of gametes.”

Page 33 (article 3.2d) – add “, and” to the end of the sentence so it now reads “the authorisation of the use of maternal spindle transfer (MST) and/or pronuclear transfer (PNT) for a named patient (under The Human Fertilisation and Embryology (mitochondrial donation) regulations 2015), and

Page 33 (article 3.2e) – delete “, and” at the end of the sentence so it now reads “the issuing of special directions for the import/export of gametes or embryos (under section 24(4AA) of the Act).

Page 33 (article 3.2f) – delete “the authorisation of the use of novel processes in licensed activities.”

Page 33 (article 3.4a) – delete “a lay” and insert “an” so it now reads “a Committee Chair (who shall be an Authority member).”

Page 33 (article 3.4b) – delete “a lay” and insert “an” so it now reads “a Committee Chair (who shall be an Authority member).”

Page 33 – insert new article 3.5 and renumber subsequent articles “The committee shall have the power to co-opt additional members for particular expertise if needed. Any such appointment, and the term of office, shall be at the discretion of the Chair of the HFEA.”

Page 34 (current article 3.10 renumbered article 3.11) – delete “or novel processes” so it now reads “Decisions of the Statutory Approvals Committee to authorise embryo testing, mitochondrial donation treatment, or to issue special directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).”

Page 36 (article 5.1) – at the end of the sentence add “and to make decisions relating to authorised processes.” so the sentence now reads “The purpose of the Scientific and Clinical Advances Advisory

Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and relation areas and to make decisions relating to authorised processes."

Page 36 (title between articles 5.1 and 5.2") – add "Delegated powers and" to the beginning of the title so that it now reads "Delegated powers and Functions of the Scientific and Clinical Advances Advisory Committee"

Page 36 (add new article 5.2 and renumber subsequent articles) – "The Authority delegates to the Scientific and Clinical Advances Advisory Committee the following power: a) to make decisions relating to authorised processes"

Page 36 (current article 5.2 renumbered article 5.3) – insert the word "other" so that it now reads "The other functions of the Scientific and Clinical Advances Advisory Committee shall be to:"

Page 37 (add new article 5.11 and renumber subsequent articles) – "At the discretion of the Chair of Deputy Chair, the committee may meet additionally at short notice (and, if necessary, by telephone or video-conference) if the Chair and Deputy Chair considers there is an item (or items) which cannot be delayed until the next meeting."

Page 37 (add new article 5.12 and renumber subsequent articles) – "Decisions of the Scientific and Clinical Advances Advisory Committee relating to authorised processes require a simple majority of voting members (and in the event of a tie, the Committee Chair shall have a casting vote). No voting member of the Scientific and Clinical Advances Advisory Committee present at a meeting shall abstain."

Page 37 (add new article 5.13 and renumber subsequent articles) – "It is open to the Chair to request a legal adviser to be in attendance for decisions relating to authorised processes."

Page 39 (article 6.6) – replace "Department of Health" with "Department of Health and Social Care".

Page 42 (article 7.15) – replace "Department of Health" with "Department of Health and Social Care".

Page 45 (article 1.9) – replace "Members of the panel shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment." with "Members of the panel shall attend training and update sessions when needed."

Page 63 (article 2 Leadership) – replace "Holder of public office should exhibit these principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs." with "Holders of public office should exhibit these principles in their own behaviour and treat others with respect. They should actively promote and robustly support the principles and challenge poor behaviour wherever it occurs."

Annex B – Authorised Processes changes to the Standing Orders

Colour legend:
Yellow highlighting denotes proposed text for deletion
Green highlighting denotes proposed text for insertion

3. The Statutory Approvals Committee

Purpose of the committee

3.1 The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing; to authorise the use of mitochondrial donation treatment; and to issue special directions for the import/export of gametes~~; and to authorise the use of novel processes in licensed activities~~.

Delegated powers and functions of the Statutory Approvals Committee

3.2 The Authority delegates to the Statutory Approvals Committee the following powers:

a) the authorisation of the use of embryo testing for conditions not previously authorised by the Authority (under schedule 2, paragraph 1ZA(1)(a), (b) and (c) of the Act)

b) the authorisation of the use of embryo testing to establish whether the tissue of any resulting child would be compatible with that of a sibling that suffers from a serious medical condition (under schedule 2, paragraph 1ZA(1)(d)

c) the authorisation of the use of embryo testing to establish whether an embryo is one of those whose creation was brought about by using the gametes of a particular person (under schedule 2, paragraph 1ZA(1)(e)

d) the authorisation of the use of maternal spindle transfer (MST) and/or pronuclear transfer (PNT) for a named patient (under The Human Fertilisation and Embryology (mitochondrial donation) regulations 2015), and

e) the issuing of special directions for the import/export of gametes or embryos (under section 24(4AA) of the Act)~~, and~~

f) ~~the authorisation of the use of novel processes in licensed activities~~.

3.3 The functions of the Statutory Approvals Committee shall include:

a) keeping under review the genetic conditions authorised by the Authority for embryo testing.

Membership of the Statutory Approvals Committee

3.4 The Statutory Approvals Committee shall operate from a pool of up to 10 members, with no more than five members attending each meeting. The membership shall include:

a) a Committee Chair (who shall be ~~a lay~~ an Authority member).

b) a Deputy Committee Chair (who shall be ~~a lay~~ an Authority member);

c) up to eight other Authority members.

3.5 The committee shall have the power to co-opt additional members for particular expertise if needed. Any such appointment, and the term of office, shall be at the discretion of the Chair of the HFEA.

3.~~5~~6 The Chair of the HFEA shall appoint the members of the Statutory Approvals Committee.

Annex B – Authorised Processes changes to the Standing Orders

Colour legend:
Yellow highlighting denotes proposed text for deletion
Green highlighting denotes proposed text for insertion

3.~~6~~7 Members of the Statutory Approvals Committee shall usually be appointed for a term of three years.

Meetings of the Statutory Approvals Committee

3.~~7~~8 The quorum for a meeting of the Statutory Approvals Committee shall be three including the Committee Chair or Deputy Committee Chair and two other members.

3.~~8~~9 The Statutory Approvals Committee shall usually meet 12 times per year. At the discretion of the Chair, the committee may meet additionally at short notice (and, if necessary, by telephone- or video-conference) if the Chair considers there is an item (or items) which cannot be delayed until the next meeting.

3.~~9~~10 No member of the Statutory Approvals Committee present at a meeting shall abstain from voting.

3.1~~0~~0 Decisions of the Statutory Approvals Committee to authorise embryo testing, mitochondrial donation treatment ~~or novel processes~~, or to issue special directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).

Attendance at meetings of the Statutory Approvals Committee

3.12~~1~~ In addition to members of the Statutory Approvals Committee, the following persons shall usually attend its meetings:

a) a legal adviser

b) a specialist adviser

c) the Licensing Manager or the Head of Planning and Governance

d) the Committee Secretary.

3.13~~2~~ The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Statutory Approvals Committee and/or to provide advice to inform the deliberations of the Statutory Approvals Committee.

3.14~~3~~ The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the committee to withdraw from the meeting to enable the committee to deliberate in private.

Annex B – Authorised Processes changes to the Standing Orders

Colour legend:
Yellow highlighting denotes proposed text for deletion
Green highlighting denotes proposed text for insertion

5. The Scientific and Clinical Advances Advisory Committee

Purpose of the Committee

5.1. The purpose of the Scientific and Clinical Advances Advisory Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas and to make decisions relating to authorised processes.

Delegated powers and Functions of the Scientific and Clinical Advances Advisory Committee

5.2. The Authority delegates to the Scientific and Clinical Advances Advisory Committee the following power:

a) To make decisions relating to authorised processes

5.3. The other functions of the Scientific and Clinical Advances Advisory Committee shall be to:

a) make recommendations to the Authority on the safety and efficacy of scientific and clinical developments (including research) in assisted conception, embryo research and related areas
b) make recommendations to the Authority on patient information relating to those scientific and clinical developments
c) advise the Authority on significant implications for licensing and regulation arising out of such developments, and
d) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments

Membership of the Scientific and Clinical Advances Advisory Committee

5.4. The Scientific and Clinical Advances Advisory Committee shall consist of at least three Authority members, which shall include:

a) a Committee Chair (who shall be an Authority member)
b) a Deputy Committee Chair (who shall be an Authority member), and
c) up to four other Authority members

5.5. In addition, up to eleven other persons, who shall not be Authority members, shall be appointed as expert advisers to the committee. Such persons shall not be entitled to vote.

5.6. At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.

5.7. The Chair of the HFEA shall appoint the members of the Scientific and Clinical Advances Advisory Committee.

Colour legend:
Yellow highlighting denotes proposed text for deletion
Green highlighting denotes proposed text for insertion

5.8. Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a maximum of two terms, with a period of one, two or three years.

Meetings of the Scientific and Clinical Advances Advisory Committee

5.9. The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be three including the Committee Chair or Deputy Committee Chair of the committee.

5.10. The Scientific and Clinical Advances Advisory Committee shall usually meet three times each year.

5.11. At the discretion of the Chair or Deputy Committee Chair, the committee may meet additionally at short notice (and, if necessary, by telephone or video-conference) if the Chair or Deputy Chair considers there is an item (or items) which cannot be delayed until the next meeting.

5.12. Decisions of the Scientific and Clinical Advances Advisory Committee relating to authorised processes require a simple majority of voting members (and in the event of a tie, the Committee Chair shall have a casting vote). No voting member of the Scientific and Clinical Advances Advisory Committee present at a meeting shall abstain.

5.13. It is open to the Chair to request a legal adviser to be in attendance for decisions relating to authorised processes.

Attendance at meetings of the Scientific and Clinical Advances Advisory Committee

5.14. The Committee Chair may invite such other persons (including employees) as he/she consider appropriate, to attend the meetings of the Scientific and Clinical Advances Advisory Committee and/or to provide expert advice to inform the deliberations of the committee.

5.15. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Scientific and Clinical Advances Advisory Committee to withdraw from the meeting to enable the committee to deliberate in private.

Donor compensation

Details about this paper

Area(s) of strategy this paper relates to:	The best care
Meeting:	Authority
Agenda item:	9
Paper number:	HFEA (20/03/2024) 9
Meeting date:	20 March 2024
Author:	Joanne Anton, Head of Policy

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to discuss and approve: • An updated compensation rate for donors who donate at UK clinics, considering inflation, of: UK sperm donors - £45 per clinic visit UK egg donors - £985 per donation cycle • A new compensation rate for overseas donors whose gametes or embryos are imported into the UK to bring in line with the updated UK rates and consider inflation. • Donor compensation rates to be reviewed by the HFEA Executive every five years, or when the GDP deflators have shown a 10% increase in inflation, whichever occurs sooner.
Resource implications:	Will require a change to General Directions and Code of Practice
Implementation date:	Executive to implement change during 2024-25, as resources allow.
Communication(s):	Circulation of a Chair's letter through Clinic Focus
Organisational risk:	Low

1. Background

1.1. In October 2011 the HFEA undertook a large-scale public consultation on its donation policies. Views were sought from clinics, the public, donors and other interested stakeholders on various donor issues, including on compensation.

1.2. The Authority considered the consultation findings and agreed to several recommendations with the aim of removing unnecessary barriers to gamete donation in the UK. This included that clinics could compensate sperm donors a fixed sum of up to £35 per clinic visit, and egg donors a fixed sum of up to £750 per cycle of donation. Donors could be compensated in excess of these amounts as long as the expenses were reasonable, and in connection with their donation within the UK.

1.3. The Authority felt that the compensation amounts struck the right balance between covering donor expenses and donors feeling valued, but not enough to remove the altruistic motivations behind donating gametes and embryos.

1.4. In 2014 an assessment was carried out to measure the impacts of these changes which found that the total number of donor cycles had increased. Sperm donation had steadily increased year on year, and egg donation had increased. This was potentially because of increased compensation, awareness, and marketing by clinics. It was also found that clinics rarely compensated donors for excess expenses, suggesting that the amount the Authority set was at the right level. Since this assessment, egg and sperm donor numbers have largely remained stable, excluding decreases due to COVID-19.

1.5. There have been no changes to the compensation rates for donors since they were agreed by the Authority in 2011. The impact of inflation, particularly since 2020-21, means that in 2024 the donor compensation rates are not reflective of the intended monetary value when the rates were set in 2011.

1.6. This paper asks the Authority to consider increasing donor compensation rates in line with inflation, and to bring the limits for the compensation of imported donors in line with the UK. The Authority is also asked to agree that going forward, donor compensation rates should be uprated on a regular basis to take account of inflation.

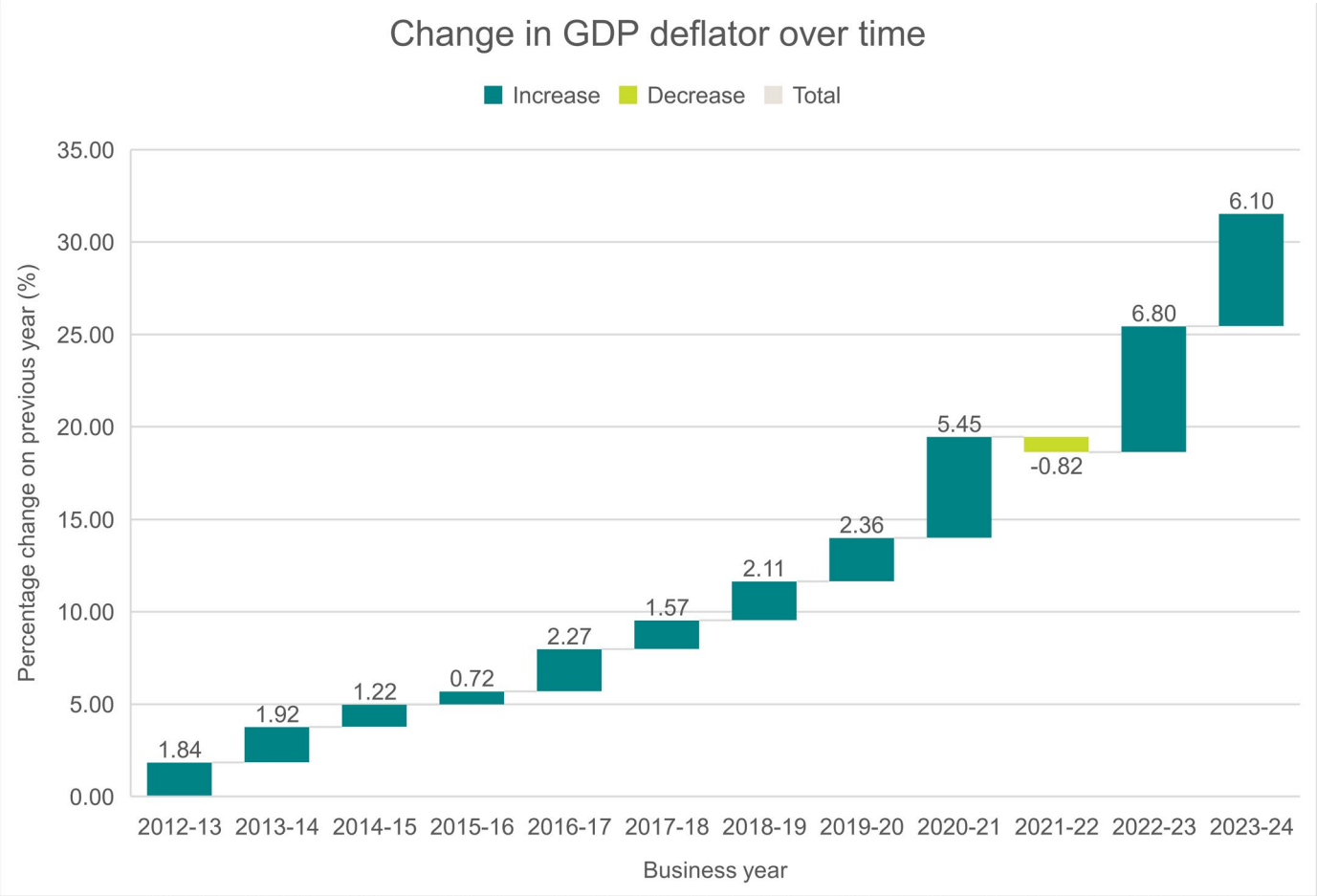
2. Compensation rate considering inflation

2.1. There are different measures of inflation used to determine the true value of a product or service with the change in price over time. Gross Domestic Product (GDP) deflators are typically used by the Treasury and public sector to estimate real term growth over time. They show the change in price for all goods and services produced in the economy, including exported goods, so indicate the general inflation in the domestic economy. This is different from other indexes, such as the consumer price index (CPI), which measures the cost of a fixed basket of goods and services at a specific time point and reflects the changes in consumers cost of living.

2.2. The impact of inflation as measured by GDP deflators is shown in Figure 1. Between 2012-13 and 2019-20, inflation was around the Bank of England target of 2%, but more recently inflation has risen to over 6%. on year, as shown in Figure 1. However, in 2022-23 there was an

increase of 6.80% compared to the previous financial year, and an estimated increase of 6.10% in 2023-24. This demonstrates the recent steep increase in inflation.

Figure 1 GDP deflators increase from 2012-13 to 2023-24



2.3. As set out above, the current compensation rate for sperm donors at £35 per clinic visit was set in 2011. Using the GDP deflators, the percentage change between 2012-13 and 2023-24 is 31.53%. This would mean an equivalent compensation rate in 2023-24 of around £45.

2.4. For egg donation, the compensation rate in 2011 was set at £750 per cycle of donation. This would mean an equivalent compensation rate in 2023-24 of around £985.

2.5. If the Authority agrees that the compensation rate of donors should be uprated to take account of inflation since 2011 then it would be beneficial to agree a process to regularly review the rate going forward to ensure it remains relevant and is adjusted for the impact of inflation over time.

2.6. The review period would need to be long enough to allow for a real impact on the compensation rate, whilst not being too long to make the compensation rate significantly out of line with the intended value. Therefore, the Executive recommends a review period of every five years, or when the GDP deflators have shown a 10% increase in inflation, whichever occurs sooner.

3. Overseas donors

3.1. Patients receiving donor treatment may choose to use gametes or embryos donated at a UK clinic or they may choose to import gametes or embryos donated abroad and imported into the UK. In recent years the use of imported sperm has increased. In 2011 imported donors represented around 27% of new sperm donors, however in 2021 65% of new donors were from overseas. In 2020 donor imports from the USA and Denmark accounted respectively for 27% and 21% of new sperm donors registered in the UK. Donor eggs are less frequently imported, with only 4% of egg donors imported in 2011, decreasing to 1% in 2021.

3.2. The compensation rate for donations that had taken place abroad was not addressed in the 2011 donation review. This was due to considerations about the difference in value of the new compensation rate in countries outside of the UK. Therefore, the compensation rate for overseas donors remained unchanged and is currently different from UK compensation rates.

3.3. Eggs, sperm or embryos donated overseas that are imported into the UK must meet the requirements set out in the relevant HFEA **General Direction**. This includes ensuring that the donor has not received compensation which exceeds:

a) reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre; and
b) loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).

3.4. When considering overseas donation, it is not practical to introduce individual compensation rates for every country and to monitor and adjust these limits as currencies and economies change over time.

3.5. To streamline the import of gametes donated overseas, we propose to bring overseas donor compensation rates in line with UK compensation rates. This would mean that one rate for compensation would be applied for all donations used within the UK, regardless of whether they were donated in the UK or abroad.

3.6. We therefore recommend that the Authority agree to bring the compensation rate for overseas donors in line with the UK rate.

4. Recommendation

4.1. The Authority is asked to discuss and approve:

- That the compensation rate for UK based gamete donors be uprated to take account of inflation, to a new rate of:
  - UK sperm donors - £45 per clinic visit
  - UK egg donors - £985 per donation cycle
- That the compensation rate for overseas donors being imported into the UK is brought in line with UK rates.
- That going forward donor compensation rates are reviewed by the HFEA Executive every five years, or when the GDP deflators have shown a 10% increase in inflation, whichever occurs sooner.