Human Fertilisation & Embryology Authority

Authority meeting

Date: 15 May 2024 –1.00pm to 2.55pm

Venue: Virtual Teams Webinar

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	1.00pm
2. Minutes of the meetings held on 20 March 2024 and matters arising (5) For decision	1.05pm
3. Chair and Chief Executive's report (10) For information	1.10pm
4. Committee Chairs' reports (20) For information	1.20pm
5. Annual Performance Report 2023-2024 (30) For information	1.40pm
6. The Register Research Panel annual report (20) For information	2.10pm
7. Proposed legislative changes on posthumous storage and screening (20) For decision	2.30pm
8. Any Other Business (5)	2.50pm
9. Close	2.55pm

Minutes of Authority meeting held on 20 March 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	15 May 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 20 March 2024 as a true record of the meeting.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Minutes of the Authority meeting on 20 March 2024

Members present	Julia Chain Tim Child Frances Flinter Zeynep Gurtin Jonathan Herring Alex Kafetz	Alison Marsden Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Graham James Alison McTavish	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Steve Pugh (Department of Health and Social Care – DHSC) Farhia Yusuf (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar	Paula Robinson Shabbir Qureshi Joanne Anton Mina Mincheva 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. Members were informed that Alex Kafetz would join online during the course of the meeting,

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 minute 8.3 be amended so that it now reads:

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. Members were assured that specialist counselling and counsellor-facilitated meetings could be organised privately by those donor conceived individuals interested and that take-up to date had been variable. These were a significant factor in the decision-making process, and it was noted that any future model of support needs to be financially sustainable.

2.2. With this amendment members agreed that the minutes of the meeting held on 24 January 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 and the Opening the Register (OTR) report in agenda item 6.

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 that she attended the Scientific and Clinical Advances Advisory Committee (SCAAC) in early February and conducted interviews for new SCAAC members towards the end of February. Ying Cheong, Peter Rugg-Gunn, and Veronique Berman have been appointed to the committee. The SCAAC Chair (Tim Child), spoke of the high calibre of candidates which reflected the high regard in which the work of the HFEA and SCAAC is held by professionals.

3.3. The Chair updated the Authority on the progress of recruitment for the four new Authority members, with the skill sets of embryology, genetics/statistics, legal/ethical and patient experience. It was reported that there is a strong short list of candidates and interviews are being held next week. The Chair reminded members that both ministerial and Number 10 approval are required for Authority members appointments.

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

3.5. The Chief Executive spoke about the Nuffield Council on Bioethics (NCOB) launch of their new strategy which was held at the end of January. He informed members that at the heart of this strategy was a move to shorter, more policy focussed reports.

3.6. The Chief Executive informed members that the HFEA will be working with NCOB on a new project exploring the ethical and regulatory questions surrounding embryo models. He spoke about the potential opportunities of this partnership and the benefits of working together on common issues. Members spoke in support of this partnership and asked that further information be sent to them on the project.

Decision

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

Action

3.8. Chief Executive to send members further details about the NCOB project on embryo models.

4. Committee Chairs' reports

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

4.2. The Licence Committee Chair (Alison Marsden) gave an overview of recent meetings, including the recent decision regarding suspension of a licence due to significant concerns, and the subsequent press coverage. She spoke about the importance of the HFEA's regulatory work and the high regard that this work is held in. She took the opportunity to thank the committee and the staff who supported it for all their work during her tenure as Chair.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further information on the review of autosomal deafness conditions which was brought to the committee by an expert reviewer. He reminded members of the regulatory requirement to consider such assessments and that the committee had approved those presented by the expert reviewer.

4.4. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child), spoke about the visit to the Newcastle Fertility Centre to learn more about the mitochondrial donation programme and informed members that the Newcastle team will be invited to attend a future SCAAC meeting to update further.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an update on the work of the committee. She informed members that the Code of Practice audit had received a substantial rating, with no recommendations for action, and that this is the highest rating that can be achieved. The committee had agreed the 2024/25 audit plan and had considered the longer-term audit planning list. The good progress on closing outstanding audit actions was noted and a deep dive discussion on specific governmental functional standards was held.

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, five are red, three amber, six green and three neutral. Members complimented the new presentation of the RAG rating.

5.2. PRISM activity levels continue to be stable with an error rate of 3.5%. The targeted approach for those clinics who have an error rate higher than 4% continues. The Chief Executive informed members that the verification process for Choose a Fertility Clinic (CaFC) has commenced and he explained the process in greater detail. The benefits of PRISM and the ability to manage and share data more easily were noted.

5.3. The Chief Executive spoke about the HR KPIs and stated that as a small organisation the KPI for staff sickness continues to be negatively impacted by long-term sick leave. As previously reported these are distinct cases unrelated to stress or workload.

5.4. The Chief Executive informed members that the KPI for staff turnover has increased slightly above the agreed target band and he informed members that other comparable organisations have a much higher turnover rate than the HFEA. He did not have any information to indicate that this trajectory will increase further.

5.5. A member asked whether it would be possible to create two new KPIs for Opening the Register (OTR) relating to the number of applications and waiting list and the average time for logging an application as completed. The member further questioned whether the Executive could predict how OTR services will be affected by the full realisation of PRISM.

5.6. The Chief Executive responded that metrics which break down the total number of applications will be possible, but that any such reports need to be relevant for the team. He stated that PRISM provides the OTR team with new data management tools and now that they are being used the Executive should be able to establish a productivity rate which could be used to measure performance going forward.

Compliance and Information

5.7. The Director of Compliance and Information informed members that OTR applications were extremely high in January and February due to raised awareness arising from the documentary Born from the Same Stranger.

5.8. It was reported that the OTR team are using the case management tools to split applications into different categories and are working on how to report KPIs and application numbers in a useful, purposeful manner. It is anticipated that by June more meaningful reports will be able to be produced.

5.9. The Director of Compliance and Information informed members that the Compliance team was being impacted by long-term absence. Whilst this and the extra inspections had put additional pressure on the inspection team it has not resulted in a clinic not being able to have a licence renewed. It was reported that in the period from January to September 2024 72 inspections had been scheduled.

5.10. A member questioned how the inspection team was bearing up under this additional pressure. The Director of Compliance and Information responded that it had been a difficult time with a busy and demanding schedule, and she took the opportunity to thank the team for all their work. Additional resources had been allocated to recruit an additional inspector and it would be necessary to consider resourcing going forward.

5.11. Turning to IT, the Director of Compliance and Information informed members that the HFEA's VPN solution was changed recently, due to a loss of confidence in the previous vendor and security vulnerabilities. The change over had been a smooth process and thanks were given to the IT team for managing this change at pace.

Strategy and Corporate Affairs

5.12. The Director of Strategy and Corporate Affairs spoke about the high media interest and the increased communications activities partly arising from the Born from the Same Stranger documentary, the BBC iPlayer programme on egg freezing and wide interest in incidents/licensing. She thanked those Authority members who had participated in various media interviews.

5.13. The success of the dashboard since its launch was highlighted. The new media centre was recently launched on the HFEA website, and thanks were given to the HFEA staff who had implemented this.

5.14. The Director of Strategy and Corporate Affairs commented that the busy period for the inspection team has a knock-on effect on the licensing team, especially the Executive Licensing Panel and the actions taken to manage this work was explained.

5.15. It was reported that planning for the new business year was well advanced and includes projects such as setting out what a workstream on AI will look like, further development of the dashboards, further work on two aspects of our work on law reform and preparation for the fertility trends report and next national patient survey.

5.16. The Director of Strategy and Corporate Affairs informed members that she had attended the Institute for Regulation annual conference, and it was a good opportunity to hear from other regulators how they are addressing similar issues to those that the HFEA are facing.

5.17. Members were informed that planning is underway for the next patient and professional stakeholder groups which are being held in April/May.

Finance

5.18. 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 around £100k 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, as well as a reduction of Grant in Aid (GIA) of £100k that had not been recognised at the beginning of the year. This position is likely to change as year-end is approached and various accounting adjustments may be made due to the audit process. He reported that there is a good exchange of information and communication with the finance business partners in the Department who have not requested that HFEA undertake any specific action to reduce the deficit.

5.19. Members were informed that communications had been issued to clinics regarding the fee increase.

5.20. The Director of Finance and Resources informed members that the bid for the Epicentre replacement had been submitted to the Department and a response was expected by the end of the month. He spoke about the consequences and actions required if the bid was unsuccessful and stated that this had also been communicated to clinics.

5.21. In response to a question regarding the reduction in IVF cycles the Chief Executive stated that it is not yet clear why but there is always an adjustment in figures before year end and past experience suggested that the number is likely to increase somewhat. The majority of IVF cycles in England and Wales are conducted privately so it could be assumed that this may have been affected by the increased cost of living, whereas cycles in Scotland are fully funded.

Decision

5.22. Members noted the performance report.

6. Opening the Register - update

6.1. The Chair introduced this agenda item and reminded members that as this was a critical year for Opening the Register (OTR) it had been agreed that this would be reported as a standalone agenda item, but members had agreed at the January meeting that further monitoring of OTR from April onwards would be through the performance report.

6.2. The Director of Strategy and Corporate Affairs presented the paper reminding members of the three workstreams contained in the report of OTR services/infrastructure, future of support services and communications.

6.3. The Director of Compliance and Information spoke positively about the benefits of the new IT systems and the reports it can produce for the OTR team; this has made training of new team members easier. The updating of SOPs is still being worked on to ensure that complex scenarios and the procedures to follow are fully captured.

6.4. The Director of Compliance and Information reminded members of the decision taken at the last meeting regarding support services and the agreement to improve and expand all the HFEA's information and signposting for donor conceived people and donors. This work will be conducted throughout 2024.

6.5. As agreed at the last meeting, options regarding the Letterbox service had been issued to members via email and members had agreed that the Letterbox service should not be brought in-house and that the HFEA should issue information and advice to donor conceived people on making initial contact with their donor or donor sibling.

6.6. The Director of Strategy and Corporate Affairs spoke about the success of the #WhoIsMyDonor campaign and the need to pause some of the activities to avoid overloading the team. In February the Corporate Management Group (CMG) has agreed to covert content from that campaign to ongoing business as usual (BAU) activities. Members were informed about the successful Instagram live Q&A session which targeted donor conceived individuals (DCIs) and donors.

6.7. The Director of Strategy and Corporate Affairs spoke about the remaining risks as identified in the paper and stated that reputational risks remain, as the HFEA manages the increasing waiting list of applications and the expectation of how long it takes to process an application.

6.8. Members were informed that each workstream will be completed by the end of the business year, with some aspects being taken forward through BAU activities.

6.9. In response to a question regarding managing the waiting list the Director of Compliance and Information stated that the number of applications received January-March were more than three times the average. An additional member of staff had been recruited to support the OTR team and applications were now being streamed into different categories so they can be managed in a more efficient way.

6.10. In response to a question the Director of Compliance and Information informed members what constitutes repeat applications.

6.11. The Chair drew the discussion to a close noting that future reporting will be in the performance report and requested that this includes information about managing the waiting list.

Decision

6.12. Members noted the update on OTR.

7. Authorised Processes Review

7.1. The Policy Manager introduced the paper and stated that 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.

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

7.3. The application process which a centre must follow if they wish to use a process which does not appear on the AP list was explained.

7.4. The Policy Manager reminded members that currently the Authority has delegated the authorisation of processes to SAC, who are advised on the matter by SCAAC. The roles of both SCAAC and SAC was explained in more detail.

7.5. The proposal is to move the AP decision making powers to SCAAC. It was reported that both committees have been consulted on and support this proposal. It was noted that the required changes to the standing orders were explained in detail in the Effective Governance paper.

7.6. The Chair of SCAAC stated that the current process is complicated as two committees consider the same matter. This proposal improves efficiency. He reiterated that both committees are fully supportive of the proposals contained in the paper.

7.7. The required updates to the decision tree were explained and the proposal is that the Executive develops the new decision tree and guidance in collaboration with SCAAC with final agreement and approval of these documents being given by SCAAC.

7.8. In response to a question the Chief Executive confirmed that the Authority had the power to delegate within the existing legal framework. The composition of SCAAC was discussed noting that it was only Authority members who had voting power.

7.9. The name of SCAAC was discussed and it was agreed that it was still relevant and suitable as almost all of the committee's work was of an advisory nature.

Decision

7.10. Members agreed the proposed updates to the AP list.

7.11. Members agreed the proposal to divert the decision-making powers relating to AP from SAC to SCAAC via changes in the standing orders.

7.12. The development of a new decision tree and accompanying guidance for decisions relevant to AP and that SCAAC be given authorisation to approve these documents.

7.13. Members agreed to delegate authority to the Chair for approving changes to GD 0008.

Action

7.14. The Executive to implement the Authority's decisions on Authorised Processes.

8. Effective Governance

8.1. The Chair introduced the agenda item and reminded members that on an annual basis all committees were required to review their own effectiveness using a standard and/or bespoke framework. Between September 2023 and early March 2024 this exercise was conducted by the Licence Committee, Executive Licensing Panel, Statutory Approvals Committee, the Scientific

and Clinical Advances Advisory Committee, the Audit and Governance Committee and the Register Research Panel. Thanks were given to all members who participated in the reviews.

8.2. The Board Governance Manager introduced the paper and informed the Authority that all committees stated that the meetings and papers were well prepared and that they had sufficient information necessary to take decisions.

8.3. Each committee had made a number of recommendations for improvement and the proposed actions against these recommendations are shown in the paper.

8.4. The proposed changes to the standing orders were explained, noting that the Authority had agreed in the previous agenda item to divert the decision-making powers relating to AP from SAC to SCAAC and these changes were shown in Annex B of the paper.

8.5. The Chair expressed their appreciation of the team that supports the various committees in their work.

8.6. The Chair noted that with the appointment of four new Authority members the composition of committees will need to be reviewed. It may also be appropriate to review the terms of reference of all the committees during the next business year.

Decision

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

8.8. Members also noted the summary of actions contained in the annual review of committee effectiveness.

Action

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

9. Donor Compensation

9.1. The Head of Policy introduced the paper and stated that there have been no changes to the compensation rates for donors since they were agreed by the Authority in 2011. When the rates were agreed in 2011 the Authority felt that the compensation amounts struck the right balance between covering donor expenses and donors feeling valued but were not enough to remove the altruistic motivations behind donating gametes and embryos.

9.2. The Head of Policy stated that 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. The proposal is to uprate the level of compensation for UK sperm donors to £45 per clinic visit and UK egg donors to £985 per donation cycle.

9.3. The proposed review period was explained with the recommendation that the Executive reviews every five years, or when the GDP deflator has shown a 10% increase in inflation, whichever occurs sooner. This would ensure that the value of donor compensation remainder broadly equivalent over time.

9.4. The Head of Policy informed members that during the 2011 review the compensation rate for donations that had taken place abroad had not been addressed and the proposal now is that that these be brought in line with UK rates. The Head of Policy explained that 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.

9.5. In response to a question regarding excess expenses the Head of Policy stated that these are set out in the Code of Practice and General Directions. It is the responsibility of clinics to record and document any such expenses and make these available for inspectors to review.

9.6. In response to a question regarding monitoring the rates of donor compensation in Europe the Chief Executive stated that it is has been looked at, and the rates set by the HFEA are in the middle of the range.

9.7. A member expressed concern that if the compensation rates are increased by inflation this might be taken as incentivising donations during a cost-of-living crisis. The member questioned whether this could be considered as removing altruistic motivation. The Chief Executive spoke about the principles of the value agreed by the Authority in 2011 and how, due to inflation, that value is considerably less than when it was agreed in 2011. The proposal contained in the paper seeks to maintain that value in principle.

9.8. A member question whether it would be possible to look at the number and profile of donors post the implementation of any increase to see whether it affects the profile of donors. The Director of Strategy and Corporate Affairs referred to the report on trends in egg, sperm and embryo donation in 2020 which was published in November 2022 and undertook to recirculate this report to members.

9.9. Several members spoke in favour of the proposals noting that egg donation is an invasive and complex procedure.

9.10. In response to a question the Head of Policy stated that the communication issued to clinics can reinforce the requirement that donors must be offered counselling.

9.11. The Director of Strategy and Corporate Affairs reminded members that whilst the HFEA is a UK wide regulator, the Scottish Government has decided that no donor compensation is given to donors via the NHS in Scotland.

9.12. The Chair drew the discussion to a close and asked members to vote on each recommendation contained in the paper.

Decision

9.13. Members agreed 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 and UK egg donors £985 per donation cycle.

9.14. Members agreed that the compensation rate for overseas donors being imported into the UK is brought in line with UK rates.

9.15. Members further agreed that donor compensation rates are reviewed by the HFEA Executive every five years, or when the GDP deflator has shown a 10% increase in inflation, whichever occurs sooner.

Action

9.16. The Executive to implement the Authority's decisions regarding donor compensation rates.

9.17. The Director of Strategy and Corporate Affairs to recirculate the report on trends in egg, sperm and embryo donation in 2020 to members.

10. Any other business

10.1. The Chair thanked all for their active participation in the meeting. She informed members that whilst the HFEA's standing orders do not allow for proxy voting, Alison McTavish had sent via email her support for all the proposals contained in the papers. The Chair asked that this be recorded in the minutes.

10.2. The Chair informed members about the potential of an Authority away day in November and she asked members to reserve the 19 November 2024 for this.

10.3. The Chair informed members that Alison Marsden's term will finish at the end of March, and this was her last Authority meeting. On behalf of the HFEA the Chair thanked Alison for her contribution and especially for her work as Chair of the Licence Committee. The HFEA was very fortunate to benefit from her skills and her contribution will be greatly missed.

10.4. There being no further items of any other business the Chair reminded members that the next meeting will be held on 15 May 2024.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 15 May 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	15 May 2024		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For discussion		
Recommendation	To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.		
Resource implications	To be updated and reviewed at each Authority meeting		
Implementation date	2024/25 business year		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

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. DHSC sent confirmation of our GIA allocation for 2024/25 on 28 March 2024, including approval of our budget request for £618k to fund epicentre. This action can now be removed.
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		As reported at the March meeting this work is being delivered and can now be considered within BAU activities. Therefore, this action is complete and can be removed.
3.18 Chief Executive to send members further details about the NCOB project exploring the ethical and regulatory questions surrounding embryo models.	20 March 2024	Chief Executive	April 2024		Completed, this action can now be removed.
7.14 The Executive to implement the Authority's decisions with regarding to AP.	20 March 2024	Head of Planning and Governance	June 2024		Executive has implemented the Authority's decision; the planned work is contained within BAU activities. This item is now complete and can be removed.
8.9 The Board Governance Manager to publish the revised standing orders.	20 March 2024	Board Governance Manager	April 2024		Standing orders published. This item is now complete and can be removed.
9.16 The Executive to implement the Authority's decisions regarding donation compensation rates.	20 March 2024	Head of Policy	October 2024		Executive is drafting guidance and amending Direction 0001 to come into force on 1 October 2024. Given this requires a change to Directions the Authority is asked to delegate responsibility for signing off on the amended Direction 0001 to the Chair.
9.17 The Director of Strategy and Corporate Affairs to recirculate the report on trends in egg, sperm and embryo donation in 2020 to members.	20 March 2024	Director of Strategy and Corporate Affairs	April 2024		Report reissued to Authority members 20 March 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:	15 May 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 March 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:

    - 25/26 March – participated in DHSC led interview panel to make recommendations to ministers on the appointment of new board members.
    - 17 April – attended (with Peter) the ALB Senior leaders meeting (chief executives and Chairs meeting). Later that evening I also spoke at the PET conference on the legacy of Mary Warnock.
    - 3 May – spoke at the SHREG (Scottish Reproduction and Embryology Group) conference in Dundee.
    - 13 May – attended the Board of Deputies Family Law Group meeting and spoke about the work of the HFEA.
    - In addition, I have conducted the annual appraisals of Board members.

2.2 Chief Executive

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

    - 27 March – attended the DHSC/HFEA Quarterly Accountability meeting.
    - 17 April – attended (with Julia) the ALB Senior leaders meeting (chief executives and Chairs 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:	15 May 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:		
7 March	1 Renewal 2 Executive updates	Renewal approved. Suspension notice and Special Directions issued to one clinic. One report noted.
2 May	1 Interim 2 Executive updates	Minutes not yet approved
Other comments:	None.	
Executive Licensing Panel:		
19 March	1 Initial 4 Renewals 1 Variation of licensed premises 2 Interims	All granted
2 April	3 Renewals 2 Interims 1 Variation of PR 1 One-year licence extension (research)	All granted
17 April	1 Initial 4 Interims 1 Variation of licensed premises	All granted
7 May	3 Renewals 2 Interim 1 Variation of Licence Holder 1 Variation of Person Responsible	Minutes not yet approved
Other comments:	None.	
Licensing Officer decisions:		
March-April	28 ITE import certificates 1 Change of LH 2 Changes of Address	All granted
Other comments:	None.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
27 February	4 PGT-M applications 1 review of autosomal deafness conditions 3 Special Directions for import/export	All approved. 32 additional conditions approved. 1 granted, 2 adjourned.
25 March	4 PGT-M applications 1 Special Direction for import	All approved. Name changes for 17 additional conditions historically described as 'Mental Retardation, Autosomal Dominant (MRD)'
30 April	5 PGT-M applications 1 Special Direction for import	Minutes not yet approved.
Other comments:	None.	
Audit and Governance Committee:		
The next meeting will be held on 26 June 2024.		
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
The next meeting will be held on 3 June 2024.		
Other comments:	None.	

3. Recommendation

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

Human Fertilisation & Embryology Authority

Annual performance report

April 2023 - March 2024

Evgenia Savchyna
Corporate Performance Officer
15/05/2024

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 5
Meeting date:	15/05/2024
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

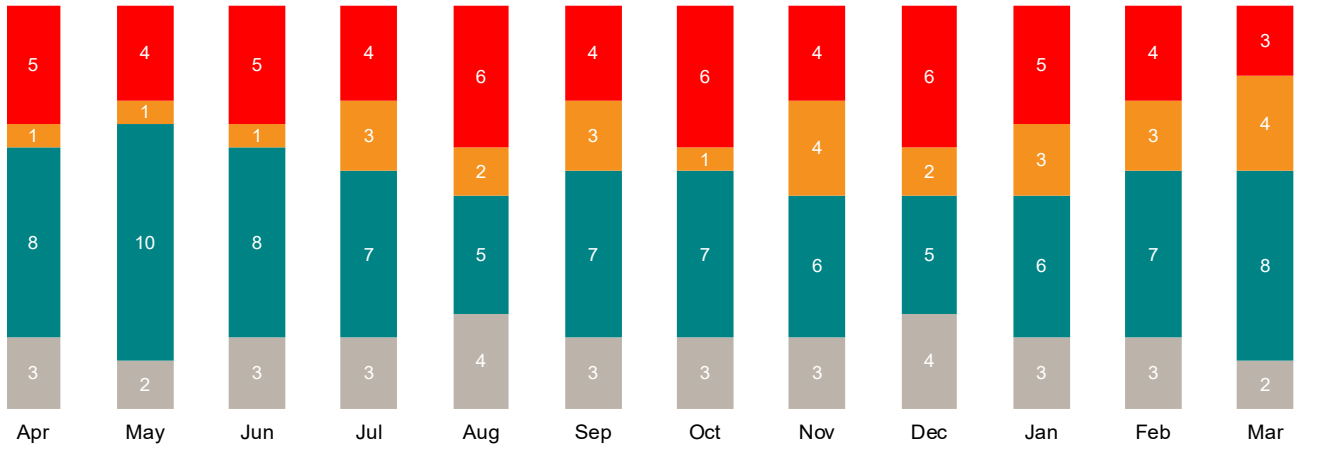
Output from this paper	
For information or decision?	For information
Recommendation:	To discuss
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Corporate Management Group (CMG) reviews performance in advance of each Authority meeting, and their comments are incorporated 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

Key performance indicators

Human Fertilisation & Embryology Authority

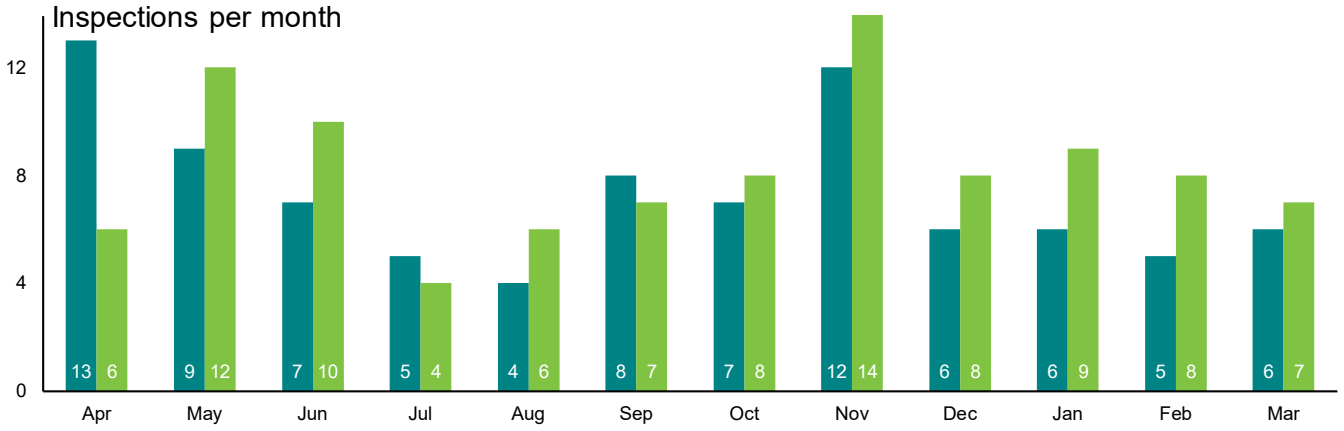
RAG status over last 12 months



RAG status over last 12 months

17 KPIs in total for each month

KPI performance over the last year has been variable with the following averages across the year:
Red = 4.7 Amber = 2.3 Green = 7.0 Neutral = 3.0



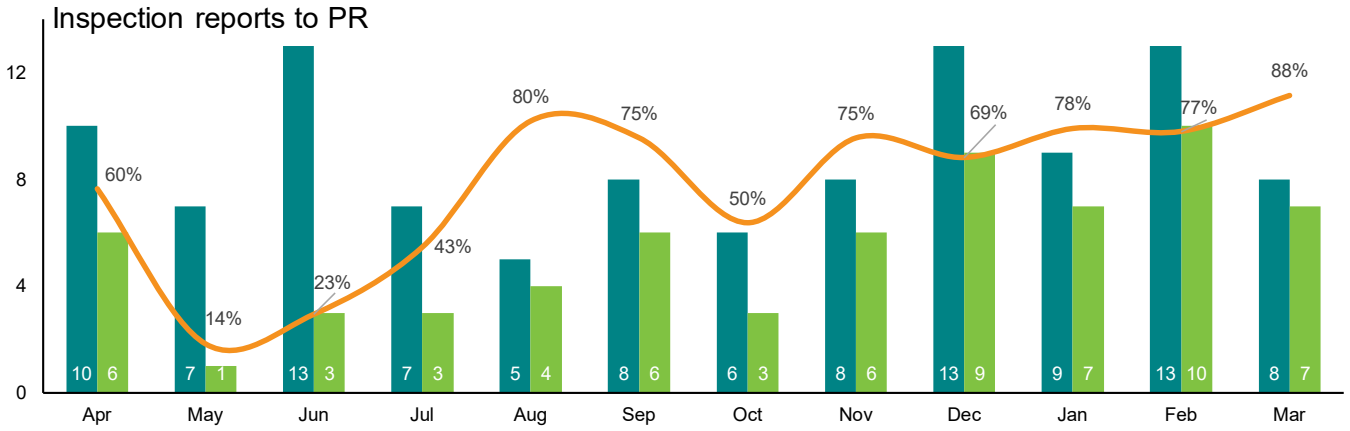
Status: **N/A**

Compliance

Inspections delivery

Target: **not defined**

Inspection workload remains higher than planned, in part due to the continuing impact from the pandemic on the schedule and in part due to additional clinic visits due to regulatory concerns.



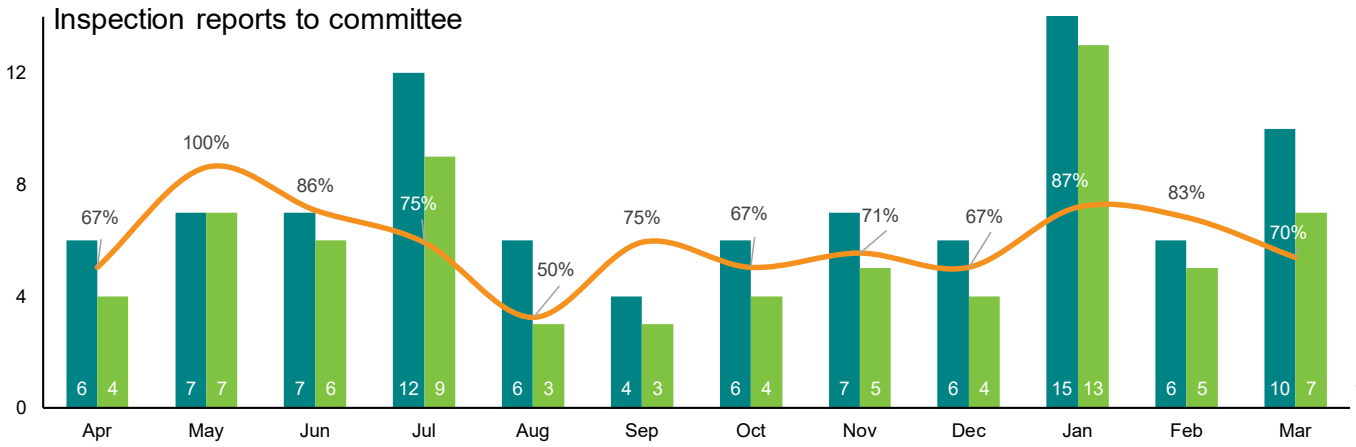
Status: **N/A**

Compliance

Inspection reports sent to PR

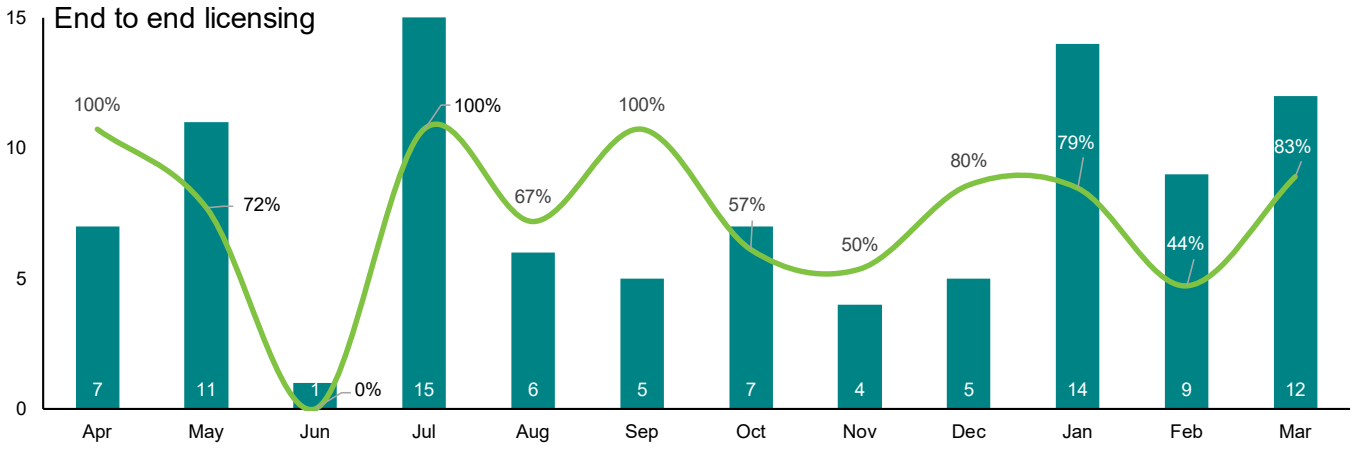
New target from Dec: **100% sent within 25 working days**

A steady improvement has been seen over the year, with an average of 73% achieving the KPI in the last 6 months.



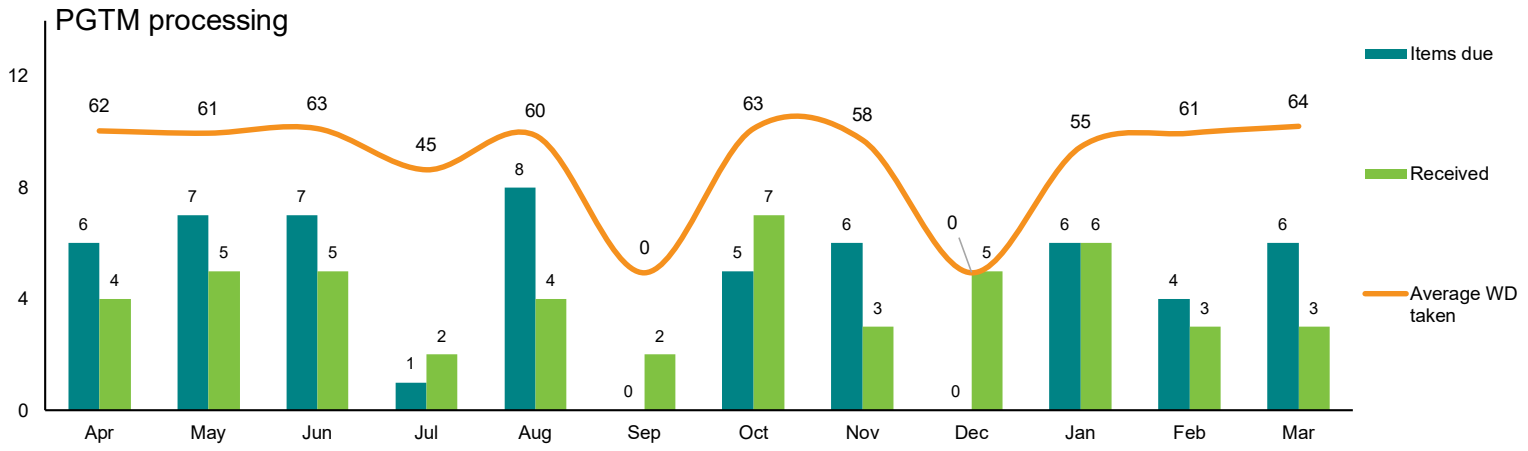
Status:	N/A
Compliance	
Inspection reports sent to relevant licensing committee	
New target from Dec: **100% sent within 65 working days**	

Inspection reports vary in complexity. Those that require extra Quality Assurance and assessments against the Compliance and Enforcement Policy which often involve senior staff which will impact on the KPI. Report KPI's are also impacted by delays in reports being returned back to inspectors. Staff turnover and absence has also affected this KPI.



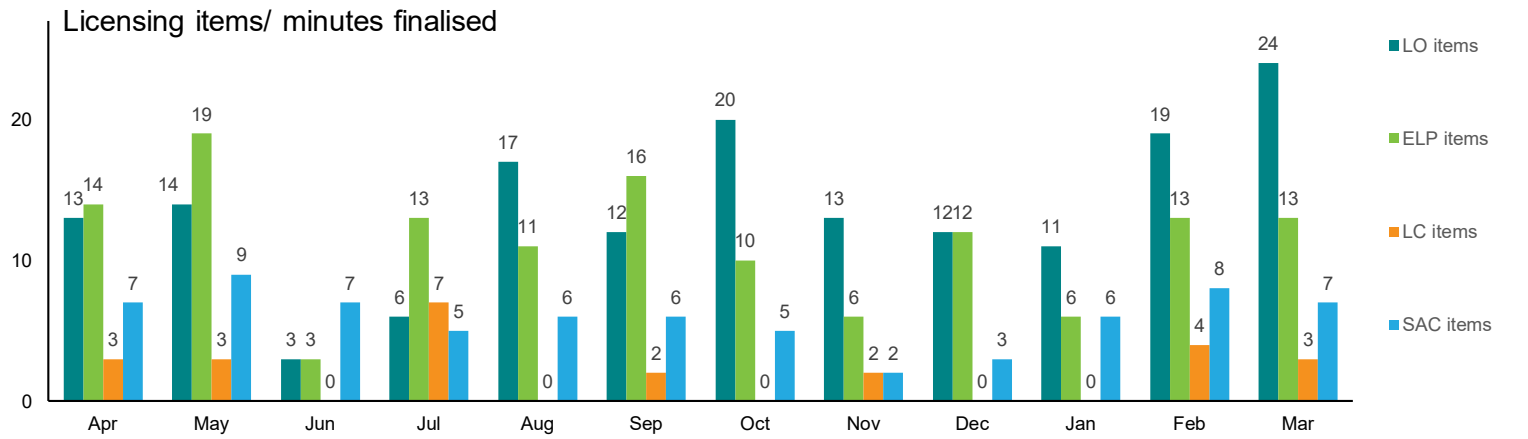
Status:	N/A
Compliance	
End to end licensing process	
New target - Dec: **100% items completed within 80 working days**	

Despite the issues referred to above the end to end licensing KPI has been met most months.



Status:	N/A
Compliance	
PGTM processing efficiency	
Target: **100% within 75 working days**	

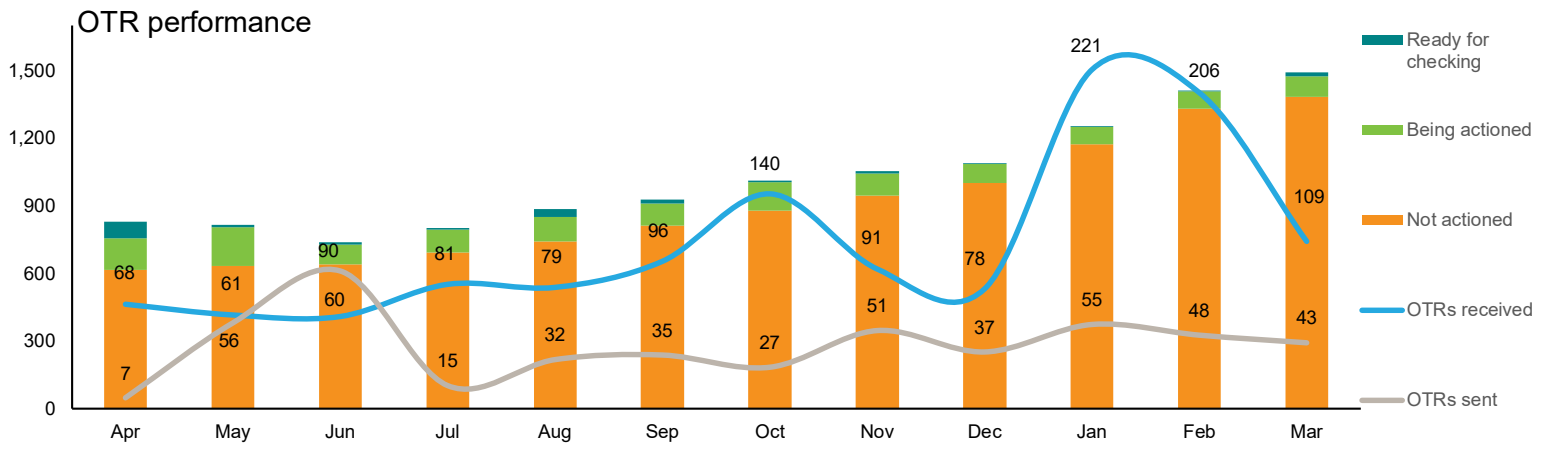
A dedicated Scientific Officer continues to provide a bespoke service which enables the KPI to be met efficiently. Senior scientific inspectors support the Quality Assurance aspect of the process.



LO:	N/A
ELP	N/A
LC	N/A
SAC	N/A
PlanGo	
Licensing efficiency	
Targets: **LO - 5 WD; ELP - 10 WD: LC - 15 WD; SAC - 20 WD.**	

Agenda loadings have been generally higher in recent months, so it is a good achievement by the Licensing team, our members and our legal advisers that KPIs for minutes have still been met throughout. Agenda loadings are unpredictable, and certain items involve more processing effort, for example when regulatory action is taken. There have been several such items in the past year.

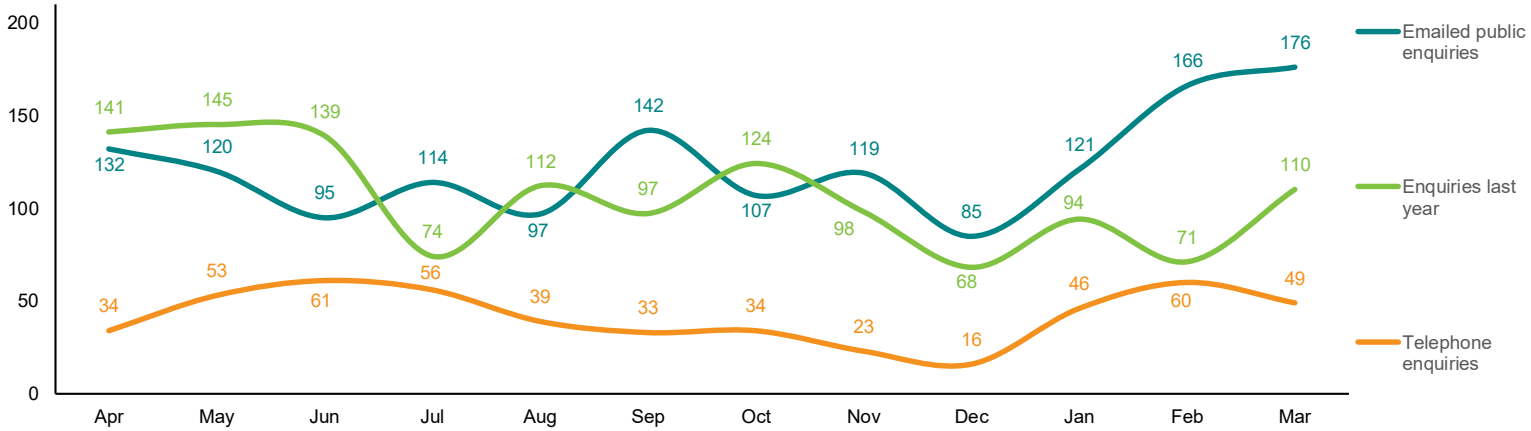
OTR performance



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

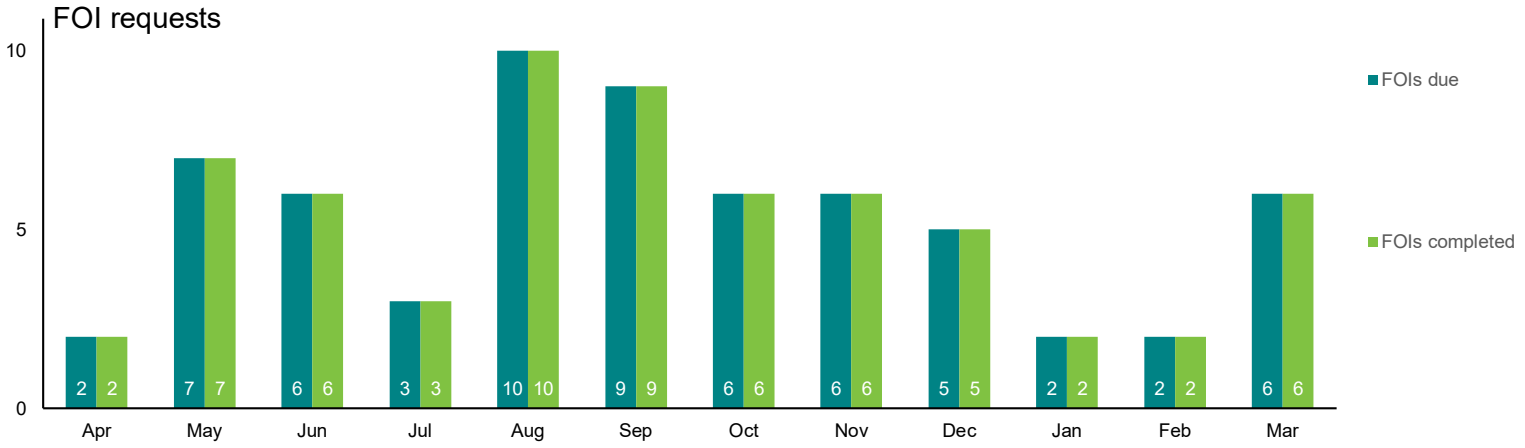
Staff turnover has affected our ability to increase OTR output. Recent media stories resulted in a significant increase in the number of new applications which are now tapering off. New staff members and systems should hopefully start showing improved outputs from April 2024.

Emailed public and telephone enquiries



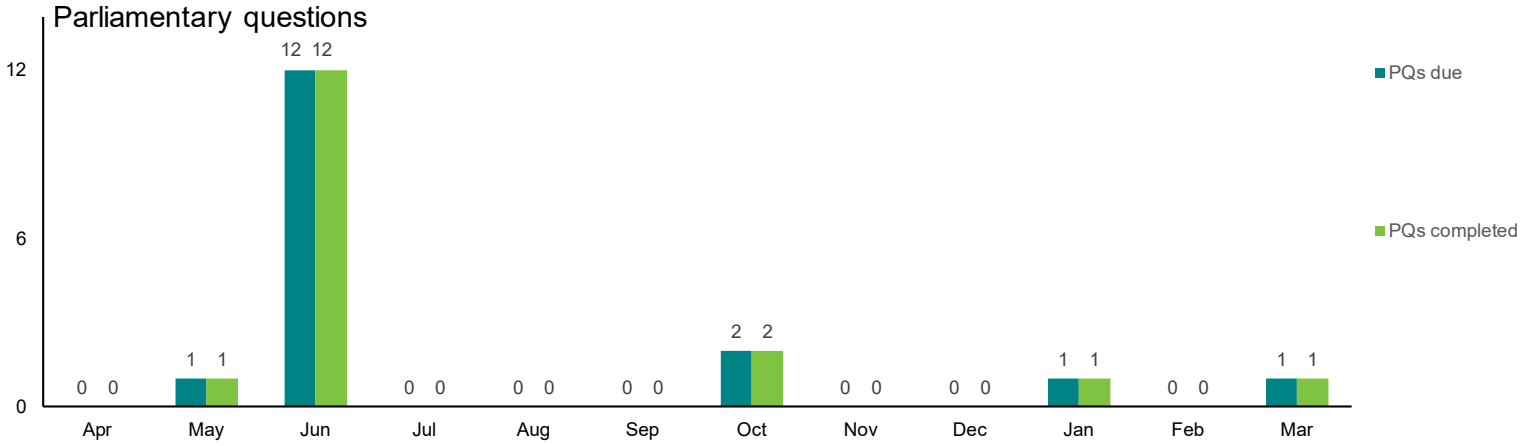
Status:	N/A
Policy/Comms	
Emailed public and telephone enquiries	
Target: **not defined**	

1474 email enquiries were received this year, up from 1132 in the previous year. The increase in the number of enquiries from January 2024 is largely due to media (ITV's "Born from the same stranger" documentary) and clinic incidents and closure. Common themes: OTR, patients who were unhappy with an aspect of their treatment, starting treatment/CaFC, medical queries, screening and testing, sperm/egg donation, and transfer of gametes.



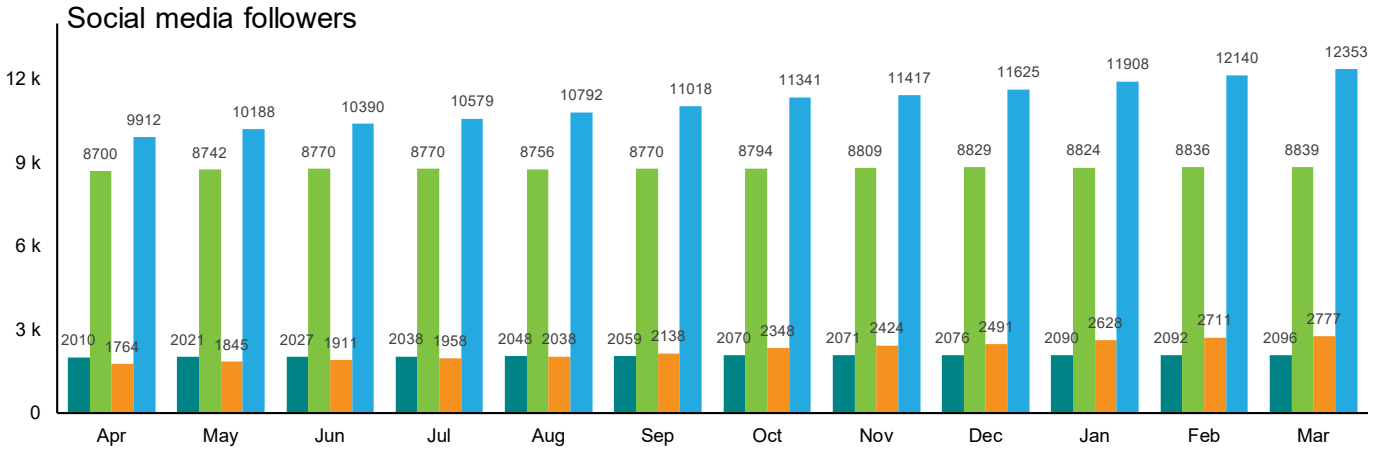
Status:	N/A
Intelligence	
FOI responses	
Target: **100% within 20 working days**	

FOIs were turned around within KPI timescales. FOI topics were mainly related to HR, finance, IT, or to do with data held on our register.



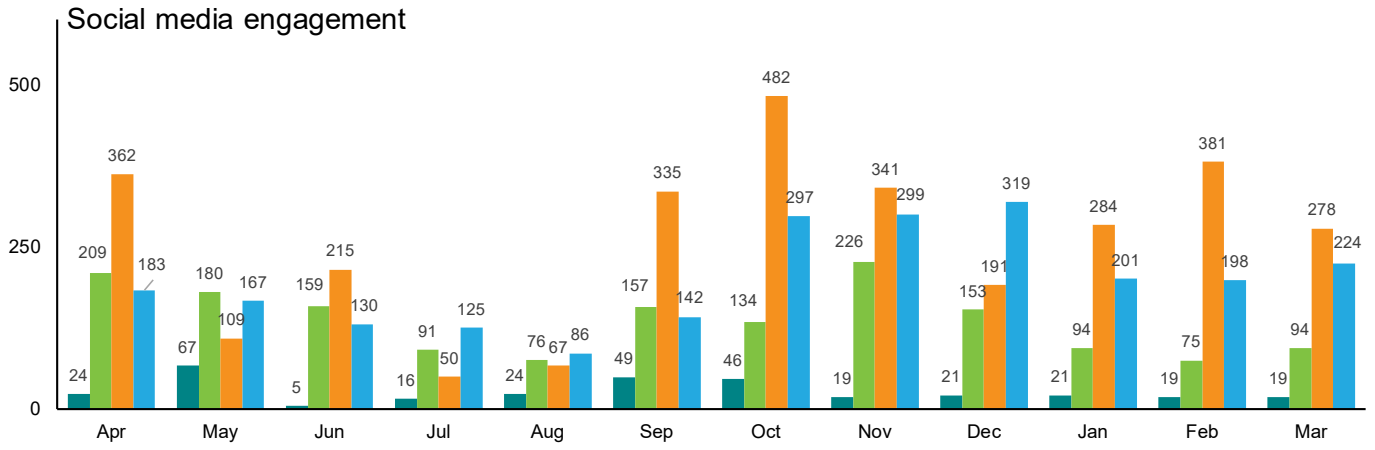
Status:	N/A
Intelligence	
PQs responses	
Target: **100% within deadlines set**	

All PQs were turned around within KPI timescales. PQ topics in May/June related to mitochondrial donation. Other PQs related to equality and diversity spending, NHS funding, total births and licensing.



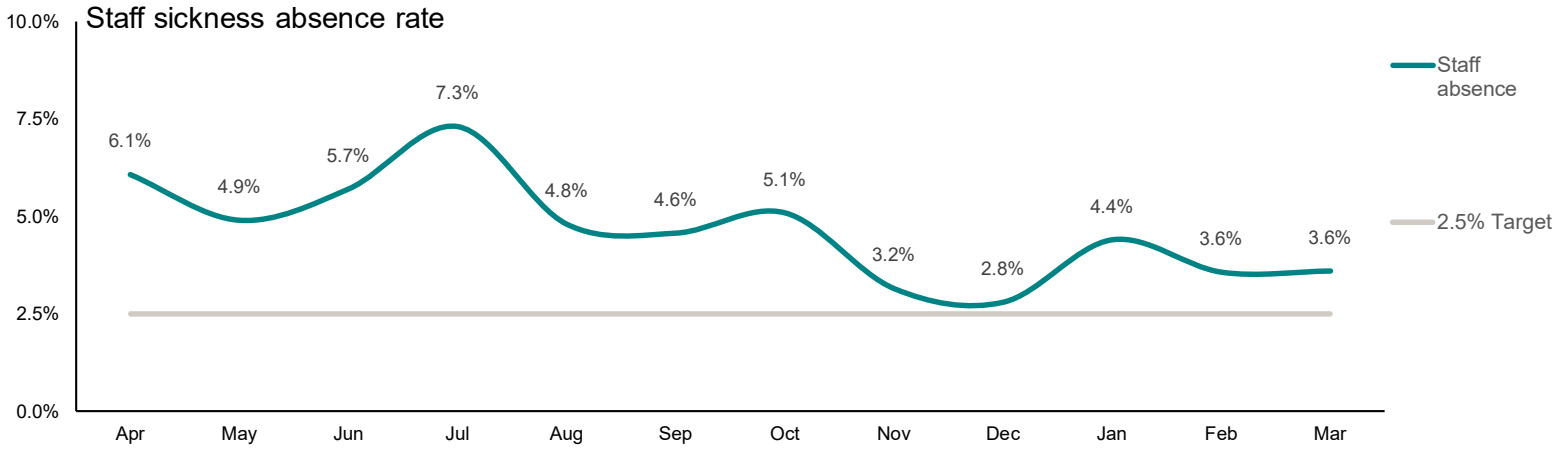
Status:	N/A
Comms	
Total number of followers across social media	
Target: **not defined**	

There has been a steady increase in the number of followers across our Instagram and LinkedIn channels, with X (Twitter) and Facebook remaining stable. The greatest month-by-month increase on Instagram coincided with the launch of our #WhoIsMyDonor campaign.



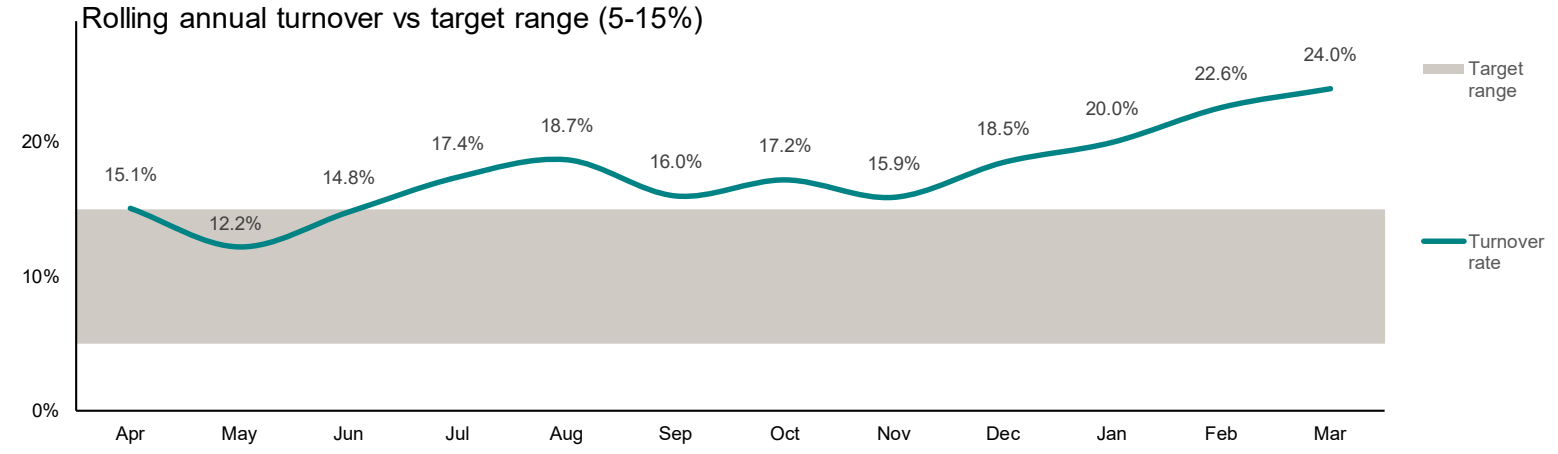
Status:	N/A
Comms	
Engagement across social media	
Target: **not defined**	

Our Instagram channel receives a higher level of engagement in proportion to the number of followers and is a growing way to reach patients. As with the number of followers, engagement was high around the launch of #WhoIsMyDonor campaign and around the ITV series “Born from the same stranger.”



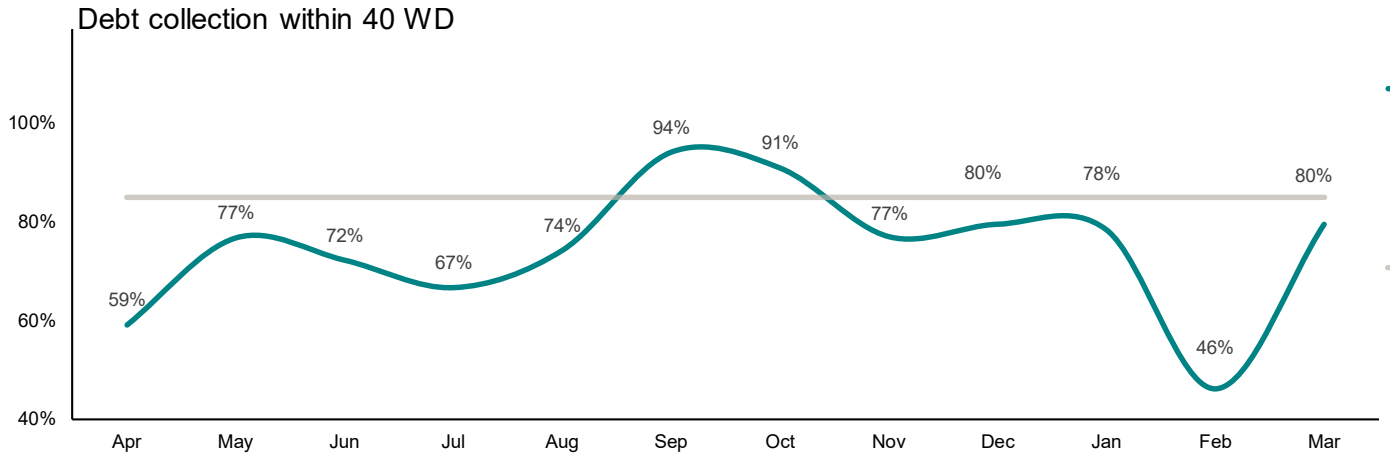
Status:	N/A
HR	
Sickness	
Target: Less than or equal to 2.5%	

We have experienced a higher than usual number of staff being on long term sick, however through the application of the sickness policy we are seeing a decline in absence numbers.



Status:	N/A
HR	
Turnover	
Target: From 5% to 15%	

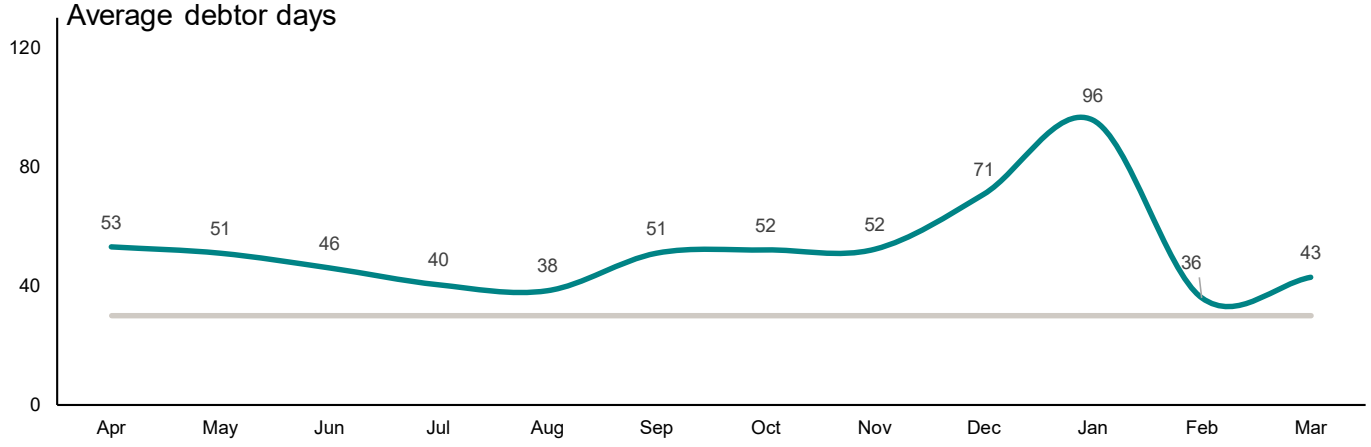
We have seen a notable increase in turnover this year, although 4% of turnover is involuntary.



Status:	N/A
Finance	
Debt collection	

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

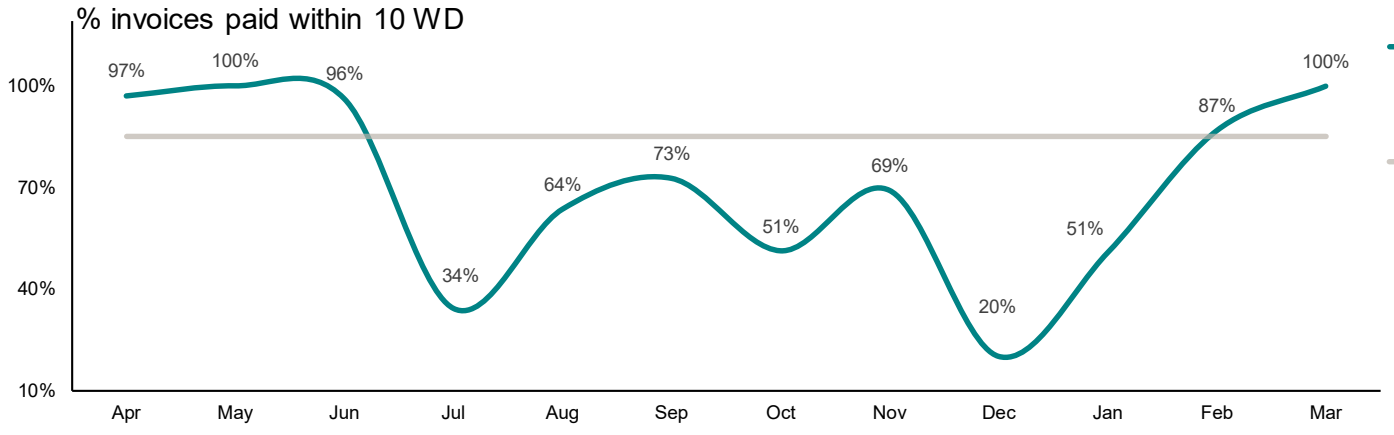
2023/ 2024 was challenging due to switch over to PRISM and the need to resolve billing queries which resulted in questions and delays. However, things improved with the year ending at 80% collected within 40 days.



Status:	N/A
Finance	
Debtor days	

Target: **30 working days or less**

Our debt collection process is robust however over the year we faced issues relating to capturing the correct contacts within finance. A concerted effort to update our records has significantly reduced debtor days.



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

Challenges with approvals over the year kept this KPI below target. Improvements in our approvals process has resulted in an increase in the last quarter, with the year ending at 100% paid within 10 days.

Register Research Panel annual report to Authority

Details about this paper

Area(s) of strategy this paper relates to:	The best care/the right information
Meeting:	Authority
Agenda item:	6
Meeting date:	15 May 2024
Author:	Amanda Evans, Head of Research and Intelligence Kazuyo Machiyama, Senior Research Manager
Annexes	Annex A – Active Register Research Panel approved projects Annex B – Publication list for approved Register Research Panel projects Annex C – Publication list for anonymised register data and FOI requests

Output from this paper

For information or decision?	For information
Recommendation:	Authority is asked to note this report
Resource implications:	Medium
Implementation date:	2023-2024
Communication(s):	Through updates to researchers, clinics, stakeholders and patients via our website and social media
Organisational risk:	Low

1. Introduction

1.1. The HFEA holds a Register of all patients, partners, donors, treatments and children born as a result of these treatments. It is believed to be the longest running database of assisted reproduction treatment in the world holding over 30 years of data.

1.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (2010 Regulations) provide that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register. High quality data research has been a key aim of the current strategy and can also contribute to our strategic ambition to provide the best care. We want to continue to engage with researchers to improve access to relevant and valuable data on our Register to that end.

1.3. The Authority has delegated to the Register Research Panel (RRP) the power to authorise access to Register data for the purposes of medical or non-medical research. The panel is required to report annually to the Authority and this paper provides that annual report.

1.4. The RRP is one of many ways in which Register data is made available. Most people seeking to access Register data do not wish to access identifiable information. To enable researchers, healthcare professionals and the public to undertake research using Register data, we proactively release as much data as possible through publications and the release of an **Anonymised Register**. We also respond to freedom of information requests (FOIs), enquiries and parliamentary questions (PQs).

1.5. We regularly publish **data research reports** which receive wide media coverage. Fertility trends is our annual statistical release and is the main point of reference for all data-related enquiries received throughout the year. It is published as an HTML report each year, with a large set of underlying data tables. **Fertility treatment 2021: preliminary trends and figures** was published in June 2023 and was viewed an average of 26,000 times in the first two months following release. Due to delays in data validation with clinics following the launch of PRISM, all data releases have included preliminary data for 2020 and 2021. We also published the **Ethnic diversity in fertility treatment 2021** in December 2023.

1.6. In January 2024, we launched the **HFEA dashboard** as a new tool to better enable public access to a wider breadth of data in a simplified and customisable format. The dashboard was viewed over 30,000 times in the first two months following launch, receiving positive feedback from stakeholders and in media coverage.

1.7. Section 2 of this paper provides an overview of Register Research Panel activity undertaken in 2023-24. Section 3 outlines work carried out in providing further information in freely available anonymised formats.

2. Register Research Panel activity in 2023-24

2.1. The role of the RRP is to decide whether to grant or refuse requests to access Register data for specific research purposes. The RRP is chaired by a Director and has membership from staff with research, information governance, data register, clinical and policy expertise.

2.2. Since the introduction of the 2010 Regulations, the RRP has approved 20 projects: 10 projects are currently active and 10 have been completed. A list of the currently active projects is available in Annex A.

2.3. The main output from RRP approved projects is typically publication of the research results in peer-reviewed academic journals. Since the last update in January 2023, there were four new peer-reviewed academic articles published from RRP approved research projects (see Annex B) and four published using anonymised register data (see Annex C). There have been 24 peer-reviewed academic articles published from RRP approved research projects and 26 from anonymous HFEA data sources such as the anonymised register since 2010.

2.4. The migration of data held in our Register as part of the PRISM project meant that the RRP was suspended from September 2021 to May 2022 as we would have been unable to provide datasets during this time. Between January 2023 and April 2024, the RRP met on five occasions to consider a total of 11 applications.

2.5. A recent internal audit was carried out by the Government Internal Audit Agency (GIAA) to assess the adequacy of the processes and procedures in place to ensure that RRP is effective in ensuring the Authority complies with its obligations when sharing the Register data for research purpose. The final report concluded that arrangements to protect Register data when shared with researchers are effective and HFEA governance arrangements, policies and procedures are adequate and suitably support the effectiveness of the decisions made by the RRP, giving a green "Substantial Assurance" rating – the highest rating the GIAA awards.

2.6. In summary, work that was carried in 2023-24 since the last update included the following:

- A new data transfer method has been introduced to improve the secure transfer of Register data extracts for approved projects.
- The **data research webpage** has been updated to provide more information for researchers on how to apply to access data. Additionally, new webpages have been created for all RRP projects to provide lay summaries and public benefit statements to increase transparency of how Register data is being used.
- A plan to increase research engagement is ongoing with several activities planned in 2024-25, including a quarterly data research newsletter, webinars to provide information on Register data for researchers and a roundtable with researchers to further improve our Register data for research purposes.
- Two new panel members were trained to replace staff and to ensure the membership covers key skills.
- A second legal advisor has also been inducted to ensure cover should the primary legal advisor be unable attend a meeting.
- Updates to the following documentation were completed: the RRP standard operating procedure handbook, application form, project renewal request form, data specification sheet, data release form and data destruction form as part of the wider work to improve the information provided to and received from researchers.

2.7. The number of new applications and approved projects have increased slightly since last year. While Register data is becoming used more widely, there is much more potential to improve patient care through increased high-quality research. Due to the delayed completion of data validation exercises with clinics to verify register data, plans to promote our data through research engagement have been delayed to coincide with completion of this work in Autumn 2024. We will be undertaking activities through the research engagement work as described above to increase awareness and demand for our data.

2.8. In the January 2023 Authority update on the RRP, Authority members agreed for a brief on proposed changes to the 2010 Regulations to be prepared and provided to DHSC. This brief was submitted to DHSC in 2023 and we await further details on planned actions. The proposal included changes in three main areas: cost recovery, research following egg, sperm and embryo donation, and child consent.

2.9. Access to Register data currently functions as an opt-in system, requiring explicit consent from patients and partners for non-contact research in order to use disclosable protected information from our Register for approved RRP projects. Authority members also agreed for the proposal to explore other consent options in the January 2023 Authority. Changes to implement an opt-out system for consent will be additionally considered in upcoming work to enable researchers to access the most information possible to ensure their research can be as accurate as possible with minimal bias introduced through consent. We hope to carry out this work during 2024-25.

Projects approved in 2023-24

2.10. **The impact of duration of freezing of IVF embryos on pregnancy and prenatal outcomes – analysis of UK national data, University of Abeerdeen.** This project aims to investigate associations between duration of embryo storage and pregnancy and perinatal outcomes in UK using the HFEA register data between 2000 and 2019.

2.11. **Predict IVF outcomes using advanced machine learning techniques, Gaia Ltd.** This project aims to build a predictive model that outputs the probability of live births in IVF treatment across successive treatment cycles, using the HFEA treatment data between 2003 and 2020. The model will be made available publicly and freely on Gaia's website, including details on methodologies used.

3. Accessing anonymous Register data

3.1. The most recent version of the Anonymised Register is available for download from the HFEA website, with the most recent validated data up to 2018. An updated version of the anonymised register will be published following data validation. The data can be used for research without having to apply for approval; it also allows researchers to access a large and rich dataset that does not contain any identifiable information.

3.2. In the 2023-24 financial year, the Research and Intelligence team responded to 215 data-related enquiries in the form of 64 FOIs, 132 enquiries and 19 PQs, as well as numerous data requests through our press office. These requests often require preparation of bespoke data; however, with recent investment in creation of the HFEA dashboard, around a third of requests have been satisfied by referrals to the dashboard since launch thereby reducing time-consuming and repetitive work carried out within the team.

Annex A: Active Register Research Panel approved projects

No	Research establishment	Chief investigator	Project title
1	University of Aberdeen	David J. McLernon	Development and validation of prognostic model to predict pregnancy outcomes following in-vitro fertilization (IVF) treatment
2	University of Edinburgh	Tom Clemens	Environmental determinants of IVF treatment
3	University of Oxford	Claire Carson	Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England (PEARL)
4	University College London	Alastair Sutcliffe	Educational outcomes in children born after assisted reproductive technology: a population based linkage study
5	University College London	Alastair Sutcliffe	General health and hospital admissions in children born after ART: a population based linkages study
6	University of Manchester	Stephen Roberts	Effects of assisted reproductive technology (ART) on long-term birth weight trends: a national cohort study
7	South London and Maudsley NHS Trust	Lauren Carson	Associations between assisted reproductive technologies and women's mental health: an investigation using clinical data linkage
8	University College London	Alastair Sutcliffe	General health outcomes in subfertile men: a UK register-based cohort study
9	Gaia Ltd.	Floriane Moy	Predict IVF outcomes using advanced machine learning techniques
10	University of Aberdeen	Edwin Amalraj Raja	The impact of duration of freezing of IVF embryos on pregnancy and perinatal outcomes – analysis of U.K. national data

Annex B: Publication list - Approved Register Research Panel projects

1. Hua, X., Rivero-Arias, O., Quigley, M. A., Kurinczuk, J. J., & Carson, C. (2023). Long-term healthcare utilization and costs of babies born after assisted reproductive technologies (ART): a record linkage study with 10-years' follow-up in England. *Human Reproduction*, *38*(12), 2507–2515. https://doi.org/10.1093/humrep/dead198
2. Ratna, M. B., Bhattacharya, S., & McLernon, D. J. (2023). External validation of models for predicting cumulative live birth over multiple complete cycles of IVF treatment. *Human Reproduction*, *38*(10), 1998–2010. https://doi.org/10.1093/humrep/dead165
3. Raja, E.A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2023). A comparison of perinatal outcomes following fresh blastocyst or cleavage stage embryo transfer in singletons and twins and between singleton siblings. *Human Reproduction Open*, *2023*(2): hoad003. https://doi.org/10.1093/hropen/hoad003
4. Kondowe, F. J. M., Clayton, P., Gittins, M., D'Souza, S. W., Brison, D. R., & Roberts, S. A. (2023). Growth of twins conceived using assisted reproductive treatments up to 5 years old: a national growth cohort. *Human Reproduction*, *38*(4), 751-761. https://doi.org/10.1093/humrep/dead018
5. McLernon, D. J., Raja, E. A., Toner, J. P., Baker, V. L., Doody, K. J., Seifer, D. B., Sparks, A. E., Wantman, E., Lin, P. C., Bhattacharya, S., & van Voorhis, B. J. (2022). Predicting personalized cumulative live birth following in vitro fertilization. *Fertility and Sterility*, 117(2):326-338 https://doi.org/10.1016/j.fertnstert.2021.09.015
6. Raja, E.A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2022). Comparison of perinatal outcomes after frozen or fresh embryo transfer: separate analyses of singleton, twin, and sibling live births from a linked national in vitro fertilization registry. *Fertility and Sterility*, 118(2), 323–334. https://doi.org/10.1016/j.fertnstert.2022.05.010
7. Ratna, M. B., Bhattacharya, S., van Geloven, N., & McLernon, D. J. (2022). Predicting cumulative live birth for couples beginning their second complete cycle of in vitro fertilization treatment. *Human Reproduction*, 37(9), 2075–2086. https://doi.org/10.1093/humrep/deac152
8. Sharpe, A., Mascarenhas, M., & Balen, A. (2022). Ethnic variation in the live birth rate and perinatal outcomes following frozen embryo transfer: an analysis of the HFEA database from 2000 to 2016. *Human Fertility*, 25(3), 583–592. https://doi.org/10.1080/14647273.2021.1913291
9. Sutcliffe, A. G., Purkayastha, M., Brison, D. R., Nelson, S. M., Roberts, S. A., & Lawlor, D. A. (2022). General health in a cohort of children conceived after assisted reproductive technology in the United Kingdom: a population-based record-linkage study. *American Journal of Obstetrics and Gynecology,* 228(1):82e1-82e17. https://doi.org/10.1016/j.ajog.2022.07.032
10. Bhattacharya, S., Maheshwari, A., Ratna, M. B., van Eekelen, R., Mol, B. W., & McLernon, D. J. (2021). Prioritising IVF treatment in the post COVID 19 era: a predictive modelling study based on UK national data. *Human Reproduction*, 36(3). https://doi.org/10.1093/humrep/deaa339
11. Purkayastha, M., Roberts, S. A., Gardiner, J., Brison, D. R., Nelson, S. M., Lawlor, D., Luke, B., & Sutcliffe, A. (2021). Cohort profile: A national, population-based cohort of children born after assisted conception in the UK (1992-2009): Methodology and birthweight analysis. *BMJ Open* 11:e050931. https://doi.org/10.1136/bmjopen-2021-050931
12. Castillo, C. M., Harper, J., Roberts, S. A., O'Neill, H. C., Johnstone, E. D., & Brison, D. R. (2020). The impact of selected embryo culture conditions on ART treatment cycle outcomes: a UK national study. *Human Reproduction Open*, *2020*(1):hoz031.
13. Cameron, N. J., Bhattacharya, S., & McLernon, D. J. (2020). Cumulative live birth rates following blastocyst- versus cleavage-stage embryo transfer in the first complete cycle of IVF: a population-based retrospective cohort study. *Human Reproduction*, 35(10):2365–2374. https://doi.org/10.1093/humrep/deaa186

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Annex C: Publication list - Anonymised Register data and FOI requests

Publications from projects that used data from the HFEA through FOI requests or from the publicly available anonymised register of which we are aware.

1. Allen, C., McLernon, D., Bhattacharya, S., & Maheshwari, A. (2023). Early pregnancy outcomes of IVF cycles using donor versus partner sperm: analysis of 1 376 454 cycles recorded by the Human Fertilisation and Embryology Authority (1991–2016)**.** *Human Reproduction*, 38(6):1191-1201. https://doi.org/10.1093/humrep/dead057
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Proposed legislative changes on posthumous storage and screening

Details about this paper

Area(s) of strategy this paper relates to:	The best care
Meeting:	Authority
Agenda item:	7
Meeting date:	15 May 2024
Author:	Annabel Salisbury, Regulatory Policy Manager

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to discuss and approve delegation of powers to the Chair to sign off on: • Updated Standard Licence Conditions (SLCs) for Great Britain and Northern Ireland. • Updated General Direction 0007, listing a new consent form. • Other guidance if needed, in line with the proposed changes set out below.
Resource implications:	Medium
Implementation date:	Will depend on Department of Health and Social Care/parliamentary timeframes however work likely to take place spring/summer 2024
Communication(s):	Updated Standard Licence Conditions, updated General Direction, updated Clinic Guide, other additional guidance where needed, Clinic Focus articles (including Special Editions), Chair's Letters and news and press releases, social media posts for patient facing information.
Organisational risk:	Low

1. Background

1.1. The Government has proposed two areas of legislative change which – if passed by Parliament – will affect the fertility sector. This paper sets out the proposed changes for information and explains how the HFEA will implement them. The Authority is asked to delegate powers to the Chair to approve specific regulatory materials in line with the planned response.

Change 1: Posthumous storage of gametes and embryos

1.2. In 2022, the law changed to allow storage of gametes and embryos for up to 55 years for all patients and to permit a maximum of 10 years posthumous storage. This had an unintended impact on a subset of patients whose partners died before the law came into force in 2022 with gametes or embryos in storage. The proposed legislative amendment is in recognition of the negative effect of the 2022 storage laws on this subset of patients. This upcoming change was communicated to clinics in the October 2023 update to the Code of Practice (p.164).

Change 2: Screening for reciprocal IVF and known donation from those who have HIV with an undetectable viral load

1.3. The Government announced in October 2023 that it intended to change the law relating to screening in fertility treatment. This news was welcomed by the HFEA. The first change would amend the definition of 'partner donation' and the second would allow gamete donation from those who have HIV with an undetectable viral load to known recipients. Both changes followed recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) based on microbiological safety only to that effect.

1.4. The changes in relation to the definition of 'partner donation' relate to how EU Tissues and Cells Directives (EUTCDs) were transposed into UK law in 2007 and in particular the fact that 'partner donation' is currently confined to heterosexual couples who 'declare that they have an intimate physical relationship'. There is no comparable provision for two women who share an 'intimate physical relationship' with the result that couples undergoing reciprocal IVF (or 'shared motherhood') are required to undergo more burdensome donor screening in line with Standard Licence Condition (SLC) T52. The proposed change would amend this definition of 'partner' and allow female same-sex couples to undergo the same screening as heterosexual couples providing gametes for their own treatment (in line with SLC T50). This is a change that the HFEA have been calling for over several years.

1.5. The changes in relation to donation from individuals living with undetectable HIV follow the recommendation from the June 2023 SaBTO meeting that UK ministers of health should consider a change in the law to allow gamete and embryo donation to known recipients.

2. Implementation

2.1. The final text of both changes are not yet published and the timeframe for implementation depends on the DHSC and the parliamentary timetable. However, we are planning the consequences of these changes to ensure we are prepared for any changes and can provide information to clinics and patients as relevant.

Posthumous storage of gametes and embryos

2.2. These changes will affect only a small number of gametes and embryos already in storage where the person who provided the gametes died before 1 July 2022 and where they consented for their surviving partner to use the material in the event of their death. The gametes and embryos also must have been already subject to an extension of storage before 1 July 2022 (for example, where the gamete provider met the criteria for premature infertility under the Human Fertilisation and Embryology (Special Exemption) Regulations 2009).It will not affect patients storing gametes and embryos for the first time.

2.3. No changes are needed to the Standard Licence Conditions (SLCs). However we will need to publish an updated Clinic Form and a new Consent Form so clinics can comply with the new legal requirements. We will also need to produce an update to General Direction 0007 to mandate the use of the new consent form. We will publish guidance to support clinics.

Screening for reciprocal IVF and known donation from those who have HIV with an undetectable viral load

2.4. Following the Government's announcement in October 2023, the December 2023 edition of Clinic Focus stated that we would deprioritise the inspection of screening same sex female couples in line with SLC T52. As such the sector should be prepared for the change. There will be no need to update the SLCs to incorporate this change however we will update guidance and produce patient information to support the sector if the proposed changes come into force.

2.5. The proposed change to allow known donation from individuals living with undetectable HIV would require a change to the SLCs, likely to be a change to SLC T52. We will also need to produce updated guidance.

2.6. Given the potential timeframes of these changes it is not feasible to update the Code of Practice at this stage. If the changes become law, we will publish a version of the Code with specific passages struck through – for example, to strike through out-of-date guidance or SLCs and direct clinics to updated guidance.

Communication to the sector

2.7. We will be publishing updates primarily via Clinic Focus (including releasing Special Editions where necessary) and requesting sign off from the Chair on Chair's Letters to release updated regulatory materials where needed.

3. Recommendations

3.1. The Authority is asked to discuss and approve delegation of powers (in line with HFEA Standing Orders) to the Chair to sign off:

- Updated Standard Licence Conditions (SLCs) for Great Britain and Northern Ireland.
- Updated General Direction 0007, listing a new consent form.
- Other guidance if needed, in line with the proposed changes set out above.