

Authority meeting

Date: 3 July 2024 – 1.15pm to 3.30pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	1.15pm
2. Minutes of the meeting held on 15 May 2024 and matters arising (5) For decision	1.20pm
3. Chair and Chief Executive's report (10) For information	1.25pm
4. Committee Chairs' reports (20) For information	1.35pm
5. Performance Report (30) For information	1.55pm
6. Risk Register (30) For decision	2.25pm
7. Fees Review (30) For information	2.55pm
8. Any other business (5)	3.25pm
9. Close	3.30pm

Minutes of Authority meeting held on 15 May 2024

Details:

Area(s) of strategy this paper relates to:	<p>The best care – effective and ethical care for everyone</p> <p>The right information – to ensure that people can access the right information at the right time</p> <p>Shaping the future – to embrace and engage with changes in the law, science and society</p>
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Agenda item	2
Meeting date	3 July 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 15 May 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 15 May 2024

Members present	Julia Chain Frances Flinter Zeynep Gurtin Jonathan Herring Alex Kafetz Graham James	Alison McTavish Gudrun Moore Geeta Nargund Catharine Seddon Christine Watson
Apologies	Tim Child Steve Pugh (Department of Health and Social Care – DHSC) Farhia Yusuf (DHSC)	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Tom Skrinar Paula Robinson	Shabbir Qureshi Amanda Evans Kazuyo Machiyama Annabel Salisbury 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 and HFEA staff to the Authority Meeting, which was being held online. She informed the meeting that DHSC colleagues had sent their apologies for this meeting.
- 1.2. The Chair also welcomed observers and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. 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)
 - Jason Kasraie (PR at a licensed clinic)

2. Minutes of the last meeting and matters arising

- 2.1. A member proposed that minute 9.4 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 20 March were a true record and could be signed by the Chair.

Matters arising

- 2.3.** Members were advised that the matters arising items had been actioned as detailed in the paper presented to the meeting.
- 2.4.** The Chair referred to action 9.16 from the March 2024 Authority meeting regarding implementing the decisions concerning donation compensation rates. She informed members that the Executive is requesting that the Authority delegate responsibility for signing off on the amended Direction 0001 to the Chair.

Decision

- 2.5.** The Authority agreed to delegate responsibility for signing off on the amended Direction 0001 to the Chair.

Action

- 2.6.** The Chair to sign off on the amended Direction 0001.

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 in early May she spoke at the SHREG (Scottish Reproduction and Embryology Group) Conference in Dundee, and her presentation had been very well received.
- 3.3.** The Chair informed members that she had participated in interviews for the recruitment of four new Authority members, with the skill sets of embryology, genetics/statistics, legal/ethical and as a patient voice or advocate. This is an ongoing process that is run by the DHSC as members are appointed by the Secretary of State for Health and Social Care.
- 3.4.** The Chief Executive provided an update on the key external activities contained in the paper presented to the Authority and spoke about the work underway to prepare for the year-end accounts and annual report which will be presented to the Audit and Governance Committee in June.

Decision

- 3.5.** 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.** The Licence Committee Chair (Graham James) gave an overview of recent meetings and informed members that the committee had renewed the suspension of a licence, and this had received some additional press coverage. He spoke about how the committee uses its powers to ensure consistent improvements and gave an example of a clinic who had previously had a long history of poor compliance but was now showing marked improvement.

- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) spoke about the busy workload of the committee and its work to review outdated terminology to ensure that language used is appropriate.
- 4.4.** It was noted that the next meetings of the Scientific and Clinical Advances Advisory Committee (SCAAC) and the Audit and Governance Committee (AGC) are being held in June and a report will therefore be given at the July Authority meeting.

Decision

- 4.5.** Members noted the Committee Chairs' reports.

5. Annual Performance report 2023-2024

- 5.1.** The Chief Executive introduced the annual performance report for 2023-2024 and spoke about the metrics for measurement of performance. He commented that over the past year there had been a marked reduction in the number of red indicators, and he thanked the staff for their work in this regard during a particularly busy year.
- 5.2.** The Chief Executive gave a brief overview of PRISM activities, including the large task of validating data for Choose a Fertility Clinic (CaFC). The updated CaFC is due to be published in the Autumn and the Chief Executive reminded members that regular reports on PRISM are given to the AGC.
- 5.3.** The HR indicators used throughout the year to measure and report to the Authority are sickness and turnover rate of staff.
- 5.4.** The Chief Executive stated that the target range for staff sickness is below 2.5%, and throughout the year this rate had declined from a high of 7.3% to 3.6%. If long term sick leave was removed, then the figure would be below the target of 2.5%. The Chief Executive remarked that he is comfortable with this figure, especially when comparison is made to other ALBs.
- 5.5.** The Chief Executive said that the target range for turnover is between 5-15% and whilst this has been exceeded, it is still manageable. As a small organisation that has to operate within the constraints of public policy on pay the HFEA is impacted by staff leaving for promotion and better pay.
- 5.6.** The AGC Chair commented that the HFEA has not been complacent regarding staff turnover and had looked at how it could improve its non-reward package to staff and had implemented wellbeing days. It was noted that the annual staff survey shows that staff morale is good.
- 5.7.** The Chief Executive informed members that the recruitment process had been improved so that vacancies were filled quicker than previously. This was not only beneficial to the HFEA but also to staff covering vacancies who could more easily manage their workload.
- 5.8.** A member commented that there may be additional media spikes and interest throughout the next year, especially regarding the law reform proposals, and they questioned where the resources would be to deal with these. The Chief Executive responded that when faced with such spikes other work is paused.
- 5.9.** In response to a question the Chief Executive confirmed that exit interviews are held when staff leave, and most people are leaving for a promotion which is not otherwise available to them in a small organisation like the HFEA.

Compliance and Information

- 5.10.** The Director of Compliance and Information informed members that over the past year the workload for inspectors had remained high with both scheduled inspections and extra unplanned inspections required for increased regulatory oversight. Workload had also been impacted by long term absence and turnover, and thanks were given to the team for managing this so that licences were issued on time.
- 5.11.** The Director of Compliance and Information spoke about the robust process which inspection reports to Committees are subject to, to ensure that consistent decisions regarding regulatory actions can be taken. This means that sometimes due to extra compliance and enforcement meetings and communication with a PR the KPI will be breached
- 5.12.** The past 12 months have also been challenging for the Opening the Register (OTR) team with a greater number of applications than in previous years, especially around increased media awareness prompted by the documentary Born from the Same Stranger.
- 5.13.** Members were informed that the introduction of the new IT system, (Microsoft dynamics) and register tools, has worked well and allowed the OTR team to develop new workstreams for different application types. 137 applications were closed in April and already 58 applications had been closed in May, so inroads were being made into the waiting list. The new systems and procedures would form the basis of the new KPIs which are being developed by the team.
- 5.14.** The Director of Compliance and Information stated that she attended the Donor Conceived Network (DCN) Conference on 4 May and had spoken about aspects of the OTR service and this had been well received.
- 5.15.** Members were informed that the infrastructure penetration test commenced on 7 May with an expected finish date of 17 May. The Government Internal Audit Agency (GIAA) conducted an audit of our business continuity plan in January, and the recommendations arising from the audit will be implemented over the coming months. The DSPT audit commenced this week, and the report is expected to be finalised at the end of June.
- 5.16.** Approval was recently received from the DHSC Digital and Technology Assurance team to proceed with the Epicentre replacement project; funding has been allocated and the project specification is undergoing further review before the tendering and procurement process can commence.
- 5.17.** The Chair recorded the Authority's thanks to both the inspection and OTR teams for their work during the past 12 months. The Chair stated that during the pandemic a hybrid method of inspections was introduced and given that inspections and regulatory work are the cornerstone of the HFEA's work she asked what the review period of assessing the inspection process was.
- 5.18.** The Director of Compliance and Information responded that the inspection process is reviewed by PR feedback and GIAA audits and improvements are made where possible.
- 5.19.** In response to a question the Director of Compliance and Information stated that OTR applications will see a year-on-year increase, but it is difficult to predict spikes arising from media interest.

Strategy and Corporate Affairs

- 5.20.** The Director of Strategy and Corporate Affairs spoke about the achievements of the Strategy and Corporate Affairs Directorate over the past 12 months. The HFEA had arranged and serviced over 60 formal committee meetings.
- 5.21.** During the year the Statutory Approvals Committee had approved 200 conditions that had been added to the approved list of PGT-M conditions.
- 5.22.** Throughout the year improvements had been made to the HFEA's Strategic Risk Register and associated documents and thanks were given to the Risk and Business Planning Manager for driving this work forward.
- 5.23.** The Director of Strategy and Corporate Affairs reported that the team had dealt with 2,000 public enquiries throughout the year, and it was noted that some parliamentary questions and freedom of information requests can require complex data.
- 5.24.** Members were informed that over the year a 30% increase in media coverage had been achieved and the HFEA dashboard was introduced, the Director of Strategy and Corporate Affairs stated that more information about the data we publish would be given under agenda item 6.
- 5.25.** The Directorate had also successfully managed two GIAA audits for the Code of Practice and the Register Research Panel, both of which had very positive outcomes.

Finance

- 5.26.** The Director of Finance and Resources informed the members that the Finance team is a small team and had carried a vacancy for a large part of the year, this had now been filled and the team was at full capacity. He thanked the team for their work.
- 5.27.** Members were informed that the year end books had been closed and the audit had commenced. The provisional year end position shows an underspend on staff and legal although IT spend had been higher than budgeted. The Director of Finance and Resources cautioned that there would be some movement of figures during the external audit and the accounts and annual report would be presented to the June AGC meeting.
- 5.28.** The Chair thanked the members of the Senior Management Team for the overview of the year and remarked that this is an opportunity for the Authority to look strategically at the performance of the HFEA over the past year.
- 5.29.** The Chair thanked the HFEA team for their work and performance throughout the year and for delivering on extra projects such as the public body review and the law reform proposals.
- 5.30.** A member thanked the Executive for the transparent and detailed report and asked whether any consideration had been given to reporting on the impact of the HFEA's work. They offered to send examples of such reporting by other public bodies to the Chief Executive.
- 5.31.** The Director of Compliance and Information reminded members of the annual State of the Sector report which details compliance and non-compliance and looks year-on-year at how the sector has performed.
- 5.32.** There being no further comments the Chair drew the discussion on the annual performance report to a close.

Decision

- 5.33.** Members noted the annual performance report.

6. The Register Research Panel

- 6.1.** The Head of Research and Intelligence introduced the paper and reminded members that the HFE (Disclosure of Information for Research Purposes) Regulations 2010 allow the disclosure of information for research purposes and that the Authority has delegated authorisation for this to the Register Research Panel (RRP).
- 6.2.** The HFEA holds a statutory register of all patients, partners, donors, treatments and children born as a result of fertility treatment and it is believed to be the largest database of assisted reproduction treatment in the world.
- 6.3.** One of the HFEA's key strategic aims is to ensure that people can access the right information at the right time.
- 6.4.** The Head of Research and Intelligence spoke of the reason why the HFEA collects data and how it can be used to have an oversight of the fertility sector and to look for trends and where improvements can be made. Reference was made to making data available to researchers conducting important research and the range of data reports which the HFEA publishes.
- 6.5.** The main data publications released in 2023-2024 were Fertility treatment 2021: preliminary trends and figures and Ethnic diversity in fertility treatment 2021. Members were reminded that a call to action was also published at the same time as the ethnic diversity in fertility treatment report. Presentations on these reports were given at Fertility 2024, ESHRE and other academic conferences.
- 6.6.** Members were informed about the purpose of the HFEA dashboard and that in the first two months since launch it had been viewed over 30,000 times. There has been positive feedback from stakeholders and wide media coverage had been obtained. The Head of Research and Intelligence informed members that the HFEA had been invited to present the dashboard at the Royal Statistical Society Conference in September.
- 6.7.** During the year over 200 data related enquiries had been received including freedom of information requests and parliamentary questions. Members were informed that a third of recent requests were signposted to the HFEA dashboard, therefore reducing the workload of the team.
- 6.8.** The Senior Research Manager informed members that since the last annual update the RRP had met five times and reviewed 11 project applications, including five new applications. During the period under review two projects had been fully approved by the panel and members were given a brief overview of these projects.
- 6.9.** There are 10 projects currently active and individual project webpages had been created for each project. The aim of this was to provide a lay summary and public benefit statements which in turn would increase the transparency of the HFEA's data use.
- 6.10.** Members were informed that one of the key outputs from the RRP publications is that since 2010 there have been 24 peer-reviewed papers from RRP projects and 26 peer-reviewed papers using anonymous HFEA data. Members were given a brief overview of the papers recently published and were informed that the HFEA's data is not only being used in high-impact factor academic journals but is also informing clinical practice and policies in the fertility sector.

- 6.11.** Members were reminded that during the RRP update presented in January 2023 they had agreed to recommend updates to the 2010 regulations on data use for research purposes and the HFEA had subsequently submitted a brief on this to the Department of Health and Social Care.
- 6.12.** The Senior Research Manager informed members that the RRP had been audited by GIAA and had achieved the highest rating possible. The audit report had also acknowledged the significant work to improve the RRP in recent years.
- 6.13.** Turning to work in 2024-2025, members were informed of the planned work to engage with researchers through a new research newsletter, webinars, presentations at academic conferences and round tables. The team will also continue to streamline the RRP processes by providing more information to researchers on application requirements, as well as quality and completeness of data held on the Register.
- 6.14.** Members expressed their appreciation for the informative presentation and the reports which had been published and promoted. The accompanying call to action on ethnic diversity in fertility treatment was especially welcomed.
- 6.15.** Members welcomed the planned work for 2024-2025 and discussed several aspects relating to some of the proposed activities.
- 6.16.** Members discussed the possibility of collaborating with other organisations on research projects. Several members undertook to send the HFEA staff a list of MSc courses that cover fertility to see whether there was any potential for research synergy beneficial to the HFEA.
- 6.17.** There being no further comments the Chair drew the discussion to a close.

Decision

- 6.18.** Members noted the annual report of the RRP.

7. Proposed legislative changes on posthumous storage and screening

- 7.1.** The Regulatory Policy Manager introduced the paper and stated that the Government has proposed two areas of legislative change, which if passed by Parliament will affect the fertility sector.
- 7.2.** The paper presented to the Authority set out in detail the changes to the posthumous storage of gametes and embryos and the screening for reciprocal IVF, also referred to as shared motherhood, and known donation from those who have HIV with an undetectable viral load.
- 7.3.** Members were informed that the final text relating to the posthumous storage of gametes and embryos has been published and the law came into force on 10 May 2024. The final text relating to the other area of change has also been published, but the timetable for implementation depends on the DHSC and the parliamentary timetable. The HFEA is planning for the consequences of these changes to ensure that it is prepared and can provide information to clinics and patients as relevant.
- 7.4.** The Regulatory Policy Manager spoke to the recommendation that the Authority delegates responsibility to the Chair to sign off the requirement documents.

- 7.5.** The Director of Strategy and Corporate Affairs informed members that the statutory instrument for posthumous storage was laid in Parliament last Friday and the statutory instrument for screening had been laid today.

Decision

- 7.6.** The Authority agreed to delegate responsibility to the Chair to sign off:
- Updated Standing 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 in the paper presented to the May Authority meeting.

Action

- 7.7.** The Chair to sign the updated documents relating to the legislative changes on posthumous storage and screening.

8. Any other business

- 8.1.** The Chair thanked all for their active participation in the meeting.
- 8.2.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 3 July 2024.
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Chair's signature

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

Signature

Chair: Julia Chain

Date: 3 July 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 03 July 2024

Author Alison Margrave, Board Governance Manager

Output:

For information or decision? For discussion

Recommendation To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.

Resource implications To be updated and reviewed at each Authority meeting

Implementation date 2024/25 business year

Communication(s)

Organisational risk Low Medium High

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
20 March 2024 Minute 9.16 15 May 2024 Minute 2.6	The Executive to implement the Authority's decisions regarding donation compensation rates. Authority delegated responsibility for signing off amended Direction 0001 to the Chair	Head of Policy	October 2024		The work is contained within planned activities. This item is now complete and can be removed.
15 May 2024 Minute 7.7	The Chair to sign the updated documents relating to the legislative changes on posthumous storage and screening.	Head of Policy			The work is contained within planned activities. This item 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:	3 July 2024
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

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

1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meeting in May 2024.
 - Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.
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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:
 - 3 June – attended the Scientific Clinical Advance & Advisory Committee (SCAAC).
 - 19 June – attended (with Peter) DHSC/HFEA Annual Accountability meeting with our sponsor team to review the HFEA’s achievements for the past year.
 - 26 June – attended the Audit & Governance Committee meeting.

2.2 Chief Executive

- The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:
 - 3 and 4 June – participated (with Frances Flinter) in the Ethics and Policy Symposium on In Vitro Gametogenesis in Leiden.
 - 19 June – attended (with Julia) DHSC/HFEA Annual Accountability meeting.
 - 26 June – attended the Audit & Governance Committee meeting.
 - 27 June – attended the Health and Social Care Regulation Forum 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:	3 July 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:		
2 May	1 Interim 2 Executive updates	Interim approved for continuation 1 Executive update noted 1 Suspension (continued)
27 June	2 Incident reports	Minutes not yet approved.
Other comments:	None.	
Executive Licensing Panel:		
7 May	3 Renewals 2 Interim 1 Variation of Licence Holder 1 Variation of Person Responsible	All granted
20 May	1 Renewal 2 T&S interims with variation of standard licence conditions 1 Research interim 2 Variations of PR	All granted
10 June	1 Renewal 2 T&S interims, 1 with variation of standard licence conditions 3 Variations of PR	All granted
25 June	4 T&S interims 1 Variation of premises 1 Variation to add embryo testing 1 Variation of PR	Minutes not yet approved
Other comments:	None.	
Licensing Officer decisions:		
May	15 ITE import certificates 2 Changes of LH 1 Change of centre name	All granted
Other comments:	None.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
30 April	5 PGT-M applications 1 Special Direction for import	All approved.
28 May	3 PGT-M applications 1 Special Direction for import 1 Special Direction for export	All approved.
24 June	4 PGT-M applications	Minutes not yet approved.
Other comments:	None.	
Audit and Governance Committee:		
26 June 2024	Main agenda items: Internal audit – results and annual opinion Progress with current internal audit recommendations Annual report and accounts – including the annual governance statement External audit completion report Risk update – strategic risk register and horizon scanning Digital projects – PRISM update Resilience, business continuity management and cyber security Information assurance and security (SIRO report) Government functional standards Bi-annual human resources report Estates.	
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
3 June 2024	Emerging technologies in embryo and gamete testing	SCAAC concluded that PGT-P (PGT for polygenic disorders or polygenic risk scores) for use in fertility treatment, is not yet able to accurately predict future health, and such predictions may not be relevant in future as clinical treatments advance. Given the imminent introduction of this technology on the European market, SCAAC agreed that the Executive working with the Committee, will

Meetings held	Items considered	Outcomes
	Artificial wombs for early or whole gestation (ectogenesis)	develop patient information about PGT-P limitations for the PGT pages of HFEA website. The Committee discussed challenges with HFEA's remit and regulatory oversight arising from early technological developments in this area, and the uncertainty of which stages of gestation these artificial technologies will cover. SCAAC will continue to monitor clinical and scientific advancements.
	Application for androgen supplementation as treatment add-on	SCAAC advised reconsidering the wording of the add-on definition to include prescribable medications. The Committee reconsidered the Executive's application for androgen supplementation and agreed it is now eligible for an HFEA rating as per the criteria in the SCAAC treatment add-ons decision tree. The Executive will commission an expert literature review and the topic will be brought to a future SCAAC meeting.
	Alternative methods to derive embryonic and embryonic-like stem cells	SCAAC acknowledged progress being made in relation to technologies used to derive cell lines, the quality of which is improving. SCAAC will continue to monitor scientific developments in this area.
Other comments:	The Chair welcomed the three newly appointed external advisers who joined SCAAC on 4 March 2024: Ying Cheong, Peter Rugg-Gunn and Veronique Bermann. The Chair also highlighted the upcoming HFEA Annual Horizon Scanning Meeting which will be held during the European Society for Human Reproduction and Embryology (ESHRE) conference.	

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 May 2024

Evgenia Savchyna

Corporate Performance Officer

03/07/2024

www.hfea.gov.uk

About this paper

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Meeting date:	03/07/2024
Agenda item:	Item 5
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

Output from this paper

For information or decision?	For information
Recommendation:	To discuss
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	<p>The Corporate Management Group (CMG) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.</p> <p>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.</p> <p>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the CMG paper).</p>
Organisational risk:	Medium

Latest review and key trends

Latest review

- The attached report is for performance up to and including May 2024.
- There were nine Green, three Amber, two Red, and three Neutral indicators.
- Finance data is excluded from this report.

Key trends

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

March (3)	April (4)	May (2)
Inspections reports to committee within 65 working days	Inspections reports to PR within 25 working days	Turnover within 5% to 15% range
Staff sickness rate below 2.5%	End to end licensing within 80 working days	Debt collection within 40 days
Turnover within 5% to 15% range	Staff sickness rate below 2.5%	
	Turnover within 5% to 15% range	

Management summary

Management commentary

- Performance has been good across KPI indicators with nine Green, three Amber, two Red, and three Neutral indicators.
- Inspection KPI have shown a significant improvement, with 'Inspection reports to PR' and 'Inspection reports to committee' both in Green, and 'End to end licensing' KPI achieving 90% of target completion.
- All licensing KPIs have met their targets.
- There has been significant progress on OTR responses since April. In May, the highest number of OTRs was sent out (175 responses per month) due to a new system being implemented. This trend is expected to continue in the near future.
- The number of email enquiries has decreased slightly compared to February and March. However, there has been a rise in complaint-related enquiries which may be a consequence of the Homerton Fertility Centre's licence suspension.
- Following the Intelligence KPI review, we have developed a new chart which shows both FOIs and PQs completed within the month with RAG ratings for each of them. FOIs in May totalled eight, covering topics such as donation (3), state of the sector, finance, CaFC (2), and egg freezing. No PQs in May.
- Following the Comms KPI review, the chart on the 'Total number of social media followers' has been removed as the numbers do not change significantly from month to month; and the new charts on 'Total number of website sessions and users' and 'Proactive and reactive media coverage' were developed. Prior to April 2024 we were not recording proactive and reactive coverage, therefore the coverage from May 2023 to March 2024 is shown as reactive on 'Proactive and reactive media coverage' chart.
- There were 41 media mentions in May, six of them were generated proactively by HFEA. Due to the general election, less content than usual has been posted.
- Following the HR KPI review, the 'Staff sickness rate' chart has been updated to show two figures: overall staff absence rate and staff absence excluding long-term sickness. One employee remains on long-term sick leave. The number of vacant posts has been added to the supplementary HR data in the 'Turnover' chart commentary.

Summary financial position as at 31 May 2024

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Variance %
Income	1,195	1,248	(53)	(4.2)
Expenditure	1,159	1,131	28	2.5
Total Surplus/(Deficit)	36	117	(81)	(68.6)

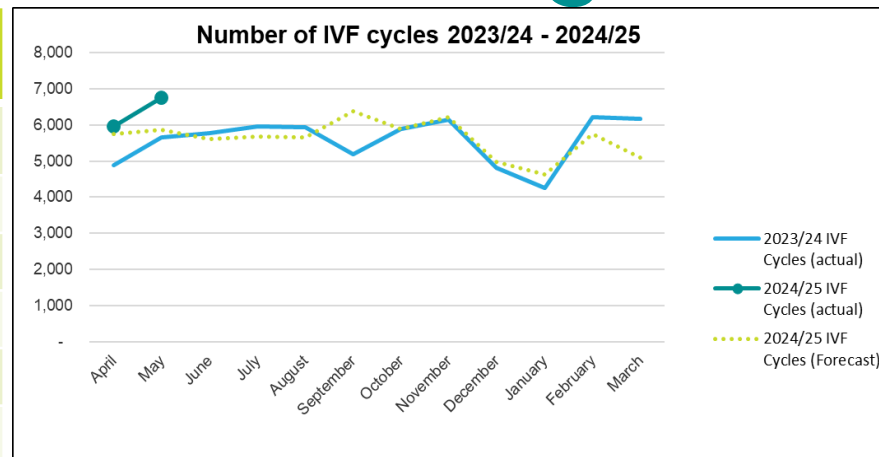
For the two months ended 31 May 2024, we have net surplus of £37k, however against budget, a deficit of £81k (68.6%).

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

We will begin our detailed forecasting at the end of June where there is an opportunity for the teams to amend their plans which will be reflected in our forecasts.

2024/25 Income - YTD Actual vs Budget

	YTD Actual	YTD Budget	Variance	Var
	£'000s	£'000s	£'000s	%
Income				
DHSC Funding	39	39	0	0
Licence Fees	1,145	1,209	(64)	5.3
Other income	40	0	40	0
Total	1,195	1,248	(53)	(4.25)

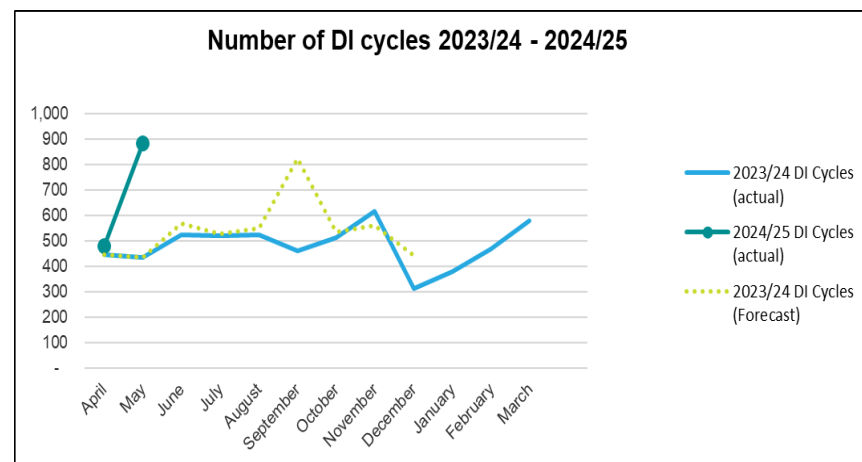


INCOME

As of month 2 (May), our income is slightly below budget (£53k or 4.3%). We are yet to draw down our first tranche of GIA which will happen in June.

Treatment fees

IVF fees are 21% higher than the same period in 2023/24 and DI are 55% higher than the same period. The latter is a little unusual as for the month of May-24, DI treatments were 881 vs 435 in 2023/24.



2024/25 Expenditure-YTD Actual vs Budget

	YTD Actual	YTD Budget	Variance	Var
	£'000s	£'000s	£'000s	%
Expenditure				
Salaries/Wages	852	917	(65)	7.1
Other Staff costs	22	25	(3)	12.0
Other costs	39	7	32	457
Facilities (estates) costs	91	62	29	46.7
IT Costs	88	87	1	1.2
Legal and Professional	67	33	34	103.0
Total	1,159	1,131	28	2.5

Salaries/wages – year to date are under budget by 7.1%, this is mainly on-costs (pension) where the budget assumed all staff are in the pension scheme.

Other Staff costs – are 12% below budget. These costs are represented by mainly travel and subsistence (T&S). The T&S for inspections are currently £8k below budget offset by smaller variances across the teams.

Other costs – non-staff costs are above budget due to profiling – the budget is profiled quarterly and the figures will have caught up by the end of June.

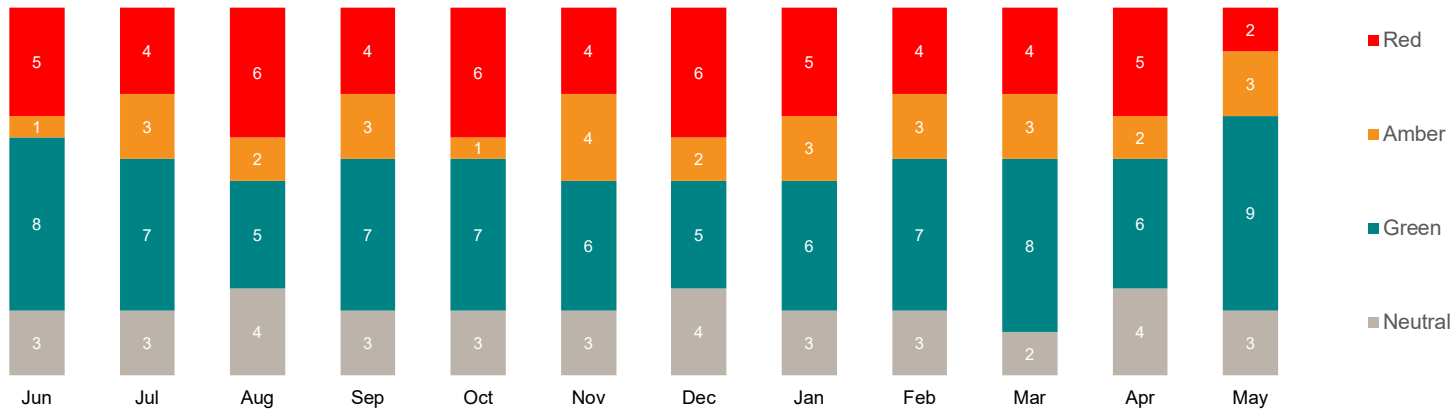
Facilities (estates) costs – these are the accommodation and non-cash costs. The overspend relates to accruals for rent charges that will be transferred out quarterly to reduce the lease liability.

Legal and Professional – are over budget by £34k because of budget profiling in legal and a small overspend in legal secondment fees.

Key performance indicators

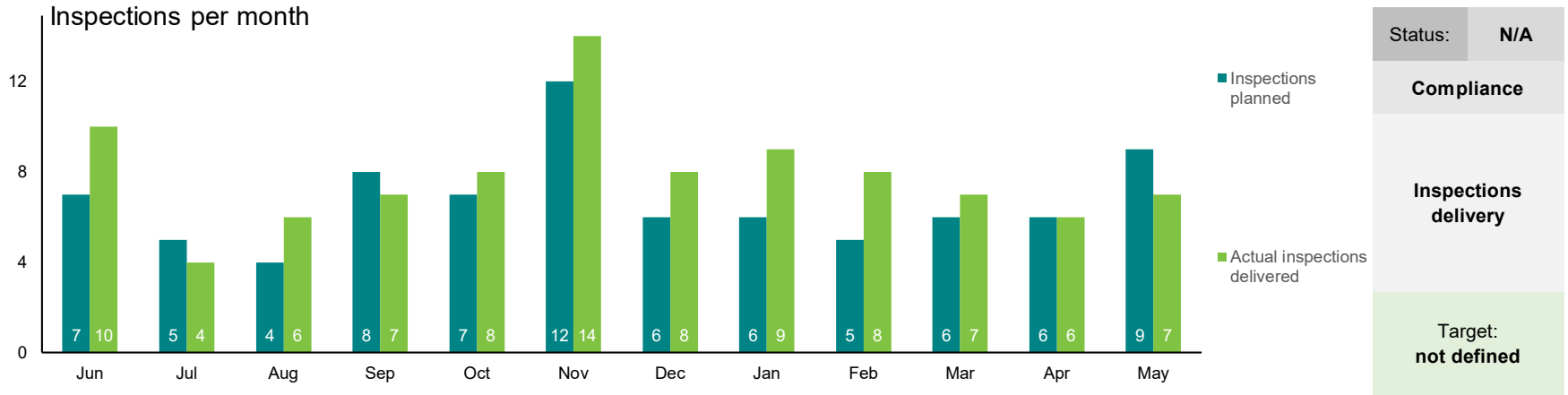


RAG status over last 12 months

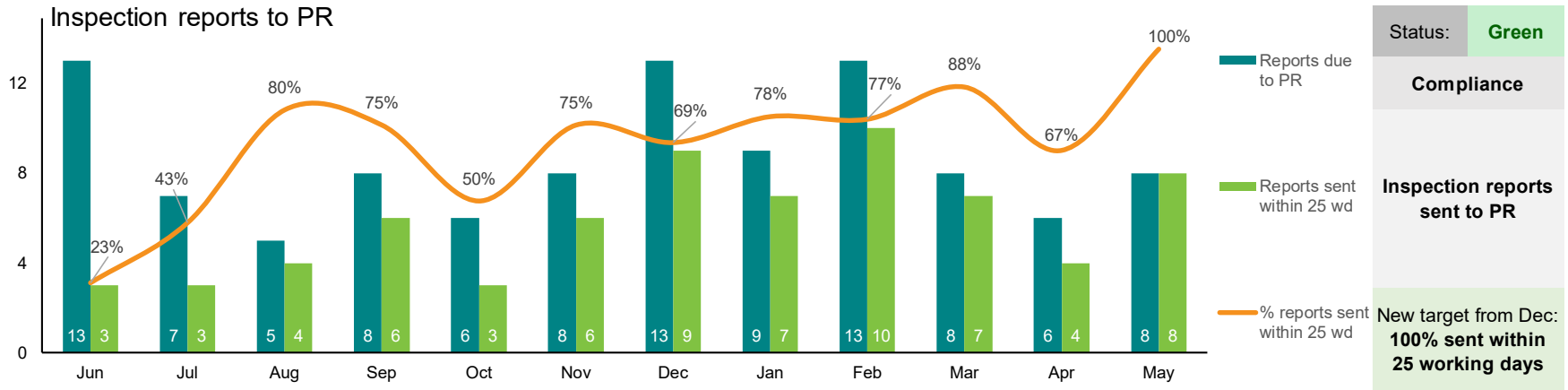


RAG status over last 12 months
17 KPIs in total for each month

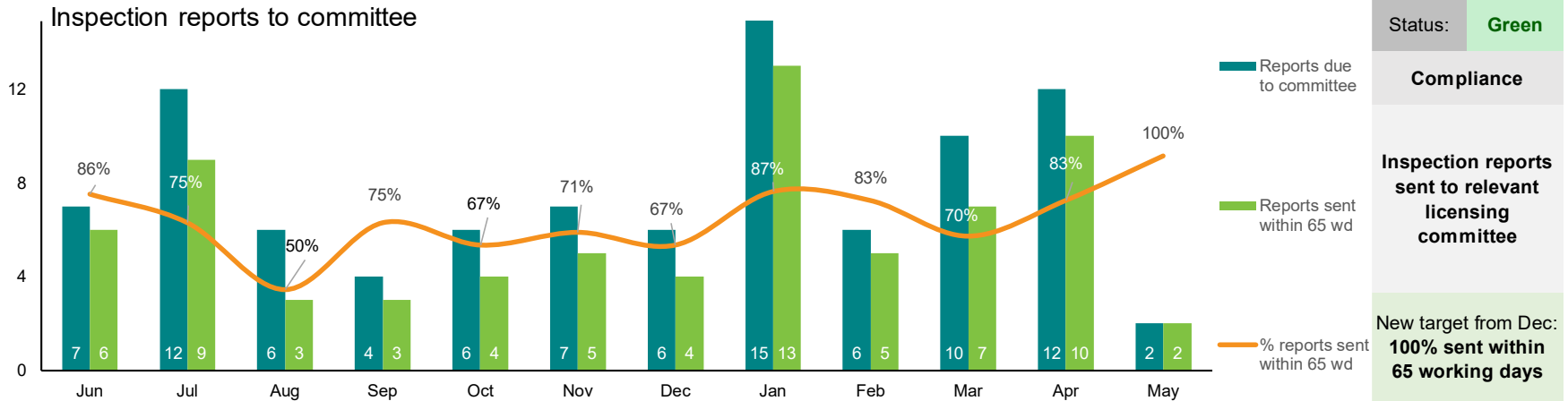
For May, the **2 red indicators** are in these teams: **Finance - 1, HR - 1.**



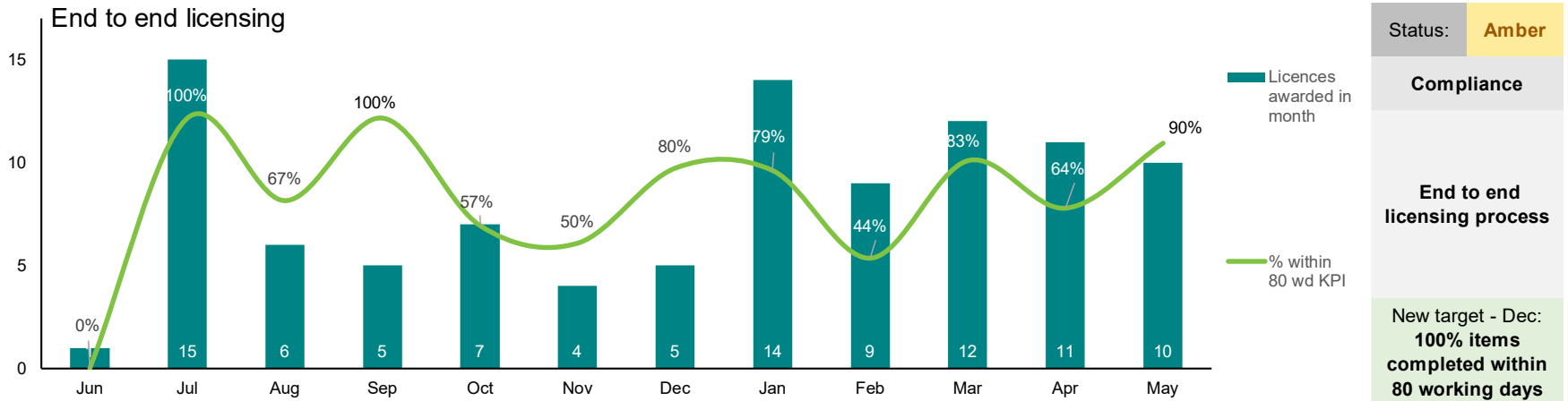
The number of inspections delivered in May was below the number of inspections planned in the beginning of the year because one licence was suspended, and another change of premises DBA inspection was moved to July.



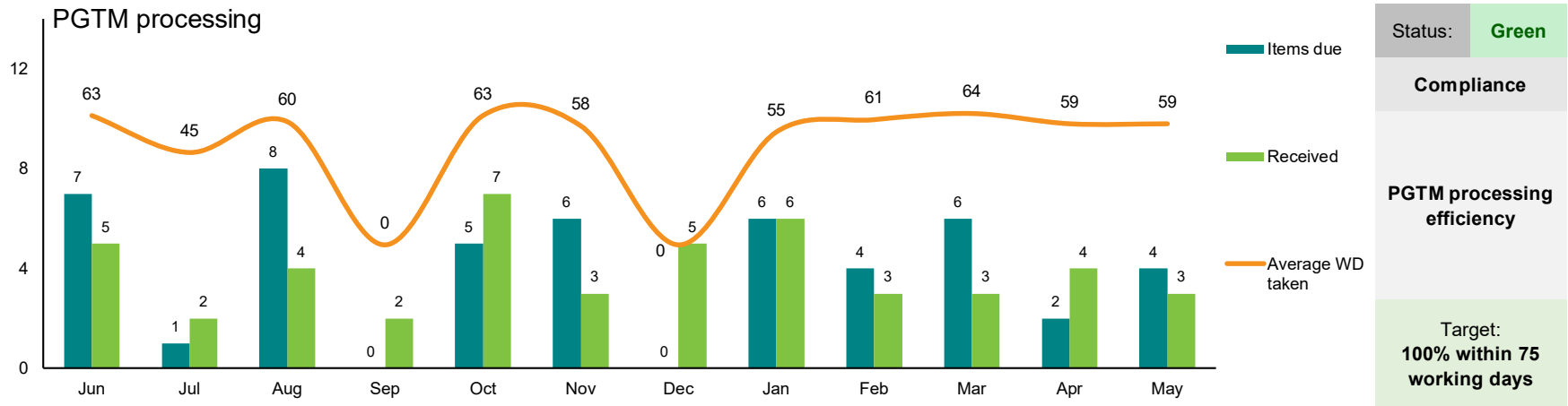
All reports were sent to PRs within the target.



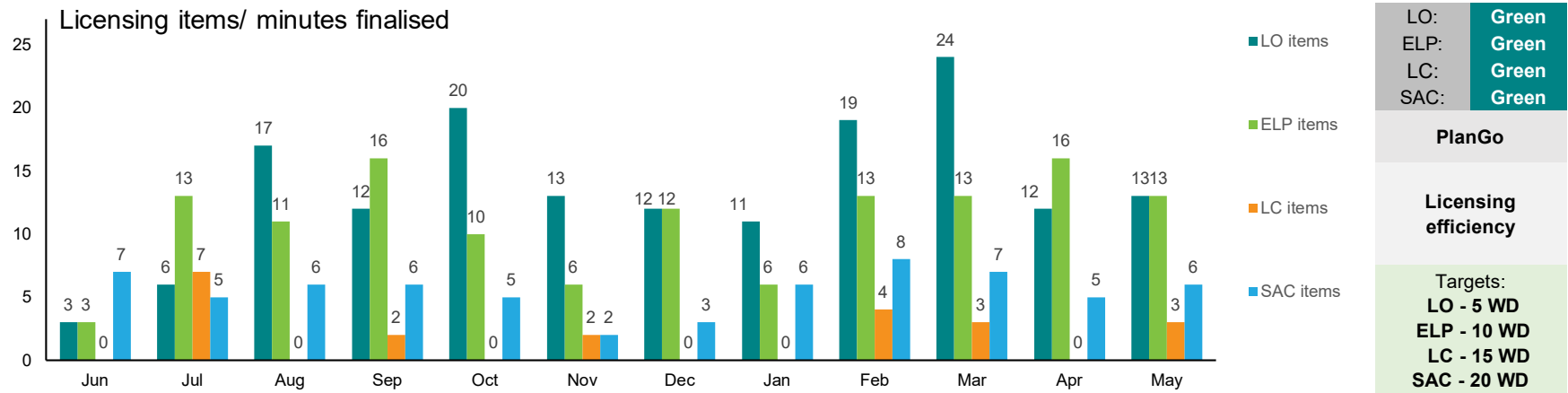
All reports were sent to committee within the target.



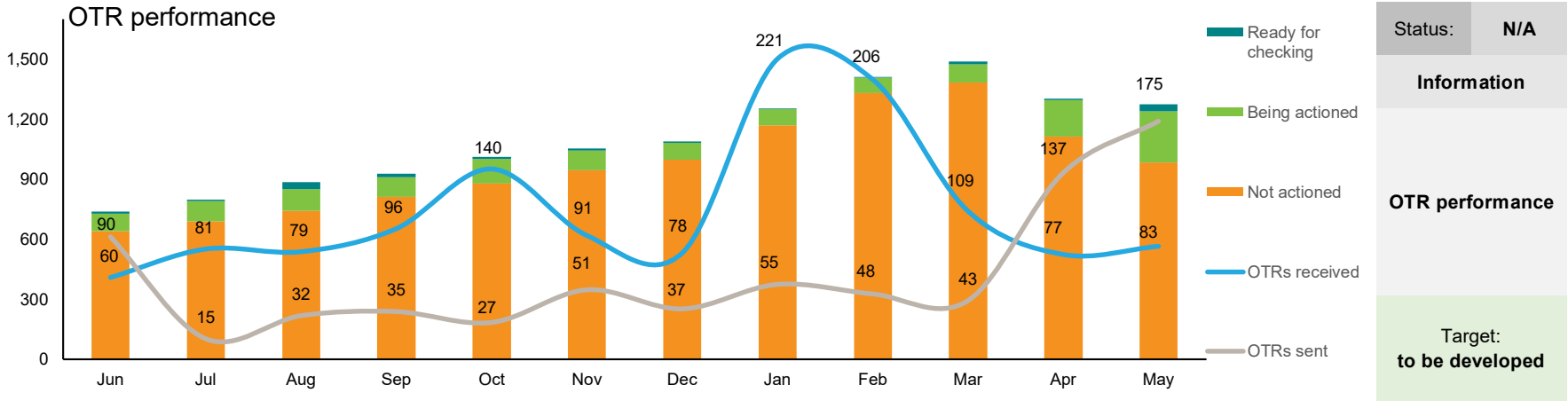
One inspection was deprioritised as a low-risk which is an IUI-only centre with no licensable activity since 2021.



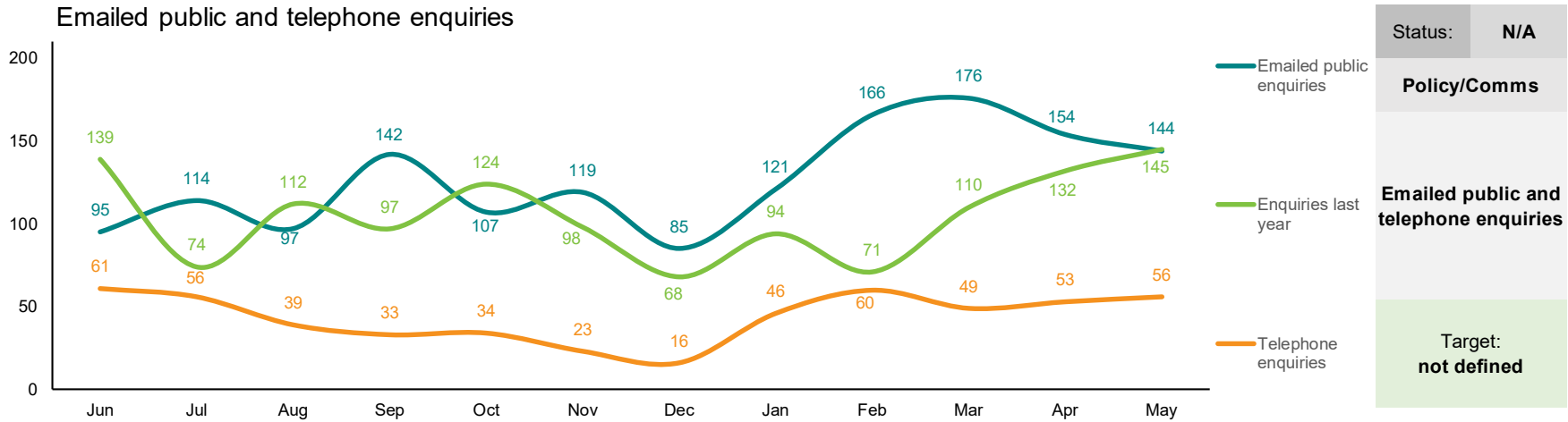
All PGTM items have been processed within KPI.



Standard month. LO items still mainly ITE certificates, but there were three variations (most of these variations can now go via the LO again rather than ELP as most centres are on the updated storage SLCs now).

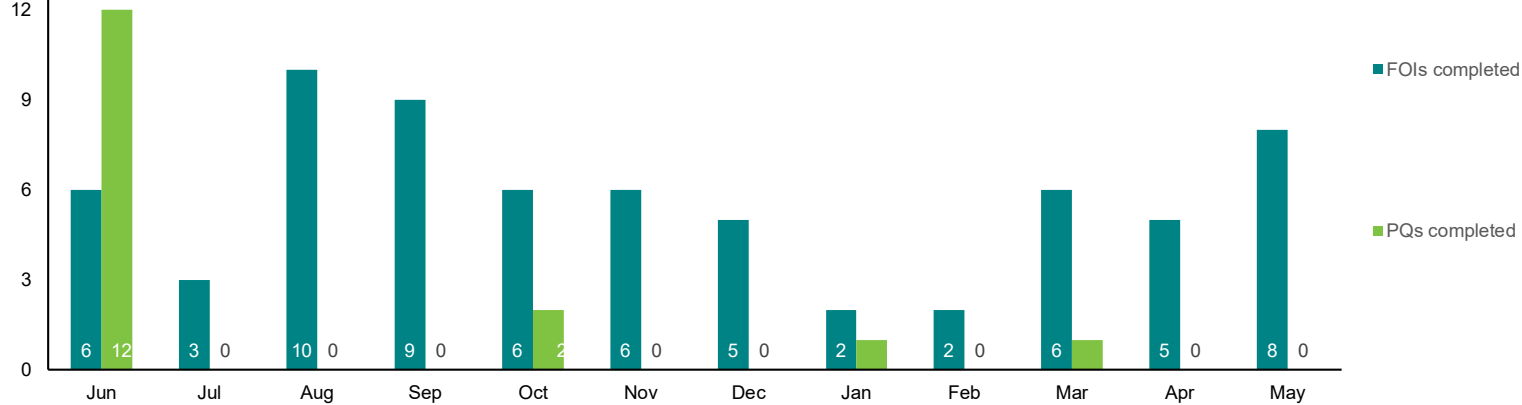


Record number of OTRs sent out due to new staff completing training, donor information manager able to dedicate more time to completing OTRs and bedding in of new system. A large proportion of OTRs being sent out are donor OTRs which are much quicker to process. We will exhaust the waiting list of this application type in approx. 4 months which will allow the new staff member to move to other application types but will also result in a fall in the number of applications we can process.



In May we received 116 straightforward enquiries, 13 complaint related, 11 complex and 4 redirected. **Themes:** OTR (33), Other (21), Donation (21), Complaints (16), Screening (12), Treatment (10) and Success rates (8). **Call themes:** Other (19), Medical queries (9), Complaints (6), Treatment (6), OTR (4), Follow-up (3) and Movement of Material (3). We received more complaints than usual, and there has been an increase in sperm donation enquiries.

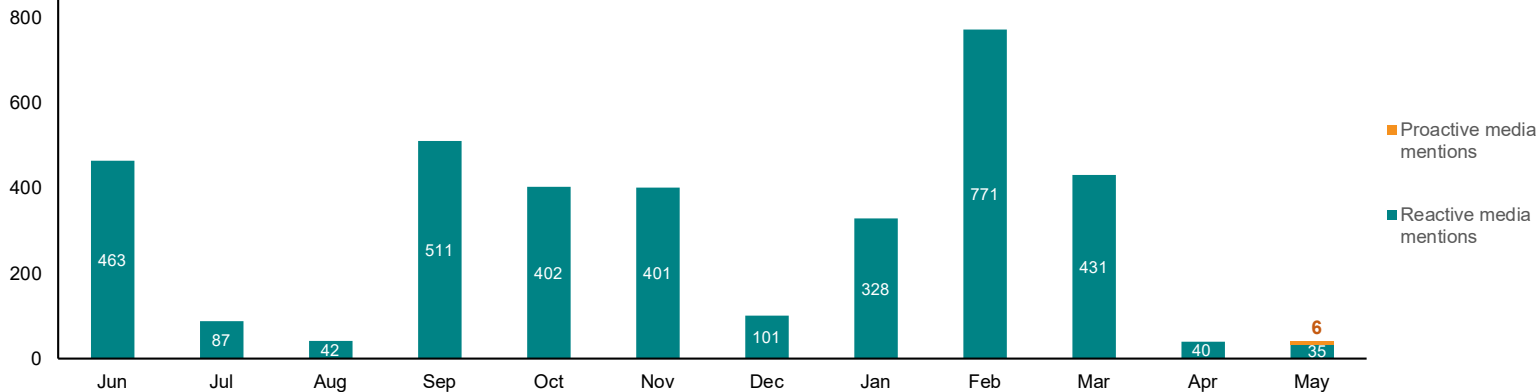
FOI requests and PQs completed



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

All FOIs were turned around within KPI timescales. FOI topics related to donation (3), Choose a Fertility Clinic (2), finance, State of the Sector and egg freezing.

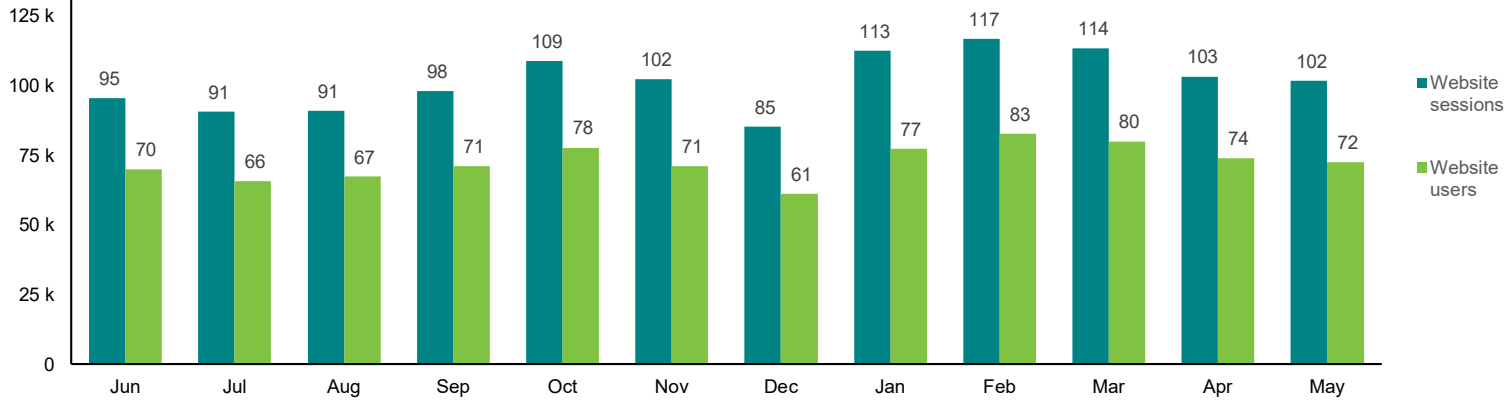
Proactive and reactive media mentions



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

We received a lower volume of press coverage due to the general election. A quote from Julia Chain was included in a DHSC press release on proposed SI changes on partner donation in relation to reciprocal IVF, and egg and sperm donation from those who have HIV with an undetectable viral load. This led to a small amount of proactive coverage.

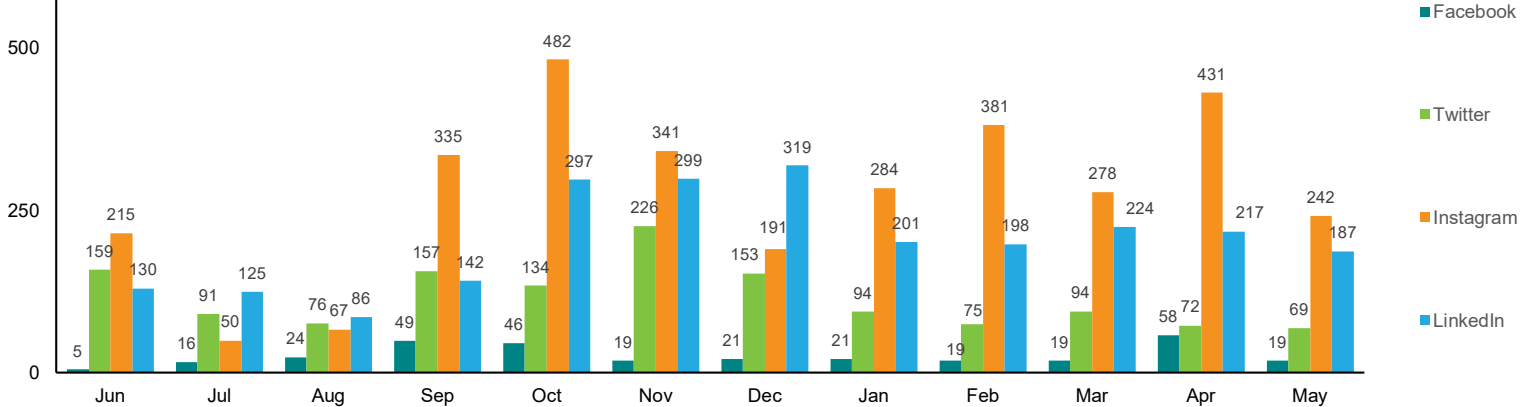
Total number of website sessions and users (in thousands)



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

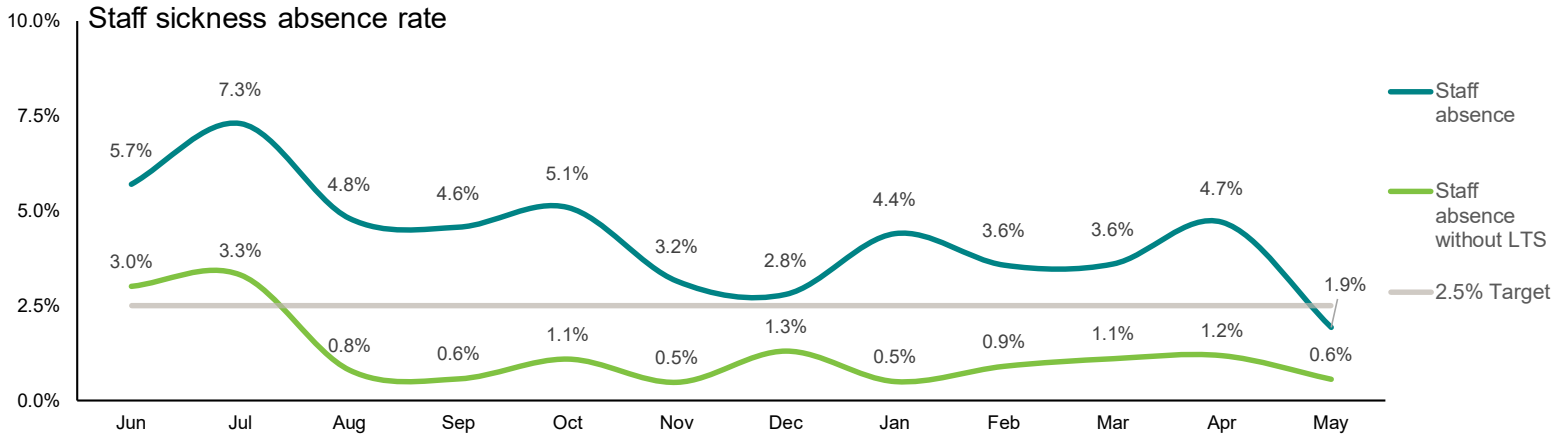
The website activity was broadly stable.

Social media engagement



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

We posted content to celebrate International Nurses Day, as well as a collaborative post with Fertility Network UK in aid of Mental Health Awareness Week. The best performing content was a quote from Julia Chain about the proposed law change. Other content focused on explaining various fertility treatments. We posted less content than usual due to the general election being called, pausing all proactive content until we had clearer comms guidance.



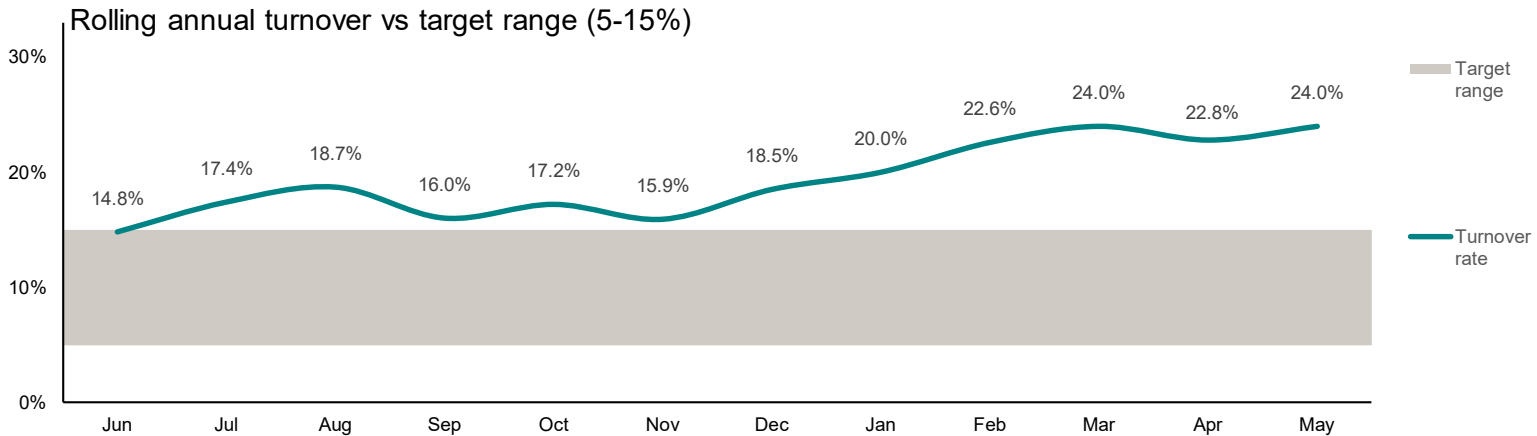
Status: **Green**

HR

Sickness

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

We have one employee who remains on LTS. A plan is in place to resolve this.



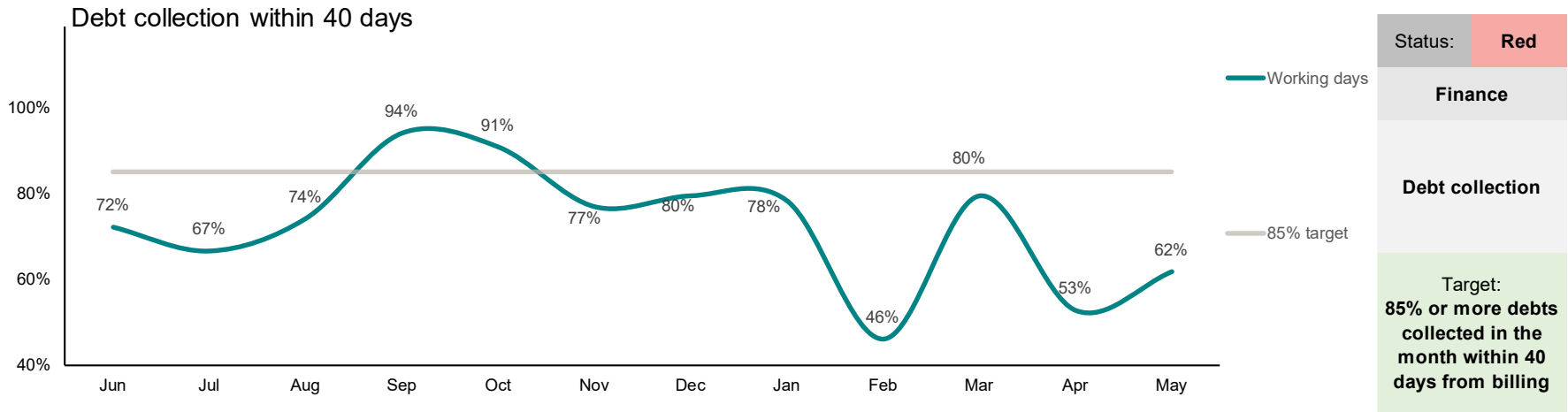
Status: **Red**

HR

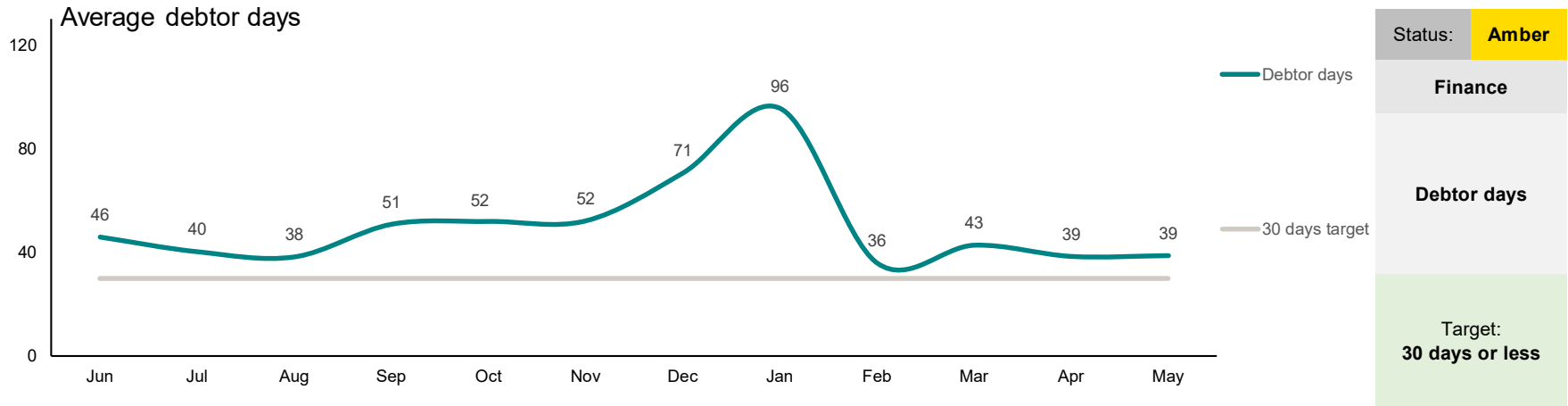
Turnover

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

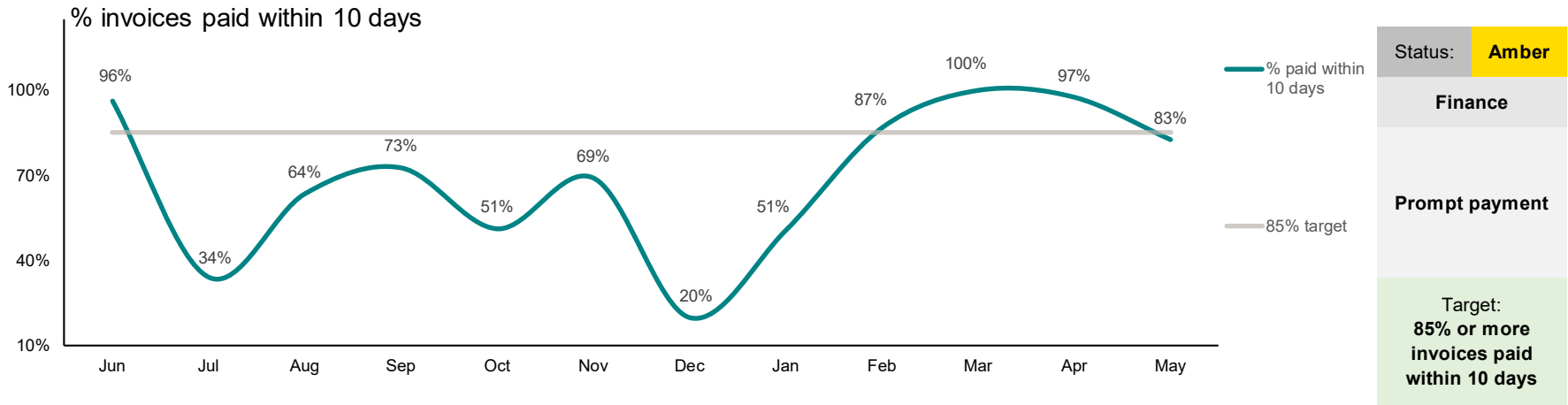
Supplementary HR data: **Headcount - 73, Posts - 76, Vacant Posts - 3, Starters - 1, Leavers - 1.**



Similar to last month the KPI shows only 62% of receipts relate to invoices less than 40 days old. This reflects a substantial payment being received from a small number of clinics to settle their overdue outstanding invoices. This has had a positive impact on the debt balance but has negatively impacted this KPI.



Debtor days continues to reduce as more progress is made on the older aged debt. £190k of the debt balance relates to three clinics that belong to a single group that have not made payment for over a year. This matter is in hand, and we hope to report a payment has been received next month.



Of the 12 payments made outside of the 10-day target six relate to staff expenses that were delayed awaiting manager approval.

Proposed approach to the upcoming HFEA fee review

Details about this paper

Area(s) of strategy this paper relates to:	<p>The best care – effective and ethical care for everyone</p> <p>The right information – to ensure that people can access the right information at the right time</p> <p>Shaping the future – to embrace and engage with changes in the law, science and society</p>
Meeting:	Authority
Agenda item:	7
Meeting date:	3 July 2024
Author:	Tom Skrinar, Director of Finance

Output from this paper

For information or decision?	For decision
Recommendation:	<p>The Authority is asked to</p> <ul style="list-style-type: none"> • Agree the principles for the review outlined in para 2.5 • Note the range of regulatory and clinic activities to be reviewed • Note the process and timing of the review.
Resource implications:	Medium
Implementation date:	Full review of fees to commence in 2024/25. Full implementation is likely to commence from 2026/27 due to consultation and the need to develop robust forecasts and fee values.
Communication(s):	None as yet. We intend to consult with the sector more widely once we have clarified options and internal requirements.
Organisational risk:	Medium

1. Background

- 1.1. It has long been the policy of UK governments that regulated entities should bear the cost of regulation. The current HFEA fee model achieves that largely by means of a charge on activity (IVF and DI treatments) coupled with modest charges for certain licence applications (see Annex A for an overview of the current fee regime). The remainder of the HFEA costs are met by way of a grant (grant-in-aid or GIA) from the Department of Health and Social Care (DHSC).
- 1.2. Due to a reduction in the number of chargeable cycles in 2019/20 and the subsequent impact on HFEA income, the Authority agreed in January 2020 that the HFEA should undertake a review of its licence fee model for the 2021/22 financial year. The subsequent impact of COVID on the sector prompted the Authority to delay the review to a future date.
- 1.3. Up to 2023/24, roughly 80% of HFEA's total income came from fees, with the remainder from GIA. As part of DHSC Efficiency and Reform work undertaken by DHSC in 2023, HFEA was asked to reduce the amount of GIA it receives in 2024/25 by £700k, which has increased the proportion coming from fees to around 95%. This has increased the HFEA's exposure to income variability, further necessitating a review of our fees and how predictable our income is to forecast. In addition, recent changes in clinical practice, such as the greater use of freezing, and the increasing cost of regulating the sector have also made the case for a fundamental review of our fee model.
- 1.4. The Public Body Review in 2023 raised the issue further and it was agreed that 'within the next 18 months [from 23/11/2023¹], HFEA should establish plans to allow it to conduct a review of its fee model'.
- 1.5. This paper sets out some early thoughts on the parameters for a review. The aim is to reach Authority agreement on the general direction of travel before beginning the detailed analysis.

2. Basis of the current fee structure

- 2.1. The current fee model (as set out in Annex A) has been in use for many years, and systems are set up within the HFEA and clinics so that billing can take place on a monthly basis. The model is broadly accepted by the sector and has, in general, been fairly predictable for the HFEA in supporting forecasting income and setting budgets effectively. Although most, if not all, clinics itemise the HFEA fee on bills to patients, it is important to note that the fee is charged to clinics not patients. The HFEA does not charge patients.
- 2.2. As the main driver of fees is chargeable activity, larger clinics that are more active pay greater fees, which is reasonable from a clinic affordability perspective. That said, the current system is not without its drawbacks. It is relatively complex as IVF and DI activity volumes are quite high and need to be tracked and verified to ensure charges are correct and any inaccuracies in the data can lead to administrative burdens on both clinics and the HFEA. It is also increasingly out

¹ [Independent review of the Human Fertilisation and Embryology Authority \(HFEA\): final report and recommendations - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/118111/independent-review-of-the-human-fertilisation-and-embryology-authority-hfea-final-report-and-recommendations.pdf)

of step with modern clinical practice. The fee is triggered by an embryo transfer and a donor insemination only. This means that a range of activities which require considerable regulatory oversight (e.g. egg and embryo storage cycles which are the fastest growing fertility treatment in the UK), do not incur a fee. Many of these non-fee activities are projected to grow year on year.

- 2.3.** From an HFEA budget management perspective, as fee income is driven by clinic activity rather than our regulatory activity, in years where volumes of IVF and DI treatments reduce, our income may go down even if our workload does not. The table below provides an overview of chargeable activity over the past five years, with an analysis of how variable activity is year on year (though clearly the pandemic has a significant impact on historic activity).

Table 1: IVF and DI chargeable activity

	2019/20	2020/21	2021/22	2022/23	2023/24
IVF activity	61,386	51,795	65,266	72,493	64,569
Movement		-16%	26%	11%	-11%
DI activity	5,676	5,598	6,968	6,638	6,383
Movement		-1%	24%	-5%	-4%

- 2.4.** We need to do more analysis to review variability from a clinic perspective, in particular to ensure we can factor in the impact of COVID and also any restructuring that has occurred within clinics. As a basic indication of the range between clinics, the average volume of chargeable IVF activity was around 700 per clinic in 2022, with some clinics performing less than 50 cycles of IVF, and some performing over 2,500 (to note this is draft data and is for indicative purposes only).

- 2.5.** If we opt to move away from the current fee structure after this review, the revised model would need to drive clear benefits for the HFEA and/or clinics and, as far as possible:

- fairly and transparently recover the actual costs of regulation incurred by the HFEA;
- be logically and administratively simple; and
- provide budgetary certainty and stability to support financial planning and management for both the HFEA and clinics.

3. Review of chargeable activities

- 3.1.** Currently, fees are driven by a mixture of regulatory and clinic-based activities (as per Annex A) but, as noted above, there have been a number of changes in both clinic and regulatory activities since the current fee model was designed, for example the growth of egg and embryo storage, and we will therefore wish to consider whether the current range of activities and the balance of fee levels applied to them are still appropriate.

- 3.2.** Chargeable activities either relate to regulatory activities carried out by the HFEA according to our regulatory duties, such as inspections and approving license applications, or through variable clinic led activities, such as the number of IVF cycles. We will calculate internally the average cost of delivering regulatory activities, but we would not be able to do the same for

clinic activities. Annex B provides an initial overview, but we will need to review the full range of activities as part of the fee review.

- 3.3.** As above, there is already a high volume of activity that drives fee charging and we do not want to design a new system that adds significantly more activity into the model (requiring increased data collection and being subject to error risks), so we must be careful not to simply add more detail.

4. Options

- 4.1.** There are a number of options in any fee model. The list below is not exhaustive and there are variations that we will want to explore more carefully that cover a range of fixed and variable cost elements based on regulatory and/or clinic activities. In summary, there are five potential models:
- A. **Status quo (mixed activity driven):** the 'do nothing' option. The current model is broadly accepted by clinics and has the technical infrastructure in place to ensure it can be collected (though is arguably becoming less equitable as it excludes growing freezing activity).
 - B. **Status quo plus (mixed activity driven):** this model remains driven by a mixed volume of clinic activity and license applications, but will involve a review of which activities should trigger costs (ie amend / add to the lists included in the Annexes) and the size of the fee relating to each activity (e.g. review the fair balance of emphasis on regulatory or clinic activities).
 - C. **Regulatory activity only:** this model will focus exclusively on regulatory activity (e.g. new licence applications, renewals, etc) and not the activities undertaken by the clinic (e.g. number of IVF cycles), with fees based on internally calculated unit costs for those regulatory activities.
 - D. **Flat annual fee:** this model will involve a move to a flat annual fee, based on a 'share' of overall HFEA costs, based on the type of license a clinic holds. This could be calculated as an average annual cost of being licenced (e.g. covering the nominal costs of the various regulatory activities required for a different types of licence, smoothed across the life of the licence).
 - E. **Banded flat annual fee:** this model will involve a move to a flat fee (as D above) within a number of different bands based on clinic activity (e.g. clinics that have a greater volume of activity are in a higher band and pay more than clinics with lower volumes of activity that would be in lower bands). Banding could be based on a basket of clinic activities from the previous year (e.g. as per Annex B).

5. Next steps and recommendations

- 5.1.** There are a number of tasks that we plan to take forward internally, starting in the summer. The initial focus will be on identifying and costing the current range of internal regulatory activities, as well as reviewing the list of clinic activities to which regulatory fees could in principle be

pegged. We will then need to undertake analysis and scenario testing to understand how the various activities and models will impact on fees levels for HFEA and the sector.

- 5.2.** Once we have completed this internal work, we will pull together a more detail range of options and recommendations for discussion with DHSC and HMT as well as the Authority, based on the principles outlined at 2.5 above but also taking into account the impact of any potentially significant changes in fees paid by individual clinics.
- 5.3.** Once we have shortened the list of options (and potentially chosen a preferred model), we will consult with clinics to test our understanding of the impact of the changes and to identify any issues or concerns. Due to the extent of work required to ensure that any future fee model does not negatively impact on clinics or the HFEA it would not be possible to implement any changes before 2026/26. We would therefore expect to consult on and refine the model in 2025/26.
- 5.4.** The Authority is asked to:
- Agree the principles for the review outlined in para 2.5
 - Note the range of regulatory and clinic activities to be reviewed
 - Note the process and timing of the review.

Annex A

HFEA fees 2024/25

Chargeable activities	DI and IVF treatment and storage centres Fee £	Storage centres Fee £	IUI treatment centres Fee £	Research centres Fee £
New licence application	500	200	975	500 or 750
Renewal licence application	250 or 500	200	500	500 or 750
3 rd party agreement (w/ centres not licensed by HFEA)	250	250	250	not applicable
Chargeable IVF treatment – embryo transfer (recurring fee)	100	not applicable	not applicable	not applicable
DI treatment - insemination (recurring fee)	40	not applicable	not applicable	not applicable
Annual activity	not applicable	not applicable	2,950	not applicable
Chargeable variations to licence – change of premises	500	500	500	500

[IUI (Intrauterine Insemination), DI (Donor insemination treatment)]

Annex B**Regulatory activity**

Core activities undertaken by the HFEA regulatory team that can be clearly identified and recognised by regulated establishments. This is a draft list, including some activities that are part of the current fee mechanism, that will need to be reviewed and activities costed as part of the fee review.

- New licence application (current fee). HFEA activity: initial licence inspection + admin, including licensing? This is the 'cost to enter the market'.
- Renewal licence application (current fee). HFEA activity: inspection + admin, including licensing.
- Interim inspection. HFEA activity: inspection + admin, including licensing.
- Research licence inspections. HFEA activity: inspection + admin, including licensing.
- Third part agreement with centres not licensed by the HFEA (current fee). HFEA activity: admin only, including licensing.
- Chargeable variations to licence – change of premises (current fee). HFEA activity: admin only, including licensing.
- Different types of licences, or different lengths of licences.

Clinic activity

Core activities undertaken by fertility clinics in providing treatment and services, that are regulated by the HFEA. This list includes activities that are part of the current fee mechanisms and will need to be reviewed and assessed as an indicator of clinic activity that may be factored into a future fee calculation.

- IVF (current fee). HFEA activity: admin only.
- DI (current fee). HFEA activity: admin only.
- Egg storage cycles. HFEA activity: admin only.
- Embryo storage cycles. HFEA activity: admin only.
- Other relevant activities.