

Authority meeting

Date: 25 September 2024 – 1.15pm to 4.00pm

Venue: 2 Redman Place

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	1.15pm
2. Minutes of the meeting held on 3 July 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. HFEA's horizon scanning function (25) For information	2.25pm
<i>Comfort break (5)</i>	
7. State of the sector plus key trends – what does this mean for the HFEA (30) For information	2.55pm
8. Communicating licensing, regulatory activity and incident information (30) For decision	3.25pm
9. Any other business (verbal) (5)	3.55pm
10. Close	4.00pm

Minutes of Authority meeting held on 3 July 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	25 September 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 3 July 2024 as a true record of the meeting.

Resource implications

Implementation date

Communication(s)

Organisational risk	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Medium	<input type="checkbox"/> High
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Minutes of the Authority meeting on 3 July 2024

Members present	Julia Chain Tim Child Frances Flinter Zeynep Gurtin Alex Kafetz Graham James	Alison McTavish Gudrun Moore Catharine Seddon Christine Watson
Apologies	Jonathan Herring Geeta Nargund	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Steve Pugh (DHSC)	
Staff in attendance	Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Rachel Cutting (Director of Compliance & Information) Tom Skrinar (Director of Finance & Resources) Paula Robinson (Head of Planning and Governance) Alison Margrave (Board Governance Manager)	

Members

There were 10 members at the meeting – 7 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.
- 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 the HFEA website to allow members of the public to hear it.
- 1.3. Declarations of interest were made by:
 - Tim Child (part-time consultant to a fertility company)
 - Jason Kasraie (PR at a licensed clinic)

2. Minutes of the last meeting and matters arising

- 2.1. The minutes of the meeting held on 15 May 2024 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

- 2.2. Members were advised that the matters arising items had been actioned as detailed in the paper presented to the meeting.
- 2.3. Members noted the matters arising report.

3. Chair and Chief Executive's report

- 3.1. The Chair gave an overview of her engagement with key stakeholders and her attendance at decision-making committees of the Authority.
- 3.2. The Chair informed members that in early June she had attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting and in late June the Audit and Governance Committee (AGC) meeting and further information about these meetings would be given by the relevant Committee Chair under agenda item 4.
- 3.3. The Chair, together with the Chief Executive, had attended the annual accountability meeting with the HFEA's sponsor team at the DHSC to review the HFEA's achievements over the past year. This was a very positive meeting with DHSC recognising the work which the HFEA had completed including delivering on the business plan commitments, completion of work on treatment add-ons, processing OTR applications, making proposals for law reform and the positive Public Bodies Review. The Chair thanked the HFEA staff for all their hard work during the past year.
- 3.4. The Chair reminded members that the DHSC recruitment process for four new Authority members had started earlier in the year, and it is hoped that appointments will be announced in the next few weeks after the General Election. Due to the delay in appointing the new members, Ministers had agreed to extend the terms of Gudrun Moore and Johnathan Herring for an additional 6 months. The Chair thanked colleagues from DHSC for their assistance in this matter.
- 3.5. The Chief Executive provided an update on the key external activities contained in the paper. He provided further details about the Ethics and Policy Symposium on In Vitro Gametogenesis (IVG) he and Frances Flinter had spoken at. He stated that SCAAC had been tracking the development of IVG for a number of years and this work has now gathered pace and it could transfer to clinical practice within the next 5-10 years. Currently IVG is lawful in research but unlawful in treatment and the HFEA would need to take a policy decision on this in the future. SCAAC would continue to monitor IVG through its work.
- 3.6. Frances Flinter commented that IVG would be of interest for same sex couples as the child would be genetically related to both parties.
- 3.7. The Chief Executive spoke of the purpose of the Health and Care Regulators Forum which the HFEA had just joined in sharing policy thinking and common issues. Continuing, he spoke of the overlap in regulation between some organisations, so a forum such as this is useful in bringing the different parties together.
- 3.8. The Chair spoke of the speed of change in the fertility sector and the need to ensure that the HFEA's regulatory framework keeps pace with such changes.

Decision

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

4. Committee Chairs' reports

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

- 4.2.** The Licence Committee Chair (Graham James) gave an overview of recent meetings and informed members that the Director of Compliance and Information had attended a recent committee meeting to explain how the Executive responds to critical incidents.
- 4.3.** The Statutory Approvals Committee (SAC) Deputy Chair (Gudrun Moore) provided a brief overview of recent meetings, noting that the last set of minutes have not yet been approved.
- 4.4.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed members that the committee had concluded that PGT-P (PGT for polygenic disorders or polygenic risk scores) is not yet able to accurately predict future health and appropriate patient information will be developed for the PGT pages of the HFEA website. With regard to artificial wombs for early or whole gestation and alternative methods to derive embryonic and embryonic-like stem cells, the committee will continue to monitor clinical and scientific advancements. The committee had also considered the application for androgen supplementation as a treatment add-on. And they welcomed the three newly appointed external advisers. The SCAAC Chair informed members that the HFEA annual horizon scanning meeting will be held during the European Society for Human Reproduction and Embryology (ESHRE) Conference in July.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had considered the draft Annual Report and Accounts and had made a provisional recommendation for the Accounting Officers to sign these, pending completion of a number of actions by the NAO. The committee had delegated authority to the AGC Chair or Deputy Chair to approve any amendments proposed by the NAO to the Annual Reports and Accounts and to authorise the Accounting Officer to sign said documents. Members were informed that the annual audit rating was 'moderate', noting good progress in a number of areas. The committee also received reports on the Strategic Risk Register, PRISM and HR.
- 4.6.** The Chair commented that it had been a very busy time for committee work and she thanked members of all the committees for their work in supporting the HFEA.

Decision

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

5. Performance report

- 5.1.** The Chief Executive introduced the performance report and stated that several KPIs had been recast to better provide clarity of what is being measured and why. He stated that performance has been good across the KPI indicators with nine green, three amber, two red and three neutral indicators.
- 5.2.** The Chief Executive referred to the HR KPIs and informed members that staff sickness rates have improved and when long-term sick leave is excluded this KPI is under the target range.
- 5.3.** Turnover rate continues to be higher than our ideal range, but the HFEA is a small organisation with limited opportunities for promotion and further constrained by pay rates set by Government. Staff surveys show high morale and HR processes to fill vacancies, when they arise, are efficient to minimise gaps and ease pressure on remaining staff.
- 5.4.** The Chair agreed with the Chief Executive's assessment, but added that HR have implemented several initiatives which make the HFEA a good place to work. She questioned whether the HFEA keeps in touch with former staff to inform them when vacancies arise.

- 5.5.** The Chief Executive responded that informal channels of communication are kept with former staff. The Chief Executive said that news of the anticipated staff pay award had been delayed by the Government until Autumn.
- 5.6.** A member congratulated the HFEA on its work and commitment under Equality, Diversity & Inclusion (EDI) which was reported to the AGC meeting via the HR bi-annual report.

Compliance and Information

- 5.7.** The Director of Compliance and Information thanked the inspection team for their hard work in improving the inspection KPIs, whilst the team is still affected by one long term absence and the need to train new members. The KPIs for 'inspection reports to PR' and 'inspection report to committee' are both in green and the 'end to end licensing' KPI is achieving 90% of target completion. It was stressed that there would always be genuine reasons why a KPI may be breached, especially regarding challenging and complex inspections.
- 5.8.** Members were informed that OTR applications remain steady with approximately 80 per month, although there are increased spikes in applications around media interest. The new case management system and register tools allowed the OTR team to close 175 cases in May and 144 in June, which has started to make an inroad into the waiting list. Members were informed that the new tools will allow the team to process applications by type and monitor individual waiting times going forward.
- 5.9.** Members were informed that this year's Data Security and Protection Toolkit (DSPT) submission had been completed and thanks were given to the staff involved. The Director of Compliance and Information stated that whilst the HFEA's compliance is improving year-on-year, the set of requirements also increase year-on-year which increases significantly the documentation required.
- 5.10.** The Director of Compliance and Information informed members that the IT infrastructure Pen Test had been completed and the team were now working through the recommendations.
- 5.11.** Members were informed that the team were working with DHSC procurement colleagues to progress the Epicentre replacement.

Strategy and Corporate Affairs

- 5.12.** The Director of Strategy and Corporate Affairs remarked that as Co-Chair of the Executive Licensing Panel she had seen an increase in Person Responsible (PR) comments on inspection reports coming to the committee and that these were positive about working with the inspection team.
- 5.13.** Members were informed about the internal audit on the Register Research Panel (RRP) noting that it had achieved a 'substantial rating' with just one recommendation.
- 5.14.** Due to the General Election communication activities have been quieter than normal, although media requests are still coming through. Members were informed about the anticipated publication dates for various reports and the patient survey.
- 5.15.** The Director of Strategy and Corporate Affairs informed members that the progress of the Statutory Instrument on screening had been paused due to the General Election. At the previous meeting the Authority had delegated responsibility to the Chair to sign the updated documents relating to these changes. Given the delay in this work she sought assurance from the Authority

that they were content with their previous decision regarding delegated responsibility. Members confirmed satisfaction with their previous decision.

- 5.16.** In response to a question the Director of Strategy and Corporate Affairs stated that data on the webpages visited is collected but this did not vary much from one month to the next. However we could add to the commentary on significant changes in future.

Finance

- 5.17.** The Director of Finance and Resources referred to the information contained in the paper and stated that whilst the first two months of the year are showing a small surplus it is too early to provide meaningful data.
- 5.18.** Members were informed that the Finance Team will begin its detailed forecasting of the first quarter and if required teams will amend their plans to reflect the forecasting.

Decision

- 5.19.** Members noted the performance report.

6. Strategic Risk Register

- 6.1.** The Chair introduced this agenda item by reminding the Authority that they receive the strategic risk register (SRR) twice a year for review; with the last review taking place in November 2023. Members were informed that the AGC had scrutinised the SRR in detail at their meeting on 26 June.
- 6.2.** The Head of Planning and Governance presented the SRR and stated that her commentary will include suggestions made by the AGC members at their meeting last week.
- 6.3.** Members were informed that the financial risk has been updated with the new fee regime and the impact from the reduction in Grant-in-Aid (GIA). The governance risk has been updated to reflect the growth in online services.
- 6.4.** Information had been updated to reflect the increase in media coverage and the work that will be required on the HFEA website once the Epicentre replacement is secured. Information 2 had been updated to reflect the changes in the OTR system.
- 6.5.** Members were informed that the operational risk commentary had been updated to reflect the risk position regarding Epicentre and a new sub-section for CaFC had been included.
- 6.6.** The People risk commentary text had been updated to reflect the single point of failure in small teams. For the People 2 risk the AGC had asked management to review the wording as the HFEA operates a robust and thorough induction process for Authority members. The issue that arises is the time needed to train and upskill new members before serving on our licensing committees, and the short lead in time from when appointments are announced.
- 6.7.** The Head of Planning and Governance stated that the AGC had agreed with the strengthened mitigations in security and had agreed to close the strategy risk as the Public Body Review had been concluded successfully.
- 6.8.** The AGC Chair informed members that the committee had held a discussion on whistleblowing by clinic staff and whether this should be captured within one of the risk categories due to the resource implication for dealing with such reports.

- 6.9.** The Director of Compliance and Information spoke of the work of the inspection team in encouraging whistleblowing and the fact that they meet with a range of clinic staff and not just the PR during an inspection. The compliance team have also encouraged whistleblowing by leaving contact cards in clinics. We have seen a positive response to this. She spoke about the experience of the clinical governance team and the Chief Inspector and the legislation around whistleblowing that the HFEA complies with. Members were reminded of the HFEA's remit and the legislation within which it operates and how some whistleblowing reports, such as clinic HR matters, are outside the remit of the HFEA. However, it was acknowledged that information received through whistle blowing was useful intelligence,
- 6.10.** A member suggested that existing members of the Licence Committee could assist in the induction of new members assigned to the Committee, as a source of sharing knowledge and upskilling new members quicker.
- 6.11.** The Chief Executive commented that one element of the risk associated with People 2 had decreased due to the extension of two existing members' term of office, but the risk associated with the lead time for new members' appointments, allowing for induction and training, was still live.

Decision

- 6.12.** The Authority noted the Strategic Risk Register.

7. Fees Review

- 7.1.** The Chair introduced this agenda item and stated that this will be a long piece of work, involving consultation and any proposed changes will need to be agreed by HM Treasury. She stressed that the Authority is not being asked to decide today, but rather to consider the options presented in the paper and give a steer on preferred options to the Chief Executive and Director of Finance and Resources.
- 7.2.** The Director of Finance and Resources introduced the paper stating that it had long been the policy of UK governments that regulated entities should bear the cost of regulation. He explained the HFEA's current fee model and the recent reduction in grant in aid (GIA).
- 7.3.** In January 2020 the Authority had agreed that the HFEA should undertake a review of its licence fee model for the 2021/22 financial year but the subsequent impact of COVID-19 on the sector prompted the Authority to delay the review to a future date.
- 7.4.** The Public Body Review that was conducted in 2023 had agreed that within the next 18 months the HFEA should establish plans to allow it to conduct a review of its fee model.
- 7.5.** The Director of Finance and Resources explained the basis of the current fee structure, noting that there are a range of activities, such as egg and embryo storage cycles, which require regulatory oversight but do not currently incur a fee.
- 7.6.** The Director of Finance and Resources stated that the principles for a review of the fee model should be to 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.

- 7.7.** The Director of Finance and Resources introduced the options contained in the paper and explained each one in detail.
- 7.8.** The Chair remarked that the fertility sector is one where activities have expanded quickly but the fee regime has not kept up with those changes.
- 7.9.** A member gave their view from a clinic's perspective stating that there is wide acceptance of how the current fee structure works but they acknowledged that activities, such as egg and embryo storage, are outside the current fee structure. Smaller clinics could be concerned about a flat annual fee and he questioned what the banded flat annual fee would be based on. The Director of Finance and Resources responded that the banding levels would be based on the level of clinic activities.
- 7.10.** In response to a question the Director of Compliance and Information informed members that a third party is a satellite clinic, such as a local regional hospital that may undertake consent work and initial paperwork while the licensed treatment activity takes place at the primary licensed centre.
- 7.11.** Several members agreed with the sentiment of decoupling the HFEA fee as a perceived 'treatment tax' which clinics levy on patients' overall bills. The banded flat annual fee could mean that clinics absorb this fee, as they do other overheads such as rent and utilities and pass on a percentage of this to their customers.
- 7.12.** A member commented that it could be helpful to have information and comparison with other regulators and what fee structure they have implemented.
- 7.13.** The Chief Executive commented that the proposals contained in the paper are set out to recover the costs of regulation and not designed to generate profit.
- 7.14.** Members discussed the benefits and advantages of the status quo plus option as presented in the paper and how this could be accepted by the sector.
- 7.15.** In response to a question the Director of Compliance and Information spoke of how intensive and time-consuming initial applications are for the inspection team and under the present fee model those costs are not recouped.
- 7.16.** A member questioned whether it was possible to incentivise clinics for compliance and perhaps implement a fining system for non-compliance.
- 7.17.** A member spoke about compliance for non-payment of bills and that the HFEA should be able to charge for non-payment.
- 7.18.** The Chair drew the discussion to a close noting that the principles for the review were agreed; that options B and E as presented in the paper were currently favoured by the Authority and warranted further development; and that if possible the decoupling of the HFEA's fee as a perceived 'treatment tax' levied on patients by clinics was welcomed.

Decision

- 7.19.** The Authority agreed that the principles for a review of the fees should 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.

- 7.20.** The Authority noted the range of regulatory and clinic activities to be reviewed and the process and timing of the review.
- 7.21.** The Authority noted that out of the options presented in the paper, options B and E warranted further development.

Action

- 7.22.** The Director of Finance and Resources to commence work on the fee review.

8. Any other business

- 8.1.** The Chair thanked all for their active participation in the meeting.
- 8.2.** The Chair reminded members of the dates of the September and November meetings and that an Authority away day will also be held in November. It is hoped that the new Authority members will be appointed by then.
- 8.3.** The Chair spoke about an event she had arranged for the 100th birthday celebration of the late Mary Warnock being held on 30 October and she would circulate details to members.
- 8.4.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 25 September 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: 25 September 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 25 September 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
3 July 2024	The Director of Finance and Resources to commence work on the fee review	Director of Finance and Resources			Initial discussions with relevant HFEA officials and work plan developed. Meeting arranged with MHRA to discuss their current fee review and public consultation. This work is already included in the HFEA's business plan, therefore can be closed.

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:	25 September 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 July 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:
 - 15 July – attended the all-staff event
 - 24 July – met (with Chief Executive) representatives of Fertilis
 - 30 July – introductory meeting with our new minister, Baroness Merron (with Chief Executive and Director of Strategy and Corporate Affairs)
 - 4 September – attended (with the Chief Executive) PET Event - BioNews birthday celebration and Writing Prize
 - 17 September – met the Scottish Minister for Health Jenni Minto and also attended the National Fertility Group meeting.

2.2 Chief Executive

- The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:
 - 15 July – attended the all-staff event
 - 24 July – met (with the Chair) representatives of Fertilis
 - 30 July – introductory meeting with our new minister, Baroness Merron (with the Chair and Director of Strategy and Corporate Affairs)
 - 4 September – attended (with the Chair) PET event

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: 25 September 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:		
27 June	2 Executive updates	1 Executive update noted 1 Continued suspension (ends 8 August)
1 August	1 Executive update	1 Executive update noted
29 August	1 Initial research licence	1 Licence granted
Other comments:	None.	
Executive Licensing Panel:		
27 June	4 T&S interims 1 Variation of premises 1 Variation to add embryo testing 1 Variation of PR	All approved
9 July	2 Interim inspection reports 1 Research interim inspection report	All approved
24 July	1 Research renewal inspection report 2 Interim inspection reports 1 Variation to licensed premises 1 Variation of PR	All approved
5 August	2 Research renewal inspection reports 3 Interim inspection reports 2 Variations to add embryo testing	All approved
20 August	1 Research renewal inspection report 1 Variation of PR	All approved
3 September	2 Interims inspection reports	1 Adjourned, 1 approved
17 September	1 Research renewal inspection report 1 Interim inspection report 1 Executive update	Minutes not yet approved.
Other comments:	None.	

Meetings held	Items considered	Outcomes
Licensing Officer decisions:		
June, July and August	64 ITE import certificates 2 Changes of LH 2 Voluntary revocations	All granted
Other comments:	Reported numbers are higher than usual, but this is because we are reporting three months at once owing to the spacing of the Authority meetings. Also, during August there were an unusually high number of ITE import certificates processed due to Born Denmark changing address, resulting in 35 UK clinics requiring updates to their certificates to reflect this.	
Statutory Approvals Committee:		
24 June	4 PGT-M applications 1 Special direction for export	1 PGT-M application refused. Remaining items approved.
30 July	1 PGT-M application 1 Special direction for export	All approved
27 August	4 PGT-M applications 1 Special Direction for export 1 Special Direction for import	1 PGT-M application refused. Remaining items approved.
Other comments:	None.	
Audit and Governance Committee:		
The next meeting will be held on 1 October 2024.		
Scientific and Clinical Advances Advisory Committee:		
The next meeting will be held on 7 October 2024. Recommendations from this meeting will be presented to the November Authority meeting. A report on the horizon scanning meeting held at ESHRE is a separate item on the Authority's agenda for this meeting.		

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 August 2024

Shabbir Qureshi

Risk and Business Planning Manager

25/09/2024

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:	25/09/2024
Agenda item:	Item 5
Author:	Shabbir Qureshi, Risk and Business Planning Manager
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 August 2024.
- There were ten Green, three Amber, one Red, and three Neutral indicators.

Key trends

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

June (5)	July (1)	August (1)
End to end licensing within 80 working days	Debt collection within 40 days	Debt collection within 40 days
Staff sickness rate below 2,5%		
Turnover within 5% to 15% range		
Debt collection within 40 days		
Average debtor days within 30 days		

Management summary

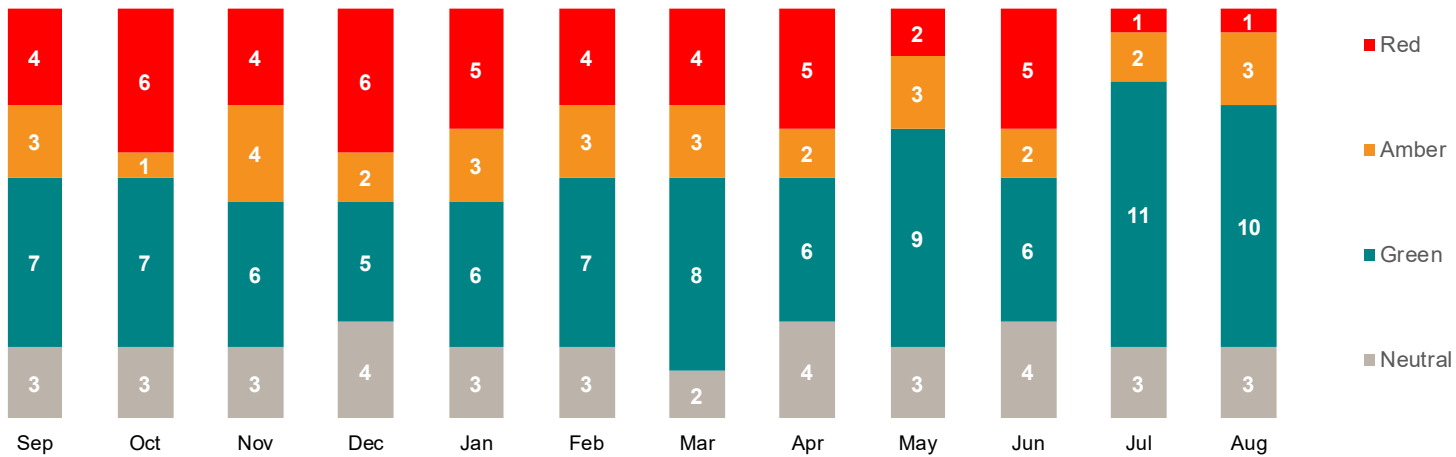
Management commentary

- Performance has been very good across KPI indicators with ten Green, three Amber, one Red, and three Neutral.
- The inspection team continues to perform well against their targets, with only the inspection reports to PR KPI as Amber. The end-to-end licencing KPI has been green for the last two months, and the inspection reports to committee has been green for the last four months.
- We have received a higher number of PGT-M applications over the last two months, the processing of which remains within the 75 working day target.
- The licencing team processed a high number of ITE certificates due to a premises change for an overseas supplier.
- The OTR team have continued to process a high number of applications. However, the high demand has continued so the overall waiting list remains of a similar size. In the last six months, we have processed three times the number of OTRs compared to the previous six months suggesting that the system reforms are having a positive impact.
- The number of email enquiries remain high; however, the majority are straightforward. OTR enquiries continue to be a focus.
- No proactive media communications were made this month, and we received slightly lower reactive media mentions.
- Social media engagement was significantly lower than last month across all channels with Clare Ettinghausen's statement on donor compensation increase receiving the most coverage.
- Staff sickness remain low and stable, with one employee on long term sickness. Turnover has also reduced but is still just above the 15%-5% target range.
- Debt collection KPI remains red and average debtor days is also above target. 17% of the payments received in August were from invoices relating to last year and are part of the ongoing task of recovering old debt.

Key performance indicators

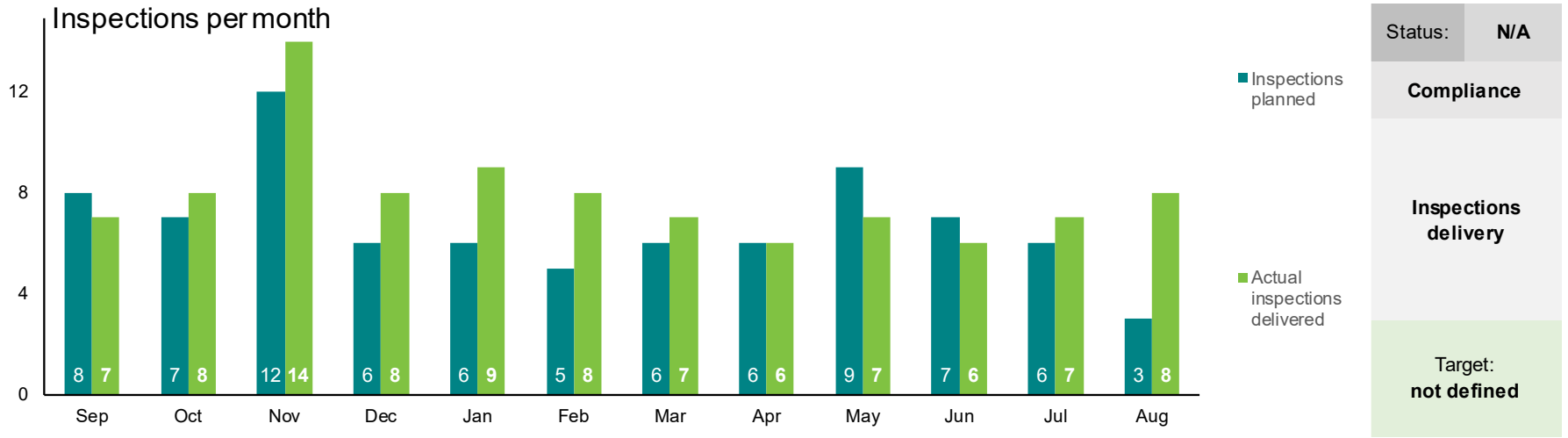


RAG status over last 12 months

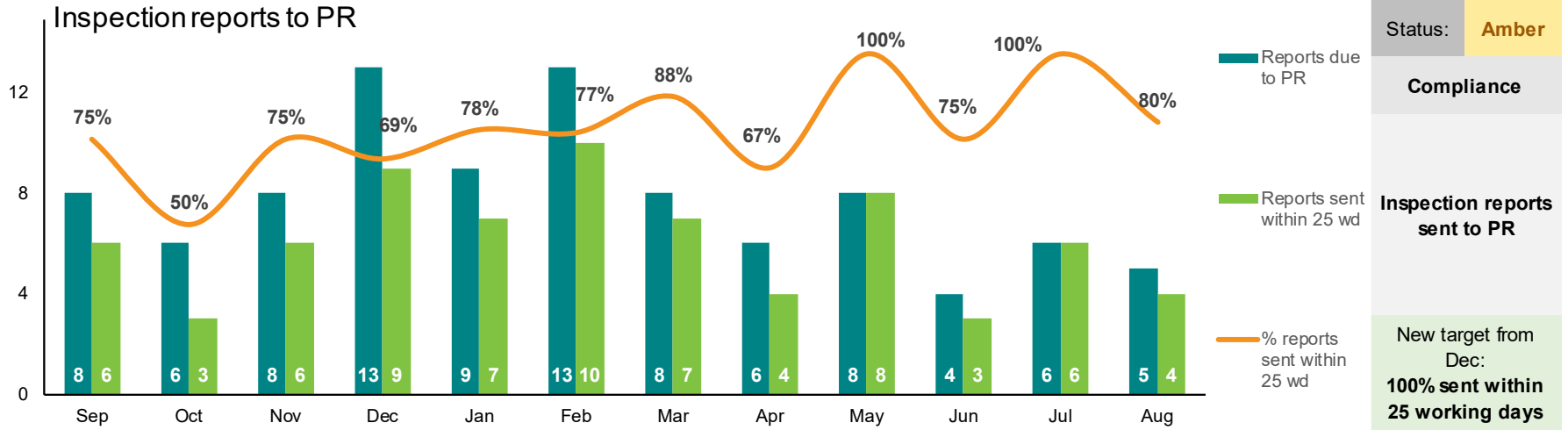


RAG status over last 12 months
17 KPIs in total for each month

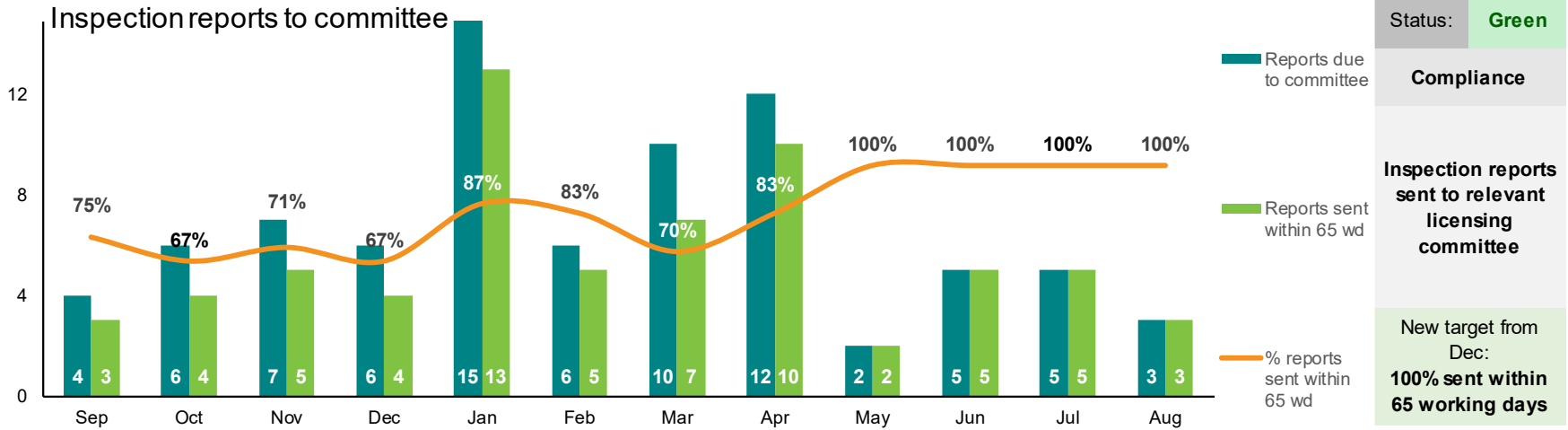
For August, the 1 red indicator is in Finance (1)



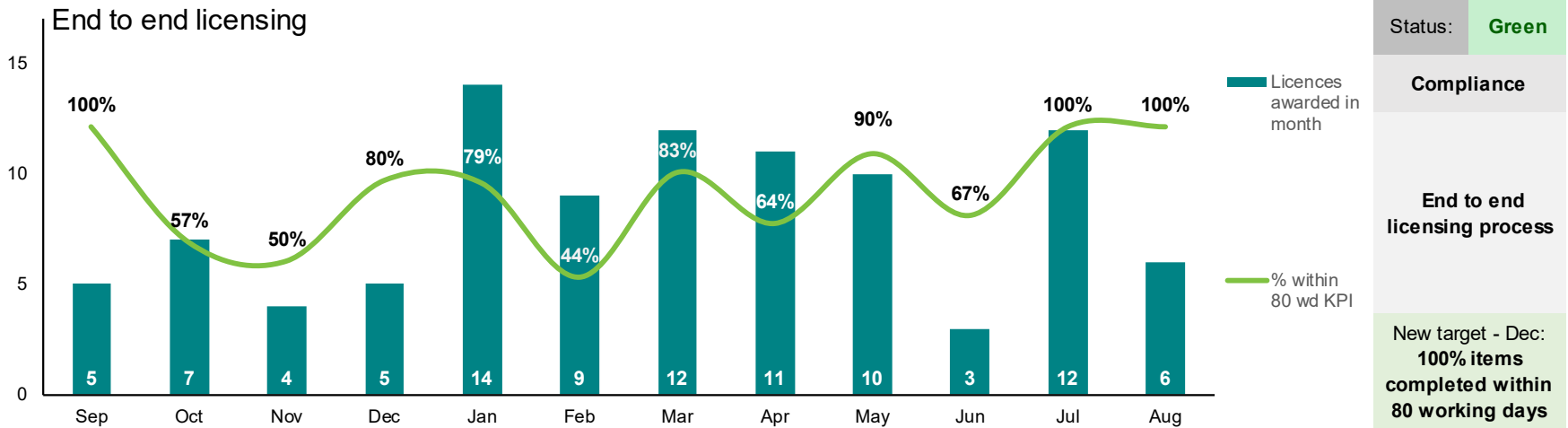
1 clinic started in July, fully delivered in August as additional information requested post inspection. 3 clinics rolled over from June to August as delays with peer reviews were expected. 1 clinic moved from December to August; inspection completed earlier due to increased regulatory oversight.



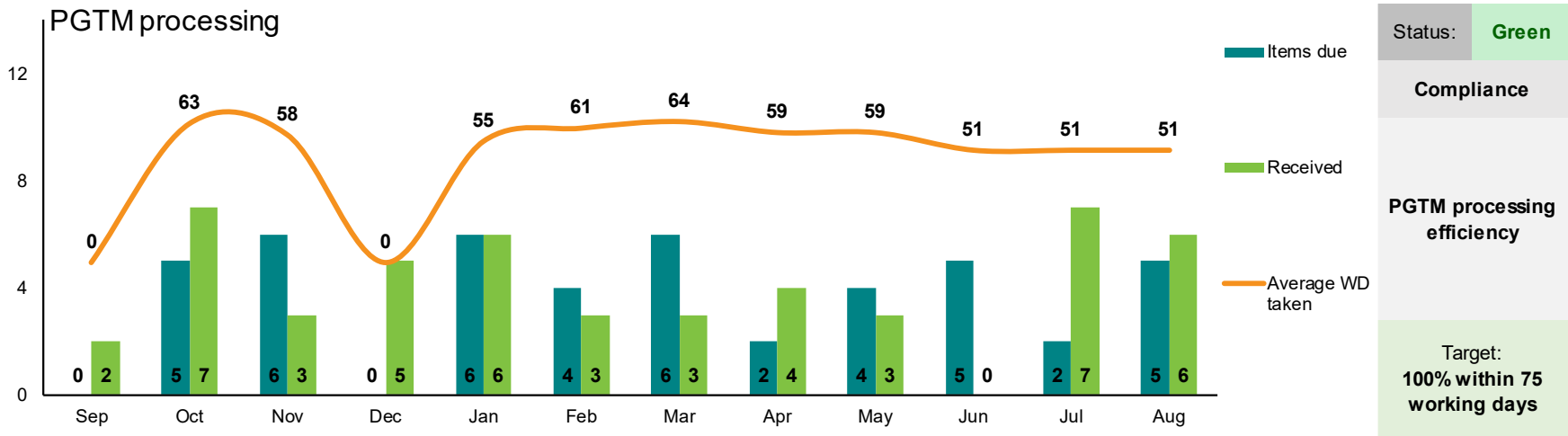
1 research clinic report delayed (55wd) as peer reviewer comments and responses from PR were required.



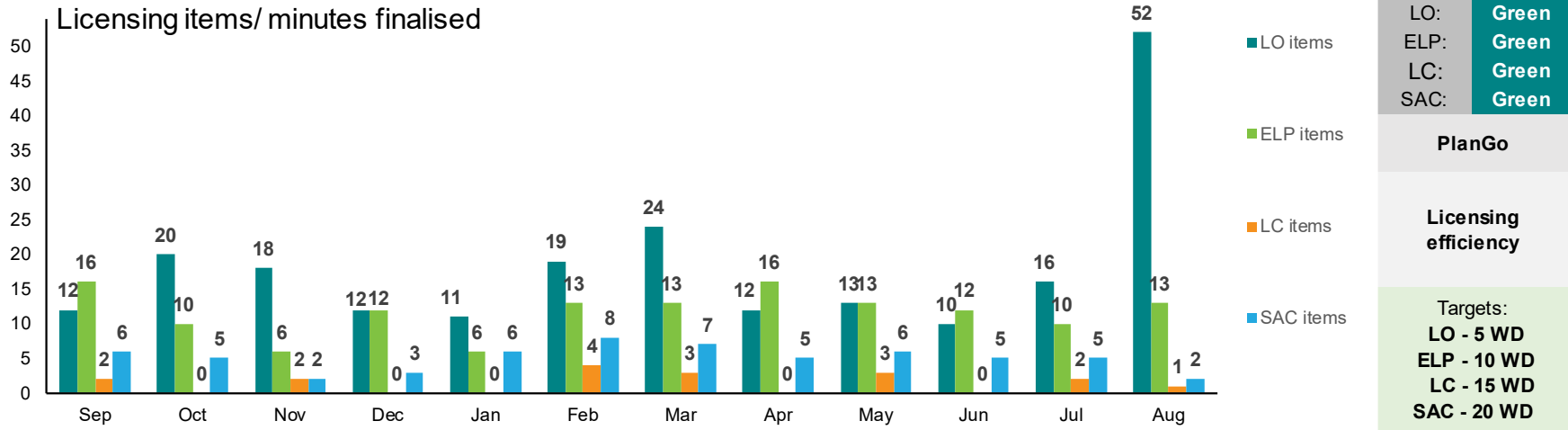
Fourth month in a row with all reports completed within the 65 working day target.



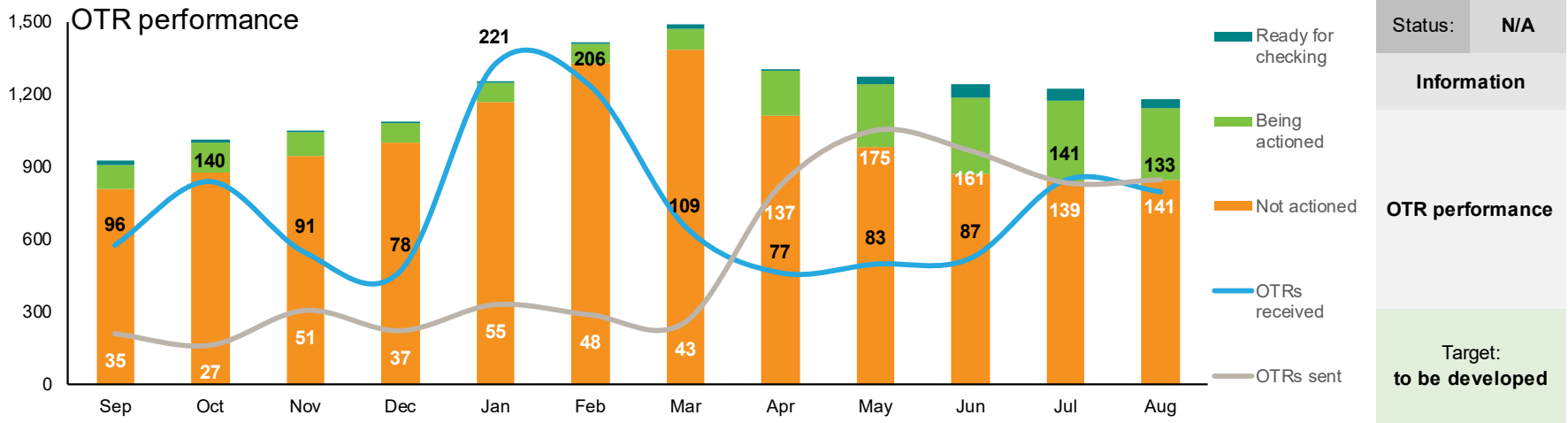
Second month with all inspection reports completing the end to end cycle within the 80 working days target. The longest report in August took 61 working days.



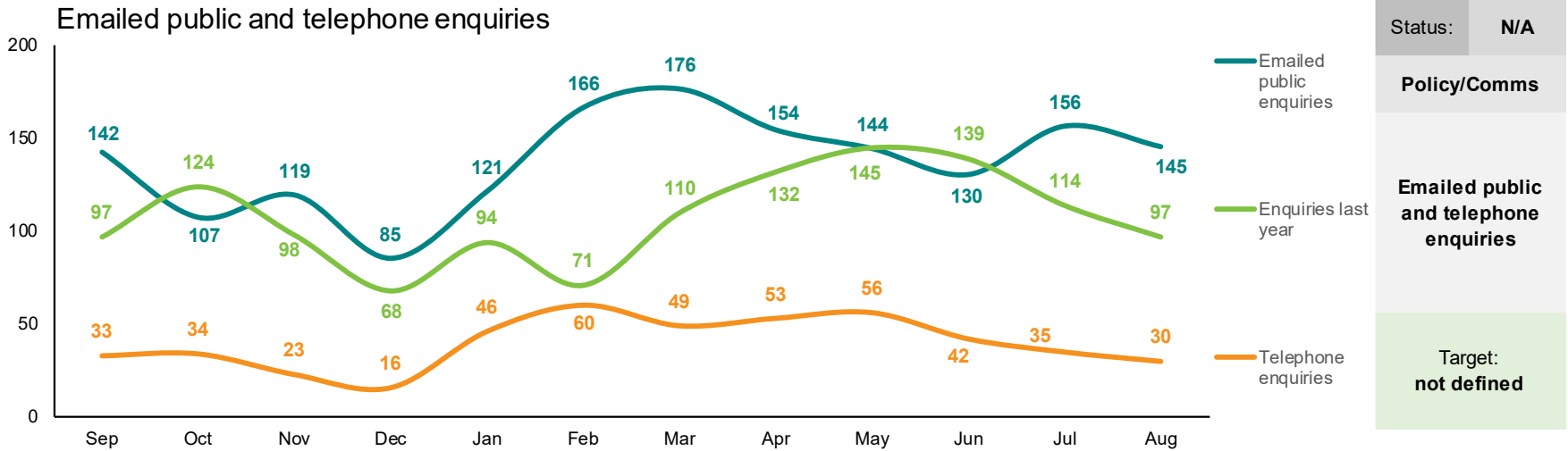
All PGTM items have been processed within KPI.



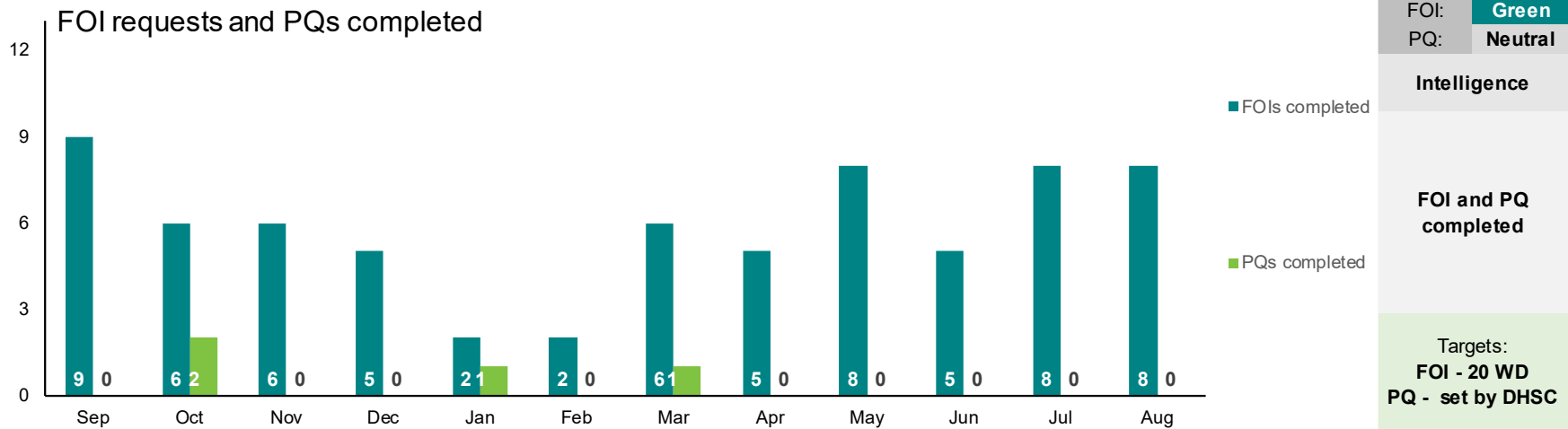
51 out of 52 LO items were ITE certificates. The high number is due to processing applications relating to the premises change of Born Denmark, a third country supplier for many UK clinics. The one set of LC minutes relates to an additional meeting, and was expedited since it related to a suspension being lifted.



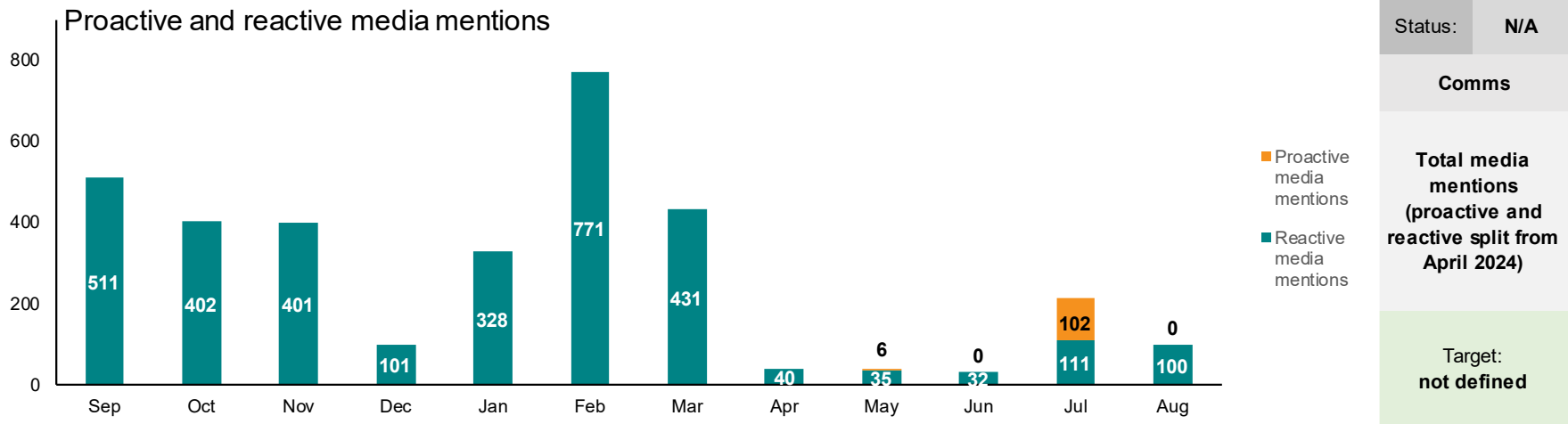
Continued high number of OTRs were sent out. A high number were also received, as such the waiting list remains a similar size. However, more applicants have received a response in the last 6 months than any previous 6 month period.



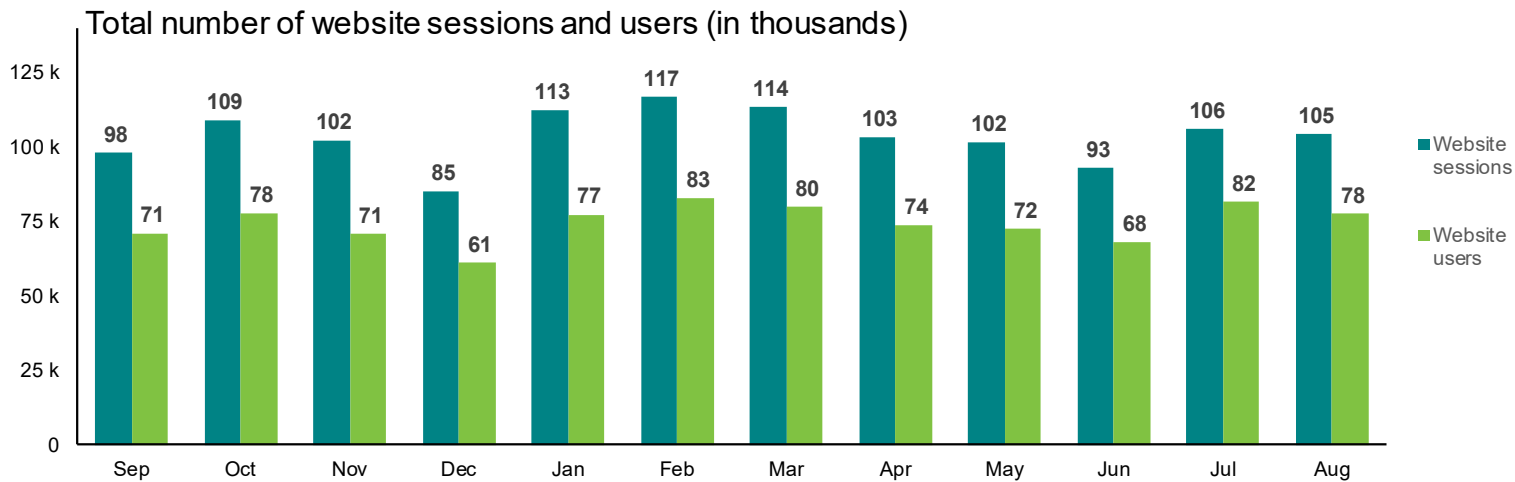
Out of the logged emails: 116-straightforward, 12-complex, 2-redirected. Themes: OTR (35), Complaints (13), Donation (18), Movement of gametes and embryos (8), Screening and testing (7), and Starting treatment (6).
 Phone call themes: Beginning treatment (9), Complaints against clinics (5), OTR (4), and Medical queries and concerns (4).



All FOIs were completed within the target timescales. FOI topics were mainly related to donation, egg storage, treatment types, and finance. No PQs in August.

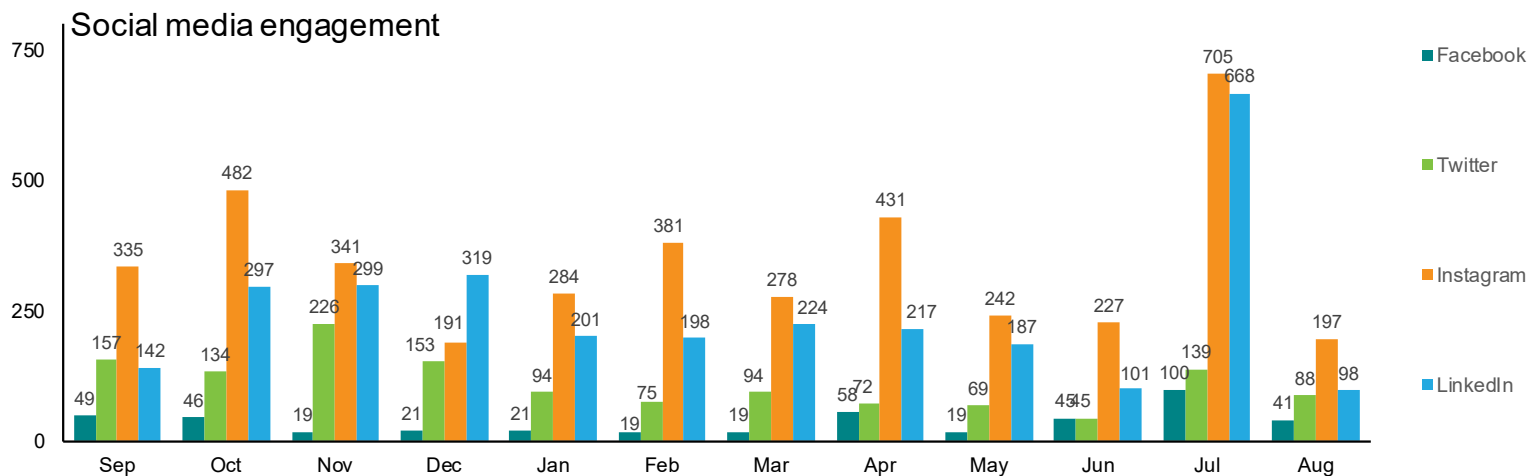


We received a slightly lower number of reactive media mentions compared to the previous month and we had no proactive communication this month. Themes included international sperm donation and donor compensation.



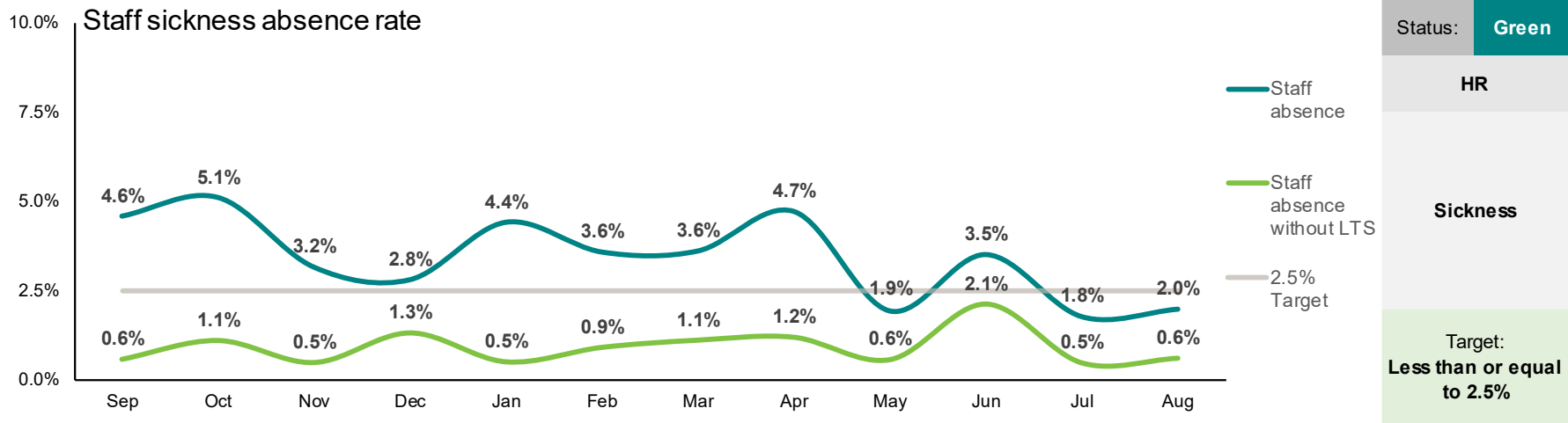
Status:	N/A
Comms	
Total number of website sessions and users (Internal traffic excluded from October 2023)	
Target: not defined	

There was a slight decrease in website sessions, users and views during August, in line with normal trends. 'Donating your eggs' became the most viewed page, followed by 'Fertility clinic search' and 'Donating your sperm'. This change could be the result of a BBC Breakfast segment about the increase in egg donor compensation and subsequent media coverage.

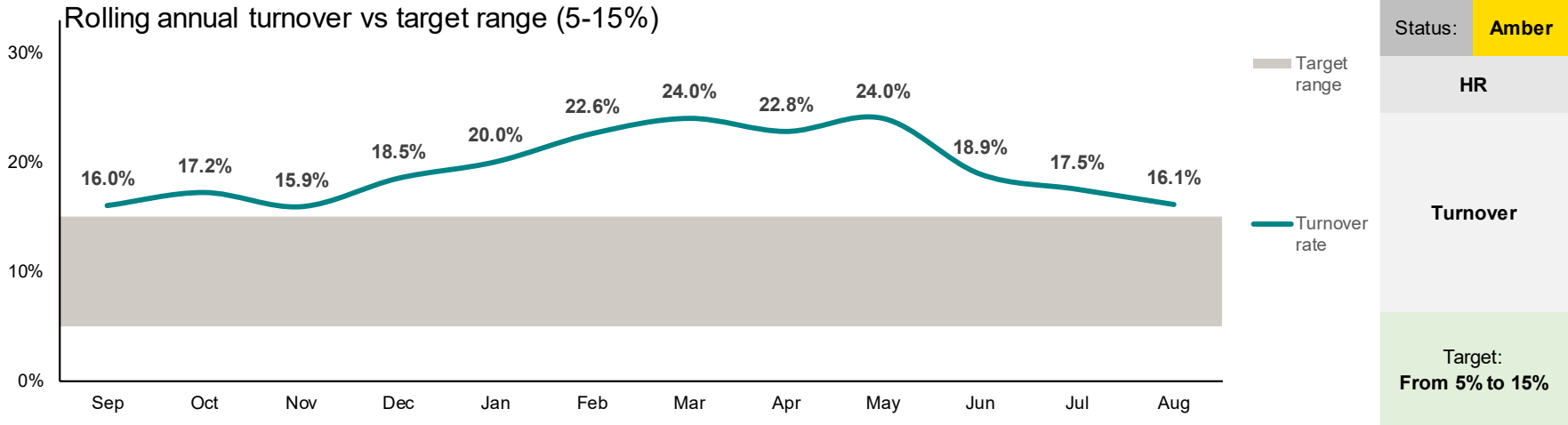


Status:	N/A
Comms	
Engagement across social media	
Target: not defined	

There was less engagement than usual on our channels during August. Content was patient-based, informing on success rates, choosing a clinic, treatments for trans and non-binary people, egg freezing and sperm donation. We also shared a video of the Chair of BICA for those considering applying for donor information. Our best performing content was Clare Ettinghausen's statement on the donor compensation increase.

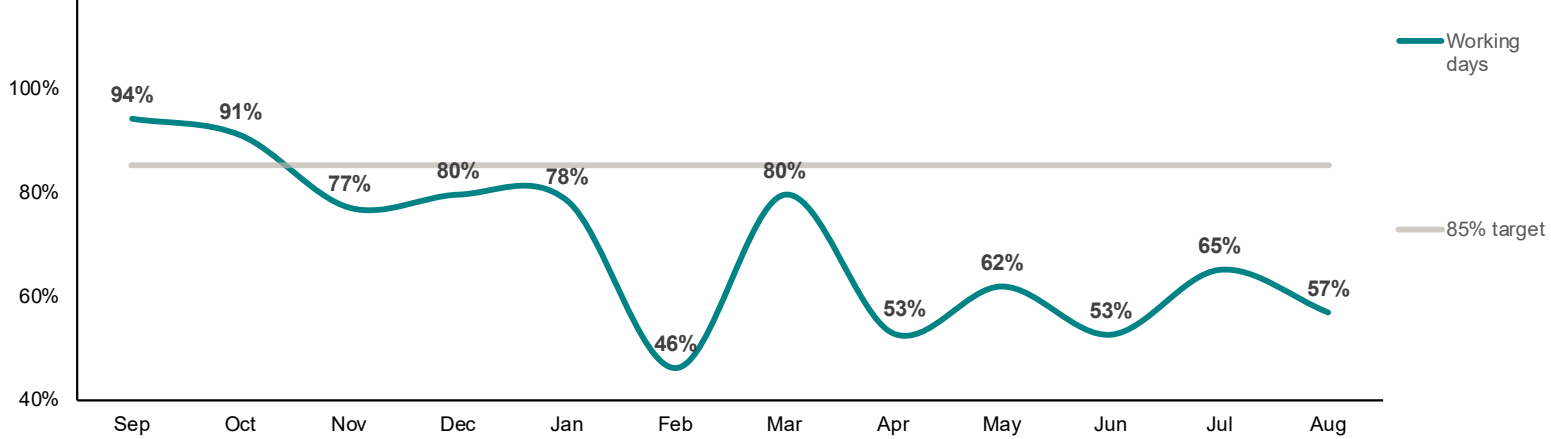


Sickness remains stable and relatively low. One long term absence has made it seem slightly higher which was one employee for routine surgery.



Turnover is 13.4 (green) if we disregard involuntary exits (x 2).
 Supplementary HR data: **Headcount - 78, Posts - 76, Vacant posts - 1, Starters - 1, Leavers - 0**

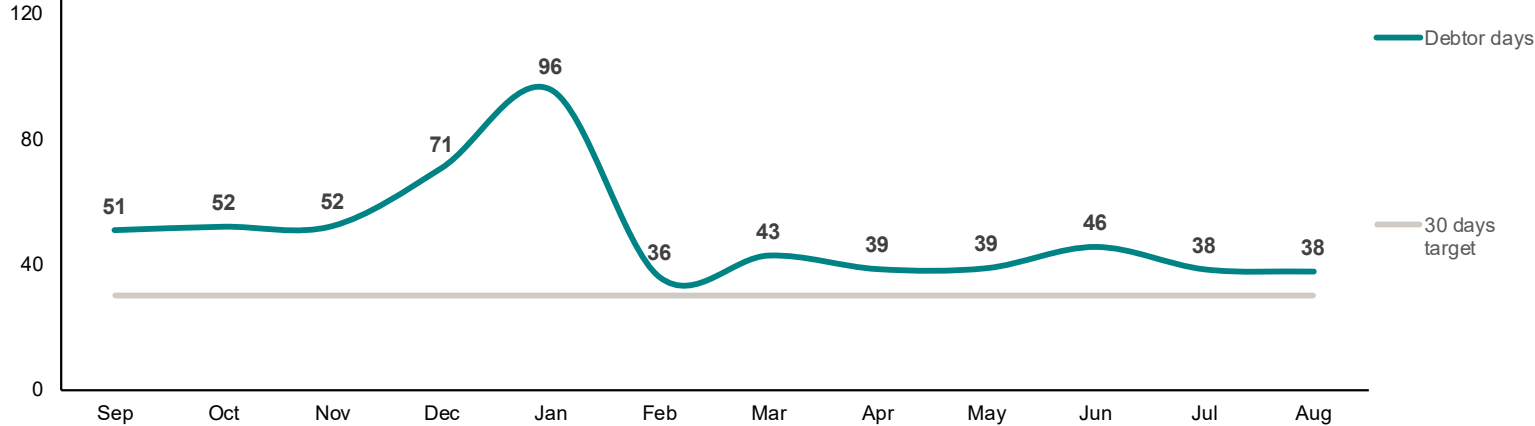
Debt collection within 40 days



Status:	Red
Finance	
Debt collection	
Target: 85% or more debts collected in the month within 40 days from billing	

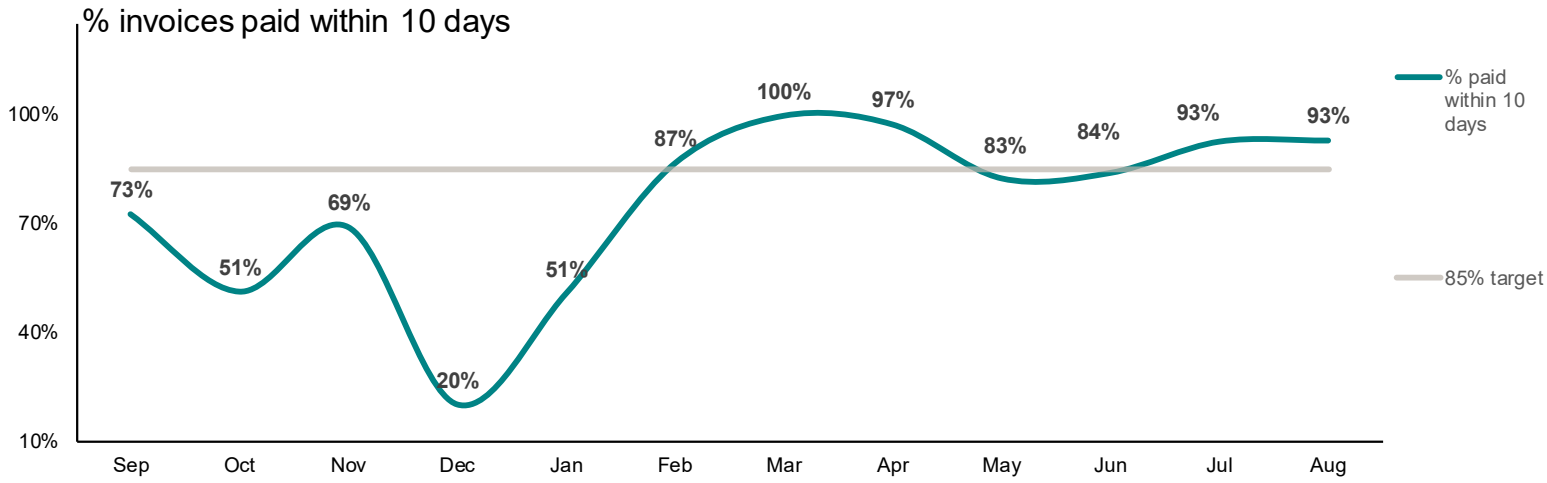
17% of payments received in August related to prior year invoices. This is part of the ongoing task to recover the older debt.

Average debtor days



Status:	Amber
Finance	
Debtor days	
Target: 30 days or less	

70% (£160k) of the debt is over 96 days. £237k relating to two linked clinics that are not yet submitting data for invoicing and are not making significant payments against estimated invoices.



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

Continued good performance in paying invoices within the 10 day target.

Summary financial position as at 31 August 2024

Type	Year-to-date				Full Year			
	Actual £'000	Budget £'000	Variance £'000	Variance %	Forecast £'000	Budget £'000	Variance £'000	Variance %
Income	3,251	3,314	(63)	(1.9)	8,073	8,230	(157)	(1.9)
Expenditure	2,881	2,995	114	3.8	8,044	8,230	186	2.3
Total Surplus / (Deficit)	370	319	51	16.0	29	0	29	

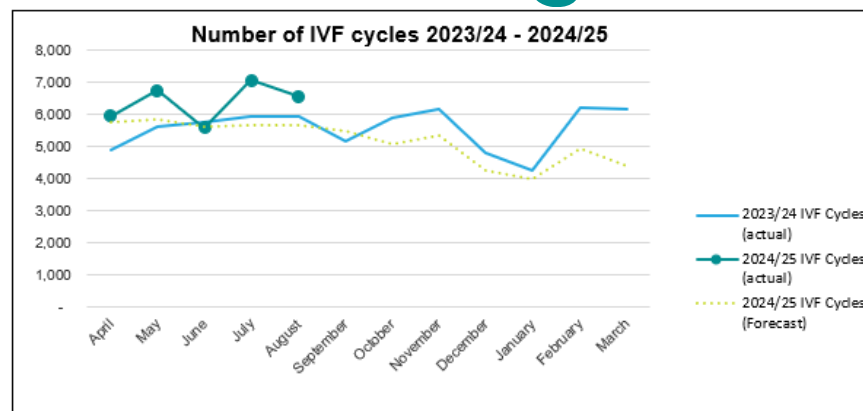
For the five months ended 31 August 2024, we have net surplus of £370k against a budget surplus of £319k. This represents a 16.0% variance.

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

The current forecast shows that below budget income will be offset by lower expenditure, resulting in a close to net position.

2024/25 Income - YTD Actual vs Budget

	YTD Actual	YTD Budget	Variance	Var
	£'000s	£'000s	£'000s	%
Income				
DHSC Funding	407	309	(98)	(32)
Licence Fees	2,742	2,981	238	8
Other income	101	25	(76)	(304)
Total	3,250	3,315	65	2

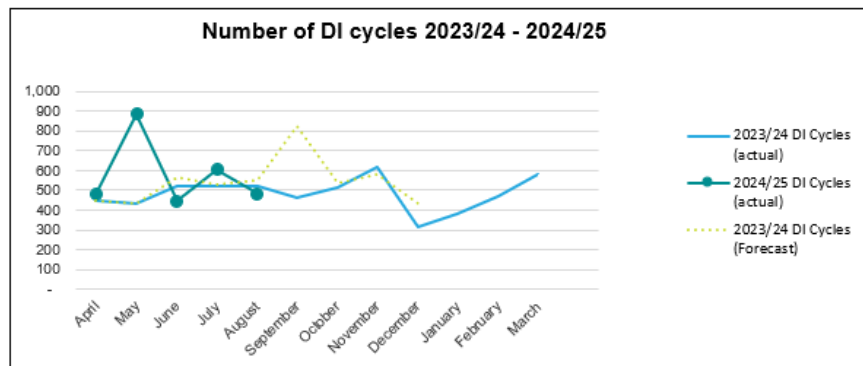


INCOME

As of month 5 (August), our income is slightly below budget (£65k or 2%). We have yet to release an income provision to reverse refunds relating to prior year(s) licence income.

Treatment fees

IVF fees are 10% higher than the same period in 2023/24 and DI are 8% lower than the same period. Both IVF and DI volumes are higher than YTD last year.



2024/25 Expenditure-YTD Actual vs Budget

	YTD Actual	YTD Budget	Variance	Var		Forecast	Full Year Budget	Variance	Variance
	£'000s	£'000s	£'000s	%		£'000s	£'000s	£'000s	%
Expenditure									
Salaries/Wages	2,120	2,233	113	5.1		5,343	5,381	38	0.7
Other Staff costs	147	159	12	7.5		453	429	(24)	(5.6)
Other costs	59	69	10	14.5		950	990	40	4.0
Facilities (estates) costs	229	185	(44)	(23.8)		513	492	(21)	(4.3)
IT Costs	184	234	50	21.4		485	588	103	17.3
Legal and Professional	143	115	(28)	(24.3)		300	353	53	15.0
Total	2,882	2,995	113	3.8		8,044	8,233	189	2.3

Salaries/wages – year to date are under budget by 5.1%, this is due to some staff not being in the pension scheme and some small gaps in posts whilst recruiting.

Other Staff costs – are £10k (14.5%) below budget. This is due to the phasing of budget and usual fluctuations of costs within this category.

Other costs – non staff costs are close to budget with a £12k variance. **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 £28k because of budget profiling in legal and a large piece of work relating to HR policy review.



**Human
Fertilisation &
Embryology
Authority**

Horizon Scanning Update

**Authority Meeting
25 September 2024**

Rebecca Taylor
Scientific Policy Manager

www.hfea.gov.uk

Why Horizon Scanning?

Build knowledge and relationships and shape strategic direction

Keep up to date with scientific and regulatory developments

- Identifying and monitoring emerging topics
- Consulting SCAAC and external experts

Build relationships with researchers and clinicians and **build HFEA reputation**

- Horizon scanning meeting
- External experts presenting at SCAAC
- Attending conferences

Use knowledge to **shape current and future work**

- Impact of scientific advances on regulation e.g. SCBEM, IVGs
- SCAAC work programme
- Clinic guidance
- Patient information
- Broader Authority work e.g. AI in HFEA strategy

Topic Prioritisation – 2024/25

High:

- Alternative methods to derive embryonic/like stem cells
- AI, robotics and automation in fertility treatment
- Emerging technologies in embryo and gamete testing
- Germline genome editing
- Impact of long-term cryopreservation
- In vitro derived gametes
- Scientific considerations of '14-day rule'
- Stem cell-based embryo models

- Testicular tissue transplantation to restore fertility in males
- Mitochondrial donation

Medium:

- Health outcomes in children conceived by ART
- Impact of microbiome on fertility and fertility treatment outcomes

Low:

- Artificial wombs for early/whole gestation (ectogenesis)
- Impact of stress on fertility treatment outcomes

Horizon scanning meetings 2019-23

2023

- AI in IVF lab – regulation
- Artificial gametes & embryos
- Metabolomic profiling
- Microbiome & fertility

2022

- AI
- Genetics – polygenic traits, non-invasive testing
- Embryo models and extended culture in ectogenesis

2021

- AI & data driven tech
- Genetics – polygenic traits, expanded carrier screening, genetic editing
- Stem cells & in-vitro gametogenesis – IVG, embryo models and 14 day rule

2020

- AI
- Genome editing
- Embryo testing
- Embryo culture media
- Treatment add-ons
- Health outcomes in children

2019

- AI
- Pre-implantation genetic testing
- Genome editing
- Non disease related mitochondrial donation
- DTC DNA testing & anonymity
- Surrogacy

Committee work plan 2024-2025

Date	Topics discussed/to be discussed
June 2024	Emerging technologies in embryo and gamete testing
	Artificial wombs for early or whole gestation (ectogenesis)
	Alternative methods to derive embryonic and embryonic-like stem cells
October 2024	Scientific considerations relevant to the '14-day rule'
	Mitochondrial donation
	Stem cell-based embryo models
	In vitro derived gametes
February 2025	Horizon scanning and agreeing workplan for 2025/26
	Health outcomes in children conceived by ART (including the impact of culture media)
June 2025	Impact of stress on fertility treatment
	Artificial intelligence (AI), robotics and automation in fertility treatment
	Germline genome editing
	Impact of long-term cryopreservation of gametes and embryo
Impact of the microbiome on fertility and fertility treatment outcomes	

Horizon Scanning Meeting 2024 – overview of discussions

- Early embryo **genetic screening** with PGT-P - Prof Shai Carmi, Hebrew University of Jerusalem
 - Target patient populations
 - Ethical and technical considerations
 - Challenges surrounding validation
- Promise of **organoids** - Dr Margherita Yayoi Turco, Friedrich Miescher Institute
 - Clinical applications of female reproductive tract organoids
 - Technical considerations related to method optimisation, good manufacturing practice for clinical use, and model fidelity
- **AI** in the IVF lab - Daniella Gilboa, AIVF
 - Regulatory challenges arising from rapid developments in AI use
 - Validation, liability and standardisation considerations
- **Ovarian rejuvenation** - Professor Emri Seli, Yale School of Medicine
 - Challenges with demonstrating efficacy of ovarian rejuvenation techniques
 - Applicability for certain patient groups



**Human
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Embryology
Authority**

Thank you!

Any questions?

Communicating licensing, regulatory activity and incident information

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Agenda item:	8
Meeting date:	25 September 2024
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs
Annexes	Annex A: Risks/Benefits of publishing more information Annex B: Publishing further information on licensing decisions Annex C: Publishing clinic level data on incidents in State of the Sector

Output from this paper

For information or decision?	For decision
Recommendation:	To make decisions in relation to how we communicate licensing, regulatory activity and incident information as set out in section 7
Resource implications:	Resources are contained within the usual production of information and collection of data. It may lead to more media, public or FOI requests.
Implementation date:	Effective post Authority meeting
Communication(s):	Letter to PRs to explain what information we will be publishing in future following Authority decisions; Clinic Focus; social media where relevant.
Organisational risk:	Low/Medium

1. Background

- 1.1. The HFEA website holds regulatory information on each licensed clinic where anyone can access the minutes of licensing committee meetings, which include inspection reports, as well as other information such as patients' ratings and success rates. Most of this information is from the HFEA but elements can be updated by the clinic such as donor waiting times or parking information. All of this information is freely available on individual clinic pages of [Choose a Fertility Clinic](#).
- 1.2. Over the past few years, the Authority has been discussing how our regulatory decisions could be made more available/accessible to the public and patients in particular, as committee minutes and inspection reports are written to meet formal governance and regulatory requirements and not specifically for a lay/patient audience. The Authority discussed this in [May 2021](#) and then again in [November 2021](#) when it was agreed that further work on transparency and regulation should be a priority for the 2022-23 business year. It was, however, de-prioritised later that business year and beyond due to other pressures on the organisation.
- 1.3. Although this work has not formally progressed, the Authority has maintained an interest in continuing this work. 'Live' examples of where we have communicated regulatory action have occurred in the past two years, where the decisions of the Licence Committee in relation to specific regulatory decisions have been considered of such public interest that we have issued patient facing communications on them, in addition to the standard publication of minutes. We have also had one appeal and, prompted by that, we have created a webpage for [appeals](#) and representations so that we can publish key documents.
- 1.4. This paper makes a number of recommendations to increase the transparency of our regulatory decisions/activity. Section 2 sets out current practice and section 3 looks at recent licensing and communication activity. Sections 4, 5 and 6 look at what we could do going forward, in respect of what other information on licensing we could publish and the publication of clinic incident information. The recommendations for Authority are then summarised in section 7.

2. Introduction – Current practice

- 2.1. The current practice around the publication of licensing decisions is as follows. All HFEA licensed clinics are regularly inspected, and each inspection report is considered by a licence committee (either the Licence Committee or the Executive Licensing Panel). Once the minutes are agreed by the committee, the Licensing team email the minutes and licence (if relevant) to the clinic and publish all the relevant documents on the individual clinic page on the Choose a Fertility Clinic (CaFC) section of our website. All committee minutes are published in the same way – whether it is a decision for continuation of licence, or regulatory action (such as suspension or conditions put on a licence).
- 2.2. It is worth noting that publication takes place at this stage despite the fact that the law allows the clinic to challenge the decision of a licence committee, whether that is a decision relating to the length or type of licence given, or an appeal against a licence suspension or revocation.
- 2.3. Each clinic page also includes an inspection rating which is based on the length of the clinic licence. Authority members have already expressed that they would like this information to be reviewed during the next strategic period (2025-2028).

- 2.4.** Turning to compliance and incidents, the HFEA publishes a summary of sector compliance and incidents in the annual [State of the Sector](#) report and quarterly summaries in [clinical governance](#) information via the [Clinic Focus](#) newsletter. State of the Sector summarises the number of non-compliance and incidents occurring and has some further information on 'grade A' (the most serious) incidents. We also report any changes resulting from regulatory activity in NHS clinics in England to the NHSE reporting recovery support system.
- 2.5.** In the previous Authority discussions in May and November 2021, there was a desire to make regulatory information more easily available to patients and the wider public, and to make it more straightforward to locate compliance decisions on the HFEA website. The Authority was mindful at the time that 'league tables' of clinics could be unhelpful as they do not account for differing patient selection criteria.

3. Recent licensing and communications activity

- 3.1.** The shortcomings of the established position set out in section 2 has been exposed in the last year or so in the light of some licensing decisions. In February 2023, the Licence Committee suspended the licences of iTrust Fertility clinics in Eastbourne and Bromley because of concerns over the risk of harm to patients, gametes and embryos. The clinic page for these clinics was updated to say "This clinic's licence is suspended" but proactive communications beyond this were not undertaken. There was one mention of this decision in the local press where [the article](#) drew on the published minutes.
- 3.2.** In February and March 2024, there were two separate instances where activities within a clinic or Licence Committee decision was communicated to the public. In the first instance (Guy's and St. Thomas ACU) the HFEA issued a [statement](#) in response to a journalist who had seen the communications issued to patients by the clinic after an incident. The statement was published on the front page of our website and sent to journalists who had contacted the HFEA. Drawing on this experience, when the Homerton Fertility Centre's licence was suspended, a [statement](#) was proactively published on the website.
- 3.3.** In both instances, it was felt that public information was important for anyone concerned, although one was in response to an incident and the other in response to a licence suspension following incidents at the clinic.
- 3.4.** Authority members were informed of both these instances prior to the information being made public on the HFEA website.
- 3.5.** However, unlike the practice of the CQC, for example, we did not issue our statement on social media. Instead, we published a statement on the news section and front page of our website, directing interested journalists towards it. A newswire picked it up and published it. The CQC routinely publishes [press notices](#) on the outcomes of their inspections, reviews and ratings and posts these on social media.

4. Publishing licensing decisions going forward

- 4.1.** Given the Authority's priority for transparency for patients, thought has been given to what should be done to appropriately communicate decisions on licence suspensions, revocations or refusals. As noted above, these decisions are presented as stand-alone at present, although

we are cognisant that there have been wider previous discussions at Authority about publishing other compliance activity, such as when there are restrictions on a licence, or a licence given for lower than the standard number of years.¹

- 4.2.** It is recommended that a standard method of publication is agreed going forward as set out in 4.3 and 4.4 below.
- 4.3.** When a licence committee suspends, revokes or refuses a clinic licence, a summary of the decision should be publicised through a news release; social media posts (currently X, Instagram, LinkedIn and Facebook); and information on the clinic's CaFC pages. This includes removing the clinic rating for the duration of the suspension/revocation and any accompanying appeal, to avoid causing confusion for patients. Publication would always follow the PR and Licence Holder being notified about the decision.
- 4.4.** Where the suspension then this should be publicised (as set out in 4.3) before the minutes are published, with a note that minutes are to follow. There is a potential reputational risk of publishing information before the end of the licensing period – that is before the end of the time that any appeal may have finished - as the original decision may be overturned. However, given that a suspension taking place with immediate effect is only likely when it is concluded that there is a high risk to patient safety or that of gametes and embryos, then this is a risk which should be managed. The potential risks / benefits of this more transparent approach are set out in Annex A.

5. Publishing further information on licensing decisions

- 5.1.** At every Authority meeting a paper is published that sets out the numbers and types of licensing decisions that have been taken in committees since the last meeting.
- 5.2.** This paper could be expanded to include the centre/clinic that the decisions refer to and a link in there so that the minutes of that decisions/inspection report etc. can be found more easily.
- 5.3.** Annex B shows in rough terms what this could look like. This would bring greater transparency for the Authority's oversight of activities, as well as greater transparency overall for our ongoing regulatory activity.
- 5.4.** In addition, this list of decisions and the centres/clinics it applies to could be available on its own (rather than as part of the Authority papers) on our website so that anyone can easily see what licensing decisions and regulatory activity has been made in a particular period. If the Authority agrees to this approach, it could be reviewed at the point of next year's State of the Sector discussion and further consideration could take place at a later date as to whether this information should be shown on a reformatted CaFC or in a different format.

6. Clinic level incident information

- 6.1.** Public information on incidents in healthcare settings can be alarming for those involved. The way in which we have approached incident reporting in the public domain to date has been to

¹ It should be noted that suspension of a licence is rare (has happened three times over the last five years) and there are over 100 licensed clinics and research establishments.

provide limited accurate information while ensuring that patients are assured that most treatment (over 99% of cycles in 2023/24) takes place without any incidents occurring.

6.2. Currently information on clinic incidents is published in a general way in our annual State of the Sector report, including the total number of incidents by grade. When we have had grade A incidents, we have published a summary of the incident, and any lessons learned.

6.3. For the last five years we have also published a quarterly clinical governance report that gives an overview of non-compliances found on inspection and incidents so that the learning can be shared with HFEA licensed clinics via the monthly Clinic Focus newsletter. These quarterly reports are clinic focused and designed to be read by regulated entities rather than the wider public and we have faced criticism from journalists that it is difficult to find incident information on our website. At present the only way to find out about incidents is where there is information within an inspection report or licence committee minutes.

NHSE incident publication

6.4. NHSE publishes incident information via [‘never events’ reports](#), which look at type of event and number per provider and frequent reports that look at all types of [incidents by provider](#) published with detail of every organisation and type of incident.

6.5. The HFE Act sets out that the PR must notify the Authority about serious adverse events and this is expanded in Licence Conditions T118-122 and requirements in General Directions 0011 and guidance given in guidance note 27 of the [Code of Practice](#).

6.6. Incident reporting is encouraged by the HFEA, as in all healthcare settings, to share any learning to other providers and change processes or systems where needed. There maybe concerns that in creating tables by provider (as NHSE do) some will be discouraged from reporting incidents to us. The benefits of transparency would need to be weighed up with the risks of underreporting – see again Annex A for a consideration of the risks / benefits.

HFEA publication going forward

6.7. NHSE publish incidents on an individual provider level, and we should consider whether fertility treatment should be subject to a different level of publication.

6.8. With recent interest in incidents in UK clinics (for example, over 650 pieces of coverage for the incident relating to Guy’s and nearly 400 for the initial Homerton clinic suspension) there is a good argument in favour of publishing this sort of information as part of the underlying data set of the annual State of the Sector report. The underlying data could include a list of licensed clinics and reported incidents by severity and by type.

6.9. In thinking about this issue, it is important to considered whether, in a competitive market, publishing incident information by clinic would be a deterrent to incident reporting. Providers may use incident information in their own marketing material against other clinics. Furthermore, incidents are self-reported by clinics so where very low or no incidents are reported, caveats would need to be introduced into the data set. As this is a self-reporting system, some clinics may have reported more incidents than others. It could also lead to an increase in FOI requests for detailed incident information which would need to be managed against resources to deal with incidents and FOI requests, as well as ensuring that, for example, whistleblowers are protected if this is linked to an incident.

6.10. Examples of what this information could look like if published as part of the dataset with the State of the Sector report is set out in Annex C.

7. Recommendations

7.1. The Authority is asked to consider the following recommendations:

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

Annex A Risks and benefits of publishing more information

7.1. The table below outlines some risks and benefits of different approaches.

Risk	Benefit
Proactively publishing information may raise concerns/stress for patients.	Where patient, gamete or embryo safety is concerned, the public have a 'right to know' and by publishing information it avoids potential for misinformation from other sources and increases transparency. Could be accused of hiding information if not published and easily accessible.
Proactively publishing decisions that a clinic is able to challenge we may increase the reputational risk to the Authority should the decision be overturned on Appeal.	This is a regular occurrence with decisions that can be legally challenged. Same information for patients as for the clinic – LC decided for XX reason licence suspended/revoked. If clinic wins appeal, then message is that following an appeal, LC has done X and Y.
Proactively publishing information may increase media interest diverting the clinic or our compliance/clinical governance team from reviewing incident information.	Media coverage would help public awareness of any specific issue and demonstrate that HFEA takes action when needed. It would also reinforce patient trust that people will have the information they need, when they need it. This should be handled separately from any compliance/clinical governance activity.
Proactively publishing may raise sector wide concerns when issue is only relevant to one or a small number of clinics.	All clinics have clear understanding of the event/incident and can use this information to ensure it doesn't happen in their facility, promoting shared learning.
Proactively publishing more information on a clinic basis on incidents may discourage reporting of incidents.	Wider healthcare system publishes regular incident reporting by provider which may make the fertility sector seem out of step with other healthcare providers.

Annex B Publishing further information on licensing decisions

The examples below show how the information set out in section 5 could look if more information about the relevant centre was added.

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

Meetings held	Items considered	Centre	Outcomes
Licence Committee:			
2 May	Interim	ABC Centre ²	Interim approved for continuation
	Executive update	ABC Centre	Executive update noted
	Executive update	ABC Centre	Suspension (continued)
27 June	2 Incident reports	Unpublished	Minutes not yet approved.
Executive Licensing Panel:			
7 May	Renewals	ABC Centre	Granted
	Renewal	ABC Centre	Granted
	Renewal	ABC Centre	Granted
	Interim	ABC Centre	Granted
	Interim	ABC Centre	Granted
	Variation of Licence Holder	ABC Centre	Approved
	Variation of Person Responsible	ABC Centre	Approved
Licensing Officer decisions:			
May	15 ITE import certificates 2 Changes of LH 1 Change of centre name	ABC Centre ABC Centre	All granted
Statutory Approvals Committee:			
30 April	5 PGT-M applications 1 Special Direction for import	Link here to minutes on relevant clinic pages	All approved.
28 May	3 PGT-M applications 1 Special Direction for import	Link here to minutes on relevant clinic pages	All approved.

² This would link to the relevant clinic webpage on the HFEA website

Annex C Publishing clinic level data on incidents in State of the Sector

If we published data on a clinic level of incidents, this is an example of what it could look like.

Number of incidents by grade and centre, 20XX/XX

Centre Number	Centre Name	Grade A	Grade B	Grade C	Near Miss
XX	ABC Fertility Centre	0	3	10	0
XX	DEF Fertility Centre	0	5	4	0
XX	GHI Hospital	0	7	1	2
XX	JKL Fertility Service	0	2	7	0
XX	MNO Clinic	0	1	0	1
XX	PQR Hospital	0	1	4	0

Number of incidents by type and centre, 20XX/XX

Centre Number	Centre Name	Administrative	Clinical	Clinical Equipment	Communication	Consent	General	Laboratory equipment	Laboratory Operator	Laboratory Process	Resources/Organisational	Centre total
XX	ABC Fertility Centre	5	0	0	2	1	1	0	0	0	1	8
XX	DEF Fertility Centre	0	0	0	1	0	0	0	0	0	0	3
XX	GHI Hospital	2	1	0	2	3	1	0	0		2	11
XX	JKL Fertility Service	0	0	0	0	0	0	0	0	0	0	0
XX	MNO Clinic	1	1	0	1	0	0	0	0	0	0	2
XX	PQR Hospital	4	1	4	0	0	0	0	0	1	0	10
Classification total		12	3	4	6	4	2	0	0	0	2	34