

# Authority meeting

**Date: 12 July 2023 – 12.45pm to 3.05pm**

**Venue: HFEA Office, 2<sup>nd</sup> Floor 2 Redman Place, London E20 1JQ**

Agenda item	Time
1. Welcome, apologies and declarations of interest	12.45pm
2. Minutes of the meeting held on 17 May 2023 and matters arising For decision	12.50pm
3. Chair and Chief Executive's report For information	12.55pm
4. Committee Chairs' reports For information	1.05pm
5. Annual performance report 2022/2023 For information	1.20pm
6. Performance report For information	1.50pm
Break	2.10pm
7. Strategy 2024-25 for decision	2.25pm
8. Opening the Register update For information	2.45pm
9. Any Other Business	3.00pm
10. Close	3.05pm

# Minutes of Authority meeting held on 17 May 2023

## 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>
Agenda item	2
Meeting date	12 July 2023
Author	Debbie Okutubo, Governance Manager

## Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 17 May 2023 as a true record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

## Minutes of the Authority meeting on 17 May 2023

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Members present	Julia Chain Jason Kasraie Frances Flinter Zeynep Gurtin Tim Child Alison McTavish	Guhrun Moore Alex Kafetz Graham James Jonathan Herring Geeta Nargund Catharine Seddon Christine Watson
Apologies	Alison Marsden	
Observer	<b>In person</b>  Steve Pugh (Department of Health and Social Care – DHSC) Roland Green – (DHSC)	<b>Online</b>  Amy Parsons (DHSC) Clare Lane (DHSC) Cassian Maciejewski (DHSC)
Staff in attendance	<b>In person</b> Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Rachel Cooper Ana Hallgarten Debbie Okutubo Shabbir Qureshi Beth Rowbottom	<b>Online</b> Paula Robinson

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### Members

There were 13 members at the meeting – Eight lay and five professional members.

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## 1. Welcome and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and DHSC colleagues present. The Chair extended a warm welcome to Professor Christine Watson as this was her first Authority meeting since becoming a member.
- 1.2.** The Chair also welcomed staff who were present and observers online and stated that the meeting was audio recorded in line with previous meetings and for reasons of transparency the recording would be made available on our website to allow members of the public hear it.
- 1.3.** Declarations of interest were made by:
  - Jason Kasraie (PR at a licensed clinic)
  - Alison McTavish (Trustee at Progress Educational Trust (PET) and British Fertility Society (BFS))
  - Frances Flinter (Trustee at PET)
  - Tim Child (PR at a licensed clinic) and
  - Geeta Nargund (Clinician at a licensed clinic).

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## 2. Minutes of the last meeting and matters arising

- 2.1.** Members agreed that the minutes of the meeting held on 22 March 2023 were a true record and could be signed by the Chair.

### Matters arising

- 2.2.** Re: 8.6 – Members were advised that a full communications plan relating to donor information was in place and had a number of different aspects including videos where relevant.
- 2.3.** Re 3.6 – On member training, the Chair requested that members who were yet to complete their mandatory training on cyber security and equality, diversity and inclusion training modules should please do so.
- 2.4.** Members were advised that item 5.18 - backlog on OTR and item 5.7 - PGT-M being out of target of the 75 working days would form part of the performance report to be presented at the meeting.

### Decision

- 2.5.** The status of all other matters arising were noted.

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## 3. Chair and Chief Executive's report

- 3.1.** The Chair gave an overview of her engagement with key stakeholders, her attendance at sector related events and the decision-making committees of the Authority.
- 3.2.** The Chair commented that member appraisals had started. The Chair and Chief Executive attended the annual accountability review meeting with our sponsors at the Department of Health and Social Care (DHSC), who had given positive feedback on the performance of the HFEA over the last year.
- 3.3.** The re-appointment of Authority members also formed part of the discussion.
- 3.4.** Following the accountability meeting the Chair had her own appraisal. The Chair stated that she will be sharing her objectives with members in due course and that this will form part of the discussion at the next away day under the review of board member effectiveness.
- 3.5.** The Chair had visited a number of clinics in Scotland, accompanied by Alison McTavish, where they were well received. At one of the clinics, a clinician commented that the relationship between themselves and the Regulator was getting better and the same applied to the inspection regime.
- 3.6.** The Chief Executive provided an update on the key external activities including his informal visits to a number of licensed clinics.
- 3.7.** Members were assured that the process to appoint the Director of Finance and Resources successor was underway. As part of the selection process, the preferred candidate had a discussion with the Chairs of the HFEA and Human Tissue Authority (HTA) audit committees, as this was a joint appointment. Members were advised that there will be a gap between when the Director leaves and before his successor starts and that the time in-between will be managed by the Chief Executive and Head of Finance.

## Strategy development

- 3.8.** The options for strategy development were discussed. The Head of Planning and Governance presented this item and reminded members that our current strategy is due to end in April 2024. Members were advised that it was not straightforward to agree a timeline for the development of the next strategy because of a number of current unknowns which would make it difficult to agree clear strategic objectives. In particular, it was not yet known how the recommendations on modernising the Act would be received; and the outcome and recommendations that would arise from our ongoing Public Body Review were not yet known.
- 3.9.** Options were presented and discussed, and members were advised that a further paper would be brought to the July Authority meeting. The options considered were:
- To develop a new strategy now, trying to work around the unknowns
  - To extend the current strategy by one year, and delay the development of the new strategy
  - To have a one-year gap between strategies, and delay the development of the new strategy.
- 3.10.** Members asked if the current strategy, which began in 2020, was out of date and whether we had received guidance from the DHSC on the timeline to get a new strategy approved. The Head of Planning and Governance responded that the majority of the content of the current strategy remained valid, although some of the envisaged activities had not been possible due to Covid and subsequent related pressures on the primary care system. The Chief Executive explained that the DHSC did not request a particular timeline in relation to strategy development; instead they maintain an overview of our performance through the annual business plan.
- 3.11.** Members supported option two, a one-year extension, as this would give us time to know the outcomes of certain key activities. It was agreed that we should communicate a clear narrative on the need for the extension and what work would be done meanwhile, in the additional year.
- 3.12.** A paper would be brought to the July meeting setting out an interim plan for the year, based on the existing vision and aims. The aim would be to then publish this with an explanation of our current thinking and plans.

## Decision

- 3.13.** Members noted the Chair and Chief Executive's report.
- 3.14.** Members agreed a one-year extension to the current strategy, which was to retain the vision and aims from the current strategy for an additional year, and delay development of the new strategy.

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## 4. Committee Chairs' reports

- 4.1.** The Chair invited Committee Chairs to add any other comments to the presented report.
- 4.2.** In the absence of the Licence Committee Chair (Alison Marsden), the Deputy Chair, Graham James, gave an overview of the last committee meeting. He commented that there was a high volume of work at this present time with more frequent meetings than usual and that there had been an Appeal hearing. He encouraged other members to read the papers from the Appeal hearing which are available on the HFEA website.

- 4.3.** The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) stated that the meetings were challenging but effective. Meetings covered a breadth of areas and the diverse skill set on the committee enabled them to address all the issues raised.
- 4.4.** The Audit and Governance Committee (AGC) Chair, Catharine Seddon commented that the committee had not met since the last Authority meeting but that they were in the process of recruiting to the two vacancies of the non-Authority members on the committee. Five candidates had been shortlisted and interviews will be taking place in June and that the final decision would be a delegated decision of the Authority Chair. The new members will take up position on 1 October 2023.
- 4.5.** Members were advised that the SCAAC meeting scheduled for June had been postponed to the end of July and will be reported back to the September Authority meeting.

#### Decision

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

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## **5. Performance report**

- 5.1.** The Chief Executive commented on staff sickness and turnover. Members were advised that sickness levels were higher than usual as there had been a number of employees absent for various short-term reasons and two employees remained on long term sick leave. The Chief Executive stated that there was nothing structural to be concerned about as our figures were largely as expected for this time of year. Turnover was on target.
- 5.2.** Members asked how sickness was being measured. The Chief Executive responded that it was measured across the organisation and they were mainly winter related illnesses of coughs and colds apart from the two staff members on long term sick leave.
- 5.3.** On PRISM, the Chief Executive commented that the system was working well. The data was in the papers presented and the detailed report formed part of the AGC meeting item. There are three clinics remaining who are yet to use PRISM but that should be resolved soon.
- 5.4.** At the June AGC meeting we would be in a position to report that over 400,000 units of activity had been entered into PRISM with an average 4% error margin. The Chief Executive thanked the clinics who were dealing with backdated errors and commented that Choose a Fertility Clinic (CaFC) should be ready to be updated before the end of the year.
- 5.5.** Members asked about the errors reported. The Chief Executive responded that the errors were typically incomplete information inputted, which could occur during data transfer. Members were assured that we were not missing any major data and that the public were not given misleading information.
- 5.6.** In response to a question, it was explained that the 10-family limit was the policy adopted that a maximum of 10 separate families can be created from any one donor.
- 5.7.** Members were advised that the annual performance report will be presented to the July Authority meeting.

## Compliance and Information

- 5.8.** The Director of Compliance and Information gave an update. Members were reminded that inspections were deferred when restrictions on travel were in place during the Covid-19 pandemic and licences were extended. This has resulted in a significant increase in the number of inspections on this year's schedule. Alongside this, staff absences and turnover had placed the team under significant pressure.
- 5.9.** Members commented that the number of inspections alone did not reflect the work done by the team and support given to centres before, during and post inspections.
- 5.10.** The Chair commented that feedback from recent visits to clinics was that they welcomed the hybrid method of inspections which was now part of the inspection regime. The Chair requested that the Director of Compliance and Information take back the Authority's thanks to staff for their hard work.
- 5.11.** The OTR backlog is still significant but there is stability in the team now and good progress is being made on the integration of the new case management system which will make the process more time efficient.

## Strategy and Corporate Affairs

- 5.12.** The Director of Strategy and Corporate Affairs commented that ongoing planning for upcoming publications was continuing, including the Fertility Trends report in June and accompanying data dashboards later in the year.
- 5.13.** The Code of Practice update previously agreed by the Authority would be finalised shortly. It was also noted that as far as we understood at present (according to the DHSC), the Windsor Framework would not require any changes to the Code of Practice.
- 5.14.** The news resulting from a Freedom of Information request relating to mitochondrial donation had been widely reported on recently in news outlets and on social media.
- 5.15.** The Chair commented that when we launched the consultation on modernising the Act there had been a lot of media interest, particularly in the areas relating to donor anonymity.
- 5.16.** Members congratulated the team on the handling of HFEA activity in the media and noted the widespread national and international interest in mitochondrial donation.

## Finance and Resources

- 5.17.** The Director of Finance and Resources commented that at the end of the 2022/23 financial year, we posted a surplus against budget of £252k. This was the interim report but overall, we were in a good position. There were two red indicators which are F1 – debt collection, which was as a result of delays in credit control due to prioritising year end and audits which affected collection; and F2 – debtor days as collection was impacted by year-end preparations for clinics which increased response times.
- 5.18.** Members were assured that there had never been a case where clinics did not pay their fees in time. In terms of finalising the accounts there could be some changes of reduction in debt but at this stage there are no overall concerns.

## Decision

- 5.19.** Members noted the performance report.

## 6. Strategic risk register

- 6.1. The Risk and Business Planning Manager presented the strategic risk register. The Chair commented that the new risk register had been driven by the AGC and thanked the committee for their leadership to date and also thanked the Head of Planning and Governance and the Risk and Business Planning Manager who had done the work.
- 6.2. The Risk and Business Planning Manager noted that all the closed risks will be removed from future Authority papers on risk, for brevity, but would continue to be presented to AGC regularly.
- 6.3. In response to a question, the Chief Executive commented that we aim to be transparent about strategic and operational risks. One example was PRISM which has had a huge operational impact in terms of opportunity costs - for example the development of a replacement for Epicentre has been delayed due to the focus on PRISM.
- 6.4. Members commented that we need to be careful how we gauge residual risk levels and gave the example of financial risk being described as below tolerance and suggested that this was perhaps understated. Also, the governance risk being at tolerance might not reflect our view given the need to modernise fertility law, and until that is done, there are associated risks. Members further commented that it was important to look at mitigations alongside the risk itself.
- 6.5. The Director of Finance and Resources commented that in terms of financial risk we will not know with certainty where we will be until after the first quarter, but we are not breaching controls.
- 6.6. The Chair asked if we were mapping the new risk categories against the areas identified in our law reform work. The Chief Executive commented that the risk register was framed against the powers we currently have and mitigations were based on what we currently do. Following the discussion, it was agreed that AGC will explore this further.
- 6.7. Members commented that we need to avoid over complicating our expression of risks. For instance, the section on legal risks had been moved into operational risks for the time being, but on reflection the strategic risk register should possibly have a legal risk category. Members were assured that under the new risk system which was dynamic, if legal (or other) risks that had been closed became a live issue again, the register was designed to enable such risks to be re-opened. It was reiterated that as a regulator we are always open to legal challenges.
- 6.8. Members commented that under the technology risk category, in terms of shaping the future there was no specific mention of artificial intelligence (AI), which was an area we were monitoring through SCAAC, since it could have an impact on the fertility sector.
- 6.9. The Chief Executive commented that we were trying to move away from having ever-present risks which form part of our business as usual. AI remained an upcoming issue so it was difficult for the HFEA to take any action to actively mitigate the potential risks. The strategic risk register however was an active live dynamic document, and risks are closed, re-opened, or introduced as needed.
- 6.10. The Chair of SCAAC commented that AI was mentioned as part of horizon scanning during their committee meetings so it had been considered and that the committee will keep the watching brief on this. Members further commented that human genome work was also being developed.
- 6.11. The Chair stated that this is a live document and would continue to be reviewed regularly.



Decision

**6.12.** Members noted the strategic risk register.

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## **7. Opening the Register - update**

- 7.1.** The Directors of Compliance and Information and Strategy and Corporate Affairs presented the update on Opening the Register (OTR).
- 7.2.** Following the presentation members asked whether we knew if donors had updated their details in response to a recent media story that we had run to cover this. The Director of Strategy and Corporate Affairs responded that most donors would likely contact the clinic they donated at in the first instance.
- 7.3.** In response to a question on the exploration of funding options for the support service, the Director of Compliance and Information responded that an options paper would be brought to the Authority later in the year.
- 7.4.** A member raised the concern that there may be an increased risk of cyber-attack due to increased publicity and risk of fraud, for example someone setting up a website 'otr.com' to take payments and give out false information. The Executive responded that we would revisit this in the risk register.
- 7.5.** The Director of Strategy and Corporate Affairs commented that although the OTR team had increased in number and new systems are being integrated, demand may continue to increase exponentially and this was a concern. There was also a resource concern on the communication workstream as there was ongoing and significant media interest in this area.
- 7.6.** The Director of Compliance and Information noted that in the workstream looking at support services, a number of roundtables would be held to get feedback on what future support might look like.
- 7.7.** Members asked if we knew how many donor conceived individuals (DCIs) approached clinics for counselling. The Director of Compliance and Information responded that we would only know about those who apply through the HFEA OTR service and take up counselling services through the Hewitt, as that was data we received. The Chair commented that this maybe a worthwhile piece of research to be considered.
- 7.8.** A member commented that they understood that for adoption services there was no fee to find out if people were adopted and wondered how that service was funded and whether that could be considered as a funding model.
- 7.9.** Members also asked what happened if someone rang in to say they believe they were donor conceived. The Executive responded that they would be advised to apply through the OTR service, and this information could be provided by checking the register.
- 7.10.** The Chair thanked the team for their work to date, commented that the team was stretched and also that when we launched the law reform consultation, donor conception was an area of great public interest. An update would be received at the July Authority meeting.

Decision

**7.11.** Members noted the update on OTR.

## 8. OTR Donor Contact

- 8.1.** The Director of Compliance and Information and the Legal Adviser presented this item. It was noted that the HFEA has a power (not an obligation) to contact donors to let them know that identifying information about them had been requested.
- 8.2.** Three options were presented to members:
- Option A: Contact donors using the most recent postal address recorded on the Register/clinic's files. Provide this same address to the DCI making the OTR request
  - Option B: Contact donors using an address obtained through an NHS database (PDS). If the donor confirmed this was their correct address and consented to the Register being updated the updated address would be provided to the DCI. In all other cases, the most recent address (between the Register and clinic notes) would be disclosed to the DCI
  - Option C: Contact donors using PDS address only where the addresses match the Register address (or that on the clinic's notes). Provide the address on the Register/clinic records to the DCI (even where it does not match the PDS address).
- 8.3.** Members were informed that we planned to attempt to contact donors using the latest contact details provided by them. This had been consistently communicated to the sector since 2004 (for example in a 2004 Chair's letter and as guidance in the Code of Practice) and licensed clinics should have explained this to donors as part of their informed consent process. However some stakeholders had raised concerns about the passage of time since donation and the accuracy of the donor's address on the register.
- 8.4.** The HFEA had investigated whether we could use a third-party database to proactively search for an updated address but found that there were several difficult legal and reputational risks to consider when appraising the options.
- 8.5.** A discussion ensued. Members commented that in terms of reputational risk the Authority needed to measure what was the greater risk, using a third-party database for updating addresses or sending sensitive information to non-verified addresses.
- 8.6.** The Director of Strategy and Corporate Affairs commented that donors were informed that their identity could be released and that they may be contacted, but donors were under no obligation to update their details. The issue was that the law predated modern forms of communication and required us to provide a postal address.
- 8.7.** In response to a question the Director of Compliance and Information stated that using the special delivery service at the Royal Mail meant we could track and trace letters. A member asked whether we could send a letter requesting that they contact the HFEA without mentioning this was about donation. However, having the HFEA on a letterhead would still provide a clear indication that this was in connection with fertility treatment in some way. This method would be resource intensive, impractical and had other risks.
- 8.8.** Members commented that some fertility clinics were standalone centres and therefore updating information with GPs would not filter through to fertility clinics. Private clinics do not have access to NHS systems.
- 8.9.** A member commented that it should be accepted that some donors might not want to be contacted and may actively choose not to update their contact details.

- 8.10.** Members commented that it was challenging to keep patient details up to date as they often do not stay in touch with a centre even when they have material in storage. This probably meant donors were less likely to stay in touch and update their details.
- 8.11.** Amongst the options presented to members, one member felt that option B was a better option because it allowed the provision of more accurate information as well as keeping information confidential. It might cost more but would involve less reputational damage. However, this was not in line with what the donor would have been told at the time of donation, which was problematic.
- 8.12.** Members commented that as the name and date of birth were released alongside the address, it was likely that by using internet searches a donor would be found, even if the address was now incorrect.
- 8.13.** Some members also felt that since the HFEA did not currently have access to the NHS database, the treating clinic should be contacting the donor. However, private clinics do not have access to the NHS systems and they would be hesitant to send letters to donors at out-of-date addresses in case a breach of confidentiality occurred.
- 8.14.** In response to a question regarding method of contact, the Director of Compliance and Information commented that in law the donor conceived individual had to be provided with the last known postal address, but a donor could also give other contact details such as an email or phone number which could also be passed to the donor conceived individual and a preferred method could be stated.
- 8.15.** The majority of members were in favour of option A as they felt that it was the simplest option with the least burden on clinics and the lowest risk. It was also preferred as it reflected the law and was in line with what information was provided to the donor at the time of donation.
- 8.16.** Members highlighted that communication with the DCI should come with clear warnings that the postal address of the donor may be out of date owing to the passage of time since it was recorded.
- 8.17.** The Chair commented that our legal duty needed to be borne in mind. Contacting the donor may be the right thing to do but it was not a legal duty. We however have a legal duty to DCIs, to provide them with defined information and we need to be careful not to compromise that statutory duty.

### Decision

- 8.18.** Following the discussion 12 members voted in favour of option A as they felt it was the best option given our current powers:
- Contact donors using the most recent postal address recorded on the Register/clinic's files.
  - Provide this same address to the DCI making the OTR request.
- 8.19.** One member voted in favour of option B.
- Contact donors using an address obtained through an NHS database (assuming access could be enabled) provided it was more recent than the latest address provided by the donor at the time of donation.
  - If the donor confirmed this was their correct address and consented to updating the Register accordingly, this address could then be provided to the DCI.

- In all other cases, - the most recent address (between the Register and clinic records) would be disclosed to the DCI.

**8.20.** Option A was therefore agreed. However, it was also agreed that the Executive would be mindful of the points made by the member who voted in favour of option B.

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## 9. Modernising Fertility Regulation - update

- 9.1.** The Director of Strategy and Corporate Affairs, Social Research Manager and the Public Policy Manager presented a preliminary analysis of the responses to the consultation.
- 9.2.** The consultation provided valuable qualitative and quantitative feedback and we had begun to analyse the responses. It was noted that the consultation was not a public vote but was helpful in hearing a range of views before the Authority finalised its proposals to the DHSC.
- 9.3.** There was broad support for the majority of the proposals, but Members were advised that four areas required more consideration following the analysis of responses received; these were:
- Elements of our regulatory powers, most notably the regulation of allied services
  - Changes in donor information provision
  - Ways in which to simplify the current consent process and
  - The potential use of secondary legislation and other mechanisms for changes to the regulation of scientific developments.
- 9.4.** Members commented that these changes were developed through a series of discussions with the Authority and from a range of expert groups including the Legislative Reform Advisory Group.
- 9.5.** Some members felt that more analysis of the responses to the consultation will help with the four areas set out above.
- 9.6.** Members noted that this consultation was never going to be fully representative of a balanced set of views and may not be typical of the wider population.
- 9.7.** Following the discussion, the Chair summarised and commented that a majority of members were in favour of moving forward to develop proposals for discussion at the July Authority meeting.

### Decision

- 9.8.** Members agreed that recommendations for law reform should be considered in July with the aim of submitting to DHSC and publicised more widely in due course.

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## 10. Any other business

- 10.1.** The Chief Executive commented that this was the last meeting of the Director of Finance and Resources, Richard Sydee, as he would be leaving the HFEA in June. Richard was thanked for his leadership and advice over the last six and a half years. The Chair reiterated this on behalf of the board.
- 10.2.** The Chair commented that there will be an away day later in the year asked that members please make themselves available. Dates to be sent out shortly.
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## Chair's signature

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

Signature

Chair: Julia Chain

Date: 12 July 2023

# Authority meeting

## Matters Arising

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### 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

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Meeting Authority meeting

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Agenda item 2

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Meeting date 12 July 2023

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Author Debbie Okutubo, Governance Manager

### Output:

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For information or decision? For discussion

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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.

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Resource implications To be updated and reviewed at each Authority meeting

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Implementation date 2022/23 business year

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Communication(s)

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Organisational risk  Low  Medium  High

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ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
<b>Matters arising from the Authority meeting – actions from 17 May 2023</b>			
3.12 A paper on the strategy development to be brought to the July Authority meeting setting out an interim plan for the year based on the existing vision and aims.	Head of Planning and Governance	July 2023	Update – this is an agenda item
<b>Matters arising from the Authority meeting – actions from 22 March 2023</b>			
8.6. Executive to consider producing a short video to manage expectations of donor conceived individuals before they receive the full information.	Director of Compliance and Information	November 2023	Head of comms emailed suggest this is closed off now as it is part of the wider OTR comms work.
<b>Matters arising from the Authority meeting – actions from 18 May 2022</b>			
3.6 Some members that are yet to complete their cyber security training.	Governance Manager	May 2023	<p>In accordance with our annual process, the 2023 Authority member training in information security has commenced, using the Civil Service Learning training portal. In addition, this year, members are also required to complete a module on Equality, Diversity and Inclusion.</p> <p>As at end of June 2023, 13 of the 14 members had completed their training in 2023. The 14<sup>th</sup> member completed their training in November 2022 but without the EDI module.</p>
<b>Matters arising from the Authority meeting – actions from 23 September 2021</b>			
5.18 Backlog on OTR	Director of Compliance and Information	March 2023	<p>The vacant post has been recruited to so the team is at its full compliment. Improved team structure will help reduce the time to sign off. However, application numbers have increased over recent months and we will need to monitor demand and capacity carefully.</p> <p>Suggest closed off as comes up under performance report.</p>

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
<b>Matters arising from the Authority – actions from 7 July 2021</b>			
5.7 PGT-M being out of target of the 75 working days	Director of Compliance and Information	January 2023	The Scientific Officer is nearly towards the end of probation. PGT-M's are progressing well (as are ITE certificates). The rate of PGT-M applications varies, which means workload can suddenly increase, this is unavoidable as it will be driven by patient needs. KPIs were met for September 2022 to January 2023. Suggest to close out as the officer is now trained and we will monitor progress through performance report



# Chair and Chief Executive's report

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## Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	12 July 2023
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

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## 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

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## 1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meeting in May 2023.
  - 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:
  - 1 & 14 June – participated in the panel for the Audit and Governance external member interviews.
  - 6 June – chaired the Law Reform Advisory Group (LRAG) meeting
  - 19 June – chaired the Remuneration Committee
  - 10 July – attended our Summer All Staff event.

### 2.2 Chief Executive

- The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:
  - 6 June – attended LRAG meeting.
  - 8 June – attended meeting of all ALB Chief Executives chaired by Shona Dunn
  - 9 June – attended the second challenge panel meeting with the ALB Public Bodies Review team
  - 14 June – presented to HDBI public dialogue online event on early human embryo research
  - 19 June – presented to the Remuneration Committee
  - 27 June – attended the Audit & Governance Committee meeting
  - 10 July – attended our Summer All Staff event.

# Committee Chairs' reports

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## 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:	12 July 2023
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

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## 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
<b>Licence Committee:</b>		
4 May 2023	1 renewal 2 special directions	All granted
29 June	1 research initial 3 executive update	Minutes not yet approved
Other comments:	None.	
<b>Executive Licensing Panel:</b>		
16 May 2023	1 renewal 2 interim	All approved
25 May 2023	1 interim 1 executive update	All approved
13 June 2023	1 renewal	
28 June 2023	4 Interim 1 Change of PR 1 Removal of condition on licence 1 Extension of Licence	All approved
Other comments:	None.	
<b>Licensing Officer decisions:</b>		
May 2023 – June 2023	17 ITE Import Certificates 1 Change of Centre Name	All granted
Other comments:	None.	

Meetings held	Items considered	Outcomes
<b>Statutory Approvals Committee:</b>		
22 May 2023	4 PGT-M 3 special directions for import/export	All PGT-Ms granted. 2 special directions granted, 1 adjourned
20 June 2023	4 PGT-M 1 special directions for import	Minutes not yet approved.
Other comments:	None.	
<b>Audit and Governance Committee:</b>		
27 June 2023	Internal audit reports and annual opinion External audit report and draft Annual Report and Accounts Annual SIRO Report Bi-annual HR report	
Other comments:	None.	
<b>Scientific and Clinical Advances Advisory Committee:</b>		
The next meeting will be held on 25 July 2023.		
Other comments:	None	

### 3. Recommendation

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



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# Annual performance report

**From April 2022 up to March 2023**

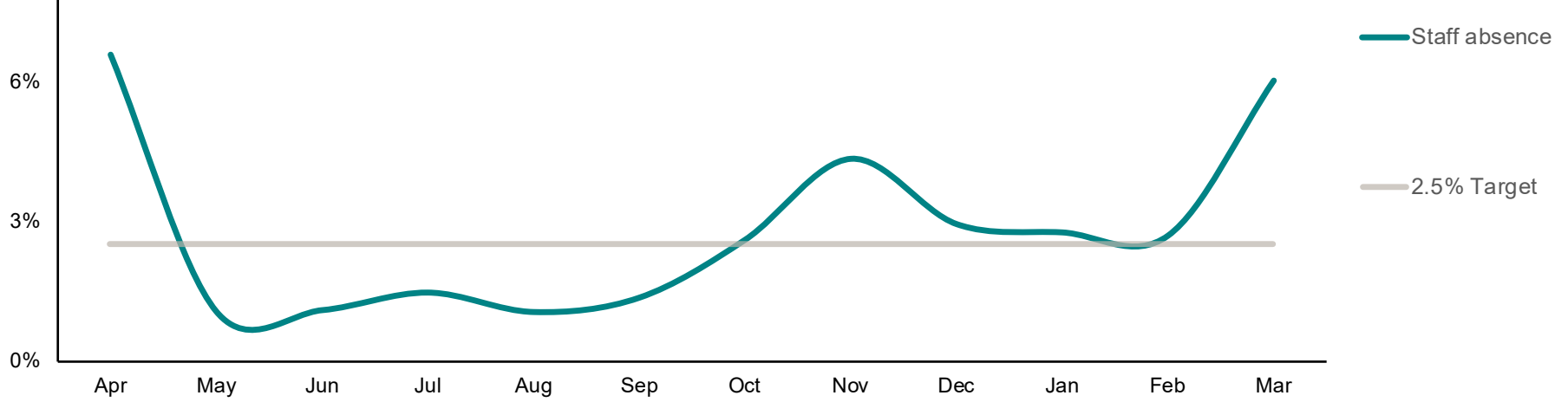
**Evgenia Savchyna**

Corporate Performance Officer

12/07/2023

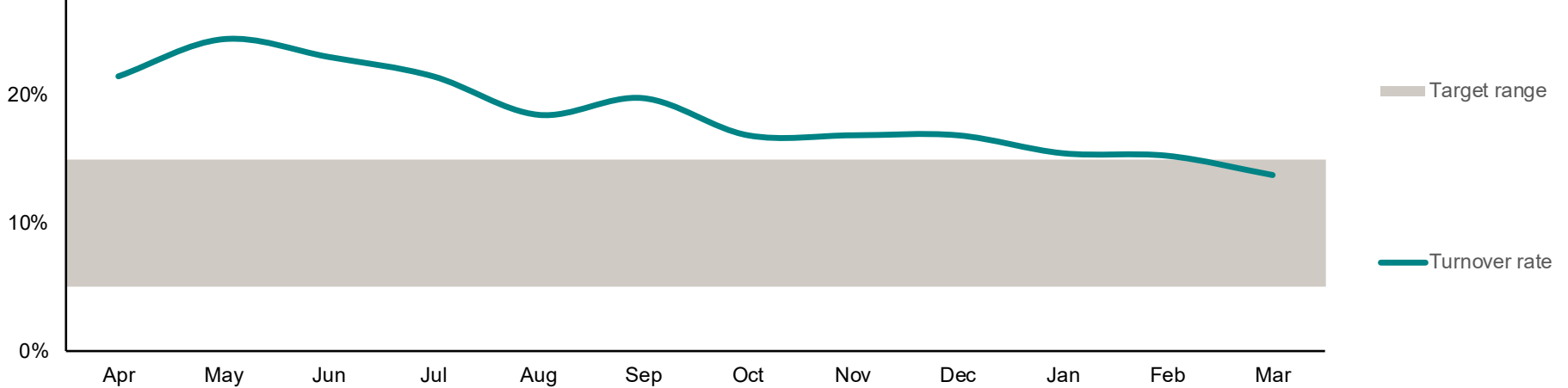
[www.hfea.gov.uk](http://www.hfea.gov.uk)

### Staff sickness absence rate

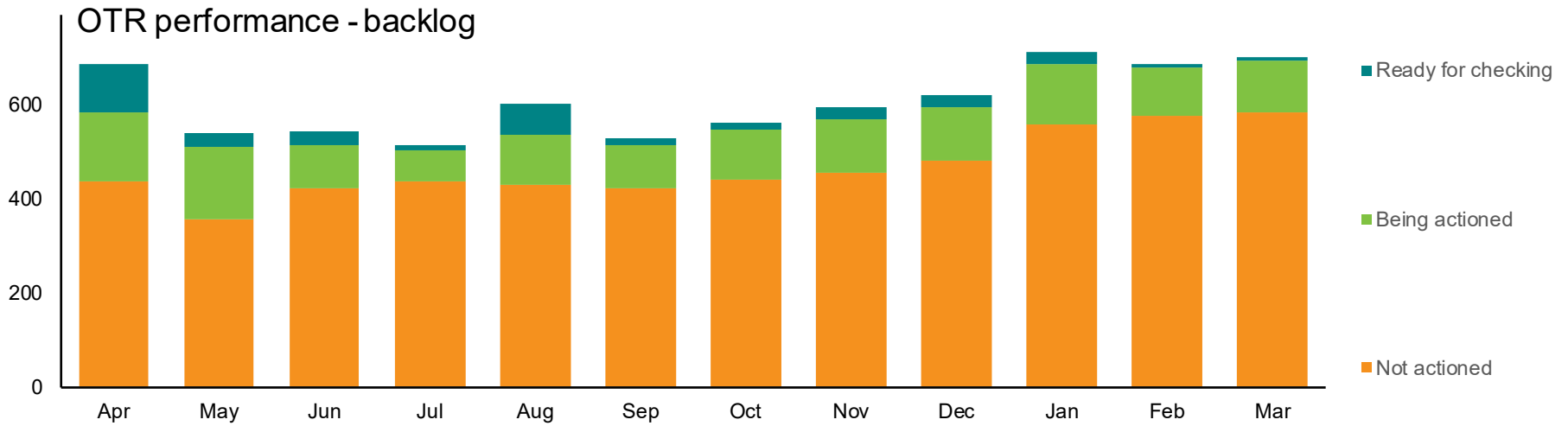


Sickness over the last year has been mostly below the KPI. The recent peak, is partly explained by seasonal coughs and colds and three staff on long term sickness.

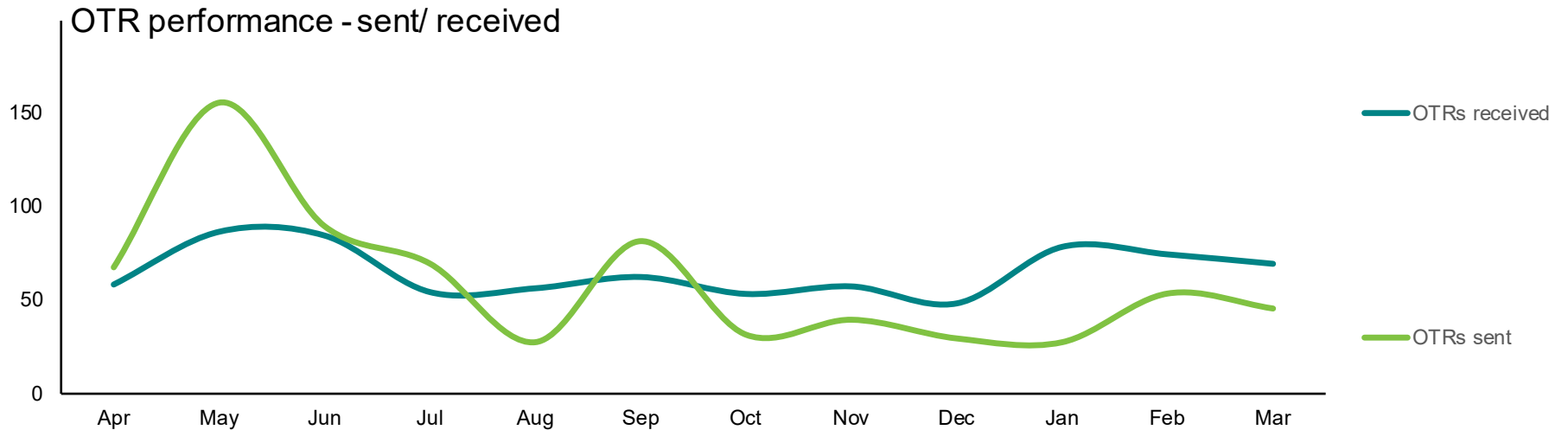
### Rolling annual turnover vs target range (5-15%)



Turnover has been above target for most of the previous year but has been improving steadily throughout this year.



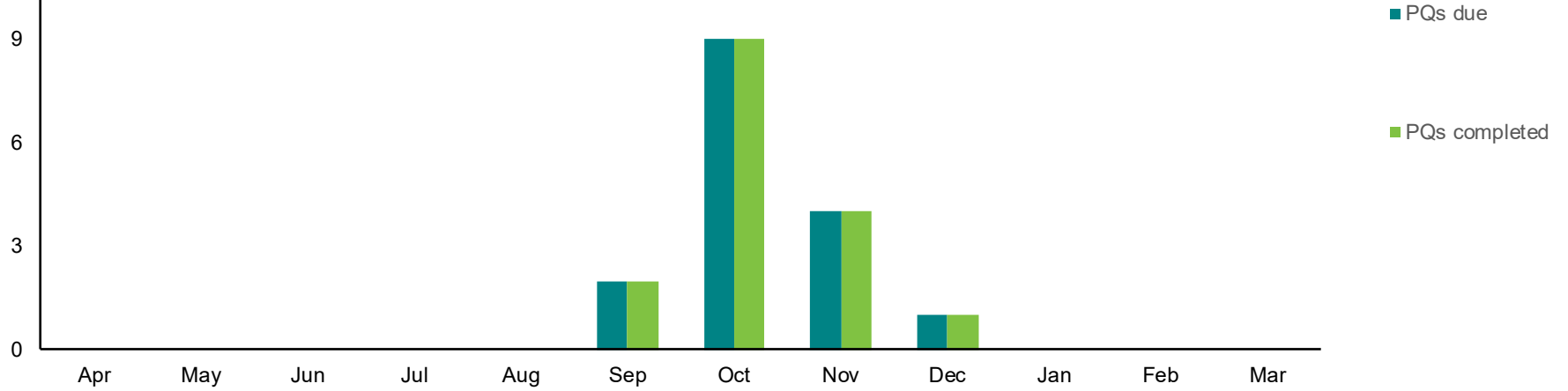
OTR performance has been complicated by staff turnover and the need to test a new case management system to access the Register through PRISM. The new system is due to go live in August 2023 and should make the process more efficient and reduce the turnaround time of OTR requests. We will have a clearer understanding of how quickly the backlog can be reduced once the new system is in use for 3 months.



The number of OTR applications has been running at a higher level than we have been able to process for most the year, for reasons of staff turnover and the testing of the new case management system. A new team structure is in place and this should bring stability and, together with the new case management system, greater productivity in future.

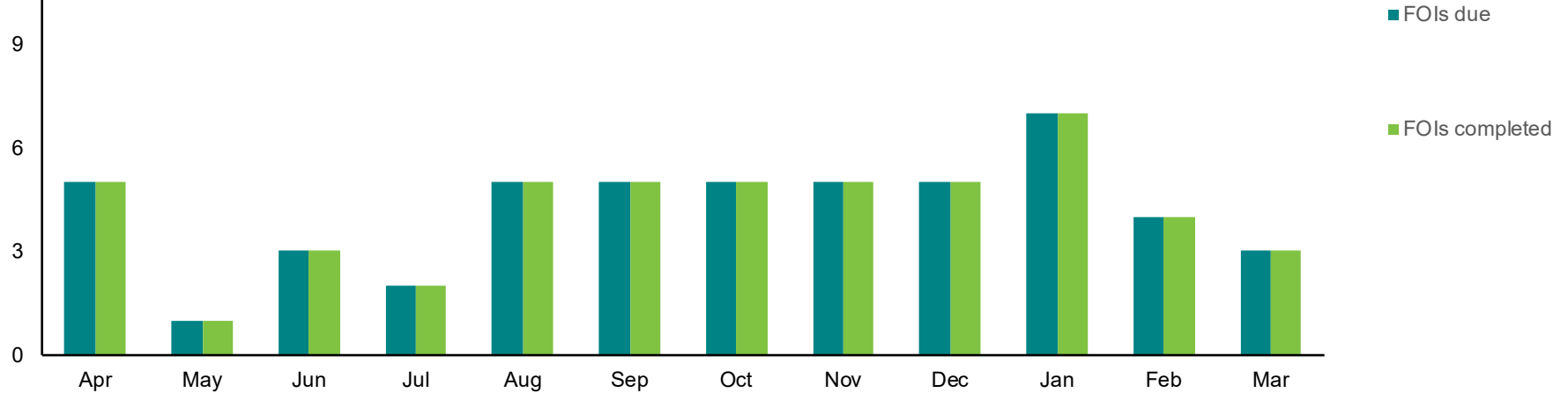


## Parliamentary questions

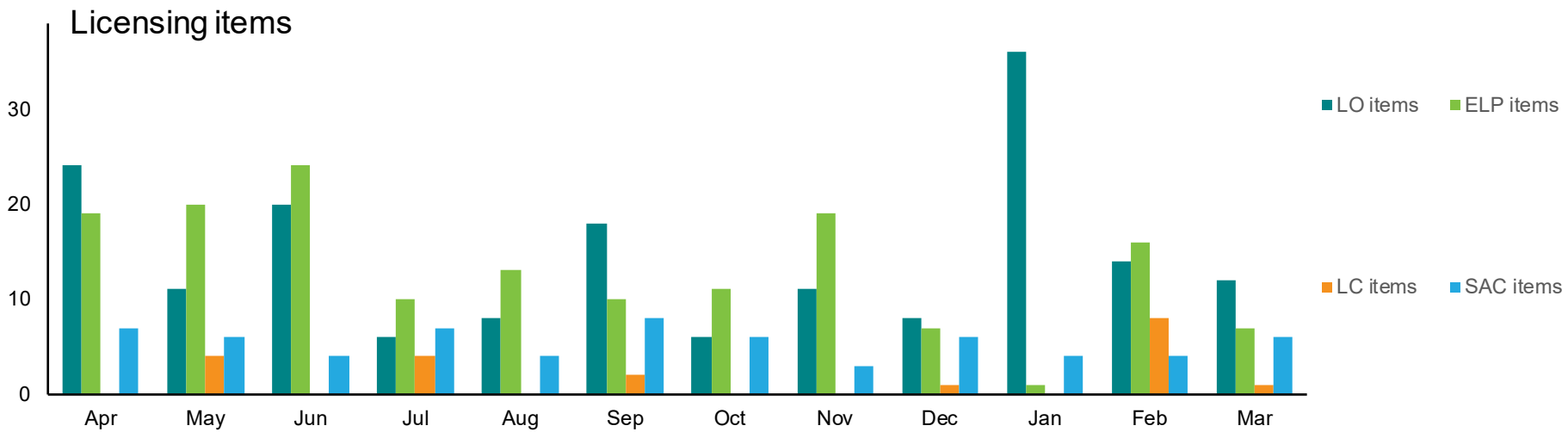


PQs were turned around within KPI timescales. PQ topics were mainly on egg freezing and mitochondrial donation.

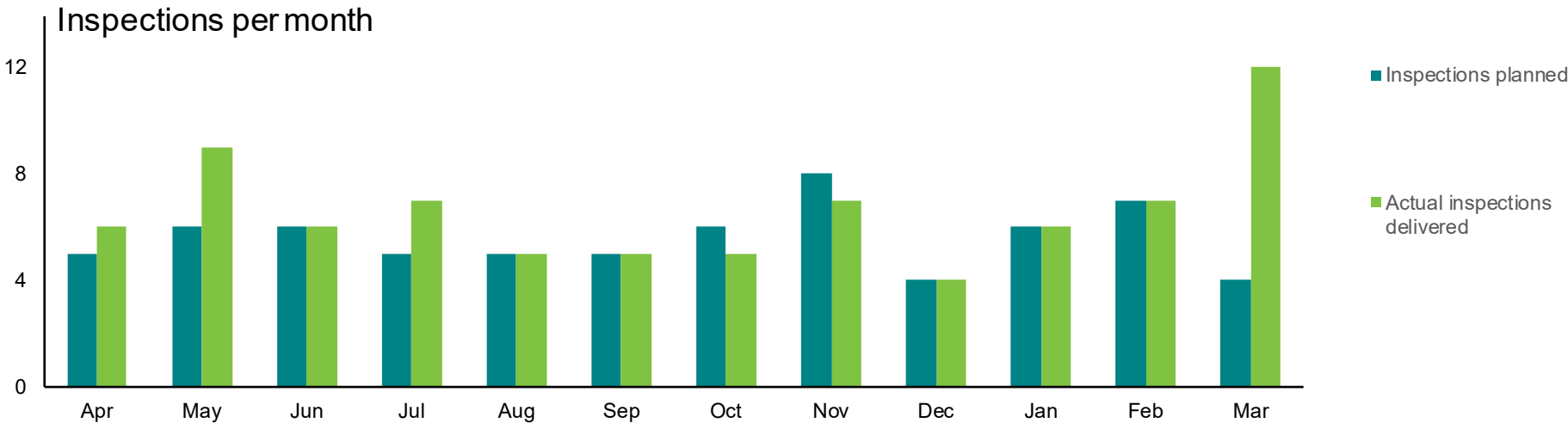
## Freedom of Information requests



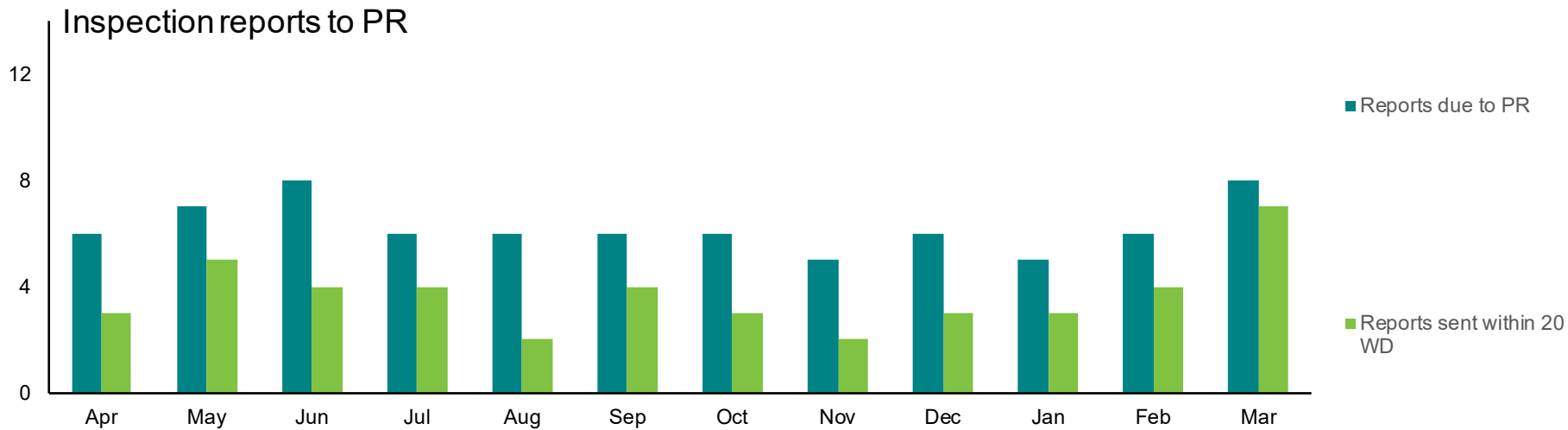
FOIs were turned around within KPI timescales. FOI topics were mainly related to HR/IT or to do with data held on our register.



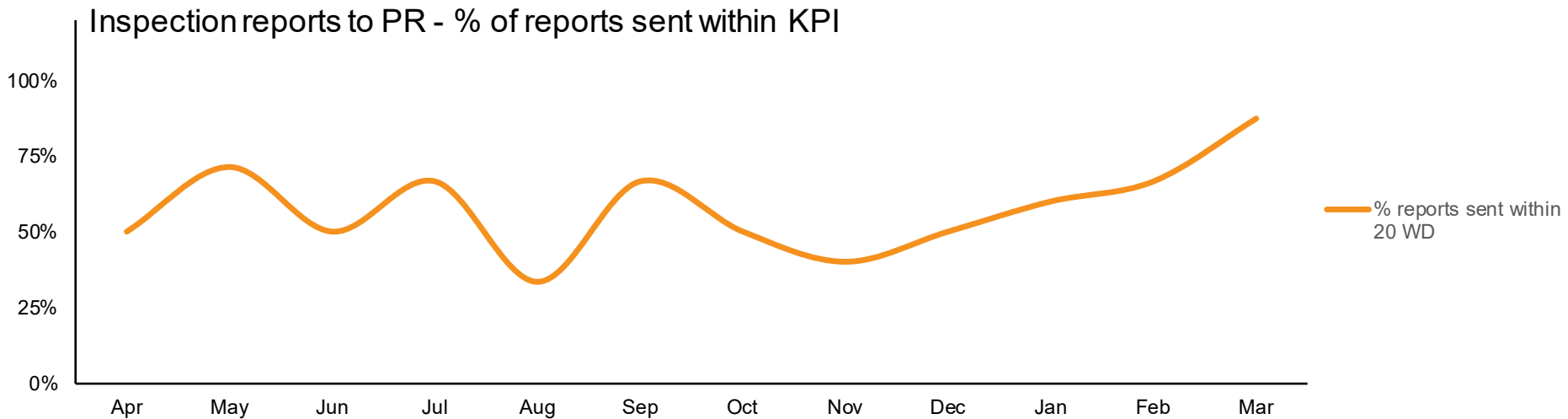
The licensing team has dealt with high volume of activity (both Committees and Licensing Officer). Some items have been complex and protracted requiring more than one meeting (some extending into the 2023/24 business year). The fact that we have still delivered most minutes within our KPI is a real achievement given the pressures.



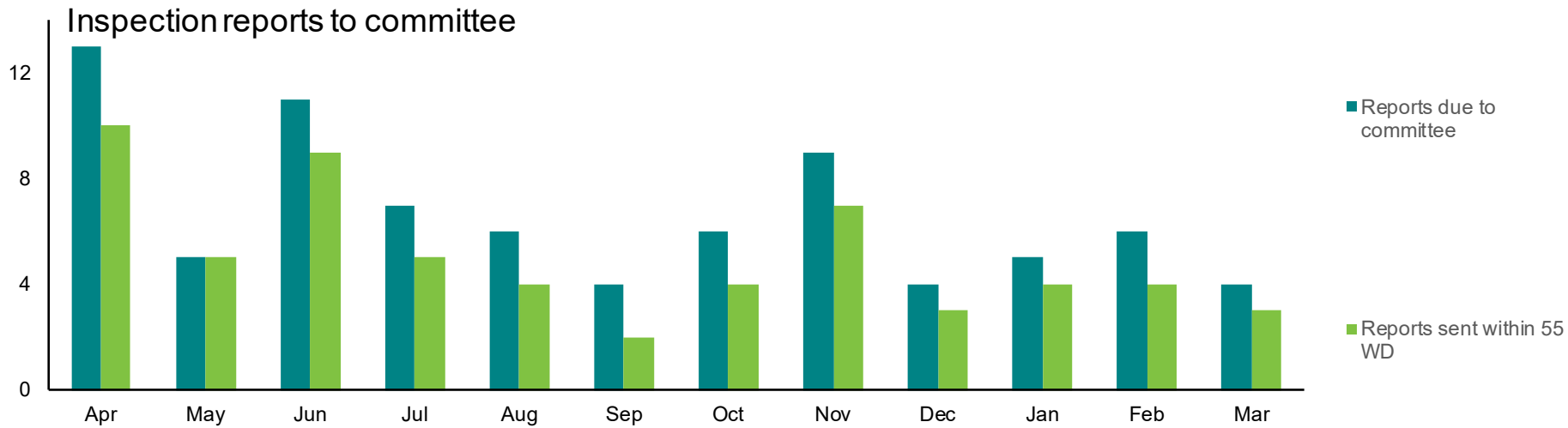
Delivery of the 2022/23 inspection schedule has been extremely challenging for several reasons. The effect of extension of licences and deferment of inspections during the pandemic has increased the number of inspections to complete. There has also been a need for extra inspections to be fitted in the schedule due to significant compliance concerns and whistleblowing allegations received.



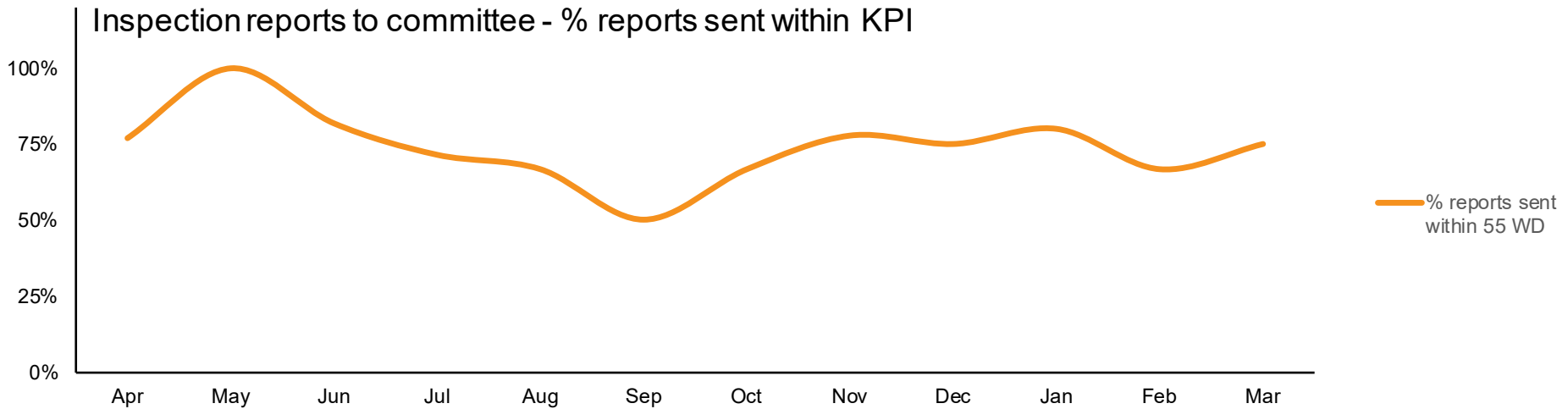
This year has seen increased sickness (including long term sickness) and an unusually high turnover in the team. Inspectors have had to take responsibility for extra clinics into their portfolios which has increased their workload - additional inspections, clinic enquiries, incidents, and patient complaints.

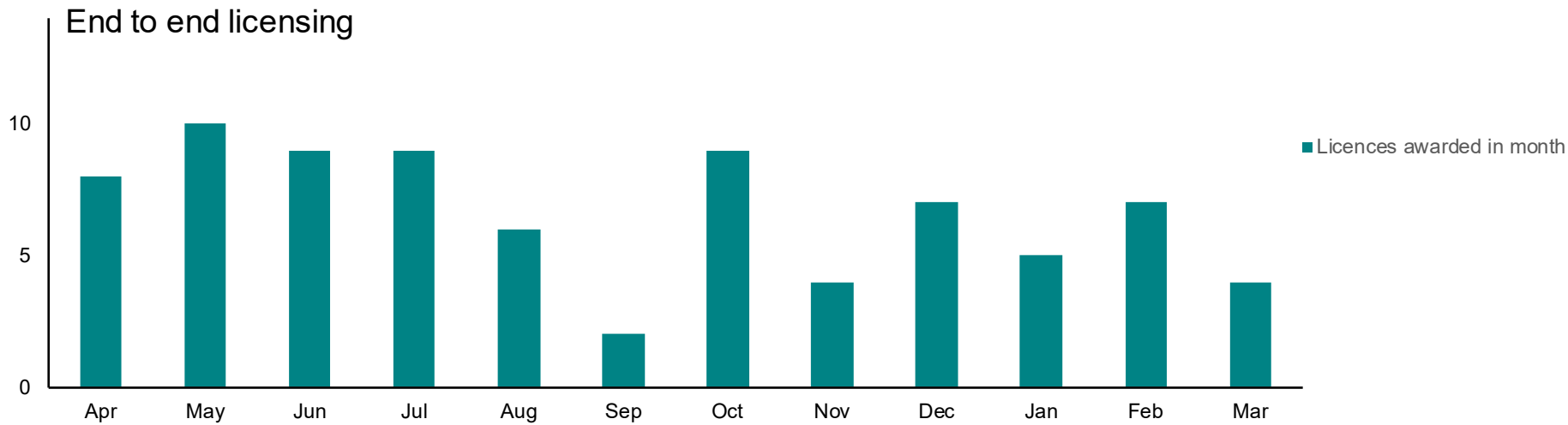


The 20 working day KPI is being reviewed with a view to extending this to 25 days to allow additional time for complex reports to be completed.

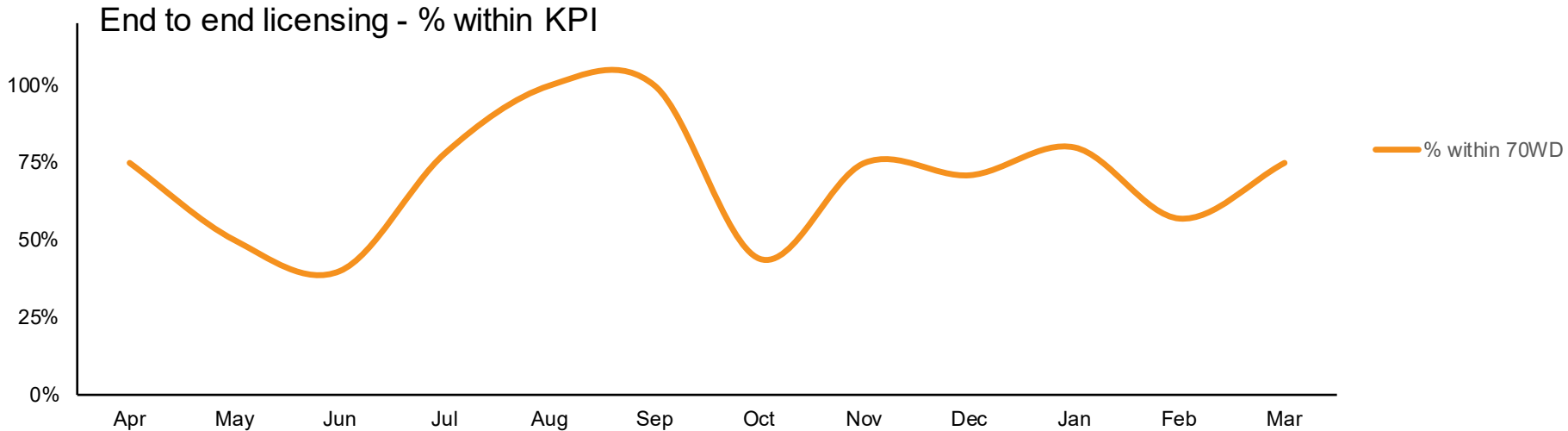


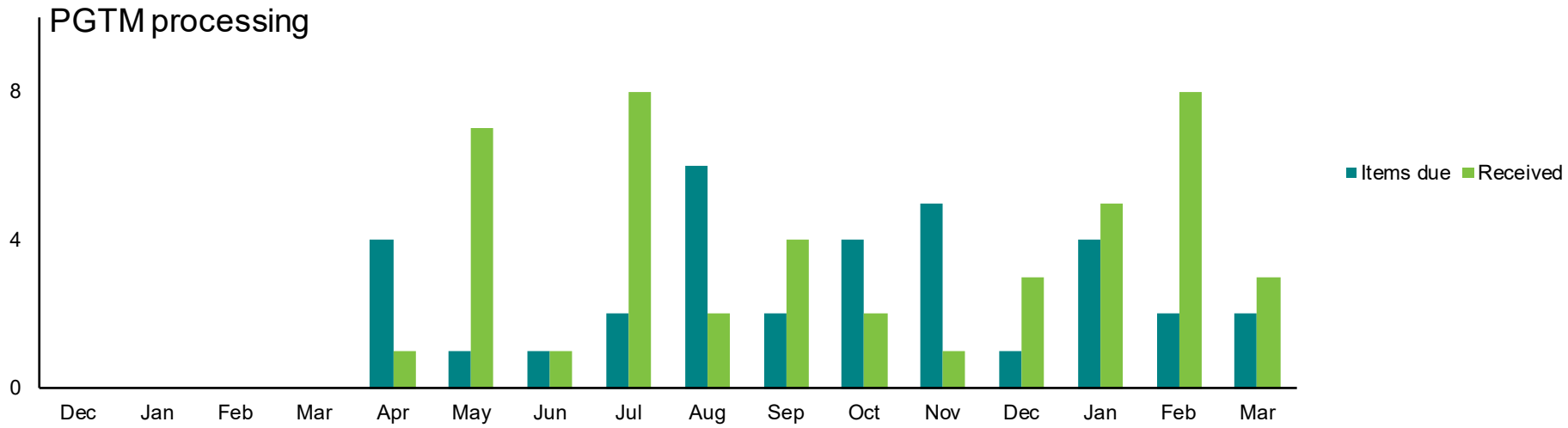
This KPI has been impacted by the pressures on the team described above. The requirement to complete a Compliance and Enforcement assessment for inspections has improved robustness and consistency to the inspection methodology but has added processing time which has not been factored into this long standing KPI. The KPI is under review.



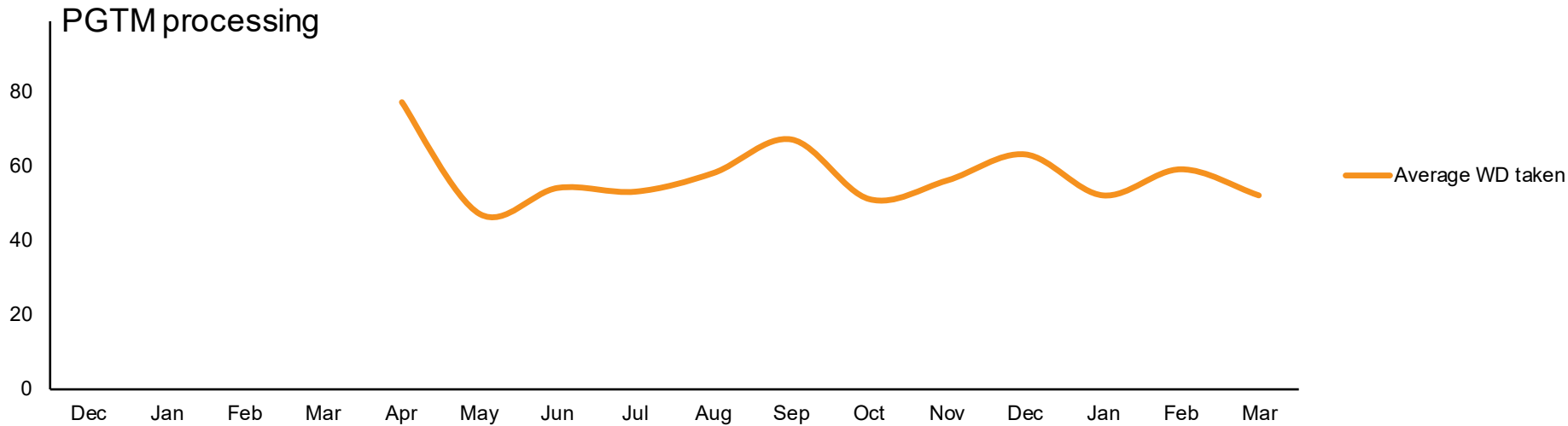


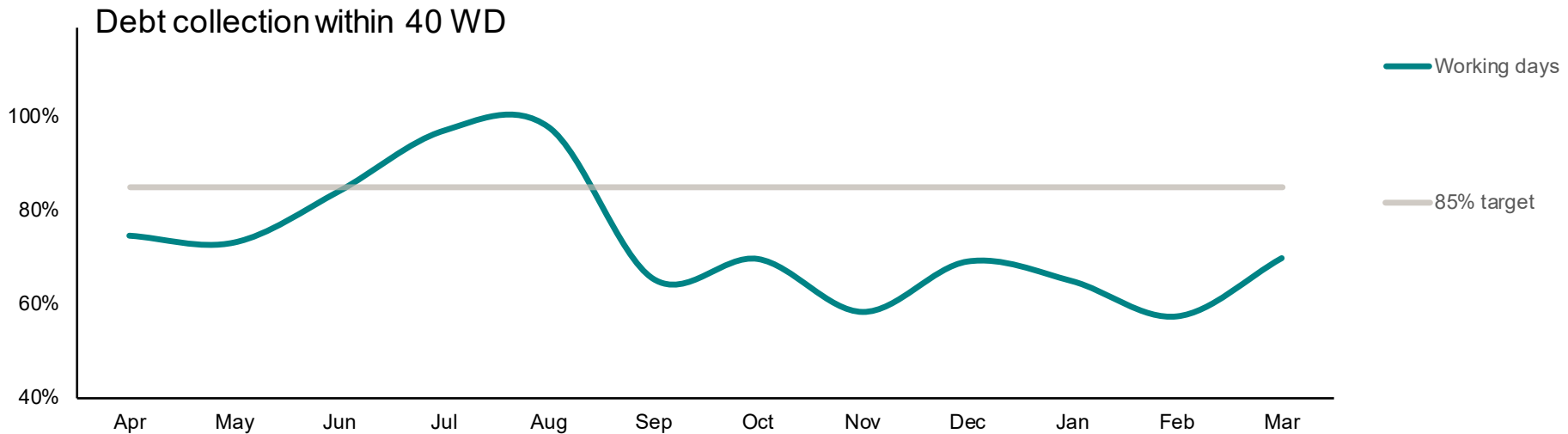
Despite the challenges outlined above, all clinics have had their licences issued within the timescales required - even when the end to end licensing KPI has been missed. Looking ahead, staff recruitment and training as well as use of external inspectors should help ease pressures in the medium to long term. Scheduling will also be reviewed for the next inspection year.



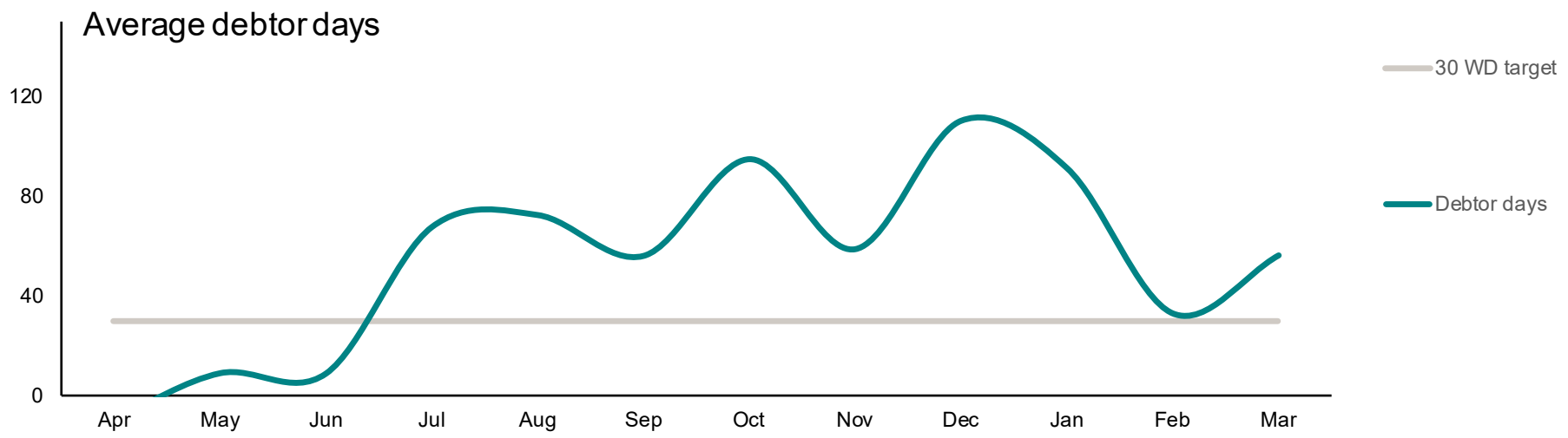


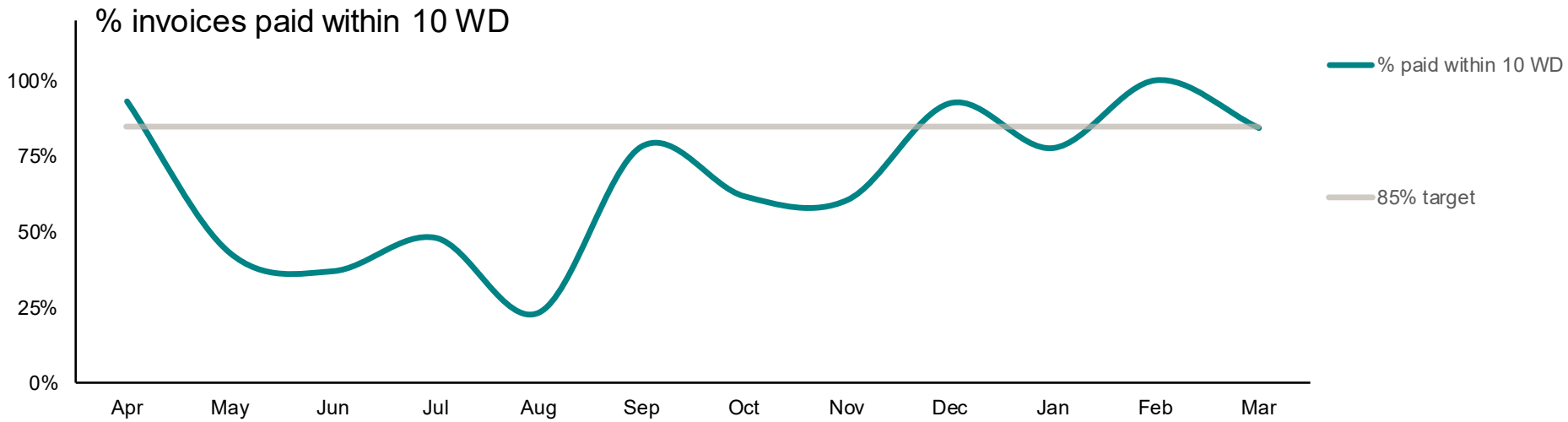
We employed a dedicated scientific application officer to manage PGTM, ITE certificates and Mitochondrial donation applications, which has been effective. Application turnaround times have all been within KPI (85 working days).



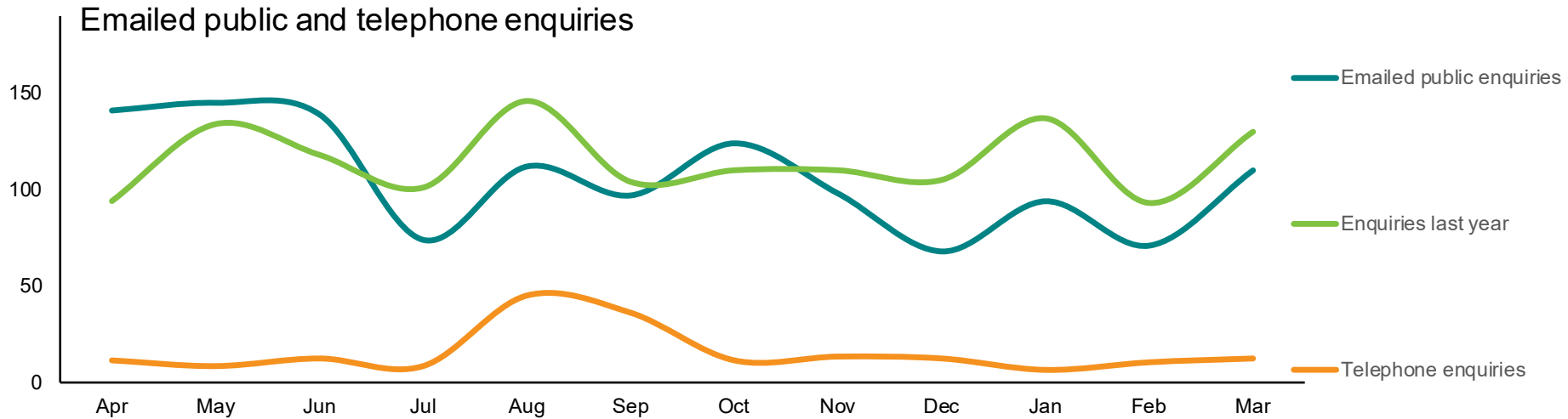


We issued estimated invoices in July covering a 3-month period. This caused an increase in the 40 WD KPI as clinics delayed payment to better understand on what basis invoices were raised. This is improving slowly as more focus is applied after year end has been finalised.





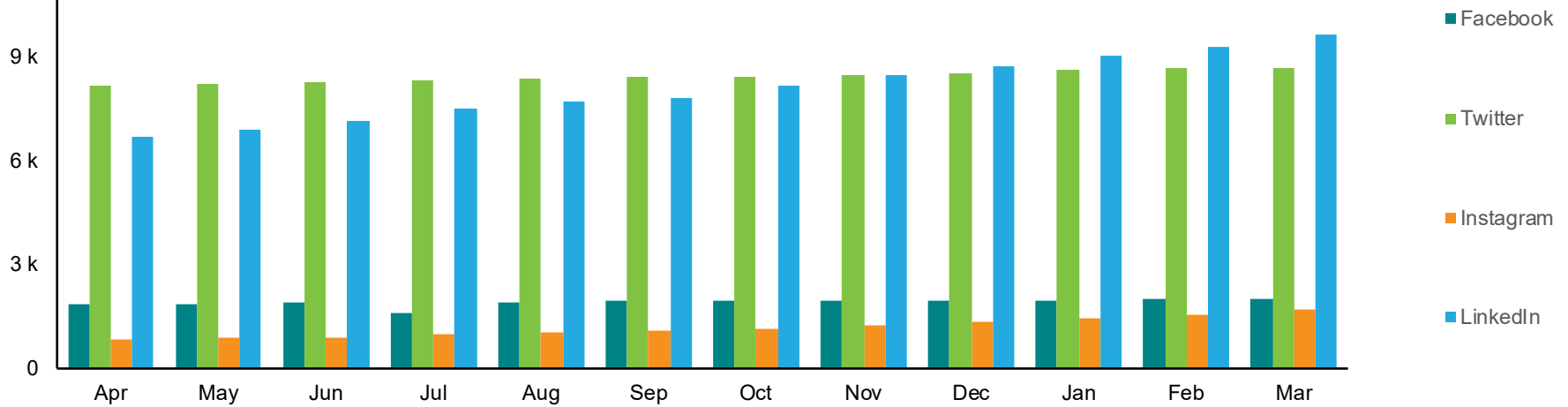
Target achieved at year end. During the year, however, issues with late approvals of invoices and payment approval impacted on this KPI. From February, we were back on track.



The majority of enquiries have been from patients with the main themes being related to complaints processes, sperm donation, import/ export, screening and testing.

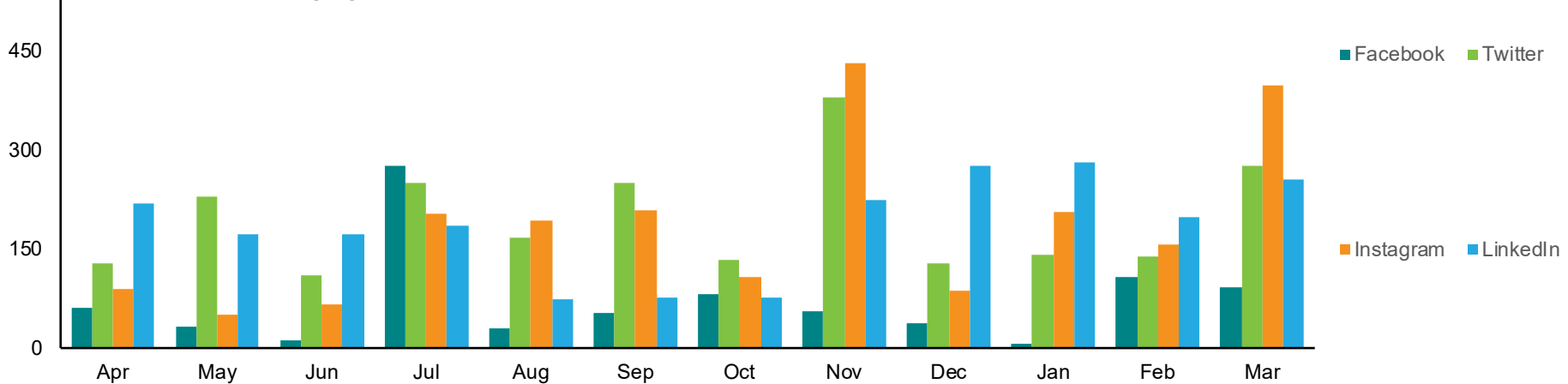


## Social media followers

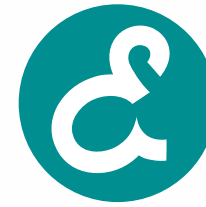


Followers have remained broadly stable on Facebook and Twitter but we are seeing a steady increase on LinkedIn (where we mainly aim to engage with sector professionals) and, from a low base, on Instagram (where we aim to engage with people going through or considering fertility treatment). We plan to expand our KPIs over the next year to cover comms more broadly, to gain a more rounded picture of our external profile.

## Social media engagement



Social media engagement varies depending on the news cycle, whether created by us or by stories elsewhere. We saw spikes in social media engagement in November (the launch of our donation report, but also a major news story around a celebrity opening up about their fertility issues, which also appears to have driven visitors to our website) and in March (where we were promoting our law reform consultation, which had also attracted press coverage).



Human  
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# Monthly performance report

**Up to May 2023**

**Evgenia Savchyna**

Corporate performance officer

12/07/2023

[www.hfea.gov.uk](http://www.hfea.gov.uk)



# About this paper

## Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	Item 6
Meeting date:	12/07/2023 (Authority)
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 Senior Management Team (SMT) 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 SMT meeting.</p> <p>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).</p>
Organisational risk:	Medium

# Latest review and key trends

## Latest review

- The attached report is for performance up to and including May 2023.
- In May performance was generally good. There were ten green, one amber, four red, and two neutral indicators.

## Key trends

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

March (4)	April (4)	May (4)
HR1 – Staff sickness rate	HR1 – Staff sickness rate	HR1 – Staff sickness rate
C4 – End to end licensing reports within 70 working days	C2 – Inspection reports sent to PR within 20 working days	C2 – Inspection reports sent to PR within 20 working days
F1 – Debt collection	F1 – Debt collection	C4 – End to end licensing reports within 70 working days
F2 – Debtor days	F2 – Debtor days	F2 – Debtor days

# Management summary

## IT and register performance reporting

- PRISM: Clinic activity is 412K units from 104 clinics. Error rate is 3.8%.
- CaFC - we have released two tranches of errors to clinics. We are continuing to encourage clinics to address errors and have reiterated our CaFC timescales and best- and worst-case scenarios (last quarter of 2023 to second quarter 2024).
- Final set of EDI errors to be released. The focus is on clinics having a steady stream of errors to fix.
- OTR and PRISM: Planned target remains to complete the reports required for the OTR team by the end of July 2023. The Register Team have successfully tested the manual matching system.

## Management commentary

- Performance has been variable across KPI indicators with four red, one amber, two neutral and ten green indicators.
- Staff sickness has remained high for the last three months (three staff members on long term sick currently). Turnover has continued its downward trend; however, we will have three leavers in June. Headcount is currently 78.
- Debt collection has improved but remains at amber with 77% within 40 days, however, 88% of the value has been paid. Average debtor days has plateaued and is now at 51 days. Over 50% of the debtors balance is from the previous year and will remain as the top priority.
- The C2 KPI (inspection reports to PR) remains red, however, the C3 KPI (reports to committee) is now green and will remain so in June as well (all reports due were already completed by the time this report was compiled).
- Agenda volumes in Licencing remains high and an additional Licence Committee meeting took place in April.
- Significant increase in OTRs being actioned this month as the whole team has prioritised working on the backlog.

# Summary financial position

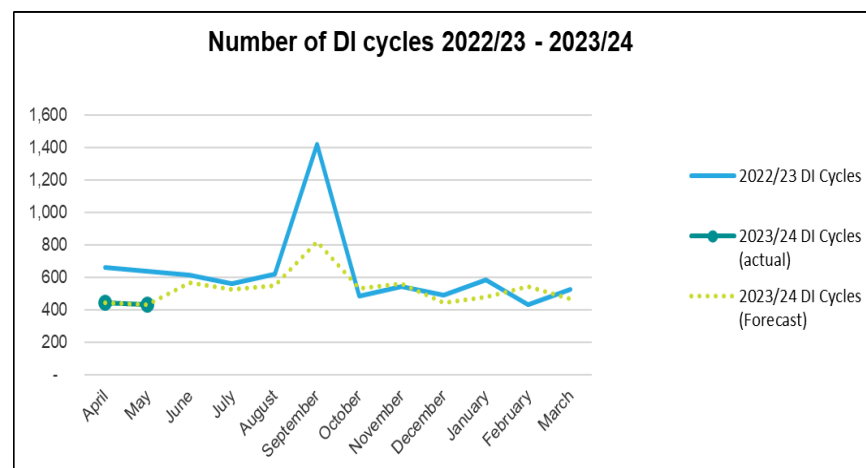
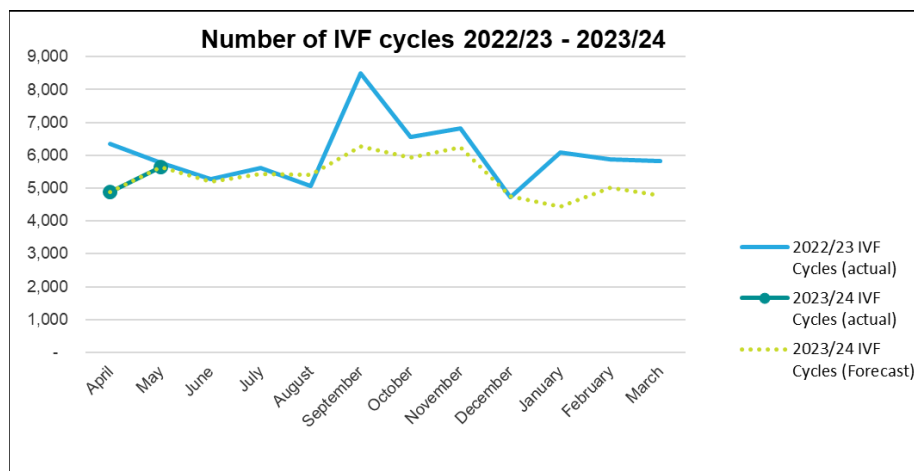
Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/2022 £'000s	Budget for 2021/22 £'000s	Variance Budget vs Forecast £'000s
Income	1,007	1,067	60	7,135	7,260	125
Expenditure	1,155	996	(159)	7,239	7,260	21
<b>Total Surplus/(Deficit)</b>	<b>(148)</b>	<b>71</b>	<b>(219)</b>	<b>(105)</b>	<b>0</b>	<b>(104)</b>

## Commentary on financial performance to May 2023

As at 31 May 23, we are posting a deficit against budget of £219k. Whilst this is largely a profiling issue, there are one or two areas that are under pressure due to the limited budget. These are explained in the detail within the income and expenditure section.

The current forecast is an overspend against budget of £104k. The first quarter outturn will be reviewed in July which will provide an opportunity to take corrective action.

# Financial management information



## IVF Cycles

	YTD		YE Position	
	Volume	£	Volume	£
2022/23 IVF Cycles (actual)	12,120	1,030,200	72,493	6,161,905
2023/24 IVF Cycles (actual)	10,520	894,200	63,996	5,439,660
Variance	(1,600)	(136,000)	(8,497)	(722,245)

IVF volumes are down against 2022/23 in the first two months of the year, although the catch-up in reporting that clinics submitted in 2022/23 may skew the overall numbers. It is too soon to tell whether our income this year will match our forecast (which is based upon the average of the last 3 years).

## DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2022/23 DI Cycles	1,303	48,863	7,589	284,588
2023/24 DI Cycles	881	33,038	6,383	239,363
Variance	(422)	(15,825)	(1,206)	(45,225)

DI volumes are also lower than 2022/23 but, as with IVF volumes, it is too early to tell whether the forecast will be matched.

A review of our forecast will be conducted at the end of Q1.

# HFEA income and expenditure

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
<b>Income</b>							
Grant-in-aid	-	-	-	-	991	991	-
Non-cash (Ring-fenced RDEL)	44	39	(5)	(0)	232	232	-
Grant-in-aid - PCSPS contribution	-	-	-	-	100	100	-
Licence Fees	932	1,028	96	0	5,717	5,829	112
Interest received	19	-	(19)	-	35	35	(1)
Seconded and other income	12	-	(12)	-	60	73	13
<b>Total Income</b>	<b>1,007</b>	<b>1,067</b>	<b>60</b>	<b>6</b>	<b>7,135</b>	<b>7,260</b>	<b>125</b>
<b>Revenue Costs</b>							
Salaries (excluding Authority)	818	861	43	5	5,105	5,145	41
Staff Travel & Subsistence	11	-	(11)	-	95	100	5
Other Staff Costs	28	7	(21)	(286)	82	66	(16)
Authority & Other Committees costs	27	28	1	5	223	235	12
Facilities Costs incl non-cash	98	39	(59)	(153)	606	610	4
IT Costs	86	21	(65)	(309)	345	312	(35)
Legal / Professional Fees	62	33	(29)	(87)	522	521	(1)
Other Costs	25	7	(18)	(279)	210	222	11
Other Project Costs	-	-	-	-	51	51	-
<b>Total Revenue Costs</b>	<b>1,155</b>	<b>996</b>	<b>(159)</b>	<b>(16)</b>	<b>7,239</b>	<b>7,260</b>	<b>21</b>
<b>TOTAL Surplus / (Deficit)</b>	<b>(148)</b>	<b>71</b>	<b>(219)</b>		<b>(104)</b>	<b>0</b>	<b>(104)</b>
<b>Adjusted for non-cash income/costs</b>	<b>(154)</b>	<b>71</b>	<b>(225)</b>		<b>(71)</b>	<b>33</b>	<b>(103)</b>

## Management commentary

### Income.

We are 2 months into the new financial year and our Licence fee income is under budget by £96k or 9%. It is too early to say whether this trend will continue. Other income (interest received and seconded income) are showing as over budget due to profiling as is our non-cash (ring-fenced RDEL).

### Expenditure (by exception)

Year to date, expenditure is over budget by £159k. A line by line analysis would normally be given to explain the variances, however, as we are only two months into the business year and our budget is profiled on quarterly basis, it would not be a helpful exercise.

**Other Staff costs** - include an accrual for Power BI training is included, but to note this training was not budgeted for as it should have taken place in the previous financial year.

**IT Costs** - are over by £65k as per the above reasons, however, against our IT Subscriptions which are profiled monthly, we are overspending by £22k. We are aware that these costs have increased but were unable to factor this into the budget at the start of the year. At the end of Q1, a re-forecast exercise will be undertaken to establish where the additional funding can be found.

### Forecast

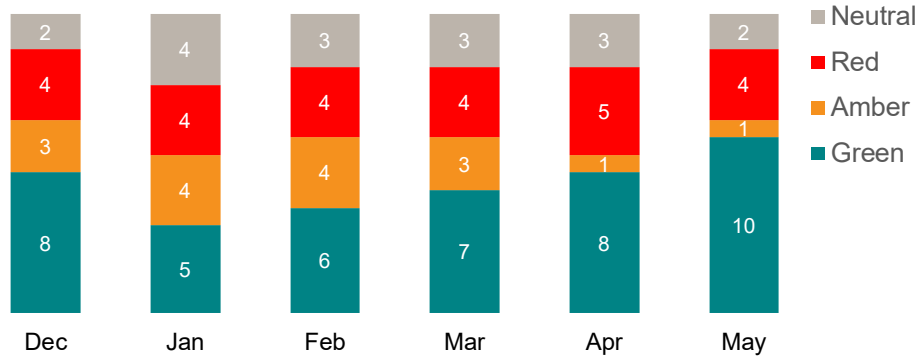
The forecast currently reflects the remaining 10 months of budget plus the year to date. There are pressures that currently have not been factored into the forecast, these include the one-off payment to staff of £1500; project costs within the Compliance and Strategy and Corporate Affairs. We will look to see how these can be funded at the end of Q1 when we will re-forecast the budget.



# Key performance indicators

**RAG status over last 6 months**

17 KPIs in total for each month



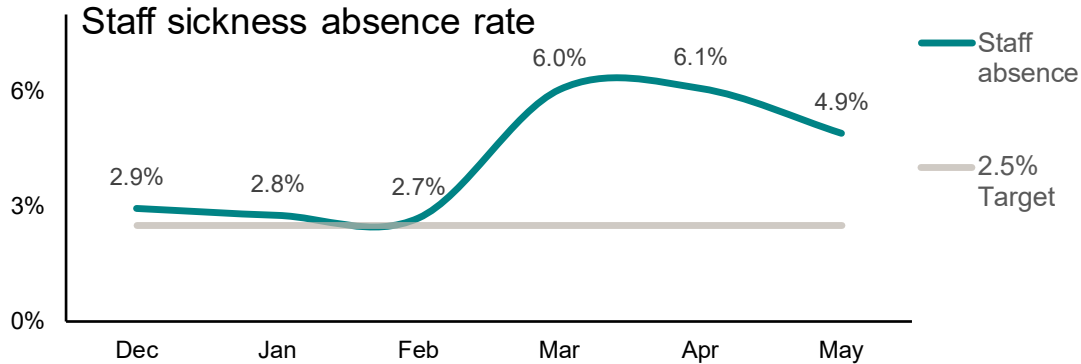
For **May**, the **4 red** indicators are in these teams:

- Comms : 0
- **Compliance : 2**
- **Finance : 1**
- **HR : 1**
- Information : 0
- Intelligence : 0
- PlanGo : 0

Status: **Red**

**HR1 – Sickness**

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

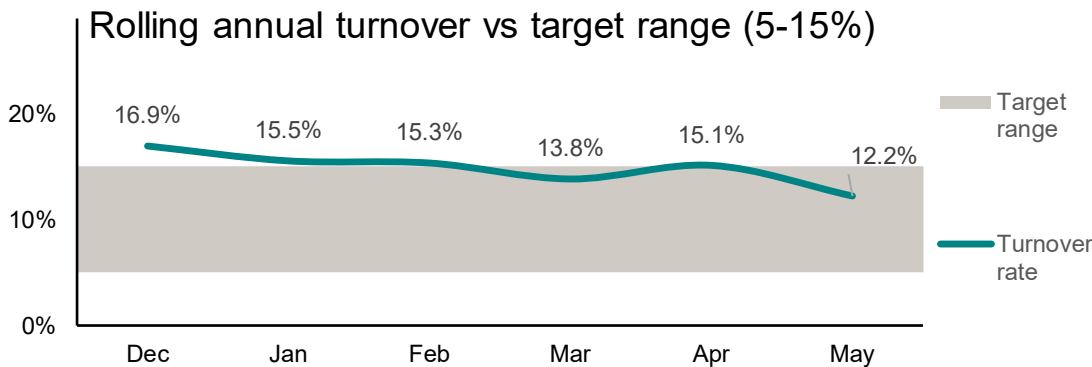


Three employees remained on long term sick during May. All are being closely monitored and referred as necessary. Two employees have been absent this month due to work stress - both have returned.

Status: **Green**

**HR2– Turnover**

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



No leavers this month - turnover will rise next month however, with three leavers planned for June.

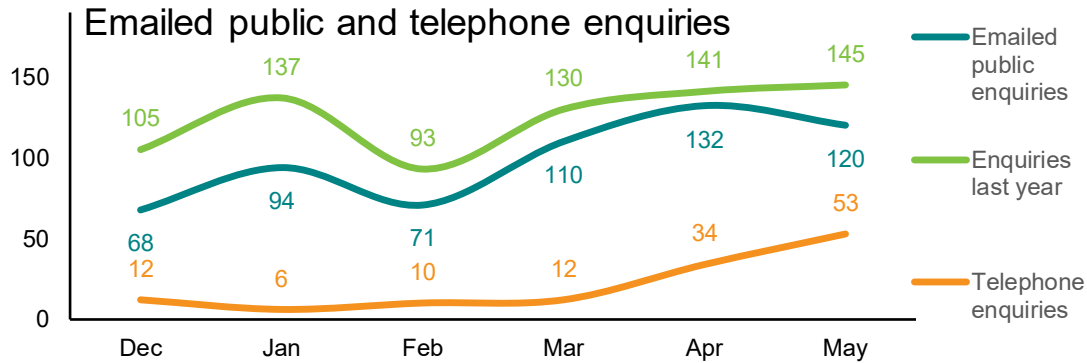
**Supplementary HR data**

- Headcount : 78
- Posts : 76
- Starters : 2
- Leavers : 0

Status: N/A

### Emailed public and telephone enquiries

Target: None defined

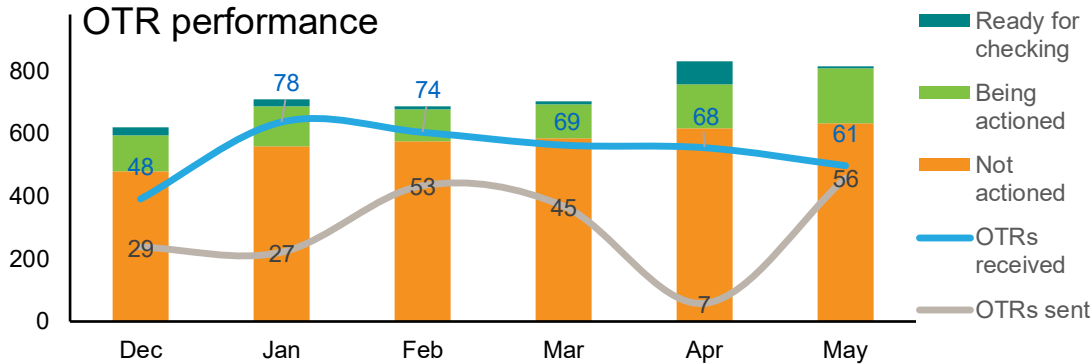


86 out of 120 email enquiries were made by patients.  
**Main themes:** Complaints related (22), general treatment (10), preservation (5), import/export (5).  
There has been a significant increase in the number of calls due to the telephone number having been put on the website.

Status: N/A

### I1 – OTR performance

Target: To be developed

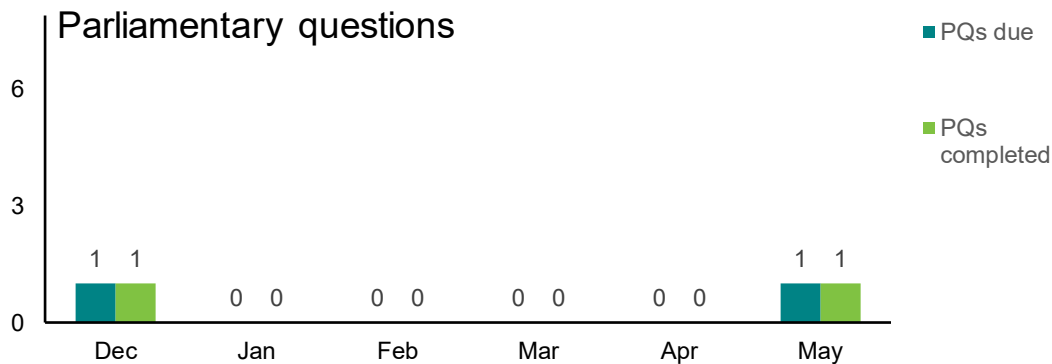


Increase in OTR's being actioned due to all members of the team working on the waiting list.

Status: Green

### RI1 – PQs responses

Target: 100% within deadlines set

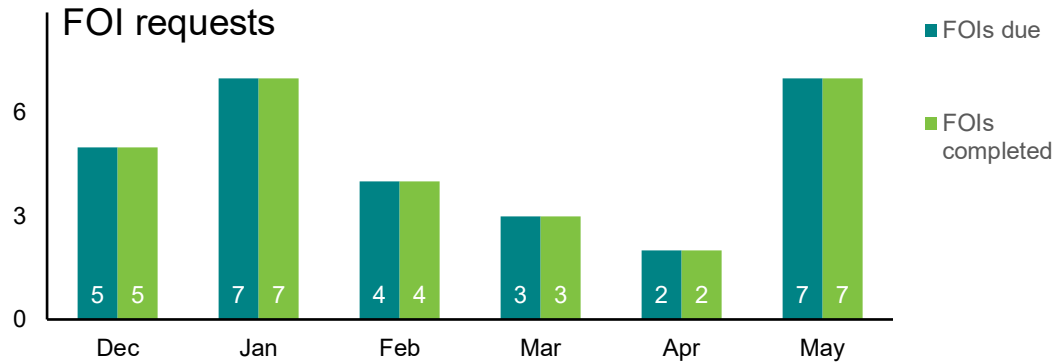


This PQ was about mitochondrial donation and adverse outcomes

Status: **Green**

### RI2 - FOI responses

**Target:**  
100% within statutory deadlines

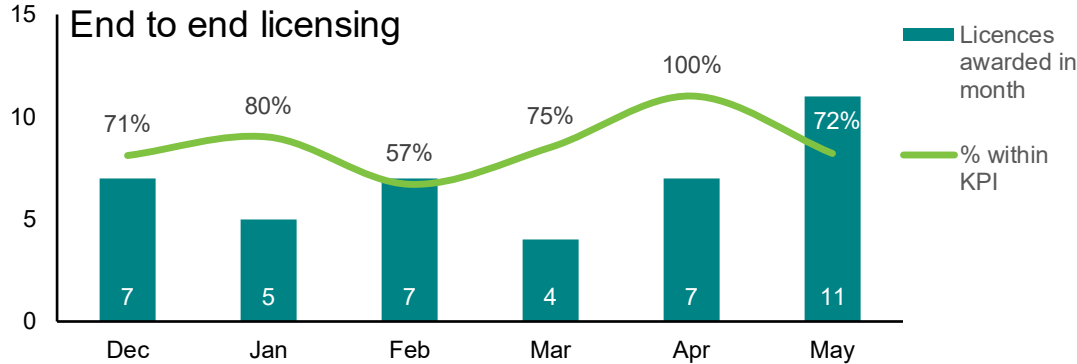


The FOIs due in May were on CCG data, Treatment in older patients, IT software, mitochondrial donation, and two about HR and finance. We have received 1 SAR which is due in June and is currently being processed.

Status: **Red**

### C4 – End to end licensing process

**Target:**  
100% completed within 70 working days

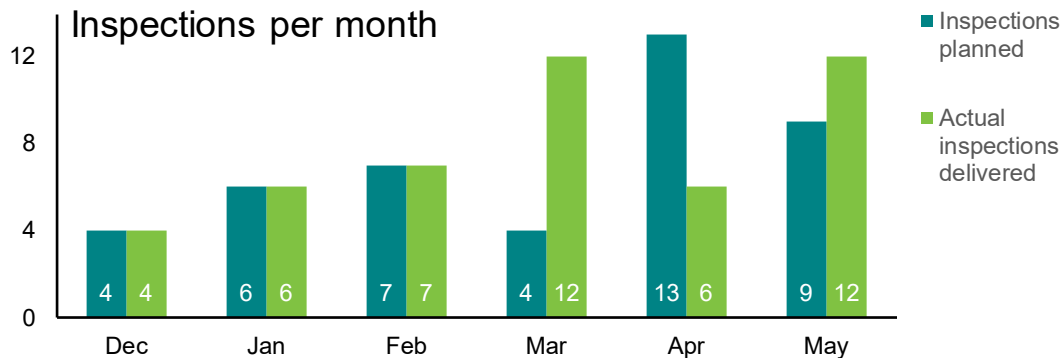


Three clinics over KPI, two at 75 working days and one at 84 working days.

Status: **N/A**

### C1 – Inspections delivery

**Target:**  
tbc

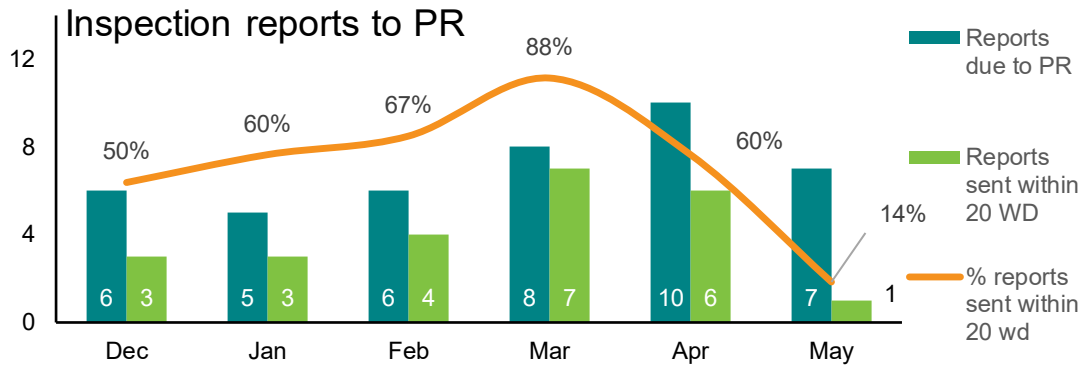


Inspections were rolled across from April and one from June.

Status: **Red**

### C2 – Inspection reports sent to PR

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

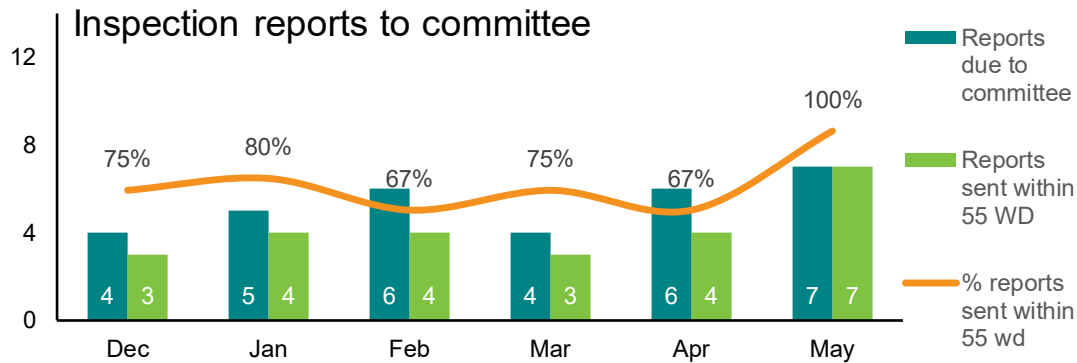


Sickness absence and staff turnover has impacted significantly this month

Status: **Green**

### C3 – Inspection reports sent to relevant licensing committee

**Target:**  
100% sent within 55

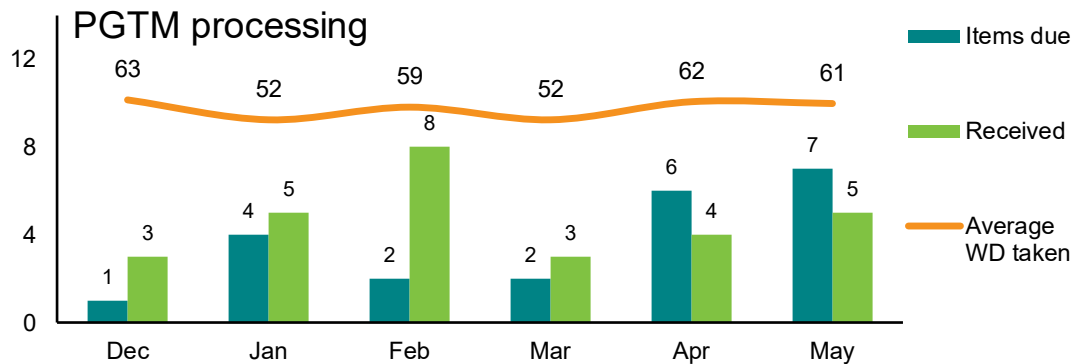


All reports have been sent within KPI.

Status: **Green**

### C6 – PGTM processing efficiency

**Target:**  
100% within 75 working days

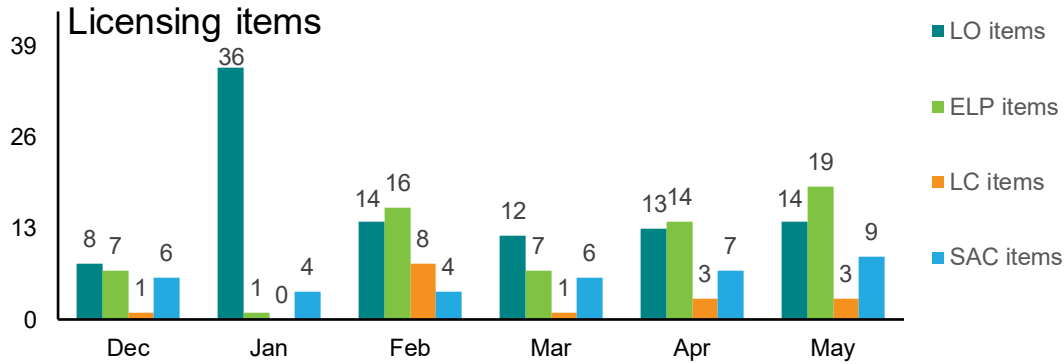


All PGTMs have been processed within KPI.

L1 - LO : Green  
 L2 - ELP : Green  
 L3 - LC : Green  
 L4 SAC : Green

**Licensing efficiency**

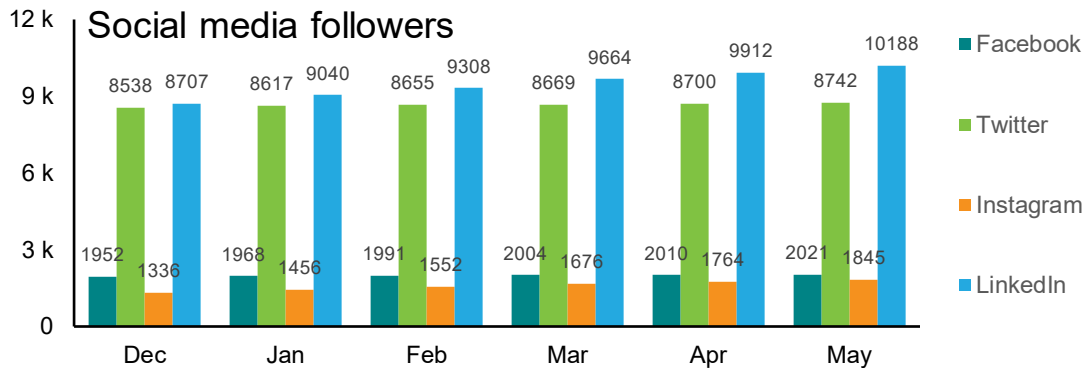
Targets (WD):  
 LO - 5, ELP - 10  
 LC - 15, SAC - 20



This represents excellent performance given the high volumes of regular and additional work during this period.

Status: N/A

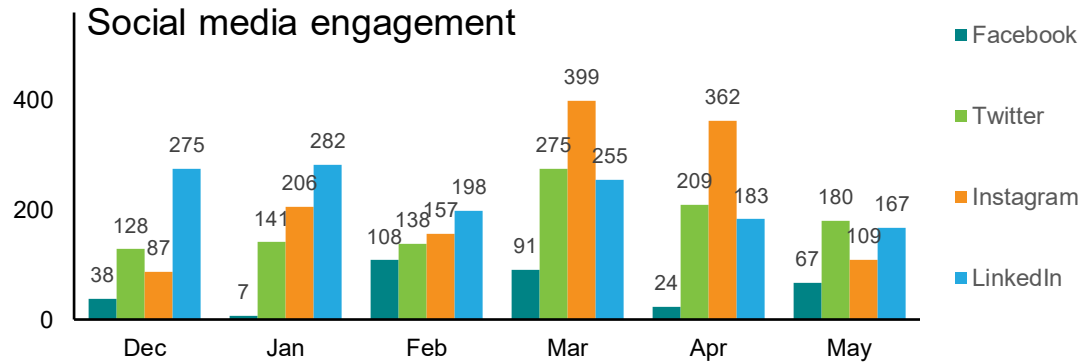
**Total number of followers across social media**



Followers have increased across channels steadily. LinkedIn seen the largest increase.

Status: N/A

**Engagement across social media (measurement systems vary)**

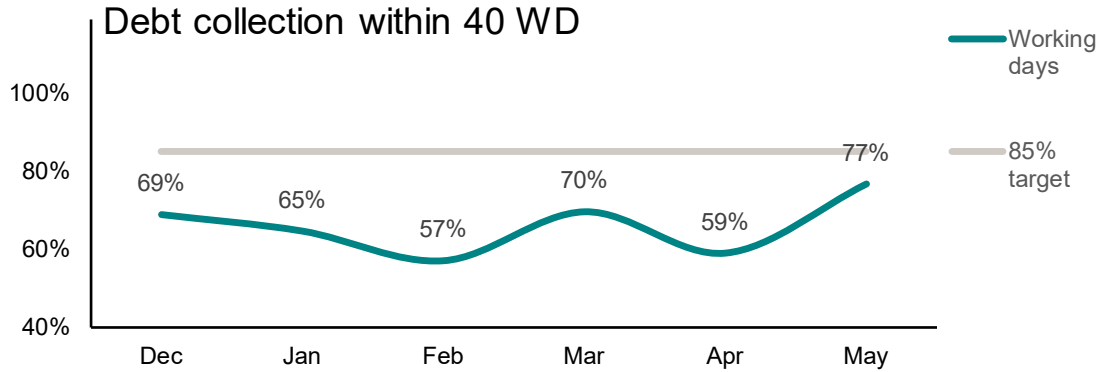


In May, we published content on choosing a clinic - this continues to be the top reason people visit our website.

Status: **Amber**

### F1 – Debt collection

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

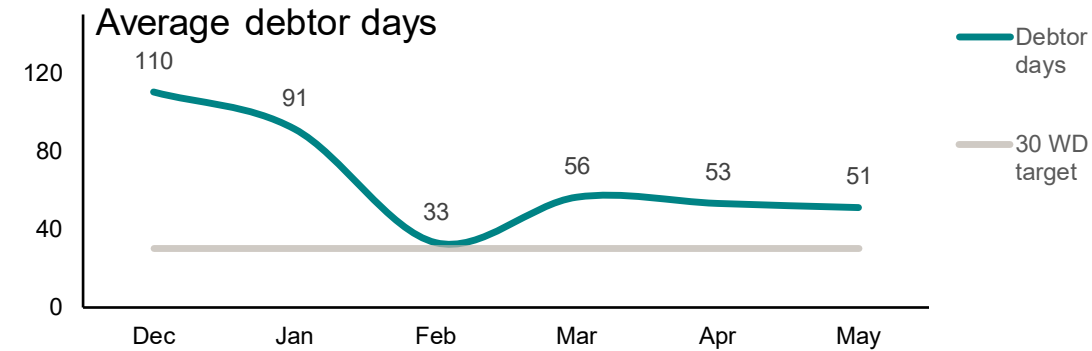


Although 77% of invoices have been paid within 40 days 88% of the value has been paid. This is a result of targeting the higher value invoices when chasing debt.

Status: **Red**

### F2 – Debtor days

**Target:**  
30 working days or less

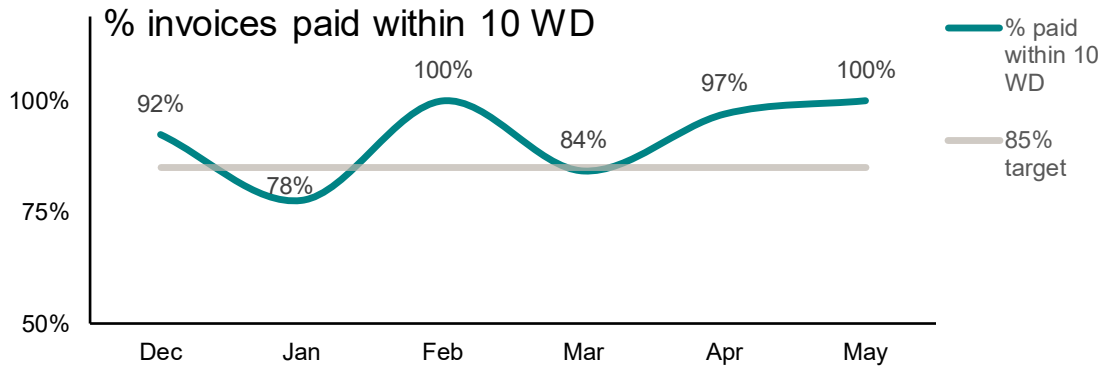


Debt collection has been the focus throughout May and this will continue in June to bring the outstanding debt figure down. Over 50% of the Debtors balance relates to prior year(s) and will remain the top priority.

Status: **Green**

### F3 – Prompt payment

**Target:**  
85% or more invoices paid within 10 days



No issues to report.

# Strategy development

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## Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Authority
Agenda item:	7
Meeting date:	12 July 2023
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

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## Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is invited to comment on and approve the proposals set out in this report.
Resource implications:	In budget
Implementation date:	April 2024 or earlier.
Communication(s):	The strategy is published on our website
Organisational risk:	Low



## 1. Introduction




- 1.1. At the May 2023 meeting, the Authority discussed options for the future development of a new strategy, given that there are currently a number of unknowns which would make detailed drafting difficult at the present time.
- 1.2. Members agreed the following:
  - That the [current strategy](#) should be extended by one year and that the development of the new strategy should follow in 2024.
  - That we should develop and communicate a clear picture of the further work on the current strategy that will be done in the business year April 2024-March 2025.
- 1.3. This paper outlines the activities we could include in this one year extension period, based on the vision and aims set out in our current strategy, together with our earlier prioritisation discussions on the current business plan.
- 1.4. The Corporate Management Group will begin the annual process for developing the 2024/25 business plan in August this year. Today’s comments from members will inform that preliminary discussion. The Authority will then receive a paper in the Autumn setting out the proposed content of the business plan for 2024/25.

## 2. Current strategy

- 2.1. Our current strategy focuses on the three main areas of the best care, the right information, and shaping the future.
- 2.2. It is summarised in brief below:

Our vision is...

**Regulating for excellence: shaping the future of fertility care and treatment**

<b>The best care</b> 	<b>The right information</b> 	<b>Shaping the future</b> 
Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.	Accurate and useful information that is provided at the right time.	Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.
A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.	Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.	Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.

Improved recognition by clinics of partners' importance in the care process.	Access to relevant and impartial information for all – particularly about the evidence base, additions and treatment options.	Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.
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**2.3.** Some strategic work has been delivered in each business year, and more will be delivered through the current year's business plan. It is proposed that we also include the following activities in our business plan for 2024/25, to reflect the main themes in our strategy that will still be ongoing:

Strategic objective	Proposed work for 2024/25
The best care: Treatment that is effective, ethical and scientifically robust	Monitoring and responding to changes in fertility trends. Developing position on use of HFEA information and data given the rise of online providers. Potentially leading to a future website update.
The right information: Improved access to information at the earliest (pre-treatment) stage	Working with Royal Colleges and others on the Government's women's health strategy, particularly with regard to primary health care information. Regulatory transparency (following work which will begin towards the end of this business year).
Shaping the future: Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI)	Taking stock of the advancing scientific landscape, monitoring developments in genetics and AI through our Scientific and Clinical Advances Advisory Committee. Consider HFEA responses to new scientific developments.
Shaping the future: Preparing for future legislative and operational changes	Monitoring of new Opening the Register service, following this year's major projects, in particular ongoing monitoring to estimate future needs and implementation of new support service arrangements following Authority consideration later this year. Modernising the Act – continuing pressing of the need for reform and identifying any areas that could be addressed in advance of reform. Completing the delivery of recommendations made in the HFEA's Public Body Review report (due in 2023).

## 3. Recommendation

**3.1.** The Authority is invited to comment on and approve the above approach, for further development by the Corporate Management Group during the business planning process for 2024/25.



Human  
Fertilisation &  
Embryology  
Authority

# Opening the Register – update

Rachel Cutting and Clare Ettinghausen

12 July 2023

[www.hfea.gov.uk](http://www.hfea.gov.uk)



# HFEA activity during 2023

## Three workstreams

### **OTR service**

Ensuring our staffing levels and team structure are appropriate for the demand and systems are effective in processing applications

### **Future of support service**

To report back to the Authority on next steps for a multi-layered support service

### **Communications**

To ensure patients, clinic and public communications are timely, informative and relevant throughout 2023

# OTR service

## Workstream update

- Good progress on the integration of the new IT system for managing applications (testing phase nearly complete, training planned in July for a planned switch over by the end of August)
- Continued work on updating policies and legal advice to inform processes, incorporated Authority decision on contacting donors into operational protocol
- Register tools under development to aid extraction of data (due for completion August)

# Future of support service

## Workstream update

- Detailed literature review complete
- Two substantial expert roundtable discussions on the future of support services. Useful intelligence gathered, key message was that there are different ways to provide good support and there is a strong need for signposting to credible high quality information.
- Questionnaire developed to gather views from people affected by donation issues on the future of support services (including kinds of support, access, funding, and costs). Due to launch mid to end of July.

# Communications

## Workstream update

- Continuing planning for targeted public facing communications activity from September
- Revamp of HFEA webpages relating to donation
- Continued stakeholder engagement to agree sharing of information and collaboration where relevant.
- Clinic communications planned via Clinic Focus
- Social media assets developed including video content and press opportunities continue to be found.

# Risks

- Unrealistic expectations of DCI, donors and clinic staff to what the HFEA can do
- Clinics not signposting donors or donor conceived individuals to the HFEA and OTR service
- Not all DCI will have the relationship they may wish for with their donor
- Reputational risk is high both for those elements we are responsible for, and those we aren't
- HFEA resources may not meet demand of applications (prediction of number of applicants very difficult)
- Unlawful practices undertaken if clinics and HFEA do not fully understand the law
- Donors and DCI not having access to information and support
- Limits of what information we can provide



# Next Steps

- Through the work streams mitigate the risks where possible
- Provide internal updates at the Project Assurance Group to ensure progress is timely
- Present options for a support service for an Authority decision later in 2023 to commission new service later in 2024
- Provide updates and engagement as needed to Authority and external stakeholders