Authority meeting

Date: 15 November 2023 –12.45pm to 4.40pm

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

Agenda item	Time
1. Welcome, apologies and declarations of interest (5)	12.45pm
2. Minutes of the meetings held on 13 September 2023 and matters arising (5) For decision	12.50pm
3. Chair and Chief Executive's report (15) For information	12.55pm
4. Committee Chairs' reports (20) For information	1.10pm
5. Performance Report (30) For information	1.30pm
6. 2024/25 Budget Proposal (20)	2:00pm
7. Strategic Risk Register (25) For information	2.20pm
8. Opening the Register (15) For information	2.45pm
Break	
9. Public Bodies review – recommendations and HFEA response (20) For information, please note that this agenda item is dependent on the final report being published by the time of the Authority meeting	3.00pm
10. Support Services update (45) For information	3.20pm
11. Treatment add-ons – final report back on publications of new ratings systems (30) For information	4.05pm
12. Any Other Business (5)	4.35pm
13. Close	4.40pm

Minutes of Authority meeting held on 13 September 2023

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	15 November 2023		
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 13 September 2023 as a true record of the meeting.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Minutes of the Authority meeting on 13 September 2023

Members present	Julia Chain Alison McTavish Graham James Frances Flinter Jonathan Herring	Gudrun Moore Alex Kafetz Geeta Nargund Catharine Seddon Christine Watson Jason Kasraie
Apologies	Zeynep Gurtin Alison Marsden	Tim Child Rachel Cutting
Observer	Steve Pugh (Department of Health and Social Care – DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Tom Skrinar Shabbir Qureshi Alison Margrave	

Members

There were 11 members at the meeting – 7 lay and 4 professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, HFEA staff and DHSC colleagues present.

1.2. The Chair also welcomed observers online and stated that the meeting was being 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 to hear it.

1.3. Declarations of interest were made by:

- Frances Flinter (Trustee at Progress Educational Trust)
- Alison McTavish (Trustee at Progress Educational Trust and British Fertility Society)
- Geeta Nargund (Clinician at a licensed clinic) and
- Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting and matters arising

2.1. Members agreed that the minutes of the meetings held on 12 and 17 July 2023 were a true record and could be signed by the Chair.

Matters arising

2.2. Members were advised that matters arising were either being actioned or were on the agenda as a separate item.

3. Chair and Chief Executive's report

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

3.2. The Chair informed the Authority of her introductory meeting with the HFEA's new sponsor from the Department of Health and Social Care (DHSC). During this meeting it has been agreed to hold monthly meetings with the sponsor to further enhance the working relationship with DHSC.

3.3. The Chief Executive provided an update on the key external activities and informed the Authority that the Annual Report and Accounts was laid in July just before recess. He expressed his thanks to members of the Audit and Governance Committee and the Head of Finance for their work in this regard.

3.4. He informed the Authority that HFEA's proposed pay settlement for all staff below Director level had been agreed by DHSC and would now be implemented. The settlement was in line with government guidelines. The Remuneration Committee will be meeting later this month to discuss the pay settlement for the senior management team.

3.5. Discussions are continuing with regard to the public body review, but this should be concluded in the Autumn.

Decision

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

4. Committee Chairs' reports

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

4.2. In the absence of the Licence Committee Chair (Alison Marsden), the Deputy Chair of the committee (Graham James) gave an overview of recent meetings and said there were several cases of notable compliance improvements. The committee had experienced higher than normal workload recently and he thanked the Chair and all committee members for their efforts in managing this workload.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) provided further insight to the work of the committee and stated that the rotation system of Authority members is working well. A special direction for export had been refused as the receiving clinic had not provided any evidence on their quality management system; this in turn had led to the committee discussing what documentation was required to satisfy assurance of a quality management system.

4.4. In the absence of the Scientific and Clinical Advances Advisory Committee Chair (Tim Child), the Deputy Chair (Jason Kasraie) gave an update on the work of the committee. He spoke about the presentation given by the team at Newcastle Fertility Centre at Life on the mitochondrial donation programme and provided further information about the committees' discussions regarding the new ratings for treatment add-ons.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed the Authority that the committee will meet in early October. The two external members had retired from the committee as their maximum term of service had been reached and a new external member had been appointed. She provided further information about the new member's experience and background. The committee will undertake an effectiveness review and skills audit later in the year and this will help to determine whether a second external member will be recruited.

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

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and stated that of the 17 KPIs, four are red, three amber, seven green and three neutral. The staff sickness rate continues to be red, and this can be attributed to four employees on long-term sick; all are distinct cases and are not related to stress or workload. Staff turnover has been declining from a historic high but is rising once more, which can be attributed to public pay not keeping pace with cost of living and limited promotion opportunities in a small organisation like the HFEA.

5.2. Noting that the Director of Compliance and Information had sent apologies as she was speaking at a conference, in response to a question, he stated that whilst inspection KPIs are not currently on target all licences have been issued on time. He expected these KPIs to improve once the new inspectors are fully trained and can undertake inspections independently.

5.3. On PRISM, activity levels were now stable with an error rate of just 3.3%. On Choose a Fertility Clinic (CaFC), the team are continuing to encourage clinics to address errors and it was felt that the previously agreed timescales are achievable. It was noted that all but three clinics are using the new system.

5.4. Members were informed that the opening the register (OTR) team had been diverted from their workstreams to test the new IT system. With testing now complete it is anticipated that the team will be able to manage and move through the backlog of work. Members noted that a fuller report will be brought to the next meeting and asked that this include anticipated levels of productivity. Members spoke about the importance of holding, managing, and integrating data and the level of additional information and reports this system will be able to provide.

5.5. The Chief Executive referred to the two data breaches that had recently come to light in other public bodies which had been reported in the media. He informed members that the HFEA's Head of IT had reviewed both to consider any issues relevant to the HFEA. A future Clinic Focus article will provide any relevant updates to the sector.

Strategy and Corporate Affairs

5.6. The Director of Strategy and Corporate Affairs informed members that the State of the Sector Report was released yesterday and provided further insight to this. Work continues on the Ethnic Disparities in Fertility Treatment report, and this is on track to be published later on in the year.

5.7. Further insight into the data dash boards was provided and information about the testing with various groups which had taken place; feedback received was positive. A member spoke about the importance of this tool for the HFEA.

5.8. Information was provided about the planned communication work regarding OTR and the treatment add ons.

5.9. Members were informed that the Code of Practice update, which had been agreed previously by the Authority is on track to be published by the end of the calendar year.

Finance

5.10. The Director of Finance and Resources referred to the report and stated that the HFEA is currently operating with a small deficit which can be attributed to increases in IT costs and the non-consolidated bonus for staff which was agreed by the Government but needed to be met out of the HFEA's current budget; income is as expected at this point in the year.

Decision

5.11. Members noted the performance report.

6. Opening the Register - update

6.1. The Director of Strategy and Corporate Affairs presented the update on Opening the Register (OTR) noting that an update on the workstream was also provided under the Performance Report.

6.2. It was reported that the new IT system for managing applications had gone live at the beginning of August, which was earlier than scheduled.

6.3. The post donation support questionnaire closed yesterday, with a positive number of responses received with a good representation across those impacted by donation. An overview of the work to date on the future of support services workstream would be brough to the November Authority meeting.

6.4. Further information was provided about the planned communication workstream, noting that several targeted public-facing communications will begin shortly. A member commented that the presentation given by the Director of Compliance and Information to clinics was very well received and consideration should be given to include further details of this in a Clinic Focus.

6.5. The ongoing risks associated with OTR were also noted.

6.6. In response to a question the Chief Executive stated that the backlog of enquiries was composed of several different types of information requests and it may be necessary to prioritise these to manage expectations and reduce the backlog.

6.7. The Chair thanked the various teams working on the three OTR related workstreams for their work. It was noted that further information would brought to the next meeting which may provide insight into the efficiencies gained from the new IT system on processing applications.

Decision

6.8. Members noted the update on OTR.

7. Law Reform Proposals

7.1. The Chair introduced this agenda item, reminding the members of their previous discussions and decisions taken in July on this important work and that the report presented to them today focuses on the three outstanding proposals on consent, access to donor information and scientific developments.

7.2. The Director of Strategy and Corporate Affairs introduced the report and informed members that nearly 7,000 responses were received for the public consultation and the team had reviewed and

considered each of these and all points contained within. She expressed her thanks to those individuals and organisations who had participated in helping to shape this work.

7.3. The risks which were outlined in the May 2022 Authority meeting remain current and whilst the majority of the proposals received widespread support, some of the proposals will go too far for some and not far enough for others. The Authority will therefore need to be content with a level of criticism from those that would like a different proposal or outcome.

Consent

7.4. The Chief Executive spoke to the issue of consent and reminded the members of the decisions they had taken in July and the further work which they had requested be brought to this meeting.

7.5. He stressed that the issue of consent referred to throughout is that which is required by the HFEA Act and that any consent taken by either NHS or private clinics relating to medical consent to treatment are entirely separate and not within the scope of this work.

7.6. The general concern is that the current system is complex and needs to be simplified, yet the opt-out proposal did not generate widespread consensus during the consultation process. The range of consents required for some people is simpler than others so a possible model where those people could chose a simplified model of consent might be possible.

7.7. The current system of consent also does not appropriately reflect the range of modern family formulations and any revised consent regime should focus on the intention to be the legal parent.

7.8. The Chief Executive reiterated the principles of consent outlined in the paper to frame any new system..

7.9. Members spoke about the distinction between an ‘opt out’ option and ‘deemed’ consent and whether it was possible to offer a ‘package’ of possible consent models for future discussion with relevant stakeholders. The Chief Executive responded that a framework of options to open and facilitate future discussion may be helpful.

7.10. Members suggested considering whether it was possible to future proof the issue of consent by including options for future scientific improvements.

7.11. Members suggested consideration in any new system of secure digital storage.

Decision

7.12. Members agreed the proposal that the HFEA recommend a thorough overhaul of the consent regime, and that this should be carried out together with interested parties among professional bodies, patient groups and licensed centres within the fertility sector.

7.13. Any revised consent regime, should uphold the following principles:

- Reflect current best practice and guidance, for example, the GMC principles of consent.
- The importance of free consent
- Dynamic consent
- Simplification
- Recognition of modern families
- The special status of the embryo

Access to donor information

7.14. The Director of Strategy and Corporate Affairs spoke to the issue of access to donor information and reminded members of the decisions they had taken in July and the further work which they had requested be brought to this meeting.

7.15. The Director of Strategy and Corporate Affairs spoke to the principles which would be upheld in any new system and outlined a number of items for further consideration as detailed in the paper.

7.16. Members discussed the issue of capacity and competency, and at what age limit it could or should be applied to a child. It was noted that a primary purpose of removing anonymity is for the benefit of the donor conceived child.

7.17. Members expressed a view that any proposals may have an impact on donor numbers, noting that some patients are seeking treatment abroad to ensure an anonymous donor or to provide greater ethnic choice.

7.18. In response to a question the Chief Executive confirmed that the 10-family limit policy is applied to any imported donations into the UK, but that the HFEA does not have any jurisdiction on donations used outside of the UK.

7.19. Members discussed the timing of removing anonymity noting that access to information is already available through DNA testing websites and other means and therefore a long timescale for this aspect of the work should not be considered.

Decision

7.20. Members agreed the proposal that the HFEA recommends the removal of donor anonymity from the birth of any child born from donation. Before any change to the law is implemented there would need to be in-depth discussions with interested parties among professional bodies, patient and donor groups, donors and donor conceived individuals and licensed centres within the fertility sector.

7.21. Any revised system for releasing donor information, should uphold the following principles:

- That there remains a need for an official ‘record of truth’ and the law should continue to require the HFEA to collect data about children born from a donor
- That consent should be properly obtained, and donors and recipients fully informed about the potential challenges to anonymity from DNA testing and matching services.
- That parents should not be legally required to disclose to their children that they are donor conceived. But patients should continue to be encouraged by clinics to be open with their children about how they were conceived.

7.22. Future consideration of the following consequences should be undertaken:

- Removal of anonymity should take place following legislative change with an implementation date to be agreed.
- Donor is known from time of birth if information is requested by parents but that a wholly ‘open’ system of donor selection is not recommended at this stage, whilst recognising that it does occur in other countries.

- Access to the donor sibling registry for non-donor conceived offspring of donors is considered as part of any further work on consequences of the changes above and views of all parties are explored.
- Continued respect of donor anonymity for pre-2005 donors and no retrospective early removal of anonymity for post-2005 donors.

Scientific developments

7.23. The Public Policy Manager spoke to the issue of scientific developments and reminded the members of the decisions they had taken in July and the further work which they had requested be brought to this meeting. She stated that the purpose is to future proof the Act and provide flexibility to accommodate future scientific developments, noting that this is a sensitive area for many.

7.24. Members discussed the speed of scientific changes, citing the recent developments led by the Weizmann Institute of Science on embryo models as an example of the pace and speed that this sector is experiencing. The Chief Executive drew an important distinction in relation to the model produced by the Institute, explaining that there is no evidence that it would grow into a foetus, and that it would be illegal to transplant the model into a womb.

7.25. Members discussed developments taking place across the world where countries do not have the same rigor and regulations as the UK and indeed a regulatory body such as the HFEA.

7.26. Members discussed issues relating to safety, innovation, and social concerns, noting that safety was not an absolute and that when thinking about medical innovation the key principle was whether the evidence suggested that something was unsafe, given the potential benefits.

Decision

7.27. Members agreed the proposal that the HFEA recommend that the Act should be amended to future proof it, so that it is better able to accommodate future scientific developments/new technologies. Ongoing policy work should take place with relevant interested parties among professional bodies, scientific researchers, patient groups and licensed centres within the fertility sector to agree a set of regulatory changes to address the challenge posed by novel scientific developments.

7.28. Any revised regime, should uphold the following principles:

- The need for public engagement and discussion coupled with appropriate consideration of any ethical and social concerns.
- The ability to set bespoke regulatory rules should be retained.
- Continuous monitoring.
- Ongoing scrutiny.
- Balance of different interests.

Next Steps

7.29. The Executive would next implement the Authority's decisions and prepare the submission for the DHSC and for wider publication. .

8. Business Planning and Strategy 2024-25

8.1. The Risk and Business Planning Manager introduced the report and provided members with an overview of the planning cycle and key dates within this cycle. He referred to the strategic priorities contained within the report and asked whether there was any further steer from Members.

8.2. The Chair commented that HFEA is a small organisation with a huge workload and stretched resources so when considering the list of priorities, it was important not only to agree what should be done but also what could not be done. She referenced the time and resource which was consumed by the Public Body Review process as one recent example.

8.3. Members questioned proposed work around increasing the focus on genetics and Artificial Intelligence (AI) and whether this should be increased from a watching brief and whether there was any link to the work of other organisations such as the Nuffield Council on Bioethics. The Chair responded that the HFEA collaborates with several organisations and these relationships will continue The Director of Strategy and Corporate Affairs confirmed that the proposed workstream on AI would be expanded from its current status of a watching brief.

8.4. Members discussed several potential priorities including Epicentre replacement, aspects of the Women's Health Strategy, Law Reform and the Fees Review.

8.5. Members discussed the resources required to undertake a review of fees and questioned whether additional resources, such as an analyst, could be obtained from DHSC. The Executive were asked to raise this item for discussion during the quarterly accountability meeting with DHSC.

8.6. Members encouraged the HFEA to continue its work on ethnic disparities and that this should continue to be a strategic priority for the Authority.

Decision

8.7. Members noted the report and that further development of the business plan for 2024/25 would now commence.

9. Any other business

9.1. There being no items of any other business the Chair reminded members that the next meeting will be held on 15 November 2023, in person, at the HFEA's offices at 2 Redman Place.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 15 November 2023

Authority meeting

Matters Arising

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	2		
Meeting date	15 November 2023		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For discussion		
Recommendation	To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.		
Resource implications	To be updated and reviewed at each Authority meeting		
Implementation date	2023/24 business year		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High

Action	Date added	Assigned to	Target date	Revised date	Progress to date
2.44 Engage with the DHSC and agree a plan with them in respect of how best to deal with areas of law reform where there are unresolved questions and where further work would be necessary in the future.	17 July 2023	Director of Strategy and Corporate Affairs	Dec 2023		Proposals have been submitted to the minister. Further updates to be given to Authority and in discussions over future strategic plans. This action is now completed and can be removed from the action log
2.45 A report on the consultation on law reform will also be published, setting out the overall quantitative and qualitative responses. The final HFEA proposals will be published with full communications support, in due course	17 July 2023	Director of Strategy and Corporate Affairs	Dec 2023		Published November 2023. This action is now completed and can be removed from the action log
7.30 The Executive to implement the Authority's decisions regarding the proposed law reform and prepare the submission for DHSC.	13 Sept 2023	Director of Strategy and Corporate Affairs	Dec 2023		Published November 2023. This action is now completed and can be removed from the action log
8.5 The Executive to raise the issue of obtaining additional resources, such as an analyst, from DHSC during the accountability meeting.	13 Sept 2023	Chief Executive	Oct 2023		Raised with the DHSC. For detailed discussion later. This action is now completed and can be removed from the action log.

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	15 November 2023
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

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

1. Introduction

- The paper sets out the range of meetings and activities undertaken since the last Authority meetings in September 2023.
- Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

2.1 Chair activities

- The Chair has continued to engage with the decision-making functions of the Authority and with key external stakeholders:

    - 18 September – chaired the Renumeration Committee
    - 26 September – attended the ALB Chairs and Chief Executives meeting at the DHSC
    - 2 October – attended the SCAAC meeting.
    - 6 September – introductory meeting with Amanda Davies, Deputy Director – Health Ethics, NHS Quality, Safety, Investigations at DHSC
    - 18 October – attended the Health Services Safety Investigations Body (HSSIB) Launch
    - 1 November – meeting with Chair of Nuffield Council on Bioethics
    - 3 November – meeting with Fertilis
    - 8 November – attended APPG on Surrogacy and Law Reform

2.2 Chief Executive

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

    - 18 September – attended the Renumeration Committee
    - 26 September – attended the ALB Chairs and Chief Executives meeting at the DHSC
    - 2 October – attended the SCAAC meeting
    - 3 October – attended the AGC meeting
    - 9 – 10 October – attended the Human embryos in medical research conference in Berlin
    - 12 October – participated in CSaP Policy Workshop on the Governance of Stem Cell-Based Embryo Models in the UK in Cambridge
    - 18 October – attended the Health Services Safety Investigations Body (HSSIB) Launch
    - 26 October – attended a roundtable discussion with other ALB CEOs on Places for Growth chaired by Baroness Neville Rolfe at the Cabinet Office
    - 1 November – meeting with Chair of Nuffield Council on Bioethics
    - 3 November – meeting with Fertilis

    8 November – attended APPG on Surrogacy and Law Reform

    - 9 November – attended the REAL Challenge annual lecture: What will the NHS look like at 100? – by Professor Dame Diane Coyle

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Item number:	4
Meeting date:	15 November 2023
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:		
31 August	2 Executive updates	1 granted, 1 adjourned
2 November	1 Renewal inspection, previously adjourned 1 Interim inspection	Minutes not yet approved.
Other comments:	The Committee plans to conduct its annual review of effectiveness at the January meeting.	
Executive Licensing Panel:		
5 September	3 Interims 1 Change of PR 1 Variation of activities 1 Variation of premises	All approved
19 September	2 Interims 1 Pre-implantation tissue typing (PTT)	All approved
4 October	2 Renewals 2 Interims	All approved
17 October	1 Initial 1 Renewal 1 Interim 1 Change of PR	All approved
7 November	2 Interims 1 Change of PR 3 Changes of LH	Minutes not yet approved.
Other comments:	The Committee is in the process of conducting its annual review of effectiveness.	
Licensing Officer decisions:		
August - October	26 ITE import certificates 2 Changes of Centre Name 1 Change of LH 1 Voluntary Revocation	All granted

Meetings held	Items considered	Outcomes
Other comments:	None.	

Statutory Approvals Committee:

29 August	5 PGT-M 1 Special Direction for export	4 PGT-Ms approved. 1 PGT-M and 1 SD adjourned
25 September	5 PGT-M	All approved
31 October	2 PGT-M	Minutes not yet approved
Other comments:	The committee will conduct its annual review of effectiveness at either the December or January meeting, depending on the size of agendas.	

Audit and Governance Committee:

3 October	The main items considered were: Internal audit Progress with current audit recommendations External audit report Risk update: Strategic risk register, risk appetite statement and discussion on potential horizon scanning items Deep dive discussion on legal risks Digital projects / PRISM update Resilience, business continuity management and cyber security Counter-fraud strategy Fraud risk assessment Reserves policy Government functional standards	
Other comments:	The Committee will conduct its annual review of effectiveness at the December meeting.	

Scientific and Clinical Advances Advisory Committee:

24 October	Health outcomes in children born from ART (including culture media) *In vitro* derived gametes	To continue to keep abreast of ongoing research and advances in the areas of health outcomes in children born from ART (including culture media) and *in vitro* derived gametes.
	Review rating for artificial oocyte activation add-on	A rating was not allocated. Artificial egg activation using calcium ionophore is to be

Meetings held	Items considered	Outcomes
		removed from our rated list of treatment add-ons as it should only be offered in specific circumstances. This is in line with artificial egg activation using calcium ionophore being an HFEA authorised process, and the professional guidelines on best practice use of artificial egg activation published by ARCS and BFS in August 2023.
	The impact of the microbiome on fertility treatment outcomes	Not discussed. To be discussed by email.
Other comments:	None.	

3. Recommendation

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

Human Fertilisation & Embryology Authority

Monthly performance report

Performance up to September 2023

Evgenia Savchyna
Corporate Performance Officer
15/11/2023

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	November Authority
Agenda item:	Item 5 (Authority)
Meeting date:	15/11/2023 (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):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

Human Fertilisation & Embryology Authority

Latest review and key trends

Latest review

- The attached report is for performance up to and including September 2023.
- There were seven Green, three Amber, four Red, and three Neutral indicators.

Key trends

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

July (4)	August (6)	September (4)
Inspection reports sent to PR within 20 working days	Inspection reports to committee within 55 working days	PTT items processed within 30 working days
Staff sickness rate	End to end licensing reports within 70 working days	Staff sickness rate
Debt collection	Staff sickness rate	Debt collection
Invoices paid within 10 working days	Turnover rate	Invoices paid within 10 working days
	Debt collection	
	Invoices paid within 10 working days	

Management summary

IT and register performance reporting

- PRISM: 509K units from 104 clinics. Error rate is 3.4%. 57 clinics have addressed the majority of their errors. However, there are 33 clinics with errors greater that 4%.
- 10 Family Limit: We have created a new suite of outcome reports, both to ensure that we can answer 10 family limit queries accurately and to address clinic requests for alerts regarding donors that are approaching limits.
- CaFC: We are aiming to complete the first steps for CaFC in December and communicate to the sector the work required.

Management commentary

- Performance has been variable across KPI indicators with seven Green, three Amber, four Red, and three Neutral indicators.
- Two Compliance KPIs are Amber, however, the ‘End to End licencing’ indicator is Green with all inspection items processed within 70 working days.
- One PTT item was over the 30-day KPI (by one day) however, PTT items are infrequent (this is the first one received in over a year and for that reason PTT are not usually reported).
- The number of OTRs received in September was the highest since 2021 (most likely in response to the #WhoIsMy Donor campaign). Low number of OTRs were sent out as resource was focussed on the testing and creation of SOPs for the new system.
- Significant increase in emailed enquiries, the highest for over a year.
- The number of FOIs continues to be high. There have been no PQs since July.
- The ‘State of the Sector’ and 'Who is my donor?' campaigns led to an increase in engagement across all social media channels, particularly on Instagram.
- Staff sickness remains high, with three employees on long-term sick leave. The turnover indicator is Amber now with one leaver in September. The headcount is currently 75 (out of an establishment of 76 posts).
- ‘Average debtor days’ and ‘% invoices paid within 10 working days’ KPIs are in Red, however, all invoices were paid within 20 working days.

Summary financial position

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2023/2024 £'000s	Budget for 2023/24 £'000s	Variance Budget vs Forecast £'000s
Income	3,821	3,675	146	7,120	7,260	(140)
Expenditure	3,596	3,587	(9)	7,211	7,260	49
Total Surplus/(Deficit)	**225**	**88**	**137**	**(91)**	**0**	**(91)**

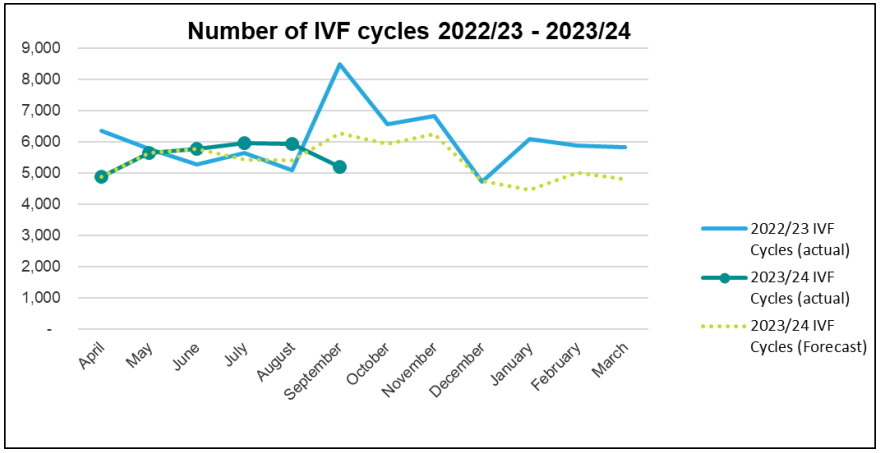
Commentary on financial performance to 30 September 2023

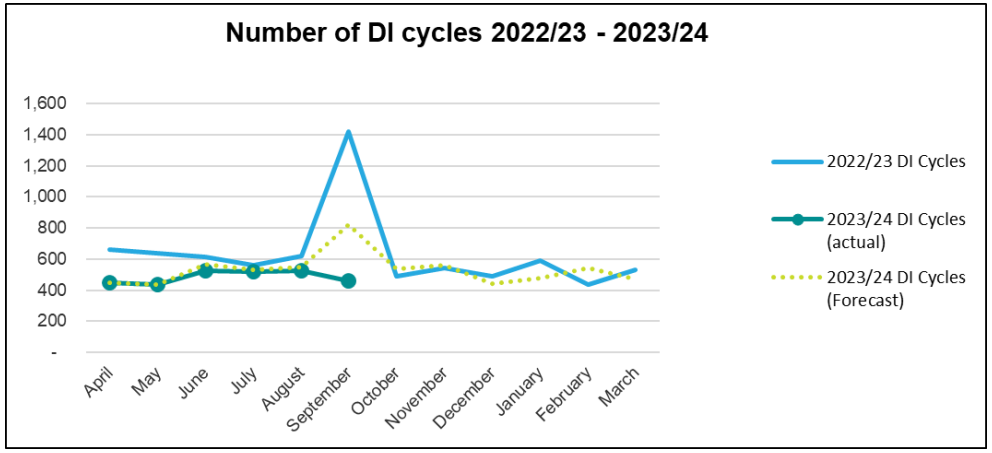
At the end of Q2 2023/24, we are showing a short-fall against budget of £137k which is a decrease of £51k reported at the end of month five (August).

Year-to-date our income is up against budget by £146k, which is mainly GIA. Our expenditure is more or less on budget. A more detailed financial position is within the main report. A further review at the end of Q3 will be undertaken, where some costs are currently being incurred at risk these will be reviewed in detail.

Our current forecast position is a small deficit against budget of £91k which is likely to change as the year progresses and we flex plans that may have a financial impact.

Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2022/23 IVF Cycles (actual)	36,587	3,109,895	72,493	6,161,905
2023/24 IVF Cycles (actual)	33,367	2,836,195	64,536	5,485,588
Variance	(3,220)	(273,700)	(7,957)	(676,317)

Year to August saw an increase in IVF volumes compared to the previous year. However, September's activity saw a small decline, which when compared to 2022/23 looks more significant, though it is important to note that the figures last year were artificially inflated by clinics pushing data through following the implementation of PRISM.

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2022/23 DI Cycles	4,519	169,463	7,589	284,588
2023/24 DI Cycles	2,908	109,050	5,940	222,750
Variance	(1,611)	(60,413)	(1,649)	(61,838)

DI volumes for the six months ended 30 September are down by 36% (1,611 cycles) compared to the same period in 2022/23. However, the comparative fall is larger due to the issue with PRISM in September 2022 as explained in respect of IVF data.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

HFEA Income & Expenditure Sep-23

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income						
Grant-in-aid	628	496	(132)	912	991	79
Non-cash (Ring-fenced RDEL)	116	116	-	232	232	-
Grant-in-aid - PCSPS contribution	50	50	-	100	100	-
Licence Fees	2,938	2,958	20	5,746	5,829	83
Interest received	63	18	(45)	70	35	(36)
Seconded and other income	26	37	11	60	73	13
Total Income	3,821	3,675	(146)	**7,120**	**7,260**	**140**
Revenue Costs						
Salaries (excluding Authority)	2,551	2,579	28	5,025	5,145	121
Staff Travel & Subsistence	39	29	(10)	108	100	(9)
Other Staff Costs	51	53	2	78	66	(12)
Authority & Other Committees costs	89	126	37	198	235	37
Facilities Costs incl non-cash	227	296	69	492	610	118
IT Costs	323	156	(169)	595	312	(285)
Legal / Professional Fees	207	214	8	467	521	54
Other Costs	85	109	24	197	222	25
Other Project Costs	24	25	2	51	51	-
Total Revenue Costs	**3,596**	**3,587**	**(9)**	**7,211**	**7,260**	**49**
TOTAL Surplus / (Deficit)	**225**	**88**	**137**	**(91)**	**0**	**(91)**

Income.
At the end of Q2 (September) our total income is 4% (£147k) above budget. This largely relates to our grant in aid (£132k over) and is a profiling issue. Our Treatment fee income is more or less on budget year to date; however, the volumes of IVF/DI are not increasing at a significant rate. Volumes were down for the month of September, compared to the same period in 2022/23 (IVF LY 8,490 vs CY 5,182) and DI (LY 1,421 vs CY 461).

Expenditure (by exception)
Year to date, expenditure is over budget by £8k.

Salaries - are under budget by £28k overall. The majority of this underspend comes from employer pension contributions (£69k) which are offset by overspends with Contingent Labour and Shared services (£26k). This overspend is expected to continue to the end of the financial year.

Staff Travel & Subsistence - are over budget by £10k (down 9k from August) which is largely Inspection costs which have increased in line with the number being undertaken and home to office travel. The profile of this budget is different from the actual spend, contributing to this variance.

Authority & Other Committees cost - are showing a surplus against budget of £37 which is due to a reversing accrual from last year that was higher than needed.
Facilities Costs - are under budget by £69k which relates to adjustments we have to make in accounting for the leave of our offices.

IT Costs - are over budget by £169k which was foreseen at the time the budget was set. There are areas that will need additional funding which have not been budgeted for and areas such as our O365 Licence costs which have increased significantly from last year c100% which will need to be funded from across the business. These are currently overspent by £53k. Our Consultancy and Support costs are also over budget (£109k). Careful monitoring of these costs will be maintained with a further review at Q3.

Legal/Professional fees - are under budget by £8k, with legal under-spent by £2k and the balance relating to internal and external audit fees totalling £6k. The audit fees are however expected to come within budget by year end.

Other Costs - are £24k under budget; communication costs in total are underspent by £17k where plans have changed, and funds will not be utilised. The balance is mainly discretionary training which is also underspent.

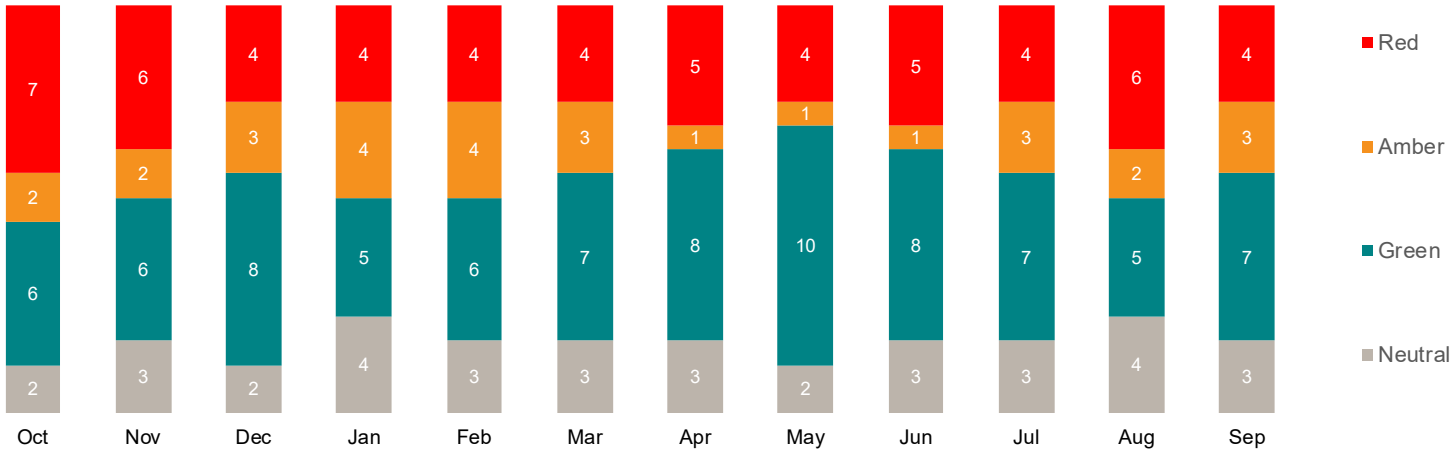
Forecast
The current forecast is an overspend of £91k for the year and against budget. This includes significant increases in our IT spend. There are unfunded project costs c£50k that require decisions to be made as to how and they are to be funded. These decisions will be taken during the re-forecast exercise at the end of Q3.

Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

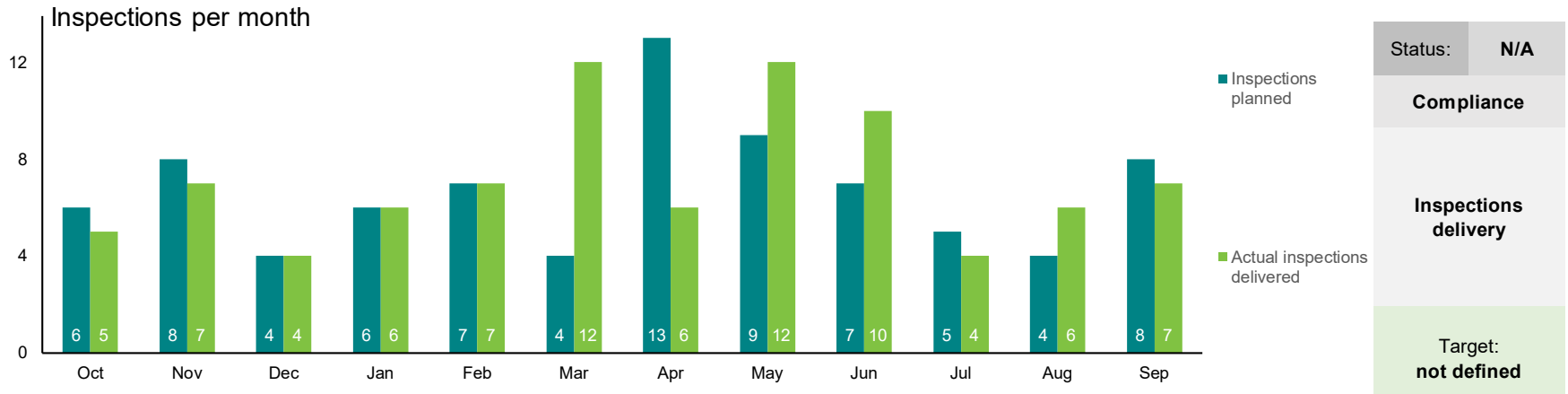
RAG status over last 12 months



RAG status over last 12 months

17 KPIs in total for each month

For September, the **4 Red indicators** are in these teams: **Compliance - 1; Finance - 2; HR - 1.**



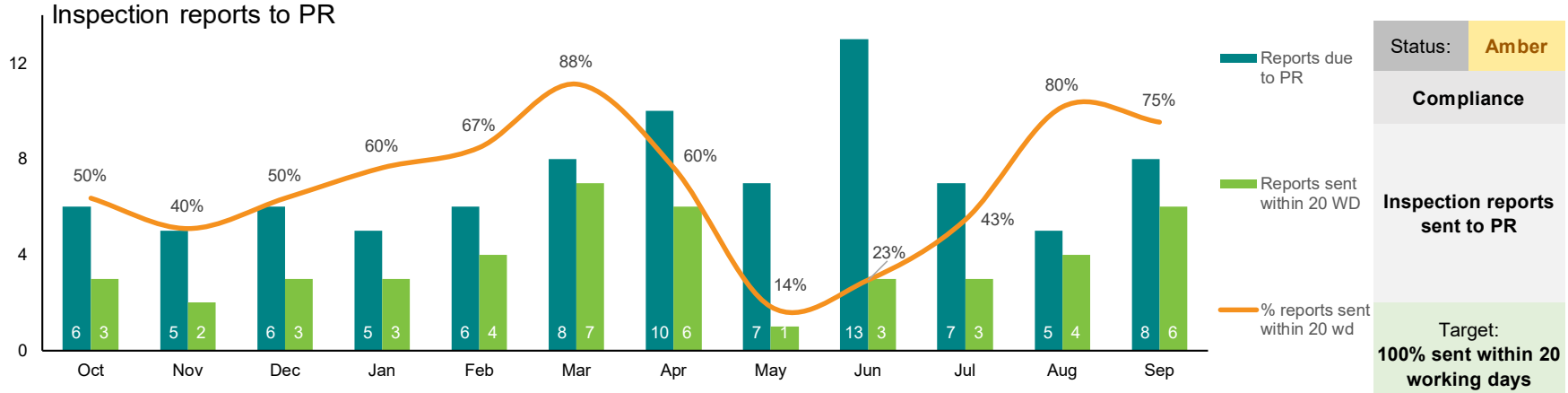
Status: **N/A**

Compliance

Inspections delivery

Target: **not defined**

One inspection was rolled over from September to December due to staff availability. Another inspection was completed in October due to clinic counsellor unavailabilty on the date of inspection in September (vitual meeting with counsellor to complete inspection). One initial inspection (new center licence) was added to the plan and delivered in September.



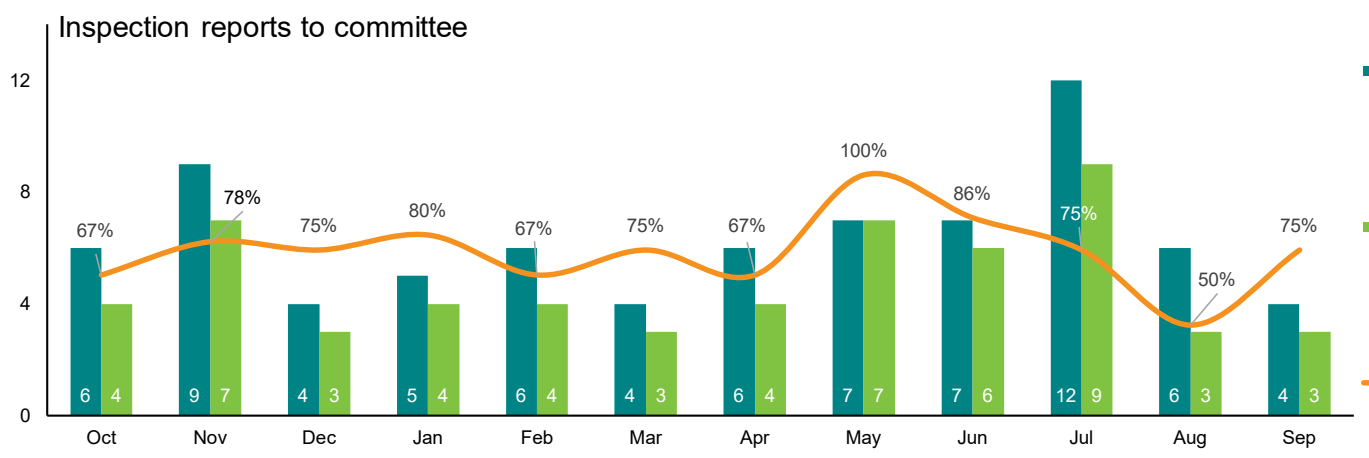
Status: **Amber**

Compliance

Inspection reports sent to PR

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

Two reports not sent to PR yet due to relocation of inspections and the impact of long-term staff absence combined with ongoing training of newly appointed inspectors.



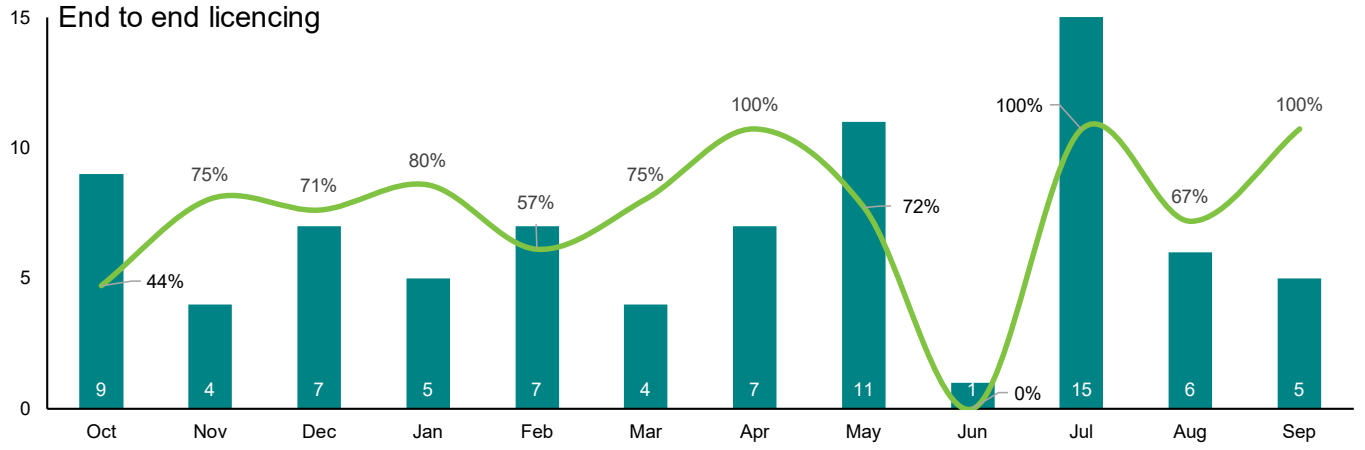
Status: **Amber**

Compliance

Inspection reports sent to relevant licensing committee

Target: **100% sent within 55 working days**

One report not sent to committee yet due to relocation of inspections and impact of long-term staff absence.



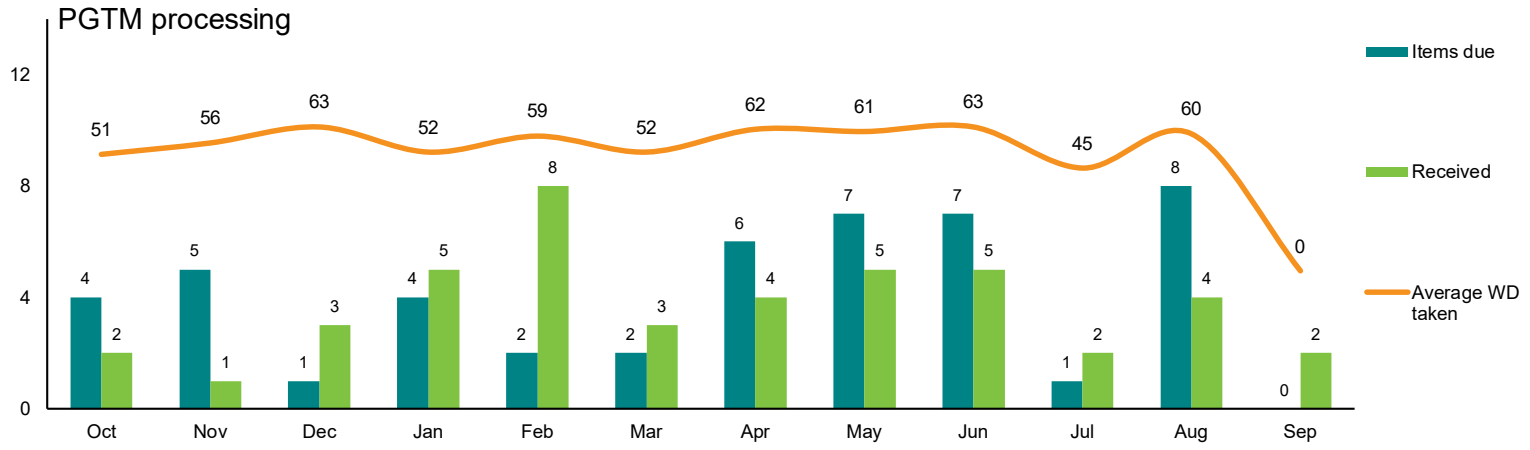
Status: **Green**

Compliance

End to end licensing process

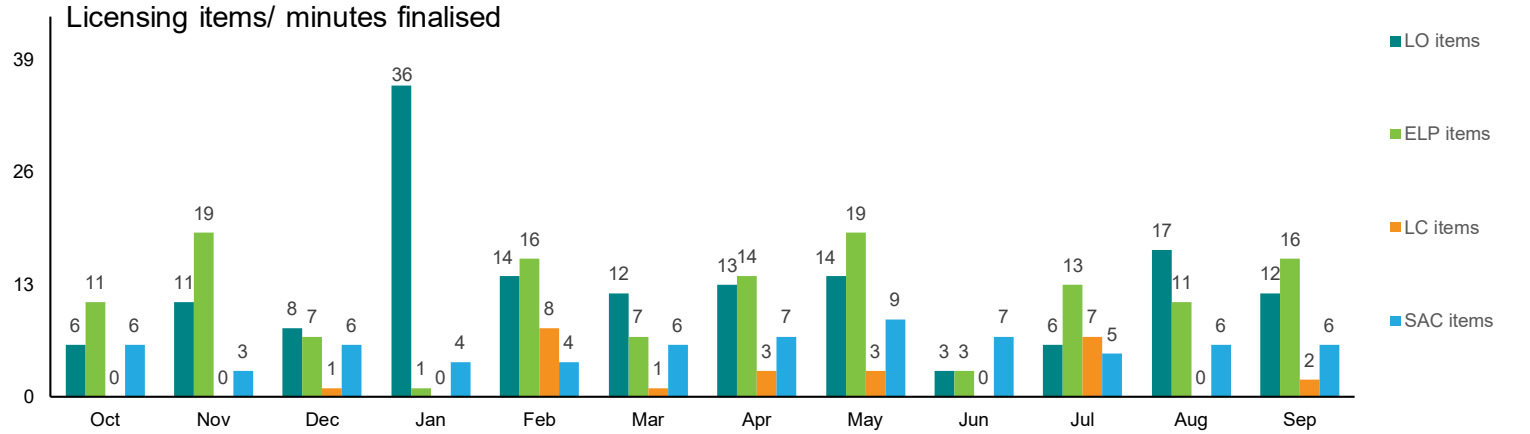
Target: **100% items completed within 70 working days**

All items processed within KPI.



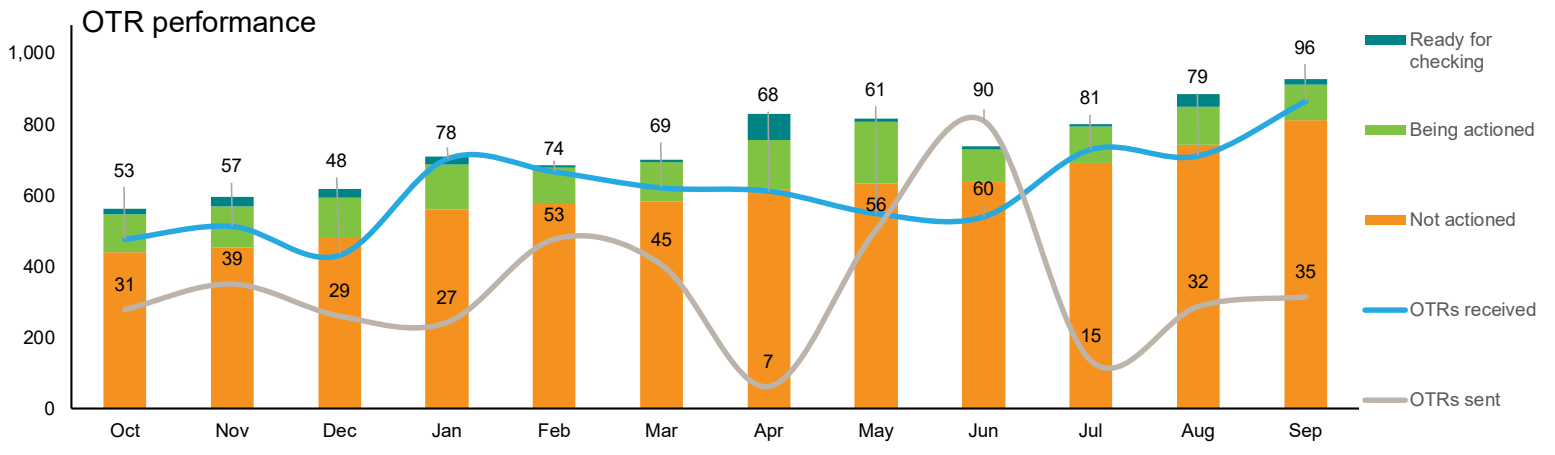
Status:	Neutral
Compliance	
PGTM processing efficiency	
Target: **100% within 75 working days**	

No PGTM items due for completion in September.



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

Targets have been met for all committees. There was a reduction in LO and LC applications, an increase in ELP applications and the same number of applications for SAC. There was also an increase in the number of ITE Import certificates that needed to be updated and re-issued due to a variation of licence for each change of PR. Overall, good performance from the Licensing Team.



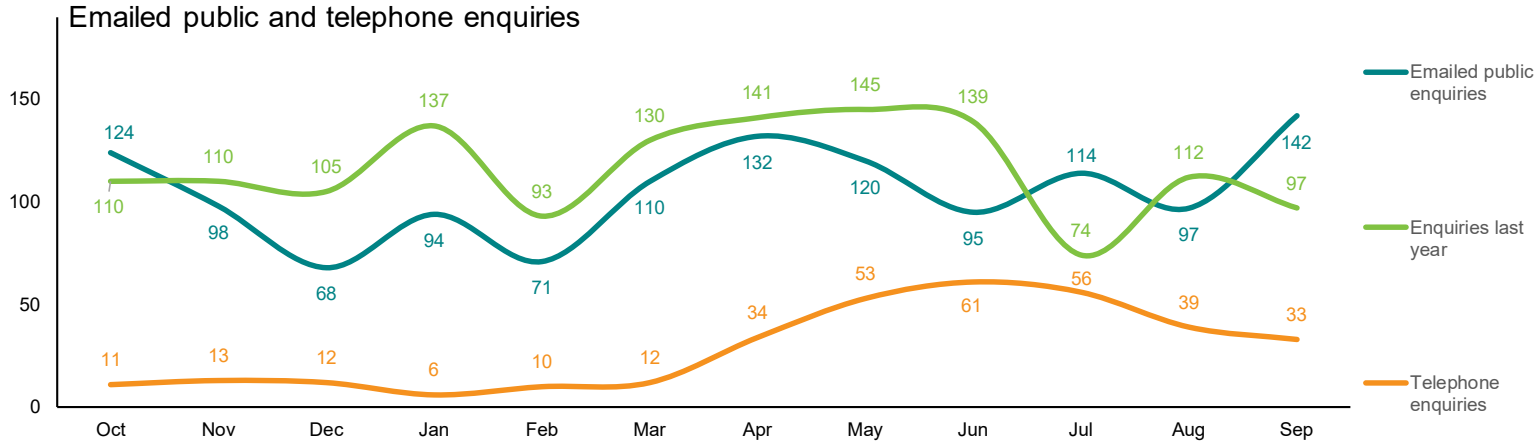
Status: **N/A**

Information

OTR performance

Target: **to be developed**

Large number of OTRs received following media coverage. 7 DSL received. A low number of OTRs were sent out as resource was focussed on the testing and creation of SOPs for the new system.



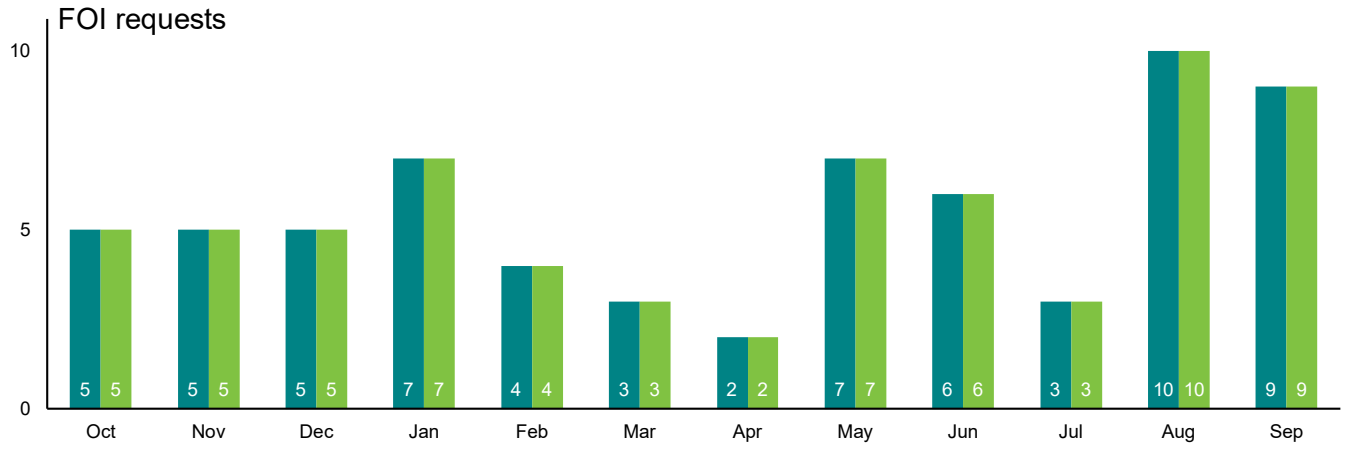
Status: **N/A**

Policy/Comms

Emailed public and telephone enquiries

Target: **not defined**

Out of 120 enquiries logged in September, the vast majority were from patients (80). **Themes:** complaints related enquiries (27), treatment (8), sperm donation (8), consent/clinic forms, data requests (6), medical queries (5), egg donation (4), clinic query (3), OTR (3) and other (49).
Tel calls: treatment (11), general donation (6), import/export (5), CaFC (2), complaints (1), and other (14).



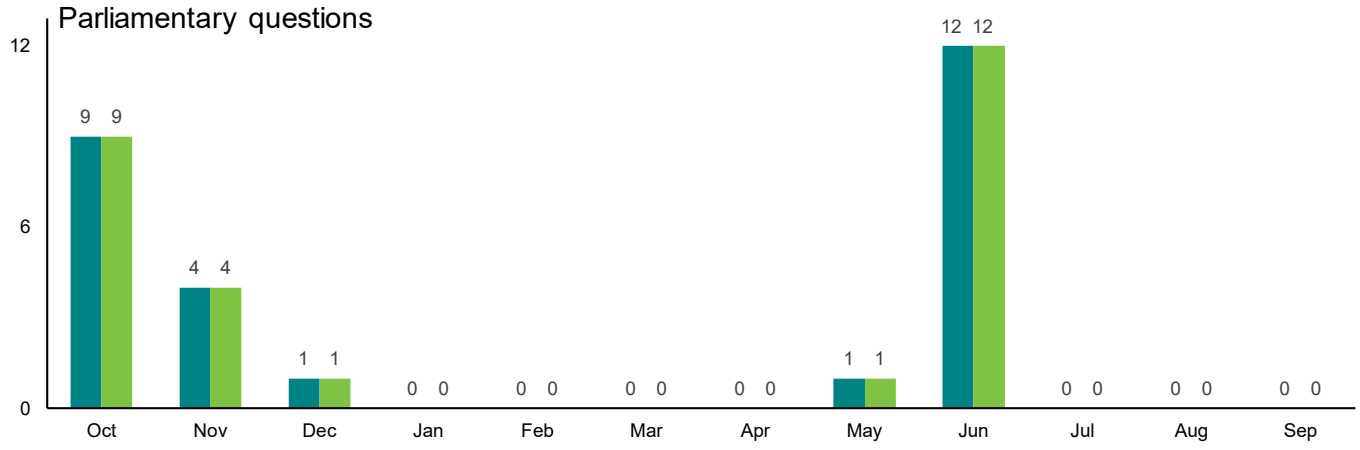
Status: **Green**

Intelligence

FOI responses

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

The FOIs were about donation, CaFC, surgical sperm retrieval, fertility trends, egg freezing, finance (x 2), IT software and hardware (x 2).



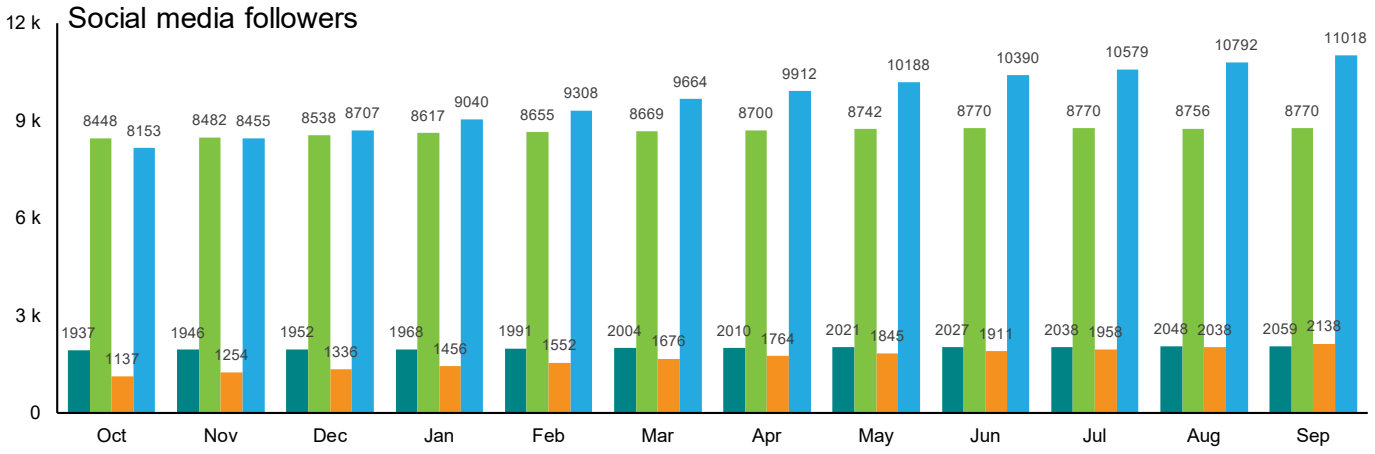
Status: **Neutral**

Intelligence

PQs responses

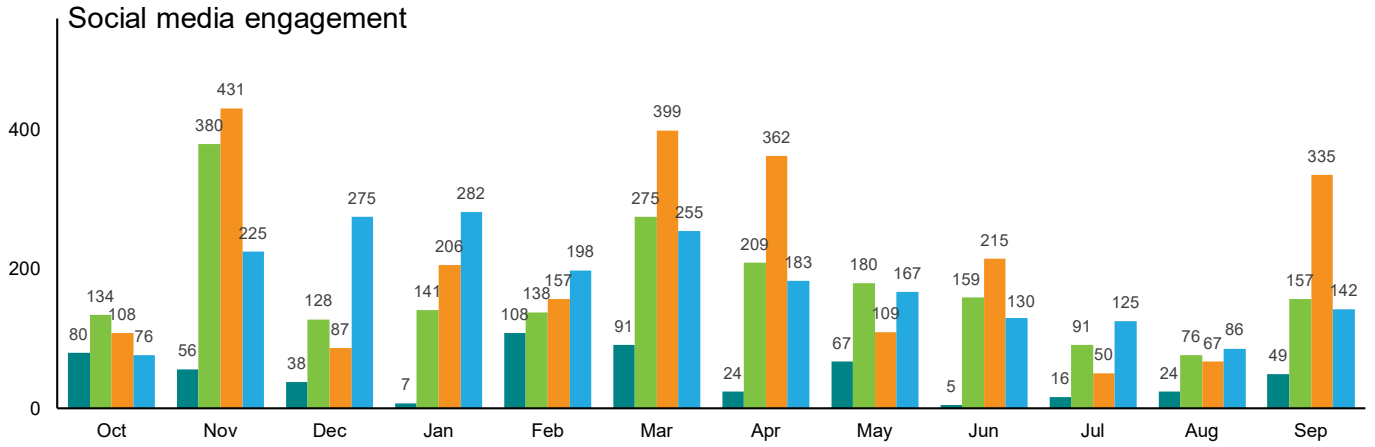
Target: **100% within deadlines set**

No PQs this month.



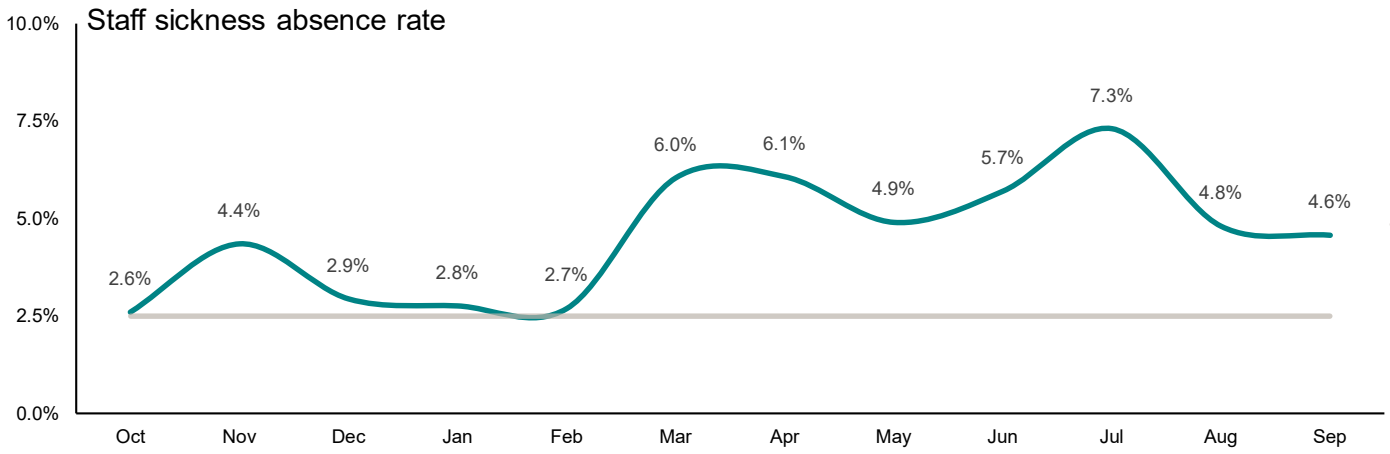
Status:	N/A
Comms	
Total number of followers across social media	
Target: **not defined**	

Steady increase across all the channels with the largest increase on LinkedIn.



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

In September we launched the State of the Sector, and also 'Who is my donor?' campaign, which increasd engagement, particularly on Instagram.



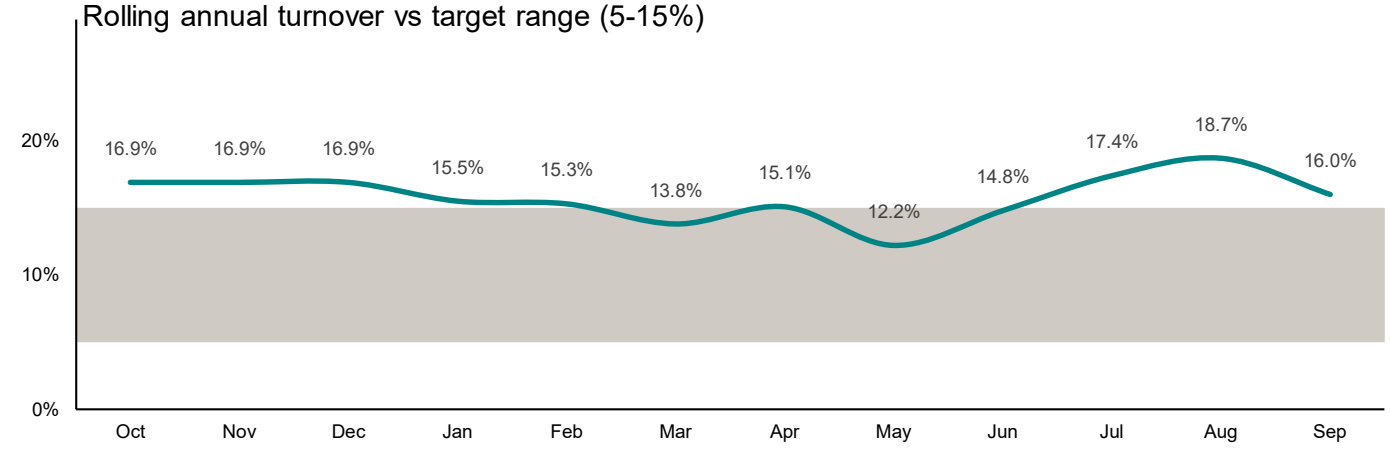
Status: **Red**

HR

Sickness

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

Sickness absence remains high with 3 employees on long term sick. However, not including the long term sickness our figures are low and below average on 0.57%.



Status: **Amber**

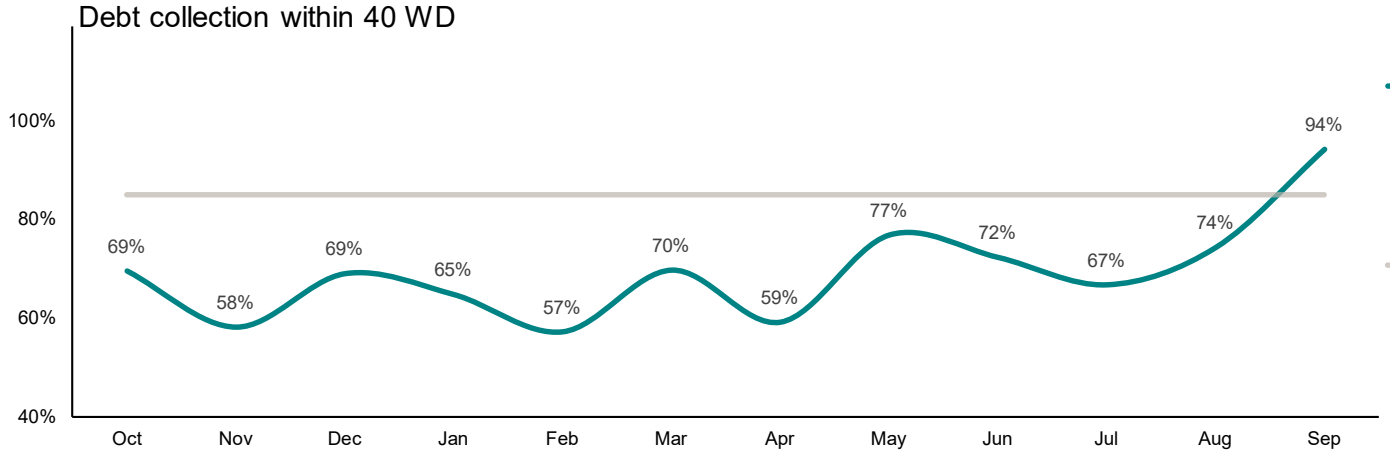
HR

Turnover

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

Just one leaver for September.
Supplementary HR data: **Headcount - 75, Posts - 76, Starters - 0, Leavers - 1.**

Debt collection within 40 WD



Status: **Green**

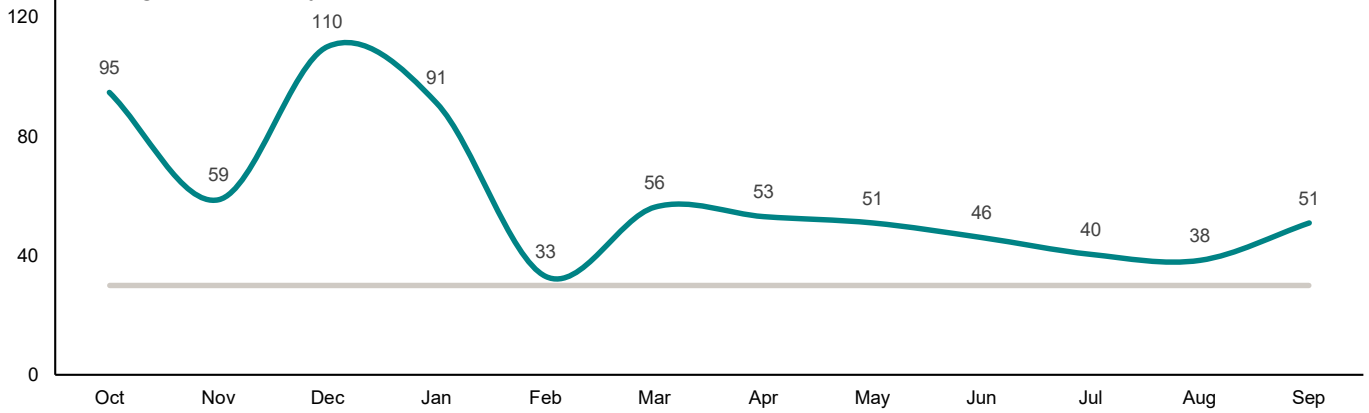
Finance

Debt collection

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

The majority of invoices were paid within 40 days of the invoice date.

Average debtor days



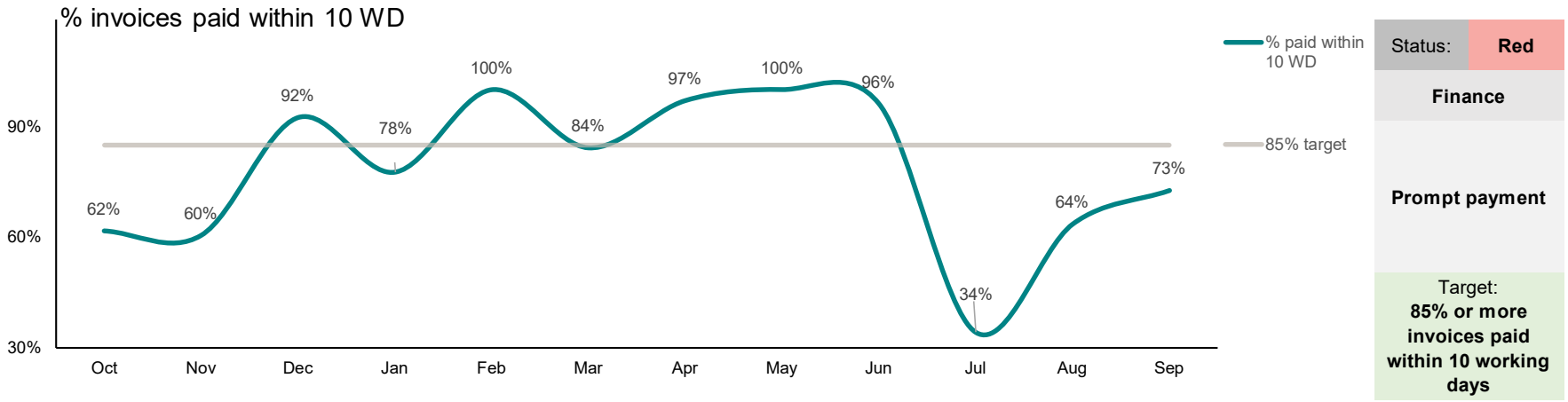
Status: **Red**

Finance

Debtor days

Target:
30 working days or less

There are currently 3 establishments with queries relating to their outstanding balance. These along with other older debt are being investigated.



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

100% paid within 20 days of invoice. Invoice approval delayed in some cases due to annual leave.

Strategic risk register

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society
Meeting:	Authority
Agenda item:	7
Meeting date:	15 November 2023
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	7a Strategic Risk Register

Output from this paper

For information or decision?	For information and discussion.
Recommendation:	Authority is invited to comment on the strategic risk register.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from Authority to AGC in December
Organisational risk:	Medium

1. Purpose

1.1. The Authority reviews the strategic risk register (SRR) twice a year. Detailed consideration is usually undertaken by AGC.

1.2. AGC were presented with the attached SRR at the 3 October meeting.

2. Updates to the SRR

With the recent appointment of the new Finance and Resources Director, and with many of the projects that will impact business activities due to be completed over the next few months, significant updates to the SRR will be done during November. These will be presented to AGC in December.

2.1. In the interim, what follows is a brief summary of proposed changes / updates for the risk categories on the SRR:

Commercial:

Closed.

Finance:

The risk will be updated further in November in light of the financial position post Q2 and to include the impact from recommendations from the PBR (on the assumption they are in the public domain).

Governance:

This risk remains; we have submitted our law reform proposals to DHSC.

Information:

We have had big increases in our media coverage, however, resource limitations limit the impact we can make in this area.

Information2:

This risk remains above tolerance despite progress made in the IT tools needed to handle OTR more efficiently. For the present, the backlog has continued to increase and higher numbers of applications are being received.

Legal:

Closed.

Operational:

This risk will be updated for AGC in December.

People:

This risk will be updated for AGC in December.

People2:

This risk has been reopened due to the board posts that will become vacant next year and the time that the public appointments process has typically taken.

Property:

Closed.

Reputational:

This risk will be updated for AGC in December.

Security:

This risk will be updated for AGC in December.

Strategy:

This will need to be revised following the publication of our PBR. In the meantime the commentary has been updated.

Technology:

Closed.

3. Recommendation

3.1. Authority is asked to comment on the SRR.

Human Fertilisation & Embryology Authority

Opening the Register – update

Rachel Cutting and Clare Ettinghausen

15 November 2023

www.hfea.gov.uk

HFEA activity during 2023

Three workstreams

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

OTR service

Workstream update

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

- Testing of the OTR RITA reports continues and feedback is being actioned by Dev team. Nearing completion.

- Once RITA reports are delivered the SOP will be updated to include these new procedures.

Future of support service

Workstream update

- Detailed update to be provided separately at ‘Support services update’ agenda item

Communications

Workstream update

- Targeted public-facing #WhoIsMyDonor campaign went live in September, resulting in 451 items of media coverage, including TV and radio
- Key stakeholders supported the campaign on social media
- The initial social media posts launching the campaign received a high level of engagement, with more than 12,500 views on X (Twitter)
- Four-fold increase in views of all website pages relating to donation (160,000 in Sept/Oct compared with 44,000 in the same period last year)
- More than 750 views of our FAQs for clinics
- Continued engagement with media outlets/ documentary makers
- Clinic Focus special edition sent to sector Positive feedback from sector about the campaign
- Campaign will continue through to 2024

Human Fertilisation & Embryology Authority

Risks

- Unrealistic expectations of DCI, donors and clinic staff to what the HFEA can do
- The communications campaign increases applicant numbers to an unmanageable level for current resource
- 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 a summary of findings in November regarding the future of support services for an Authority decision in January 2024
- Internal discussions about mechanisms to reduce the backlog including modelling of activity against future required resources
- Ongoing information for clinics about the OTR service – 3 large groups and individual clinic presentations
- Provide updates and engagement as needed to Authority and external stakeholders

Human Fertilisation & Embryology Authority

Treatment add-ons update

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future - to encourage responsible innovation that improves current practice The best care – to encourage clinics to use add-ons responsibly The right information – to ensure that people can access the right information at the right time
Meeting	Authority
Agenda item	11
Meeting date	15 November 2023
Author	Dina Halai, Head of Regulatory Policy, Scientific (job-share)
Annexes	Annex A – Outline of the new ratings system and ratings allocated

Output from this paper

For information or decision?	For information
Recommendation:	The Authority are asked to note the work undertaken to update the add-ons rating system and the suggested next steps
Resource implications:	Within budget
Implementation date:	With immediate effect
Communication(s):	Clinic focus articles and engagement with the sector and patients/public
Organisational risk:	Medium

1. Introduction

1.1. Addressing treatment add-ons has long been a priority issue for the HFEA and access to relevant and impartial information on add-ons are a key feature of our organisational strategy for 2020-24.

1.2. We introduced evidence-based ratings for selected add-ons in 2017 with a traffic-light rating system consisting of three colours (red, amber and green) that indicated whether the evidence, in the form of high-quality randomised controlled trials (RCTs), shows that a treatment add-on is effective at improving the chances of having a baby for most fertility patients. The HFEA was the first regulatory body in the world to publish information for patients on the efficacy of treatment add-ons.

1.3. Since its introduction there has been considerable debate about the merits of the traffic light ratings and the information on the HFEA website about treatment add-ons. Some patients and professionals liked the traffic light ratings; others thought it ran the risk of being too simplistic. At the November 2020 Authority meeting, we reported that we had conducted user testing to determine patients' understanding of the traffic light rated information, and that findings from the survey showed that that although four in five (83%) participants found the content easy to understand, it was clear that some of the subtleties were not always understood and that there was more we could do to develop the information.

1.4. The Authority last discussed add-ons in July 2022 and agreed the following:

- The definition of treatment add-ons that the HFEA will provide information on
- To move to a five-category rating scale and the presentation therein
- To rate additional outcomes, such as miscarriage, and outcomes for specific patient groups, such as male-factor infertility, in addition to live births for specific add-ons
- To expand the evidence base in line with SCAAC's recommendation that in the absence of high-quality randomised controlled trials (RCTs) or systematic reviews, non-randomised studies of intervention (NRSIs) should also be considered.

1.5. The remainder of this paper sets out how the add-ons information has been updated through SCAAC; the updated consensus statement; the launch of the new ratings and next steps.

2. Update to the HFEA's treatment add-ons information

2.1. At the Authority meeting in September 2021 it was agreed that work would be undertaken to develop the presentation of the rating system for treatment add-ons and to consider whether the evidence base for those ratings should be broadened. The Authority reiterated that patients should remain the primary audience for any future system. It was also agreed that SCAAC (Scientific and Clinical Advances Advisory Committee) should review the evidence base it considered as part of their add-ons review.

2.2. Early scoping work on how best to develop the presentation of the rating was presented to the Authority in November 2021 and March 2022. In summary, this work included:

- meeting with researchers with expertise in data presentation and risk communication

- presentation at a Licensed Centres Panel (LCP) meeting to gain the views of clinic staff and at a Patient Organisation Stakeholder Group (POSG) meeting to gain the views of patient organisations
- one-to-one patient interviews
- a targeted patient survey and a clinic survey
- patient focus groups

2.3. At the **July 2022** Authority meeting, the direction of travel for the presentation of the rating system for treatment add-ons was agreed.

2.4. At the **October 2022** SCAAC meeting, the Committee agreed the decision tree for considering the evidence base, including expanding - in the absence of RCTs or systematic reviews - to NRSIs, and allocating ratings to outcomes in addition to live births for specific add-ons.

2.5. In October 2022, user acceptance testing (UAT) was carried out on mock webpages, designed to look at how the updated information with new ratings could be presented. The aim was to find out what the overall user experience of the public/patients looking for information on treatment add-ons. We found that people moved through the list of headers that can be clicked to reveal or hide content associated with them ('accordions') easily and having content split in clear sections helped people understand the structure of the page better as it was clear where one section ended an another started, with people less likely to scroll past sections of content. Participants with visual impairment had no major difficulties consuming or understanding the content and for most the ratings were useful and easy to understand. Feedback about some of the descriptions feeling somewhat wordy and the order of the information presented were also provided.

2.6. At the **February 2023** SCAAC meeting, the methodology for the new rating system was discussed and recommendations were made to improve the literature search and ensure completeness of the review process. A specialist librarian was instructed to assemble a list of search terms and recommend a methodology to perform the literature searches. The search terms and the list of papers resulting from the searches were reviewed by SCAAC with the Committee taking ownership of the list of papers. After SCAAC's review, the papers were sent to an external independent reviewer to analyse the quality of the evidence base and produce a report with a recommendation for ratings of each outcome for each treatment add-on.

2.7. At the **July 2023** SCAAC meeting, the Committee assigned the new ratings for all add-ons and outcomes, apart from artificial egg activation. In August 2023, ARCS and BFS published **professional guidelines on best practice use of artificial egg activation**, and given that it is already an authorised process, artificial egg activation was removed as a rated add-on because it should only be offered in specific circumstances and not be offered to the general population.

2.8. The HFEA's information on treatment add-ons was updated with the new ratings and with consideration to the patient and professional guidance already collated. Members of SCAAC were then invited to review the text to ensure the messaging was correct.

2.9. On 19 October 2023, the new ratings and patient information, which has been developed with patient and professional guidance, went live on the HFEA **website**.

3. Update to the consensus statement

3.1. The HFEA and eight professional and patient bodies have repeated their commitment to the responsible use of treatment add-ons in an **updated consensus statement**. This sets out that add-ons without strong evidence of their safety and/or effectiveness should only be offered in a research setting. The consensus statement also makes it clear that patients should not be charged more to take part in research, including clinical trials. This updated statement reflects the signatories ongoing commitment to monitor the evidence base for treatment add-ons and their offering in UK clinics.

3.2. The signatures are the Association of Reproductive and Clinical Scientists, British Fertility Society, British Infertility Counselling Association, European Society for Human Reproduction and Embryology, Fertility Network UK, Human Fertilisation and Embryology Authority, Royal College of Nursing, Royal College of Obstetricians and Gynaecologists, Senior Infertility Nurses Group.

3.3. Clinic staff should be aware of the updated consensus statement and consider the signatories' expectations of them and best practice when offering add-ons to patients.

4. Communications activities

4.1. All Persons Responsible (PRs) for licensed treatment clinics in the UK were notified of updates via a letter from Tim Child as Chair of SCAAC and the HFEA's Chief Executive, which also informed them that clinics should highlight the new ratings to patients before treatment, as set out in guidance note 4 of the **HFEA Code of Practice.** The messaging will be reiterated in the November Clinic Focus.

4.2. On the go live date of 19 October 2023, we had over 270 pieces of media coverage that stretched from National print, online and broadcast to regional and local titles, including the top story on the BBC website's health page. Most of the coverage contained our key messages as well as a supportive comment from Fertility Network UK.

4.3. There were 45,189 visits (by 5,657 users) to our treatment add-ons webpages between 19-31 October. This is 16% of all users to our website within that time period.

4.4. Our social media posts which outlined the new rating system were well received across all our platforms and we have seen some very positive comments about the new ratings. These will be regularly reposted to our media platforms on a rolling basis.

5. Looking ahead

5.1. The launch of the new ratings completes two years of work together with SCAAC members, patients, clinic staff, stakeholders and academic experts to provide more useful information for patients so that they are able to make informed decisions about the use of treatment add-ons. We have no plans for further policy work at present. Looking ahead, we plan to find ways to highlight and provide up to date information on add-ons for patients, including those set out below.

5.2. To continue to promote our add-ons information across our various social media platforms and by presenting at workshops/meetings.

5.3. To develop a BAU process for reviewing the evidence base for treatment add-ons and to consider the frequency of review necessary.

5.4. As noted earlier, the HFEA was the first regulatory body in the world to publish information for patients on the efficacy of treatment add-ons. This picture is now changing, and we will continue to monitor new sources of reviewed evidence to ensure that HFEA resources continue to respond to UK patients' needs. For example,

- In October 2020 a **Cochrane Special Collection** review looking at some of the same add-on treatments, and which also includes some patient-facing content, was published.
- ESHRE have published a **good practice recommendation paper** which outlines a set of treatment add-on tests and treatments, describes their rationale and any evidence of their efficacy and safety, and provides a recommendation for clinical practice.

The ratings allocated for the HFEA's list of treatment add-ons are in line with the conclusions drawn by Cochrane and ESHRE.

5.5. Continue to monitor the potential for any collaborative opportunities in future, in order to make the clearest high-quality information offer to patients and the best use of HFEA resources. We are in ongoing discussion with the Victorian Assisted Reproductive Treatment Authority (VARTA) in Australia, who have similar concerns around the offering of add-ons and are considering developing their own evidence-based information for patients.

5.6. Consider a voluntary collection of treatment add-ons data at some point in the future working with professional bodies.

6. Recommendation

6.1. The Authority are asked to note the work undertaken to update the add-ons rating system and the suggested next steps outlined above.

7. Annex A – Outline of the new ratings system and ratings allocated

The HFEA's new ratings has five ratings that indicate whether the evidence from studies shows that an 'add-on' is effective at improving treatment outcomes for someone undergoing fertility treatment.

- **Green:** On balance, findings from high quality evidence shows this add-on is effective at improving the treatment outcome.
- **Yellow:** On balance, it is not clear whether this add-on is effective at improving the treatment outcome. This is because there is conflicting moderate/high quality evidence – in some studies the add-on has been found to be effective, but in other studies it has not.
- **Grey:** We cannot rate the effectiveness of this add-on at improving the treatment outcome as there is insufficient moderate/high quality evidence.
- **Black:** On balance, the findings from moderate/high quality evidence shows that this add-on has no effect on the treatment outcome
- **Red:** There are potential safety concerns and/or, on balance, findings from moderate/high quality evidence shows that this add-on may reduce treatment effectiveness.

The treatment add-ons below have been rated by the HFEA's Scientific and Clinical Advances Advisory Committee (SCAAC). The ratings indicate whether the treatment add-on is effective at improving the chances of having a baby for most fertility patients.

 Assisted Hatching

 Elective freeze all cycles

 Endometrial Receptivity Testing

 Endometrial scratching

 Hyaluronate enriched pre-transfer culture medium (e.g. EmbryoGlue)

 Immunological tests and treatments for fertility - Intralipids

 Immunological tests and treatments for fertility- Intravenous immunoglobulin (IVIG)

 Immunological tests and treatments for fertility - Steroids (Glucocorticoids)

 Intracytoplasmic morphologic sperm injection (IMSI)

 Intrauterine culture

 Physiological intracytoplasmic sperm injection (PICSI) – in use for patients having ICSI treatment for male factor infertility

 Pre-implantation genetic testing for aneuploidy (PGT-A)

 Time-lapse imaging and incubation