Human Fertilisation & Embryology Authority

Authority meeting

Date: 14 September 2022 – 1.30pm to 4pm

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

Agenda item	Time
1. Welcome, apologies and declarations of interest	1.30pm
2. Minutes of the meeting held on 19 July and matters arising For decision	1.35pm
3. Chair and Chief Executive's report – to note For information	1.40pm
4. Committee Chairs' reports For information	1.45pm
5. Performance Report For information	1.50pm
6. Implementation of the new gamete and embryo storage rules For information	2.15pm
Break	2.45pm
7. Update on ethnic diversity in fertility treatment For information	3.00pm
8. Modernising Fertility Regulation – update For information	3.30pm
9. Any Other Business	3.55pm
10. Close	4.00pm

Minutes of Authority meeting held on 19 July 2022

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	14 September 2022		
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 19 July 2022 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 19 July 2022 held via teleconference

Members present	Julia Chain Catharine Seddon Jason Kasraie Tim Child Frances Flinter	Gudrun Moore Alex Kafetz Frances Ashcroft Graham James Geeta Nargund
Apologies	Zeynep Gurtin Alison Marsden	Alison McTavish Jonathan Herring
Observers	Steve Pugh (Department of Health and Social Care – DHSC) Amy Parsons DHSC	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting	Debbie Okutubo Shabbir Qureshi Sonia Macleod Ana Hallgarten

Members

There were 10 members at the meeting – six lay and four professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and staff present online. The Chair stated that the meeting was audio recorded in line with previous meetings and for transparency reasons, and that the recording would be made available on our website to allow members of the public hear it.

1.2. Declarations of interest were made by:

- Tim Child (PR at a licensed clinic)
- Jason Kasraie (PR at a licensed clinic) and
- Geeta Nargund (Clinician at a licensed clinic).

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 18 May 2022 were a true record and could be signed by the Chair.

2.2. The status of all matters arising was noted.

3. Chair and Chief Executive's report

3.1. The Chair gave an overview of her engagement with key stakeholders and the decision-making committees of the Authority. The Chair commented that the final meeting of this phase of the Legislative Reform Advisory Group (LRAG) had taken place and she wanted to record her and the board's thanks to all stakeholders involved.

3.2. It was noted that a new Secretary of State for Health had not yet been appointed but that the board will be kept abreast of developments. The DHSC representative, Steve Pugh commented that we had a Junior Minister for Health and Social Care, James Morris, should political decisions need to be made.

3.3. The Chief Executive provided an update on the key external activities that he has been involved in since the last Authority meeting.

3.4. He highlighted the associated media work seen in the press lately which was a reflection of the interest in our work, in particular donor anonymity.

3.5. Members asked if the HFEA's work on identifying potential legislative reform will continue given the current political context. The Chief Executive responded that we would continue with this work but any decision to progress to a firm legislative timetable is a matter for the government.

3.6. Members requested that they could be pre-warned if we are going to speak to the press as patients and the press were asking questions about the recent press coverage.

Decision

3.7. 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 reports.

4.2. The Licence Committee Chair (Alison Marsden) sent her apologies for the meeting but sent in comments to the Chair. The Committee considered some thought-provoking research licence applications recently. At the May meeting, discussions had resumed on a research licence application involving complex PGT-A related issues (having previously requested more information from the applicant) – which was granted.

4.3. It was noted that the July meeting minutes was still being finalised. They were also delighted that new members had joined the Licence Committee.

4.4. The Statutory Approvals Committee (SAC) deputy Chair (Gudrun Moore) commented that they had met three times since the last Authority meeting and that most items were approved. At the meeting held on 30 June, some decisions were deferred.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an overview of the last meeting held in June, at which the Authority Chair was also present. She commented that there were two internal audit reports presented, one of which concerned the effectiveness of the Inspection process which had received substantial audit rating – the highest available. She also gave assurance to the board that the auditors present at the meeting had said there would be no qualifications to our accounts but until the reconciliation had occurred with actual income, rather than the current estimated figures, they would be unable to sign off the accounts. She invited the Director of Finance and Resources to give an explanation.

4.6. The Director of Finance and Resources explained that the issue concerned the switch over to PRISM and further work was being done to get the actual figures from clinics rather than rely on estimates. It was noted that the hope was to conclude this work over the summer.

4.7. The AGC Chair continued that there would be refresher training for AGC members and that this will be opened up to any Authority member who would like to participate.

4.8. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) gave a summary of the last SCAAC meeting. It was noted that amongst the discussions at the meeting there was detailed consideration of the evidence base used to determine the assessment of Treatment add-ons. The conclusion was that in the absence of good robust randomized controlled trials (RCTs) or meta-analysis, expanding the evidence base may be helpful when assigning treatment add-on ratings.

4.9. Following the European Society of Human Reproduction and Embryology (ESHRE) conference the annual SCAAC horizon scanning meeting occurred.

Decision

4.10. Members noted the Committee Chairs' updates.

5. Performance report

5.1. The Chief Executive commented that some key performance indicators had been redefined. There were three red indicators in May:

- HR2: Turnover
- C1: Efficiency of the end-to end inspection and licencing process
- C4: Mito application average processing.

5.2. Members were advised that staff turnover remained high and placed parts of the organisation under additional pressure.

5.3. C1 - Efficiency of the end-to-end inspection and licensing process: five inspections were over the 70 working day target.

5.4. C4 - Mito average processing time: both of the applications due in the month were above the 90-working day target by four days.

5.5. With PRISM, there were three clinics that were yet to deploy and may not be online until September. Members were assured that we continue to actively engage with clinics to support them in improving submission rate quality to PRISM.

5.6. Members asked whether a review should be undertaken on the red indicators. The Chief Executive responded that all the RAG ratings were set by the Authority and they were internal indicators. RAG ratings helped us be accountable to the Authority and gave a picture of the constraints that we were working under, which supported the oversight function of members.

5.7. Some members commented that we should not change targets as repeated discussion drives progress. It was noted that at the AGC meetings, they continue to look at the matrix around the corporate culture of recruitment and retention.

5.8. On turnover, members noted the disruption but some commented that if people were using the HFEA as a steppingstone to get jobs that were promotions, then this was positive and the Authority should embrace it.

5.9. In terms of financial performance, members commented that the number of fresh cycles was reducing and asked if this was having an overall effect on income received by the Authority. The Director of Finance and Resources responded that cycles that are billable have seen a drop since the pandemic but we were however yet to do the analysis to see if this is a trend. This will be looked at, at a future date.

5.10. The Chair commented that herself and the Chief Executive have regular catch ups at which staff pay is discussed, they also consider other incentives than pay that might help retain staff. The Chair also said that when we agreed the fee increase the intention was to come back to the board and do a wider review as the five-pound increase was viewed as a stopgap.

Strategy and Corporate Affairs

5.11. The Director of Strategy and Corporate Affairs presented this item. She introduced her new heads including Amanda Evans, the Head of Research and Intelligence; Angharad Thomas, the Head of Communications and Rachel Cooper, the Legal adviser to the policy team.

5.12. She commented that the directorate has been busy and a lot has been done in terms of the storage work. It was noted that stakeholder group meetings and the Legislative Reform Advisory Group (LRAG) meetings continued to happen.

5.13. Members were advised that at the last Ethnic Diversity in Fertility Treatment group meeting, it was agreed that there would be recommendations to clinics to review their websites to make them more inclusive and that an update would be reported at the September Authority meeting.

5.14. It was noted that the next persons responsible (PR) event will be held in October and that feedback received from previous events had always been positive.

5.15. Members commended the ongoing work on ethnic diversity and inclusion and asked how members could support the Authority in reaching patients from ethnic backgrounds and how these patients could access material that will be produced in different languages. Members welcomed the image reviews on clinic websites.

5.16. Staff responded that there would be different materials (including videos) and that the work would be phased in.

Compliance and Information

5.17. The Director of Compliance and Information presented to the Authority. Members were advised that the new storage regulations went live on July 1 and that there was a dedicated area on the Clinic portal for help and guidance. It was noted that the next task was to produce short training videos on consent.

5.18. The new consent forms had gone live and feedback received from clinics had been positive. The Director of Compliance and Information was chairing drop-in sessions as part of the guidance on how to complete consent forms.

5.19. There was good progress being made on the backlog on the Opening the Register (OTR) service. Someone left the team but the position has now been filled. A number of cases were closed in June and 84 received in the month but the waiting list continued to reduce.

5.20. Members were advised that there was a nationwide shortage of one of the medicines used in IVF which had led to delays in treatment for some patients. We have been told that from mid-August

the situation should improve. Professional members on the Authority commented that this is a major problem and another drug was also affected.

5.21. IT infrastructure penetration tests are scheduled for September and we are trying to recruit a data analyst.

5.22. As regards Inspections, the business support team has now been recruited to and they are settling in.

5.23. Members commented that for PGT applications, that part of the portal crashed regularly which was frustrating for clinic staff and requested that this be looked into.

5.24. Members commended the Director of Compliance and Information and her team on the work done on consent forms and the drop-in sessions. The Director of Compliance and Information requested that the sessions be publicised across the sector.

5.25. The Director of Compliance and Information thanked DHSC colleagues and noted that were now looking into how changes would be implemented.

5.26. The Chair on behalf of the board thanked the Director of Compliance and Information and her team for the extra work on the drop-in sessions.

Finance and Resources

5.27. The Director of Finance and Resources presented this item. As noted earlier in the meeting he commented that we had not closed last year's accounts but that we should be able to close them shortly.

Decision

5.28. Members noted the performance report.

6. Treatment add-ons: updating the rating system and evidence base

6.1. The Scientific Policy Manager presented this item. Members were reminded that Treatment add-ons had been discussed at three Authority meetings since September 2022.

6.2. Since March 2022 further work had been carried out on the presentation of the ratings system and the potential inclusion of additional outcomes.

6.3. Members were invited to comment. They congratulated the team for a job well done and asked if treatment outcomes went beyond live births.

6.4. They also asked if 'no effect on treatment' meant 'no beneficial effects' because such add-ons would not do anything.

6.5. Members also asked for examples of safety concerns. The Chair of SCAAC gave examples of add-ons that could fit into the five categories in Option C, for example IVIG and PGT-3 showed detriment to live birth rates, which would be red. Some studies such as the Star PGT-A trial showed that for women in their 30s there was zero benefit, but no detriment, which would therefore be Black.

6.6. Members asked if numbers were published in relation to the studies done.

6.7. In response to some of the questions, the Scientific Policy Manager responded that we would develop a decision tree or algorithm which would be shared with SCAAC. A decision would also be made on whether we want to publish summaries of RCTs and that the independent reviewer comments on the studies along with the SCAAC minutes were published on our website.

6.8. Members wanted assurances that the information on the website will be user friendly with clear explanations in plain English. The Scientific Policy Manager responded that once the webpage had been developed it would be tested with users.

6.9. The Chair of SCAAC commented that when we consider expanding the evidence base beyond RCTs we need to align with other organisations to make us more robust. Also, that there will be cost implications for consequential changes.

6.10. Members wanted clarity on what was meant when we say 'most' fertility patients. Also, if there was evidence for 35+ or 40+ age categories and lastly how the ranking for the webpage could be improved. The Chair of SCAAC responded that the current system says 'most'. We were therefore continuing with the existing language. It has to be very clear on the website that the rating refers to 'most' patients.

6.11. Members requested that the webpage be made to be shareable on other sites.

6.12. Members had concerns on the red rating due to the language used where it said 'potential safety concerns'.

6.13. Members commented that the symbols will mean different things in different settings, also that the lack of advice on costs of add-ons should be evaluated.

6.14. Some members suggested that the frequency of reviews of add-on ratings will require a balance of public interest, supporting updating the ratings and resource allocation and that there should be a publicly available position on when we will review each add on.

6.15. Members noted that reliance on a single statistician should be considered.

6.16. The Scientific Policy Manager commented that a full communications plan would be put in place once the new add-ons' pages were live and the treatment add-ons had been rated by SCAAC using these new ratings. A standard operating procedure (SOP) was being developed for rating add-ons. During patient interviews, patients were more concerned with harm than safety and they commented on that the most. Lastly that the lack of transparency in costs was not within our regulatory powers, although it is recognised that this can be of great concern to patients.

6.17. The Director of Strategy and Corporate Affairs commented that we have data on how our website is used, which we will use to develop the communications plan. We want to make the HFEA the first port of call for patients. In the Code of Practice there is a requirement for clinics to refer patients to the HFEA website information on add-ons. The commitment to patients should be that if any significant new evidence or information comes to light then it will be reviewed by SCAAC.

6.18. The Chief Executive commented that the frequency of reviewing add-ons and potentially adding in another reviewer have resource implications. While very little research is ground-breaking a framework will need to be developed which incorporates the need to be flexible enough to review the ratings in the event of a significant publication, while working within available resources. It also needed to be reiterated that standard treatment remained effective.

6.19. The Chair of SCAAC commented that there are a number of specialists on the committee therefore the frequency of updates will need to be made available as soon as possible. Members agreed that we should publish when the next review will be done.

6.20. The Chair of SCAAC commented that the proposed definition of an add-on could potentially limit SCAAC's ability to review add-ons. It was agreed that this definition would be refined as part of the work on the SOP and decision tree/algorithm development work.

6.21. The Director of Strategy and Corporate Affairs reminded the board that we had publicly stated that treatment add-ons were being reviewed, we publish summaries of Authority meetings in Clinic Focus and we also publish the SCAAC meeting minutes and summarise them in Clinic Focus.

6.22. The Chair summarised the discussion and commented that once this part of refining the add-ons system was complete then it would become 'business as usual' for SCAAC and the policy team. Consideration will need to be given to what capacity was needed to support this.

Decision

6.23. The Authority approved the option C and the wording attached to each circle/symbol for developing the treatment add-ons' ratings system.

6.24. The Authority approved the additional outcomes other than live births, SCAAC will be tasked with determining which additional outcomes should be rated by HFEA and which add-ons each additional outcome should apply to.

6.25. The Authority approved the proposal to use an expanded evidence base when appropriate.

6.26. The Authority agreed the consequential changes to the criteria the HFEA use when defining add-ons, subject to further refining under the guidance of the Chair of SCAAC during the SOP, decision tree/algorithm development process.

7. Modernising Fertility Regulation - update

7.1. The Public Policy Manager presented this item. Members were reminded that the aim of this work was to deliver an outline proposal on the Modernisation of the HFE Act to the DHSC around the end of the year.

7.2. Members were informed that three LRAG meetings had taken place discussing:

- Consent and data sharing
- Donor anonymity and information provision and
- Scientific Developments.

7.3. It was noted that the drafting of the consultation had begun with a communications plan and that the risks outlined at the May Authority meeting continued to apply.

7.4. It was noted that the next steps in the consultation would allow the HFEA to set out why specific changes to the Act may be necessary, and outline proposals for reform.

7.5. Following discussion, the Chair commented that the Director of Strategy and Corporate Affairs will send out a request to all Authority members for any member that could provide assistance.

7.6. On behalf of the board, the Chair expressed gratitude to the LRAG group for their assistance and support in shaping the changes proposed. It was noted that they had met four times to help gather views and develop ideas.

7.7. In response to a question, it was noted that there was a LRAG member who was a Royal College of Obstetricians & Gynaecologists (RCOG) member on the group. It was reiterated that LRAG members were there in their professional capacity rather than representing any group.

7.8. Authority members were informed that regarding data sharing, LRAG members had agreed that amending the Act to permit easier sharing of fertility patient data in medical settings outside the fertility clinic would aid patient protection and safety. It would also improve care, speed up diagnosis, and provide important centralised records for research or commissioning. The Chair commented that this was all still subject to further discussion.

7.9. Members commented that regarding Artificial Intelligence (AI) it should be clear what areas of AI was going to be pursued and if we wanted to link in with Genomics England. It was suggested that there could be a HFEA/Genomics Chair meeting.

7.10. In response to a comment, it was noted that limit on costs was in the paper as one of the things we were looking to change in the Act.

7.11. Members cautioned that political differences over time needed to be borne in mind and that we should endeavour to future proof what changes we were putting forward. We should also consider including all fertility patients in the category of vulnerable people.

7.12. Members further commented that raising items like 14-day rule was subject to political constraints, discussions therefore needed to be held elsewhere.

7.13. The Director of Strategy and Corporate Affairs asked if members felt that we or LRAG had missed anything that they felt need to change in the Act.

7.14. The Chair commented that we need to remember that we are not re-writing the whole Act but recommending changes in areas we felt needed to be updated.

Decision

7.15. Members agreed the plan for a targeted consultation to take place later this summer.

8. Any other business

8.1. The Chair reminded members that the Away day private session was scheduled on September 13 and part of what would be discussed was Modernising the Act. There would also be time to consider the effectiveness of the board.

8.2. A member asked that in light of the rising cost of living and covid rates if fees could be added to the agenda at the away day. The Chair agreed that it would be considered.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 14 September 2022

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	14 September 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For information		
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	2022/23 business year		
Communication(s)			
Organisational risk	**X** Low	☐ Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters arising from the Authority meeting – actions from 19 July 2022			
7.15 A targeted consultation to occur by summer and the outcomes reported to the board.	Director of Strategy and Corporate Affairs	November 2022	This is an agenda item at the September meeting.
Matters arising from the Authority meeting – actions from 18 May 2022			
3.6 Some members that are yet to complete their cyber security training.	Governance Manager	May 2022	Four members are yet to let the Governance Manager know if they have completed their Security & Data Protection online training.
Matters arising from the Authority meeting – actions from 24 November 2021			
11.10 Options on how compliance information including inspection reports and licensing decisions could be made more visible and easier to find on the website.	Director of Strategy and Corporate Affairs	November 2023	No further progress. Legislative changes relating to storage and other key areas have taken priority at this point. Recommendation is that it be delayed for 12 months to Nov 2023 and that the Authority discuss in context of business plan for next year as to prioritisation.
Matters arising from the Authority meeting – actions from 23 September 2021			
5.18 Backlog on OTR	Director of Compliance and Information	March 2023	Staff are gaining competence and there is a significant increase in the amount of OTRs being processed. An improved way of reporting the performance indicator is being discussed and will be introduced as an increased amount of applications in the backlog are now being worked on. This remains a standing agenda item under director's performance report.
9.15 Discussion to be held with multiple birth outliers	Director of Compliance and Information	September 2022	To be raised at inspections. MBR is requested at each renewal and interim inspection. This is currently based on unverified data held by

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
			the clinic as we are unable to draw the data from PRISM at the moment.
Matters arising from the Authority – actions from 7 July 2021			
5.7 PGT-M being out of target of the 75 working days	Director of Compliance and Information	July 2022	We have employed a dedicated scientific application officer to manage this in the future (along with ITE certificates and mito applications). This takes the task away from inspectors who have a heavy workload with their clinic portfolios. Training has commenced. This should improve the KPI in future.

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:	14 September 2022
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

1.1. The paper sets out the range of meetings and activities undertaken since the last Authority meeting in July 2022.

1.2. Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

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

- 21 July – I chaired the Renumeration Committee meeting
- 27 July – Peter and I had a meeting with the CMA
- 8 September – I presented at an evening seminar for jnetics.org

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

- 21 July – I presented to the Renumeration Committee
- 27 July – As Julia has mentioned in her report, we had a meeting with the CMA
- 12 September – We held a joint meeting with the BFS/ARCS and ourselves

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:	14 September 2022
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:		
1 July 2022	2 Renewals	1 renewal & ITE Certificate granted 1 renewal & ITE Certificate adjourned with proposal to vary existing licence without application to exclude embryo testing (centre has confirmed acceptance and licence varied).
8 September 2022	1 Renewal 1 Interim / Variation to include new SLCs	The minutes of this meeting have not yet been finalised.
Other comments:	None	
Executive Licensing Panel:		
13 July 2022	3 Renewals 1 Change of Centre Name 1 Interim	All granted/approved
26 July 2022	2 Renewals 1 Interim 1 Change of Person Responsible 1 Change of Licence Holder	All granted/approved
9 August 2022	1 Renewal 1 Variation of Premises 1 Change of Person Responsible	All granted/approved
23 August 2022	1 Renewal 2 Changes of Person Responsible 1 Variation of Activities	All granted/approved
6 September 2022	1 Interim 1 Change of Licence Holder 1 Variation of Premises	All granted/approved
Other comments:	None.	

Meetings held	Items considered	Outcomes
Licensing Officer decisions:		
	ITE Certificates – 12 Voluntary Revocations – 1	All granted/approved
Other comments:	None.	
Statutory Approvals Committee:		
30 June 2022	2 Mitochondrial Donation applications 5 PGT-M applications	All granted/approved
28 July 2022	2 PGT-M applications 2 Special Directions	All granted/approved
25 August 2022	5 PGT-M applications 2 Special Directions	The minutes of this meeting have not yet been finalised
Other comments:	None.	
Audit and Governance Committee:		
The next meeting will be on 4 October 2022.		
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
The next meeting will be on 3 October 2022.		
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

For performance up to July 2022

Shabbir Qureshi
Risk and business planning manager
01/09/2022

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	SMT & Authority
Agenda item:	-
Meeting date:	05/09/2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs Annex 4: SMT detailed KPIs

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 July 2022.
- Performance was reviewed by SMT at its 5 September 2022 meeting.
- In July performance was generally good. There were five red indicators based on the new KPIs. This does not include the Finance KPIs.

Key trends

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

July (5)	June (5)	May (6)
C2 – Inspection reports within 55 working days (pre committee)	C1 – Inspection delivery for the financial year	C1 – Inspection delivery for the financial year
C3 – Inspection reports within 70 working days (post committee)	C2 – Inspection reports within 55 working days (pre committee)	C2 – Inspection reports within 55 working days (pre committee)
F2 – Debtor days	C3 – Inspection reports within 70 working days (post committee)	C3 – Inspection reports within 70 working days (post committee)
F3 – Prompt payment	F3 – Prompt payment	F1 – Debt collection
HR2 – Staff turnover	HR2 – Staff turnover	F3 – Prompt payment
		HR2 – Staff turnover

Human Fertilisation & Embryology Authority

Management summary

IT and register performance reporting

- The development handover has continued to progress well.
- The main outstanding areas of known issues on PRISM are: Movements, Validations, Legacy data issues and clinics using Meditex.
- 226K submissions from PRISM. All clinics deployed except ARGC group where we are waiting for Meditex to undertake a special technical deployment.
- Average error rates are 4.5% but still unstable. The development team is working on a manual revalidations system prior to an the development of an automated process.

Management commentary

- The performance report spreadsheet has had substantial changes made to automate the creation of charts and commentary. The SMT and Authority report have been changed into a PowerPoint slideshow to allow automatic updates of graphs, taking data directly from the performance spreadsheet.
- These changes will significantly reduce the time taken to create reports and reduce errors in reporting.
- Performance has been variable across teams with five red and two amber indicators.
- The finance data missing for this financial year have now been added to the report.
- BSIS have been using a new data gathering spreadsheet to better identify where gaps in performance occur within the end to end inspection cycle. Some data prior to May is missing and will be backfilled where possible.
- We are also working to improve KPI reporting for PGTM applications and portal support requests.
- The comms team are actively working to improve data gathering which has been impacted by system and technical issues. New social media tracking software needs to be sourced which can provide better impact assessment reports.

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	2,446	2,509	(62)	7,542	7,451	91
Expenditure	2,217	2,417	(200)	7,470	7,469	(1)
Total Surplus/(Deficit)	**229**	**92**	**137**	**72**	**(18)**	**90**

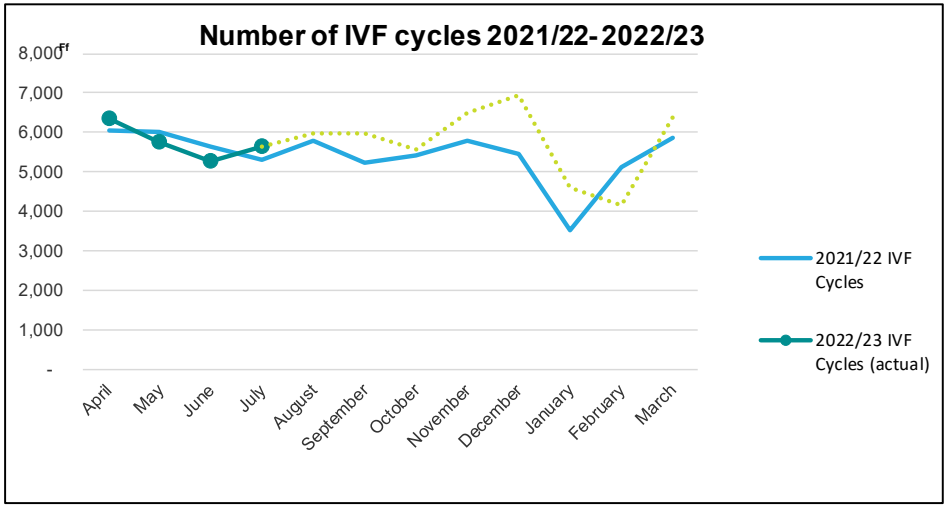
Commentary on financial performance to July 2022

- At the end of month 4 (July) we are under budget by £137k which is represented by a small short fall in our income against budget of £62k and an underspend of £200k within our expenditure.
- The billing of clinics using data from 2020/21 continues whilst we await all clinics to catch up with their data inputs. This does raise the risk of over estimation of our income which in turn will impact on expenditure for the remainder of the year. We are trying to mitigate against this by conducting reconciliations each month.
- Our forecast position is in line with budget and will change once our income position is agreed, after which discussions will take place with teams as to their plans for the remainder of the year.

Human Fertilisation & Embryology Authority

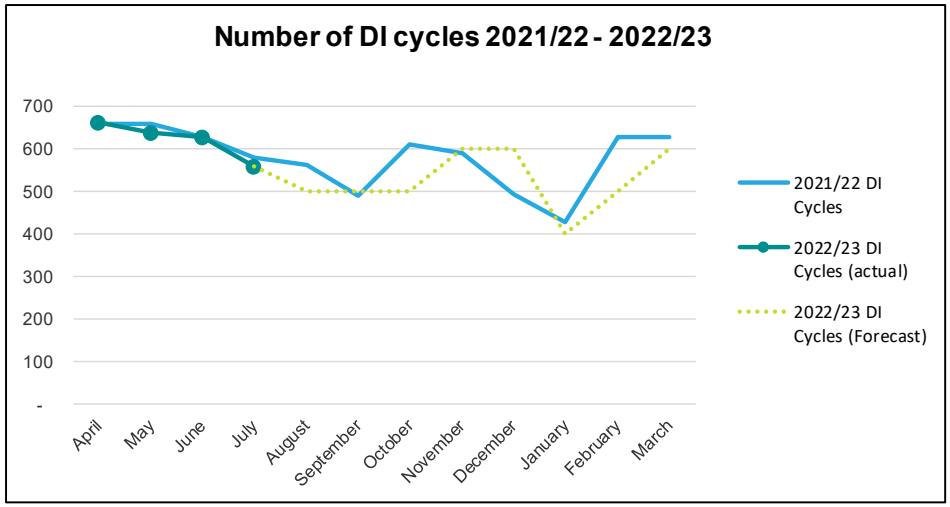
Financial management information

2022/23 Income



IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2021/22 IVF Cycles	23,031	1,842,480	65,266	5,221,253
2022/23 IVF Cycles (actual)	23,018	1,841,440	69,108	5,528,640
Variance	(13)	(1,040)	3,842	307,387

There is a small variance of IVF cycles against 2021/22 as at 31 July; a 0.06% drop. If the trend continues, our forecast year end position suggests a drop in income of c5% (£5,528k vs £5,806k as per management accounts).



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2021/22 DI Cycles	2,528	94,800	6,968	261,300
2021/22 DI Cycles	2,491	93,413	6,691	250,913
Variance	(37)	(1,388)	(277)	(10,388)

DI volumes are higher 1.5% lower than the same period last year. Year end position suggests a 3.9% reduction on last year.

The introduction of PRISM last year required that we raise estimated bills based upon the 2020/21 financial year. This has continued whilst clinics catch up with their submissions. There is a risk that our estimations may be significantly different from the actuals when they are finally agreed. Reconciliations are being conducted monthly and it is hoped that clinics will have caught up by Q2.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

HFEA Income & Expenditure **Jul-22**

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	373	373	-	-	1,098	1,098	-
Non-cash (Ring-fenced RDEL)	88	88	-	-	352	265	87
Grant-in-aid - PCSPS contribution	25	25	(0)	(0)	100	100	-
Licence Fees	1,909	1,973	64	3%	5,881	5,842	39
Interest received	8	0	(7)	(16)	1	1	(0)
Seconded and other income	43	48	6	12	110	145	(35)
Total Income	2,446	2,509	62	**2**	**7,542**	**7,451**	**91**
Revenue Costs							
Salaries (excluding Authority)	1,611	1,685	74	4	5,068	5,068	-
Staff Travel & Subsistence	19	32	13	42	127	127	-
Other Staff Costs	22	28	6	22	106	106	-
Authority & Other Committees costs	78	74	(4)	(5)	231	231	-
Facilities Costs incl non-cash	146	233	87	37	711	711	-
IT Costs	121	217	96	44	657	657	-
Legal / Professional Fees	178	82	(96)	(117)	328	328	-
Other Costs	42	64	22	34	241	240	(1)
Other Project Costs	0	-	(0)	-	-	-	-
Total Revenue Costs	**2,217**	**2,417**	**199**	**8**	**7,470**	**7,469**	**(1)**
TOTAL Surplus / (Deficit)	**229**	**92**	**137**		**72**	**(18)**	**90**
Adjusted for non-cash income/costs	**186**	**90**	**96**		**(15)**	**(18)**	**3**

Management commentary

Income.
At the end of July (month 4)y our total income is under budget by 2.5.% (£62k).We continue to bill clinics based upon activity levels in 2020/21. Over 60% of clinics are more or less caught up with entering their treatment data into PRISM, however there are a few large clinics who are yet to catch up. This makes it challenging to ascertain what our total income for 2022/23 will be. Further reconciliations are being conducted at the end of each month. It is hoped that by the end of Q2, we will have more certainty over our income.

Expenditure by exception (over £10k variance).
At the end of July, we are under budget by £199k
Salaries - currently under budget by £74k. There are underspends within salaries and wages of £190k which are offset by overspends within contingent labour of £110k and shared services of £6k.

Staff Travel & Subsistence - £12k under budget, all relate to inspections.

Facilities costs - underspent by £87K, We are underspending on accommodation costs by £32k which relate mainly to Service Charges which were based upon figures supplied by DHSC last year. Actual charges have come n lower than accrued. We are underspending on internal meeting costs by £7k where meetings such as AGC have been held virtually. In addition we have an underspend (£43k) within our non-cash costs, all of which relates to the capitalisation f PRISM costs. At the end of last year, we impaired (wrote down the value) of PRISM after conducting assessment based upon the original budget and business case and the advice of our external auditors. This reduction has impacted the amortisation costs being charged to the income and expenditure account in year which is lower than budgeted for..

IT Costs - underspent by £96k. The main underspends are within our Support costs £90k, IT Subscriptions of £13k and Low value fixed assets of £3k. The reduction in both support and subscription costs is due to reduced usage of Alscient (Support contract) and within the contract renegotiated for Microsoft Office subscriptions. Offsetting the above are small under and overspends within Photocopying, IT Low value software, Internet and Consumables.

Legal/Professional fees - are over budget by £96k. All of the overspend is within Legal and in particular, spend on policy advice is over budget by £56k; Committee Advice, Litigation and Register/FOI are overspent in total by £21k. Legal Other which contains the cost of seconded staff and is over budget by £32k.The balance are within Reps, Hearings and Appeals and Governance where no expenditure has been incurred year to date.

Other costs - are underspent by £22k with the most significant variances are within Strategy and Corporate Affairs Stakeholder Events costs of £13k which usually covers the costs of annual conference or regional workshops. There are small over/under spends sub £5k across areas within the Compliance and Information directorate.

Forecast - due to the ongoing issue with reconciling our income, we are currently forecasting to budget. This is expected to change once we are more certain of what our income is to be for the year which will impact on what funds are available for the remaining 8 months of the year. At the end of Q2 we will conduct a detailed assessment of both income and directorate plans.

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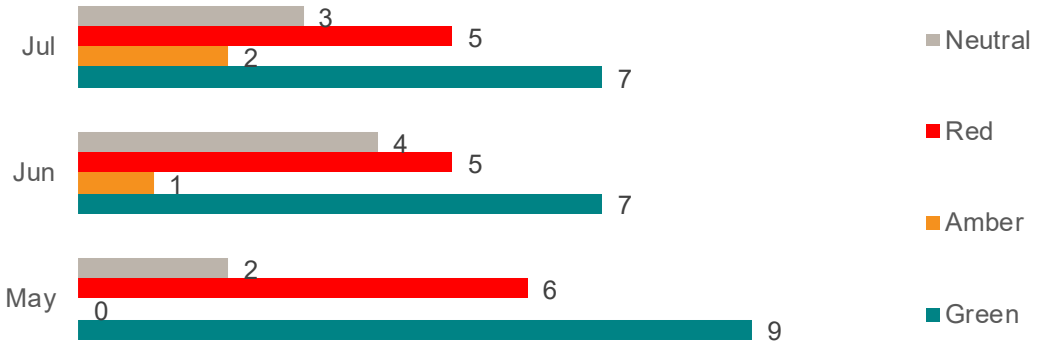
Key performance indicators

Human Fertilisation & Embryology Authority

RAG status over last 3 months

17 KPIs in total



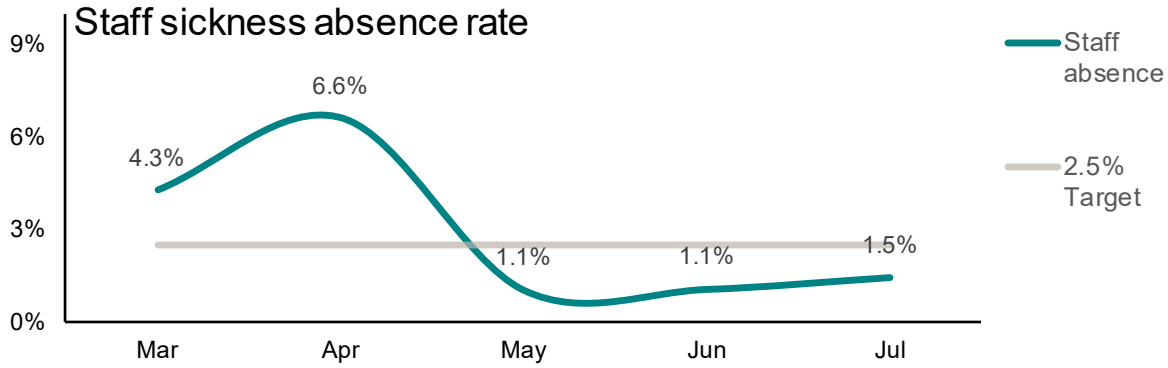
For July, the red indicators are:

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

Status: Green

HR1 – Sickness

Target:
Less than or equal to 2.5%



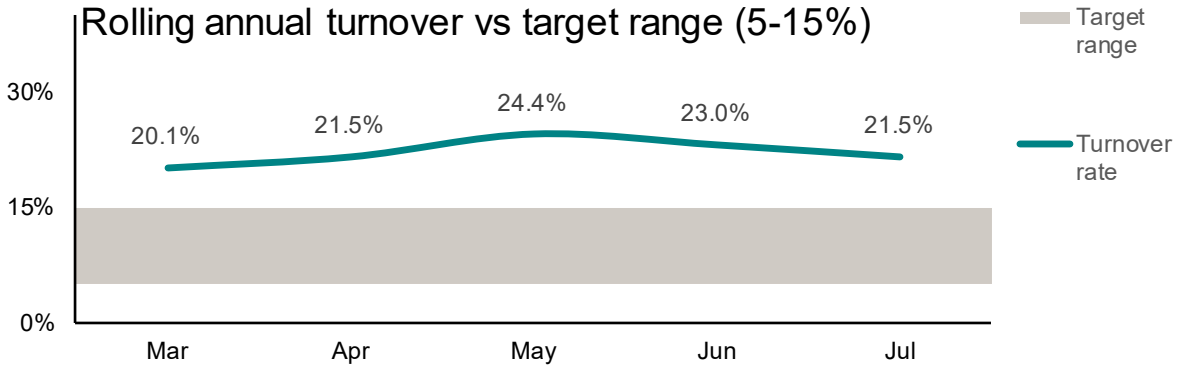
Sickness absence is relatively low - we have seen an increase in Covid numbers with 17/24 days lost to Covid related cases.

Turnover is coming down.

Status: Red

HR1 – Sickness

Target:
Less than or equal to 2.5%



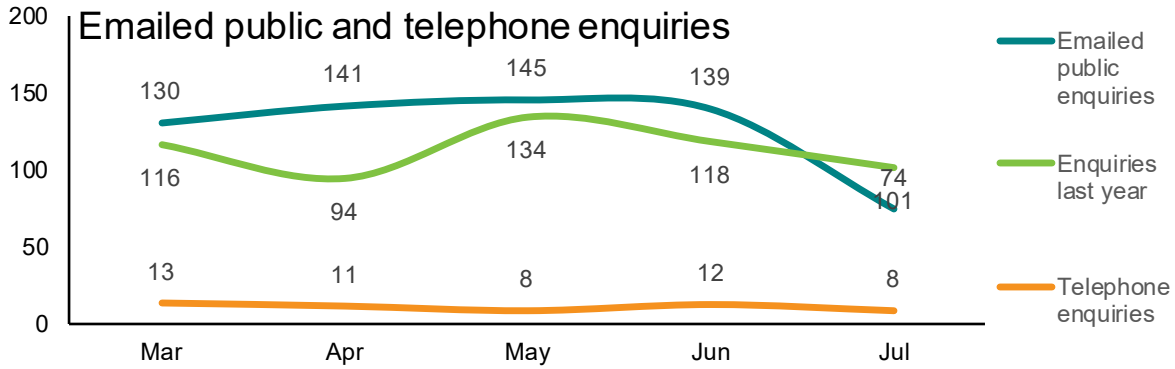
Supplementary HR data

Headcount : 71
Posts : 76
Starters : 3
Leavers : 1

Status: N/A

Emailed public and telephone enquiries

Target:
None defined

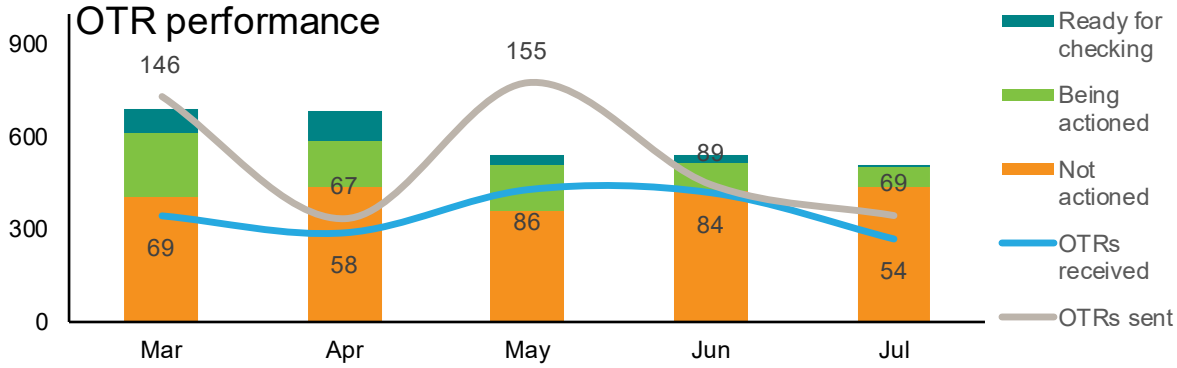


No commentary entered in report.

Status: N/A

I1 – OTR performance

Target:
To be developed

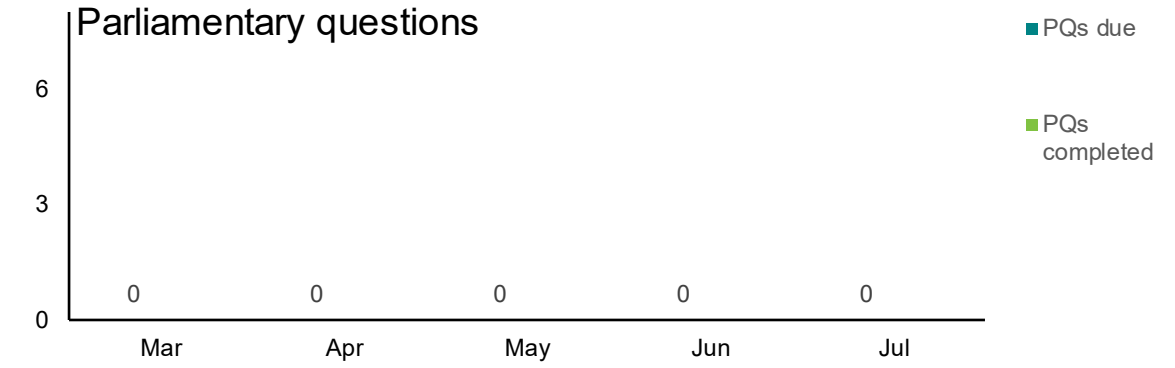


Fewer OTRs sent out and allocated due to staff shortage from annual leave and attrition. Fewer numbers of OTRs and DSL applications (12) received.

Status: Neutral

RI1 – PQs responses

Target:
100% within deadlines set

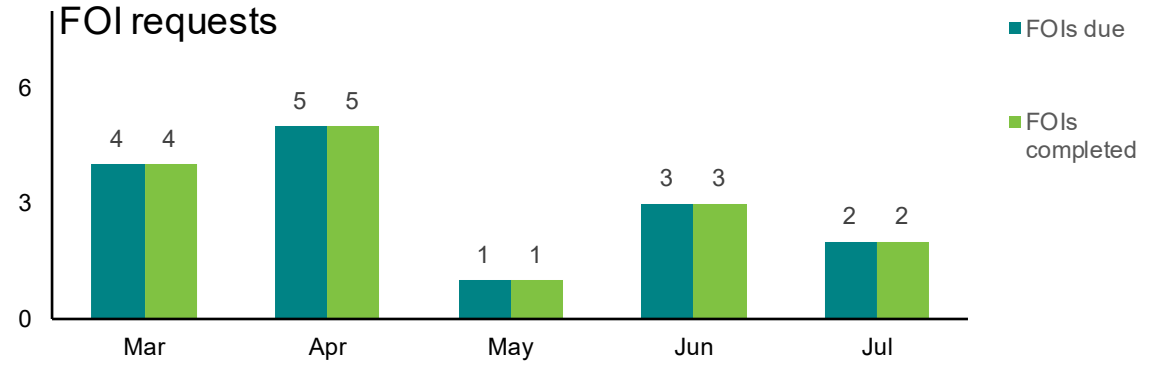


No PQs received or due

Status: Green

RI2 - FOI responses

Target:
100% within statutory deadlines

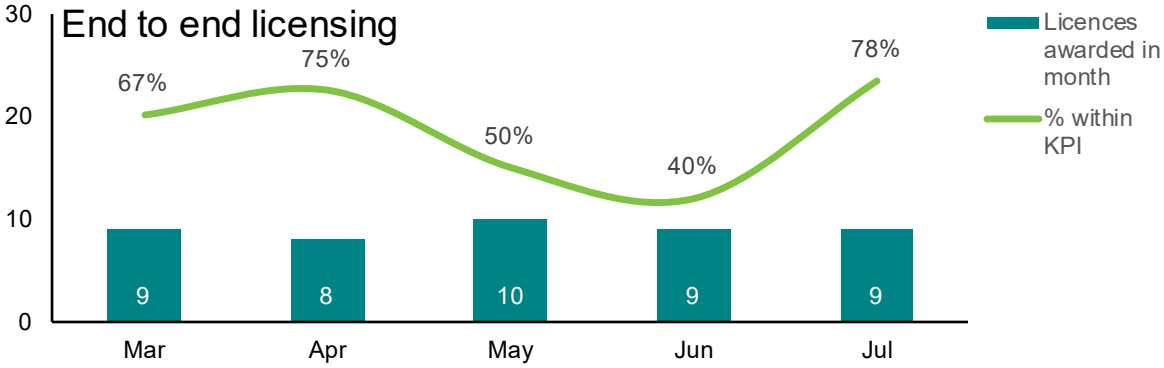


Enquiries have decreased, however the complexity of data requests seems to have increased.
There have been a number of requests for data that can be found published in CaFC.

Status: Red

C3 – End to end licensing process

Target:
100% completed within 70 working days



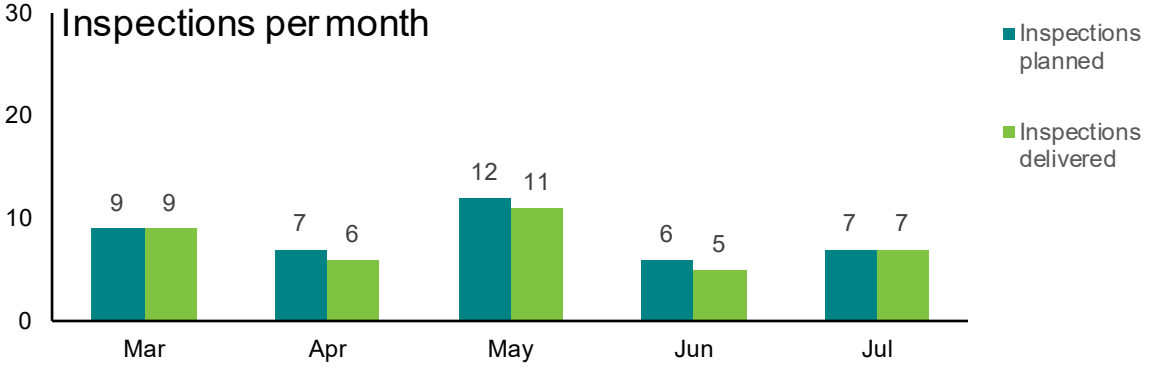
(83 days): concerns post inspection, 2nd virtual inspection, meetings with PR; several revisions of report post QA.

(113 days): complex report; conflicting availability of the inspection team; lead dealing with complaints/whistleblowing work; additional targeted inspection.

Status: Amber

C1 – Inspections delivered to date

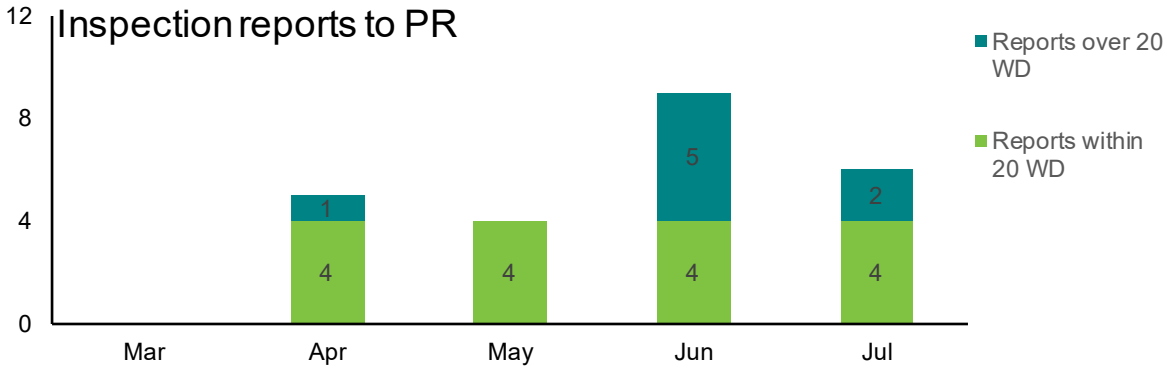
Target:
95% completed



*1 additional inspection (change of premises).

Status: N/A

Reports sent to the PR within 20 working days of an inspection



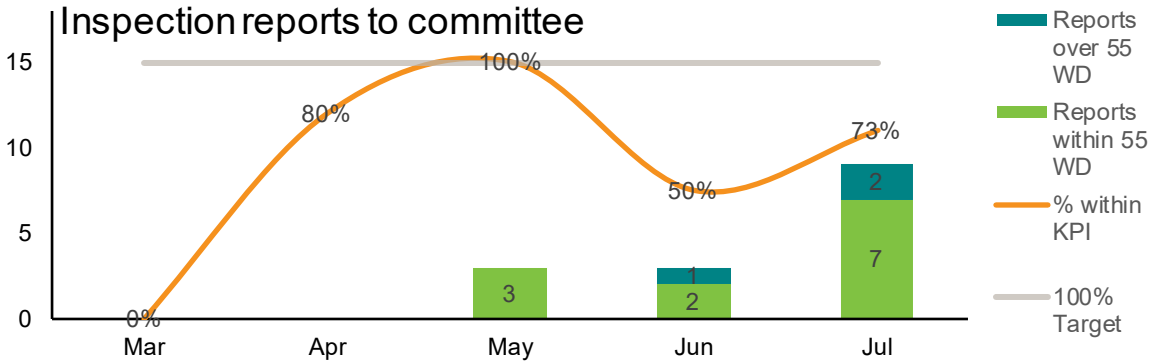
25 days - delay in sending to PR due to PR leave.

Not sent yet to PR - delay with team QA due to annual leave, requirement for a C&E assessment and further amends to report; change of inspector writing report to PR (August) due to unforeseen circumstances.

Status: Red

C2 – Inspections reports sent to committee

Target:
100% sent within 55 working days



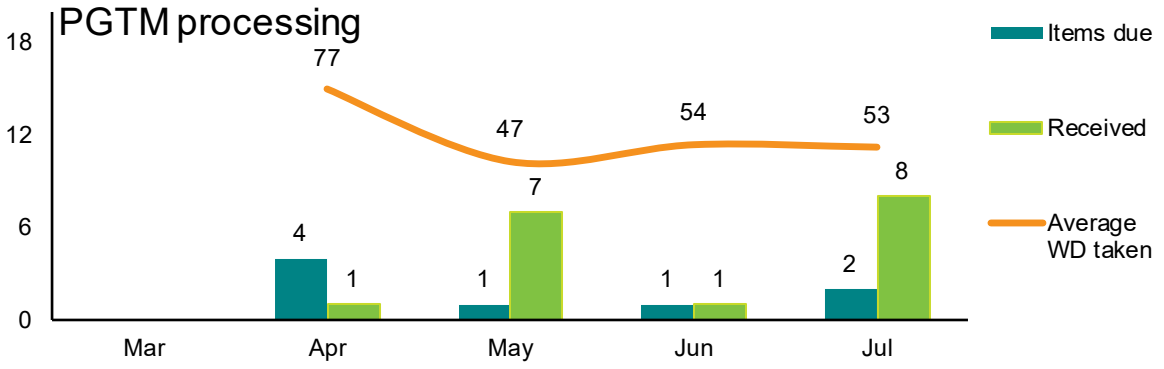
59 days - delay in sending report to PR due to re-allocation of QA due to annual leave.

Not yet sent to Committee - change of PR so report returned late; PR invited to meet with HFEA 01/09/2022; complex report and centre history; requires to LC instead of ELP.

Status: Green

C5 – PGTM processing efficiency

Target:
100% within 75 working days

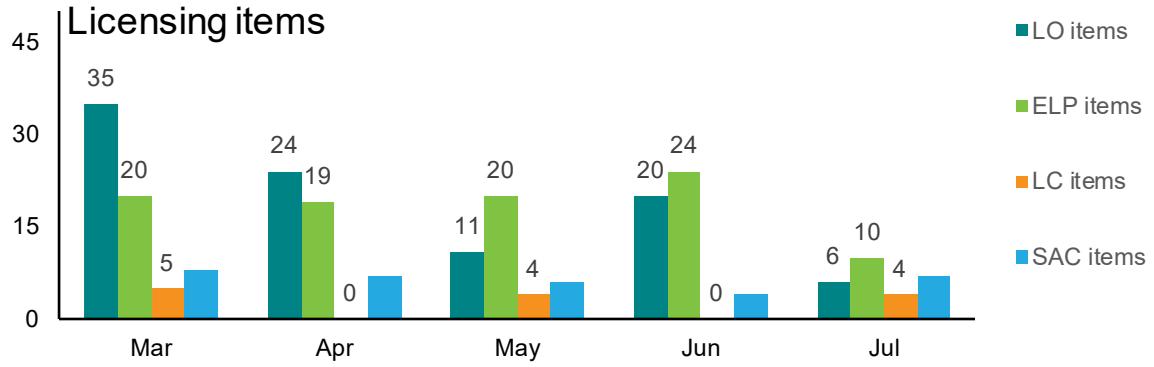


No commentary entered in report.

LO status:	Green
ELP status:	Green
LC status:	Amber
SAC status:	Green

L1 - L4 Licensing efficiency

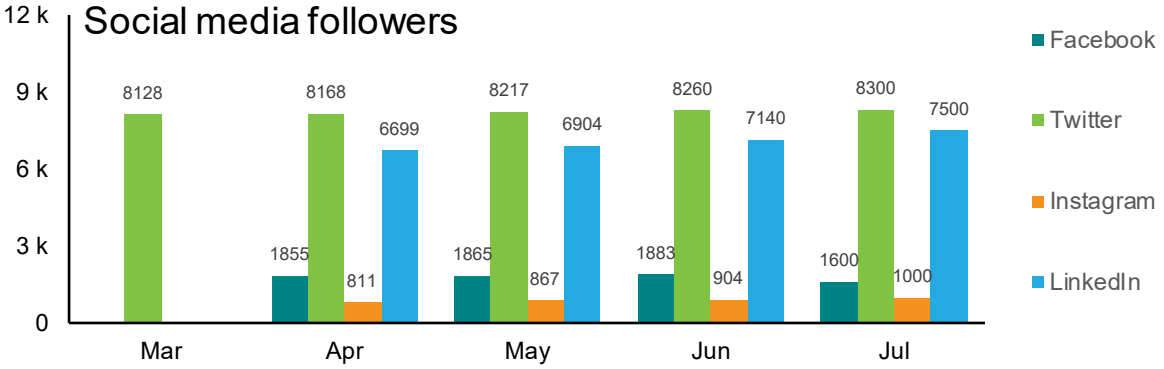
Targets (WD):
LO - 5, ELP - 10
LC - 15, SAC - 20



LC - one especially complicated decision made (to vary a licence without application, to remove an activity type) which involved extra liaison with legal adviser when drafting minutes, notices and licences

Status: N/A

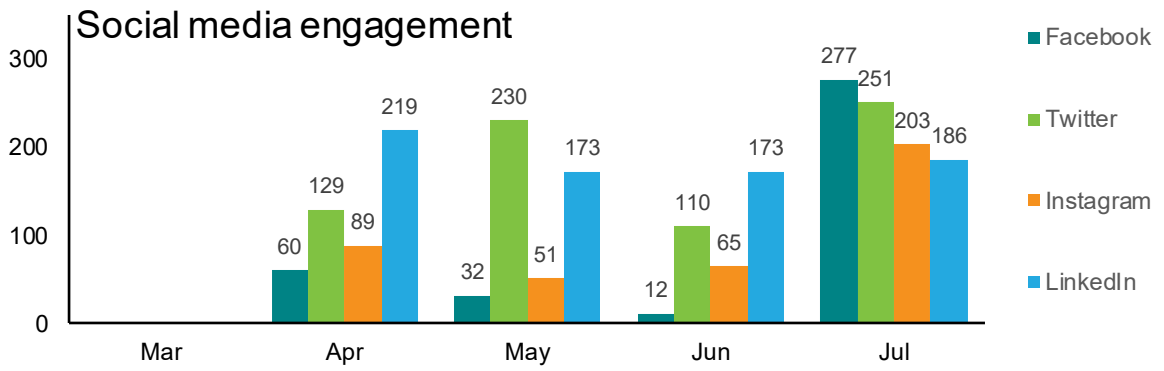
Total number of followers across social media



The engagement on all our channels increased this month. Our highest performing posts related to the changes to the storage law. This was well received and highly engaged with by our audience and stakeholders across all our channels.

Status: N/A

Engagement across social media (measurement systems vary)

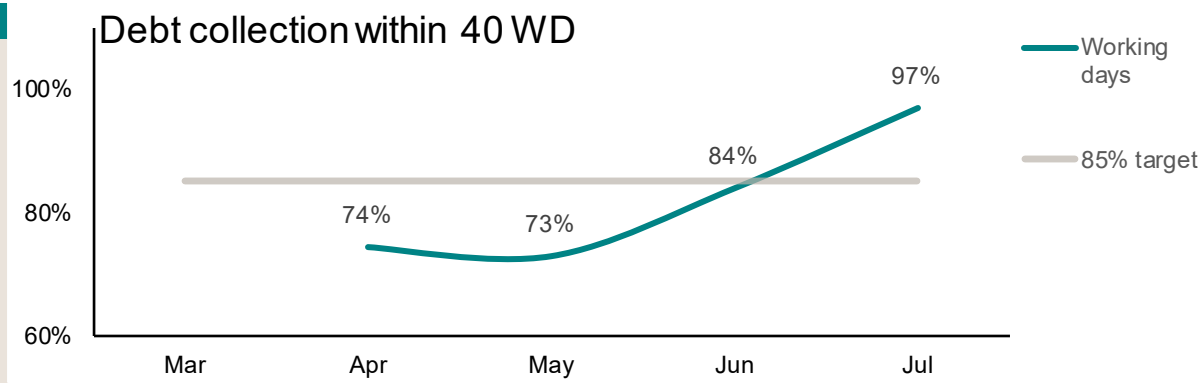


Commentary combined with social media followers.

Status: Green

F1 – Debt collection

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

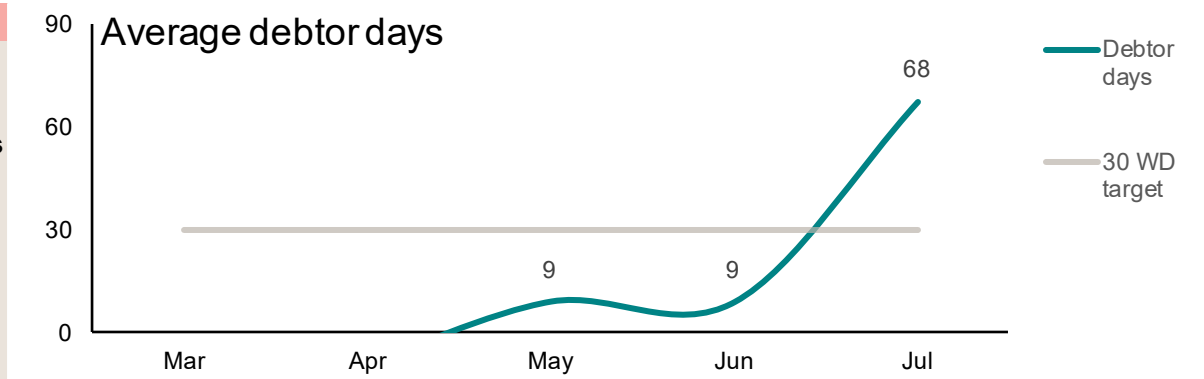


F1 - no commentary

Status: Red

F2 – Debtor days

Target:
30 working days or less

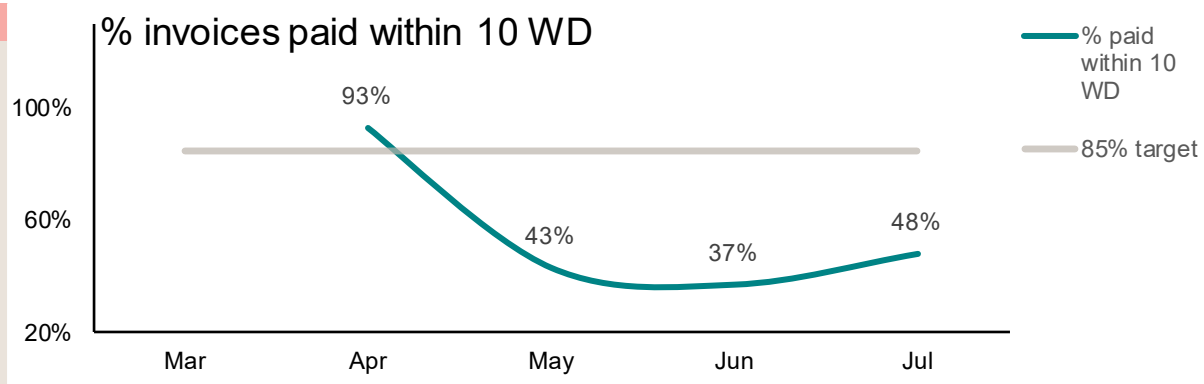


F2 - 2 months billing carried out which resulted the high debtors balance. Once PRISM rollout is complete and figures can be fully verified, this metric will return to normal.

Status: Red

F3 – Prompt payment

Target:
85% or more invoices paid within 10 days



F3 - non PO invoicing and late invoice approval caused the delay in payment here. New staff and others will be given greater awareness of finance procesess.

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Implementation of the new gamete and embryo storage rules

- The storage changes follow a successful campaign to extend the reproductive choices of patients who previously could only store for a maximum of 10 years unless they were prematurely infertile.

- We welcomed the changes, but the new rules have also given rise to some significant challenges.

Anna Wilkinson
Regulatory Policy manager
14 September 2022
www.hfea.gov.uk

Key changes for patients and donors

- **All patients** may store their gametes or embryos for their own treatment for the maximum of 55 years, but they can only do this if they ‘renew’ their consent to storage, and this must take place within 10 years of first storage and at each successive 10-year period. There is no longer a requirement for patients to satisfy premature infertility criteria.

- **Donors** storing gametes or embryos can give consent to storage for 55 years and are not required to renew their consent

- Patients storing their gametes or embryos for treatment who have consented to **posthumous use and/or use in the event of losing capacity** centres can store for a maximum period of 10 years from the date of death / patient is certified as having lost capacity.

- New storage periods for **training and research** material

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Project team

- Dedicated team to work on implementing new storage rules with expertise from across the organisation and external support including sector professionals who helped to develop materials
- All other work was deprioritised recognising the urgency and time-dependent nature of this work, with impacts on the broader organisational capacity
- Advice was sought from sector professionals, such as BFS and ARCS and others on reviewing new consent forms and guidance

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Key challenges for the HFEA

- Short lead in time to implementation meaning large volume of work needed to take place in short period, with extra internal and external resources required
- Complex legislation meaning consent forms are longer, and interpretation of legal implications in specific areas not always clear, e.g posthumous use
- Updating consent forms to reflect the new legal requirements
- Producing clinic guidance and explaining the change in approach to consent to clinics

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Achieved between 1 February 2022 and 1 July 2022

- Issued 17 updated consent forms
- Published 5 new consent forms
- Published 6 new statutory notices for use when renewing consent
- Developed detailed clinic practical guide
- Updated General Directions
- Updated Licence Conditions
- Range of draft materials published by end of May

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Support for clinics

Aim to support sector understanding of how the new legislation applies to new patients and for those with material in storage pre 1 July 22

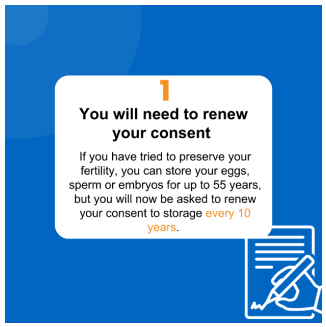
- Weekly drop-in sessions with Director of Compliance: Presentation followed by open questions. 6 conducted to date with 184 clinic staff sign-ups (though attendance likely to be higher)
- Over 200 separate clinic enquiries received
- Flow charts published to aid clinic processes
- Staff have given presentations at stakeholder events e.g. BFS study week
- Information video on re-consenting patients under new legal regime published with others in development
- FAQ in development to support clinics staff

How have we engaged with patients?

1. Provided a **stakeholder toolkit** which contained:
- Infographics
- Social media schedule
- News story
- Key messaging

2. Sourced **speaking opportunities** e.g. FNUK / Chana Webinar and Insta live event

3. Building partnerships with patient facing organisations to share **patient experiences** and raise awareness. For example, a blog for HFEA website with *Young Lives vs Cancer*



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Feedback from Clinics

- Clinics face challenges in terms of timeframe for implementation
- The new legislation is particularly complex for patients with material already in storage e.g. defining renewal periods depends on the regulations currently stored under 1991 / 1996, 2009, 2020
- Lengthy consent forms required to ensure compliance with new provisions
- Many centres re-consenting existing patients so that they can benefit from new provisions
- Implications of women consenting to posthumous use on WT is time consuming (to note no change by 2022 regulations but arising from Jennings case)
- Difficult to interpret and understand implications for patients already deceased with material in storage on 1 July 2022

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Risks

- **Patients already storing under the 2009 regulations**: these patients were previously able to consent for up to 55 years' storage without needing to re-consent. Clinics could complete MPS in the relevant periods without patient involvement. Under new legislation these patients must now reconsent when their MPS expires and every 10 years after. Clinics concerned they will not be able to contact patients, and material that patients would consider to be lawfully stored for up to 55 years will need to be disposed of

- Donors can now store for up to 55 years. Risk of donors and recipients not being counselled adequately on the implications of using material from donors that has been in long term storage

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Looking forward

- Continue to support clinics through enquires, information videos, flowcharts and drop-in sessions
- Take a proportionate approach at inspections during the first 12 months of the transitional period
- Publish an updatable FAQ in September/ October 2022
- Update Code of Practice to reflect storage changes in 2023

Human Fertilisation & Embryology Authority

Update on ethnic diversity in fertility treatment

Details about this paper

Area(s) of strategy this paper relates to:	The best care/the right information
Meeting:	Authority
Agenda item:	7
Meeting date:	14 September 2022
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Anna Coundley, Policy Manager
Annexes	Table of Actions following publication of report in March 2021

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to: • Outline any areas where further work that could be carried out • Agree the prioritisation for this work given resource pressures and capacity • Agree any next steps and involvement for Authority members going forward.
Resource implications:	Staff resources required to continue with this work
Implementation date:	Ongoing
Communication(s):	Through updates to clinics, stakeholders and patients via our website and social media
Organisational risk:	Low

1. Introduction

1.1. In March 2021 we published the Ethnic Diversity in fertility treatment 2018 report, which highlighted disparities in access to, and outcomes of, fertility treatment by ethnic group from 2014-18. The report, which is based on data from our Register, includes broad interpretations of why disparities may exist with reference to peer-reviewed academic or other publications.

1.2. Key findings showed that people from ethnic minority backgrounds undergoing fertility treatment are less likely to have a baby, with Black patients having the lowest chances of successful treatment. Black patients also had the highest multiple birth rates of any ethnic groups. While disparities for Black patients are the most notable, other ethnic groups also have worse outcomes when going through fertility treatment. Asian patients, who represent a larger proportion of IVF users are struggling to access donor eggs if needed.

1.3. In response to the findings in the report, the HFEA committed to take several actions to address the findings of the report.

1.4. This paper updates the Authority on these actions and outlines possible next steps to be taken.

2. Key findings from Ethnic Diversity in Fertility Treatment report

2.1. The key findings from the Ethnic Diversity in Fertility Treatment report were:

- Black patients had lower IVF birth rates: for Black patients aged 30-34, the birth rate per embryo transferred was on average 23% compared to Mixed and White patients at 30% from 2014-2018. Black patients reported higher rates of tubal factor infertility, accounting for 31% of patient-based infertility compared to the 18% average from 2014-2018
- Black patients had the highest multiple birth rates of any ethnic groups at 14%, compared to a national average of 12% from 2014-2018.
- Black patients generally started IVF at later ages than other ethnic groups at an average age of 36.4, compared to the national average of 34.6 in 2018.
- White egg donors were most commonly used among most ethnic groups, with White egg donors used in 98% of cycles with a White patient, 59% of cycles with a Mixed patient, and 52% of cycles with an Asian patient. Sperm donations from Mixed (76%), Other (64%) and Black (63%) donors were more likely to be imported from 2014-2018.
- There was some variation in NHS-funded IVF cycles across ethnic groups, particularly in younger patient age groups.

2.2. This work should be considered within the wider context of the Government's objective of reducing health inequalities, particularly among Black and ethnic groups. There have also been several other recent reports highlighting health inequalities, particularly for Black women, including the NHS Race and Health Observatory 's (RHO) Ethnic Inequalities in Healthcare: A Rapid Evidence Review and the MBRRACE-UK Saving Lives, Improving Mothers' Care report, as well as the government's Women's Health Strategy for England.

3. Actions taken since March 2021

3.1. The table in Annex 1 gives more detailed information about the actions taken in response to the findings published in March 2021. As noted above, there has been a wider focus on inequalities in healthcare and in particular on negative impacts on Black women. This has meant that our report is now placed in these discussions, but that does not mean there are resources to resolve the issues identified in fertility treatment.

Patient views

3.2. In 2021, we carried out our second national patient survey and included additional questions relating to issues raised in the Ethnic Diversity in Fertility Treatment report. Of the 1,233 responses, 6% of respondents were Asian, 2% Mixed, and 2% Black. The resulting Patient Survey report, published in April 2022. 'Black, Asian, Mixed and Other' ethnicities were grouped to allow comparison by ethnicity, due to small numbers of Black respondents. Findings relating to differences in patient experience between ethnicities are unlikely to be statistically significant because of the small numbers, but some of the findings mirrored those from the data report - for example, White patients are also more likely than Black, Asian, Mixed or Other ethnicity patients to have spoken to their GP earlier.

3.3. We will continue to work to understand patient views further, including potential joint working with Fertility Network on specific areas such as information on success rates.

Clinic views

3.4. The findings have been discussed with different groups including at our professional bodies' stakeholder group and with clinic staff. A working group of clinic staff met for two workshops to discuss specific topics raised in the report.

3.5. A workshop on **donor availability and multiple births** took place in March 2022.

3.6. The group discussed the issues patients from ethnic minorities may have finding a 'matching' donor. The group agreed that the specific background, community and religious beliefs of a person may influence willingness to donate and that different approaches may be needed to tackle factors that impact different communities. The relationship between donor and clinic is important for recruitment and the pandemic has impacted on 'word of mouth' referrals. It was suggested that there may be uneven distribution across the UK of donations from particular ethnicities, depending on the region.

3.7. The idea of a National Sperm Bank for England was discussed as way to address some of the issues e.g., local variation. There are existing questions about the funding available for this. Learning from the example of Scotland's National Sperm Bank would be useful.

3.8. In terms of the higher rate of multiple embryo transfer (and corresponding higher multiple birth rate) in patients from some ethnic groups, the interactions between ethnicity, age and access to treatment was seen as contributing to this. There was agreement that the desired outcome of treatment is one healthy baby, and this should be clear to patients from the beginning of their treatment.

3.9. The group discussed ways to overcome barriers to communication where they exist for some patients whose first language is not English, including the possibility of the HFEA working with Fertility Network to create content in key languages

3.10. The second workshop on **success rates and access to treatment** took place in June 2022.

3.11. Many attendees reported that their clinic did not discuss ethnicity with patients as a specific factor affecting the chance of a live birth. The group was not sure that a patient being from a particular ethnicity means that they will automatically (when other factors are controlled for) have a lower/different chance of success e.g., there is a higher prevalence of fibroids amongst Black women, but only some Black women are affected. The group described the importance of providing transparent information about success rates, but there was concern about whether it was accurate or helpful to tell a patient that their ethnicity may result in a lower chance of a live birth, given the limits of the available data.

3.12. The group agreed on the importance of early access to treatment with no delays from primary care onwards and discussed reasons for later entry into treatment, mentioning cultural stigma about fertility treatment and a reluctance, particularly amongst male partners, to come in for treatment or investigations. Ways of reducing barriers to access suggested by the group included clinic websites being more representative of different ethnicities, equality and diversity training for clinic staff, more counsellors who are Black or from different ethnic communities, the availability of interpreters and information provision in different languages and the importance of co-production and working with communities when designing initiatives to support these groups.

Our data

3.13. The report identified a need to better enable research on the disparities between Black and ethnic minority groups within the fertility sector. In response to this we have added information to our annual data report, Fertility Trends, to provide up-to-date information on fertility outcomes by patient ethnicity. Our publicly available anonymised dataset for 2017-2018 now includes variables that enable research on variation in treatment and outcomes by ethnicity. We will also be discussing with some clinicians what more can be done to use the data we hold in this area.

3.14. We hope to provide an update from our Register on the Ethnic Diversity in fertility treatment report over the next 12-18 months.

Encouraging research

3.15. We recognise that our report was limited by the data we hold on our Register and that there is a need for more research to understand the many external factors that contribute to disparities our report identifies. We have been contacted by researchers using our publicly available anonymised register to research differences by ethnicity – some currently submitting for peer review. We have also been working with some other researchers using our data.

Information provision

3.16. We have been looking at what information we provide, for example, whether new web content is needed to better serve patients from ethnic minority communities. We could pursue, with Fertility Network, patient information for clinics to use to explain the ethnic diversity data to patients, especially around success rates.

National Sperm Bank for England

3.17. Further discussions could take place in due course regarding the establishment of a National Sperm Bank for England. The HFEA could bring together various professional bodies and others to discuss this if there was enthusiasm for carrying forward in future. However, progress

on this would require resources from other organisations. The HFEA does not have such resources, nor would it be appropriate for the regulator to fund (or part fund) a regulated entity.

Wider health service changes

3.18. Although we had some early engagement with primary health care staff, including through the Primary Care Women's Health Forum, we have not been able to prioritise this in large part because of the pressures on primary care post pandemic. We have had various discussions through the RCOG Race Equality Taskforce and the British Fertility Society about joint actions that could be taken but this needs some further time to identify specific actions. Our data is being used in the current discussions regarding the NICE fertility guideline review. In our response to the government's consultation on the Women's Health Strategy we highlighted the disparities between ethnicities in treatment outcomes, access to 'matching' donor gametes, and patient age at their first IVF cycle and that more work and research should be done on exploring the inequalities faced by Black and ethnic minority patients.

4. Next steps

4.1. We have committed in our 2022-2023 Business plan to continue our work addressing disparities in access, experience and outcomes, including those identified in the 'Ethnic Diversity in Fertility Treatment 2018' report and patient survey.

4.2. We will work with the RCOG Race Equality Taskforce, British Fertility Society, Fertility Network and others to ensure the issues raised by our findings continue to be addressed.

4.3. If this work is to be prioritised then we will need to effectively resource it, likely meaning other work is deprioritisied.

5. For decision

5.1. The Authority is asked to review the actions taken in response to the Ethnic diversity in fertility treatment report and to:

- Outline any areas where further work could be carried out
- Agree the prioritisation for this work given resource pressures and capacity
- Agree any next steps and involvement for Authority members going forward.

Annex A - Table of Actions following publication of Ethnic diversity in fertility treatment in March 2021

	Action	Update
1.	We will speak to patients to determine where differences in patient experience may exist and use this information to identify where we, as a regulator, can promote greater equity across the fertility sector.	Patient survey took place in November 2021. Of a total 1,233 responses, 6% (n=73) were Asian, 2% Mixed (n=28), 2% Black (n=25). Small numbers will make the analysis challenging, but work will be done to understand any differences where possible. The Patient Survey report has been published, and within this we were able to look at differences by ethnicity. However, in order to do this, we had to combine 'Black, Asian, Mixed and Other' ethnicities. Due to low numbers, findings are unlikely to be statistically significant, but provide a baseline. The findings were also presented and discussed at the Spring 2021 patient organisations stakeholder meeting.
2.	We will review the feedback from clinics and patients against our Code of Practice to see if we should make any changes, for example, relating to information provision.	Findings discussed at July 2021 Licensed Centres Panel meeting. Members for more in-depth clinic workshops were asked to volunteer. Two workshops took place as outlined above and attendees maybe consulted as further work develops. The report was also presented and discussed at the Spring 2021 professional stakeholder group meeting. More evidence is needed before we know what changes need to be made to Code, if any Any future Code updates may consider including wording about personalisation of success rates following discussions at clinic workshops.
3.	We will consider whether we should provide further specific information on our website for Black and Ethnic minority patients, for example, in relation to particular medical issues or donor availability.	Information provision was discussed in more detail at the second clinic workshop and there is appetite for the HFEA to work with Fertility Network to provide patient facing information for clinics to use. This could be developed in future.

	Action	Update
4.	To better enable research on the disparities across ethnic groups within the fertility sector, we will include more information on ethnicity in our regular data releases. We will add tables to our annual statistical release, Fertility Trends, to provide up-to-date information on fertility outcomes by patient ethnicity. The upcoming release of our publicly available anonymised dataset for 2017-2018 in Spring 2021 will also include variables that enable research on variation in treatment and outcomes by ethnicity.	The anonymised Register was published in November 2021 with the updated information. We have also added further information to our annual Fertility Trends data as agreed.
5.	The issue of accessing donors of certain minority ethnic backgrounds has been identified here, and in other publications. While we are not involved in donor recruitment, we must be conscious of the difficulties some patients face in finding a donor with a shared ethnic background and raise awareness of this where we can. We will continue to monitor and publish figures on donor use to draw attention to any lack of donors from a particular group.	This was discussed at the clinic workshops and there are some suggested ideas to take forward, subject to resources.
6.	We will work with grassroots and other organisations to further understand cultural and religious beliefs that may impact on donor recruitment and help to overcome any barriers that may exist.	We have worked directly with some individuals who have helped promote the findings of the report at a grassroots level but would need further resources to do more. Potential to work with Fertility Network on this in the future.
7.	We have committed to engaging with GPs in our 2020-2024 strategy and will ensure we share the data we have with them, highlighting for example that in some communities, access to fertility treatment is starting at a later age.	We have promoted the findings via the Primary Care Women's Health forum to primary care staff. Wider work with GPs has stalled because of the pandemic but has now been written into the Government's Women's Health Strategy.
8.	The Royal College of Obstetricians and Gynaecologists (RCOG) recently established a Race Equality Taskforce and one of its key priorities is to look at inequalities in women's health outcomes, including areas of women's health where ethnic disparities may exist. We will present the findings of this report to the RCOG Race Equality Taskforce and we look forward to their feedback and any further recommendations of actions we or others could take.	April 2021- presentation to the NHS Race Health Observatory maternal health group September 2021 – presentation to the RCOG Race Equality Taskforce Various follow up discussions ongoing with the RCOG Race Equality Taskforce and the BFS.

	Action	Update
9.	We urge clinics to review their own information provision in relation to the statistics in this report to ensure all patients are informed of their own likely chance of success based on all factors, including ethnicity.	This was reiterated by the clinic workshops. We now need to decide how to take this forward.
10.	We publish donor waiting times by ethnicity on our Choose a Fertility Clinic webpage and we encourage all clinics to regularly update this information **–** especially if the wait is longer for different ethnicities – to help patients who require donated sperm and eggs to plan their treatment.	Clinics have been reminded of the importance of updating donor waiting times on the Choose a fertility clinic pages of our website.
11.	Clinics should be mindful of the higher multiple birth rate in certain ethnic groups and seriously consider a review of their multiple birth minimisation strategies where necessary.	Some data relating to this was published in our report on **multiple births** in February 2022. Further work to be discussed possibly via the BFS.
12.	Clinics are also asked to ensure ethnicity information is collected from patients. Currently 12% of patients have no ethnicity data recorded on our Register.	Reminders to go out relating to this in Clinic Focus
13.	We encourage all those who commission fertility services to review their funding eligibility criteria to consider whether these have an adverse impact on access to treatment among particular ethnic groups.	This is to be fed into discussions regarding NICE fertility guidelines review.
14.	This report is limited by the data we hold on our Register and more research is needed to understand the many external factors that contribute to these disparities to inform evidence-based decision-making	Working towards publication with clinicians in a peer-reviewed journal. June 2021 - presented at ESHRE pre-congress in June 2021 Sit on the stakeholder advisory group of a research project looking at *Bordering Reproductive and Maternal Healthcare of Ethnic Minority and Migrant Women in England*. The stream on infertility draws on recommendations from our report. We have been contacted by researchers using our publicly available anonymised register to research differences by ethnicity – some currently submitting for peer review We are working with a research team at UCL looking further at

	Action	Update
		disparities in access by ethnicity using bespoke updated ethnicity data and data from our National Patient Survey.
15.	More in-depth data is available to researchers upon application through the HFEA Register Research Panel and we encourage researchers to get into contact with us at **register.research@hfea.gov.uk** if interested.	Further work on promoting register data is planned to take place in 2023.

Modernising Fertility Regulation - update

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	8
Meeting date:	14 September 2022
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Laura Riley, Head of Policy (Scientific) Ana Hallgarten, Public Policy Manager

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to: • Discuss the topics outlined • Consider any particular issues they would like to discuss further
Resource implications:	Staff resources as planned in the current business plan
Implementation date:	Ongoing
Communication(s):	As outlined in the paper – through regular public and stakeholder updates
Organisational risk:	Medium

1. Introduction

1.1. A key HFEA strategic priority is to develop a proposal on modernising the law to ensure it remains relevant. This is a long-term piece of work with several distinct stages culminating initially with a report to the DHSC probably in December/January. It will be for the Government to take forward any reform proposal, which given the parliamentary timetable could yet be some time away.

1.2. Previous updates to the Authority in February 2022, May 2022, and July 2022 have noted the background to this work and developments to date.

1.3. This paper provides an update on activities and issues since the last Authority meeting in July 2022.

1.4. Section 2 summarises the key topics that the Authority have agreed to focus on. Section 3 outlines activity since the last Authority meeting. Section 4 outlines the progress made with the targeted consultation. Section 5 introduces the next stage in the project, the report, and Section 6 the next steps.

2. Key topics

2.1. To recap, the key topics that the Authority has previously agreed to look at in more detail are:

Patient protection

- The Act is silent on patient centred care
- There is a limited range of enforcement mechanisms or sanctions to drive improvement and current sanctions are blunt or slow
- There are no economic sanctions which have been shown to be an effective driver of improvement in other competitive markets
- The Act assumes a clinician ownership model which increasingly no longer exists – where does that leave the 'person responsible'?
- Work of the Competition and Markets Authority is welcome but raises questions of what should be within HFEA's remit and extent to which patients would be better protected if all aspects of the fertility sector were subject to 'end to end' regulation by the HFEA
- The Act is overly prescriptive - e.g., requires inspections every two years – which limits the scope to reward good compliance with more streamlined regulation

Scientific developments

- The Act is at risk of being overtaken by research advances
- 14-day rule has proved effective and any replacement would need to offer the same degree of certainty and regulatory clarity
- Process is overly prescriptive e.g., in relation to mitochondrial donation
- There are no means to encourage new technology or other innovation through trials or regulatory experimentation

Consent, data sharing, anonymity

- Consent is overly complicated which creates costs for clinics and increases risk of errors

- Patient and donor confidentiality and disclosure of register data maybe out of step with other areas of healthcare and with new challenges such as DNA testing websites. Is the idea of data confidentiality out of date? Where will this go in another 10 years or more?

3. Activity since July 2022

3.1. Since July significant work has been conducted on the targeted consultation document that we plan to issue this autumn. This will aim to gather professional, key stakeholder patient groups and clinic staff views on our emerging proposals for legislative reform, although it will be publicly available for anyone to respond to.

3.2. The consultation aims to summarise some of the key issues we are considering as part of the legislative reform proposals. The proposals are deliberately pitched at a high level and have been developed from the Legislative Reform Advisory Group meetings, expert roundtables, and feedback from the Authority. LRAG papers and summary of discussions are on the HFEA website.

3.3. We are also considering any further roundtable discussions with experts,

4. Targeted consultation

4.1. The consultation has been designed in a format that enables the HFEA to set out why we think specific changes are necessary and the outline proposals we have for reform. We do not propose to consult on changes which are largely technical, and which aim to improve on the operation of the existing law. Instead, the survey focuses on proposals which are new, or significantly develop or depart from the existing policy consensus.

4.2. The issues being consulted on consider the key areas outlined in section 2 of this paper, and are set out in four main topics in the consultation:

- Patient protection
- Consent and data sharing
- Scientific developments
- Donor anonymity, and donor information sharing by the HFEA

4.3. It is not intended that this consultation will establish wider public views on these issues. The aim rather is to establish a series of broad consensus on what needs to change; the precise detail will come later. If the Government do decide to review the legislation, then the usual process includes wider opportunity for public discussion as part of a formal government consultation on the detail of any proposed changes to the Act.

5. Next steps

5.1. The consultation will be launched in the early Autumn.

5.2. The consultation will be communicated widely, and we know there is some interest in the area as highlighted by a recent Guardian article on scientific developments. We will report back to Authority on the consultation responses and key areas for discussion at the November 2022 meeting.

5.3. The consultation responses will form part of the evidence base that will inform the report that the Authority will prepare for the Government setting out our key proposals for reform.

5.4. The risks outlined in the **May Authority meeting** are ongoing and in some cases have been challenged further by the intense activity that has been required for the implementation of the new storage laws for July.

6. For decision

6.1. Authority is asked to:

- Consider any particular issues they would like to discuss further in relation to this work.