Human Fertilisation & Embryology Authority

Authority meeting

Date: 25 January 2023 – 12.45pm to 3.50pm

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

Agenda item	Time
1. Welcome, apologies and declarations of interest	12.45pm
2. Minutes of the meeting held on 16 November 2022 and matters arising For decision	12.50pm
3. Chair and Chief Executive's report – to note For information	12.55pm
4. Committee Chairs' reports For information	1.05pm
5. Performance Report For information	1.15pm
6. Draft Business Plan 2023/24 For decision	1.45pm
Break	2.15pm
7. The Register research panel (RRP) and data research For decision	2.30pm
8. Presentation on Opening the Register (OTR) year ahead For information	3.00pm
9. Any Other Business	3.45pm
10. Close	3.50pm

Minutes of Authority meeting held on 16 November 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	25 January 2023		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 16 November 2022 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High

Minutes of the Authority meeting on 16 November 2022

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

Members

There were 11 members at the meeting – eight lay and three professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and DHSC colleagues both in person and online. The Chair also welcomed observers who were online and stated that the meeting was audio recorded in line with previous meetings and for reasons of transparency, and that the recording would be made available on our website to allow members of the public hear it.

1.2. A declaration of interest was made by:

- Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 14 September 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, her attendance at sector related conferences and the decision-making committees of the Authority.

3.2. Members were advised that following the cabinet reshuffle Steve Barclay MP has been re-appointed as the new Secretary of State for Health and Social Care. We also have a new team of ministers at the Department and Maria Caulfield MP had taken on the HFEA brief.

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

3.4. Members were advised that amongst other meetings, he was in dialogue with the bio-science community and that there were several developments in this area pertaining to our sector which had led to discussions taking place at the Scientific and Clinical Advances Advisory Committee (SCAAC) meetings.

3.5. The Chief Executive continued that he was yet to meet the new Minister, but he hoped that discussions would centre around Government new priorities and HFEA concerns including early access to primary care for fertility patients. The cost-of-living crisis was also an issue and we were keeping an eye on the effect on fertility treatment as people's disposable income reduced.

3.6. Members were advised that the Public and Commercial Services Union (PCS) had balloted their members for strike action across the civil service. The PCS recently notified the Chief Executive that PCS members who worked for the HFEA would not be joining the strike action as not enough voted to reach the required threshold.

3.7. Members asked about the CE peer meetings that took place with other ALB CEOs and if the issue of proportionality and government expectations had been discussed. The Chief Executive responded that it was mentioned but it did not form a major part of the discussion.

Decision

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

4. Committee Chairs' reports

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

4.2. The Licence Committee Chair (Alison Marsden) noted that a number of recent cases were very complex. One particular case involved a complex licence renewal following a history of non-compliance, where the clinic had since improved to the extent that it now met the required standards. The committee also carried out their annual committee effectiveness review.

4.3. The Statutory Approvals Committee (SAC) Chair, (Jonathan Herring) noted that there had been three meetings since the last Authority meeting. SAC had considered various PGT-M applications and requests for Special Directions. He then went on to give a synopsis of the discussion that took place on a particular special direction case.

4.4. The Scientific and Clinical Advances Advisory Committee (SCAAC) deputy Chair (Jason Kasraie) gave an update in the absence of the Chair (Tim Child). At the meeting they had discussed public health developments relevant to fertility treatment and embryo research and the treatment add-ons review and agreed that the primary outcome for ratings will remain live births. SCAAC also asked the Executive to consider developing a framework to identify artificial intelligence (AI) models falling within HFEA remit.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave an overview of the last meeting held in October. It was noted that actions were agreed in three key areas:

- closing of internal audit reviews once completed.
- escalation of concerns; and
- deep dives to be scheduled in conjunction with internal audit reviews.

4.6. She continued that the committee had pressed for a clearer timetable for the completion of post PRISM activities like CaFC to be presented to the December meeting. The December meeting would also involve training for AGC members on the analysis of financial reports and it was open

to Authority members who wanted to attend. An e-mail will be going out to that effect from the Governance Manager.

Action

4.7. The Executive to consider developing a framework to identify artificial intelligence (AI) models falling within HFEA remit.

4.8. An email inviting Authority members to the AGC training at the December meeting to be circulated by the Governance Manager.

Decision

4.9. Members noted the Committee Chairs' updates.

5. Performance report

5.1. The Chief Executive commented on the recent results from the staff survey carried out and shared headline indicators with the Authority. Members were advised that the general results were positive.

5.2. There were a few areas where the results were less good than hoped for, notably on issues on diversity & inclusion and staff feeling unable to do their work because they did not have the right tools, though it was not clear exactly what factors were driving these results.

5.3. It was noted that the Corporate Management Group (CMG) will take this forward and an action plan will be developed with further discussion held at the December AGC meeting.

5.4. The Chair commented that given the difficulties with the rising cost of living, the responses were positive but that the areas of concern needed to be addressed.

5.5. The Chief Executive updated the Authority on progress with PRISM. AGC had oversight on the roll out of PRISM. PRISM had been deployed across all clinics including those with third party suppliers. Our attention was therefore now on re-establishing links with the Register for reporting purposes, including giving the OTR team the tools to do what they need to do in good time before the impact of the removal of donor anonymity is felt in 2023.

5.6. Members commented that regarding PRISM there was tremendous improvement over the last six months and it was good to see issues being fixed and that this showed good leadership.

Strategy and Corporate Affairs

5.7. The Director of Strategy and Corporate Affairs presented this item.

5.8. It was noted that a report looking in detail at egg and sperm donation in the UK will be published soon.

5.9. The persons responsible (PR) event took place on 31 October and feedback had been positive. The Director of Strategy and Corporate Affairs thanked Alison McTavish, Zeynep Gurtin, Geeta Nargund and Tim Child who all presented at the event and Jason Kasraie for chairing sessions.

5.10. Members were advised that because of the volatile political situation in recent months, we will be publishing the consultation on proposed changes to the Human Fertilisation and Embryology Act in the new year.

5.11. Members were advised that the two winter stakeholder meetings were taking place – the Patient Organisation Stakeholder group (POSG) and Professional Stakeholder group (PSG). Updates on our work on ethnic disparities in fertility treatment and the new treatment add-ons rating system would be outlined as well as discussions relating to Opening the Register (OTR). These meetings were useful for getting feedback on our work and hearing developments from patient and professional groups.

5.12. Members were also informed that in preparation for the SCAAC review of add-ons early in 2023 (using the new rating system) work was underway to design and user test new webpages.

5.13. The Chair commented that we had gone through a number of political changes recently, including Prime Ministers and Secretaries of State for Health and Social Care, and it was therefore only right to allow things to settle down and that in the new year we would go out to consultation. Members were assured that this work remained a priority.

5.14. Continuing, the Chair said that in terms of the PR event, we were going to do some analysis on feedback received from attendees and that she intended to continue visiting clinics and invited other members to join her.

Compliance and Information

5.15. The Director of Compliance and Information commented on the performance data for the OTR service. The service remained busy with 81 applications being closed in September. The number of closed applications fell in October due to a vacant post. However, recruitment was ongoing and the structure of the team had been improved to enable more staff to be able to carry out final checks. It was hoped that the new structure would also help with staff retention.

5.16. When OTR applications are received, they are considered for their complexity. Less complex requests can be responded to with less resource and on average take 30 working days to complete. This had come down from 77 working days at the start of the year. More complex applications require significant input from clinics, increased checking and therefore take much longer.

5.17. A Licenced Centres Panel (LCP) meeting was held on 2 November 2022 with the focus being the challenges of 2023. Members were advised that the Head of Information gave a presentation to outline the OTR service. There was also discussion about how best to support those affected by donor conception.

Finance and Resources

5.18. The Director of Finance and Resources commented on the financial indicators in the performance report. Members were advised that the HFEA accounts were laid before parliament in October.

5.19. In year efficiencies have been asked for by the DHSC but we were not yet clear to what extent. We would report back to the January Authority meeting once we have more details.

5.20. Debtor days and collection rates had been affected by income estimation in the switch over to PRISM but these had now been reconciled and the trajectory was showing that by this financial year-end we will have an underspend which would mainly be as a result of unspent staff costs.

Decision

5.21. Members noted the performance report.

6. Strategic risk register & Risk Strategy review

6.1. The Risk and Business Planning Manager presented this item. The Authority was asked to note the risk review which looked at the risk structure and background, the new risk strategy and associated risk registers and to discuss the underlying risk appetite which formed part of the risk strategy.

6.2. It was noted that the application of our risk appetite will be dynamic and overseen by AGC.

6.3. Three options for a risk appetite statement were discussed in detail by members.

6.4. Members commented that the difference between risk appetite and risk tolerance and should be more clearly differentiated. It also needed to be taken into consideration what risk appetite best served our strategic objectives.

6.5. Continuing, Members commented that option three provided a number of categories but they were not all of equal weighting, however, option two seemed proportionate and afforded the opportunity to group together risk areas for which our risk appetite was similar.

6.6. Following further discussion, the majority of members agreed that we would proceed with option two and discuss this in detail at the AGC meeting in December. The risk appetite statement would be reviewed in a year's time to see how it was embedding and to consider whether option three (the most detailed option) might then be preferable.

Decision

6.7. The Authority agreed on option two and that this be reviewed at the November 2023 Authority meeting.

7. Business planning 2023/24

7.1. The Head of Planning and Governance presented this item. Members were advised that a draft of the business plan will be brought back to the January 2023 Authority meeting for approval prior to submission to our sponsors at the DHSC.

7.2. In discussion, one member commented that a fees review should be a priority area due to the centrality of resources on all of our ambitions, including crucially OTR work.

7.3. Some members felt that we could be criticised if we did not prioritise regulatory transparency and suggested that we deprioritise another area – possibly further work on ethnic disparity in fertility treatment, with a view to looking at this in a wider sense as part of a new broad priority on inequalities under the next strategy.

7.4. Members asked if we knew what patients would want to see as our priorities. The Director of Strategy and Corporate Affairs responded that it depended on who we spoke to, for instance some patients saw ethnic disparities as an area to be prioritised, while others would have different priorities depending on their own perceptions and experiences.

7.5. The Director of Compliance and Information responded that at LCP, the priority was seen as OTR and donor related work as these were the areas, they wanted to see the Authority focus on.

7.6. The Chair commented that regarding the Legislative Reform work, we are focused on putting patients at the heart of any law reform and therefore this should remain a priority.

7.7. Continuing the Chair argued that in thinking about prioritisation, we should be clear about the distinction between what only we can do and what we can do working with others. We should look to see if anyone else is doing expert work, or whether we could partner with others to do certain activities, for instance on ethnic disparity, or AI & genetics horizon scanning.

7.8. Members felt that the effects on the patient should be at the heart of our decision-making on priorities.

7.9. The Chair commented that there was recognition from members on areas that needed to be prioritised and the Executive should consider the framework above, prior to discussion of a draft business plan in January.

7.10. The Director of Strategy and Corporate Affairs commented that staff would go away and work out what resources are required for the prioritised areas and we would be grateful to hear from professional members and professional stakeholder bodies.

7.11. The Chair commented that as the Regulator we need to understand that we do not have the resources to do everything we would like to do, and hence prioritisation was necessary.

7.12. The Chief Executive commented that by the January meeting we would produce a further paper for members to help them make final prioritisation decisions. This would include looking at what work could only be undertaken by the HFEA, what can or should be done in partnership with others, and what should be done by others. There would be a further opportunity for discussion when the draft business plan was presented to the January meeting.

Decision

7.13. Members agreed the course of action and noted that it would be an agenda item at the January meeting.

8. Support services for donors and donor conceived people

8.1. The Head of Information presented this item regarding the OTR support service, which provides limited counselling for those affected by donation in the UK born after 1991 and who have contacted the OTR service. The service is currently delivered by the Hewitt Fertility Centre and is funded by the HFEA. The current contract expires on 31 March 2023.

8.2. The HFEA was anticipating an increase in applications to the OTR service from late 2023 onwards as the first cohort of donor conceived (DC) people turned 18, following the legal change to donor anonymity in 2005.

8.3. It was noted that the 1990 Act did not expressly impose an obligation on the HFEA or licensed centres to provide counselling to donors or donor conceived people. The 1990 Act provides that donor-conceived applicant must be given “a suitable opportunity to receive proper counselling about the implications of compliance with the request” before the Authority can disclose information to an applicant about their donor (s 31ZA). There is no suggestion that donors should receive counselling at the point where their identifiable information is released - although they should have received implications counselling at the time of their donation.

8.4. It was put forward that the likely increase in applicants post OTR 2023 could mean that the money required to continue to fund the support service will be become unaffordable under the current

arrangements. Without action, the HFEA could find itself in a position where it was unable to fund other strategic priorities and/or some of its statutory duties.

8.5. Four options were presented to members:

- Option 1 – status quo
- Option 2 - those affected by donor conception pay for any counselling support
- Option 3 - the clinic pays directly for any counselling support
- Option 4 - the HFEA charges a levy to fund a support service
- Option 4a & 4b – Continue the support service current model or commission a new multi-layered support service.

8.6. Members asked if there were charities available to offer a counselling service. The Head of Information responded that the Donor Conceived Network (DCN) currently provide information and peer support. It potentially could establish this in future, but he was not sure about other charities.

8.7. Members commented on the fact that only 7.9% of applicants took up the offer of counselling in 2021 and asked if the Executive had any intelligence on the 92% that did not take up the offer and what they did instead. During discussion it was noted only a small number of people take up counselling and therefore it may be beneficial to provide further information through the website or leaflets as a supportive mechanism. This would be particularly beneficial if counselling became chargeable to those accessing it.

8.8. Members felt that the status quo was not sustainable and that some further exploration of the other options was required, in particular option 4.

8.9. Members commented on option 3 and asked what would happen if clinics were no longer in existence, who would then pay that cost?

8.10. It was suggested that fertility counsellors may not be trained to counsel 18-year-old donor conceived children and that the DCN still appeared to be the best place to offer this service. The Director of Compliance and Information responded that the DCN offered peer support and not counselling but this was also an example of how support could be offered.

8.11. It was felt that a multi layered support service appeared to be what was required and stakeholders needed to be involved in this discussion. Likewise, who receives counselling needs to be decided on a pragmatic level as family members might also wish to access the service. A majority of members felt that donor conceived individuals should be prioritised over others who might be affected.

8.12. A majority of members agreed that the viable option was to explore how costs could be met by making the support service a chargeable service. It was agreed it was not sustainable for the HFEA to continue to fund the service in the current model.

8.13. A member asked about other forms of counselling including grief counselling and raised the point that GPs refer patients on to specialist counsellors and asked why that was not the same for donor conceived people.

8.14. Other members responded that in theory it should work that way but there may be long waiting lists and there may not be access through this route to this highly specialist type of counselling.

8.15. The Executive commented that post autumn 2023, counselling required would be different due to the complexities of identifiable information being released.

8.16. Members felt that the focus for counselling was very important. There are differences between implications counselling and therapeutic counselling, and it was important both aspects are considered.

8.17. Members also commented that if a fee were raised from clinics by charging per treatment the fee would be passed to patients. The Director of Finance commented that as a Regulator we do not charge patients. The Director of Finance also commented that should we decide to raise a charge to cover the costs for this service we would need to be careful where the funds sit.

8.18. The Chair summarised the discussion and commented that we would engage with stakeholders and explore options, also noting that the number accessing the service would be different every year which would have its own inherent risks.

8.19. The Chief Executive noted that the Authority did not wish to continue the status quo and that we would talk with the Hewitt Centre with the aim of extending the existing service for a year.

Decision

8.20. Members agreed that the Executive should talk with the Hewitt Centre with the aim of extending the service for a 12-month period and undertake further work to consider the future model of support.

9. State of the sector 2021/22 & inspection themes

9.1. The Chief Inspector presented this item. The state of the sector report was issued on 3 October 2022. It was noted that this was the annual report which summarised what we have seen through regulatory work conducted during the previous 12 months.

9.2. The presentation highlighted the inspection themes to be focussed on during interim inspections.

9.3. Following the presentation, members commented that clinics had reported that at the conclusion of the inspection feedback was often positive, but when they received the draft report, it was not always as positive as they had felt on inspection.

9.4. The Chief Inspector responded that this had also been fed back to the Inspection team and they are creating guidance for inspectors to be used during the closing meeting. This will allow a more standardised format for reporting back to clinics in order to manage expectations and improve consistency.

9.5. On the data quality review members suggested that this be brought back in due course.

9.6. In response to a question on capturing examples of best practice in the quarterly clinical reports the Chief Inspector commented that at present only non-compliances are reported.

9.7. The Director of Compliance and Information responded that we have a code of practice to highlight best practice and there is also published professional body guidance. As a consequence, we need to tread with caution to ensure that any best practice we highlight is not at odds with that professional guidance. As a regulator we highlight best practice through events that we organise or attend and gave the example of the recent PR event.

9.8. The Chief Executive commented that we are a regulatory licensing body and that needed to be our primary focus during inspections.

Decision

9.9. Members noted the State of the Sector 2021/22 and inspection themes.

10. Any other business

10.1. The Chair commented that this was the last Authority meeting in 2022 and wished everyone compliments of the season and a very happy new year in advance.

10.2. The next meeting was scheduled for Wednesday, 25 January 2023.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 25 January 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	25 January 2023		
Author	Debbie Okutubo, 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	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 16 November 2022			
4.7 The Executive to consider developing a framework to identify artificial intelligence (AI) models falling within HFEA remit.	Chief Executive	For SCAAC during 2023	Discussions will be held at future SCAAC meetings where relevant.
6.7 The risk appetite statement would be reviewed in a year's time to see how it was embedding and to consider whether option three (the most detailed option) might then be preferable.	The Risk and Business Planning Manager	November 2023	This was presented to the December 2022 AGC meeting and will remain under review.
8.20 Executive to talk with the Hewitt Centre with the aim of extending the service for a 12-month period and undertake further work to consider the future model of support.	Director of Compliance and Information	March 2023	The discussion has taken place and the Hewitt have verbally agreed an extension for an 18-month period to October 2024. Awaiting formal contract to be drafted.
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	January 2023	Law reform consultation due to launch at end of February 2023.
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	January 2023	All members completed their training in 2022. In accordance with our annual process, 2023 Authority member training in information security will commence shortly, using Civil

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
			Service Learning. In addition, members will be required to complete a module on Equality, Diversity and Inclusion.
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. Work on transparency and regulation will be addressed as part of the 2023-24 business plan.
Matters arising from the Authority meeting – actions from 23 September 2021			
5.18 Backlog on OTR	Director of Compliance and Information	March 2023	The vacant post has been recruited to so the team is at its full compliment. Improved team structure will help reduce the time to sign off.
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	January 2023	We have employed a dedicated scientific application officer to manage this in the future (along with ITE certificates and mitochondrial donation applications). This takes the task away from inspectors who have a heavy workload with their clinic portfolios. Training is going well and improvement seen in the KPI.

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	25 January 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

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

- 17 November – visit to the Evewell Clinic
- 29 November – Newcastle Centre for Life
- 7 December – spoke at the Progress Educational Trust annual conference
- 8 December – spoke at Jenetics event. Later that day I also had a meeting with Lesley Regan, Womens Health Ambassador
- 15 December – visit to Bourn Hall
- 11-13 September – attended Fertility 2023 conference in Belfast

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

- 22 November – attended a meeting of the Association of Chief Executives
- 1 December – attended the Huxley Summit held by the British Science Association
- 2 December – attended meeting with Secretary of State for Health with other Chairs and Chief Executives of DHSC ALBs
- 5 December – HFEA All-Staff event
- 8 December – attended the Audit & Governance Committee
- 14 December – Quarterly Accountability Meeting with DHSC (along with SMT)
- 23 January – meeting with the National Aids Trust

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Item number:	4
Meeting date:	25 January 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:		
10 November 2022	1 Renewal	Granted
12 January 2023	1 initial (research) 4 renewals 1 additional targeted inspection	Minutes not yet approved.
Other comments:	The Committee also conducted its annual review of effectiveness after the November 2022 meeting. The outcomes will be fed into the annual governance paper to the Authority in March 2023.	
Executive Licensing Panel:		
15 November 2022	3 Renewals	All granted/approved
29 November 2022	2 Renewals	All granted/approved
13 December 2022	2 Renewals 1 Interim 1 Change of Premises 1 Change of Person Responsible	All granted/approved
10 January 2023	1 Renewal	Granted/approved
Other comments:	The Panel also conducted its annual review of effectiveness, at a separate meeting in November 2022. The outcomes will be fed into the annual governance paper to the Authority in March 2023.	
Licensing Officer decisions:		
September 2022 – November 2022	ITE Import Certificates – 39 1 Voluntary Revocation	All approved.
Other comments:	28 of the ITE import certificate items were due to a change of centre name and location in Denmark. We expect further additional items in relation to this change but have now processed the majority.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
27 October 2022	2 PGT-Ms 1 Special Direction	2 items approved/1 PGT-M refused
24 November 2022	3 PGT-Ms 3 Special Directions	All approved
15 December 2022	3 PGT-Ms 1 Special Direction	3 items approved/1 PGT-M refused
23 January 2023	2 PGT-Ms 2 Special Directions	Minutes not yet approved.
Other comments:	The Committee also conducted its annual review of effectiveness after the December 2022 meeting. The outcomes will be fed into the annual governance paper to the Authority in March 2023.	

Audit and Governance Committee:		
8 December 2022	• Internal audit report & progress with recommendations • External audit planning report • Strategic risk: ▪ Risk management strategy ▪ Operational risk register ▪ Strategic risk register ▪ Risk appetite ▪ Proposal for deep dive topics ▪ Financial risk on potential income position and government funding ▪ Horizon scanning • Digital Projects/PRISM update • Resilience, cyber security and business continuity management • Human resource bi-annual update • Review of AGC effectiveness	-
Other comments:	The Committee uses an NAO form for audit and risk committees for its annual review. The feedback will be included in the annual governance paper to the Authority in March 2023. In addition, members received training in the interpretation of financial statements following the meeting.	

Meetings held	Items considered	Outcomes
Scientific and Clinical Advances Advisory Committee:		
The next meeting will take place on 6 February 2023.		
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 November 2022

Shabbir Qureshi
Risk and business planning manager
29/12/2022

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	Authority 25 Jan 23
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 November 2022.
- Performance was reviewed by SMT at its 9 January 2023 meeting.
- Performance for this month was generally good. There were seven red indicators.

Key trends

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

September (6)	October (7)	November (7)
C2 – Inspection reports sent to PR within 20 working days	C2 – Inspection reports sent to PR within 20 working days	HR1 – Staff sickness
C3 – Inspection reports sent to committee within 55 working days	C3 – Inspection reports sent to committee within 55 working days	C2 – Inspection reports sent to PR within 20 working days
F2 – Debtor days	C4 – End to end licensing reports within 70 working days	C3 – Inspection reports sent to committee within 55 working days
F3 – Prompt payment	C7 – Mito processing within 90 working days	C4 – End to end licensing reports within 70 working days
HR2 – Staff turnover	F1 – Debt collection	F1 – Debt collection
L3 – Licence committee minutes within 15 working days	F2 – Debtor days	F2 – Debtor days
	F3 – Prompt payment	F3 – Prompt payment

Management summary

IT and register performance reporting

- 306k units of activity from 102 clinics. Activity is dropping in advance of Christmas.
- The first tranche of backdated validation errors (4600 registration errors) were released to clinics on 7 December as part of our OTR and CaFC plans. Further releases of errors will be needed back to January 2020.
- The revised CaFC and OTR plan was approved by AGC on 8th December. Reports for OTR to be completed by July 23. Best case scenario for CaFC is September 23, worst case June 24 depending on validation errors being fixed and verification period needed. We are aiming to have CaFC timelines confirmed between April and June 23.

Management commentary

- Performance has been variable across KPI indicators with seven red, one amber and six green indicators.
- The reduced capacity in the OTR team continues to impact performance. Work has been done with the team to create a new tracking spreadsheet which will allow much more robust data gathering and simplify data entry. This is an interim solution until a new system is developed and installed in 2023.
- Social media engagement has more than doubled since last month on the back of the new 'Trends in Egg, Sperm and Embryo Donation' report and a post on fertility treatment myths.
- The red indicators are in HR, Compliance and Finance:
  - Sickness absence has increased significantly, mainly due to two staff newly on long term sick leave.
  - C4 (end to end licencing within 70 working days) has improved with only one report (out of four) at 88 working days. However, the average working days taken across all four licences was 68.
  - Both C2 (reports to PR within 20 working days) and C3 (reports to committee within 55 working days) continue to be below target. Since we began recording this data (April 2022), 58 reports were due to be sent to the licencing committees, however, 42 were completed within the 55 working day turnaround target. Considering the complexity and the amount of management review meetings over this period, this is a great achievement.
  - All three Finance KPIs are in red again this month. Finance process training for all staff to be developed in Q4 to improve finance process compliance.

Summary financial position

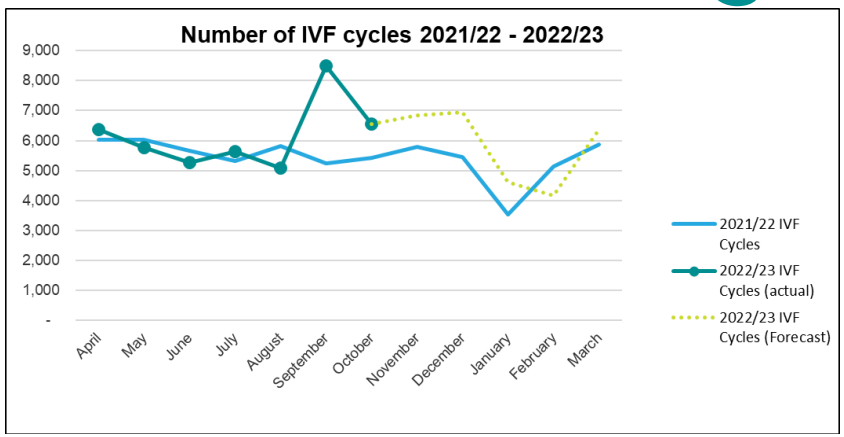
Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/2022 £'000s	Budget for 2021/22 £'000s	Variance Budget vs Forecast £'000s
Income	5,243	5,042	(201)	7,878	7,451	(427)
Expenditure	4.512	4.840	328	7,296	7,468	172
Total Surplus/(Deficit)	**731**	**202**	**529**	**582**	**(17)**	**599**

Commentary on financial performance to November 2022

- As at month eight (November) we are posting a variance against budget of £529k. The reasons for this variance are explained in the detailed commentary. Main highlights are our income which continues to exceed budget. There are less than 10 clinics that have not caught up with their submissions, the remaining 92 have all been reconciled and are billed on actual submissions.
- Our expenditure remains under budget (£327k), however this variance will reduce when projects such as the OTR ramp up in the remaining months.
- The forecast outturn currently shows a surplus against budget of £599k which is largely due to our income and the underspends within our expenditure.

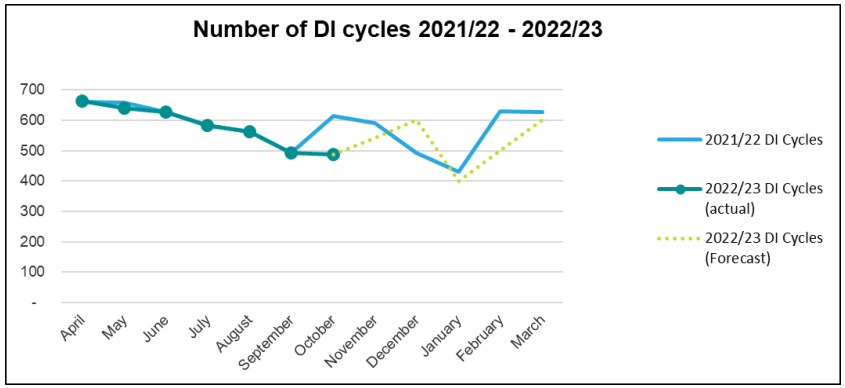
Human Fertilisation & Embryology Authority

Financial management information



IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2021/22 IVF Cycles	45,273	3,621,813	65,266	5,221,253
2022/23 IVF Cycles (actual)	49,972	3,997,760	72,062	6,125,270
Variance	4,699	375,947	6,796	904,017

YTD IVF volumes are up 10.38% on the same period in 2021/22 and 5% over budget. For November we have seen an increase of 18% on the same month for 2021/22. This is likely to be because greater activity over estimates from last year.



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2021/22 DI Cycles	4,788	179,550	6,968	261,300
2021/22 DI Cycles	4,598	172,425	6,698	251,175
Variance	(190)	(7,125)	(270)	(10,125)

DI volumes are down by 4% against 2021/22 for the same period and 7% above budget. The reduction against 21/22 is unusual, however, as with IVF, where a few clinics are still inputting cycles post PRISM roll-out, this may be a factor.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

HFEA Income & Expenditure **Nov-22**

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	748	736	(12)	(0)	892	1,098	206
Non-cash (Ring-fenced RDEL)	177	177	-	-	352	265	(87)
Grant-in-aid - PCSPS contribution	50	50	(0)	(0)	100	100	-
Licence Fees	4,184	3,981	(203)	(0)	6,426	5,842	(584)
Interest received	18	1	(17)	(19)	18	1	(17)
Seconded and other income	66	97	31	32	90	145	55
Total Income	5,243	5,042	(201)	**(4)**	**7,878**	**7,451**	**(427)**
Revenue Costs							
Salaries (excluding Authority)	3,251	3,371	120	4	4,786	5,068	282
Staff Travel & Subsistence	50	63	13	21	127	127	-
Other Staff Costs	71	57	(14)	(25)	110	106	(4)
Authority & Other Committees costs	148	149	1	1	248	231	(18)
Facilities Costs incl non-cash	293	467	174	37	700	711	11
IT Costs	279	435	156	36	678	657	(22)
Legal / Professional Fees	310	169	(141)	(84)	412	328	(84)
Other Costs	110	129	19	15	234	240	6
Other Project Costs	0	-	(0)	-	-	-	-
Total Revenue Costs	**4,512**	**4,840**	**328**	**7**	**7,296**	**7,468**	**172**
TOTAL Surplus / (Deficit)	**731**	**202**	**529**		**582**	**(17)**	**599**
Adjusted for non-cash income/costs	**633**	**180**	**453**		**495**	**(18)**	**512**

Management commentary

Income.
Year to date our Licence fee (treatments) income is over budget by £201k or 5% which in part is due to the increase in fees. We expect all clinics to have submitted treatments up to the end of December and a final reconciliation will be conducted in January. The small variance within our grant in aid is due to budget profiling. However we expect not to draw down all of our grant in aid due to savings required across the public sector.

Expenditure by exception (over £10k variance).
At the end of November, we are under budget by £328k.
Salaries - includes contingent labour costs, are below budget by £119k. The underspend is mainly within staff salaries and on-costs which are offset by overspends within Shared Services (£11k) and Contingent Labour (£160k) which relates to PRISM.
Staff Travel & Subsistence - are under budget by £13k year to date, which all relate to Inspections travel and home to office travel costs (Inspectors).
Other Staff Costs - are £14k over budget. This is largely due to cost of the staff survey not budgeted for (£6k) and DHSC charges for HR services relating to 2021 (£2k).
Facilities costs - underspent by £173K, We are underspending on accommodation costs by £67k which is due to rent/rate and service charge costs accrued for being less than the actual charge and all relate to 2 Redman place. In addition we are underspending against Meetings costs (£14k). There is an underspend against Finance interest which relates to our lease (£6k). This will change in December when the accounts will be updated with depreciation and a lease expense (notional interest).We are checking with other ALBs on our floor plate to ensure consistency in treatment. In addition we have an underspend (£86k) within our non-cash costs, the majority of which relates the lease for our offices which are to be brough onto our balance sheet (capitalised) in Q3.
IT Costs - are underspent by £156k. The areas with significant variances are within our Consultancy and Support costs £143k. IT Subscriptions of £23k and a total of £15k underspend in Low value fixed assets, telephone and photocopying costs. Offsetting this underspend, are overspends within Consumables, Internet and Low value software costs.
Legal/Professional fee - are over budget by £141k. This is represented by an overspend within the legal budget of £140k and offsetting the contingency of £13k. The legal spend includes the secondment cost of a legal advisor which is not fully funded from the staff cost for a Head of Legal. in addition, we have overspends within Internal and External Audit Fees (£14k).
Other costs - are underspent by £18k. The most significant variances are within the Stakeholder Events (£22k), plus smaller underspends sub £5k across areas within both the Compliance and Information and Strategy and Corporate Affairs directorate. We are overspending against our publication costs (£8k) and Media monitoring (£4k).

Forecast - we are currently forecasting an underspend of £582k and an underspend against budget of £599k. The increase in income is a contributing factor in addition to the underspends within our expenses.

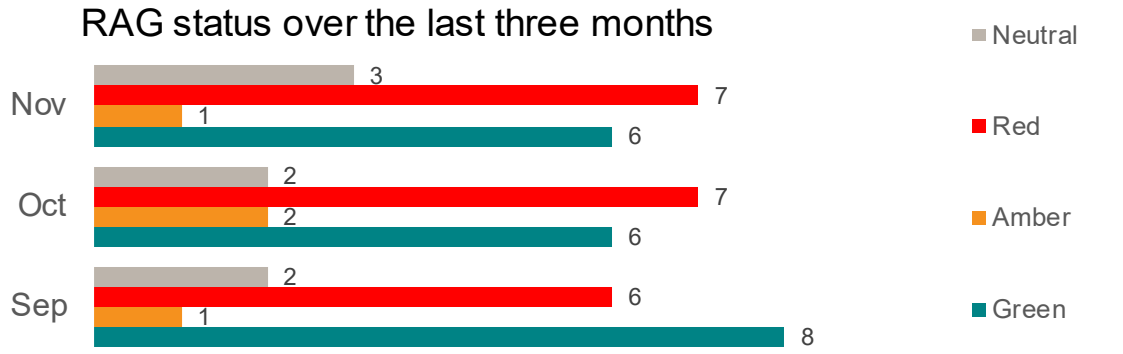
Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

RAG status over last 3 months

(17 KPIs in total)

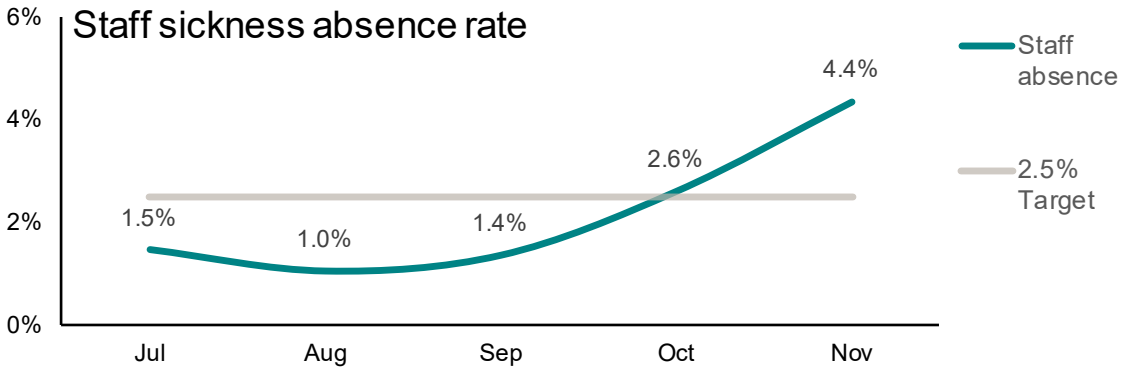


For November, the red indicators are:
- Comms : 0
- **Compliance : 3**
- **Finance : 3**
- **HR : 1**
- Information : 0
- Intelligence : 0
- PlanGo : 0

Status: Red

HR1 – Sickness

Target:
Less than or equal to 2.5%

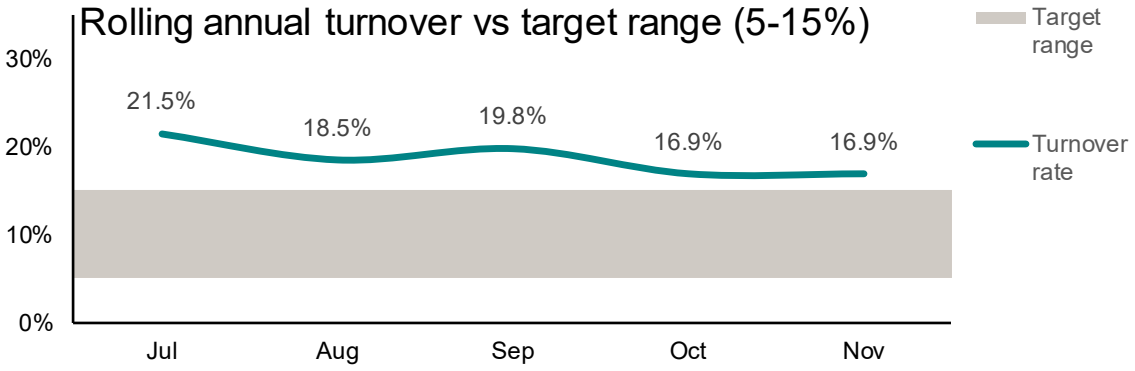


Sickness absence has increased this month, we have two staff members on long term sick and the potential for a third.

Status: Amber

HR1 – Sickness

Target:
Less than or equal to 2.5%



Turnover remains at the same level with one leaver and one starter.

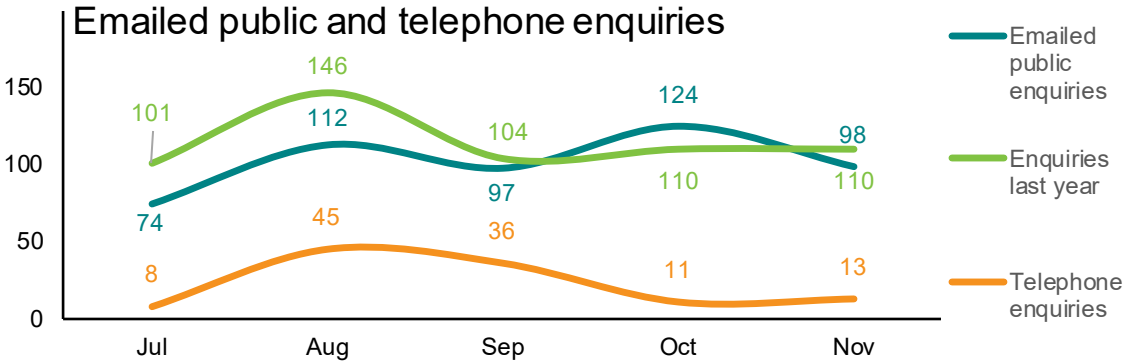
Supplementary HR data

Headcount : 73
Posts : 76
Starters : 1
Leavers : 1

Status: N/A

Emailed public and telephone enquiries

Target:
None defined



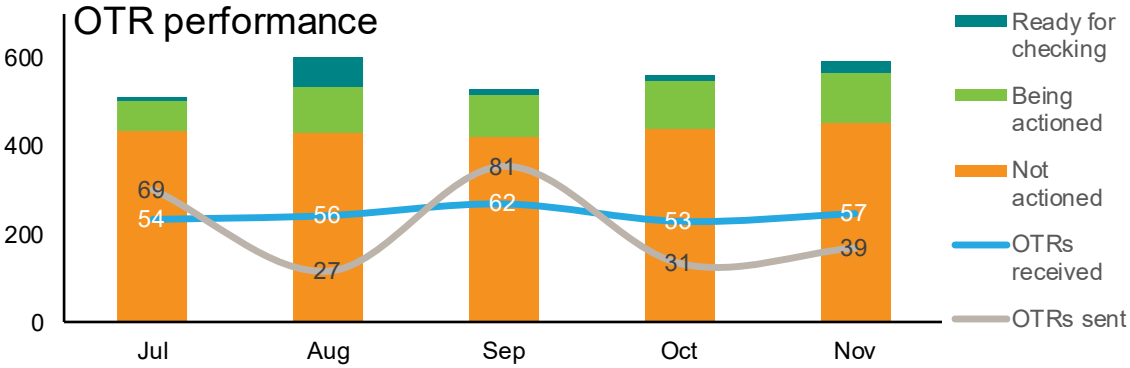
Emails breakdown:

Complaints process (19)
Complex (5)
Straightforward (51) - Donation (8), Funding (6)
COVID related (1)

Status: N/A

I1 – OTR performance

Target:
To be developed

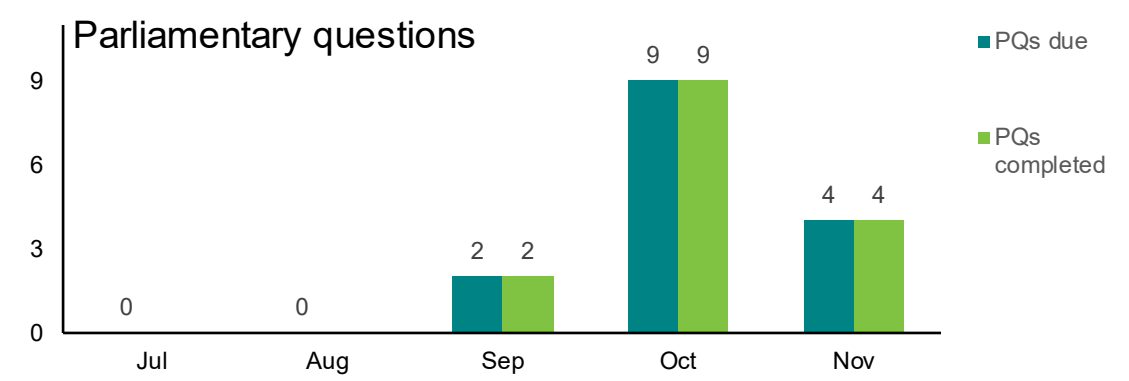


Continued reduced capacity in the team so still fewer OTRs being sent out. One SDIO is now checking OTRs but it will take time for numbers to increase due to number of OTRs she's processing (transitioning to checking more and processing less).

Status: Green

RI1 – PQs responses

Target:
100% within deadlines set

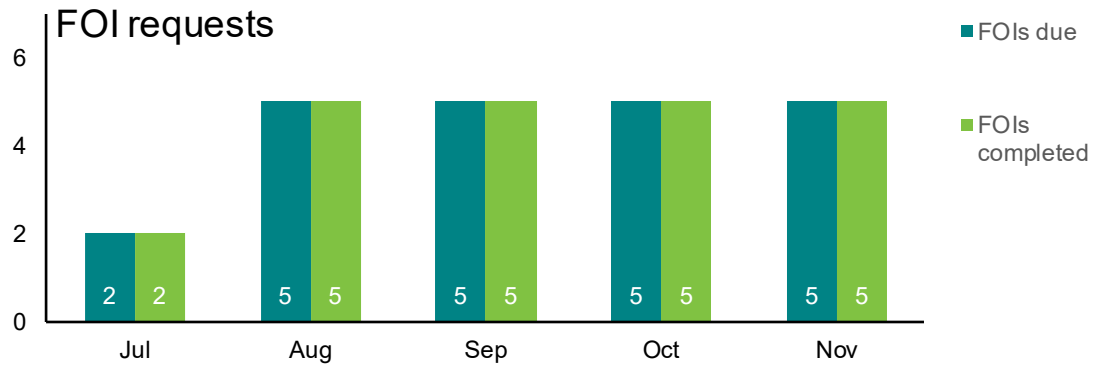


All PQ's completed within timescales.

Status: Green

RI2 - FOI responses

Target:
100% within statutory deadlines

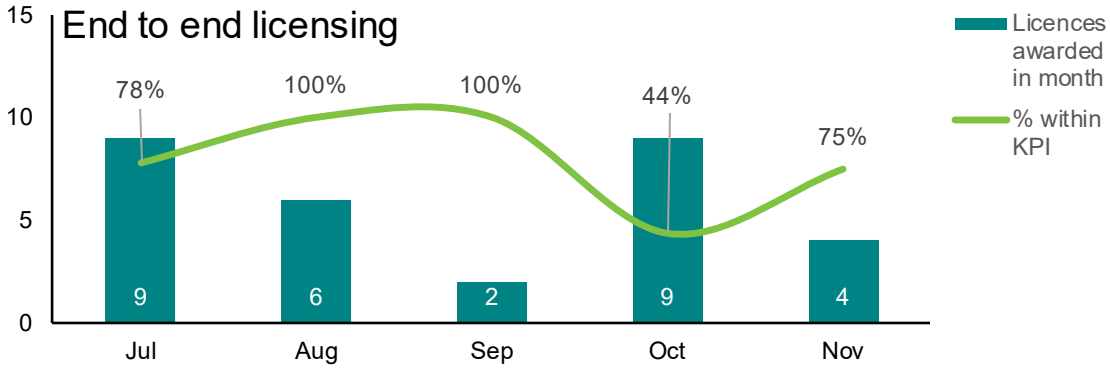


FOIs were mainly organisational and financial.

Status: Red

C4 – End to end licensing process

Target:
100% completed within 70 working days

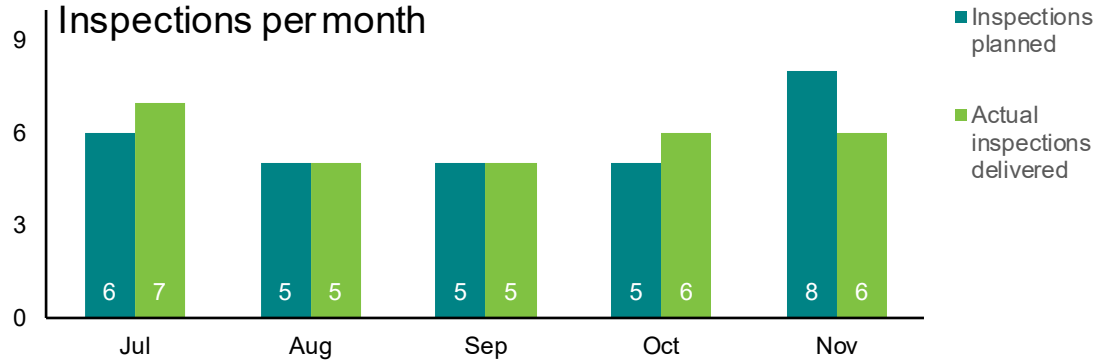


Clinic A (88 w days) Delayed due to report being passed to another of inspector due to staff sickness. The report required significant work.

Status: N/A

C1 – Inspections delivery

Target:
tbc

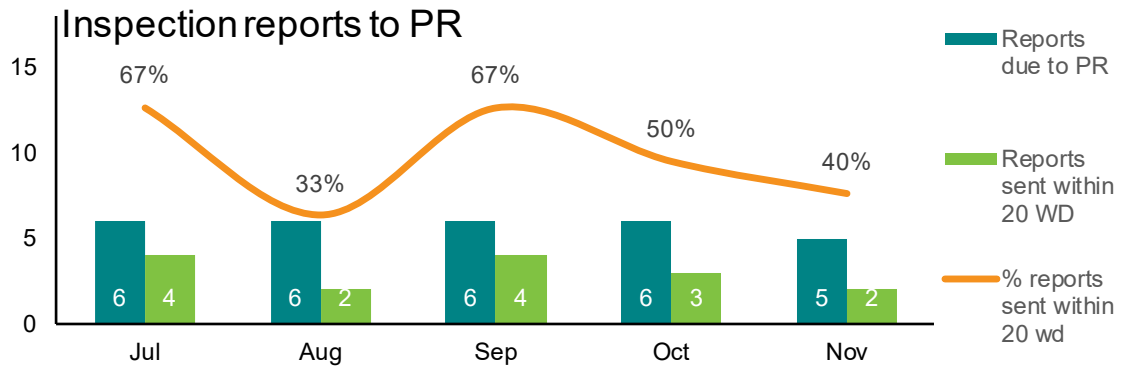


Clinic A (interim research) was moved from Sep to Nov - availability of research PR. Clinic B (renewal) rolled over from Nov to Dec; centre had an onsite interim inspection in Apr 22. Further info on research licence requested, however this arrived mid-Nov. Due to the allocation of inspectors, the DBA was in Dec.

Status: Red

C2 – Inspection reports sent to PR

Target:
100% sent within 20 working days

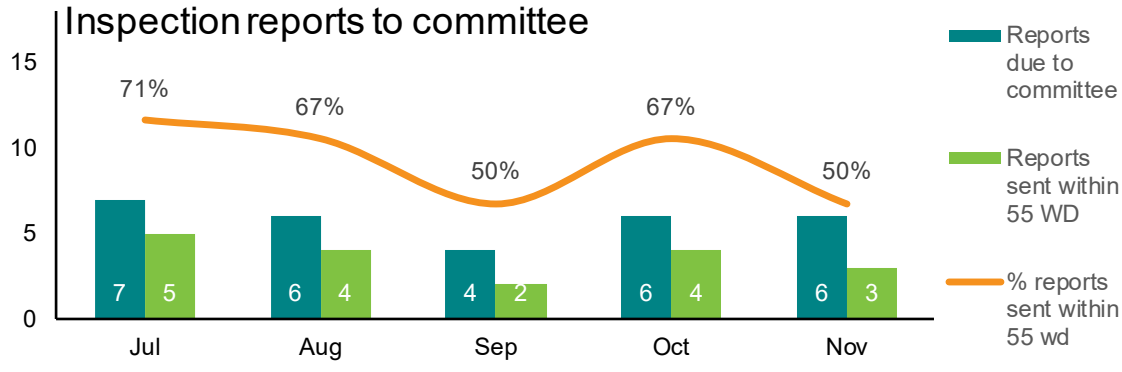


Clinic A (25 d) Complex report with additional meetings with PR & Director of Compliance.
Clinic B (32 d) Team member sickness delayed post inspection meeting. Also, non-compliances needed redrafting so QA process took longer.
Clinic C not finished yet due to sickness of the inspector, who couldn't go onsite till 21 of Nov.

Status: Red

C3 – Inspection reports sent to relevant licensing committee

Target:
100% sent within 55 working days

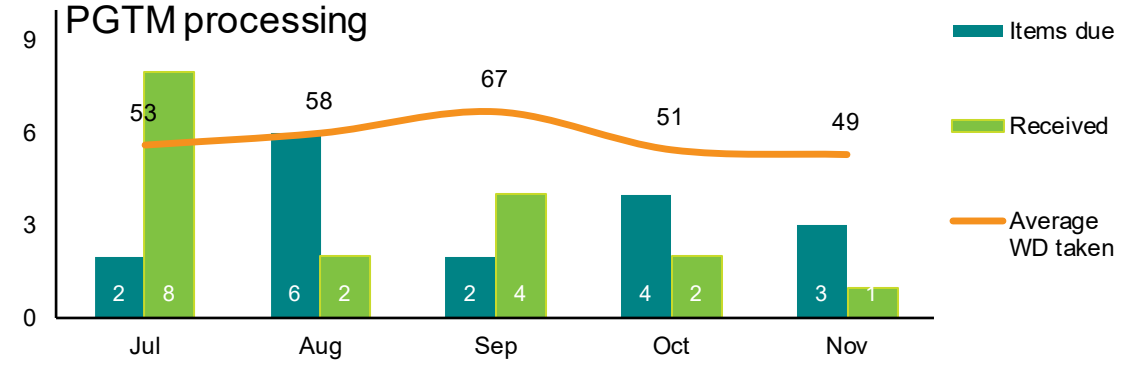


Clinic A (96 wd) licence fee not paid, centre not provided responses to recommendations.
Clinic B (84 wd) change of lead inspector; PR requested more time to respond to the report.
Clinic C (62 wd) prioritised report for another clinic; report sent for '2nd' QA without further support QA (due to inspector sickness).

Status: Green

C6 – PGTM processing efficiency

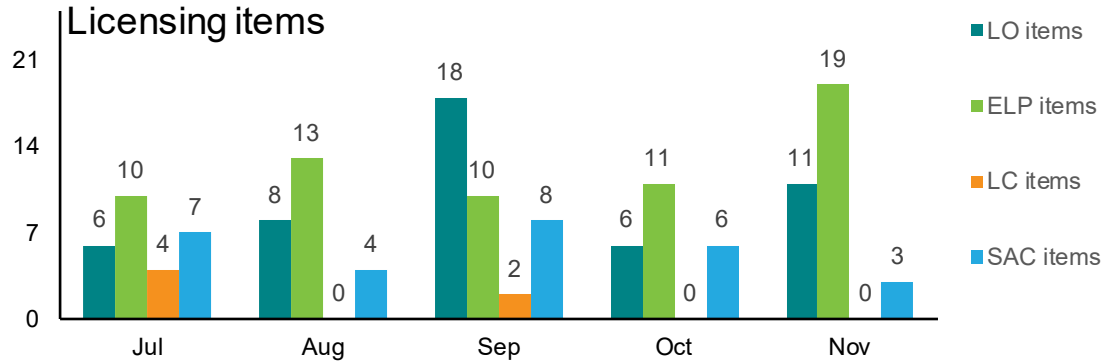
Target:
100% within 75 working days



Improvements in processing are continuing.

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

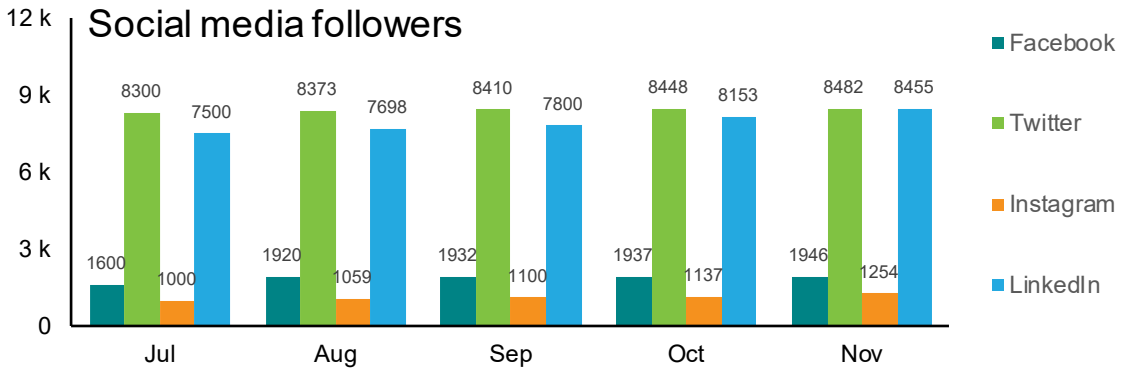
Licensing efficiency
Targets (WD):
LO - 5, ELP - 10
LC - 15, SAC - 20



All items completed within timescales.

Status: N/A

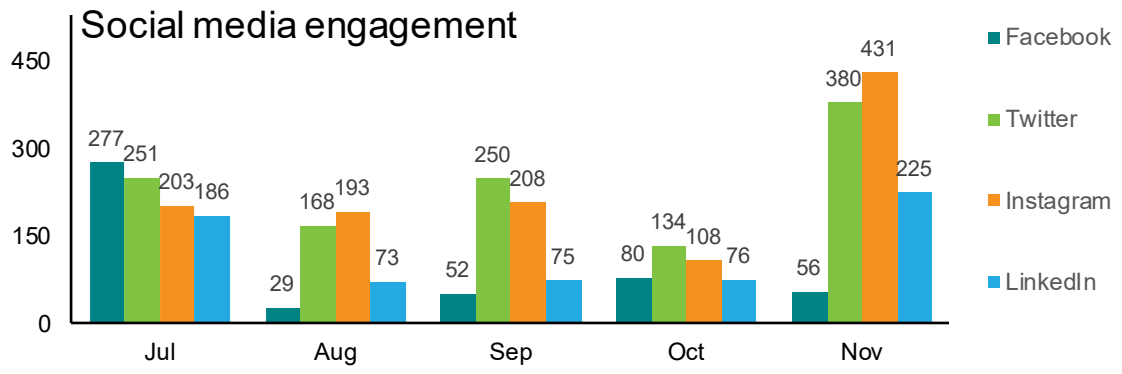
Total number of followers across social media



In November, the content on the HFEA's social media channels focused on our new report 'Trends in Egg, Sperm and Embryo Donation', the daily National Fertility Awareness Week themes and the FAQs we produced on the new storage law.

Status: N/A

Engagement across social media (measurement systems vary)

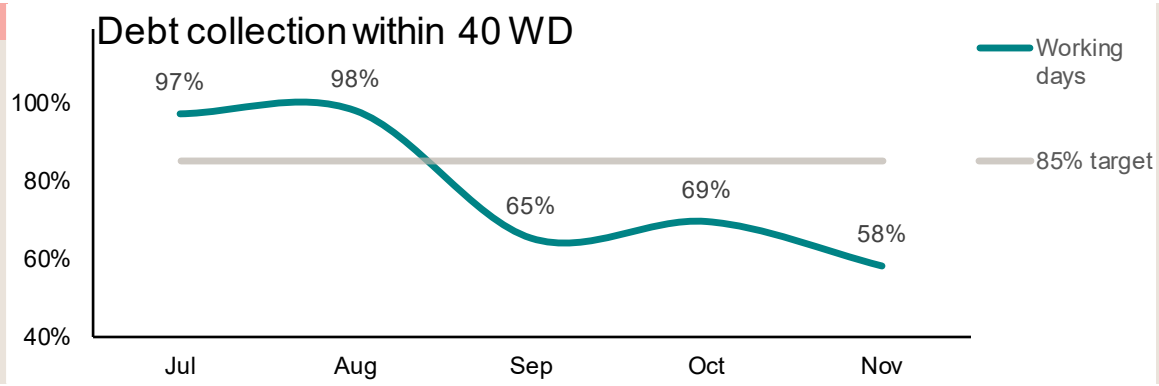


Our top performing posts were about the data we shared from the new 'Trends…' report and a post about fertility treatment myths.

Status: Red

F1 – Debt collection

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

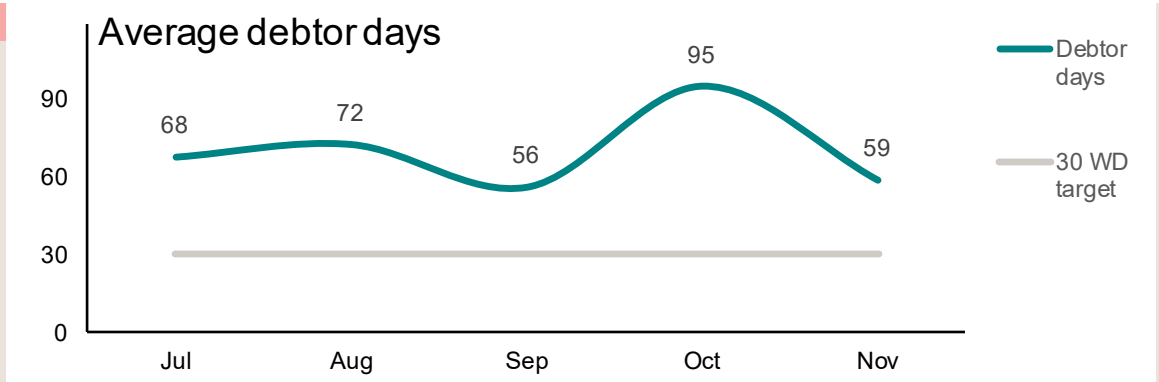


F1 - Collections is improving slightly, and more efforts are being made to chase and reduce drastically the debtors balance. This was held up slightly by updated contact details causing contact bounce backs. Details to be updated by BSIS in January and synchronisation with Finance to occur.

Status: Red

F2 – Debtor days

Target:
30 working days or less

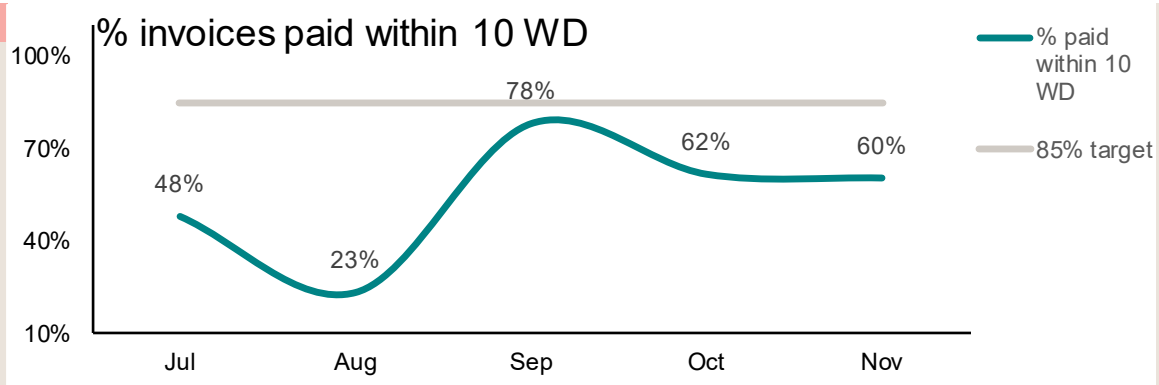


F2 - Delays in receipt of invoices due to incorrect customer details held. Slower settlements due to estimation. More clinics have caught up and days should fall in Q4 as estimation is eliminated and correct details are held across the board.

Status: Red

F3 – Prompt payment

Target:
85% or more invoices paid within 10 days



F3 - Delays in authorisation of invoices, invoices received via non PO route contributed to delays in payment. Staff training to be developed for Q4 to improve finance procedure compliance.

Draft business plan 2023-24

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy: 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:	6
Meeting date:	25 January 2023
Author:	Paula Robinson, Head of Planning and Governance
Annexes	1: Draft activities section of business plan 2023/24

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to approve the main section of the business plan for 2023/24, for further development over the next two to three months.
Resource implications:	In budget
Implementation date:	1 April 2023 – 31 March 2024
Communication(s):	HFEA website
Organisational risk:	Low

1. Introduction

1.1. Following an initial discussion at the November 2022 Authority meeting, a further paper on prioritisation for 2023/24 was circulated to members, setting out how we could incorporate some early work on regulatory transparency into our priorities for 2023/24. Members commented positively on that paper.

1.2. The annex to this paper sets out the first full draft of the activities section of the business plan for 2023/24 and is presented for comment and approval.

1.3. Other sections of the business plan will be developed over the next two to three months, and during this period the Department will also review the business plan and confirm our budget allocation. The sections yet to be produced at this point in the year are:

- Standard material about our role, our strategy and our legislation
- Delivery of the current (2022/23) business plan priorities
- Performance measures and other data
- Financial picture and budget
- Other information required under business planning guidance.

2. Planning priorities in 2023/24

2.1. In the first half of the coming business year, we know that our major resourcing priorities will be development work on the Opening the Register (OTR) service, servicing our public body review, and completing our current work on Act reform (following a consultation in early 2023).

2.2. We will then assess the resource available to further progress actions relating to the Government's Women's Health Strategy and the scoping of future work on transparency and regulation.

2.3. The draft business plan also includes all of our normal statutory work, and other priorities agreed earlier in this process, including a Code of Practice update to incorporate storage limits changes made in 2022, further work on ethnic disparities in treatment, work on our core IT systems including PRISM, the conclusion of this year's project on authorised processes, and further work with our patient engagement forum.

2.4. During 2023 we will also start to develop our new strategy for 2024-2027.

3. Recommendation

3.1. Authority members are asked to approve the attached draft business plan (activities section) for 2023/24. Further development of the business plan will follow, and Department colleagues will review the plan prior to publication.

Annex 1 – Draft business plan activity section – 2023/24

Activities for 2023-2024

This business plan represents the final year of delivery for our 2020-2024 strategy, which launched in October 2020. The effects of the Covid-19 pandemic continued to be felt within the sector and the HFEA itself throughout 2022/23, and this has had an impact on our strategic delivery. The Authority will be considering its next three-year strategy during the coming year, and will review outstanding items from the current strategy when making decisions about new priorities.

In the first half of the business year, the HFEA's major resourcing priorities will be development work on the Opening the Register (OTR) service in anticipation of a marked increase in the numbers of applicants from the autumn onwards, servicing our public body review, and completing our current work on Act reform (following a consultation in early 2023). We will then assess the resource available to further progress actions relating to the Government's Women's Health Strategy and future planned work on transparency and regulation. In addition to our statutory duties, our other main priorities for the year will be:

- Completion of a CoP update to incorporate storage limits changes made in July 2022
- PRISM, CaFC and Register team tools to enable us to fulfil our statutory functions
- Further work on ethnic disparities in fertility treatment
- Maintaining our systems eg Clinic Portal, Epicentre to enable us to fulfil our statutory functions
- AI/genetics horizon scanning (maintaining a watching brief in this developing area)
- The impact of changes to the Northern Ireland Protocol (detail as yet unknown) and any consideration of changes to the EUTCD
- The conclusion and implementation of the work on authorised processes begun in 2022/23
- Input to NICE fertility guideline review
- Compliance with the DSPT toolkit
- Further work with our patient engagement forum
- The development of a new strategy for 2024-2027.

Our plans align well with the Department of Health and Social Care's planning priorities for the coming year. Through our activities we aim to support their overall vision of enabling everyone to live more independent, healthier lives for longer, through supporting healthy behaviours, improving our health and care system and creating healthy environments.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2023-2024.

The best care

Our first aim is for effective and ethical care for everyone. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 1 - Strategic objective 1. Treatment that is effective, ethical and scientifically robust. Table outlining planned activities for April 2023 to March 2024

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes continuation of the revised approach developed in response to the Covid-19 pandemic.	All clinics and research establishments in the sector are: • appropriately inspected and monitored against the requirements of the Act and published performance indicators, and • if they meet the required standards issued with licences for up to five years. Clinics that are well led and see compliance and the provision of high-quality care, including excellent support, as good business. Assurance of consistent standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics publish (eg, on their websites) and provide to us. Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances.	Throughout the year
Respond to any developments relating to Covid-19 and their impact on the fertility sector and the HFEA. Clear actions and communication.	Clear ongoing inspection plan and assistance for clinics in response to any new Covid-19 related situations and government guidance. We respond as required to the Covid-19 public inquiry.	Throughout the year
Collaborative and partnership working with other ALBs and health regulators UK wide as needed, to ensure streamlined regulation.	Joint working as and when required, including the provision of input into the current review of NICE fertility guidelines. Revised NICE guidelines are informed by HFEA input and data, such as on ethnic diversity and fertility treatment and family formations to ensure that health	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
	inequalities are addressed. NICE guidance updated to reflect current practice across the sector. Implementation of any changes into the inspection regime. Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the most effective approach if any new areas of regulatory overlap should arise. We maintain clear and appropriate memoranda of understanding (MOUs) to ensure that we have clearly defined responsibilities and ways of working collaboratively with key regulators.	
Further work on ethnic disparities in fertility treatment, including an updated report on register data in this area, and a joint call to action/statement Autumn 2023.	Continue to address disparities in access, experience and outcomes identified in our 'Ethnic Diversity in Fertility Treatment 2018' report (published March 2021) and patient survey by issuing an updated report and a call to action. Continue to engage with stakeholders and to support the Government's objective of reducing health inequalities particularly among Black and ethnic minority groups.	Autumn 2023
Conclusion of work on changes to the ratings system on treatment add-ons.	Ethically and medically responsible supply of add-ons, only where these are safe and appropriate, by clinicians/clinics based on good evidence. Where add-ons are offered, this is: • with full information so patients can make informed decisions • only to specific groups where there is evidence of effectiveness and safety. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence. A refined presentation of the rating system and further consideration of the most appropriate forms of evidence to base it on.	Summer 2023

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Effective handling of and communication about: • clinical incidents and adverse events, including publication of a 2022-2023 'State of the Sector' report and quarterly compliance reports • complaints about clinics	Continued strong focus on learning in dialogue with the sector including engaging with clinic leaders. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to a proactive approach being taken to learning from own and others' mistakes. Learning gained, to inform future inspections. Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse events.	Throughout the year, with the state of the sector report published in Autumn 2023
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually ensuring improvements are made as required.	Throughout the year
Processing applications for the licensing of preimplantation genetic testing for monogenic gene defects (PGT-M) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. Mitochondrial donation and PGT-M approvals taken in an accountable and transparent way.	Throughout the year
Ongoing review of guidance for clinics to ensure this remains fit for purpose, including: • delivery of any necessary updates to the Code of Practice (this year, in relation to storage limits changes in 2022) • issuing other clinic-facing communications, such as Clinic Focus,	Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. A clear Code of Practice as required by law and other guidance for clinics. An update incorporating updated guidance to clinics on the storage of gametes and embryos as a result of changes to storage limits introduced by the Health and Social Care Act 2022.	Throughout the year.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
on issues that require further clarification to the sector.		
Servicing the legal information needs of the HFEA including: • provision of legal advice to inform other HFEA work • management of team of external legal advisers to support effective licensing processes. • supporting any changes to the law.	HFEA licensing decisions are sound and supported by legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year
Maintain up to date information on the HFEA website about routine treatments, continuing our focus on clinics providing good support, and testing new information using the patient engagement forum.	We use our communications channels to make sure patients receive the right information at the right time to ensure our statutory duty to provide information is informed and effective. Information is reviewed on a cyclical basis to ensure that it is fit for purpose. New information added when needed. We use our social media channels to signpost people to the website information and if we include new information on the website, we promote this widely using our social media.	Throughout the year
Ongoing implementation and oversight of the changes being considered to the Northern Ireland Protocol and responding to any new developments that may arise.	We continue to work with the DHSC and others on any issues arising from the Northern Ireland Protocol. We will engage with any changes to the EUTCD and work with others on the implications of these.	Throughout the year

Table 2 - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Table outlining planned activities for April 2023 to March 2024

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	**Benefits and outcomes**	**Timescale**
No specific work in this area planned for this business year.		

The right information

Our second aim is to ensure that people can access the right information at the right time. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 3 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for April 2023 to March 2024

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	Benefits and outcomes	Timescale
Use our social media and other channels to communicate relevant information to the wider general public and those who are not having fertility treatment.	We will utilise feedback to improve the information provided to the public and to position our information effectively, maximising our impact. We will communicate via a range of channels and methods so people can access the right information at the right time for them. We will raise our profile and provide the general public, not just current fertility patients, with useful information.	Throughout the year

Table 4 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for April 2023 to March 2024.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Maintaining communication with our stakeholder groups, the patient engagement forum and our followers on social media.	The information we publish is informed by stakeholder needs and insights. We meet with our patient and professional stakeholder groups twice a year and engage with them on a range of issues. We will involve members of the patient engagement forum to gain feedback on our work to inform what we do. We maintain our social media channels to reflect the work we are doing and try to make these as interactive as possible to encourage feedback and discussion.	Throughout the year
Ensuring that patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant, impartial and accurate information.	We will ensure our website is up to date and reflects the latest information. Patients see HFEA information as 'go to' impartial advice. People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. People can easily find relevant information and signposting on our website to inform their next steps.	Throughout the year
Position and promote information via our various channels.	Access to relevant and impartial information for patients, partners, professionals, surrogates, donors, donor-conceived people, and their families. Maximising the positive impact of the information we provide. We ensure we make an impact with our information by using a range of metrics to evaluate the impact of our digital and social channels and media work. We use our social media channels to drive people to our information both online and in the media. Promote information of relevance to the Government's Women's Health Strategy and work with the Women's Health Ambassador and others on this.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Responding to media reports and requests.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wide range of issues.	Throughout the year
Scoping of future developmental work on regulatory transparency.	Scoping of potential future work to increase regulatory transparency. Consideration of how best to deliver this work in the most effective and efficient way possible.	Throughout the year
Ongoing work to ensure that we maintain our compliance with accessibility requirements and make changes as necessary.	Stakeholders' accessibility needs are considered so that they are able to access our information. We ensure that our website meets the Government accessibility guidelines and that HFEA staff produce accessible documents, especially those for the website.	Throughout the year
Work following the completion of the PRISM reporting system, to enable Choose a Fertility Clinic (CaFC) to be updated.	We ensure quality metrics and verification reports are in place. Clinics are able to fix validation errors. We ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions. New CaFC data published for the first time from the new system. Increased ability to analyse data and report from the Register.	Between September 2023 and June 2024
Continued support for the PRISM data submission system.	PRISM fully bedded in with clinics and data being submitted into the register. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime. 'Right first time' data quality and reduction in effort by clinics submitting the data.	July 2023 onwards
Further development work on the Register Information Team Application (RITA), to enable us to query the new register and run reports.	Targeted support to improve data quality across the sector. Reports being provided and the ability to query the new register to internal HFEA teams' requirements to enable Register team and OTR team to provide an acceptable level of service.	By July 2023

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
	Ability for OTR team to provide statutory service and search across the new register. Ability for register team to provide support to clinics and provide cross-sector reporting. Ability for register team to improve their data quality focus, addressing patterns or trends of data quality issues across sector or within specific areas.	
Maintaining an effective Opening the Register (OTR) service.	OTR requests continue to be met in a sensitive manner. The backlog of requests stemming from the clinic closure period during the pandemic and a subsequent increase in the ongoing number of requests is dealt with, and realistic timescales introduced.	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet.	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI), parliamentary question (PQ), and subject access requests.	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion. We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.	Throughout the year
Continue to engage with the requirements of the NHS Digital Data Security and Protection Toolkit.	We continue to maximise the quality of our submissions in the toolkit, in particular areas of improvement previously highlighted. Maintain our oversight group, which combines best practice from other organisations and collects toolkit documentation on an ongoing basis to allow for faster, more complete submissions going forward.	June 2023 (annual process) Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
	We assure ourselves that we are practising good data security and personal information is handled correctly.	
To publish good quality statistical and other reports.	We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatments, trends and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment. We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. High quality data available to develop patient information and respond to information requests.	Throughout the year
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. Promoting our Register data to ensure it is widely used in research. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing compliance with government information requirements.	We respond to government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual report published including required information.	Throughout the year
Effective records management and information governance.	Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times. Information governance arrangements comply with latest requirements. Records management and information governance risks are managed effectively.	Throughout the year
Responding to external consultations, calls for evidence and reviews including from the Department of Health and Social Care, other departments, regulators and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector.	Throughout the year

Shaping the future

Our final aim is to embrace and engage with changes in the law, science and society. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 5 - Strategic objective 5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Table outlining planned activities for April 2023 to March 2024.

Objective 5 Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI) - methods and channels	Benefits and outcomes	Timescale
Maintain a watching brief over patient-facing AI and data-driven new technologies that are in or potentially approaching clinical use, via the Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning process and reviews. Ongoing horizon scanning on genetics policy issues.	We understand new developments and are responsive to these. We ensure that our regulatory regime and guidance is fit for purpose. Regular reports to SCAAC detailing issues raised used to inform our policy working and to be shared more widely as relevant. Our internal working group on AI meets regularly to monitor this. Regular horizon scanning information on genetics policy issues is considered by SCAAC and integrated into our other work as relevant (eg the work on the modernisation of the Act). Emerging new policy frameworks related to these areas are taken account of in our policy work. That responsible innovation is encouraged.	Throughout the year
To complete and implement a review of the methodology for authorising new processes for use in clinics.	Robust and up to date methodology for authorising new processes. Processes on the authorised processes list are clear and reflect up to date practices. Awareness among clinics of the requirements for introducing new processes.	July 2023

Table 6 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for April 2023 to March 2024.

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
To review responses to a targeted consultation on the HFE Act and complete proposals to government on changes we would like to see to the Act.	Any future review is informed by well-informed proposals based on engagement with our stakeholders. The Government is provided with useful proposals setting out the ways in which the Act could be developed.	Summer 2023
Respond to any requests for consultation on legislation or emerging proposals and consider how these might impact the HFEA.	We inform any work by DHSC on legislation relating to our functions. Early consideration of possible impacts of any planned changes on the sector and the HFEA.	As these arise
Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Horizon Scanning Panel meets once per year. The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues.	June 2023 Throughout year
Working to ensure the HFEA has prepared the ‘Opening the Register’ (OTR) service for future levels of demand.	The HFEA is operationally prepared for the existing and future growth in demand as more donor-conceived people become eligible to make OTR requests from 2023 onwards. Excellent OTR service maintained. Communication and engagement in place to ensure that the public, clinic staff, donors, donor conceived children and their families understand and are prepared for the changes.	Autumn 2023
Considering new arrangements for the provision of support services for OTR applicants.	Consideration of the future of support services for all OTR applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information.	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
	OTR applicants feel supported and prepared to deal with the information they receive from us.	
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2024.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. People strategy in place, setting out our vision for ensuring we strike the right balance of staff skills, capacity and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need through training and other means. We take into account equality and diversity in the design and implementation of our policies, to ensure that these are fair and appropriate for all staff. Staff feel valued and motivated to deliver our strategic aims, by taking action on the results of our staff survey. We reflect our values and behaviours in all our work to ensure that quality and service improvement is part of our ongoing way or working.	Throughout the year
Maintaining the stability of our core IT systems.	Core systems including Epicentre and the Clinic Portal are maintained and upgraded as necessary in order to ensure business continuity.	Throughout the year
Servicing a public bodies review HFEA (‘ALB review’).	Responding and engaging to any public bodies review of the HFEA to ensure the organisation is best presented at any discussions about our role and activities.	Timescale not yet known
The first phase of a structural review of the HFEA’s fee regime, informed by our income forecasting model.	We ensure that we meet the financial needs for effective regulation through a fair and transparent fee structure.	To commence by March 2024
The development of a new strategy for the HFEA from 2024 onwards.	We set a clear vision for the future, enabling us to plan for the next three year period.	Throughout the year

Register Research Panel annual report to Authority

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:	25 January 2023
Author:	Amanda Evans, Head of Research and Intelligence
Annexes	Annex A – Publication list for approved Register Research Panel projects Annex B – Publication list for anonymised register data and FOI requests

Output from this paper

For information or decision?	For decision
Recommendation:	• Authority is asked to note this report. • Authority is asked to consider proposals to ask the DHSC for changes to the regulations in relation to access to HFEA register data for research purposes.
Resource implications:	Medium
Implementation date:	2022-2023
Communication(s):	Through updates to researchers, clinics, stakeholders and patients via our website and social media
Organisational risk:	Medium

1. Introduction

1.1. The HFEA holds a Register of all patients, partners, donors, treatments and children born as a result of these treatments. It is believed to be the largest database of assisted reproduction treatment in the world.

1.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (the 2010 Regulations) provide that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register.

1.3. As a result, the HFEA is uniquely positioned to enable high quality research on treatments and outcomes via authorised access to Register data – see Annexes A and B for a full list of academic publications using Register data to date.

1.4. Under Standing Orders, the Authority delegates to the Register Research Panel (RRP), the power to authorise access to Register data for the purposes of medical or non-medical research. The panel is required to report annually to the Authority (see section 2 below). This paper provides that annual report.

1.5. High quality data research can contribute to our strategic ambition to provide the best care and we want to continue to engage with researchers and work to enable access to relevant and valuable data on our Register to that end.

1.6. This paper is structured as follows. Section 2 provides an overview of Register data activity undertaken in 2022. Section 3 sets out work carried out to provide data for research purposes in freely available anonymised formats. Section 4 outlines a series of suggested changes to the 2010 Regulations which we believe would improve data research using our Register data.

2. Register Research Panel activity in 2022

2.1. The role of the RRP is to decide whether to grant or refuse requests to access Register data for specific research purposes. The RRP is chaired by a Director and has membership from staff with research, information governance, data register, clinical and policy expertise.

2.2. Since the introduction of the 2010 Regulations, the RRP has approved 20 projects: nine projects are currently active and 11 have been completed.

2.3. The main output from RRP approved projects is typically publication of the research results in peer-reviewed academic journals. In 2022, there were five new peer-reviewed academic articles published from RRP approved research projects (see Annex A) and four published using anonymised register data (see Annex B). There have been 19 peer-reviewed academic articles published from RRP approved research projects and 21 from anonymous HFEA data sources such as the anonymised register since 2010.

2.4. The migration of data held in our Register as part of the PRISM project meant that the RRP had to be suspended from September 2021 to May 2022 as we would have been unable to provide datasets during this time. During the suspension, the RRP met three times to review six project amendment requests such as project extensions, all of which were approved. Since May, the RRP has met on two occasions to consider two new applications, one of which was approved.

2.5. In addition, work in 2022 has focused on updating decision-making tools and supporting documents that allow the RRP to function and securing extra staff capacity so that we can better realise our data ambitions.

2.6. In summary, work that was carried in 2022 included the following:

- Backlogs were cleared from previously approved projects awaiting data due to delays with PRISM.
- All panel members received legal training on the 2010 Regulations in May 2022.
- A legal advisor is now available to attend panel meetings to advise when necessary on interpretations of the 2010 Regulations and provide guidance on data protection laws.
- Updates to the following documentation were completed: the data release form, application form, data quality assurance form, data specification sheet and data destruction form as part of the wider work to improve the information provided to and received from researchers.
- Following data migration and the launch of PRISM in 2021, we have built new infrastructure from this new database to enable reporting (e.g. publications, FOI, PQs) and production of datasets for research projects.
- A new decision tree was created, similar to what is used in licensing committees, to aid decision-making based on the 2010 Regulations. This was created with guidance from the RRP's external legal advisor.
- We recently launched a **new data research webpage** that provides more information for researchers on how to apply to access data.

2.7. We have recently recruited a Senior Research Manager and Data and Insights Analyst to the Research and Intelligence team, which will both aid in the administrative work of the panel or preparing data. The Senior Research Manager will lead on increasing engagement with researchers through new avenues, such as webinars, events or mailing lists. The Data and Insights Analyst will allow us to more quickly prepare and disseminate data to researchers, as well as improve our quality assurance process for data releases.

2.8. The data released under the 2010 Regulations is very sensitive. To date, the number of applications has been disappointing low and whilst the overall number of projects approved is correspondingly low, we must uphold high standards of data protection. Work described above to improve the RRP processes, including the creation of a wide range of standard operating procedures and templates, should make the processes more robust and ensure we can support increased demand for our data in future.

Projects approved

2.9. **General Health Outcomes in Subfertile Men: a UK register-based cohort study, University College London.** This is a linkage study project using HFEA register data and NHS medical records to examine whether health outcomes are different for males following a subfertility diagnosis compared to males in the general population.

3. Accessing anonymous Register data

3.1. The RRP is just one of many ways in which Register data is made available. In fact, most people seeking to access Register data do not wish to access identifiable information. To enable researchers, clinicians and the public to undertake research using Register data, we

proactively release as much data as possible through publications and the release of an Anonymised Register. We also respond to freedom of information requests (FOIs), enquiries and parliamentary questions (PQs). See Annex B for details of academic publications using anonymous Register data releases since 2010.

3.2. We regularly publish data research reports with anonymous Register data which receive wide media coverage. Fertility trends is our annual statistical release and is the main point of reference for all data-related enquiries received throughout the year. It is published as a HTML report each year, with a large set of underlying data tables. **Fertility treatment 2019: trends and figures** was published in May 2021 and was viewed an average of two thousand times each month from 2021. Due to the work in data migration and PRISM referred to above, an update of this report was not published in 2022, instead an interim report using preliminary unvalidated data was published in the **Impact of COVID-19 on fertility treatment report 2020**.

3.3. Additionally, the Research and Intelligence team produced an updated report on **Multiple births in fertility treatment 2019** in February 2022 and an updated report on **Trends in egg, sperm and embryo donation 2020** in November 2022. All reports we publish include underlying supplementary tables covering topics included in the report.

3.4. Data validation for 2020 and 2021 data has been delayed due to PRISM and data migration and we are currently exploring options for publishing further information this calendar year while data validation work is in progress.

3.5. The most recent version of the **Anonymised Register** is available for download from the HFEA website, with the most recent validated data up to 2018. An updated version of the anonymised register will be published as soon as possible following validation of 2019 and 2020 outcomes. The data can be used for research without having to apply for approval or bespoke datasets; it also allows researchers to access a large and rich dataset that does not contain any identifiable information.

3.6. In the 2022 calendar year, the Research and Intelligence team responded to 208 data-related enquiries in the form of 49 FOIs, 143 enquiries and 16 PQs, as well as numerous data requests through our press office. These requests often result in the release of bespoke information.

4. Modernising data research legislation

4.1. As part of our work in reviewing the Act we met with eight researchers in June 2022 who have used HFEA register data in their research to discuss where legislative changes would be of benefit to improve data research. A short paper was provided to researchers to prompt discussion and is available **here**. The majority of suggestions for reform concern the 2010 Regulations and these proposals are summarised below.

Cost recovery

4.2. The 2010 Regulations allow the HFEA to charge research applicants a fee to cover the cost of the collation and disclosure of information from our Register. The fee is based on a charge of £500 per day, to a maximum chargeable cap of ten working days, at £5,000 for the disclosure of identifiable/de-personalised data.

4.3. The current limit of £5,000 is frequently insufficient to cover staff time for preparing data for researchers.

4.4. There is considerable administration time required to ensure we review and assess data research applications. This work is not covered by the fee. Similar public organisations charge £800-£1,000 for an application fee, as well as further fees for additional administrative costs.

4.5. The maximum £5,000 is much lower than typical costs for obtaining comparable types of research data obtained from other sources that function on cost recovery models such as NHS Digital or CPRD. In our roundtable discussion with researchers, some mentioned typical costs being around £20,000 or more for accessing datasets.

4.6. The costs for accessing datasets for research projects is typically funded from academic grants and was not considered in the roundtable to be a major barrier to researchers applying for HFEA data, some commented on fees resulting in higher quality applications. Additionally, we regularly publish anonymised register data freely available on our website for use by data researchers.

4.7. Studies involving linkage to third party datasets require data sharing agreements among multiple organisations and requires consulting external legal advisors to ensure we are compliant with data protection laws. These costs are not covered under the regulations, but are critical for permitting high quality research linking to other datasets such as Hospital Episode Statistics, Department for Education datasets and cancer registries.

4.8. Researchers at the roundtable agreed that the HFEA should be able to charge full cost recovery to researchers for access to our register data, at a rate set by the Authority. Ideally, rates should not be explicitly set through legislation, but function in a full cost recovery model.

Research following egg, sperm or embryo donation

4.9. The 2010 Regulations prevent the HFEA from sharing register data with researchers where it would identify gamete or embryo donors, patients and their partners undergoing treatment with donated gametes or embryos, and donor-conceived offspring.

4.10. Only HFEA register information about gamete or embryo donors, patients and their partners undergoing treatment with donated gametes or embryos, and donor-conceived offspring that has been completely anonymised, can be shared with researchers. This means that various other kinds of important research that could benefit single patients, surrogates and same-sex couples, as well as all others who use donated gametes (and donors and donor-conceived people themselves) are prevented by these legal restrictions.

4.11. Given the removal of donor anonymity in 2005, which is effective from 2023, the growth of genetic testing websites and the general increase in public discussion on this subject, the concerns around donation are arguably less than when the regulations were first drawn up in 2010.

4.12. Due to these societal changes and the removal of donor anonymity, the risks are reducing while the potential benefits of the research are increasing. The 2010 Regulations could therefore be amended to allow register information from the donors of gametes and embryos to be shared for all kinds of research, beyond anonymised research.

Consent to non-contact research

4.13. Since the introduction of the 2010 Regulations, we have to require explicit consent for non-contact research in order to use disclosable protected information from our register for approved RRP projects.

4.14. Access to Register data functions in an opt-in system, whereas other databases such as NHS Digital function on an opt-out system that generally has higher rates of data consent that can be used in research. Consent rates for non-contact research is around 70-80% for HFEA Register data in recent years, whereas opt-out percentage for the NHS is usually around 3% (see more information here), meaning that over 95% of individuals are eligible to have their data used in research.

4.15. Researchers raised concerns about the bias introduced through opt-in consent systems and how this would impact their research.

4.16. Other consent options could be explored in order to enable researchers to access the most information possible to ensure their research can be as accurate as possible with minimal bias introduced through consent.

Child consent

4.17. Since the 2010 Regulations were introduced, parental consent recorded on consent forms apply to data about a child born as a result of treatment. With respect to treatment undertaken since 1 October 2009, data about children will automatically be excluded from disclosure for research purposes once that child reaches the age of 16. Anyone born as a result of treatment undertaken since 1 October 2009 who is 16 years or older will be able to consent to disclosure of their personal identifying data for research purposes.

4.18. It is expected that in such cases the relevant individual will contact the HFEA and will be required to verify their identity.

4.19. Children born since this change was introduced by the 2010 Regulations will start to reach the age of 16 from October 2025 onwards. It is not expected that children or adults conceived through fertility are likely to contact the HFEA to opt-in at the age of 16 or later to prove their identify and request their information be provided in approved HFEA data research projects using disclosable protected information.

4.20. This means that long-term follow-up studies of adults conceived through fertility treatment will no longer be possible using data from 2010 onwards and will prevent newer procedures or techniques from being evaluated long-term in the UK.

4.21. Most respondents in the original consultation when developing the 2010 Regulations considered that the age 18 upper limit should be reduced to age 16 to bring the regulation in to line with the Mental Capacity Act 2005, Adults with Incapacity (Scotland) Act 2000 and guidance to General Practitioner on the treatment of young people.

4.22. Databases such as NHS Digital do not require children born in the UK to opt-in to consent to their data being shared for research once they reach a certain age, but rather allow all individuals to opt-out of their data being used in research.

4.23. Options should be explored to ensure that high quality long-term follow-up studies on individuals born through fertility treatment is possible in a UK setting.

5. For decision

5.1. The Authority is asked to:

i. Note the annual report of the Register Research Panel

ii. Consider the suggested proposals to reform the 2010 Regulations to encourage more data research as outlined in section 4. If the Authority is convinced of the case for reform we shall approach the DHSC.

Annex A: Publication list - Approved Register Research Panel projects

1. McLernon, D. J., Raja, E. A., Toner, J. P., Baker, V. L., Doody, K. J., Seifer, D. B., Sparks, A. E., Wantman, E., Lin, P. C., Bhattacharya, S., & van Voorhis, B. J. (2022). Predicting personalized cumulative live birth following in vitro fertilization. *Fertility and Sterility*, 117(2). https://doi.org/10.1016/j.fertnstert.2021.09.015
2. Raja, E.-A., Bhattacharya, S., Maheshwari, A., & McLernon, D. J. (2022). Comparison of perinatal outcomes after frozen or fresh embryo transfer: separate analyses of singleton, twin, and sibling live births from a linked national in vitro fertilization registry. *Fertility and Sterility*, 118(2), 323–334. https://doi.org/10.1016/j.fertnstert.2022.05.010
3. Ratna, M. B., Bhattacharya, S., van Geloven, N., & McLernon, D. J. (2022). Predicting cumulative live birth for couples beginning their second complete cycle of in vitro fertilization treatment. *Human Reproduction*, 37(9), 2075–2086. https://doi.org/10.1093/humrep/deac152
4. Sharpe, A., Mascarenhas, M., & Balen, A. (2022). Ethnic variation in the live birth rate and perinatal outcomes following frozen embryo transfer: an analysis of the HFEA database from 2000 to 2016. *Human Fertility*, 25(3), 583–592. https://doi.org/10.1080/14647273.2021.1913291
5. Sutcliffe, A. G., Purkayastha, M., Brison, D. R., Nelson, S. M., Roberts, S. A., & Lawlor, D. A. (2022). General health in a cohort of children conceived after assisted reproductive technology in the United Kingdom: a population-based record-linkage study. *American Journal of Obstetrics and Gynecology*. https://doi.org/10.1016/j.ajog.2022.07.032
6. Bhattacharya, S., Maheshwari, A., Ratna, M. B., van Eekelen, R., Mol, B. W., & McLernon, D. J. (2021). Prioritising IVF treatment in the post COVID 19 era: a predictive modelling study based on UK national data. *Human Reproduction*, 36(3). https://doi.org/10.1093/humrep/deaa339
7. Purkayastha, M., Roberts, S. A., Gardiner, J., Brison, D. R., Nelson, S. M., Lawlor, D., Luke, B., & Sutcliffe, A. (2021). Cohort profile: A national, population-based cohort of children born after assisted conception in the UK (1992-2009): Methodology and birthweight analysis. In *BMJ Open* (Vol. 11, Issue 7). https://doi.org/10.1136/bmjopen-2021-050931
8. Cameron, N. J., Bhattacharya, S., & McLernon, D. J. (2020). Cumulative live birth rates following blastocyst- versus cleavage-stage embryo transfer in the first complete cycle of IVF: a population-based retrospective cohort study. *Human Reproduction*, 35(10), 2365–2374. https://doi.org/10.1093/humrep/deaa186
9. van Eekelen, R., van Geloven, N., van Wely, M., Bhattacharya, S., van der Veen, F., Eijkemans, M. J., & McLernon, D. J. (2019). IVF for unexplained subfertility; whom should we treat? *Human Reproduction*, 34(7), 1249–1259. https://doi.org/10.1093/humrep/dez072
10. Hann, M., Roberts, S. A., D'Souza, S. W., Clayton, P., Macklon, N., & Brison, D. R. (2018). The growth of assisted reproductive treatment-conceived children from birth to 5 years: a national cohort study. *BMC Medicine*, 16(1). https://doi.org/10.1186/s12916-018-1203-7
11. Williams, C. L., Bunch, K. J., Murphy, M. F. G., Stiller, C. A., Botting, B. J., Wallace, W. H., Davies, M. C., & Sutcliffe, A. G. (2018). Cancer risk in children born after donor ART. *Human Reproduction*, 33(1). https://doi.org/10.1093/humrep/dex333
12. Williams, C. L., Jones, M. E., Swerdlow, A. J., Botting, B. J., Davies, M. C., Jacobs, I., Bunch, K. J., Murphy, M. F. G., & Sutcliffe, A. G. (2018). Risks of ovarian, breast, and corpus uteri cancer in women treated with assisted reproductive technology in Great Britain, 1991-2010: data linkage study including 2.2 million person years of observation. *BMJ (Online)*, 362. https://doi.org/10.1136/bmj.k2644

13. Cameron, N. J., Bhattacharya, S., Bhattacharya, S., & McLernon, D. J. (2017). Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women. *Human Reproduction*, 32(11). https://doi.org/10.1093/humrep/dex293
14. Maalouf, W., Maalouf, W., Campbell, B., & Jayaprakasan, K. (2017). Effect of ethnicity on live birth rates after in vitro fertilisation/intracytoplasmic sperm injection treatment: analysis of UK national database. *BJOG: An International Journal of Obstetrics and Gynaecology*, 124(6). https://doi.org/10.1111/1471-0528.14241
15. McLernon, D. J., Maheshwari, A., Lee, A. J., & Bhattacharya, S. (2016). Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women. *Human Reproduction*, 31(3). https://doi.org/10.1093/humrep/dev336
16. McLernon, D. J., Steyerberg, E. W., te Velde, E. R., Lee, A. J., & Bhattacharya, S. (2016). Predicting the chances of a live birth after one or more complete cycles of in vitro fertilisation: population based study of linked cycle data from 113 873 women. *BMJ (Online)*, 355. https://doi.org/10.1136/bmj.i5735
17. Smith, A. D. A. C., Tilling, K., Nelson, S. M., & Lawlor, D. A. (2015). Live-birth rate associated with repeat in vitro fertilization treatment cycles. *JAMA - Journal of the American Medical Association*, 314(24). https://doi.org/10.1001/jama.2015.17296
18. Lawlor, D. A., & Nelson, S. M. (2012). Effect of age on decisions about the numbers of embryos to transfer in assisted conception: A prospective study. *The Lancet*, *379*(9815). https://doi.org/10.1016/S0140-6736(11)61267-1
19. Nelson, S. M., & Lawlor, D. A. (2011). Predicting live birth, preterm delivery, and low birth weight in infants born from in vitro fertilisation: A prospective study of 144,018 treatment cycles. *PLoS Medicine*, *8*(1). https://doi.org/10.1371/journal.pmed.1000386

Annex B: Publication list - Anonymised Register data and FOI requests

Publications from projects that used data from the HFEA through FOI requests or from the publicly available anonymised register of which we are aware.

1. Lewin, J., Lukaszewski, T., Sangster, P., Williamson, E., McEleny, K., Al Wattar, B. H., & Yasmin, E. (2022). Reproductive outcomes following surgical sperm retrieval in couples with male factor subfertility: A 10-year retrospective national cohort. *Fertility and Sterility*. https://doi.org/10.1016/j.fertnstert.2022.12.041
2. Allen, C. P., McLernon, D. J., Bhattahcharya, S., & Maheshwari, A. (2022). Perinatal outcomes of 221,709 singleton and twin pregnancies after the use of donor versus partner sperm. *Fertility and Sterility*, *118*(5), 948–958. https://doi.org/10.1016/j.fertnstert.2022.08.015
3. Henderson, I., Lacey, L., Akhtar, M. A., & Quenby, S. (2022). Ethnic group and reason for ART failure: analysis of HFEA registry data from 2017-2018. *Fertility and Sterility*. https://doi.org/10.1016/j.fertnstert.2022.11.005
4. Roberts, S. A., Wilkinson, J., Vail, A., & Brison, D. R. (2022). Does PGT-A improve assisted reproduction treatment success rates: what can the UK Register data tell us? *Journal of Assisted Reproduction and Genetics*. https://doi.org/10.1007/s10815-022-02612-y
5. Mascarenhas, M., Mehlawat, H., Kirubakaran, R., Bhandari, H., & Choudhary, M. (2021). Live birth and perinatal outcomes using cryopreserved oocytes: an analysis of the Human Fertilisation and Embryology Authority database from 2000 to 2016 using three clinical models. *Human Reproduction (Oxford, England)*, *36*(5). https://doi.org/10.1093/humrep/deaa343
6. Goyal, A., Kuchana, M., & Ayyagari, K. P. R. (2020). Machine learning predicts live-birth occurrence before in-vitro fertilization treatment. *Scientific Reports*, *10*(1). https://doi.org/10.1038/s41598-020-76928-z

7. Kamath, M. S., Antonisamy, B., & Sunkara, S. K. (2020). Zygotic splitting following embryo biopsy: a cohort study of 207 697 single-embryo transfers following IVF treatment. *BJOG: An International Journal of Obstetrics and Gynaecology*, *127*(5). https://doi.org/10.1111/1471-0528.16045
8. Supramaniam, P. R., Granne, I., Ohuma, E. O., Lim, L. N., McVeigh, E., Venkatakrishnan, R., Becker, C. M., & Mittal, M. (2020). ICSI does not improve reproductive outcomes in autologous ovarian response cycles with non-male factor subfertility. *Human Reproduction*, *35*(3). https://doi.org/10.1093/humrep/dez301
9. Marconi, N., Raja, E. A., Bhattacharya, S., & Maheshwari, A. (2019). Perinatal outcomes in singleton live births after fresh blastocyst-stage embryo transfer: a retrospective analysis of 67 147 IVF/ICSI cycles. *Human Reproduction*, *34*(9), 1716–1725. https://doi.org/10.1093/humrep/dez133
10. Supramaniam, P. R., Mittal, M., Ohuma, E. O., Lim, L. N., McVeigh, E., Granne, I., & Becker, C. M. (2019). Secondary sex ratio in assisted reproduction: an analysis of 1 376 454 treatment cycles performed in the UK. *Human Reproduction Open*, *2019*(4). https://doi.org/10.1093/hropen/hoz020
11. Henderson, I., Lacey, L., Akhtar, M. A., & Quenby, S. (2022). Ethnic group and reason for ART failure: analysis of HFEA registry data from 2017-2018. *Fertility and Sterility*. https://doi.org/10.1016/j.fertnstert.2022.11.005
12. Sharpe, A., Avery, P., & Choudhary, M. (2018). Reproductive outcome following pre-implantation genetic diagnosis (PGD) in the UK. *Human Fertility*, 21(2). https://doi.org/10.1080/14647273.2017.1336259
13. Kamath, M. S., Antonisamy, B., Mascarenhas, M., & Sunkara, S. K. (2017). High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births. *Reproductive BioMedicine Online*, *35*(3). https://doi.org/10.1016/j.rbmo.2017.06.013
14. Sunkara, S. K., Antonisamy, B., Selliah, H. Y., & Kamath, M. S. (2017a). Perinatal outcomes after gestational surrogacy versus autologous IVF: analysis of national data. *Reproductive BioMedicine Online*, *35*(6). https://doi.org/10.1016/j.rbmo.2017.08.024
15. Sunkara, S. K., Antonisamy, B., Selliah, H. Y., & Kamath, M. S. (2017b). Pre-term birth and low birth weight following preimplantation genetic diagnosis: Analysis of 88 010 singleton live births following PGD and IVF cycles. *Human Reproduction*, *32*(2). https://doi.org/10.1093/humrep/dew317
16. Ghuman, N. K., Mair, E., Pearce, K., & Choudhary, M. (2016). Does age of the sperm donor influence live birth outcome in assisted reproduction? *Human Reproduction*, 31(3). https://doi.org/10.1093/humrep/dev331
17. Maheshwari, A., Raja, E. A., & Bhattacharya, S. (2016). Obstetric and perinatal outcomes after either fresh or thawed frozen embryo transfer: an analysis of 112,432 singleton pregnancies recorded in the Human Fertilisation and Embryology Authority anonymized dataset. *Fertility and Sterility*, 106(7). https://doi.org/10.1016/j.fertnstert.2016.08.047
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20. Maalouf, W. E., Mincheva, M. N., Campbell, B. K., & Hardy, I. C. W. (2014). Effects of assisted reproductive technologies on human sex ratio at birth. *Fertility and Sterility*, *101*(5), 1321–1325. https://doi.org/10.1016/j.fertnstert.2014.01.041
21. Sunkara, S. K., Rittenberg, V., Raine-Fenning, N., Bhattacharya, S., Zamora, J., & Coomarasamy, A. (2011). Association between the number of eggs and live birth in IVF treatment: An analysis of 400 135 treatment cycles. *Human Reproduction*, *26*(7). https://doi.org/10.1093/humrep/der106
22. Roberts, S. A., McGowan, L., Hirst, W. M., Brison, D. R., Vail, A., & Lieberman, B. A. (2010). Towards single embryo transfer? modelling clinical outcomes of potential treatment choices using

multiple data sources: Predictive models and patient perspectives. *Health Technology Assessment*, *14*(38). https://doi.org/10.3310/hta

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Opening the Register – the year ahead

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25 January 2023

www.hfea.gov.uk

Opening the Register activity 2023

Overview

- Background to 2023
- Challenges for donors
- Challenges for donor conceived individuals (DCI)
- Challenges for clinics
- Challenges for the HFEA
- HFEA activity during 2023
- Workstreams
- Risks
- Next steps

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Background

Changes in 2023

- Change in the law in 2005 means that donor conceived children can access identifying information about their donor once they turn 18 –
  - full name,
  - date of birth,
  - last known postal address

- The HFEA expects a surge in interest from the media and social media, as well as a steady increase in applications in 2023 from donor-conceived children turning 18.

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Challenges for donors

- All donors will have given informed consent for identifying information to be released. However, as it's 18 years ago, they may well have forgotten in general, or be unable to recall the specific details, for example release of postal address.
- Circumstances may have changed since donating, for example, family may be unaware of the donation and no way of knowing if or when they may be contacted
- Meeting expectations of donor conceived individuals (DCI)
- Donors cannot access identifying information

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Challenges for donor conceived individuals

- Donors may not respond to correspondence, for example, they may choose not to, or the donor has moved address or passed away
- The donor may not meet the expectations of the donor conceived individual
- Family communications around disclosing an OTR application
- They may find out they are donor conceived through other means
- In first years after law change may still be from a pre-2005 donor that has not re-registered as identifiable

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Challenges for Clinics

- Resource implications if they choose to proactively contact donors to check postal addresses and signpost support
- Increased demand on administration from HFEA to check postal addresses when an application is received
- Increased demand on counselling due to increased contact of donors, patients and DCI
- Ensuring compliance with the law, for example, obtaining donor postal addresses for identity release directly from donors not third party databases (the Explanatory Notes to the 2004 Regulations explain that "The information as to the identity of donors which will be provided will be restricted to information which donors supply to clinics on or after 1 April 2005").

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Challenges for the HFEA

- Meeting expectations of all those involved - DCI and their families, donors, and clinics
- Ensuring information is accurate and timely for OTR applicants
- Providing useful and practical guidance to clinics and professional/patient organisations
- Ensuring those affected are signposted to appropriate information and support
- Meeting media/wider world expectations – e.g. that we will proactively seek donors' current addresses
- Balancing this work with other statutory responsibilities

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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

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OTR service

Workstream aims

- Integration of a efficient IT system for managing applications
- Internal staffing redesign and resourcing (complete for current and near future demand)
- Updated policies and legal advice to develop an internal OTR handbook

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Future of support service

Workstream aims

- Develop options for a multi-layered support service including the intermediary service
- Literature review and international comparison of other models and systems where insights can be gained for a future UK model.
- Explore funding options for a new support model to seek Authority decision later in 2023
- Targeted engagement with key stakeholders regarding ways donors and donor conceived people can access specialist counselling and peer support
- Link with other activity on donor information in 2023 on what information can be provided on the HFEA website for those who don’t access further support

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Communications

Workstream aims

- Review and update website information
- Review and update clinic information
- Create new information sources if needed
- Engage with the media and on social media
- Engage with speaking opportunities and other events to ensure our role in OTR is understood
- Raising awareness of 2023 and the implications for past donors/parents/d/c children, and how we can do that most effectively within the resources we have.
- Stakeholder engagement with patient and professional groups, LCP, clinic staff etc

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Risks

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

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Next Steps

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

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