Authority meeting

Date: 17 May 2023 – 12.45pm to 4.30pm

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 22 March 2023 and matters arising For decision	12.50pm
3. Chair and Chief Executive's report and Strategy Development For information	12.55pm
4. Committee Chairs' reports For information	1.05pm
5. Performance report For information	1.20pm
6. Strategic risk register For decision	1.50pm
Break	2.20pm
7. Opening the Register - update For Information	2.30pm
8. OTR Donor contact For decision	2.50pm
9. Modernising Fertility Regulation - update For decision	3.40pm
10. Any Other Business	4.25pm
11. Close	4.30pm

Minutes of Authority meeting held on 22 March 2023

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	17 May 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 22 March 2023 as a true record of the meeting.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High

Minutes of the Authority meeting on 22 March 2023

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

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

1. Welcome and declarations of interest

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

1.2. Declarations of interest were made by:

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

2. Minutes of the last meeting and matters arising

2.1. Members agreed that the minutes of the meeting held on 25 January 2023 were a true record and could be signed by the Chair.

Matters arising

2.2. Action 8.12, the Audit and Governance Committee (AGC) Chair, Catharine Seddon stated that the Authority will receive updates on cyber security via the committee.

2.3. Action 6.7, the risk appetite statement will be on the AGC forward plan for December 2023.

2.4. Action 7.15, the consultation on law reform was launched on 28 February and is an agenda item for this meeting.

Decision

2.5. The status of all other matters arising were 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 events and the decision-making committees of the Authority.

3.2. The Chair commented that we received a lot of press coverage following the launch of the consultation on modernising fertility law. She gave a brief description of the interviews she had done alongside other HFEA senior staff.

3.3. The Chief Executive (CE) provided an update on the key external activities including clinic visits, in particular to Wales, that he had been involved in since the last Authority meeting and his attendance at the recent international summit on gene editing held in London.

3.4. Members commented that it was good that we were engaging with Scotland and Wales as we are a UK wide regulator and asked how much the devolved governments were engaged with the HFEA. The Chief Executive responded that our conversations in the devolved nations sometimes differed from that in England, reflecting the policy differences in the four nations, but we must ensure that our work is applicable across the UK and we therefore engage in a variety of ways.

Decision

3.5. 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 there was a high volume of work at this present time and that they were meeting in addition to their normal meeting cycle to review and conclude on complex cases.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) stated that applications received were reliant on peer reviews and the committee also considered similar conditions to those applied for to save future patients from having to apply to have such conditions approved.

4.4. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave a summary of the last meeting held. She commented that the Executive were making good progress to close internal audit recommendations. Also, a number of deep dive topics had been agreed and in October they will be reviewing the increased reporting of corporate governance standards. Lastly, in December there will be a training session on good governance and issued an open invitation to any Authority members to attend.

4.5. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) commented that the bulk of the discussion at their meeting in February was on the add-on ratings. However, more work was required in this area and that there will be a further review at a later meeting.

4.6. The Chair thanked all Authority members for their hard work and time commitment on the various committees. Continuing, the Chair commented that she observed a recent SAC committee

meeting noting that over 600 serious inherited conditions had now been licensed for PGT-M by the HFEA. The list increased every month as the HFEA was presented with new conditions and importantly once a condition is approved, then future patients do not need to go through an application process.

Decision

4.7. Members noted the committee Chairs' reports.

5. Performance report

5.1. The Chief Executive commented on staff sickness and turnover. Members were advised that sickness levels remained stable - as at the end of January it was at 2.8% against the target of 2.5%. On turnover it was now approaching target at 15.5%.

5.2. On PRISM, the Chief Executive commented that the system was working well. All clinics had caught up on their submission backlogs, except three clinics that had yet to transfer to PRISM because of technical issues with their preferred third-party provider. He commented that we were making good progress towards our end of July 2023 target to complete the reports required for the OTR team. He also gave the assurance that we update on PRISM at every AGC meeting.

Compliance and Information

5.3. In the absence of the Director of Compliance and Information, the Chief Executive gave an update. Members were advised that there were improvements to the inspection performance but that the KPI was a complex one to achieve and we were therefore pleased that this was going in the right direction. Members were informed that over the next few months we were expecting performance to dip due to some complex compliance issues but that staff were working to ensure that this was not detrimental to the entire service.

5.4. On the OTR service, we had recruited and trained new staff but there was an increase in applications, so we still had the backlog to deal with. The systems used by the team were being updated as part of a wider piece of work. The new systems will improve efficiency.

5.5. On PRISM and incomplete data, members asked how we were planning on getting feedback from clinics. The Chief Executive responded that it was important to understand that incomplete data did not mean that we were missing treatment cycles, rather it reflected errors within a treatment record. Where we had identified such errors the PRISM Programme Manager had regular updates with clinics to rectify them. We had also created a unique identifier for each record in PRISM, which will be useful to identify errors and other issues with individual cycles.

5.6. Members commented that this was a huge amount of work and congratulated everyone involved and asked how the Executive would know if a whole record was missing and if missing data could be inputted manually. The Chief Executive responded that we had several ways of assuring the accuracy of the Register. For historic data we keep testing. For recent data we validate it and because records are live or only recently inputted, we are able to plug the gaps. It was also a requirement of all persons responsible (PRs) to submit accurate data and we carry out sample audits. He continued that it was important that we hold accurate information because it is a regulatory requirement. Further confidence came from the fact that our annual report was externally audited before being laid before Parliament. Taking all this together we believe that the data we hold is generally accurate information and tallies with the income receive.

5.7. The deputy Chair of AGC (Alex Kafetz) had recently had an assurance meeting regarding the new system for supporting OTR requests and was impressed with its proposed functionality.

Strategy and Corporate Affairs

5.8. The Director of Strategy and Corporate Affairs noted that members had all received the 2024 committee and Authority dates and were asked to mark their respective calendars with the relevant meeting dates.

5.9. Members were informed that public events and communications activity to promote the consultation on law reform was ongoing. We plan to publish an updated Fertility Trends report later in the year.

5.10. On the Communication Strategy, the Head of Communications had spoken to Authority members at the end of last year and it was noted that we have seen a huge increase in engagement and media coverage in the last 12 months.

5.11. In response to a question, it was noted that the new add-on ratings had been agreed by the Authority and SCAAC were asked to rate individual add-ons according to these ratings.

5.12. The Chair thanked the Director of Strategy and Corporate Affairs and her team for all the hard work done to date and commented that there had been a huge uptake of media coverage and we were a trusted voice in a range of areas.

Finance and Resources

5.13. The Director of Finance and Resources commented on the full year forecast which shows a surplus against the budget of £335k, this was impacted by underspends in our expenditure. It was also noted that we had amended our forecast income to reflect the impact of the reconciliation of clinic activity against estimates raised during the earlier part of the financial year.

5.14. Members were advised that debt collection was under target. This had however improved over the last month, but it was still low due to estimation and the need to update customer details. Members were assured that effort was being made in debt chasing and securing promises of settlement.

5.15. Lastly, we were awaiting the DHSC to confirm to us our budget for 2023/24.

Decision

5.16. Members noted the performance report.

6. Effective Governance

6.1. The Governance Manager presented this item. Members were reminded that on an annual basis all committees were required to review their own effectiveness using a standard and / or bespoke framework. Between September 2022 and January 2023 this exercise was conducted by the Audit and Governance Committee, Licence Committee, Executive Licensing Panel, Statutory Approvals Committee, the Scientific and Clinical Advances Advisory Committee and the Register Research Panel.

6.2. The Chair commented that the board effectiveness review was carried out in September 2022 and we were now six months in. A number of issues were raised during the exercise and in September 2023 members would meet again to review the list of actions.

6.3. Members were advised that during the discussion at the AGC meeting in March, it was suggested and agreed that it would be beneficial to have the option of bringing in additional independent non-executive expertise (if/when required) during discussion on specific topics. To accommodate this, there was a proposed change to the terms of reference of the committee.

Decision

6.4. Members unanimously voted on the change to standing orders. It was agreed that there will be an addition to state:

> "The committee shall have the power to co-opt additional members for particular expertise if needed. Any such appointment, and the term of office, shall be at the discretion of the Chair of the HFEA".

6.5. Members also noted the summary of actions in the annual review of committee effectiveness.

7. Code of Practice update

7.1. The Regulatory Policy Manager presented this item. Members were advised that since the Code was last updated in 2021 there have been legislative changes that now need to be incorporated into the Code. Also, that these changes had been communicated to licensed clinics through Chair's letters and clinic focus, and that the requirements were already in force.

7.2. It was noted that the changes were in three categories: legislative changes, less substantive changes and other changes.

7.3. The Director of Strategy and Corporate Affairs commented that we needed to strike a balance where the Code of Practice needs to be up to without bringing changes to the sector too often. The Windsor Framework will however have an impact on the Code of Practice.

7.4. Professional members commented that they were aware that there was new professional guidance likely to be issued later this year and this may need to be incorporated into the Code.

7.5. The Director of Strategy and Corporate Affairs responded that depending on the Authority decision, we could be in a position to publish the updated Code in October. However, should the Authority decide that we should postpone, to allow the aforementioned to take effect, the current Code would continue to be out of date although all information relating to storage law changes was available on the clinic portal.

7.6. Members commented that they were aware that information was already available on the clinic portal but it was better to have all information in the Code. It was therefore better to publish now to reduce the risk of an out-of-date Code of Practice.

7.7. In response to a question about the Secretary of State approving the Code of Practice, the Chief Executive explained that this was set out in law and following discussion, it was suggested that this could be part of the law reform proposals we plan to submit to the DHSC, as this would provide useful flexibility in future.

7.8. The majority of the members wanted the Code of Practice to be published this year, although this could be delayed to later during the year if the changes from the Windsor Framework and/or professional body guidance came through over the summer.

Decision

7.9. Members agreed that the proposed changes to the Code of Practice.

8. Opening the Register (OTR) update

8.1. The Director of Strategy and Corporate Affairs presented this item. Members were given an update on the three work streams since the January meeting. It was noted that there was good progress on the integration of the new IT system for managing applications and work was continuing on updating policies.

8.2. Members commented that we need to look at reputational risks and that this needed to be reflected in the communication strategy. It was noted that there were some areas that were out of our control but we should do what we could to mitigate such risks.

8.3. Members also asked if we could consider use of short videos to manage expectations for donor conceived individuals before they received the full information from the HFEA. The Director of Strategy and Corporate Affairs responded that this will be considered as part of the wider communications activity.

8.4. The Chair stated that when we launched the modernising fertility law consultation, the press focused on the proposals on donor anonymity.

8.5. Members were assured that we will present options for a support service later in due course.

Decision

8.6. Members noted the ongoing activities relating to Opening the Register.

9. Modernising Fertility law

9.1. The Director of Strategy and Corporate Affairs presented this item. Members were reminded that this piece of work started in 2020 and that the public consultation was now underway.

9.2. There has been widespread media and social media coverage and commentary. There has also been good engagement with professional and patient groups including stakeholders, experts, patients and interested individuals.

9.3. Members were informed that risks outlined in the report were still valid and that one major risk was not completing this work on time due to lack of capacity. We were however doing what we could to keep to the agreed timetable.

9.4. It was noted that once the consultation ended, the responses will be analysed and we plan to present recommendations to the July Authority meeting.

9.5. Members commented that the press coverage of this consultation was very encouraging and congratulated everybody involved.

9.6. A member commented that getting a wide range of views was very important and would we consider extending the consultation period if needed. The Director of Strategy and Corporate Affairs responded that this would be kept under review.

9.7. Members asked if we were confident that the timetable would not be impacted by other pressing priorities. The Director of Strategy and Corporate Affairs responded that a number of issues could impact our timetable, it was therefore under constant review.

9.8. The Chair thanked all members for engaging with the process and noted that members would be fully involved in the recommendations.

Decision

9.9. Members noted the progress to date on modernising fertility law.

10. Any other business

10.1. The Chair advised that Professor Dame Frances Ashcroft will be stepping down from the Authority due to health issues. As a member of SCAAC, she will be asked if she would like to remain on that committee as an expert adviser. The Authority wished Francis well and thanked her for her work to date.

10.2. The next meeting will be on 17 May 2023.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 17 May 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	17 May 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 22 March 2023			
8.6. Executive to consider producing a short video to manage expectations of donor conceived individuals before they receive the full information.	Director of Compliance and Information	November 2023	Head of comms emailed
Matters arising from the Authority meeting – actions from 18 May 2022			
3.6 Some members that are yet to complete their cyber security training.	Governance Manager	May 2023	In accordance with our annual process, the 2023 Authority member training in information security has commenced, using the Civil Service Learning training portal. In addition, this year, members are also required to complete a module on Equality, Diversity and Inclusion. As at 26 April, seven have completed their Equality, Diversity and Inclusion learning; and six have completed their Information Security training. A reminder was sent to members on 19 April.
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. However, application numbers have increased over recent months and we will need to monitor demand and capacity carefully.
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	The Scientific Officer is nearly towards the end of probation. PGT-M's are progressing well (as are ITE certificates). The rate of PGT-M applications varies, which means workload can suddenly increase, this is unavoidable as it will be driven by patient needs. KPIs were met for September 2022 to January 2023.

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:	17 May 2023
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

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

1. Introduction

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

2. Activities

2.1 Chair activities

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

    - 27 March – informal clinic visits to Edinburgh Fertility Clinic and Glasgow Fertility Clinic. Meeting with Scottish Executive fertility lead.
    - 28 March – informal clinic visits to Ninewells Fertility in Dundee and Aberdeen Fertility Clinic
    - Throughout April and May I have also conducted several appraisal meetings with members of the board
    - 11 May – spoke at the Royal College of Physicians on opportunities and changes to the law.
    - 12 May – Peter and I had our Annual Accountability meeting with our sponsor team at the Department of Health and Social Care.

2.2 Chief Executive

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

    - 27 March – talk to Fertility Network UK on changes to the Act.
    - 28 March – informal visit to Leicester Fertility Clinic.
    - 29 March – First meeting with Public Bodies Review team. Also, the same day participated in debate at PET on shaping UK Fertility and Embryo Law.
    - 3 April – Julia and I attended meeting with all ALB Chairs and Chief Executives chaired by Shona Dunn
    - 5 April – informal visit to Herts and Essex Fertility Clinic
    - 12 April – informal visit to Bristol Fertility clinic
    - 20 April – meeting with the BFS and ARCS
    - 25 April – meeting with Dr Lucy Van de Weil, Lecturer in Global Health & Social Medicine, Postgraduate Research (PGR) Director, King's College London
    - 10 May – interviews for the shared Director of Finance & Resources for the HFEA & HTA
    - 12 May – Julia and I had our Annual Accountability meeting with our sponsor team at DHSC.

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:	17 May 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:		
9 March 2023	1 renewal (research)	Granted
29 March 2023	3 executive updates	Adjourned
4 May 2023	1 renewal 2 special directions	Minutes not yet approved
Other comments:	An Appeals Committee hearing was also held on 22 March. The outcomes from this have been published on the website.	
Executive Licensing Panel:		
8 March 2023	1 Renewal (research) 1 Interim	Both granted
21 March 2023	1 Interim 1 Change of Person Responsible 1 Special Directions	2 items granted. 1 Interim deferred pending further information on non-compliances
4 April 2023	1 Renewal 3 Interims (1 research) 2 Changes of Person Responsible 1 Change of Licence Holder 1 Change of Centre Name	All granted
18 April 2023	2 Renewals 3 Changes of Person Responsible 2 Changes of Licence Holder 1 Change of Premises	All granted
2 May 2023	4 Renewals (2 research) 2 Interims 1 Change of Centre Name 1 Change of Licence Holder	All granted
Other comments:	None.	

Meetings held	Items considered	Outcomes
Licensing Officer decisions:		
March 2023 – April 2023	27 ITE Import Certificates 1 Change of Centre Name	All granted
Other comments:	None.	
Statutory Approvals Committee:		
28 February 2023	4 PGT-M 2 Special Directions	5 items granted 1 Special Direction adjourned
27 March 2023	6 PGT-M 1 Special Direction	All granted
25 April 2023	5 PGT-M 4 Special Directions	8 Items granted 1 Special Direction adjourned
Other comments:	None.	
Audit and Governance Committee:		
The next meeting will be held on 27 June 2023.		
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
The next meeting will be held on 5 June 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 March 2023

Shabbir Qureshi
Risk and business planning manager
28/04/2023

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	SMT & Authority
Agenda item:	5 (Authority)
Meeting date:	02/05/2023 (SMT) and 17/05/2023 (Authority)
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Contents	Latest review and key trends Management summary Summary financial position Key performance indicators

Output from this paper	
For information or decision?	For information
Recommendation:	To discuss
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	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

Latest review and key trends

Latest review

- The attached report is for performance up to and including March 2023.
- Performance was reviewed by SMT at its 02/05/2023 meeting.
- In March performance was generally good. There were seven green, three amber, four red, and three neutral indicators.

Key trends

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

January (4)	February (4)	March (4)
C2 – Inspection reports sent to PR within 20 working days	C2 – Inspection reports sent to PR within 20 working days	HR1 – Staff sickness rate
C4 – End to end licensing reports within 70 working days	C3 – Inspection reports sent to relevant licensing committee within 55 working days	C4 – End to end licensing reports within 70 working days
F1 – Debt collection	C4 – End to end licensing reports within 70 working days	F1 – Debt collection
F2 – Debtor days	F1 – Debt collection	F2 – Debtor days

Human Fertilisation & Embryology Authority

Management summary

IT and register performance reporting

- PRISM: Clinic activity is 388K units submitted from 103 clinics. The overall error rate is 4.1%.
- Meditex have been doing a large amount of testing which ensures clinics don't submit data more than once and have ironed out a number of glitches in this process as a result of this work. This is the same process which we will take to the ARGC clinics which will fully complete PRISM deployment.
- As part of our plan for CaFC, we have three tranches for backdated validations errors which we are asking clinics to fix. The first tranche (approx. 6000 registration errors) was released in December. The second tranche was released in two stages; approx. 3000 backdated PRISM cycle errors in March and the second part (approx. 2000 errors in April). So far, 30% of the cycle errors have been corrected. The final tranche relates to EDI errors, and will be before the end of Spring.
- We are making good progress towards our end of July 23 target to complete the reports required for the OTR team.
- For finalising the new Person ID structure for OTR and 10FL, we have now also built the manual matching system to match records that our automatic algorithm cannot match. There are about 2300 donors that need to be reviewed.

Management commentary

- Performance has been variable across KPI indicators with four red, three amber, three neutral and seven green indicators.
- Sickness has increased significantly this month 16 members of staff being absent for various reasons along with two staff on long term sickness absence.
- Turnover has been reducing steadily over the last few months and is now below 15% for the first time in over a year.
- OTR performance has shown a slight improvement due to staff completing training. Further improvements should be realised in the next few months due to new case management system.
- High number of inspections in March to balance workload and clinic staff availability in April.
- Performance in C2 – Inspection reports to PR within 20 working days continues to improve, with only one over the target.
- Three additional Licencing Committee meetings already this year have significantly increased workload in the team.
- The Act reform consultation has driven social media engagement this month, especially on Twitter.

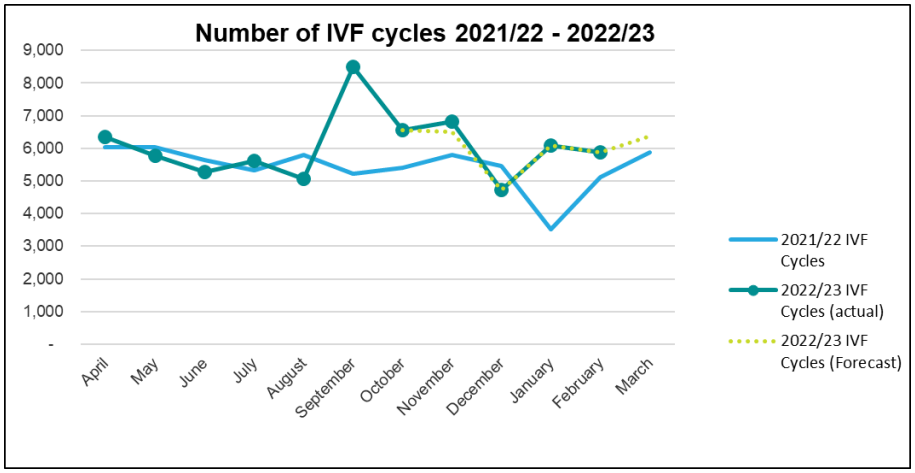
Summary financial position

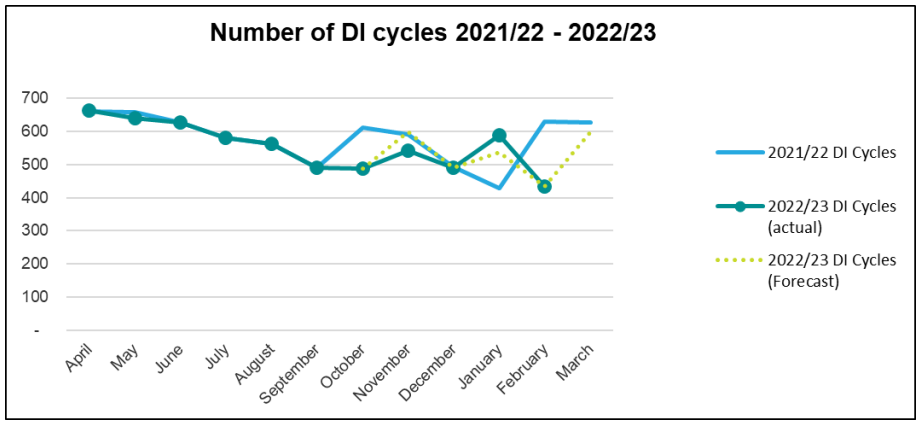
Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s
Income	7,275	7,451	176
Expenditure	7,044	7,472	428
Total Surplus/(Deficit)	**231**	**(21)**	**252**

Commentary on financial performance to March 2023

At the end of the 2022/23 financial year, we are posting a surplus against budget of £252k. This surplus is largely due to the underspends within expenditure as detailed overleaf. Our total income is under budget by £176k which is in part due to a reduction in our grant in aid which has been reduced by the DHSC as part of the 'reform and efficiencies' programme.

Financial management information





IVF Cycles	YTD	
	Volume	£
2021/22 IVF Cycles	65,266	5,221,253
2022/23 IVF Cycles (actual)	72,493	6,161,905
Variance	7,227	940,652

DI Cycles	YTD	
	Volume	£
2021/22 DI Cycles	6,968	261,300
2021/22 DI Cycles	6,638	248,925
Variance	(330)	(12,375)

The year end position for 2022/23 is higher than that reported in the accounts due to adjustments from reconciling clinic activities that cannot be factored in. The year-to-date position is a better reflection of where we believe we are. As per the management accounts, we are posting a year end position of £5.8m which includes DI cycles.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

HFEA Income & Expenditure **Mar-23**

	Year to Date			
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %
Income				
Grant-in-aid	942	1,098	156	0
Non-cash (Ring-fenced RDEL)	265	265	-	0
Grant-in-aid - PCSPS contribution	50	100	50	0
Licence Fees	5,875	5,842	(33)	(0)
Interest received	53	1	(52)	(40)
Seconded and other income	90	145	55	38
Total Income	7,275	7,451	176	**2**
Revenue Costs				
Salaries (excluding Authority)	4,968	4,979	11	0
Staff Travel & Subsistence	84	126	42	34
Other Staff Costs	94	106	12	12
Authority & Other Committees costs	288	231	(57)	(25)
Facilities Costs incl non-cash	448	711	264	37
IT Costs	484	657	174	26
Legal / Professional Fees	510	417	(93)	(22)
Other Costs	168	244	76	31
Other Project Costs	-	-	-	-
Total Revenue Costs	**7,044**	**7,472**	**428**	**6**
TOTAL Surplus / (Deficit)	**231**	**(21)**	**252**	
Adjusted for non-cash income/costs	**215**	**(21)**	**236**	

Management commentary

Income.
Year to date our Licence fee (treatments) income is over budget by £32k or 1% which in part is due to the increase in fees. We have reconciled the majority of our clinics and are estimating for three. The small variance within our grant in aid is due to a reduction in our GIA mandated by DHSC. We will therefore not draw down the remainder of our grant in aid due to savings required across the public sector.

Expenditure by exception (over £10k variance).
At the end of March, we are under budget by £427k.
Staff Travel & Subsistence - are under budget by £42k year to date, which all relate to Inspections travel and home to office travel costs (Inspectors).

Other Staff Costs - are £12k under budget. This is largely due to staff training, recruitment and related costs underspend (£26k) offset by an overspend of £11k on staff welfare.
Authority & Other costs - are over budget by £57k with the main areas relating to costs for Appeals £25k over budget and Non-committee costs which are £22k over budget.

Facilities costs - underspent by £264K, We are underspending on accommodation costs by £217k which is due to: rent paid but released to the balance sheet as part of the process of accounting for our lease with DHSC for 2RP (£134k); rates and service charge costs accrued being less than the actual charge and all relate to 2 Redman place. In addition we are underspending against Meetings costs (£26k). There is an underspend against Finance interest which relates to our lease (£4k). We are checking with other ALBs on our floor plate to ensure consistency in treatment. In addition we have an underspend (£16k) within our non-cash costs, the majority of which relates the lease for our offices which have reduced after being brough onto our balance sheet (capitalised) in Q3.

IT Costs - are underspent by £174k. The areas with significant overspends are: Consultancy and Support costs £205k, Telecoms £15k, Photocopying £5k, Low value Fixed Assets £10k. Offset by overspends within IT Subscriptions and Low value Software of £17k each, Internet costs £2k and Consumables £24k. The underspend within Consultancy is due to the budget including £130k for OTR work that does not appear to have materialised and we budgeted £313k for use of Alscient and other Consultants which again have not been utilised or a cheaper option has been used.
Legal and Professional fees - are over budget by £93k. This is represented by an overspend within the legal budget of £119k. 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. Professional fees (audit fees) are under budget by £26k which relates to the contingency.
Other costs - are underspent by £74k. The most significant variances are within the Stakeholder Events (£47k), plus smaller underspends sub £5k across areas within both the Compliance and Information and Strategy and Corporate Affairs directorate. We are overspending against our External networking and conferences (£10k), publication costs (£8k) and Media monitoring (£7k).

Outturn - we have a surplus against budget of 252k; an underspend of £0.4m against budget of £7.4m. This underspend of expenditure is a contributing factor in addition to the small increase in treatment fee and other income.

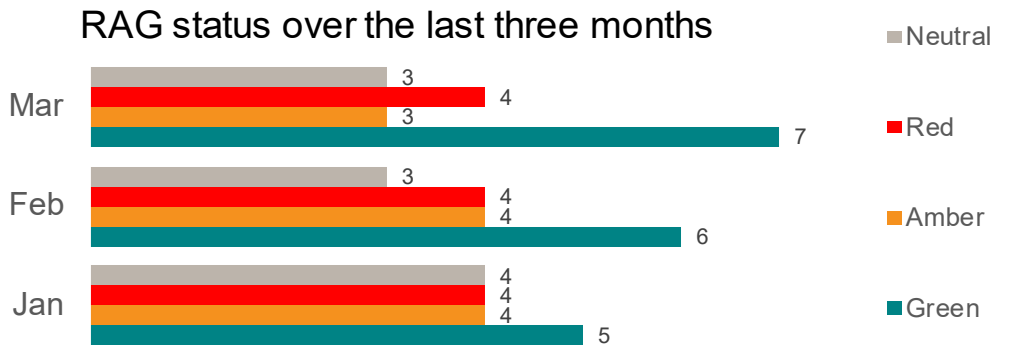
Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

RAG status over last 3 months

(17 KPIs in total for each month)

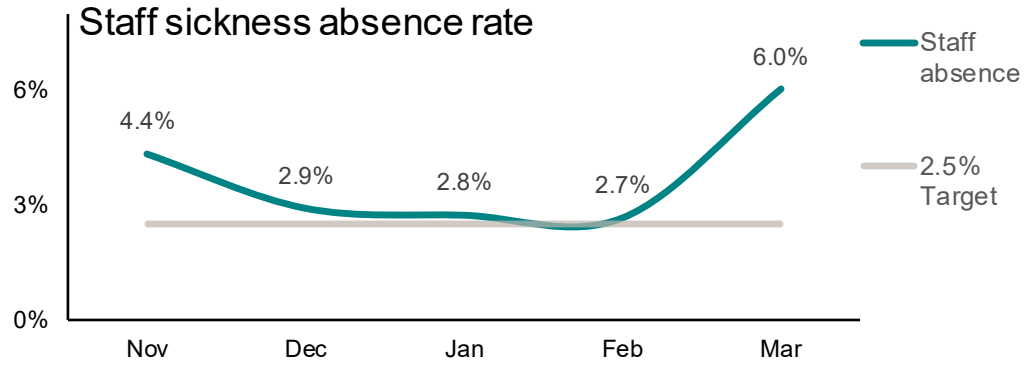


For March, the **4 red** indicators are in these areas:
- Comms : 0
- **Compliance : 1**
- **Finance : 2**
- **HR : 1**
- Information : 0
- Intelligence : 0
- PlanGo : 0

Status: Red

HR1 – Sickness

Target: Less than or equal to 2.5%

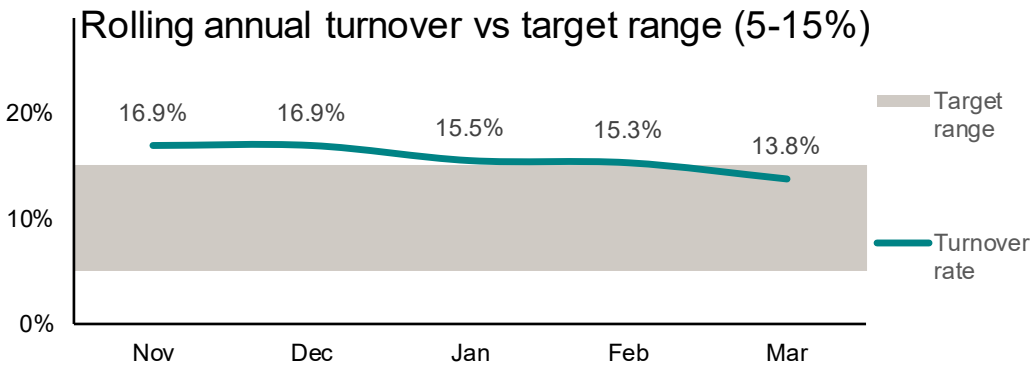


Sickness is high this month. We have had 16 employees absent for various short term reasons. Two employees are on long term sick and one is close to reaching it. We had a similar increase in April last year.

Status: Green

HR2– Turnover

Target: Less than or equal to 2.5%



Turnover is now in the target range.

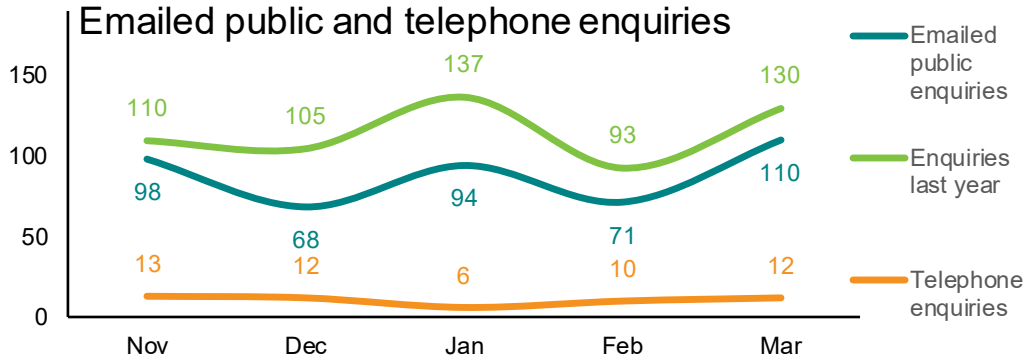
Supplementary HR data

Headcount : 77
Posts : 76
Starters : 1
Leavers : 0

Status: N/A

Emailed public and telephone enquiries

Target:
None defined



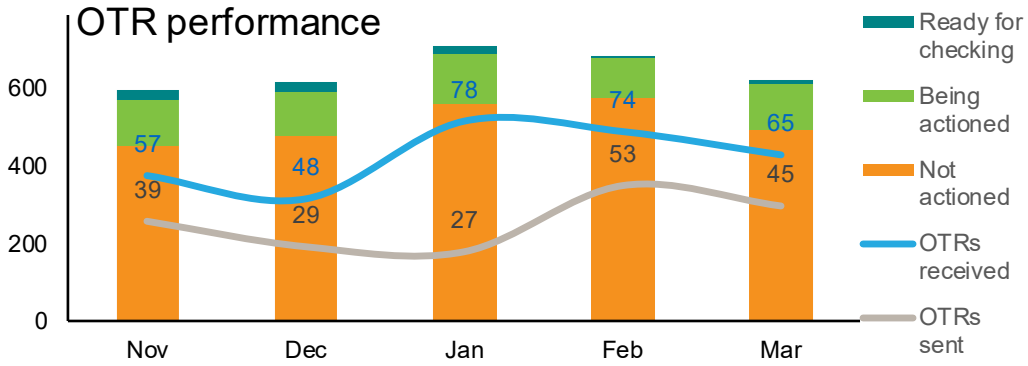
85 out of the 110 enquiries were from patients.

Themes included:
Complex (19)
Straightforward (50)
Complaint process related (35)

Status: N/A

I1 – OTR performance

Target:
To be developed

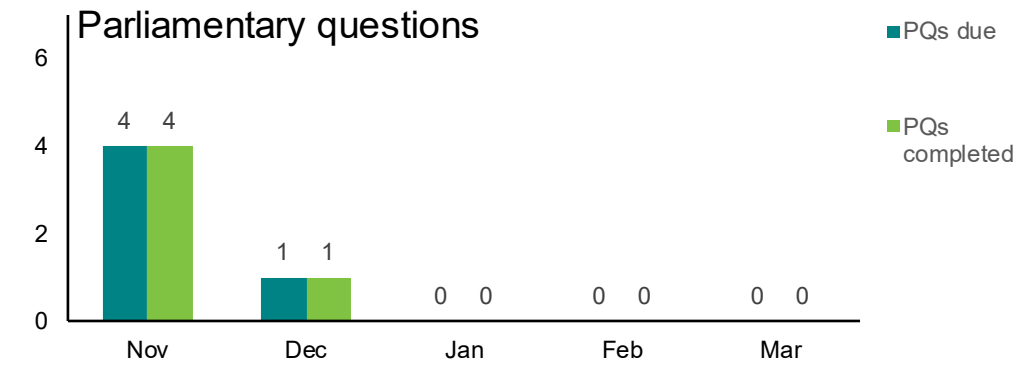


Slight decline in total number of new OTR's received this month. More OTR's being actioned this month, as new member of the team is trained in OTR's.

Status: Neutral

RI1 – PQs responses

Target:
100% within deadlines set

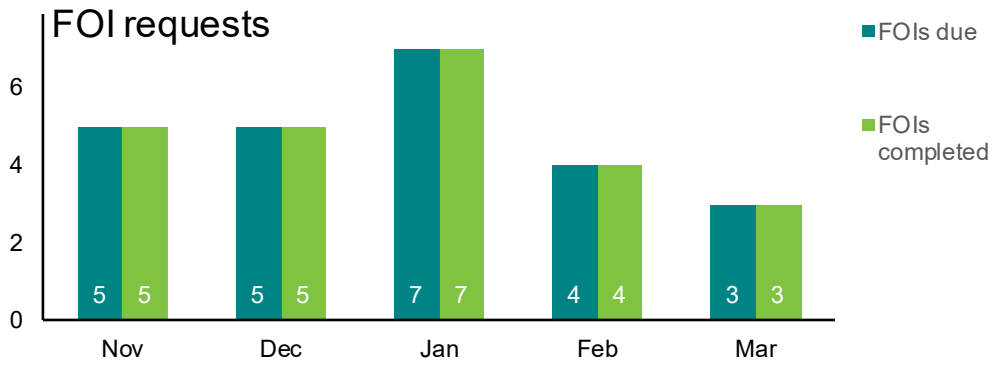


No PQs in March.

Status: Green

RI2 - FOI responses

Target:
100% within statutory deadlines

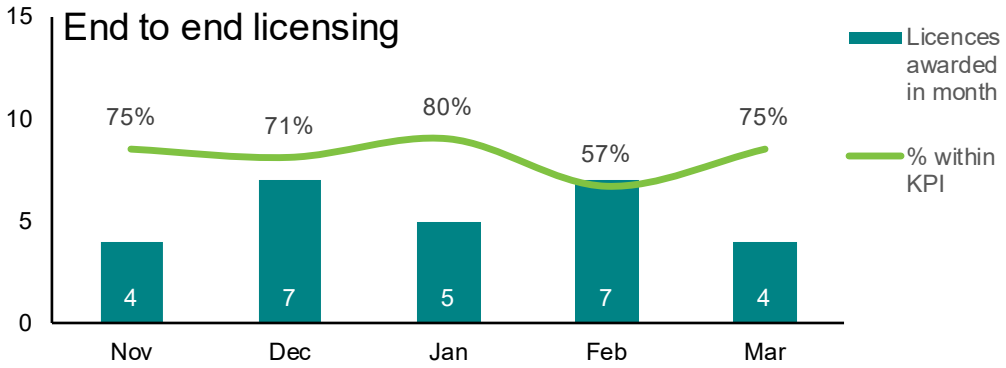


3 FOIs were answered within the deadline in March. They were on the following topics: recruitment, treatment funding by region, and embryo storage.

Status: Red

C4 – End to end licensing process

Target:
100% completed within 70 working days



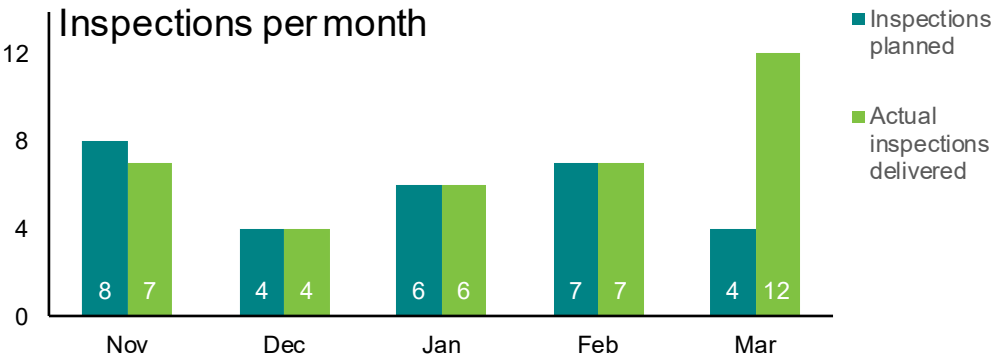
1 clinic - (85 days): delay in sending report to PR due to awaiting post-inspection documents review.

One inspection cycle out of four was delayed.

Status: N/A

C1 – Inspections delivery

Target:
tbc

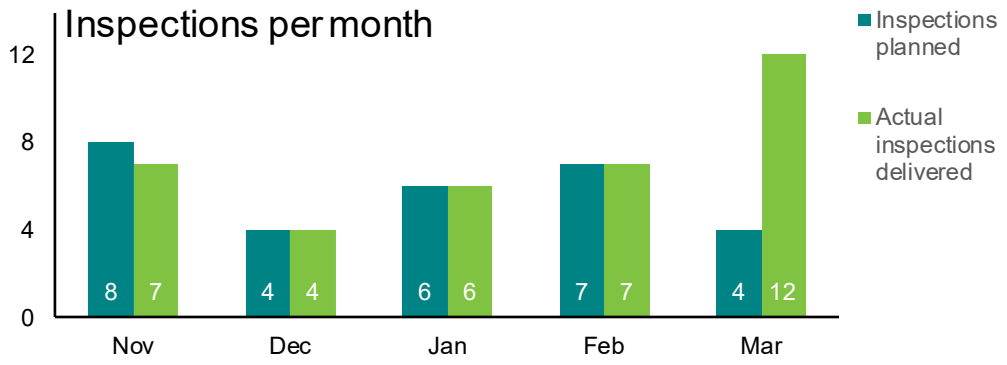


Two clinics - additional inspections.
1 clinic rolled-over from Jan to Mar; then licence revoked.
1 clinic rolled-over from Apr to Mar 2023 to balance workload.
4 clinics rolled over from Apr to Mar 2023 due to PR/key staff availability.
1 clinic conducted in Feb but delivered on 02/03/2023.

Status: N/A

C1 – Inspections delivery

Target: tbc

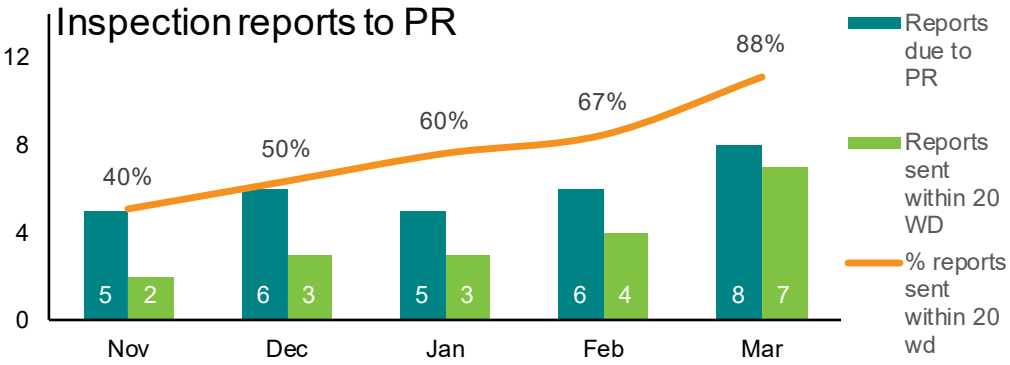


Two clinics - additional inspections.
1 clinic rolled-over from Jan to Mar; then licence revoked.
1 clinic rolled-over from Apr to Mar 2023 to balance workload.
4 clinics rolled over from Apr to Mar 2023 due to PR/key staff availability.
1 clinic conducted in Feb but delivered on 02/03/2023

Status: Amber

C2 – Inspection reports sent to PR

Target: 100% sent within 20 working days



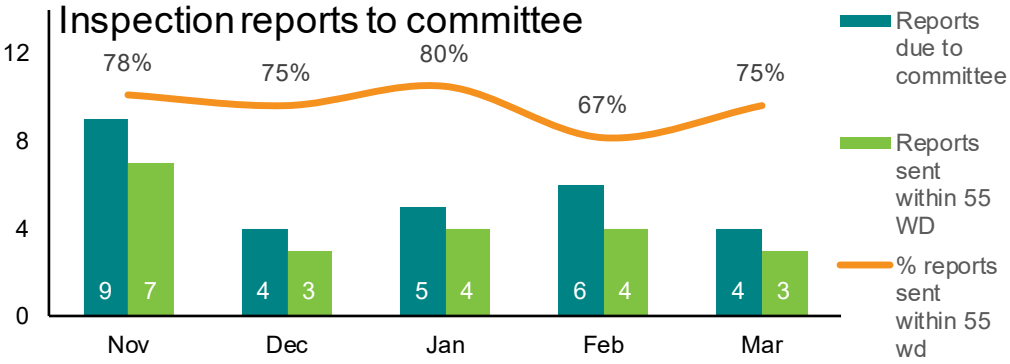
1 clinic report not yet sent to PR due to sickness; report allocated to another inspector.

The overall performance trend is improving as the turnaround times decrease.

Status: Amber

C3 – Inspection reports sent to relevant licensing committee

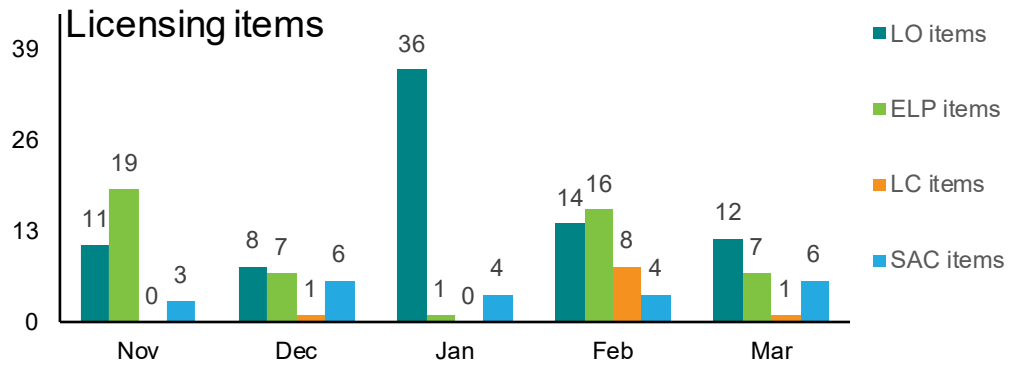
Target: 100% sent within 55



1 clinic report not yet sent to Committee due to ongoing review of PR response by a different SCI inspector (due to original SCI inspector leaving the HFEA).

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

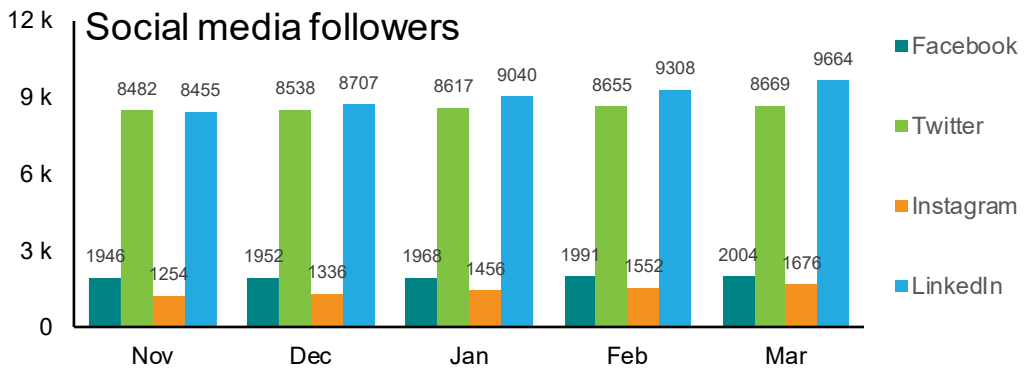
Licensing efficiency
Targets (WD):
LO - 5, ELP - 10
LC - 15, SAC - 20



No issues to report.

Status: N/A

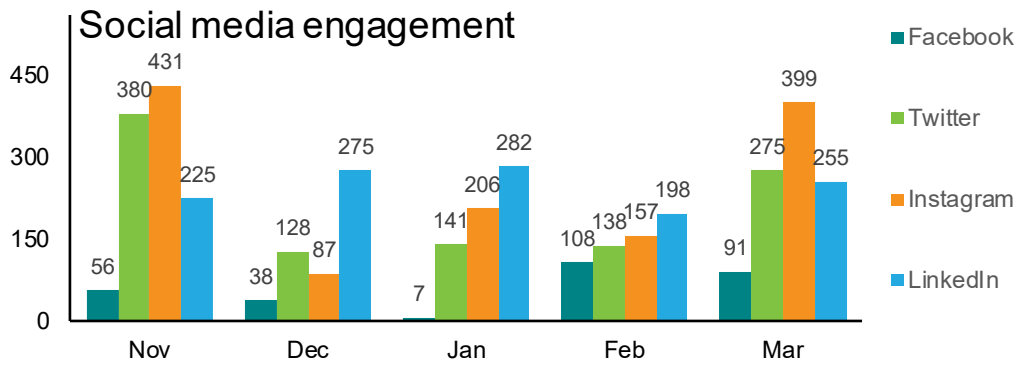
Total number of followers across social media



In March, our content included recruitment, International Women's Day and the launch of the HFEA consultation.

Status: N/A

Engagement across social media (measurement systems vary)

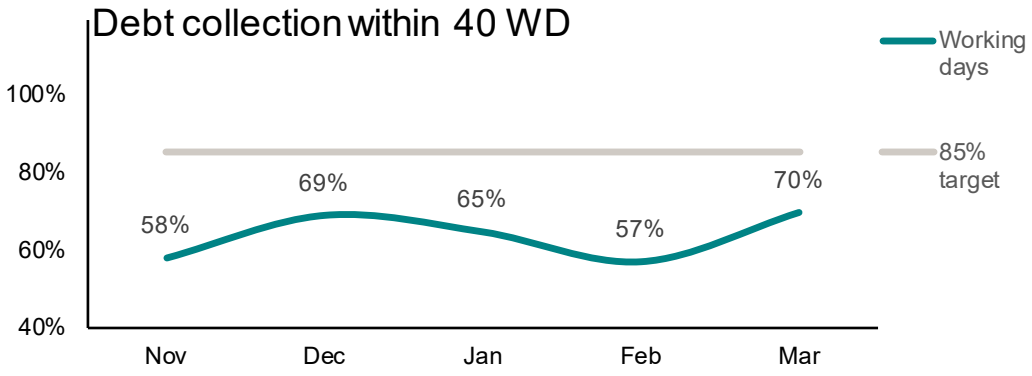


The posts that performed the best were the posts about the consolation which included a Q&A video with Julia Chain, reposts of articles about the consultation, and posts about areas of the act that the HFEA thinks modernisation is most needed.

Status: Red

F1 – Debt collection

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

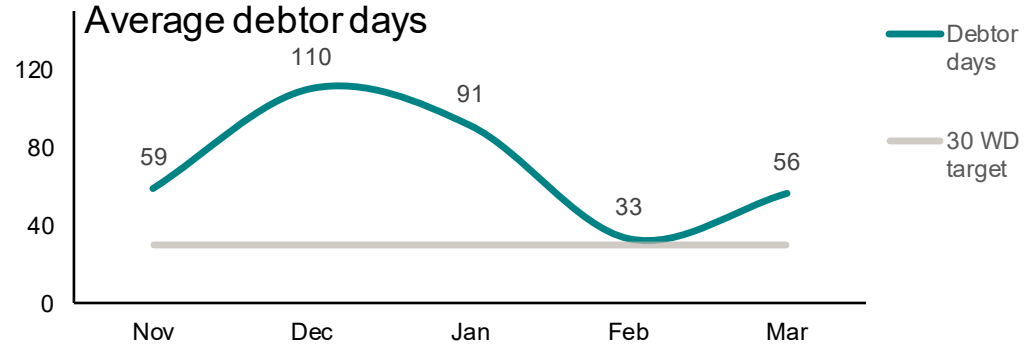


F1 - Delays in credit control due to prioritising year end and audits affected collection.

Status: Red

F2 – Debtor days

Target:
30 working days or less

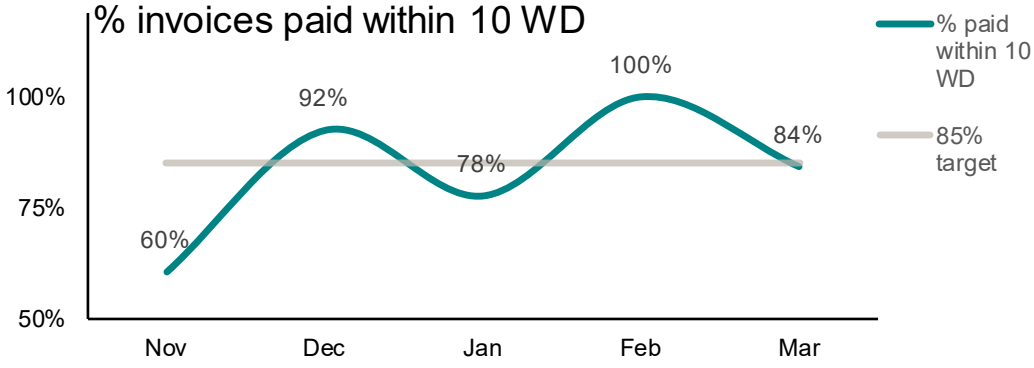


F2 - Collection impacted by year end preparations for clinics, increasing response times.

Status: Amber

F3 – Prompt payment

Target:
85% or more invoices paid within 10 days



F3 - A small number of POs were not approved before the last pay run.

Strategic risk register

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society
Meeting:	Authority
Agenda item:	6
Meeting date:	17 May 2023
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	6a – Strategic risk register

Output from this paper

For information or decision?	For information
Recommendation:	Authority is asked to note the latest edition of the strategic risk register
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from Authority will inform the next SMT review, the risk policy and the risk registers
Organisational risk:	Medium

1. Purpose

1.1. The HFEA SMT have made some minor updates to some of the risks.

1.2. The previously closed People 2 risk (loss of senior leadership) has been reopened following the Director of Finance leaving in mid-June.

1.3. A more extensive review of the register is due to take place prior to the next AGC in June.

1.4. Further information about the Public Bodies Review may be available once the draft report is available and SMT will update the register accordingly.

2. Recommendation

2.1. Authority are requested to note and comment on the attached strategic risk register.

Risk category	**Guidance notes -** risks may fall under more than one category; assign these to the category which will have the most impact. You should not duplicate the same risks into multiple categories.
Commercial	Risks arising from weaknesses in the management of commercial partnerships, supply chains and contractual requirements, resulting in poor performance, inefficiency, poor value for money, fraud, and/ or failure to meet business requirements/ objectives.
Financial	Risks arising from not managing finances in accordance with requirements and financial constraints resulting in poor returns from investments, failure to manage assets/ liabilities or to obtain value for money from the resources deployed, and/ or non-compliant financial reporting.
Governance	Risks arising from unclear plans, priorities, authorities and accountabilities, and/ or ineffective or disproportionate oversight of decision-making and/ or performance.
Information	Risks arising from a failure to produce robust, suitable and appropriate data/ information and to exploit data/ information to its full potential.
Legal	Risks arising from a defective transaction, a claim being made (including a defence to a claim or a counterclaim) or some other legal event occurring that results in a liability or other loss, or a failure to take appropriate measures to meet legal or regulatory requirements or to protect assets (for example, intellectual property).
Operational	Risks arising from inadequate, poorly designed or ineffective/ inefficient internal processes resulting in fraud, error, impaired customer service (quality and/ or quantity of service), non-compliance and/ or poor value for money.
People	Risks arising from ineffective leadership and engagement, suboptimal culture, inappropriate behaviours, the unavailability of sufficient capacity and capability, industrial action and/ or non-compliance with relevant employment legislation/ HR policies resulting in negative impact on performance.
Property	Risks arising from property deficiencies or poorly designed or ineffective/ inefficient safety management resulting in non-compliance and/ or harm and suffering to employees, contractors, service users or the public.
Reputational	Risks arising from adverse events, including ethical violations, a lack of sustainability, systemic or repeated failures or poor quality or a lack of innovation, leading to damages to reputation and or destruction of trust and relations.
Security	Risks arising from a failure to prevent unauthorised and/ or inappropriate access to the estate and information, including cyber security and non-compliance with General Data Protection Regulation requirements.
Strategy	Risks arising from identifying and pursuing a strategy, which is poorly defined, is based on flawed or inaccurate data or fails to support the delivery of commitments, plans or objectives due to a changing macro-environment (e.g. political, economic, social, technological, environment and legislative change).
Technology	Risks arising from technology not delivering the expected services due to inadequate or deficient system/ process development and performance or inadequate resilience.

Risk Dashboard

This dashboard provides a total count of sub-risks against categories.

Team	Open risks	Future risks	Closed risks
Commercial	0	0	0
Financial	3	0	2
Governance	1	0	0
Information	1	0	0
Information2	2	1	0
Legal	0	0	2
Operational	0	0	0
People	1	0	1
People2	0	0	2
Property	0	0	0
Reputational	2	0	0
Security	0	0	1
Strategy	0	2	0
Technology	0	0	0
HFEA Total	**10**	**3**	**8**

Commercial risks

Updated by	Shabbir Qureshi	Updated date	01/02/23
Risk name	No risks in this category at present		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			

Risk owner		Link to strategy		Trend since last update	
Management commentary - on current live risks	This was reviewed by SMT in January 23 and confirmed the HFEA do not have any risks that would fall within this category, both present and future.				
Management commentary - views on mitigation					

Risk external interdependencies	Control arrangements	Owner

Sub-risk title		**Risk status**	**Date identified**		**Next review date**	
			Target closure date		**Actual risk closure date**	
Cause						
Consequence						
Controls						
Actions / Owners / Dates						

Financial risks

Updated by	Morounke Akingbola	Updated date	06/03/23
Risk name	There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	4	4	16	2	3	6	6	9	Below tolerance

Risk owner	Richard Sydee	Link to strategy	Whole Strategy	Trend since last update	↓

Management commentary - on current live risks	This risk considers the likelihood that treatment activity on which HFEA licence fees are charged may fall, or that we may see a reduction in the level of Grant in Aid funding we receive from our sponsor Department. Material reductions in activity, coupled with current inflationary pressures, could reduce the level of funding available for the HFEA's core activity. As c 60% of IVF treatment is privately funded there is a possibility that the current economic conditions could lead to reductions in billable cycles.
Management commentary - views on mitigation	Due to the impact of PRISM implementation on clinic reporting, we are only now returning to monthly invoicing based on actual activity data for most clinics. As a result we do not have profiled activity data over the last 18 months on which to undertake any detailed analysis. Although our income to date is slighty above budget this is likely due to reconcilation of actual activity against prudent forecasts. Intelligence from some clinics does suggest a reduction in activity levels, although this is not a sample size on which to base conclusions. We would expect to have sufficient data to forecast by June 2023.

Risk external interdependencies	Control arrangements	Owner
DHSC - legal costs exceed budget DHSC - GIA funding could be reduced	Monthly forecasting of expenditure provides intelligence on current financial position, emerging overspends would intially be controlled by reducing non essential activity in the short term. Cash reserves ensure that there are no short or medium term pressures on meeting financial liabilities and would allow sufficient time to approach our sponsor Department to provide cover in extremis.	Richard Sydee

Sub-risk title	**Risk that reduced treatment fee income will have negative impacts on our services.**	**Risk status**	**Date identified**	**Oct 22**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Jul 23**	**Actual risk closure date**	
Cause	There is uncertainty about the annual recovery of licence fee income. Treatment activity is likely to drop.					
Consequence	That the HFEA would not have sufficient income to cover its annual spend.					
Controls	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections - although this model has been unable to accurately profile data for the past 18 months as a result of the migration to PRISM and the suspension of clinic reporting.					
Actions / Owners / Dates	SMT receive performance reports and CMG and Authority when required – Richard Sydee					

Sub-risk title	**Managing variable spend across the year**	**Risk status**	**Date identified**	**Mar 22**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Mar 24**	**Actual risk closure date**	
Cause	Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.					
Consequence	Difficulties in profiling the overall budget meaningfully, and lack of insight into potential variables that could affect management information that supports decision making on under/overspends against individual and organisational budgets.					
Controls	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.					
Actions / Owners / Dates	Quarterly meetings with Directorates (on-going) – Morounke Akingbola, Richard Sydee					

Sub-risk title	**Risk that the HFEA is not in compliance with DHSC spending controls**	**Risk status**	**Date identified**	**Oct 21**	**Next review date**	**Apr 24**
		Open	**Target closure date**	**Apr 24**	**Actual risk closure date**	
Cause	Failure to comply with new DHSC spending controls and finance policies and guidance, last updated Dec 2022.					
Consequence	This may lead to serious reputational risk and a loss of financial autonomy or ability to secure future funding.					
Controls	The oversight and understanding of the Finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).					
Actions / Owners / Dates	Continuous monitoring - Richard Sydee					

Sub-risk title	**Risk that planned work is extended or expanded, with higher costs.**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Mar 23**
		Closed	**Target closure date**	**Mar 24**	**Actual risk closure date**	**Mar 23**
Cause	The requirement to fully finish the implementation of PRISM which has been on-going since September 2021 could require further resources both financial and human. This is irrespective of whether budgets agreed at the start of the year. Should PRISM continue to require additional development.					
Consequence	Other areas of spend will need to be deprioritised in order to meet the funding gap and this could impact on the delivery of HFEA strategic objectives					
Controls	Oversight of PRISM by the CEO and Director of Compliance; reporting to CMG and regular reporting to the Audit and Governance Committee, in addition to monitoring of spend in year through quarterly budget management processes.					
Actions / Owners / Dates	Significant changes brought up at CMG - Richard Sydee					

Sub-risk title	**Risk that insufficient attention is paid to budgeting**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Mar 23**
		Closed	**Target closure date**	**May 23**	**Actual risk closure date**	**Mar 23**
Cause	Inadequate decision-making and lack of focus on the detail of budget assumptions and expenditure decisions.					
Consequence	Leads to incorrect financial forecasting and insufficient budget.					
Controls	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.					
Actions / Owners / Dates	Quarterly meetings (on-going) – Morounke Akingbola/ Richard Sydee **Closed Feb 23 as this is more a BAU item.**					

Governance risks

Updated by	Shabbir Qureshi					Updated date	01/02/23	
Risk name	**There is a risk that the regulatory framework in which the HFEA operates is overtaken by developments and becomes not fit for purpose.**							
Risk levels	**Inherent risk levels**			**Residual risk levels**			**Optimal risk level**	**Tolerable risk level**	**Risk tolerance**
	Likelihood	**Impact**	**Risk level**	**Likelihood**	**Impact**	**Risk level**			
	2	4	**8**	2	4	**8**	**8**	**8**	**At tolerance**
Risk owner	**Rachel Cutting**			**Link to strategy**	**Whole Strategy**		**Trend since last update**		↔
Management commentary - on current live risks	The main risk is that the current legal regime is dated and means we cannot always act on areas where patients' have concerns and we are limited in the actions we can take.								
Management commentary - views on mitigation	Our work on the Act may eventually mitigate this risk, but is still in progress. Recent licensing activity has demonstrated that it can be hard to be agile in particular circumstances								

Risk external interdependencies	Control arrangements	Owner
DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.	Early engagement with the Department to ensure that they are aware of the HFEA's position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation setting out HFEA position.	Peter Thompson

Sub-risk title	**Outdated or absent regulatory powers in areas which impact the fertility sector**	**Risk status**	**Date identified**	**Jan 20**	**Next review date**	**Oct 23**
		Open	**Target closure date**	**Apr 26**	**Actual risk closure date**	
Cause	We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance advertising or artificial intelligence). Our Act has not been reviewed in many years.					
Consequence	Limited regulatory levers that we can pull in the event of moderate non-compliances. Lack of remit/tools in some areas that are coming into use in the sector. It is necessary to interpret the wording in the Act in the light of new developments that were not envisaged at the time it was written.					
Controls	Strengthening or building connections with relevant partners (we collaborated on the CMA and ASA's work in this area to strengthen the information and advertising provision for patients in 2020-2021). Working with other expert regulators is effective in areas where we do not have effective powers. We take external legal advice as relevant where developments are outside of our direct remit (e.g., on an incidence of AI technology being used in the fertility sector) and utilise this to establish our legal/regulatory position. We are analysing where there are gaps in our regulatory powers so that we may be able to make a case for further powers if these are necessary, whenever these are next reviewed. (Consultation in early 2023.)					
Actions / Owners / Dates	Peter Thompson/Clare Ettinghausen/Rachel Cutting - on-going					

Information risks

Updated by	Clare Ettinghausen					Updated date	04/05/23	
Risk name	**There is a risk that the appetite for information does not match the resources/priority of our website capacity**							
Risk levels	**Inherent risk levels**			**Residual risk levels**			**Optimal risk level**	**Tolerable risk level**	**Risk tolerance**
	Likelihood	**Impact**	**Risk level**	**Likelihood**	**Impact**	**Risk level**			
	4	3	**12**	3	3	**9**	**6**	**8**	**Above tolerance**
Risk owner	**Clare Ettinghausen**			**Link to strategy**	**The right information**		**Trend since last update**		↔
Management commentary - on current live risks	Work being undertaken as part of the Women's Health Strategy will identify shared areas of promotion of fertility information with the NHS.								
Management commentary - views on mitigation	A new communications strategy was discussed with the Authority and progress is being made against it. We have seen an big increase in media coverage of the HFEA, which is helpful in promoting the HFEA website and information on it. This has been matched by an increase in social media activity. We continue to be constrained in the potential reach of our website and information by the limited resources we have to work on this area.								

Risk external interdependencies	Control arrangements	Owner
None.		

Sub-risk title	**It can be difficult to find information from our inspections on the website and therefore our information is not as transparent as it could be.**	**Risk status**	**Date identified**	**Sep 21**	**Next review date**	**Dec 23**
		Open	**Target closure date**	**Mar 24**	**Actual risk closure date**	
Cause	The way our website information is structured means that those seeking inspection report and licensing information can only do so on a 'per clinic' basis by looking at the individual clinic entries on CaFC and finding the relevant reports and minutes. We do not provide this information in one easily accessible place.					
Consequence	Patients wanting to research multiple clinics will need to look at each clinic entry individually; and anyone looking for the latest reports would need to check all clinics' CaFC entries to find the most recent documents.					
Controls	Early work on transparency and regulation will take place in 2023/24 to look at solutions to this.					
Actions / Owners / Dates	Clare Ettinghausen					

Information2 risks

Updated by	Clare Ettinghausen	Updated date	01/02/23
Risk name	**There is a risk that the OTR function becomes incapable of issuing accurate information at sufficient pace**		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	4	4	16	3	4	12	8	8	Above tolerance

Risk owner	Rachel Cutting	Link to strategy	The right information	Trend since last update	↔

Management commentary - on current live risks	The donor information service has been under review in readiness for the increased demand expected from 2023 onwards. This has involved a restructure of the team and reassessment of the tools available to the team for processing OTR applications (e.g. case management system). A member of the register team has trained to allow fluidity between the register and OTR service, however, there has been significant turnover in the team and a backlog remains. There is also a future risk that our reputation could be damaged by slow handling or inaccurate information being issued - we do need to carefully consider our wider communications and handling when the demand begins to increase.
Management commentary - views on mitigation	The donor information service project is part of the mitigation for this risk. The re-shaping of the current team to provide better resilience has occurred, however, the last post to be recruited to was in January 2023 and the officer is currently being trained. Once the team is fully operational this should enable us to increase the rate of progress in dealing with the OTR backlog. The register team will undergo training in advance of October 2023 to enable a pool of resource to be drawn upon by the OTR team if required. The new case management system and RITA reports are due to be in place by summer 2023; until this time the risk remains above **tolerance**.

Risk external interdependencies	Control arrangements	Owner
None.		

Sub-risk title	**Resources needed to ensure delivery of statutory OTR function are not working at capacity.**	**Risk status**	**Date identified**	**Jan 22**	**Next review date**	**Aug 23**
		Open	**Target closure date**	**Apr 24**	**Actual risk closure date**	
Cause	Development resource and expertise in the IT team have impacted the delivery timeline for the team's RITA tool. In addition, turnover within the team affects capacity.					
Consequence	If RITA is not completed in a timely way, the Register and OTR team will still be able to use manual workarounds to get access to the information they need to support clinics and / or to provide information to support our regulatory work. Although these workarounds will result in a substantial delay to responding to an OTR request or providing clinic support. As time passes increasingly out of date information will be used which means uptodate information will not be provided to applicants. Team capacity is important for processing the OTR backlog, engaging with the donor information service project, and preparing for future increased volumes of requests.					
Controls	RITA Phase 2 has been prioritised against other development work. The development team has demo'd RITA report capabilities to the OTR team who agreed they met the initial requirements. Development can now begin with projected delivery for July 23. The team has been re-structured to increase resilience and reduce turnover.					
Actions / Owners / Dates	Rachel Cutting - ongoing work					

Sub-risk title	**OTR workload will change in 2023 and we may lack the capability to deal with requests in a timely way.**	**Risk status**	**Date identified**	**Jan 20**	**Next review date**	**Mar 24**
		Future	**Target closure date**	**Mar 25**	**Actual risk closure date**	
Cause	The increase in the volume of requests from October 2023 onwards.					
Consequence	Inability to process requests at a high enough rate to prevent a backlog.					
Controls	Service development work to review resourcing and other requirements for OTR to ensure these are fit for purpose. Service development project in progress. Intelligence gained of demand and capacity and reviewed against risk at frequent intervals.					
Actions / Owners / Dates	Rachel Cutting - ongoing work					

Sub-risk title	**Beaches of confidentiality occurring**	**Risk status**	**Date identified**	**Oct 22**	**Next review date**	**Jan 24**
		Open	**Target closure date**	**Oct 23**	**Actual risk closure date**	
Cause	A breach of confidentiality may occur due to Information being given to someone who is not entitled to have it due to phishing / malicious access.					
Consequence	Confidential and sensitive information may be released unintentionally.					
Controls	The OTR team follow a robust SOP and only release information to applicants through the formal electronic application process which includes a proof of ID, checks against the register and records held at clinics. The ID check is via DocuSign and ID is verified before any further processing is carried out. Information is not released by any other form of communication other than email after a double QA check. If an applicant requests updated information this can only be released after a new application is made.					
Actions / Owners / Dates	Rachel Cutting - ongoing work					

Sub-risk title	**The donor information service project may result in a new system that does not fully deliver our aims**	**Risk status**	**Date identified**	**Oct 22**	**Next review date**	**Jan 23**
		Closed	**Target closure date**	**Feb 23**	**Actual risk closure date**	**Jan 23**
Cause	Problems would arise if the donor information service project does not yield a system that works well, produces accurate data, and can cope with the higher expected volume of requests.					
Consequence	System becoming overwhelmed, or incorrect data issued to applicants.					
Controls	The project is overseen by PAG, with risks and issues reported regularly to CMG. **The controls in place mean this can now be closed as this is no longer a strategic risk. Clare & Rachel are overseeing both project streams.**					
Actions / Owners / Dates	Rachel Cutting - ongoing work					

Legal (closed now) risks

Updated by	Paula Robinson	Updated date	28/11/22
Risk name	There is a risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates.		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	4	5	20	3	4	12		12	At tolerance

Risk owner	Peter Thompson	Link to strategy	Whole Strategy	Trend since last update	↔

Management commentary - on current live risks	**For discussion:** When formulating the new risk register, we considered closing this risk. Although it is an ever-present background risk, there has not been a high level of legal actions involving the HFEA for several years.
Management commentary - views on mitigation	In the past ten years we have improved our governance processes across the organisation with a view to being more resilient to legal challenges - i.e. we are less likely to lose a case. This work is done, and in place - integrated into our general ways of working. Therefore it is proposed that this risk be closed, and that in the future we create a particular legal risk if and when there is (or could be) a serious live issue, e.g. a particular decision being challenged. **AGC's views on closing this risk, on the above basis, would be welcomed. AGC have agreed to closing this risk (November 2022).**

Risk external interdependencies	Control arrangements	Owner
DHSC	If this risk was to become an issue, then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it. Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. We highlight when science and medicine are changing so that they can consider whether to make changes to the	Peter Thompson

Sub-risk title	The HFEA is subject to legal challenges that divert resources from other work.	Risk status	Date identified	Apr 20	Next review date	Dec 22
		Closed	Target closure date	Dec 22	Actual risk closure date	
Cause	Legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics challenging decisions taken about their licence.					
Consequence	Diversion of staff resources and additional costs.					
Controls	At every Licence Committee there is a legal advisor present and where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best possible position to make out a robust case and defend any challenge. We have in place good governance and ways of working that mean we are less likely to lose a case on procedural grounds. Evidence-based and transparent policymaking is in place, with stakeholder involvement and communications during policymaking. Major changes are consulted on widely.					
Actions / Owners / Dates	Peter Thompson - in place					

Sub-risk title	Specific legal challenges arise from time to time	Risk status	Date identified	Apr 20	Next review date	Dec 22
		Closed	Target closure date	Dec 22	Actual risk closure date	
Cause	Legal challenges related to clinical implementation of regulation in terms of individual cases (i.e., consent-related cases). Ongoing legal parenthood and storage consent failings in clinics and related cases are specific examples.					
Consequence	The case-by-case nature of the Courts' approach to matters means resource demands are unpredictable when these arise.					
Controls	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases show how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action. Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal advisors at the start of any legal challenge.					
Actions / Owners / Dates	Peter Thompson - ad hoc when issues arise					

Operational risks

Updated by	Rachel Cutting	Updated date	10/02/23
Risk name	PRISM project has delayed the review and/or replacement of other organisational wide systems		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	4	5	20	4	4	16	6	12	Above tolerance

Risk owner	Peter Thompson	Link to strategy	Whole Strategy	Trend since last update	↔

Management commentary - on current live risks	PRISM has improved the quality of the register however due to the programme running for several years other systems across the HFEA have had to be delayed for review and replacement. This includes Epicentre which is used across the organisation for inspection, licensing and finance. Impact of PRISM has also caused delays in register functionality such as the ability to publish CAFC and OTR reporting.
Management commentary - views on mitigation	We are to date able to keep Epicentre functional in house through devising work arounds and use of in house expertise. However, there is acknowledgment that the system needs re-platforming to improve stability and facilitate integration of systems across the organisation. The detailed risks and handling are set out in the operational risk register.

Risk external interdependencies	Control arrangements	Owner
None	The operational risk register is regularly reviewed and updated with relevant details, mitigations and actions.	Rachel / Sharon/ Martin

Sub-risk title		**Risk status**	**Date identified**		**Next review date**	
			Target closure date		**Actual risk closure date**	
Cause						
Consequence						
Controls						
Actions / Owners / Dates						

People risks

Updated by	Shabbir Qureshi	Updated date	01/02/23
Risk name	**Resources needed to carry out statutory work are not sufficient to manage the range of responsibilities**		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	5	4	20	4	3	12	9	12	At tolerance

Risk owner	Peter Thompson	Link to strategy	Whole Strategy	Trend since last update	↔

Management commentary - on current live risks	Turnover in specific areas (e.g. OTR and Licensing teams) can create gaps where specific statutory functions cannot easily be met.
Management commentary - views on mitigation	The demanding nature of the statutory work - much of it cyclical - means that staff are stretched to capacity at all times. This has consequent issues for their health and resilience as well as pressures on managers and resource to support from HR.

Risk external interdependencies	Control arrangements	Owner
Government/DHSC (EU exit) **In-common risk (Covid-19)** **NICE/CQC/HRA/HTA (working arrangements)** **In-common risk (job markets)**	None.	Peter Thompson

Sub-risk title	**High turnover and unplanned absences, causing capability and capacity gaps in some teams**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Dec 23**	**Actual risk closure date**	
Cause	High turnover, sick leave or other unplanned absences.					
Consequence	Temporary knowledge loss and capability gaps. Possible inability to perform some functions. Note: this is a more acute risk for our smaller teams.					
Controls	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise. Contingency: In the event of knowledge gaps, we would consider alternative resources such as using agency staff, or support from other organisations, if appropriate. This has been required for certain posts.					
Actions / Owners / Dates	Yvonne Akinmodun - induction/ documentation etc., vacancy management Peter Thompson - CMG used for work prioritisation Directors/ Heads - contingency planning/ execution					

Sub-risk title	**Recruitment difficulties for some roles**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jan 23**
		Closed	**Target closure date**	**Apr 23**	**Actual risk closure date**	**Feb 23**
Cause	Inability to quickly appoint to key posts is extending the duration of capability and capacity gaps in some cases. Salary may also sometimes be an issue (for example, highly paid governance roles in the NHS, which the HFEA cannot match).					
Consequence	Difficulties covering normal workload or completing specialist tasks; pressures on other team members while there is a gap.					
Controls	Looking for alternative ways to allocate skills and resources for hard-to-fill roles, to cover gaps.					
Actions / Owners / Dates	Hiring managers & Yvonne Akinmodun - look for alternates					

People2 risks

Updated by	Clare Ettinghausen	Updated date	05/05/23
Risk name	Loss of senior leadership (whether at Board or Management level) leads to a loss of knowledge and capability which may impact formal decision-making and strategic delivery		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	4	4	16	3	3	9	6	6	Above tolerance

Risk owner	Peter Thompson	Link to strategy	Whole Strategy	Trend since last update	↑

Management commentary - on current live risks	There are no current pressing risks in this area, following the induction period for new members in April-July. The view is to close this risk as this is not a live risk at present, this will be re-activated should the circumstances arise. Comments about sub-risks may need to be moved to other risks if required. To be confirmed at March AGC. **Risk closure approved at March AGC.** This risk has been re-opened as the Director of Finance will be leaving mid-June. Recruitment is underway and the responsibilities will be shared between SMT and the Head of Finance. The likelihood inherent risk has been raised to 4 and residual to 3 to recognise this development.
Management commentary - views on mitigation	Mitigations are particular to the role, the work being done by the role at the time, and the time available to put plans in place prior to someone's departure. This is approached proactively as and when it occurs, by developing a particular plan for that role and its associated workload. Recruitment is underway and the responsibilities will be shared between SMT and the Head of Finance. Once the director has been appointed, we will re-categorise the risk where necessary.

Risk external interdependencies	Control arrangements	Owner
Government/DHSC	The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines. DHSC is responsible for having an effective arm's length body in place to regulate ART. HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process.	Peter Thompson

Sub-risk title	**Leadership capability and capacity gaps**	**Risk status**	**Date identified**	**Apr 23**	**Next review date**	**Sep 23**
		Open	**Target closure date**	**Dec 23**	**Actual risk closure date**	
Cause	The loss of a member of the senior leadership team (for instance through retirement, leaving the organisation for a new role etc) creates a leadership/knowledge gap. In this case the Director of Finance and Resources who leaves in mid-June 2023.					
Consequence	Loss of leadership skills, capacity and knowledge. Impacts on staff in their teams and wider impact from this role as Chair of PAG and takes on some chairing of ELP.					
Controls	Finance responsiblities can be undetaken in the interim by the Head of Finance although it will put considerable pressure on that individual and the small supporting team. Annual Report and Accounts 2022/23 will almost be complete by the time the Director leaves. Chief Executive can maintain relationships with external auditors and Chair of AGC in interim. SMT can cover wider responsibilities in the interim. Process for recruiting new Director underway and assuming it can be filled relatively quickly then this is manageable. A longer gap would have significant impact on other individuals.					
Actions / Owners / Dates	Peter Thompson					

Sub-risk title	Recruitment duration for key senior posts	Risk status	Date identified	Apr 21	Next review date	Dec 22
		Closed	Target closure date	Apr 23	Actual risk closure date	
Cause	Recruitment to SMT or Head post often takes some time which could create a leadership gap.					
Consequence	A gap which would need to be managed proactively, requiring some degree of resource diversion.					
Controls	Heads could temporarily act up into Director roles to manage any pre-recruitment gaps. The same would be true of manager-level staff acting up for Heads. (Control employed to manage Chief Technology Officer recruitment gap in early 2022.)					
Actions / Owners / Dates	Peter Thompson - ad hoc					

Property risks

Updated by	Shabbir Qureshi	**Updated date**	01/02/23
Risk name	No risks in this category at present		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			

Risk owner		**Link to strategy**		**Trend since last update**	

Management commentary - on current live risks	**This was reviewed by SMT in January 23 and confirmed the HFEA do not have any risks that would fall within this category, both present and future.**
Management commentary - views on mitigation	

Risk external interdependencies	Control arrangements	Owner

Sub-risk title		**Risk status**	**Date identified**		**Next review date**	
			Target closure date		**Actual risk closure date**	
Cause						
Consequence						
Controls						
Actions / Owners / Dates						

Reputational risks

Updated by	Clare Ettinghausen					Updated date	04/05/23	
Risk name	**There is a risk that we do not position ourselves effectively and so cannot influence and regulate optimally for current and future needs.**							
Risk levels	**Inherent risk levels**			**Residual risk levels**			**Optimal risk level**	**Tolerable risk level**	**Risk tolerance**
	Likelihood	**Impact**	**Risk level**	**Likelihood**	**Impact**	**Risk level**			
	4	4	**16**	2	3	**6**	**6**	**9**	**Below tolerance**
Risk owner	**Clare Ettinghausen**			**Link to strategy**	**Shaping the future**		**Trend since last update**		↔
Management commentary - on current live risks	We have worked hard on the positioning of the HFEA in recent years, and particularly worked closely with DHSC and with ALBs, professional and patient groups and others during the pandemic to re-position ourselves. Opportunities created by Act reform work to cement stakeholder relationships.								
Management commentary - views on mitigation	Our new communications strategy will address this risk, but the implementation of the strategy will need to have a focus in any particular year, in accordance with our current priorities and resources. At times that may mean our communications resources are stretched. Prioritisation is essential. Analysis of consultation responses will provide some insight into our current position with a wide range of groups and individuals.								

Risk external interdependencies	Control arrangements	Owner
DHSC & Government	Ongoing engagement with the DHSC and ministers to ensure influence in any changing political developments and links with the HFEA strategy. We would also do any horizon scanning as the political landscape changed if needed.	Peter Thompson

Sub-risk title	**We fail to position ourselves effectively on an issue.**	**Risk status**	**Date identified**	**Sep 22**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Oct 23**	**Actual risk closure date**	
Cause	Failure to anticipate and/or address issues that require strategic positioning and communications.					
Consequence	Lack of positioning on issues such as the modernisation of the Act or the increase in OTR requests in 2023 could lead to: Lack of awareness of our policies and practices Lack of understanding of our aims and ambitions Reputational damage and disappointing coverage of the HFEA Failure to achieve the strategic outcome that we desired.					
Controls	New communications strategy has now been put in place.					
Actions / Owners / Dates	Clare Ettinghausen - updated May 2023.					

Sub-risk title	**Lack of early engagement in relation to change and innovation**	**Risk status**	**Date identified**	**Nov 22**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Dec 23**	**Actual risk closure date**	
Cause	We lack opportunities to engage with early adopters or initiators of new treatments/innovations or changes in the sector.					
Consequence	This could leave us trying to catch up with developments that others were already aware of.					
Controls	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these. We have ongoing monitoring of developments in AI and reporting back to SCAAC on this.					
Actions / Owners / Dates	Clare Ettinghausen - in place and on-going					

Security risks

Updated by	Shabbir Qureshi					Updated date	01/02/23	
Risk name	**There is a risk that the HFEA is subject to a cyber-attack, resulting in data or sensitive information being compromised, or IT services being unavailable**							
Risk levels	**Inherent risk levels**			**Residual risk levels**			**Optimal risk level**	**Tolerable risk level**	**Risk tolerance**
	Likelihood	**Impact**	**Risk level**	**Likelihood**	**Impact**	**Risk level**			
	5	4	**20**	3	3	**9**	**9**	**9**	**At tolerance**
Risk owner	**Rachel Cutting**			**Link to strategy**	**Whole Strategy**		**Trend since last update**		↔
Management commentary - on current live risks	Current overall threat levels remain high. The HFEA holds sensitive information on its register. The register (since 1991) holds data on patients, parents and donors undergoing licenced fertility treatment and includes details of their identity, treatment, and outcomes.								
Management commentary - views on mitigation	We have appropriate mitigations in place for both cyber-attacks and the possibility of equipment losses or technical failures that could result in increased risks or loss of access. This is an ever-changing area, in which new threats emerge constantly, but we monitor for these and take actions where indicated.								

Risk external interdependencies	Control arrangements	Owner
In-common risk across all DHSC ALBs.		

Sub-risk title	**Cloud hosting and our remote access connections provide a potential attack surface**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Apr 24**	**Actual risk closure date**	
Cause	Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties. Clinics have internet facing applications to access our systems e.g. into PRISM via EPRS third-party software					
Consequence	Any successful attack could lead to loss of data or control over our systems.					
Controls	All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place. Staff internally have encrypted laptops and access is controlled through Multi-Factor Authentication (MFA). Annual penetration testing to detect vulnerabilities in our systems is carried out by specialist third-party IT security companies. In 2023's application pen test we will include API testing. API is used by EPRS third-party software suppliers to communicate with PRISM. We are implementing Mimecast in March/April 2023 to improve malicious email detection rates and provide simulated phishing awareness training to HFEA staff.					
Actions / Owners / Dates	Martin Cranefield - in place and ongoing					

Sub-risk title	**System level changes create new vulnerabilities**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jun 23**
		Open	**Target closure date**	**Apr 24**	**Actual risk closure date**	
Cause	Changes to the digital estate open up potential attack surfaces or new vulnerabilities.					
Consequence	Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.					
Controls	Penetration security testing of newly developed or modified systems assure us that development has appropriately considered cyber security and informs us of any vulnerabilities that may have been introduced as a result of change. We undertake penetration testing regularly (annually) and this includes infrastructure (main network services) and application testing (PRISM and portal). Clear information security guidance to HFEA staff about how identifying information is shared, especially by the Register team, to reduce the chance of this being vulnerable.					
Actions / Owners / Dates	Martin Cranefield - in place and ongoing					

Sub-risk title	**Lack of capacity makes it more difficult to deal with any attacks**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jan 23**
		Closed	**Target closure date**	**Apr 24**	**Actual risk closure date**	**Jan 23**
Cause	The IT support function is small so may not provide us with the cyber security resource that we need (i.e., emergency support in the case of dealing with attacks).					
Consequence	Difficulties dealing with a live attack, e.g. slower investigation and response time, and/or poorer outcomes.					
Controls	The IT team in house is small, however, we have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason. There is also external resource through NHS England (security operation centre). Cyber incidents can be reported through this and support can be accessed.					
Actions / Owners / Dates	Martin Cranefield - Contract in place until June 2023					

Sub-risk title	**Lack of awareness of new cyber security threats.**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jan 23**
		Closed	**Target closure date**	**Apr 24**	**Actual risk closure date**	**Jan 23**
Cause	We cannot mitigate effectively for emerging or developing cyber security threats if we are not aware of these.					
Consequence	Lack of mitigations, meaning a higher chance of a successful attack through a new route or method.					
Controls	We maintain external linkages with other organisations (such as ALB CIO network and NHS Digital Cyber Associates Network) to learn from others in relation to cyber risk. We receive regular security alerts and action the high priority ones when they arrive. Our infrastructure telemetry is reported to NHS on a daily basis for their oversight. Any high-level risks are identified by NHS and reported to us. Cyber alerts must be acknowledged.					
Actions / Owners / Dates	Martin Cranefield - in place and ongoing					

Sub-risk title	**Loss of HFEA devices**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jan 23**
		Closed	**Target closure date**	**Apr 24**	**Actual risk closure date**	**Jan 23**
Cause	Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.					
Consequence	Increased chance of an attempt being made to access HFEA data; risk of data loss.					
Controls	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) to implement encryption. Conditional access being put in place for remote access by HFEA staff. This will reduce the risk of attack by devices that are not owned by HFEA. Staff are instructed to inform IT immediately if a device is ever stolen or lost.					
Actions / Owners / Dates	Martin Cranefield - in place and ongoing					

Sub-risk title	**Lack of adequate Authority insight and/or oversight**	**Risk status**	**Date identified**	**Apr 20**	**Next review date**	**Jan 23**
		Closed	**Target closure date**	**Apr 24**	**Actual risk closure date**	
Cause	Insufficient board (or AGC) oversight and scrutiny of cyber security risks					
Consequence	This would result in risks potentially not being managed effectively, or factors being overlooked.					
Controls	Routine cyber risk management delegated from Authority to Audit and Governance Committee which receives reports at each meeting on cyber-security and associated internal audit reports to assure the Authority that the internal approach is appropriate and ensure they are aware of the organisation's exposure to cyber risk. The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual and perceived cyber risks. These would be discussed with the wider board if necessary. Cyber security and information security training included in standard induction process for Authority members. A new induction process was introduced in March 2022.					
Actions / Owners / Dates	Martin Cranefield - in place and ongoing					

Strategy risks

Updated by	Clare Ettinghausen/Peter Thompson	Updated date	05/05/23
Risk name	The HFEA's public body review in early 2023.		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	5	5	25	5	4	20	15	15	Above tolerance

Risk owner	Peter Thompson	Link to strategy	Whole Strategy	Trend since last update	↑

Management commentary - on current live risks	The review started in March 2023 and is approaching the end of the initial evidence gathering stage. That work has required a great deal of involvement from SMT to the detriment of other business plans priorities and wider organisational and people priorities The Terms of Reference has only recently been finalised and follow quite closely the tests set out in Cabinet Office guidance. At this point it is unclear where the recommendations of the review are likely to focus, although review is still scheduled to complete at the end of July. Beyond the review itself, there are likely to be recommendations, as yet unknown, that we will need to implement, and which may pose further risks.
Management commentary - views on mitigation	Close working relationship with the review team and DHSC sponsor to provide accurate and timely information as required. Authority members directly involved by interviews with the lead reviewer and frequent SMT meetings with the review team. As the report is drafted, we expect to be able to feedback our views on drafts and will have a better indication of any impacts at this stage.

Risk external interdependencies	Control arrangements	Owner
DHSC - further discussions may be required on resourcing the review.	For discussion at regular ALB review meetings.	Peter Thompson

Sub-risk title	**The review will be difficult to service owing to resource constraints.**	**Risk status**	**Date identified**	**Nov 22**	**Next review date**	**Jun 23**
		Future	**Target closure date**	**Jul 23**	**Actual risk closure date**	
Cause	It will be necessary to free up some staff time to deal with the requests for information that arise from the review process. This will be difficult to achieve given other work pressures and the small size of the HFEA.					
Consequence	Since the review must be supported, the impact will be on other work. We may need to delay or cancel other planned work, and it may be necessary to seek backfill for key staff - this is difficult to accomplish in such a small, expert organisation.					
Controls	Prioritisation and planning will be done to free up sufficient staff time. This has not yet been put in place. In practice this has been undertaken by SMT not only because the level of detail required has been more suitable for SMT but also because there are no resources within the HFEA that could be freed up without impacting on statutory responsiblities.					
Actions / Owners / Dates	Peter Thompson - under discussion now.					

Sub-risk title	**Risks may arise from the review itself.**	**Risk status**	**Date identified**	**Oct 22**	**Next review date**	**Jun 23**
		Future	**Target closure date**	**Jul 23**	**Actual risk closure date**	
Cause	Recommendations or requirements may include changes to our future budget and/or staffing model.					
Consequence	Not yet known.					
Controls	Not yet known.					
Actions / Owners / Dates	Peter Thompson - for future discussion					

Technology risks

Updated by	Shabbir Qureshi	Updated date	01/02/23
Risk name	**No risks in this category at present**		

Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			

Risk owner		Link to strategy		Trend since last update	
Management commentary - on current live risks	**This was reviewed by SMT in January 23 and it was decided that the technology based risks fit better within the Operational category as this is where the main impact is.**				
Management commentary - views on mitigation					

Risk external interdependencies	Control arrangements	Owner

Sub-risk title		**Risk status**	**Date identified**		**Next review date**	
			Target closure date		**Actual risk closure date**	
Cause						
Consequence						
Controls						
Actions / Owners / Dates						

Human Fertilisation & Embryology Authority

Opening the Register – update

Rachel Cutting and Clare Ettinghausen

17 May 2023

Opening the Register activity 2023

Overview

- Update on activity since March 2023 Authority meeting
- Workstreams update
- Risks
- Next steps

Human Fertilisation & Embryology Authority

Opening the Register activity 2023

Activity since March 2023 Authority meeting

- Ongoing media interest, especially from documentary companies
- Good coverage of our call for donors to update addresses on International Donor conception Awareness Day
- Presentation and feedback at Licence Centres Panel and Patient Organisation Stakeholders Group
- Presentation and Q & A at Donor Conception Network annual conference
- Focus day to review and finalise (where possible) operational procedures for applications
- Finalising stages of new IT system
- Paper presented to April CMG for using third party systems for updating donor contact details (decision to present to Authority)

Human Fertilisation & Embryology Authority

HFEA activity during 2023

Three workstreams

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

OTR service

Workstream update

- Good progress on the integration of the new IT system for managing applications (testing phase)
- Continued work on updating policies and legal advice to inform processes.
-
- Presentation at Donor Conception Network Annual Conference with good opportunity to discuss the service and receive feedback

Human Fertilisation & Embryology Authority

Future of support service

Workstream update

- Develop options for a financially viable multi-layered support service for review later in the year by Authority
- Business case presented to CMG in March
- Project work will include
  - Literature review and international comparison of other models of support services
  - Explore funding options
  - Targeted engagement with key stakeholders
  - Option appraisal of different support mechanisms including for example professional counselling, peer support, intermediary services and information provision.

Human Fertilisation & Embryology Authority

Communications (1)

Workstream update

- Plans for reviewing all communications materials over coming months.
- 27 April – International Donor Conception Awareness Day included a mainstream media call for donors to update their contact details, which received widespread coverage.
- A number of production companies have been in touch with us to research a possible series or one-off films related to donor anonymity and OTR.
- Exploring the use of influencers to raise awareness of donation.
- Website and social media videos: Short videos linking back to the donation landing page, raising awareness of our wider patient information.

Communications (2)

Workstream update

- Stakeholder toolkit: to include key messaging, any relevant FAQs and infographics.
- Q&A with an HFEA spokesperson to be shared on the HFEA Instagram account. We will ask followers to ‘send in your questions’ and then film and promote the responses.
- Clinic Focus articles setting out what is expected of clinics and the process for managing OTR requests.
- Internal communications on how we are preparing.

Risks

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

Next Steps

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

Human Fertilisation & Embryology Authority

OTR Donor Contact

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Agenda item:	8
Meeting date:	17 May 2023
Author:	Rachel Cutting, Director of Compliance and Information and Rachel Cooper, Legal Adviser
Annexes	Annex A: Risk Rating Table

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority are asked to agree an option from those presented in the paper
Resource implications:	Dependent on decision – but the decision will be communicated widely as part of the wider HFEA communications activity on opening the register.
Implementation date:	TBC
Communication(s):	Stakeholder and clinic communication, as well as wider public facing information as needed.
Organisational risk:	High

1. Overview

1.1. This paper outlines the legal and reputational risks for the HFEA when contacting donors to notify them that a donor conceived individual (DCI) has requested identifiable information about them. The Authority is presented with three different options and is asked to decide on which one to adopt going forward. None of the options are risk free, and any decision will require consideration of legal, reputational and operational issues. All options involve balancing the rights of the donor and the DCI.

1.2. Section 2 of the paper provides a background to the issues; section 3 summarises the legal issues; section 4 sets out the different options; and section 5 asks the Authority to decide on the best process going forward.

2. Background

2.1. This year, the first cohort of people who were conceived from donations from donors registered on or after 1 April 2005 (when new UK donors could no longer donate anonymously) will turn 18. As such, they will be able to contact the HFEA to request identifying information about their donors by making an Opening the Register (OTR) application.

2.2. The HFEA has a power (not an obligation) to contact donors to let them know that identifying information about them has been requested and this has been our policy to date where previously anonymous donors have re-registered as identifiable. Looking ahead to OTR 2023, our intended strategy is to attempt to contact donors using the latest contact details provided by them, which might be the address recorded on the HFEA Register or a more recent address provided by the donor to their clinic. This has been consistently communicated to the sector since 2004 (for example in a 2004 Chair's letter and as guidance in the Code of Practice) and licensed clinics should have explained this to donors as part of their informed consent process.

2.3. However, concerns have been raised to the HFEA from some professional stakeholder groups that the HFEA and/or clinics may not have the donor's latest address, given how long it will have been since their donation.

2.4. It has been suggested that the HFEA should pro-actively search for a donor's current contact details in NHS records and use these details to contact the donor. Even if this were a practical option, it will only be possible for UK donors who still reside in the UK.

2.5. This paper considers a number of different options and outlines the significant legal, resource or reputational risks of each option.

3. Legal Context

3.1. The HFEA's obligations are set out in the Human Fertilisation and Embryology Acts 1990 and 2008 and the Human Fertilisation and Embryology (Disclosure of Donor Information)

Regulations 2004 (the 2004 Regulations)[1]. These are supplemented by guidance in the Code of Practice (predominantly, Guidance Note 11).

Prohibitions of Disclosure under the 1990 Act

3.2. When considering disclosure of any information held by the HFEA, the starting position is s33A of the 1990 Act, which prohibits the disclosure of any information falling within subsection 31(2) (information relating to the provision of treatment, storage or use of gametes or embryos etc). Disclosure in breach of s33A is a criminal offence[2]. There are several exceptions to the prohibition on disclosure – the relevant one in this context is "(k) the disclosure is made in accordance with sections 31ZA to 31ZE".[3]

Information Disclosure to DCIs

3.3. Donors registering on or after 1 April 2005 could no longer donate anonymously. The 1990 Act enables DCIs who reach 18 to have access to identifying information about their donor. There is also a corresponding obligation on the HFEA to disclose this information (s31ZA of the 1990 Act).

3.4. The contact information the Authority is required to give a DCI is limited. Under s31ZA, an applicant can require the Authority to confirm whether or not someone on the Register is their donor and if so, require the Authority to give the applicant "so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information)"[4].

3.5. Paragraph 2 of the 2004 Regulations states:

> (1) Subject to paragraph (4), the information contained in the register which the Authority is required to give an applicant by virtue of section 31(4)(a) of the Act is any information to which paragraph (2) or (3) applies….
>
> (3) This paragraph applies to information from which the donor may be identified which he provides after 31st March 2005 to a person to whom a licence applies, being information as to—
>
> (a) any matter specified in sub-paragraphs (a) to (h) of paragraph (2);
>
> (b) the surname and each forename of the donor and, if different, the surname and each forename of the donor used for the registration of his birth;
>
> (c) the date of birth of the donor and the town or district in which he was born;
>
> (d) the appearance of the donor;
>
> (e) the last known postal address of the donor.

[1] The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 (legislation.gov.uk)
[2] S41 1990 Act: *(5) A person who discloses any information in contravention of section 33A of this Act is guilty of an offence and liable - (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both*
[3] 1990 Act, s33A(2)(k)
[4] 1990 Act, s31ZA(1) and (2)(a)

3.6. The wording of the 1990 Act read in conjunction with the 2004 Regulations, means that the Authority can only be required to give a DCI the following donor contact information:

- Information that is on the Register;
- Information that is provided by a donor (after 31 March 2005); and
- The last known postal address of the donor.

3.7. This is reinforced by the Explanatory Notes to the 2004 Regulations which 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".

3.8. Where a donor has provided the clinic with more recent contact details than those recorded on the Register, the Register should be updated to reflect this. The DCI can require the Authority to disclose the Register address (as updated). Similarly, as is the case with re-registered donors, if a donor requests that other information, such as an email address, is given to the DCI, this can be done and we can advise the DCI if this is the donor's preferred means of contact. However, the postal address on the Register will still have to be disclosed in accordance with the 2004 Regulations.

3.9. Were the Authority to provide the DCI with information which it is not, by law required to give, and which the donor has not specifically consented to the HFEA providing, this would likely be in breach of the disclosure prohibitions in the 1990 Act as well as a breach of data protection laws.

Power to Notify Donors

3.10. The HFE Act 2008 introduced a statutory power enabling the HFEA to notify donors that a request for information about them has been made (now s31ZC, 1990 Act). Although there is no legal obligation on the HFEA to contact a donor prior to releasing information about them (even identifying information), the HFEA recognised that releasing their identifying information could have significant implications for the donor and so a decision was made to try to contact the donor before releasing identifying information.

3.11. The HFEA has consistently told the sector that it would attempt to contact donors before releasing identifying information about them, and that donors should keep their contact details up to date so that they can be contacted for this purpose. This is included in the Code of Practice as part of the information that clinics should provide to donors prior to donation (Guidance Note 11.35(k) and 11.45).

3.12. The Act does not specify how the HFEA must contact a donor for this purpose[5]. To date, our policy has been to contact the clinic to see whether a donor had updated their information, and if not, use the address as recorded in the Register. This is consistent with the intention behind the legislation as expressed in the Explanatory Notes to the 2008 provision introducing this statutory power, which state:
"…In practice, the HFEA would try to forewarn the donor before identifying information is given to the donor-conceived applicant. This might not be possible in all cases, for example if the donor has moved and has not updated their address."

[5] S31ZC says that the HFEA "*may notify*" a donor that a request has been made.

3.13. This is also what is communicated to donors by clinics at the time of donation.

Data Protection Laws

3.14. The specific provisions relating to donor contact and identification pre-dates modern data protection legislation. In recent years there has been an emphasis on ensuring that data is held and processed securely and lawfully but at times, rules under the UK General Data Protection Regulation (GDPR)[6] may be in tension with the data disclosure obligations and powers in the HFE Acts and Regulations.

3.15. A donor's contact details are 'personal data' within the UK GDPR. Article and 5(1)(a) of the UK GDPR requires personal data to be processed "lawfully, fairly and in a transparent manner in relation to the data subject".

Lawfully

3.16. Lawfully means both (i) having a valid lawful basis under Article 6(1) of the UK GDPR, and (ii) ensuring that the processing complies with all other applicable legal obligations on the controller.

3.17. The most obvious lawful basis to rely on is Article 6(1)(e) of the UK GDPR, which allows processing that is necessary for the performance of a public task. This could justify using a third-party database to find the current address of a donor in order for the HFEA to contact that donor to alert them to an OTR request. It could be argued that the processing here is necessary to enable the HFEA to fulfil one of its public functions set out in law – the power to notify donors as set out in s31ZC, 1990 Act.

3.18. However, disclosing contact details obtained from a third-party database (like one held by the NHS) to a DCI in response to an OTR request is much harder to justify. As above, the HFEA is by law required to disclose the last known postal address on the Register as provided by the donor. The wording of the 1990 Act and 2004 Regulations contains an implicit acknowledgement that the address details held by the HFEA may not be up to date. It is therefore not necessary for the HFEA to have an up-to-date address in order to respond to an OTR request.

3.19. Even if a valid lawful basis is established, the HFEA will still need to ensure that our processing complies with our wider legal obligations, including the HFE Act and associated regulations. The HFE legislation is very prescriptive as to what information must be provided to an OTR applicant and does not appear to give the HFEA flexibility to unilaterally update a donor's address and then provide that updated address to the applicant. If the law does not permit this particular activity, it would automatically be unlawful and therefore a breach of data protection legislation.

[6] Implemented by the Data Protection Act 2018 (legislation.gov.uk)

Fairly

3.20. The proposal to contact donors in advance of any identifying disclosure could be considered appropriate from a fairness perspective, to ensure that donors are reminded of what personal data will be disclosed. Fairness also suggests that attempts are made to contact donors merely because that is what the HFEA has said it would do. However, there is a risk that some donors may not wish to be contacted and may have deliberately chosen not to update their postal address. Use of a third-party database to obtain updated addresses could lead to complaints from these individuals, although this risk is reduced if the updated addresses are only used to contact donors, and not disclosed to applicants.

In a Transparent Manner

3.21. The transparency principle requires uses of personal data to be consistent with the purpose(s) for which the data was collected and outlined to donors. As above, donors **should** have been informed (albeit many years ago) that they should keep their contact details up to date if they wish to be able to be notified about an identifying OTR request. If the HFEA used a third-party database to trace those donors, a donor could argue that this was not what they consented to and contravenes the transparency principle.

3.22. Compliance with data protection law will also be key for the HFEA to be granted access to an NHS database. This is explored further below at 4.10 - 4.11.

4. Options

4.1. In thinking about the available options, we have to remember that the guiding principle must be what is lawful. At the same time, we have also to recognise that the context in which the HFEA has to provide identifying information from the Register has changed significantly since the HFE Act and regulations were drafted. As 3.3 - 3.9 above makes clear, we are only able to provide the DCI with specified identifying information held on our Register as provided by the donor. However, the growth of information held online and wider social media means that in practice the donor may be easily found after an internet search, even without a current postal address. That fact alone carries reputational risks for the Authority as it makes our obligation of supplying postal addresses look out of date, which we will have to mitigate as best we can.

4.2. The options below outline different processes that could be adopted for contacting donors. Options A to C are the only ones that are recommended, the other options are included for the sake of completeness only. The risks and resource implications of the different options are summarised in Annex 1.

Option A

- Contact donors using the most recent postal address recorded on the Register/clinic's files.
- Provide this same address to the DCI making the OTR request.
- Recommended Mitigation Options: 1 - 5

Analysis of option A

4.3. This is the process that we currently follow when a donor re-registers and is the process originally envisaged by the HFEA for OTR 2023. It has the benefit of being the simplest option procedurally and is the least resource-intensive. However, there is a significant risk that the address will be out of date and a letter from the HFEA will be opened by the wrong person. This could be a stranger or someone the donor knows such as a parent or ex-partner. If the address is out of date, the donor will not be warned that their identifying information will be released and equally the DCI may be disappointed to receive an incorrect address for their donor. The DCI might also write to the wrong person or even go to the address in person.

4.4. It is possible that a donor could bring a claim where disclosure about their donation was accidentally made to the wrong person due to a letter being sent to an out-of-date address. However, the risk of a successful claim with this option is comparatively low because the donor should have been told that this is how we would contact them and that it was their responsibility to keep their details up to date.

4.5. Legally, this is the least risky option and the option that is likely to most closely align with donor interests and expectations. Some donors may have deliberately not updated their contact details and would not expect to be traced to their latest address. This does, however, present a reputational risk to the HFEA, particularly around the best interests of DCIs.

Option B

- Contact donors using an address obtained through an NHS database (assuming access enabled) provided it is more recent than latest address provided by donor
- If the donor confirms this is their correct address and consents to updating the Register accordingly, this address can then be provided to the DCI
- In all other cases, - the most recent address (between the Register and clinic records) will be disclosed to the DCI.
- Recommended Mitigation Options: 1 - 5

Analysis of option B

4.6. This option could provide more accurate contact information and therefore communication with a larger number of donors. It is hoped that a proportion of these donors will also confirm their address with the HFEA, allowing the Register to be updated and a current contact address to be sent to the DCI.

4.7. However, there are greater legal risks with this option. As well as risks similar to those outlined in Option A (letter sent to an incorrect address or indeed to a correct address not provided by the donor and opened by someone other than the donor) there is also the risk of contacting some donors who have intentionally not updated their details and had not expected (or wanted) their current address to be sought from a third-party database. Donors could argue that they did not consent to being communicated with in this way. The risks could be somewhat mitigated by targeted communications, using the double envelope method and not disclosing this address to the DCI.

4.8. There are also the GDPR and reputational risks that the HFEA will knowingly disclose an incorrect, out of date address to the DCI (because that is the last address on the Register) whilst also having access to a more recent and accurate address.

4.9. Finally, this option has significant resource implications with a knock-on effect on time for OTR responses. It would involve checking three sources for the donor's address, comparing the dates of each source (if that is even possible – see below), writing to the donor and, where the addresses on the third-party database and Register do not match, asking the donor whether they consent to updating the Register address. The donor would need to be given time to respond, and if they do, we would need to verify their identity before updating the Register.

Logistical issues

4.10. As it currently stands, the HFEA does not have access to any NHS portal – data collected by the HFEA from licensed centres and stored on the Register is completely separate from NHS data collection and storage. Options B and C assume that the HFEA could get access to an NHS Portal. A database run by the NHS, the Personal Demographic Service (PDS), has been identified as being appropriate for these purposes although it only covers patients in England and Wales so an equivalent database would need to be identified for Scotland and Northern Ireland. The PDS stores non-clinical information about NHS patients, including their names, addresses, phone numbers, email addresses and NHS numbers and would therefore limit access to only the information that is needed, which is in keeping with the data minimisation principle under the UK GDPR. On a practical note however, to be granted access to the PDS, the HFEA would need to illustrate that it has a clear legal basis for processing the information and that it can comply with strict data security requirements, in particular compliance with NHS Digital's Data Security and Protection Toolkit and its cloud storage rules.

4.11. In addition, even if PDS access is granted, the HFEA might struggle to find the correct person on the PDS as we do not hold NHS numbers for all donors; centres have the option of verifying a donor's identity through either their NHS number or passport number. We would also not have NHS numbers for people who donated abroad[7]. Another consideration is that the HFEA would need to know when the PDS address was last updated to ensure that it was more recent than the last address we would otherwise have used.

Option C

- Contact donors using PDS address only where addresses match the Register address (or that on the clinic's notes)
- Provide the address on the Register to the DCI (even where it does not match the PDS address)
- Recommended Mitigation Options: 1 - 5

Analysis of Option C

4.12. This is similar to Option B but with this option, even if we have a very recent address on the PDS, we would not write to a donor to notify them of the OTR request if it did not match the

[7] This number has been steadily rising over time and in 2020, this was over half of new sperm donors registered in the UK.

latest address provided to us by the donor. The benefit of this option is that it is the most legally defensible – we would not write to an address that we know to be out of date and equally we would not write to a new address that was not provided by the donor. However, as a consequence, the number of donors that the HFEA writes to will decrease (probably quite significantly). The legal security this option provides might be offset by the reputational losses (e.g. "the HFEA have access to the donor's current address but are not contacting donors") and additional resource implications. In addition, in situations where the addresses do not match, we would knowingly disclose an out-of-date address to a DCI.

4.13. Most of the logistical obstacles relevant to Option B (outlined above in 4.10- 4.11) will also apply to Option C.

Other Options (Not Recommended)

4.14. **D. Do not contact donors at all**: As there is no obligation to contact donors, in some ways this is may seem like a viable option as it carries the lowest legal risk from a GDPR perspective. However, the HFEA has regularly said it would attempt to contact donors and so to backtrack from that would be very damaging from a reputational perspective. It may also give rise to a challenge on grounds of legitimate expectation although we have not looked into how defensible a challenge on these grounds might be.

4.15. **E. Contact donor via the PDS address (where this is the most recent address we have) and disclose this address to the DCI**: Whilst this option may be the most appealing to DCI stakeholders, it is very risky from a legal perspective as detailed above (section 3). In addition, it fails to take into account the interests of donors, who would not have been told they would be traced and that their latest contact details (which they did not provide) would be passed onto the DCI.

Mitigation Options

4.16. As can be seen from the analysis above, there are risks with every option. It is therefore important to mitigate these risks as much as possible. Below we consider possible mitigation strategies:

1. Check with the clinic: To see whether the donor has updated their details – if so, the Register should be updated accordingly.

2. Double envelope: In this option, the outer envelope would have no reference to the HFEA, would be clearly marked 'Private and Confidential' and addressed to the donor. It is a criminal offence to open other people's post.

3. Incorrect address: Do not send any notification to the donor where the address is known to be incorrect – although this address will still need to be sent to the DCI.

4. Effective communications: This should have the dual aim of encouraging donors to update their details and managing DCI expectations. There are many limitations on what we can disclose to a DCI and only some of them are explored in this paper. For example, even if we are aware that a donor has died, we are unable to tell the DCI, but must still disclose their details (including the last known address) to the DCI.

5. DCI response: Comprehensive and carefully worded response letter to DCI about the limitations of the information provided.

6. No confidential information in letter to donor: Do not send any confidential information in the initial contact letter but instead advise the donor we hold important information that

concerns them and that they should contact the HFEA (we could set up an email address specifically for this purpose). We have considered this option but think it would be of limited benefit as there are very few reasons why the HFEA would write to an individual and it would at least raise suspicion that the intended recipient was a donor. If a donor were to email in requesting further information, we would have to then validate their identification before providing them with the relevant information which would be resource intensive and time-consuming, affecting the turnaround for OTR applications. The current staffing structure and number would not be able manage this suggested process.

5. Next Steps

5.1. As this paper illustrates, there are a number of different legal, reputational and ethical risks to consider, and these often conflict with each other. No option offers a perfect solution and with any option, there are risks of public criticism, disappointment from those involved (potentially DCIs and/or donors) and legal challenge. Mitigation strategies will be key to delivering any option.

5.2. The Authority to asked to:

- Review the information set out in this paper;
- Consider the legal and reputational risks and resource implications; and
- Decide which option should be implemented by the donor information team as part of the OTR process going forward.

Annex A

Risk Rating Table

This table illustrates the comparative risks and resource implications of the various options. Only options A, B and C are recommended.

Option	Notify Donors	Disclose to DCI	Legal Risk Rating	Reputational Risk Rating	Resource implications
A	Contact donor via address on Register*	Register address* to DCI	**LOW**	**MEDIUM/ HIGH**	**LOW**
B	Contact donor via PDS address (where most recent) even where it does not match address on Register*	Register address* to DCI	**MEDIUM/ HIGH**	**MEDIUM**	**VERY HIGH**
C	Contact donor via PDS address only where it matches address on Register, otherwise do not contact donor	Register address* to DCI	**LOW**	**MEDIUM/ HIGH**	**HIGH**
D	None	Register address* to DCI	**MEDIUM**	**VERY HIGH**	**LOW**
E	Contact donor via PDS address (where most recent) even where it does not match address on Register*	PDS address to DCI (even where it does not match address provided by donor)	**VERY HIGH**	**MEDIUM**	**VERY HIGH**

*Or address recorded on clinic's notes, if more recent

Modernising Fertility Regulation - update

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	9
Meeting date:	17 May 2023
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Ana Hallgarten, Public Policy Manager

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to note the headline findings from the recent public consultation on law reform and next steps outlined in this paper and decide on options for taking this work forward.
Resource implications:	Staff resources as planned in the current business plan
Implementation date:	Ongoing
Communication(s):	As outlined in the paper – through regular public and stakeholder updates
Organisational risk:	Medium

1. Introduction

1.1. Following a number of Authority decisions, a public consultation on modernising fertility law (the Human Fertilisation and Embryology Act 1990 (as amended)) was launched in February 2023.

1.2. Previous updates to the Authority in **February 2022**, **May 2022**, **July 2022**, **September 2022**, and **March 2023** have noted the background to this work and developments to date.

1.3. This paper provides an introduction to the responses to the consultation. Section 2 summarises the public consultation and related activities. This will be supplemented in the Authority meeting itself by a presentation outlining the headline responses. Sections 3 and 4 set out some options as to the proposed next steps in relation to this work.

2. Public consultation

2.1. The consultation ran from 28th February to 14th April and we received a wide range of responses from individuals sharing their personal views and experiences, those sharing their professional views, organisational responses and wider members of the public.

2.2. The consultation summarised some of the key issues we are considering as part of the legislative reform proposals. The proposals were deliberately pitched at a high level and were developed from discussion with the Legislative Reform Advisory Group (LRAG), expert roundtables, and feedback from the Authority.

2.3. The consultation was designed in a format that enabled the HFEA to set out why we think specific changes are necessary and the outline proposals we have for reform. We did not consult on changes which are largely technical and which aim to improve on the operation of the existing law. Instead, the consultation focused on proposals which are new, or significantly develop or depart from the existing policy consensus.

2.4. The issues consulted on were set out in four main areas:

- Patient safety and promoting good practice
- Access to donor information
- Consent
- Scientific developments

2.5. Respondents were given the choice of commenting on proposals in terms of agreeing or disagreeing with each proposal (from 'strongly agree' through to 'strongly disagree') and/or submitting detailed written comments. A number of organisations submitted detailed written responses and a considerable number of respondents choose to also add comments to some or all of the proposals also. We are now in the process of analysing the quantitative and large qualitative data.

2.6. The consultation was communicated widely and there was significant interest from national media and social media, as well as a sector and patient focused event that the Chief Executive participated in.

2.7. There was widespread media and social media coverage of the consultation with over 350 pieces of media coverage, including in 17 national outlets. The main focus of the coverage was on proposals relating to any potential changes to donor anonymity. Many members of our patient and professional stakeholder groups circulated the consultation on social media and to

their members and two high profile blogs were written during the consultation. On social media, initial posts about the consultation performed well on Twitter, a video from Julia Chain performed well on Instagram and on LinkedIn, a post outlining the four areas of consultation attracted wide interest.

2.8. It is assumed that should the Government decide to introduce proposals for legislative change in future then there will be further public consultation on some or all of these proposals.

2.9. The risks outlined in the **May 2022 Authority meeting** are ongoing, and there have been a significant number of responses regarding the use of embryos in research, as well as the wider proposals regarding scientific developments. These risks include:

- The short time available to complete the work
- Criticism of the presented issues or focus
- A lack of consensus
- Wider challenges for or against the idea of regulation itself.

3. Next steps

3.1. The consultation responses are being analysed, including where there are detailed responses on some aspects.

3.2. There was broad support across most of the proposals that were set out in the consultation. When considering both the quantitative data and the ongoing qualitative analysis, key proposals that require more examination include (in no particular order):

- Changes in donor information provision
- The potential use of secondary legislation and other mechanisms for changes to the regulation of scientific developments
- Ways in which to simplify the current consent process
- Elements of our regulatory powers, most notably the regulation of allied services

3.3. Once that analysis is complete, we will return to the Authority with refined proposals for discussion and agreement. It is important to note that the consultation was never intended as a plebiscite; rather the aim was to establish public views to inform Authority thinking.

4. For decision

4.1. Authority is asked to:

Note the initial outcome of public consultation on law reform and next steps.

In broad terms:

4.2. The proposals that were developed by Authority with input from LRAG and others were widely supported by individual respondents, professionals and organisations responding to our consultation. There were a large number of ‘general public’ respondents on particular questions who did not support the proposals on embryo research and scientific developments.

4.3. The ambition of this work was always to provide high level outlines of where the HFEA thinks modernisation of the Act is most needed and not detailed drafting.

4.4. Of the proposals that were consulted on, our initial analysis suggests that further thinking is most needed in respect of simplifying consent, the age and extent of access to identifying donor information; allied fertility services and which scientific developments may fall under future primary or secondary legislation. We also think there is a case for further clarification of areas where there was widespread agreement (e.g. in relation to the HFEA's regulatory powers) but which need further explanation or examples to illustrate our proposals.

4.5. Options that Authority could consider are:

1. Proceed as planned and present Authority with recommendations for law reform in July to be sent to the Department for Health and Social Care and publicised more widely.

2. Proceed as planned and present Authority with recommendations for law reform in July only those areas where little further work needs to be done. This would mean that some of the areas set out in the consultation would require further work with individual Authority members, LRAG members and individual stakeholders, with the aim of returning to the Authority later this year with proposals on those specific areas, for example, in relation to simplifying consent. Although this will give us some time to do further thinking, this option would not involve wide engagement and detailed stakeholder discussions on these issues.

3. As option 2 but hold back on the areas where further work is needed and to provide time for detailed discussions with licensed clinics, patient and professional stakeholders and other experts to work out proposals in more detail. This would result in more specific proposals but would have an impact on other planned activity for 2023/24

4. Hold back on all proposals until later this year or next year, depending on the level of detail the Authority would want to provide on those proposals that need further thinking and then submit proposals at a later stage in one go.

4.6. All of these options have reputational and other consequences and Authority are asked to discuss which is the preferred way forward.