Human Fertilisation & Embryology Authority

Authority meeting

Date: 16 November 2022 – 12.45pm to 4.15pm

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 14 September and matters arising For decision	12.50pm
3. Chair and Chief Executive's report – to note For information	12.55pm
4. Committee Chairs' reports For information	1.15pm
5. Performance Report For information	1.30pm
6. Strategic risk register & Risk Strategy review For discussion	1.50pm
7. Business planning 2023/24 For decision	2.15pm
Break	2.45pm
8. Support services for donors and donor conceived people For decision	3.00pm
9. State of the sector 2021/22 & inspection themes For discussion	3.45pm
10. Any Other Business	4.10pm
11. Close	4.15pm

Minutes of Authority meeting held on 14 September 2022

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	16 November 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 14 September 2022 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 14 September 2022 held via teleconference

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

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 staff present. The Chair stated that during this time of national mourning following the death of Her Majesty Queen Elizabeth II, we had decided that our meeting should not be held in public nor audio recorded but the minutes will be published on our website.

1.2. On behalf the HFEA, the Chair passed on condolences to the Royal family.

1.3. Declarations of interest were made by:

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

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 19 July 2022 were a true record and could be signed by the Chair subject to the following changes:

4.7. To read:

"…The AGC Chair continued that there would be refresher training on the analysis of financial statements for AGC members and that this would be opened up to Authority members who would like to participate".

6.1. To read:

"The Scientific Policy Manager presented this item. Members were reminded that Treatment add-ons had been discussed at three Authority meetings since September 2021"

2.2. The status of all matters arising was noted.

3. Chair and Chief Executive's report

3.1. Members noted updates on activities from the Chair and the Chief Executive. Some speaking engagements were postponed because of the mourning period.

3.2. The Authority were informed that there is a new Secretary of State for Health and Social Care who is also the Deputy Prime Minister. Members were also advised that following the mourning period we will be advised of ministerial portfolios at the DHSC and which minister will be responsible for our area.

Decision

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

4. Committee Chairs' reports

4.1. The Chair invited Committee Chairs to comment on the presented reports.

4.2. The Licence Committee Chair (Alison Marsden) commented that the Committee considered some particularly serious cases of non-compliance which underline the limitations of our current regulatory powers.

4.3. The Statutory Approvals Committee Chair (Jonathan Herring) commented that they had been meeting monthly and an example of the kind of issues being discussed included where PGT-M could be allowed in relation to deafness where a range of ethical considerations need to be looked at. The licence was allowed as the committee had to consider the worst-case scenario and, in addition, just because something is licensed, does not mean patients *have* to test for the condition.

4.4. The Chair suggested that it would be proper for Authority members to be made aware of exceptional licensing issues following any regulatory decision. Authority members agreed that there should be space at Authority meetings to discuss such issues where they raised wider concerns about the state of the sector, policy issues or the regulatory options open to us.

4.5. The Chief Executive commented that we would get back to the Chair on how to take this forward.

Decision

4.6. Members noted the Committee Chairs' updates.

5. Performance report

5.1. The Chief Executive commented that the review of the key performance indicators (KPIs) had led to a number of changes. In particular, some KPIs had been expanded, notably the efficiency of the end-to-end inspection and licensing process, which should provide greater transparency of any arising issues.

5.2. The Chief Executive commented that the red indicator on staff turnover remained from previous months. Part of the explanation was pay, where we had received approval from the DHSC and Treasury to award a pay settlement of 2% to all staff under the level of the Senior Management Team (SMT). It was noted that the pay settlement in the Civil Service was less than that awarded to the NHS, and this differential could impact on turnover as many HFEA staff have the skills and experience to work in organisations on the NHS pay scale. In a small organisation like the HFEA, the lack of progression in the civil service pay scale meant that promotion elsewhere was the main way staff could increase their pay.

5.3. The Chief Executive expressed his gratitude to staff who have to carry the workload when other staff members leave the HFEA. Members were advised that the previous staff survey had indicated that majority of staff liked working for the HFEA but pay rates remained a problem.

5.4. On PRISM, it was noted that all but three clinics are now submitting their data through PRISM.

5.5. We were also building our expertise in-house to support PRISM long term. We now need to ensure that the legacy data that was brought over to PRISM undergoes a validation exercise.

5.6. The Chair commented that the Authority recognised the issues of pay and its effect on staff turnover.

Strategy and Corporate Affairs

5.7. The Director of Strategy and Corporate Affairs presented this item. She commented that the publications planned for later this year were firstly, the annual State of the sector report, that looked at the sector from a compliance angle, noting trends in compliance, incidents and complaints. Later in the year, a report on donation would be published to provide information on who is having donor treatment, numbers of children born through donation and other relevant data in advance of opening the register (OTR) in 2023.

5.8. It was noted that the next persons responsible (PR) event will be held in-person in our Stratford office on 31 October 2022 and will focus on the recent change to the law on the storage of gametes and embryos as well as preparing for 2023.

5.9. The National Institute for Health and Care Excellence (NICE) were consulting on their review of fertility guidelines and we will respond. Members requested that the HFEA response be shared with them.

Compliance and Information

5.10. The Director of Compliance and Information presented to the Authority.

5.11. On Compliance, it was noted that we have a busy inspection schedule with a mix of renewals and interims alongside extra visits where there are concerns.

5.12. On IT, the current focus was on infrastructure security improvements. An Infrastructure penetration test was scheduled for week commencing 12 September 2022.

5.13. On the data security and protection toolkit (DSPT), Members were advised that we had started preparing for next year's submission. However, NHS Digital have raised the bar this year and moved Arms-length bodies (ALBs) to category 1, which is the same level as NHS Trusts. This meant that there are now 113 mandatory items (out of 133), a 28% increase from 2021/22 (where there were 88 mandatory items). The Director of Compliance and Information commented that this was putting further pressure on the team and our resources.

5.14. On OTR, the waiting list did not change in terms of absolute numbers as more applications were received than were closed over the last two months. This was due to staff turnover in the team but we were now recruiting to the vacant positions. On a more positive note, only 7% of applications received in 2021 remained open.

5.15. The Chief Executive commented on the significant increase in the number, scope and requirements of what is now required to meet the DSPT. The Chief Executive also noted that there was an increase in the audit demands that were coming from the central government (rather than the DHSC as our sponsor department), and that this was placing additional pressure on resources.

5.16. As a small organisation we have to prioritise our limited resources on 'frontline' activities. The additional requirements to the DSPT and other corporate reporting standards meant that we were in danger of spending more time on such exercises at the expense of carrying out our statutory role as a regulator.

5.17. Members asked if the case of proportionality could be made to the government department responsible for Arms-length bodies (ALBs) and with the sponsor team.

5.18. The Chief Executive responded that we will be taking this forward with our sponsor.

5.19. The Chair stated that this will be kept under review.

Finance and Resources

5.20. The Director of Finance and Resources presented this item. It was reported that the estimated billing of clinics using data from 2020/21 continued whilst we were awaiting all clinics to catch up with their data inputs. This raised the risk of over/under estimation of our income which in turn impacted on expenditure for the remainder of the year.

5.21. It was noted that the auditors were now content and our accounts would be laid before Parliament as soon as possible in October 2022.

Decision

5.22. Members noted the performance report.

6. Implementation of the new gamete and embryo storage rules

6.1. The Regulatory Policy Manager presented this item. Members were advised that the storage changes followed a successful campaign to extend the reproductive choices of patients who previously could only store for a maximum of 10 years unless they were prematurely infertile or at risk of becoming prematurely infertile.

6.2. The key changes were explained including all patients being able to store their gametes or embryos for their own treatment for a maximum of 55 years. However, this could only be done if patients renewed their consent to storage at the first 10-year consent expiry period and at each successive 10-year period. It was explained that this meant there was no longer a requirement for patients to satisfy the premature infertility criterion.

6.3. To enable us to accomplish this piece of work, other work was deprioritised to recognise the urgency and time-dependent nature of the introduction of the new storage regulations. This

impacted on the capacity of the organisation as a dedicated team was put together from across the HFEA with external support and advice was sought from sector and legal professionals.

6.4. It was noted that members of the British Fertility Society (BFS) and the Association of Reproductive and Clinical Scientists (ARCS) provided advice and reviewed the new consent forms and guidance.

6.5. Members were advised that a lot of material was ready before the deadline on 1 July 2022 including:

- updated consent forms
- new statutory notices for use when renewing consent and
- a detailed clinic practical guide.

6.6. To assist implementation the HFEA also drafted flowcharts for clinics with worked examples as a visual component to aid understanding of how the new legislation applied to new patients and those with gametes in storage pre-1 July 2022.

6.7. It was noted that feedback from clinics often focussed on the limited time available to prepare given the legal implementation date. The HFEA also engaged in a number of ways with patients.

6.8. Members were advised that there were a number of risks, including patients not knowing that they needed to re-consent as they might not be aware of the change in law. Weekly drop-in sessions for clinic staff were held throughout July and August which were well attended.

6.9. Looking ahead, Members were informed that we would publish an updated frequently asked questions (FAQs) in the autumn of 2022 and update the Code of Practice in 2023 to reflect the storage changes.

6.10. Members commented they were they were happy with the close engagement with clinics, and given the anxiety expressed by many clinics the outcomes were reassuring. Members also asked if the feedback included comments from patient groups.

6.11. The Director of Strategy and Corporate Affairs responded that we were planning to do further work with patient groups particularly with patients who stored their gametes some years ago. Patient groups had re-purposed our information on their social media platforms, which was helpful.

6.12. Members welcomed the proportionate approach adopted and commented that they were looking forward to further discussions at the persons responsible (PR) event.

6.13. Some members wanted to know whose responsibility it was to remind patients about the need to renew consent every 10-years. The Director of Compliance and Information responded that the renewal period is now a defined legal process and clinics have a legal responsibility to get in touch with patients, which includes writing to the patients before the start of the renewal period and at consent expiry. Statutory notices also have to be issued to patients at defined time points in the renewal process.

6.14. The DHSC representative thanked the HFEA for the hard work put in considering the very tight timeframe.

6.15. Members asked about the lessons learned exercise and if it pointed to anything that could have been done differently. The Regulatory Policy Manager responded that a there were few areas we

could have been improved on and the use of external advice was very beneficial. There were staff joining at later times through the project which meant there was a slight overlap but on the whole the project worked well.

6.16. The Director of Strategy and Corporate Affairs commented that because of the tight timeframe we dedicated a number of staff to the project including a Director, Head and other staff. The consequence of this however, was that other work these staff members were involved in had to be de-prioritised or dropped all together.

6.17. A member commented that the resource issue was also felt in clinics and to ensure that it was fully embedded it was suggested that the support from the HFEA should continue.

6.18. The Chair commented that the resource issue was an important one considering the work was not fully completed and thanked everyone for getting us to a good place.

Decision

6.19. Members noted the implementation of the new gamete and embryo storage rules.

7. Update on ethnic diversity in fertility treatment

7.1. The Director of Strategy and Corporate Affairs presented this item. Members were reminded that in March 2021 we published the Ethnic Diversity in fertility treatment 2018 report, which highlighted disparities in access to, and outcomes of, fertility treatment by ethnic groups.

7.2. The key findings from the report were discussed.

7.3. It was noted that there was good engagement from clinic staff. The findings were also discussed with various groups and professional bodies including the Royal College of Obstetricians and Gynaecologists (RCOG), the BFS and Fertility Network.

7.4. A working group of clinic staff met for two workshops to discuss specific topics raised in the report, which were chaired by Jason Kasraie and Tim Child.

7.5. It was noted that this remained an area of huge concern for the Authority, clinics and patients and we needed to look at future work in this area when we considered of our draft 2022/23 business plan at our November Authority meeting.

7.6. The Director of Strategy and Corporate Affairs thanked Anna Coundley, Policy Manager for facilitating the work on the clinic workshops.

7.7. Members congratulated the HFEA for their work highlighting this area and commented that the data would need to be reviewed in future. It was important to ensure consistency on how clinics collect data, use it and ensure that it was in line with recognised ethnic categories.

7.8. Members commented that delayed access to fertility treatment could be due to co-morbidities in women from ethnic backgrounds as those medical issues needed to be handled before these women were referred to fertility clinics. There might also be cultural issues for males to give sperm samples.

7.9. Members commented that we needed to address the disparities working in partnership with other organisations, professional bodies and the DHSC.

7.10. Members suggested that single embryo transfers should be promoted in older woman with co-morbidities and the translating service could be improved on.

7.11. Members advised that ethnic diversity in fertility treatment should be discussed at the PR event in October and that it could also be escalated to the Equalities Minister, as well as working with Fertility Network. This also needs to be reflected in the new HFEA communication strategy.

7.12. Members suggested that other avenues available to reach more black and ethnic groups could be through churches and places of worship. Community leaders could also help raise awareness on these issues.

7.13. The Chair commented that prior to the Covid pandemic there were delays in black and minority ethnic women accessing fertility treatment and post pandemic those delays may have worsened.

7.14. Members commented on the National Sperm Bank in Scotland; setting it up was costly and time consuming but what helped was a lot of support from the Scottish Government. The Director of Strategy and Corporate Affairs responded that we could only facilitate the discussion of a national sperm bank for England but it was not for the regulator to take this on.

Decision

7.15. Members agreed the prioritisation for this work and noted the involvement of Authority members going forward.

8. Modernising Fertility Regulation - update

8.1. The Director of Strategy and Corporate Affairs presented this item with the Public Policy Manager in attendance.

8.2. It was noted that a key HFEA strategic priority was to develop proposals on modernising the law to ensure it remained relevant. Significant work is being conducted on the targeted consultation document that we plan to issue this autumn.

8.3. The aim was to gather professional, key stakeholder patient groups and clinic staff views on our emerging proposals for legislative reform. It was noted that although this was a targeted public consultation it would also be publicly available for anyone to respond to.

8.4. Members were reminded that we were going through several distinct stages and that the last stage would be a report to the DHSC around the turn of the year.

8.5. Members were reminded that there were three key areas that we were focusing on to ensure that patients were at the heart of what we and clinics do. These areas are:

- Patient protection
- Scientific developments and
- Consent, data sharing & anonymity.

8.6. The Director of Strategy and Corporate Affairs gave a brief overview of some of the issues in each of these areas that had been outlined in published Legislative Reform Advisory Group (LRAG) papers.

8.7. Members were also reminded that future proofing the Act was important.

8.8. The Chair commented that this discussion was the result of the work done by LRAG and the Board away day discussion. She reiterated that in the autumn we will release a targeted consultation.

Decision

8.9. Members noted the work done to date on modernising fertility regulation.

9. Any other business

9.1. The Chair reminded members that the PR event was on 31 October 2022 and that it was an in-person event and that she hoped that all PRs will attend.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 16 November 2022

Authority meeting

Matters Arising

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	2		
Meeting date	16 November 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed.		
Resource implications	To be updated and reviewed at each Authority meeting		
Implementation date	2022/23 business year		
Communication(s)			
Organisational risk	**X** Low	☐ Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters arising from the Authority meeting – actions from 14 September 2022			
4.4 Authority members to be made aware of exceptional licensing issues.	Chief Executive	January 2023	This will form part of the standing agenda item should there be issues that need to be brought to the attention of the board.
5.9 HFEA response to NICE consultation on the review of fertility guidelines to be shared with members.	Director of Strategy and Corporate Affairs	December 2022	Copy of consultation response sent to members on 16/09/2022
Matters arising from the Authority meeting – actions from 19 July 2022			
7.15 A targeted consultation to occur by summer and the outcomes reported to the board.	Director of Strategy and Corporate Affairs	January 2023	Ongoing work to launch consultation and report to DHSC.
Matters arising from the Authority meeting – actions from 18 May 2022			
3.6 Some members that are yet to complete their cyber security training.	Governance Manager	January 2023	One member is yet to let the Governance Manager know if they have completed their Security & Data Protection online training.
Matters arising from the Authority meeting – actions from 24 November 2021			
11.10 Options on how compliance information including inspection reports and licensing decisions could be made more visible and easier to find on the website.	Director of Strategy and Corporate Affairs	November 2023	No further progress. Legislative changes relating to storage and other key areas have taken priority at this point. Recommendation is that it be delayed for 12 months to Nov 2023 and that the Authority discuss in context of business plan for next year as to prioritisation.
Matters arising from the Authority meeting – actions from 23 September 2021			
5.18 Backlog on OTR	Director of Compliance and Information	March 2023	There has once again been staff turnover and there is currently a vacant post. The structure of the team has changed to hopefully improve retention in the future. . An improved way of reporting the

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
			performance indicator has been introduced The number of applications remain high however 93% of applications from 2021 are closed and 84% of applications from 2022 are closed. This remains a standing agenda item under director's performance report.
Matters arising from the Authority – actions from 7 July 2021			
5.7 PGT-M being out of target of the 75 working days	Director of Compliance and Information	January 2023	We have employed a dedicated scientific application officer to manage this in the future (along with ITE certificates and mito applications). This takes the task away from inspectors who have a heavy workload with their clinic portfolios. Training is ongoing. This should improve the KPI in future.

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	16 November 2022
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

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

1. Introduction

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

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

2. Activities

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

- 20 September – attended a meeting on Diversity in Public Appointments
- 29 September – meeting with Fertilis
- 3 October – attended SCAAC committee meeting
- 4 October – attended our Audit & Governance Committee
- 7 October – filmed for ITN Understanding Fertility programme
- 31 October – attended our PR event

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

- 16 September – attended a meeting of all CEOs of health ALBs at DHSC
- 29 September meeting with Fertilis
- 29 September – spoke at CSaP policy workshop on organoid regulation at Christ's College, Cambridge
- 3 October – attended SCAAC committee meeting
- 4 October – attended our Audit & Governance Committee
- 26 October – interviewed for Sanger Institute project on Synthetic Genomes
- 31 October – attended our PR event
- 4 November – attended a meeting of all Chairs and CEOs of health ALBs at DHSC
- 7 November – introduced our central Induction programme for staff

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:	16 November 2022
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is invited to note this report, and Chairs are invited to comment on their Committees.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	None
Organisational risk:	Low

1. Committee reports

1.1 The information presented below summarises Committees' work since the last report.

2. Recent committee items considered

2.1 The table below sets out the recent items to each committee:

Meetings held	Items considered	Outcomes
Licence Committee:		
8 September 2022	1 Renewal 1 Interim / Variation to include new SLCs	Adjourned Approved
10 November 2022	1 Renewal	The minutes for this meeting have not yet been approved.
Other comments:	None.	
Executive Licensing Panel:		
20 September 2022	1 Change of Centre Name 1 Change of Person Responsible 1 Change of Licence Holder 1 Executive Update	All granted/approved
5 October 2022	1 Renewal 1 Change of Person Responsible 1 Executive Update	All granted/approved
18 October 2022	5 Renewals 1 Variation of Activities	All granted/approved
1 November 2022	1 Renewal	Granted/approved
Other comments:	None.	
Licensing Officer decisions:		
-	ITE Certificates – 27 Expiry of Research Licence - 1	All granted/approved
Other comments:	None.	
Statutory Approvals Committee:		
25 August 2022	5 PGT-M applications 2 Special Directions	All granted/approved

Meetings held	Items considered	Outcomes
29 September 2022	1 Mitochondrial Donation 3 PGT-Ms 2 Special Directions	All granted/approved
27 October 2022	2 PGT-Ms 1 Special Direction	The minutes for this meeting have not yet been approved.
Other comments:	None.	

Audit and Governance Committee:		
4 October 2022	Internal audit report and implementation of recommendations External audit report Strategic risk register and risk management policy Horizon scanning and deep dive topics Digital projects and PRISM update Resilience and business continuity management Reserves policy Fraud risk assessment Legal risks Update on goodwill letters	-
Other comments:	None.	

Scientific and Clinical Advances Advisory Committee:		
3 October 2022	Public health developments relevant to fertility treatment and embryo research	Information about additional risks of treatment related to hypertension in pregnancy following frozen embryo transfer to be included on HFEA website for patients.
	Treatment add-ons review - evidence base	SCAAC support the proposed decision tree for published evidence to consider when rating add-ons. The primary outcome for ratings will remain as live birth. Where this is not possible the rating system may refer to ongoing pregnancy rate (at least 10-11 weeks post-transfer). The rating system may also refer

Meetings held	Items considered	Outcomes
		to other relevant outcomes or population groups.
	Scientific considerations relevant to the '14-day rule'	Committee to continue monitoring developments on this priority topic.
	Artificial Intelligence	Committee to continue monitoring developments on this priority topic. Executive to consider developing a framework to identify AI models falling within HFEA remit.
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 September 2022

Shabbir Qureshi
Risk and Business Planning Manager
25/10/2022

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	-
Meeting date:	16/11/22
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs Annex 4: SMT detailed KPIs

Output from this paper	
For information or decision?	For information
Recommendation:	To discuss
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

Human Fertilisation & Embryology Authority

Latest review and key trends

Latest review

- The attached report is for performance up to and including September 2022.
- Performance was reviewed by SMT at its 2 November 2022 meeting.
- Performance for this month was generally good. There were six red indicators.

Key trends

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

July (5)	August (5)	September (6)
C2 – Inspection reports sent to PR within 20 working days	C2 – Inspection reports sent to PR within 20 working days	C2 – Inspection reports sent to PR within 20 working days
C4 – Inspection reports completed within 70 working days (post committee)	C3 – Inspection reports sent to committee within 55 working days	C3 – Inspection reports sent to committee within 55 working days
F2 – Debtor days	F2 – Debtor days	F2 – Debtor days
F3 – Prompt payment	F3 – Prompt payment	F3 – Prompt payment
HR2 – Staff turnover	HR2 – Staff turnover	HR2 – Staff turnover
		L3 – Licence committee minutes within 15 working days

Human Fertilisation & Embryology Authority

Management summary

IT and register performance reporting

- 267k submissions from 101 clinics. Three clinics remaining to deploy.
- Error rates are 1.1% (direct) and 4.4% (API). PRISM has been stable for the last 4 weeks.
- Two main issues:
  - Movements – sending clinic does not complete the movement, the receiving clinic cannot process any activity. Doing a deep dive and expect to complete work in coming weeks.
  - Validations – lots of work over the summer to update validation rules and now incorporated an auto-validation routine in PRISM which is being tested prior to release.

Management commentary

- Performance has been variable across indicators with six red, one amber and eight green.
- For two months in a row, the Compliance team have achieved a green status for 70 working day turnaround for inspection reports. From September 2021 through to July 2022, this indicator had been red.
- However, the new 20 day and 55 day inspection reports (to PR and licensing committee respectively) have been consistently red or amber since April. The focus on reporting these figures has delivered early identification of common issues and this should allow the Compliance team to address them.
- Two out of three finance KPIs have been red for the past three months. F1 (debt collection) and F2 (debtor days) have been impacted due to estimates being used. F3 (prompt payment) has been due to late invoicing and approval; this should improve in October.
- Although the OTR team sent out significantly higher numbers, reduced staffing has impacted how many are in the ‘ready for checking’ queue and this may impact how many OTRs are sent next month.

Summary financial position

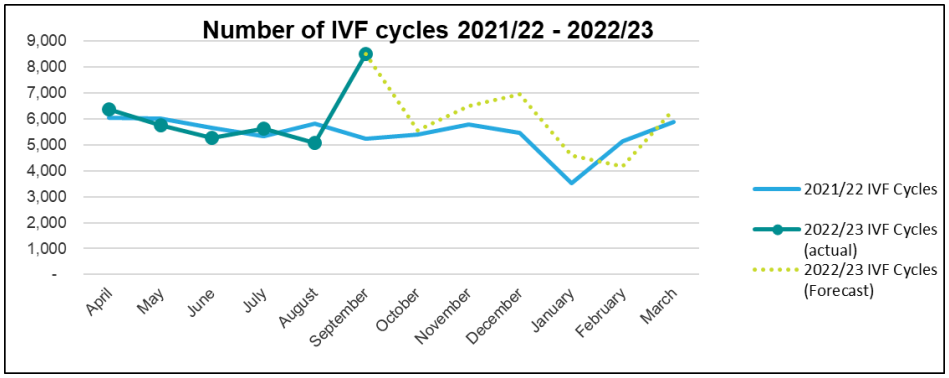
Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/2022 £'000s	Budget for 2021/22 £'000s	Variance Budget vs Forecast £'000s
Income	4,176	3,958	(208)	7,622	7,451	171
Expenditure	3,324	3,725	402	7,222	7,468	246
Total Surplus/(Deficit)	**852**	**243**	**609**	**400**	**(17)**	**417**

Commentary on financial performance to September 2022

- Year to date we are £609k up on budget. This is due to our income being higher than expected and underspends within our expenditure.
- Our income continues to be a source of focus whilst clinics are still updating their submissions. Agreement is to be sought as to when a final cut-off point can be had where-by billing will be based upon actual cycles rather than the estimates we have been using since September 2021.
- Whilst there are some significant underspends, it is expected that these will be reduced as projects commence within the next quarter.
- Our forecast outturn is currently showing a surplus against budget of £417k. This may change as our expenditure increases with planned work and our income remains constant.

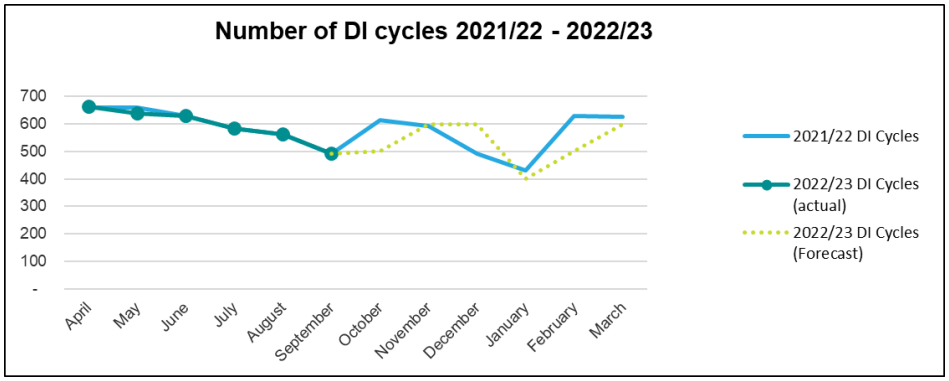
Human Fertilisation & Embryology Authority

Financial management information



IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2021/22 IVF Cycles	34,073	2,725,813	65,266	5,221,253
2022/23 IVF Cycles (actual)	36,587	2,926,960	70,737	5,658,960
Variance	2,514	201,147	5,471	437,707

YTD IVF volumes are up 7.4% on the same period in 2021/22 and 3% over budget. For September we have seen an increase of 62% on the same period for 2021/22. This is likely to be because clinics are still uploading their submissions.



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2021/22 DI Cycles	3,583	134,363	6,968	261,300
2021/22 DI Cycles	3,568	133,800	6,768	253,800
Variance	15	563	200	7,500

DI volumes are down by 0.4% against 2021/22 for the same period and 12% above budget. The reduction against 21/22 is unusual, however, as with IVF, where a few clinics are still inputting cycles post PRISM roll-out, this may be a factor.

As we are almost two-thirds into the year, a hard cut-off date will need to be agreed where by all clinics will be billed based upon actual activity rather than estimations.

Human Fertilisation & Embryology Authority

HFEA income and expenditure

	Year to Date				Full Year		
	Actual	Budget	Variance	Variance YTD	Forecast	Budget	Variance
	£'000	£'000	£'000	%	£'000	£'000	£'000
Income							
Grant-in-aid	748	736	(12)	(0)	1,098	1,098	-
Non-cash (Ring-fenced RDEL)	133	133	-	-	352	265	87
Grant-in-aid - PCSPS contribution	50	50	(0)	(0)	100	100	-
Licence Fees	3,180	2,975	(205)	-7%	5,961	5,842	119
Interest received	11	1	(10)	(16)	1	1	(0)
Seconded and other income	54	73	19	27	110	145	(35)
Total Income	4,176	3,968	(208)	**(5)**	**7,622**	**7,451**	**171**
Revenue Costs							
Salaries (excluding Authority)	2,415	2,534	119	5	4,754	5,068	314
Staff Travel & Subsistence	23	63	40	63	127	127	-
Other Staff Costs	48	53	5	9	106	106	-
Authority & Other Committees costs	115	115	0	0	245	231	(14)
Facilities Costs incl non-cash	238	356	118	33	700	711	11
IT Costs	190	329	139	42	657	657	-
Legal / Professional Fees	219	154	(65)	(42)	399	328	(71)
Other Costs	76	121	45	37	234	240	6
Other Project Costs	0	-	(0)	-	-	-	-
Total Revenue Costs	**3,324**	**3,725**	**401**	**11**	**7,222**	**7,468**	**246**
TOTAL Surplus / (Deficit)	**852**	**243**	**609**		**400**	**(17)**	**417**
Adjusted for non-cash income/costs	**788**	**243**	**544**		**314**	**(18)**	**331**

Management commentary

Income.
At the end of Q2 (September) our total income is above budget by 5%.This is mainly due to our licence fee income which currently is £205k above budget and may be a result of clinics catching up with their submissions. We have a small variance against our Grant in aid (GIA) where the profile and drawdowns are slightly out of sync.

Expenditure by exception (over £10k variance).
At the end of March (year end), we are under budget by £401k.

Salaries - are below budget by £166k. The majority of this variance comes from Contingent Labour which mainly relates to PRISM which is over by £396k and offset by underspends within wages and social security costs.
Staff Travel & Subsistence - are under budget by £40k. A review of the cost of an inspection is being undertaken which may help to explain this underspend. In addition, the move to reduce the number of days on site and virtual visits may play a part in this.

Facilities costs - underspent by £118K, We are underspending on accommodation costs by £47k which is due costs accrued for being less than the actual charge and relate to 2 Redman place. The is an underspend against Finance interest which relates to our lease. This will change in Q3. In addition we have an underspend (£66k) within our non-cash costs, the majority of which relates the lease for our offices which are to be brough onto our balance sheet (capitalised) in Q3.

IT Costs - are underspent by £139k. The main underspends are within our Consultancy and Support costs £118k, however this will be spent in year through the OTR project. IT Subscriptions of £29k and a total of £12k underspend in Low value fixed assets, telephone and photocopying costs. Offsetting this underspend, are overspends totalling £20k within Consumables, Internet and Low value software costs.

Legal/Professional fee - are over budget by £65k. This is represented by an overspend within the legal budget of £78k and offsetting the contingency of £13k. The legal spend includes the secondment cost of a legal advisor which should be offset against the staff cost for a Head of Legal. Removing the overspend relating to the legal advisor (£46k) still leaves and overspend of £32k.

Other costs - are underspent by £45k. The most significant variances are within Compliance Other (4k), Stakeholder Events (£27k), Donor Information (£5k), plus smaller underspends sub £5k across areas within both the Compliance and Information and Strategy and Corporate Affairs directorate. We are overspending against our publication costs (£8k) and Media monitoring (£3k).

Forecast - we are currently forecasting an underspend of £400k and an underspend against budget of £417k. This will chage as directorate plans are enacted during Q3 and Q4. A further review will be undertaken in January 2023.

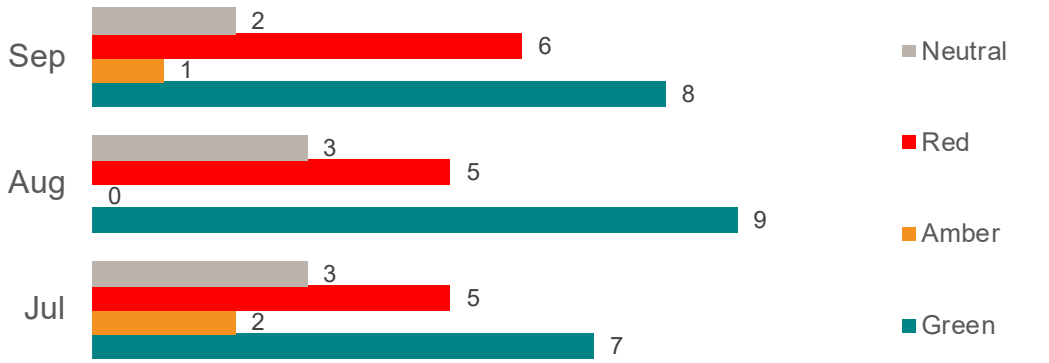
Human Fertilisation & Embryology Authority

Key performance indicators

Human Fertilisation & Embryology Authority

RAG status over last 3 months

(17 KPIs in total)



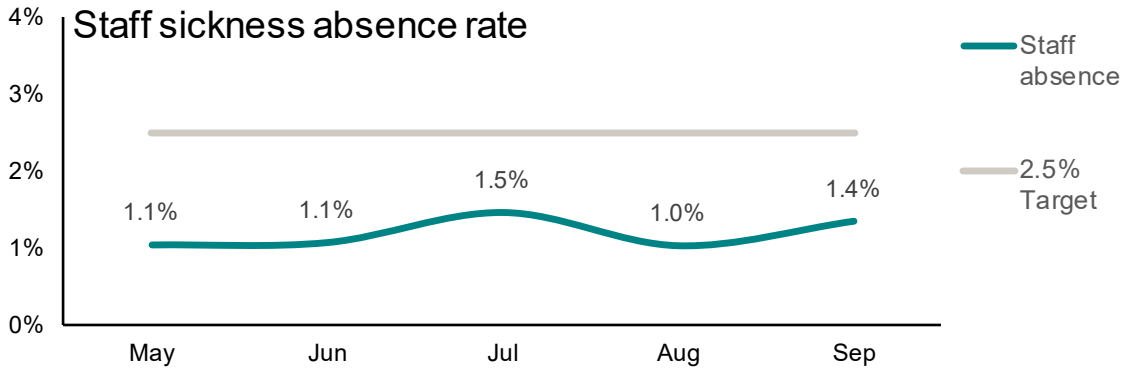
For September, the red indicators are:

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

Status: Green

HR1 – Sickness

Target:
Less than or equal to 2.5%

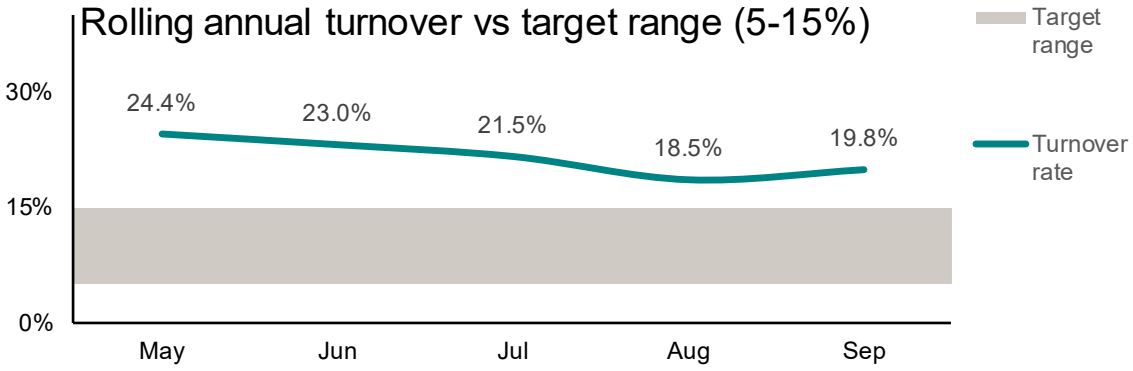


Sickness absence is slightly higher this month, however, it is due to one member of staff absent for more than 5 days.

Status: Red

HR1 – Sickness

Target:
Less than or equal to 2.5%



As expected turnover has increased this month.

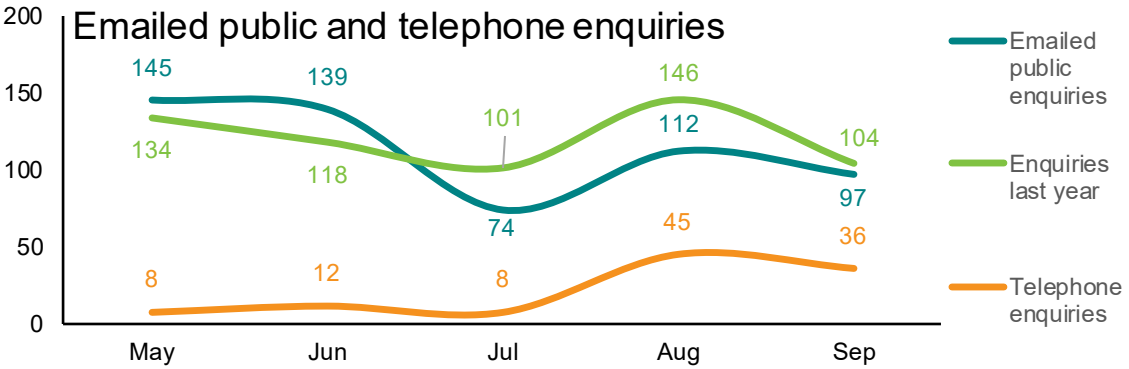
Supplementary HR data

Headcount : 72
Posts : 76
Starters : 2
Leavers : 3

Status: N/A

Emailed public and telephone enquiries

Target:
None defined

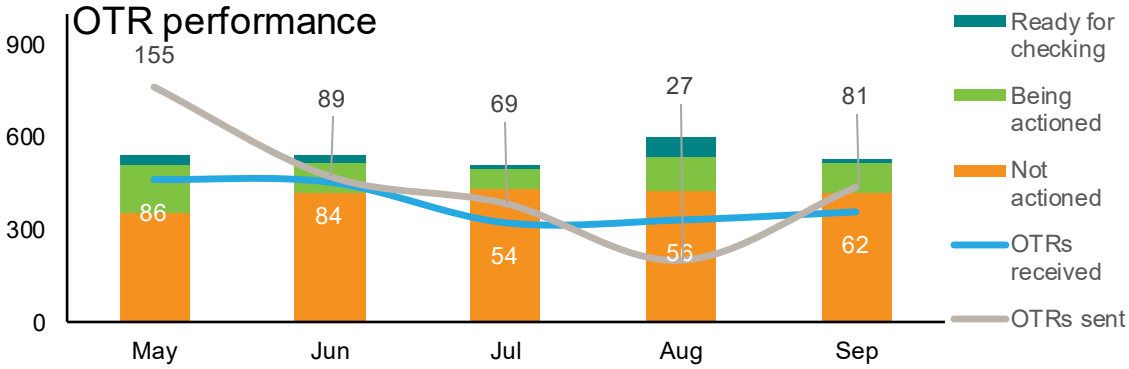


Complaints system: (12) - 2 with patients having difficulties raising a complaint.
Complex (4).
Straightforward (48) themes - donation (9), treatment (6), preservation (5) and fees (3).
No COVID-related enquiries in September.

Status: N/A

I1 – OTR performance

Target:
To be developed

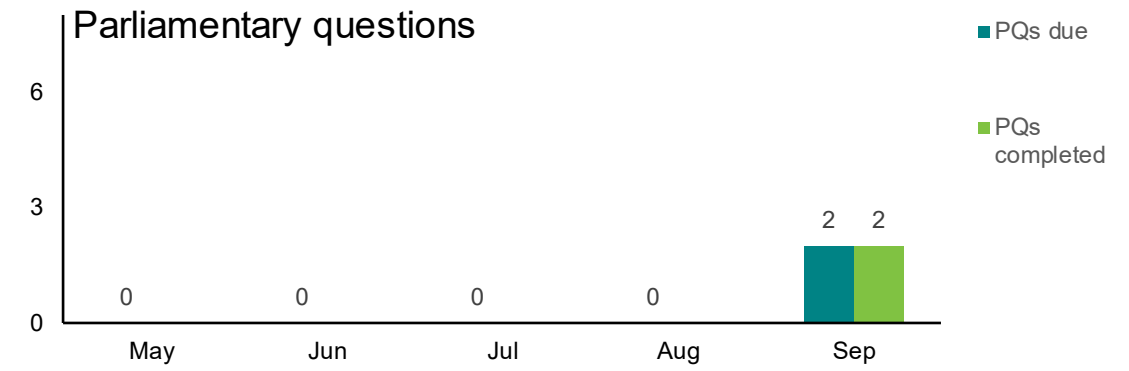


The team co-ordinated a higher number of DSL matches this month, many of which were complex (more than 2 siblings). More OTRs were sent out than last month but fewer are ready for checking due to reduced Officer resource.

Status: Green

RI1 – PQs responses

Target:
100% within deadlines set

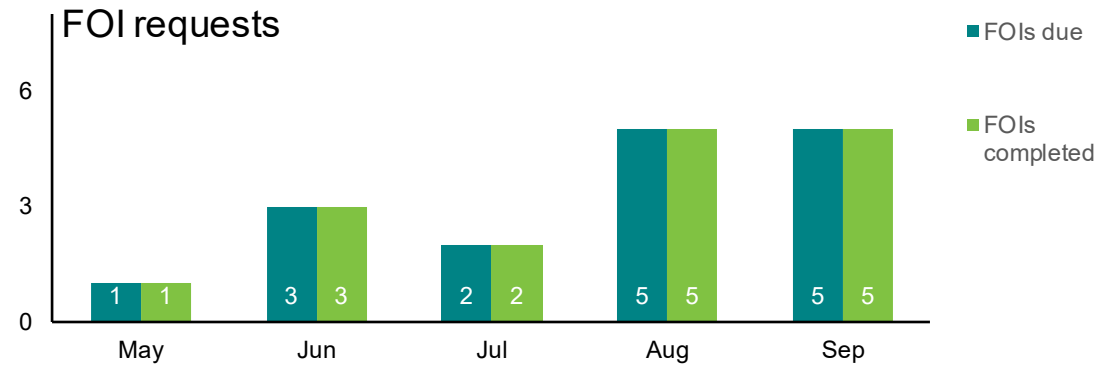


All PQs completed within timescales.

Status: Green

RI2 - FOI responses

Target:
100% within statutory deadlines

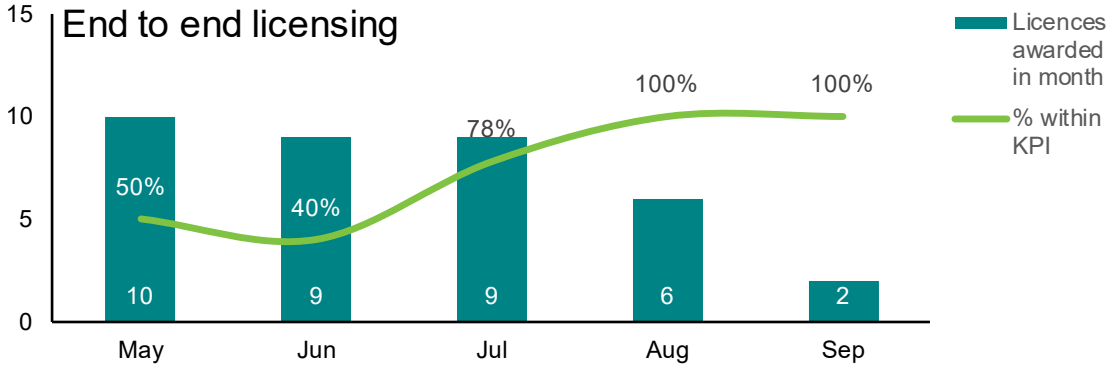


We have received increased numbers of enquiries/ FOIs on adverse outcomes and genetic testing, likely relating to recent publications on health impacts of frozen embryo transfers. We have also had continued numbers of enquiries about donations.

Status: Red

C3 – End to end licensing process

Target:
100% completed within 70 working days

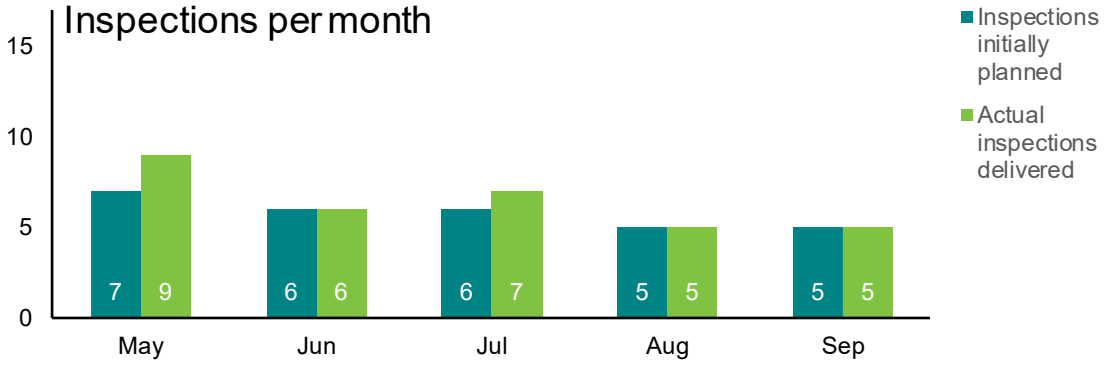


This KPI has been green for two months in a row.

Status: N/A

C1 – Inspections delivery

Target:
tbc

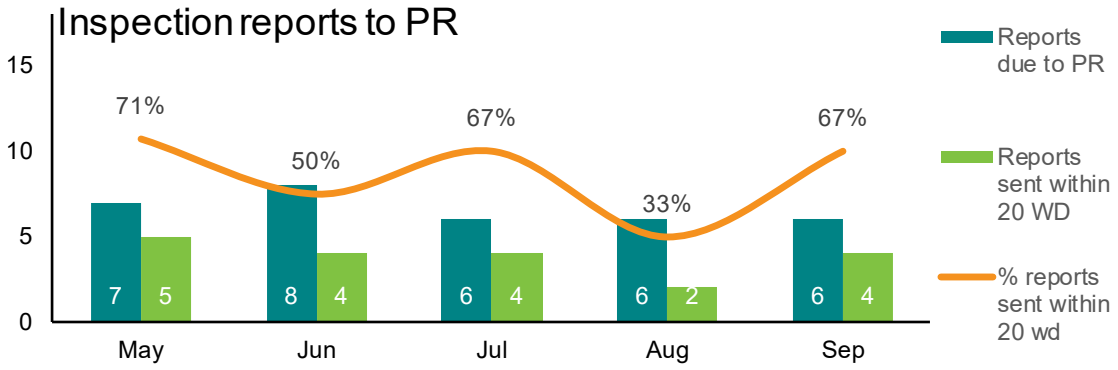


The following inspections have been moved:
Clinic A - from Jul to Sep 22 due to PR's sick leave.
Clinic B - from Aug to Sep 22 due to change in Lead.
Clinic C - from Aug to Sep due to Lead A/L; then due to unforeseen personal circumstances, change of lead and moved to Oct 22.

Status: Red

C2 – Inspection reports sent to PR

Target:
100% sent within 20 working days

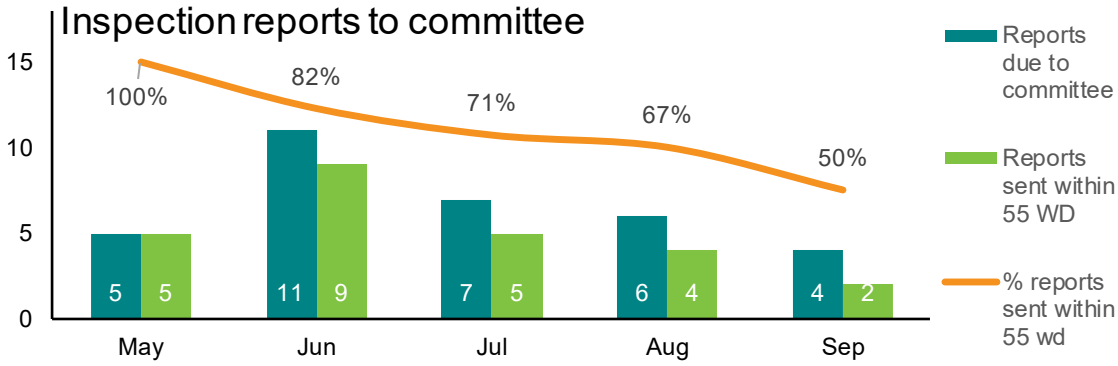


Clinic A - (28 days): delay in QA process due to other compliance work and overlapping A/L.
Clinic B - (report not yet sent to PR); support QA delayed due to inspector's sickness

Status: Red

C3 – Inspection reports sent to relevant licensing committee

Target:
100% sent within 55 working days

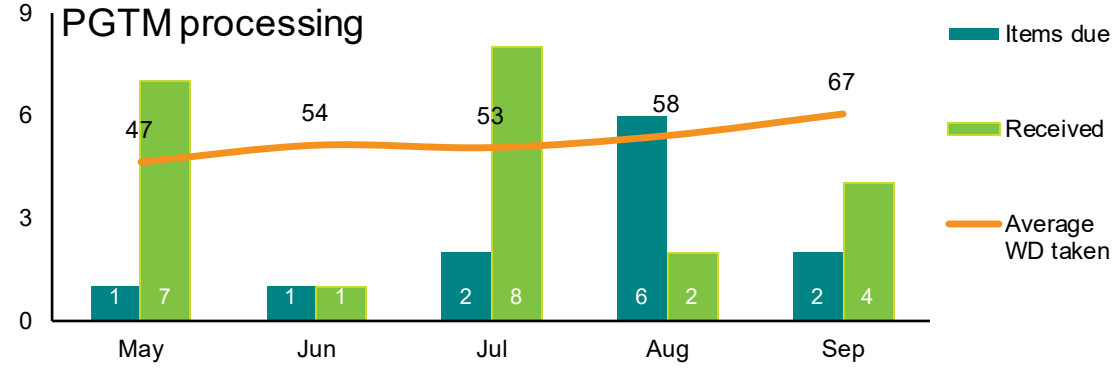


Clinic A - (66 days): report to PR in 51 wd - delay with QA (a/l); C&E assessment; change of inspectors writing report; stage 2 (PR took 13 wd to return rather than 10).
Clinic B - (report not yet sent to licensing): requires legal input prior to final QA. Also delay due to stage 1 (report sent to PR within 42 days).

Status: Green

C6 – PGTM processing efficiency

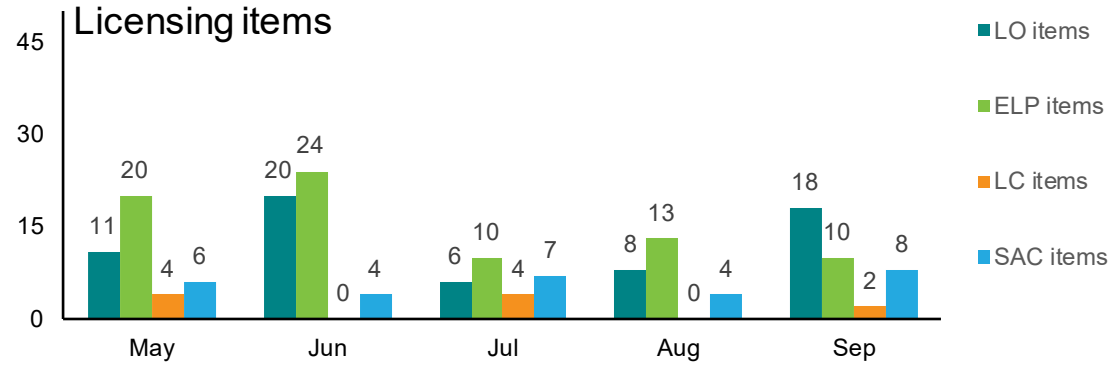
Target:
100% within 75 working days



We have a dedicated applications officer in place now and improvements in processing should continue.

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

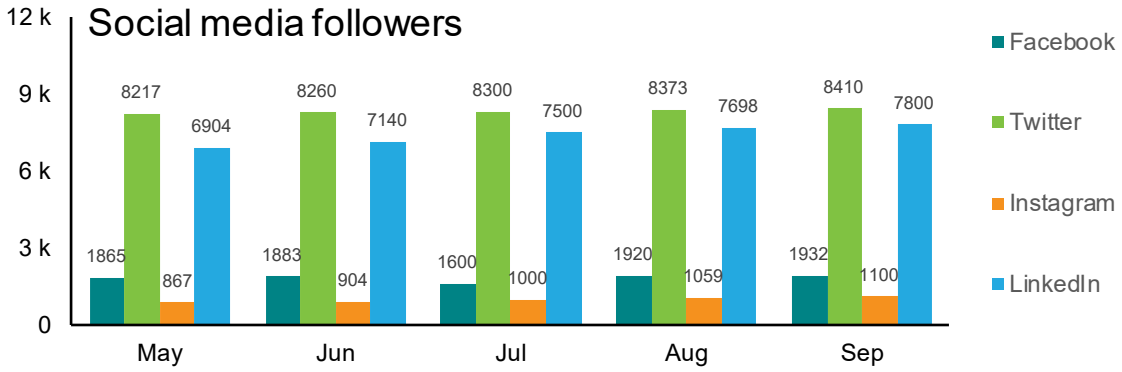
Licensing efficiency
Targets (WD):
LO - 5, ELP - 10
LC - 15, SAC - 20



LC - one especially complicated decision made to adjourn decision on renewal licence and issue Special Directions to continue activities. Extra liaison with legal adviser to draft minutes/Special Directions.

Status: N/A

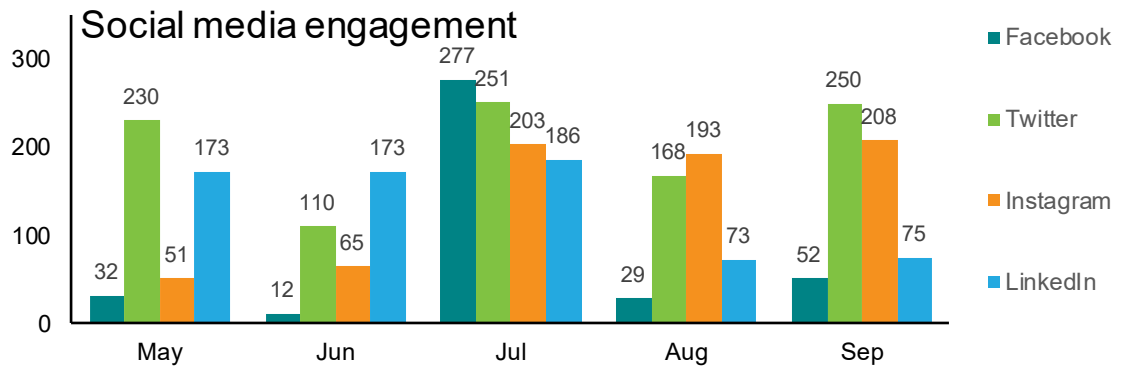
Total number of followers across social media



The HFEA's social media channels covered a range of topics during September. These included recruitment posts, a blog post and posts about coping during treatment.

Status: N/A

Engagement across social media (measurement systems vary)

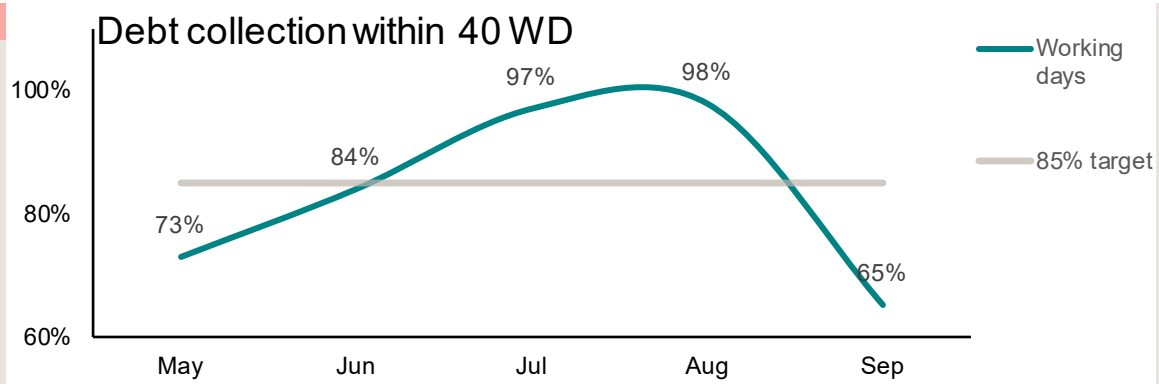


Our top performing post was about coping during treatment and was well received by our audience.

Status: Red

F1 – Debt collection

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

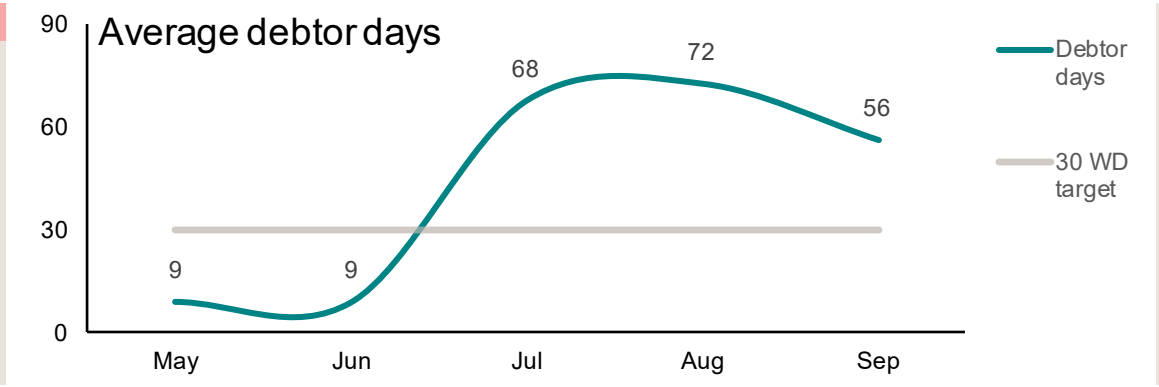


F1 - Collection rate affected by estimation. As number of estimations reduce the rate of collections should improve.

Status: Red

F2 – Debtor days

Target:
30 working days or less

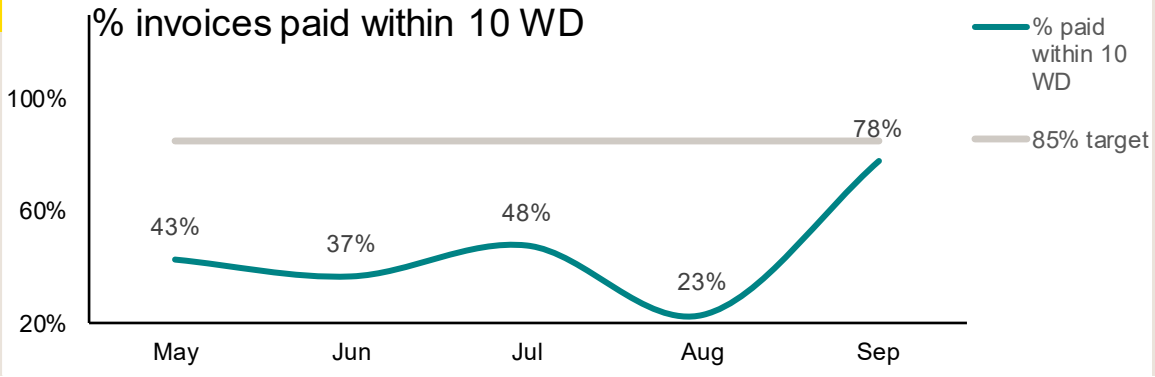


F2 - Days affected by estimation, which has resulted in slower settlements.

Status: Amber

F3 – Prompt payment

Target:
85% or more invoices paid within 10 days



F3 - Payments affected by leave, which prevented BACS approvals. Should improve in October as we catch up on outstanding approvals.

Strategic risk register and risk review

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:	16 November 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	6a – Risk review, 6b – HFEA Risk Strategy, 6c – Operational & Strategic risk register screenshots, 6d – Risk appetite statement

Output from this paper

For information or decision?	For decision and discussion on Risk Appetite. The final decision on Risk Appetite will be with AGC.
Recommendation:	Authority is asked to note the risk review paper, the HFEA Risk Strategy, the strategic risk register and the operational risk register. Authority is asked to discuss the underlying risk appetite within AGC.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from Authority will inform AGC in December
Organisational risk:	Medium

1. Purpose

1.1. Effective and meaningful risk management in government remains as important as ever in taking a balanced view to managing opportunity and risk. The Orange Book risk management guidance was updated in February 2020 to support public sector organisations to improve risk management further and to embed this as a routine part of how we operate.

1.2. The HFEA has long had a framework for the management of risk, but we needed to revisit that framework in the light of the Orange Book and best practice more generally. That work has been undertaken with oversight of AGC.

1.3. AGC were given an updated timeline for the review of the risk strategy in October 2022. The new risk strategy and associated documentation was approved at October CMG and are included in the annexes for information.

1.4. A new operational risk log has been launched and teams are migrating their existing risk registers. We are aiming to complete this for all teams by December AGC.

1.5. A new strategic risk register document has been created and the existing register is also being migrated. As part of this, a review of the strategic risks is being undertaken, with a view to have this completed by December AGC.

1.6. More substantial changes to the content of the strategic risk register will be made in the final quarter of 2022/23 in line with the new business plan.

2. Recommendation

2.1. The Authority is requested to note the attached risk review which looks at the risk structure and background, the new risk strategy and associated risk registers (at annexes 6a, 6b and 6c).

2.2. The Authority is asked to discuss the underlying risk appetite (annex 6d) which forms part of the risk strategy. The aim of the discussion is to identify the degree to which, and in what cases, the Authority is prepared to take risks. That risk appetite is likely to vary depending on the issue at stake. In practice the application of our risk appetite will be dynamic and overseen by AGC.

HFEA 2022 Risk Management review

1. Overview

1.1. The risk management policy and associated processes were due to be reviewed in 2021 but this had to be delayed because of staffing pressures and before that, the Covid pandemic.

1.2. A review plan was first submitted to AGC in June 2021. This plan was subsequently updated for AGC in March 2022, with progress reports to the June and October meetings.

1.3. As part of this review, we sought a GIAA operational risk management audit in February 2022. The opinion of this audit was 'Limited' with a summary of 'There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective'. That audit has been helpful in informing our review of the operational aspects of our risk management.

2. Plan for the risk review

2.1. Below is the plan provided to AGC with progress notes:

Month	Proposed plan	October update
March	Support the internal audit of our risk systems and begin to consider recommendations once the report is ready.	Completed. Final internal audit report presented to AGC on 28 June 2022.
April	Review of best practice guidance and other organisational approaches with reference to the revised Orange Book and risk improvement groups (DHSC and Cross-government). Consideration of how to feed latest best practice into a revised version of our risk strategy.	Completed. A draft of the updated strategy is attached. Details below.
May	Commence review of operational risk management practices and identification and mitigation of weaknesses, in line with recommendations arising from the current audit, and our own observations about current team practices. Redrafting of policy to begin.	Completed. See details below.

	Consideration of content/structure changes in the strategic risk register, to surface the most active issues and improve presentation. Feedback for AGC on progress to date to be drafted in readiness for the June meeting.	The strategic risk register is being restructured in readiness for the December AGC meeting and will be developed further following the full implementation of the new operational risk register.
June-September	Design and implementation of rolling improvement plans for operational risk management. Ongoing work on the revised risk strategy and risk register. Consideration of how to frame the discussion on our overall risk appetite and the setting of tolerances for individual risks. Design of a horizon scanning methodology.	Completed. See details below.
October	Revised draft of risk strategy and risk register completed and presented to AGC for consideration. Discussion on risk appetite and tolerance levels.	Timeline shifted to accommodate updates to the strategic and operational risk registers, and CMG approval.
November	Agreement of risk appetite with Authority alongside their periodic review of the risk register.	Authority to note the new risk strategy and hold risk appetite discussion.
December	Finalisation and launch of the revised risk strategy and feedback to AGC on the Authority's discussion on risk appetite.	Completed risk strategy and strategic risk register presented to AGC, with feedback from the Authority discussion.

3. Policy changes

3.1. The previous risk management policy was released in November 2018 and was due to be reviewed in 2020 but was put back to 2021 due to COVID.

3.2. The GIAA audit stated: 'The current risk management policy is out of date and doesn't incorporate some of the recent changes that have been made to the Orange Book or the introduction of Risk Champions within the Authority.'

3.3. The Orange book was revised in 2020 and updated in August 2021 to include a Risk Management Skills and Capabilities framework, a Good Practice guide to risk reporting and a revised Risk Appetite guidance note.

3.4. The new 'Risk strategy' (changed from 'Risk policy') has addressed the following, using both Orange book principles and audit feedback:

- The structure and some of the text from the Orange book has been used.

- The role and responsibilities of the Risk Champions have been amalgamated into the strategy.
- A continuous improvement and horizon scanning methodology have been included.
- Guidance to aid with the assessment of the impact of risk; taking into account the legal, financial, regulatory and reputational risks have been included. The risk categories from the Orange book have been included in the new operational risk register.
- The risk strategy and departmental risk registers have been framed using the causes/ events/ consequences system. The strategic risk register template will use the same system.
- Guidance for Heads on selecting the top three risks to bring to CMG and the process of escalating risks to the Strategic Risk Register have been included in the new strategy.
- The risk appetite concept has been referenced, highlighting the differences between current/ tolerable/ optimal risk positions.
- A section on horizon scanning and future risk identification has been added. This is to identify opportunities and focussing on making risks both dynamic and time-framed where appropriate.
- The 'deep dives' concept and references to risk assurance mapping have been added taking into account resource limitations to frame actions and mitigations.
- The links between risk management, service delivery plans and performance management have been included.
- The 'Risk Management Skills and Capability Framework' has been included which includes risk inductions and the requirements of both informal and formal risk training.

4. HFEA risk registers

4.1. The 'Project Risk Registers' were identified in the audit as having some good practice elements and these have been adopted into the new operational risk register template which will be used by all teams. A separate project to update the Project Management system used by HFEA has been approved by CMG and is being implemented. A new monthly project performance report, completed on an online form, is now available on the Hub and is used to identify current risks to make the focus on in-project risks more dynamic and targeted.

4.2. A standardised Excel template for the operational risk register has been created. This has incorporated the following:

- All teams have a tab on a single sheet so they can compare each other's risks and scores.
- Teams can 'tag' other teams where the risk is shared or impacted by actions from other teams.
- Risks have an 'Open/ Closed/ Future' system to make risks dynamic.
- The sheet has automation built in, so calculations and colours for risk scores are selected automatically.
- There is also a 'dashboard' which shows how many risks have been identified across teams and the residual risk scores total.

4.3. Guidance on completing the operational risk register along with 'best practice' examples have been developed.

4.4. A new Excel based strategic risk register has been created and this will be further developed once the new operational risk register has been completed by all teams.

5. The role of Risk Champions

5.1. The previous risk champions policy has been amalgamated with the new risk strategy.

5.2. A key addition is the clarification that the risk champions are not expected to spend more than a half day each month on risk-based activities. Their role is to support Heads, but the responsibility for each team's operational risk management remains with the Head.

5.3. Risk champions are expected to undergo additional training and development work, so they are better able to support heads. Collaboration activities between the risk champions will be restarted with quarterly meetings to share best practice and learning from internal incidents.

6. Performance reporting

6.1. A new performance reporting sheet has been put in place for reporting data from the new financial year. This has had the following changes:

- Tabs for each team to aid navigation.
- The sheet is 'locked' to prevent formulas and formatting to be restricted.
- All RAG ratings are automated.
- The majority of data, comments and charts required for generating the performance reports for SMT, Authority and AGC have been automated.

6.2. All teams have reviewed their KPIs; some are still under review, with Comms KPIs the most challenging as some indicators are not available with the systems HFEA currently use. The new Compliance KPIs have been running since April and are now revealing a better picture of inspection reporting and licensing activity.

6.3. A 'dip check' system is being developed and will be in place from 2023. During the process of updating KPIs, the data used has been interrogated and assessed to gain an accurate picture of how robust data gathering processes are. Several changes have been implemented in teams' data collection already and this work is ongoing.

7. Service delivery plans

7.1. A standardised Excel template for SDPs will be created and referenced after the new risk strategy is in place. Where possible, in line with the performance reports and risk registers, this will be a single document with each team having their own tabs. However, as there are significant differences between how teams articulate delivery, there will need to be scope to adapt the template to suit each team. This work is due to be completed in the first quarter of 2023.

8. A 'joined up' approach

8.1. The new risk strategy makes it clear that risk management sits alongside performance reporting and service delivery plans to shape operational delivery. Impact from one area should be reflected in the other areas. Specific examples are referenced in the strategy using a cyclical

approach demonstrating how service delivery plans should be updated based on previous performance with risk management linking the two.

8.2. This approach will make both the risk registers and service delivery plans more dynamic and allow us to anticipate future performance risks.

8.3. Interdependencies between these three areas will be easier to identify and this move to a more evidence-based approach will enhance our ability to demonstrate at audits how we identify risks in a timely manner and apply controls to minimise impact. Where risks sit between teams, again the new register will allow teams to formally record plans, note any follow up actions and once resolved, close the risk.

9. Internal incidents

9.1. The internal incident system is in the process of being updated with a new online form which is in the final phase of testing. This is due to be launched in November.

9.2. The new web-based form is more user-friendly and allows for more automation as the data captured from the form is made available in both a pdf document and an automated Excel document.

9.3. A report will be presented at CMG meetings quarterly to summarise the issues and learning.

9.4. The internal incident reporting system will be placed as a link on the intranet homepage (the Hub) to allow for greater visibility of the process and to encourage timely reporting and follow-up. This will also be used to highlight learning, promote best practice and hold links to appropriate policies and procedures.

9.5. Examples to better define the differences between internal incidents, near misses and data breaches are included.

9.6. As part of the role of the Risk Champions, reporting and learning from internal incidents will be a key focus area.

9.7. The KPIs used for internal incidents are also under review and will be in place by the time the new system is launched.

10. Training and development

10.1. The GIAA audit findings were that “individuals in the Business Planning & Governance team who have overall responsibility for risk management arrangements in the organisation [should] receive formal training, in line with the requirements of the Risk Management: Skills and Capability Framework (2021)”.

10.2. The audit also recommended that the HFEA assess the training needs with regards to Risk Management across the organisation and ensure staff deemed to be in scope are provided with regular training.

10.3. Formal training needs will be assessed, and plans put in place after the new risk strategy is in place, for the Risk and Business Planning Manager and the Head of Planning and Governance.

10.4. A full training needs analysis will be completed in the first quarter of 2023, with more risk training added to the formal induction for all staff.

11. Risk appetite

11.1. The Orange book has further expanded on risk appetite and referenced the further challenge for public sector organisations to achieve value for money. A key consideration for the HFEA is ensuring risk management is proportionate, taking into account the size of the organisation and the resource constraints this creates.

11.2. The HFEA approach has changed over the years from a view that we should be naturally cautious as a regulator, to more of a view that there are opportunity costs in that stance, and that we need to consider our appetite for risk in relation to key Authority decisions and new areas of policy or law. We want to support innovation, but we also then need to consider how we would mitigate and manage the resulting risks.

11.3. Using more dynamic risk registers, increasing awareness of how we approach risk within the organisation and having a more balanced approach, the HFEA will highlight its risk position, better defining the current, optimal and tolerable risk positions.

11.4. The new strategy will define risk appetite levels, stating examples from the Orange book and providing guidance to define risk approaches from risk averse, to cautious, to eager.

11.5. The development of the new strategy will include references to increasing risk appetite and will include a risk appetite summary, defining the HFEA's position for risk tolerance. Some areas, such as our register functions, we will be risk averse, whereas in others, our position may be more open.

Human Fertilisation & Embryology Authority

Managing risk at the HFEA

HFEA risk management strategy

www.hfea.gov.uk

General approach to risk

1. Overview

1.1. The HFEA's risk management system sits within its wider corporate governance system, which is described in the Annual Governance Statement set out in each year's Annual Report.

1.2. The overall system of corporate governance is designed to ensure that responsibility and accountability is clear and, that internal controls support the mitigation of strategic and operational risks. It is also designed to ensure that Authority members and the Chief Executive can be assured that appropriate oversight over operational responsibilities is in place. The HFEA complies with the requirements of the Corporate Governance in Central Government Departments: code of good practice, in so far as they relate to ALBs.

1.3. The HFEA's general approach to the management of risk is based on the principles of good practice set out in HM Treasury's 'Orange Book' on risk management, last updated in 2021.

1.4. The Orange book further recognises risk as being inherent in everything we do to deliver high-quality services. Effective and meaningful risk management remains as important as ever in taking a balanced view to managing opportunity and risk. It must be an integral part of informed decision-making, from policy or project inception through implementation to the everyday delivery of our regulatory functions.

1.5. The HFEA therefore actively considers risks and controls in all business and project planning, and in our ongoing management of our staff and our operational delivery. The policies, tools and reporting systems used have all been redesigned to ensure that effective risk management is integrated in the way we lead, direct, manage and operate.

1.6. The risk framework is integrated into our management systems, and through the flow of information, used to identify and manage the uncertainties identified, anticipating and preparing successful responses.

2. Risk and capability

2.1. The Authority's attitude to, and management of, the risks it faces in carrying out its functions is robust but proportionate. Risk appetite in the Authority has increased in recent years and a more comprehensive approach to risk management has been identified, making risk identification more dynamic.

2.2. The framework the HFEA has established to identify and manage risk is proportional to its small size and allows for reasonable controls to be in place, without adversely impacting on the successful delivery of objectives.

2.3. The relationship between risk, performance management, service delivery plans and strategic business planning has been improved with more emphasis on the interdependencies, especially between teams.

Risk management structure in the HFEA

3. Risk management framework

3.1. The risk management framework supports the consistent and robust identification and management of opportunities and risks within desired levels across HFEA, supporting openness, challenge, innovation, and excellence in the achievement of objectives. The following principles have been applied:

- Risk management is an essential part of the governance and leadership delivered by the Authority, AGC and SMT. This is fundamental to how the HFEA is directed, managed, and controlled at all levels.
- Risk management will be an integral part of all activities at the HFEA to support decision-making which is informed by the best information available in an environment of collaboration.
- Risk management processes are structured to include:
  - risk identification and assessment to determine and prioritise how the risks should be managed
  - the selection, design and implementation of risk treatment options that support achievement of intended outcomes and manage risks to an acceptable level
  - the design and operation of integrated, insightful, and informative risk monitoring
  - timely, accurate and useful risk reporting to enhance the quality of decision-making and to support management and oversight bodies in meeting their responsibilities.
- A system of continuous improvement has been implemented throughout the risk strategy.

3.2. The HFEA's system of internal risk management gives assurance that the risks the organisation faces when exercising its statutory functions are managed appropriately and mitigated against proportionately. Risks are formally managed at several different levels in the HFEA:

- Strategic risk register – capturing risks to delivery of the HFEA strategy and business plan
- Operational risk logs – capturing team level risks to functional delivery
- Project/ programme risk logs – capturing risks to successful project delivery
- Business continuity risks – managed through the business continuity plan with regular appraisal of business-critical functions
- Internal incidents system – an adjunct to the risk system, which enables understanding of and corporate learning from, internal adverse events.

3.3. Alongside its arrangements for managing risk within the organisation, the HFEA also takes a risk-based approach to the way it regulates the fertility sector. In inspecting and regulating clinics, the Authority uses a risk-based assessment tool, ensuring that the HFEA's regulatory resources are targeted proportionately and reasonably. This tool (and all other processes used by the HFEA in

carrying out its functions) is subject to a rigorous quality assurance regime. Regulatory risks will not be discussed further in this strategy, which focuses on the management of the HFEA's own risks, rather than clinic-based risks. Clearly there is an interaction between the two, and this is recognised where relevant in the strategic risk register and in operational risks, particularly those of the Compliance and Information Directorate.

3.4. The Authority takes its responsibilities for information security most seriously. In this regard, the HFEA has a low tolerance for information risks and follows stringent information security good practice. Keeping secure the information the Authority holds, including sensitive personal patient data, is of the highest priority. The HFEA continually works hard to avoid the occurrence of any data losses. Distinct information risks are captured where relevant in the strategic risk register, in operational risk logs maintained by teams, and in project risk logs. A data protection and information governance system are also in place with a nominated Senior Information Risk Owner (SIRO), currently the Finance Director, using the Data Security and Protection Toolkit (DSPT) as a point of reference.

4. HFEA in a wider risk context

4.1. The HFEA engages with the Department of Health and Social Care ALB Risk Network whenever it is convened by the Department. This is an occasional forum for discussing common risk issues and systemic risks and the approach of the Department towards risk management.

4.2. The HFEA has committed to consider system-wide and common, interdependent, risks. The strategic risk register includes sections for identifying risk interdependencies between the HFEA, the Department of Health and Social Care and the wider health and social care system.

5. Risk appetite and tolerance

5.1. Risk appetite and tolerance are two different but related terms. Risk appetite is a key concept in the Orange book and refers to a tolerable risk position against an optimal risk position. Risk appetite provides a framework which enables the HFEA to make informed management decisions, defining optimal and tolerable positions.

5.2. As a regulator, our overall risk appetite will tend to be naturally cautious, in that we are averse to risks which threaten our ability to perform our regulatory functions, and for most of our history our overall risk appetite has been low.

5.3. However, the volatility of risks does mean the HFEA may need to periodically re-evaluate the optimal and tolerable positions for different types of risk and seek opportunities where they may be available. Where we have identified scope to realise specific strategic aims through innovation, we are not averse to having higher risk tolerance. Specific examples include our engagement with stakeholders, where we may sometimes take the view that a higher risk strategy is worthwhile, for the potential dividends of that approach.

5.4. Risk tolerance will vary according to the perceived importance of risks and the timing (we may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. For example, because we operate in a regulatory environment, our decisions are open to legal challenge. This means that we must be willing to accept a higher level of legal risk, as we have limited control over the number of legal cases that we must deal with. Equally, when our strategy involves extending ourselves into work that is

beyond the boundaries of our normal regulatory remit, we may tolerate greater risk, as we believe the benefits to patients outweigh the threats. On the other hand, we deal with confidential medical data in our Register, and we have a statutory duty to maintain this securely. We therefore need to reduce our risk of cyber security threats to a low level and our tolerance for such risk is set as low.

5.5. Tolerance thresholds are dynamically set for each risk, and they are considered with all other aspects of the risk each time the risk register is reviewed. For instance, during a period of organisational restructure, the tolerance for this risk might be raised as the activities that need to be undertaken, such as changes to job descriptions, are inherently risky. We may choose to accept a higher risk level because it is necessary to take and tolerate certain risks in order to implement and take advantage of a new structure.

5.6. Within the strategic risk register, we also consider optimal risk levels as this is where we expect the effective management of controls to lead the risk to. However, in most circumstances, we would expect our tolerance to be higher than this; the differential will vary according to the risk, especially where we are willing to accept a higher risk level, so opportunities can be maximised. This also includes situations where our tolerance is expected to reduce or increase over time as our actions and/ or strategy evolve.

5.7. When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation has to achieve a balance between the costs and resources involved in limiting the risk compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance, it may be necessary to consider additional controls. Both the departmental and strategic risk registers include opportunities to time limit and close risks as appropriate.

5.8. When a risk exceeds its tolerance threshold, or when a risk becomes a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate. For further detail, see the section on risk escalation.

Procedures and roles

6. Staffing and structure

6.1. The Risk and Business Planning Manager leads on risk management organisationally, supported by the Head of Planning and Governance, and is responsible for ensuring:

- The maintenance and regular review by SMT of a strategic risk register. This is regularly reported to the Corporate Management Group (CMG), the Authority, Audit and Governance Committee (AGC) and the DHSC Sponsor team.
- That teams apply risk management principles in their own areas, maintaining their operational risk log and including risk management as a key consideration in every project.
- That project risks are actively monitored by project teams and by the Project Assurance Group (PAG), and that lessons learned from projects are recorded, and learning implemented.
- That quarterly meetings with 'Risk Champions' from each team take place to promote best practice within teams.
- The maintenance and monitoring for internal incident reporting, ensuring the system is used for organisational learning.
- Inducting all new staff into risk management and acting as a specific point of contact for all risk related queries.
- That our overall corporate risk management and business continuity planning remain aligned.

6.2. The CMG, which comprises Heads of Department and Directors, is responsible for reviews of teams' top three operational risks each quarter. These risks are reported from teams' operational risk registers, maintained by Heads. Internal incidents and near misses are also reviewed regularly.

6.3. The Senior Management Team (SMT) reviews the strategic risk register monthly to ensure that it accurately reflects all new and emerging risks. This is then circulated to CMG.

6.4. The Project Assurance Group (PAG) is responsible for monitoring project risks, referring issues upwards to CMG when necessary. Project managers and sponsors are clear about their obligation to provide reports to PAG, on a monthly basis, which include information about the current risk level and sources of risk within the project. Non-reporting results is an automatic escalation to CMG.

6.5. Each team reviews their operational risk logs monthly, ensuring these are dynamically managed with appropriate actions to mitigate risks reviewed. Where risks identified impact or are impacted by actions from other teams, these should be discussed directly and reviewed, as appropriate, at CMG meetings.

7. Authority and AGC

7.1. Both AGC and the Authority have critical roles in the HFEA's risk management process, ensuring appropriate reporting and governance are in place to provide effective assurance. This includes reviewing periodic audits of our risk management arrangements and ensuring that appropriate actions are taken to improve processes. They key aims are to capitalise on opportunities and proactively raise standards.

7.2. The Authority is accountable for the oversight of the management of risk, part of which it delegates to AGC. The Authority sets the overall organisational appetite for risk for various risk types and reviews this annually.

7.3. The Authority and AGC both receive the strategic risk register for comment on a regular basis. The report goes to every quarterly AGC meeting and comes to Authority at least twice a year.

7.4. When reviewing the strategic risk register, AGC ensure that the organisation is properly identifying and controlling strategic risks, noting areas of opportunity, and effectively escalating risk developments to the Authority.

7.5. AGC also receives "deep dive" papers on specific subjects agreed by the committee, and these papers include some risk assurance mapping, exploring the effectiveness of the control framework for risks within the area in question.

7.6. The Authority receives the strategic risk register for oversight and information, at which point members are invited to discuss the executive's approach to addressing risks, particularly those which are high or above tolerance.

8. Internal audit

8.1. AGC commissions an ongoing internal audit programme which includes audits of risk management, relating to both specific topics of risk, such as cyber security and the general risk management system.

8.2. Actions following on from internal audits are tracked by AGC and progress is reported by the executive at each meeting. Internal audit provides ongoing assurance that the risk system is working, controls are appropriate and effective, and any issues identified have been effectively addressed.

8.3. Internal Audit provides AGC with an annual assurance report, which includes a formal opinion, based on their assessment of whether the controls in place support the achievement of our objectives.

9. Strategic risk register

9.1. The HFEA strategic risk register (SRR) is reviewed monthly by SMT, with reporting to AGC and Authority.

9.2. In addition, a grass roots review, starting from a blank sheet of paper, is undertaken periodically, and at least once every three years, in line with the strategy reviews. The current SRR document is due to be reviewed in the first quarter of 2023 following the updates to the departmental risk register in 2022 and the development of the business plan for 2023.

9.3. The most recent such review was undertaken in 2020, following the publication of the HFEA's three-year Strategy (in April 2020). The purpose of this grass-roots review is to capture afresh the risks to delivering our current strategic aims and business plan. As part of this exercise, we consider the HFEA's current operating context, environment, and resources.

9.4. A new format of the SRR has been created in 2022, with the Orange book recommendations for section headings. This allows key strategic risks to be defined using a headline, using distinct sub levels with their own summaries, controls, key dates, and risk status. This allows the SRR to become more dynamic, easier to understand and allows the HFEA to be more forward looking.

10. Operational risk logs

10.1. The operational risk logs that feed into the Authority's strategic risks have been reviewed and revised in 2022, and the top risks are reported on a quarterly basis to CMG in an updated format.

10.2. The quarterly review also allows CMG to further discuss, and make decisions on, risks that are impacted by, or from, more than one team.

10.3. In addition to noting individual operational risks, and discussing their sources and controls, CMG also takes a managerial overview of current operational risks, identifying prevalent themes and considering whether these are adequately reflected in the strategic risk register, and whether any issues or trends require further discussion and decision-making.

10.4. This allows for a proactive and proportionate approach to risk management throughout the work of the Authority and its executive. The system facilitates continual identification and monitoring of operational risks, and the regular reviews by CMG act as a prompt for any needed decision as to whether to escalate an operational risk or to recognise a new or emerging issue.

11. Project and programme risks

11.1. Projects are scrutinised by the HFEA's Project Assurance Group (PAG). Risk assessment and management are a substantial aspect of this oversight arrangement and both the Project Manager and the Project Sponsor (usually a Director) must report to PAG at monthly intervals. In turn, PAG reports to CMG every month, with a highlight report outlining progress, risks, and issues for each live project.

11.2. The project management system includes a new monthly reporting system introduced in 2022. This enables PAG to be assured that project risks are reviewed in a timely manner and risks are dynamic.

11.3. The SMT is also briefed on current project risks and issues following each monthly PAG meeting, enabling prompt management of any new or increasing project risks.

11.4. The Risk and Business Planning Manager is responsible for the HFEA's Programme Management Office (the PMO), which runs PAG. The PMO consists of the Risk and Business Planning Manager and one Programme Support Officer (PSO). The PMO/ PSO gives frequent guidance and support to Project Managers on all aspects of project management, including the identification, reporting and management of project risks, and the identification of lessons learned at the end of projects, for future risk prevention purposes. The PMO provides a toolkit, including a

risk log and other templates, and both corporate and personalised training for staff in project management methodology as needed.

11.5. One of the main sources of project risk within the HFEA is the amount and complexity of the interrelations between the HFEA's various systems and our legal and regulatory framework. The PMO therefore provides an interdependencies review process to assist with good risk management at the early planning stage of a project. This is regularly reviewed and kept up to date to reflect any changes in our systems, information assets or structure.

11.6. The Project Management Toolkit is under review during 2022, with the aim of producing a simpler process with options for less complex projects to have more oversight from PAG and CMG. This will allow prospective projects to be brought before PAG for consideration with a particular focus on risk management before a business case is produced.

12. Internal incidents

12.1. The HFEA's executive maintains an internal incident procedure, which ensures that any process failures are quickly and thoroughly investigated. This allows CMG to learn lessons and correct procedural vulnerabilities. All reported incidents are recorded, regardless of whether there was a need to investigate in order to understand what went wrong. This is to encourage a learning culture and transparent recording of perceived adverse events.

12.2. The process is being relaunched in 2022 with a new, online, reporting system. This will allow information to be captured in an easier, consistent, and simpler format to encourage wider reporting. The process has been created with a more transparent reporting, investigation and lessons learned system.

12.3. The new reporting system seeks to capture internal incidents, near misses and data breaches. Where a data breach has been confirmed, separate processes apply which the Information Governance and Records Manager continues to lead on.

12.4. As part of this review, a new Incident/ Risk Management web page is due to be in place, later in 2022, on the HFEA intranet, the Hub, to centralise all documentation of the risk system in one area.

13. Risk escalation

13.1. Where a risk changes or a new one arises where the impact is beyond the capability or capacity of the relevant team to control or mitigate it, or when it becomes a higher-level risk (for instance when a project risk threatens HFEA strategic delivery) it should be escalated. The escalation process depends upon the type of risk, the severity and urgency of it, and where in the organisation it has been recognised as an escalation issue.

13.2. Project risks recognised by the Sponsor can be escalated to the HFEA Project Assurance Group. The Project Assurance Group can then report to CMG and highlight any action that is needed that is beyond the project team or Project Assurance Group's power to implement.

13.3. Operational risks are escalated through monthly CMG meetings. There is a standing item on the agenda and Heads are responsible for raising new operational risks that have arisen and any that are becoming more severe. CMG are then able to note this or offer assistance in planning mitigations. This also allows risks to be discussed within and between teams as necessary.

13.4. CMG also review the top 3 operational risks every quarter. These should be the risks which have the biggest impact on operational delivery rather than the highest scores.

13.5. If either a project risk or an operational risk needs to be escalated quickly, or between meetings of the Project Assurance Group or CMG, this can also be achieved through weekly SMT meetings, for expediency.

13.6. Any severe or increasing risk with high residual risk level and impact on delivery should be added to the strategic risk register. If the risk proximity, likelihood or impact are such that the risk requires immediate counter measures to be put in place, the Risk and Business Planning Manager, Head of Planning and Governance, and the individual raising the risk should consider whether a paper to CMG or a more immediate discussion with the SMT may be necessary.

13.7. Once the risk has been escalated, CMG or SMT will guide the risk owner to plan an appropriate approach to dealing with the risk. If necessary, additional reporting to AGC or the Authority can also be put in place.

14. Risk management methodology

14.1. The HFEA considers the following as the key stages of risk management:

- Identification – this includes defining if the risk is a current (open) one or one which may occur in the future (horizon scanning)
- Link risks to performance reporting and service delivery plans as appropriate
- Place the risk within the defined categories as per the Orange book
- Proposing a realistic date where the risk is expected to be closed
- Clear description including the cause, consequences and impact should the risk occur
- Likelihood/ probability of risk occurring
- What controls or actions can be put in place?
- What is the ‘residual risk’?
- Is this risk tolerable and why?
- Is this risk linked to another team(s) or is there an interdependency with an external agency?
- Who is responsible for managing the risk?
- Where risks are deemed to have ‘closed’ these should be archived for reference purposes

14.2. When articulating risks, the HFEA follows the following principles:

- Risks should relate to objectives, and should also include generic risks which affect all objectives
- State risks, NOT impact
- Avoid defining risks with statements which are simply the converse of an objective
- Consider the risk using legal, financial, regulatory, and reputational lenses
- Use a horizon scanning methodology to identify future risks.

14.3. In considering what controls can be put in place, the HFEA considers the following options, based on a common model:

- Tolerate the risk (make an informed decision to do nothing)
- Treat the risk (change the consequences/ likelihood, including planning contingency activities)
- Transfer the risk (share the risk e.g., to an insurer or contractor)
- Terminate (don't start/ stop doing the activity that causes the risk)
- Take (or increase the risk in order to pursue an opportunity).

14.4. In setting out controls, the HFEA:

- Assigns internal controls to named individuals with authority to undertake or delegate the relevant actions
- Identifies specific actions
- Keeps on monitoring and reviewing residual risks and internal controls
- Escalates risks to CMG/ SMT/ SRR as appropriate.

14.5. In any grass roots review of risks, the HFEA considers the following factors:

External:

- PESTLE model:
  - Political
  - Economic
  - Social
  - Technological
  - Legal
  - Environmental.

Operational:

- Delivery:
  - Service/ product failure; project (delivery failure)
- Capacity and capability:

  - Resources (money, people, information and evidence, physical assets); planning; relationships (partners, clients, accountability); quality management; operational delivery (overall capacity and capability); reputation (confidence and trust in the organisation)
- Risk management performance and capability:
  - Governance (oversight and scrutiny, propriety, compliance, ethics, due diligence); scanning (failure to identify threats); resilience (capacity to withstand adverse impacts, business continuity); security (of assets and information).

Change:

- Environmental changes and challenges
- New targets and performance indicators
- Change programmes
- New projects
- New policies
- Changes in resource availability.

14.6. Horizon scanning methodology forms a key part of risk management. The HFEA considers this using:

- A formal item annually at CMG where horizon scanning is discussed with all teams and reflected in both the operational and strategic risk register. The monthly risk discussions at CMG also provide another opportunity to identify future risks.
- A discussion at every AGC meeting alongside the SRR highlighting any future risks and opportunities.
- The deep dive items at every AGC meeting, on pre-agreed areas of concern, will also include risk assurance mapping and consideration of future or upcoming risks.

15. The role of Risk Champions

15.1. The purpose of Risk Champions is to raise awareness across their teams of risks and awareness and can be any member of the team other than the Head.

15.2. They play a key role in prompting their team to consider risk management in all areas of the team's work and include this in the operational risk log. They also encourage the team to report adverse event occurrences using the internal incident reporting function.

15.3. The team Head has overall responsibility for managing risk within the team; the Risk Champion supports the Head in ensuring the operational risk register is completed and learning from internal incidents is shared. They may lead risk review meetings in the absence of the Head.

16. Training and development

16.1. A full training needs analysis is due to be completed in Q4 of 2022/ 2023.

16.2. The Orange book sets out behavioural and technical competencies for the skills and capability framework. These include recommended qualifications for risk management roles within the organisation.

16.3. The Risk and Business Planning Manager and the Head of Planning and Governance are the two key roles that fall within the framework and the recent Government Risk Profession's "Accredited Risk Manager" accreditation includes three specific elements:

- The completion of The Institute of Risk Management's International Certificate in Enterprise Risk Management
- The completion of both these Civil Service Learning training courses:
  - Influencing Skills: Workshop
  - Future, Engage, Deliver: 1 day leadership masterclass
- Completion of a self-awareness tool.

16.4. Civil Service Learning offers several free risk management courses and all staff, especially Risk Champions, should be encouraged to complete these modules.

17. Assessing and estimating risk:

17.1. The HFEA defines inherent risk as:

> 'The exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

17.2. HFEA defines residual risk (also known as 'exposure') as:

> 'The exposure arising from a specific risk after action has been taken to manage it, and making the assumption that the action is effective.'

17.3. Any given risk score is a combination of:

- The likelihood of something happening
- The impact which arises if it does happen

17.4. Risk scoring system

We use a five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Highly likely
Impact:	1=Very low	2=Low	3=Medium	4=High	5=Very high

The risk matrix can be seen below:

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Highly likely (≥90%)
5. Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium

Risk Score = Impact x Likelihood

Likelihood

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Approved date	
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Total pages	??

Version/ revision control

Version	Changes	Updated by	Approved by	Release date
0.1	Original draft approved	Paula Robinson	Audit and Governance Committee	2014-06-11
1	Final version launched	Paula Robinson	Corporate Management Group	2015-01-01
1.1	Revised to reflect new roles and responsibilities and include clearer guidance on risk tolerance and appetite	Helen Crutcher	Audit and Governance Committee and Authority	2018-11-14
2	Delayed review following COVID to include updates to the Orange book, AGC and Authority guidance and Audit recommendations	Shabbir Qureshi	tbc	tbc

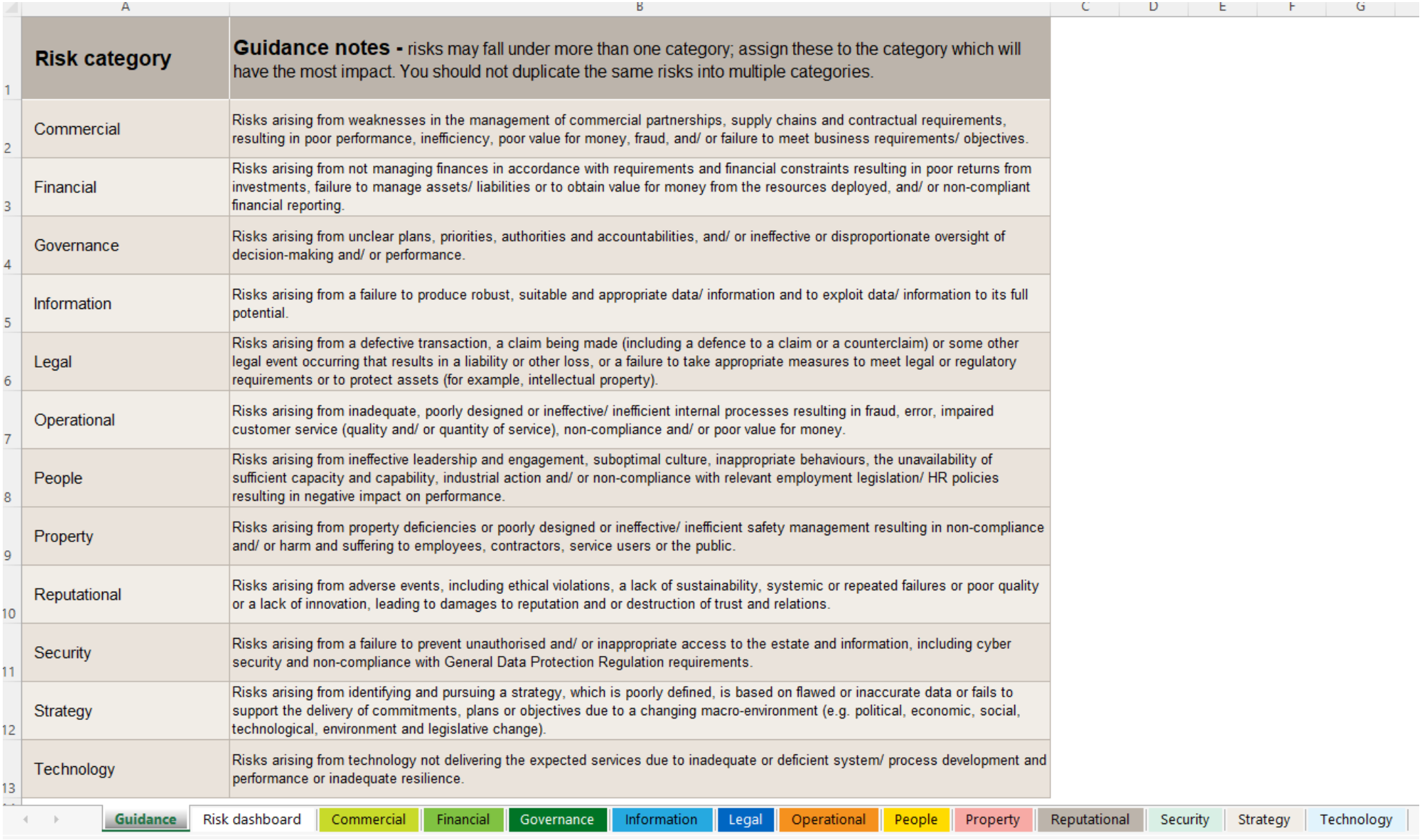
Operational risk register screenshots

	A	B
1	**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.
2	1. 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.
3	2. 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.
4	3. Governance	Risks arising from unclear plans, priorities, authorities and accountabilities, and/ or ineffective or disproportionate oversight of decision-making and/ or performance.
5	4. Information	Risks arising from a failure to produce robust, suitable and appropriate data/ information and to exploit data/ information to its full potential.
6	5. 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).
7	6. 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.
8	7. 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.
9	8. Project / programme	Risks that change programmes and projects are not aligned with strategic priorities and do not successfully and safely deliver requirements and intended benefits to time, cost and quality.
10	9. 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.
11	10. 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.
12	11. 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.
13	12. 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).
14	13. Technology	Risks arising from technology not delivering the expected services due to inadequate or deficient system/ process development and performance or inadequate resilience.
15		

	A	B	C	D	E	F	G	H	I
1	Team	Open risks	Future risks	Closed risks	Open residual risk detail				
2					Very low	Low	Medium	High	Very high
3	Comms	0	0	0	0	0	0	0	0
4	Compliance	0	0	0	0	0	0	0	0
5	Finance	0	0	0	0	0	0	0	0
6	HR	0	0	0	0	0	0	0	0
7	Information	0	0	0	0	0	0	0	0
8	Intelligence	0	0	0	0	0	0	0	0
9	IT	0	0	0	0	0	0	0	0
10	Legal	0	0	0	0	0	0	0	0
11	PlanGo	0	0	0	0	0	0	0	0
12	Policy	0	0	0	0	0	0	0	0

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1		**Updated by:**					**Update date:**										
2							**Inherent risk**				**Residual risk**						
3	**Risk category** (insert a new row below then copy & paste category title)	Open / Closed / Future	Date risk identified	Date risk last updated	Proposed / actual closure date	**Description of risk** (risk identified/ cause/ consequence)	IR Likelihood	IR Impact	IR score	**Internal / management controls**	RR Likelihood	RR Impact	RR score	**Is the risk currently tolerable?** (add commentary to explain why this is or isn't)	**Is this risk linked to any other team(s) ?** (use team names from tabs separated by a ,)	**Risk owner(s)**	**Comments / actions** (with dates)
4	**1. Commercial**																
5	**2. Financial**																
6	**3. Governance**																
7	**4. Information**																
	5.																

Strategic risk register screenshots



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.

Team	Open risks	Future risks	Closed risks
Commercial	0	0	0
Financial	0	0	0
Governance	0	0	0
Information	0	0	0
Legal	0	0	0
Operational	0	0	0
People	0	0	0
Property	0	0	0
Reputational	0	0	0
Security	0	0	0
Strategy	0	0	0
Technology	0	0	0
HFEA Total	**0**	**0**	**0**

Updated by								**Updated date**				
Risk name												
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												
Management commentary - views on mitigation												
Risk external interdependencies				**Control arrangements**							**Owner**	
Sub-risk title								**Risk status**	**Date identified**		**Next review date**	
									Target		**Actual risk**	

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						

Sub-risk title		**Risk status**	**Date identified**		**Next review date**	
			Target closure date		**Actual risk closure date**	
Cause						

HFEA Risk appetite statement

1. Overview

1.1. The new risk strategy includes a risk appetite and tolerance section which is based on the recommendations from the Orange book.

1.2. The HFEA should have a risk appetite statement which will also need to be included when the new strategy is developed.

2. The options for a risk appetite statement

2.1. Below are possible options to use for developing a risk appetite statement:

Option 1	Option 2	Option 3
Have a single statement of the HFEA's risk appetite.	Combine some of the categories used in the strategic risk register and produce risk appetite statements that cover our position based on our risk appetite and tolerance.	Create a risk appetite statement for each of the categories currently on the strategic risk register: Commercial, Financial, Governance, Information, Legal, Operational, People, Property, Reputational, Security, Strategy and Technology.
The key advantage of this system is simplicity; however, this approach may not allow enough flexibility in risk approach to be articulated.	This will allow the HFEA to make clear the areas where we are more likely to be risk averse and the ones where we would consider a higher tolerance and acceptance of risk. The new risk strategy reflects this option currently, however, not all the categories are directly named.	This is the most comprehensive method and allows for each category to be given a suggested risk tolerance. However, as we develop the strategic risk register over the coming months, and possibly change the categories to better reflect the organisation, this will in turn require updates to the risk appetite statements.

3. Recommendation

3.1. Authority is asked to note and comment on the above options.

3.2. A draft risk appetite statement will be presented to December AGC.

Business planning 2023-24

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy: The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Authority
Agenda item:	7
Meeting date:	16 November 2022
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to note the report, and to comment on the proposed priorities for inclusion in the 2023/24 business plan.
Resource implications:	In budget
Implementation date:	1 April 2023 – 31 March 2024
Communication(s):	HFEA website
Organisational risk:	Low

1. Introduction

1.1. This paper forms part of our annual business planning process. Each year, the Corporate Management Group meets in August or September to discuss work for the following year's business plan, using the strategy and our statutory duties to guide and prioritise our planning. We have a three year outline strategic delivery plan in place, which is reviewed whenever CMG discusses business planning.

1.2. This paper follows from that initial discussion, and outlines the proposed activities to be included in the next business plan. Comments from members are invited. It is important that we make early decisions now about priorities so that we can plan our resource allocation appropriately as we develop the business plan itself.

1.3. The business plan will then be drafted in the ensuing months, and submitted to the Department for approval in February-March 2023 (on request). Therefore, the Authority will receive a draft plan at its January meeting.

1.4. Once the business plan (incorporating our budget) is approved by the Department, it is then published on our website.

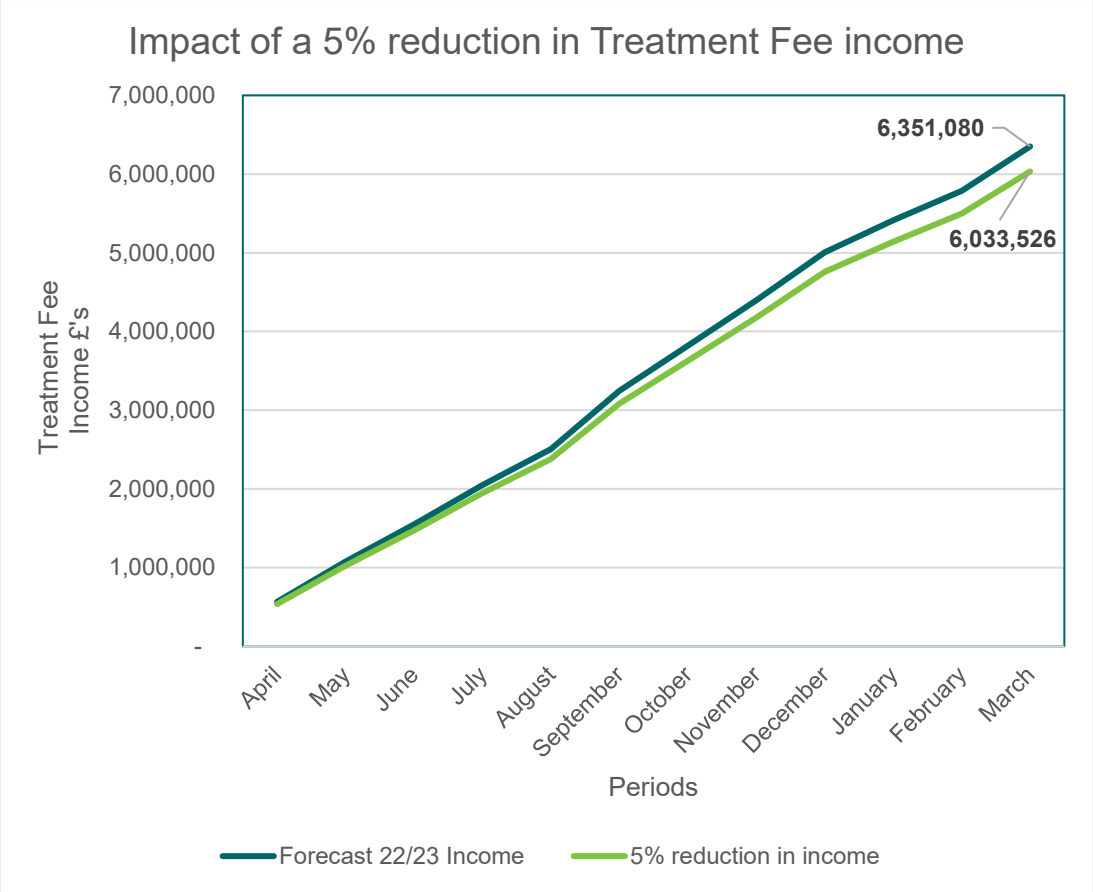
1.5. The plan set out below is still very much under discussion, and details will change over the coming months.

1.6. It is important to acknowledge the context of this year's planning round. Firstly, 2023/24 will be the final year of our current strategy. We therefore need to agree whether it will be feasible or desirable to deliver all elements of the strategy. During the next year, we will discuss and shape our new strategy for April 2024 onwards.

1.7. Meanwhile, the political and economic background to our discussions is likely to affect the wider public sector generally, including the HFEA, in ways we cannot yet predict with certainty. This will inform our planning and prioritisation for the next year, and beyond. As the situation evolves, we will need to consider our operating environment carefully and take stock of risks and opportunities, both in finalising next year's business plan, and in deciding a new vision for the following years. There are other unknowns that we have not specifically set out, such as any legislation resulting from the Law Commission's review of surrogacy, which is planned to report in Spring 2023.

1.8. Our current funding is a mix of fee income from the sector we regulate (80%) and grant in aid from the DHSC (20%). We should know in the next few weeks whether the Department will reduce our grant in aid. Our fee income is essentially a levy on treatment numbers, which have historically risen at a rate of around 2% per year. But we must acknowledge that the increase in the cost of living is impacting on people's disposable income and it would be prudent to assume that treatment numbers will decline over the next 12 months and possibly beyond. It would also be reasonable to assume that the volume of NHS commissioned cycles may fall.

1.9. The graph below illustrates what a 5% drop in treatments would look like financially for the HFEA:



2. Proposed priorities for 2023/24

2.1. In addition to our strategic priorities we must prioritise our core statutory work, which accounts for the majority of our staff time and annual budget. We need to take care to ensure that our business plan can be delivered within our available resources, and we need to be cognisant of factors such as turnover, and work started in this year that will continue into the next, as well as wider pressures resulting from central requests and the public bodies review.

2.2. We have based our planning on an assumption that the HFEA will have the same resources as now for the next business year: approximately the same budget, and the same number of staff, with the existing skill mix. As noted above, that may be an overly optimistic assumption.

2.3. The following activities are proposed for inclusion in our business plan for 2023/24. We will continue to discuss the details of the various activities over the next two to three months, while the business plan is being drafted.

Statutory work

- Inspection process and ongoing compliance activity
- Licensing regime for treatment, storage and research centres and PGT-M and mitochondrial donation applications and special directions

- Information provision to better enable patients to make informed decisions
- Opening the Register (OTR) requests, which are likely increase from late 2023 onwards when the first cohort of donor conceived people turn 18 following the lifting of anonymity
- Maintaining the Register to meet statutory information requests and to provide a rich and transparent data resource to drive more effective clinical outcomes
- Information for researchers to enable high quality research
- Annual horizon scanning and maintenance of the Code of Practice to ensure that care is safe and of high quality
- Fulfilling any wider DHSC or healthcare requests such as responding to consultations or providing information (for example responding to any requests from the Covid Inquiry)
- Meeting external legal and other requirements, for example responding to statutory information requests such as Freedom of Information requests or parliamentary questions
- Continued support and maintenance of PRISM, Choose a Fertility Clinic (CaFC) and the tools used by the Register team
- Maintaining our core IT systems e.g. Clinic Portal, Epicentre.

Areas of work continuing from 2022/23 into 2023/24

The following were prioritised for the current business plan, and will be ongoing into the next:

- Engagement with NICE on their fertility guidelines review
- PRISM support and continuing post-PRISM tasks
- Donor information service development project to ensure our systems can meet the increased demand for information
- Review of our fees regime (options to be presented to a future Authority meeting)
- Continuing work, as required, on the Northern Ireland Protocol following EU exit and changes to the European Tissue and Cells Directive (EUTCD)
- Continued work towards compliance with the Data Security Protection Toolkit (DSPT).

Proposed strategic priorities in 2023/24:

The following pieces of work would address aspects of the strategy:

Best care

- Continued activity to support licensed clinics and patients with the new storage regime
- Further work on ethnic disparities in fertility treatment (to discuss)

- Activity relating to patients, donors and donor conceived people in light of the forthcoming changes in 2023 (to discuss)
- Reviewing actions relating to the Women's Health Strategy and engagement with NICE on their fertility guidelines review (referenced above) (to discuss)

Right information

- PRISM support and maintenance, and further development of internal data tools to continue to improve the use of our data
- Reviewing actions relating to the Women's Health Strategy in relation to information provision (to discuss)
- Publication of data reports including Fertility Trends to drive improvements in clinical practice and informed patient choice
- Continued work to ensure accurate and timely OTR information release
- Further activities with our Patient Engagement Forum to ensure the patient voice is included in our work(subject to this year's pilot proving to be successful) (to discuss)

Shaping the future

- Completion of our donor service development project to prepare for future higher levels of OTR requests (referenced above)
- Monitoring of patient-facing artificial intelligence (AI), data-driven new technologies and genetics policy issues through our Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning process and reviews
- Improvements to the authorised process framework to better support responsible innovation
- Follow-up work after our planned consultation on changes to the HFE Act (to discuss)
- A structural review of our fees regime to ensure it reflects the current range of fertility treatments
- Support for and implementation of the government's Public Bodies Review.

3. Deprioritised activities

3.1. During last year's planning round, we deprioritised a number of items and undertook to review whether they could be included in the 2023/24 business plan instead. We have reviewed the list below and considered whether each piece of work is pressing for some underlying reason, and whether the actions we could take would make an appreciable impact.

- Review of guidance on the ten family limit
- Review of donor egg availability

- Review of compensation for overseas donors
- Work with primary care organisations on information provision to patients about fertility (however, we may plan for future work, following the Women's Health Strategy, in 2023/24)
- Project on reducing clinic variation
- Review of guidance to clinics on conditional donation
- Further work on encouraging responsible innovation
- Guidance and information focused on partners and further signposting to accurate information sources on male fertility
- Regulatory transparency and doing more with our existing regulatory tools.

3.2. Some elements of the above work have been done or are being planned – for example, we are currently starting a project on the authorisation of new processes, which will help to support our broad aims regarding fostering a culture of responsible innovation. We already publish signposting information relating to male fertility, and clinics can add information about donor egg availability via the Portal.

3.3. However, some of our ambitions, such as our aim to work with bodies like the Royal Colleges to improve the information patients receive at the earliest stage of treatment, have not yet been possible. Some aspects of this work may be achievable as part of our support for the Government's Women's Health Strategy, although it is not yet clear what the timescale will now be for progressing that work.

3.4. Our original plans also included a linked set of work on transparency in regulation, a review of the inspection report and clinic variation. The purpose of this work was to meet our commitment in the strategy to 'Regulate effectively, transparently and consistently, and provide clinics with more comparative information about performance to encourage improved care.' Our current assessment is that this work will not be able to be prioritised within the current strategic period without trade-offs with other pieces of work.

4. Prioritisation decisions

4.1. The Authority is asked to discuss prioritisation options.

4.2. There are undoubtedly some difficult choices to be made, with limited resources and some environmental uncertainties. However, there are choices. Depending on our financial position over the coming months those choices may become more constrained.

4.3. In some instances these are relatively straight either/or choices. For example we could either continue to support PRISM or we could (say) update the clinic portal.

4.4. In other instances, our choices will depend in part on how big a piece of work we would wish to do. For instance, if we wished to reprioritise the work on transparency, we would need to devote less attention to the work on ethnic disparities in treatment, or the patient engagement forum. It is also important to recognise that in some cases, a minimal amount of work will not achieve our ambitions and therefore it may be better to defer any work entirely, to a later year.

5. Recommendation

5.1. Authority members are asked to note this paper, and to comment on the proposed priorities for inclusion in the 2023/24 business plan.

Support services for donors and donor conceived people

Details about this paper

Area(s) of strategy this paper relates to:	The best care
Meeting:	Authority
Agenda item:	8
Meeting date:	16 November 2022
Author:	Neil McComb – Head of Information Rachel Cutting – Director of Compliance and Information
Annexes	Annex A – options appraisal of support services going forward

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to decide whether it wishes the existing arrangements for providing support service for donors and donor conceived people to continue (Option 1, Section 9 and Annex A). If not, then the Authority is asked to provide a broad steer on the other options identified (Options 2, 3, 4, Section 9 and Annex A) to inform policy development and any subsequent public engagement.
Resource implications:	Depending on option
Implementation date:	Ongoing.
Communication(s):	Depending on option
Organisational risk:	Medium

1. Introduction

1.1. The Human Fertilisation and Embryology Act 1990 ("the 1990 Act") requires the Authority to keep a Register of information about donors and treatments involving the use of donor gametes and embryos in the UK since August 1991. The Register also records the notified births resulting from these treatments.

1.2. Applications for Register information can be made by donor-conceived individuals, donors and parents; we term these Opening the Register (OTR) requests. More details about who can access what information is set out in section 2 below.

1.3. We anticipate an increase in applications to the OTR service from late 2023 onwards as the first cohort of donor conceived (DC) people turn 18, following the legal change to donor anonymity in 2005.

1.4. A project to improve the efficiency of the OTR service is currently in progress and we have recently increased the staffing resources to better meet the anticipated increase in applications. There is however a further aspect of the OTR service that needs review due to the expectation of applications rising from 2023 onwards: the OTR support service, which provides limited information and counselling for DC people and donors. The service is currently delivered by the Hewitt Fertility Centre and is funded by the HFEA. More details on the current support service are set out in section 3 below.

1.5. The OTR support service dates from 2015, following an Authority decision to commission the service on an initial 3-year trial basis. The service was retendered in 2018 and awarded to the Hewitt. A decision on the future of the service must be made before the current contract expires at the end of March 2023.

1.6. The original decision to fund the OTR support service was because of the widespread view among experts that the offer of support to DC people and donors at the point of accessing Register information was important given the impact that such information could have on a person's sense of self and family identity. However, it is important to note that there is no statutory requirement for the HFEA to provide such a service; the Act only requires donor-conceived applicants to be given the opportunity to receive counselling before information can be disclosed to them (our legal obligation is further discussed in section 6).

1.7. To date, the small number of individuals accessing the support service have meant that the costs have been manageable, but the anticipated rise in number of applicants post 2023 mean that the cost of the service is likely to increase over the coming years, possibly significantly. Given the very real constraints on public expenditure we must now accept that the HFEA cannot continue to provide unlimited financial support to a growing service.

1.8. This paper sets out the essential background to the support service and considers a range of options. In considering these options the Authority will need to take into account the potential impact of any increased cost on the other strategic activities of the HFEA. Put starkly, without a new source of funding more money for the OTR support service would mean less money for

other HFEA responsibilities. Some form of public engagement will be necessary if the Authority wishes to explore the alternative options set out.

1.9. In considering this issue, the Authority should be aware that the HFEA also provides funding pursuant to section 31ZG of the 1990 Act to support the keeping of the Donor Conceived Register (DCR), which is also currently delivered by the Hewitt. The DCR supports pre-August 1991 anonymous donors and donor-conceived individuals/siblings sharing the same donor and facilitates registrants establishing links. The service includes DNA testing, providing support and maintaining the DCR which confirms register matches with individuals. Originally the DCR was run by the voluntary sector, with the financial support of the Department for Health. In April 2017, at the request of the DHSC, responsibility for the DCR transferred to the HFEA. In **May 2017** the Authority discussed the future of the DCR and agreed to contract out the entire service to another suitable organisation. The DCR is funded within the current Hewitt contract and will need to be considered in time, depending on the decision made in respect of the OTR support service.

2. Background: The HFEA statutory duty to those affected by Donor Conception

2.1. Donor-conceived individuals have a statutory right of access to information held on the Register.

2.2. 16-year-old donor-conceived individuals can find out:

- If they are donor-conceived
- Non-identifying information about their donor
- The number, sex and year of birth of any donor-conceived genetic siblings
- If their donor has removed their anonymity
- If they might be related to an intended spouse or partner

2.3. 18-year-old donor conceived individuals can find out:

- identifying information about their donor (if the donor is identifiable, i.e. if the donor donated after the removal of anonymity on 1 April 2005, or if the donor has voluntarily removed their anonymity)
- identifying information about their donor-conceived genetic siblings, if both sides consent (via Donor Sibling Link, a voluntary contact register)

2.4. Donors also have a statutory right of access to information held on the Register. They can:

- Find out the number, sex and year of birth of any children conceived from their donation
- remove their anonymity - which is relevant to those who donated before the law changed on 1 April 2005.

3. The support service

3.1. The origins of the decision to provide a support service for Register applicants can be dated back to 2013. The Nuffield Council on Bioethics report 'Donor conception: ethical aspects of information sharing', published in April of that year, made recommendations relating to donor information and support for applicants to the Register, and the McCracken review of the HFEA (also in 2013) recognised the importance of this work.

3.2. The HFEA decided in March 2014 to contract a counselling provider to ensure that those effected had access to professional advice. A three-year pilot was agreed, with the contract awarded to PAC-UK, an adoption support service. In 2018, after a competitive tender exercise, the contract for the Donor Conceived Register and the provision of counselling and DNA testing services was awarded to the Hewitt Fertility Centre at Liverpool Women's Hospital Foundation Trust (LWH).

3.3. Since October 2019 the Hewitt Fertility Centre have provided support services to people affected by donation in the UK after 1991 and who have contacted the OTR service. The service includes provision for the OTR emotional support and contact-making intermediary service for individuals who wish to access information from the HFEA Register.

3.4. Referrals to this service are made by the HFEA and administrative staff contact applicants with further information. Each person is normally offered two free one-hour long sessions.

3.5. Support sessions are usually accessed remotely and are provided by a team of infertility counsellors who are familiar with donor conception. The counselling service delivery is in line with the BICA guidelines for good practice and the BACP ethical framework. The support service is administrated by the same staff who run the DCR, who receive referrals and contact applicants with information and service contracts.

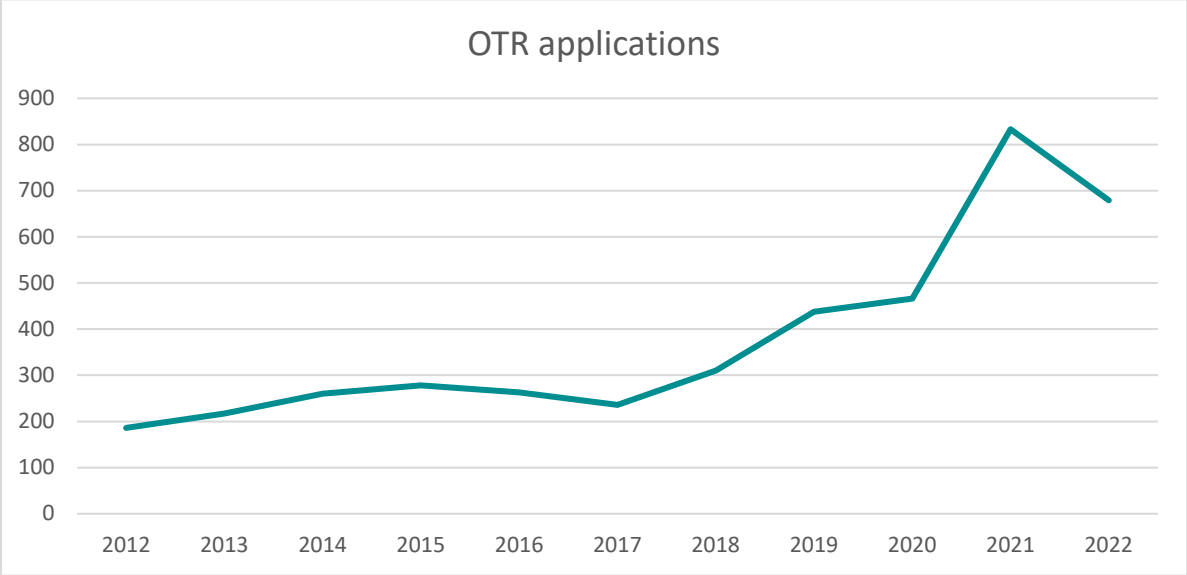
3.6. The Hewitt also provides an intermediary 'anonymous post-box' service where donor-conceived siblings who consent can swap anonymous messages prior to deciding whether to swap contact details. This is also used by donor-conceived young people contacting their donors for the first time.

3.7. The people who can access the service include:

- Donors who donated before April 2005 who are considering becoming identifiable
- DC offspring applying for identifying information on their donor
- DC offspring applying for non-identifying information on their donor
- Donors who are aware that DC offspring have applied for identifying information

4. Current service uptake and costs of support service

4.1. The number of applications to the OTR service have risen year on year as set out below. The sharp increase in 2021 was due to applications being suspended for 6 months due to the Covid-19 pandemic in 2020.



The service with the Hewitt commenced in April 2019 and the contract expires on 31 March 2023. In 2021 only 7.9% of OTR applicants accessed the support service.
The costs for each year (which includes the cost for the DCR service) since the Hewitt contract commenced are as follows:

2019/20	£52,506
2020/21	£49,068
2021/22	£51,730
2022/23	£51,730

5. The role of support

5.1. The role of support has been assessed in a number of professional and academic papers. In December 2013, a policy and practice document produced jointly by UK professional bodies was published in Human Fertility1. The paper outlined the importance of support services for those affected by donor conception and set out recommendations and underlying principles to inform best practice within clinics and within the HFEA.

1.R Wilde , A Mctavish 2 & M Crawshaw. Family building using donated gametes and embryos in the UK: Recommendations for policy and practice on behalf of the British Infertility Counselling Association and the British Fertility Society in collaboration with the Association of Clinical Embryologists and the Royal College of Nurses Fertility Nurses Forum. Human Fertility, 2014; 17(1): 1–10

5.2. The paper highlighted the need to address the long-term wellbeing of donor conceived offspring and their families and raised concerns that there was no clear duty of care to those affected by donor conception. The authors compared the needs to those similar to those of adopted people.

5.3. There are many implications to consider for those affected by donor conception when applying for or receiving information, especially identifiable information. Some individuals (whether donors, donor-conceived people or their families) may need support to navigate this, whereas others, to date a majority of OTR applicants, may not need support at all.

Support needs of donor conceived people

5.4. Research indicates that some DC people, especially those learning of their genetic origins later in life and/ or in unplanned ways and/or who have had dysfunctional family experiences, may experience acute and lasting emotional distress.[2]

5.5. DC people may need support when considering if they wish to access identifying information, to think about what they are hoping for if they are able to contact their donor and to prepare themselves for contact. If they are unable to trace the donor, the donor has died, or the donor does not want contact, support may be needed to manage emotions around this.

5.6. If there is contact the DC person may need help in navigating this new relationship, negotiating how often there will be contact and talking to his or her own family about this. Contact arrangements have occasionally proved difficult to manage.[3]

5.7. There may also be questions around managing relationships with any donor siblings, especially if some siblings want identifying information about the donor, and others do not.

Support needs of donors

5.8. Donors may also need support in managing contact with donor conceived offspring. They may welcome contact or be more cautious. They may have not thought much about donating years previously and contact could come as a shock, or this may have been something they have been waiting for. Donors may need support to talk about this with their partner, if they have one, or with any children. Some donors may not have told their family they donated gametes previously.

5.9. The HFEA tries to contact donors before we release their information in an identifying OTR. However, for donors registered after 2005 we only have their last known address which may be out-of-date (email addresses have been collected for pre 2005 donors who reregistered as

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[2] Marilyn Crawshaw, Lucy Frith, Olga van den Akker & Eric Blyth (2016): Voluntary DNA-based information exchange and contact services following donor conception: an analysis of service users' needs, New Genetics and Society, DOI: 10.1080/14636778.2016.1253462

[3] Marilyn Crawshaw, Lucy Frith, Olga van den Akker & Eric Blyth (2016): Voluntary DNA-based information exchange and contact services following donor conception: an analysis of service users' needs, New Genetics and Society, DOI: 10.1080/14636778.2016.1253462

identifiable directly with the HFEA). It is therefore possible that the HFEA will release information about a donor without being able to inform them first.

5.10. One research study[4] investigating the use of professional support through UK Donor Link asked respondents (who were all registered with the service) whether they had used professional support to help them decide whether to register and whether the availability of intermediary services affected their decision. The potential availability of intermediary services influenced the decision to register for just under half of the sperm donors surveyed (10, 48%).

6. What the law says

6.1. The 1990 Act provides that donor-conceived applicant must be given "a suitable opportunity to receive proper counselling about the implications of compliance with the request" before the Authority can disclose information to an applicant about their donor (s 31ZA)..

6.2. Similarly, the Authority may only disclose information about donor conceived genetic siblings if the half-sibling whose information is being released consents to the disclosure and both siblings have had a suitable opportunity to receive counselling about the implications of that disclosure (s 31ZE).

6.3. Conversely, whilst the Authority 'may' notify donors that their donor-conceived child has requested information about them (s 31ZC), there is no suggestion that they should receive counselling at that point - although they should have received implications counselling at the time of their donation. There is also no obligation to provide counselling to people who find their half-siblings through the voluntary contact register for treatments that occurred before the HFEA was set up in 1991 (s31ZF).

6.4. It is worth noting that while the requirement for donor conceived individuals to have been given a suitable opportunity to receive proper counselling under ss 31ZA and 31ZE of the 1990 Act is a condition precedent for the disclosure of relevant information under those sections (and, arguably, the functioning of the OTR service), the 1990 Act does not expressly impose any corresponding statutory obligations on the Authority, or licensed centres, to provide that offer to donor conceived individuals.

[4] Marilyn Crawshaw, Lucy Frith, Olga van den Akker & Eric Blyth (2016): Voluntary DNA-based information exchange and contact services following donor conception: an analysis of service users' needs, New Genetics and Society, DOI: 10.1080/14636778.2016.1253462

7. Future projections: OTR applicants, users of the support service and potential costs to the HFEA

7.1. Predicting the future take up of any support service is very difficult. We simply do not know how many OTR applications there will be in any given year and, crucially, how many of those will request a support session. However, we anticipate that the complexities of releasing identifying information could result in higher demand for support. The estimate that follows should therefore be treated with caution.

7.2. Intelligence we can draw upon includes:

- we do know that the OTR service sees a rise in applications year on year. In 2021 there were 833 OTR applications.
- we also know that the number of DC people turning 18 in a specific year with identifiable donors rapidly increases year on year, from 111 in 2023, 1495 in 2025 and 3695 in 2035.
- we know that 7.9% of applicants took up the offer of counselling in 2021.

Taking that past performance as a benchmark and projected demand the following sets out the potential costs over the first 5 years from OTR 2023[5].

Year	No. OTR applications	Cost based on 7.9% support service uptake (£)	Cost based on 10% support service uptake (£)	Cost based on 20% support service uptake (£)	Cost based on 50% support service uptake (£)
2023	1064	67977	79149	132349	292949
2024	1202	73428	86049	146149	326449
2025	1358	79590	93849	161749	365449
2026	1535	86582	102699	179449	409699
2027	1734	94442	112649	199349	459449
2028	1960	103369	123949	221949	515949

[5] NB this is based on an assumption that applications will rise by 13% each year (calculated from the average annual rise between 2012 and 2020)
The Hewitt indicated costs for 2023 of charging £56,594 for 62 referrals plus £500 for each additional referral

As these estimates show, the cost of any support service varies significantly depending on the take up. Were take up to continue at the current rate (7.9% of all applicants) then the cost of the service might rise by c.80% by 2028 (to £103k); were take up to rise to 25% of all applicants, for example, then the cost of the service would increase fourfold by 2028 (to £222k).
Looking further ahead, it is of course possible that the numbers wishing to access support services may decline as a proportion of OTR applicants as donation becomes more widely known.

8. Stakeholder engagement

8.1. HFEA has been involved in discussions regarding the importance of support provision in recent years including membership of the SEED working group and discussions informally and formally with BICA and other stakeholders.

8.2. On 12 October 2022 the HFEA hosted a stakeholder engagement event attended by HFEA staff, clinical representatives (including PRs, embryologists and councilors), stakeholders from the sector (including DCN, DCR, SEED and BICA) and other interested parties to discuss issues arising from 2023 and how support could and should be provided.

8.3. The participants agreed that:

- Support was vital for those affected by donor treatments, however, there was an acknowledgement that significant cost was involved and there was no clear answer where this should come from
- That provision was patchy
- That clinics may not be the best place for this support to take place. For example, 18-year-old donor-conceived individuals might not want to attend a fertility clinic
- That professional counselling was important but not enough. A multi-layered support approach is needed e.g. including the option of peer support
- That clinics had a responsibility to provide additional support and it was acknowledged that would increase the costs to patients

8.4. The HFEA Licenced Centres Panel discussed the challenges of OTR 2023 when it last met in October and unanimously agreed that a funded support service was essential for all affected by donor conception, that clinics had a responsibility, and they were supportive of increasing the HFEA fee per donor treatment to fund such service.

9. Options for future commissioning of support services

9.1. There are a number of options for how support services could look after April 2023.

9.2. Option 1 – status quo

9.3. The HFEA currently funds the OTR support service from its own budget, the majority of which is raised from licence fees on the sector we regulate (the remainder is in the form of Grant in Aid from the DHSC).

9.4. However, as outlined in section 6 above there is no express statutory duty for the HFEA to fund the OTR support service. While the sums of money involved to date have been manageable, looking ahead the likely increase in applicants post OTR 2023 (see section 7 above) will mean that the money required to continue to fund the support service will be become unaffordable under the current arrangements. Without action, the HFEA could find itself in a position where it was unable to fund other strategic priorities and/or some of its statutory duties.

9.5. The Authority is therefore asked to consider **whether it wishes to continue with the OTR support service under the current arrangements**. If not, then we need to consider other options, which are set out below.

9.6. At this stage we do not need firm decisions on the merits of those options but a broad steer would be helpful in the necessary policy development before any public engagement on the way forward.

9.7. Option 2 – those affected by donor conception pay for any counselling support

9.8. As has been established in section 6 above, while the HFEA has no express statutory duty to fund support services, a failure to provide applicants with, at the very least, information about suitable opportunities to receive proper counselling about the implications of the Authority's compliance with their information request could potentially undermine the functioning of the OTR service

9.9. Under this option the Authority would discontinue the support service described at section 3 above and only signpost applicants to suitable organisation(s) that provide the counselling in question. This could be through charitable support networks or private counselling arrangements or signposting to clinics.

9.10. Option 3 – the clinic pays directly for any counselling support

9.11. Another possibility would be for the Authority to issue guidance inviting clinics to directly bear the cost of support.

9.12. Schedule 3 of the 1990 Act and Guidance Note 3 of the HFEA Code of Practice requires clinics to provide implications counselling to donors and patients before they store, renew or use their games/embryos. Paragraph 3.5 of the CoP also requires clinics to provide counselling after treatment and following adverse events and/or successful outcomes. It further requires clinics to take all practicable steps to help people who have previously donated gametes or embryos or have had treatment to access counselling (at a later stage) if requested.

9.13. However, our view is that the requirements for clinics to offer counselling in the legislation are limited to offering counselling to donors and patients and does not include an express requirement to offer counselling to donor-conceived individuals. Whilst the Authority could reasonably issue guidance to encourage clinics to provide (or at least pay for) this service too, compliance by licensed clinics with the guidance will not be enforceable. There is also the

practical problem that clinics may be closed by the time a DC person is requesting information about their genetic parent(s)/siblings.

9.14. Option 4 – the HFEA charges a levy to fund a support service

9.15. Under this option the HFEA would require clinics that provide donation services to pay a levy which could be used to collectively fund a support service. Such an "insurance-based" model ensures that the clinic that benefitted from the treatment contributes to the downstream costs. It would take more time to put such an arrangement in place on the basis that it will likely require legal assurance from an external legal advisor, followed by public engagement and discussion with the DHSC and HMT.

9.16. This option would reduce the impact on the HFEA budget and safeguard other HFEA strategic priorities.

9.17. The current licence funding model, although defined as a charge to clinics, is very often passed on to patients. This therefore raises an ethical consideration as to whether recipients accessing donor treatment (where clinics have passed the licence fee direct to patients) should pay for future support services they may never access.

9.18. If the Authority were minded to explore this option then we recommend that the current contract with the Hewitt be extended for at least 12 months at a direct cost to the HFEA.

9.19. Option 4a & 4b – Continue the support service current model or commission a new multi-layered support service

9.20. If the Authority were minded to put in place a new levy to fund the OTR support service (Option 4 above) then there is further consideration of how this future service may be delivered.

9.21. Option 4(a): continue with the current service model - As noted above the current contract with the Hewitt ends on 31 March 2023. It would be possible to extend the contract to provide a similar offer of counselling and support services. This would have the benefit of continuity at least in the short term as Hewitt Fertility Centre have a team of experienced counsellors who have provided a satisfactory service over the past 3.5 years.

9.22. However, looking further ahead if this is the preferred service model then we should open that tender up to other providers (the Hewitt would of course be entitled to reapply).

9.23. Option 4(b): a new multi-layered support service - The HFEA would seek bids to put in place a multi-layered support service that offered more than just professional counselling. This would provide choice to those affected by donor conception in accessing support and could include options of either professional counselling or peer support via an organisation which provides support, community and information and resources for donors. The current support service model would be evaluated in this process, and this could, for example, include a review of the number of free sessions offered. A formal tender exercise would have to be undertaken.

9.24. This is a newly suggested model, discussed at the recent stakeholder engagement event, which would require a feasibility study and further development work. A detailed costing exercise would need to be undertaken and full business case formulated. If this option was taken forward the current support contract with the Hewitt would need to be extended for at least an extra year to allow for the development of this new service.

10. Risks

10.1. The advantages and disadvantages of the models set out above are outlined in Annex A and a summary of the risks are set out below.

10.2. **Reputational:** As a regulatory body we hold life changing information which we release to individuals. There are reputational risks if the service ceases and other reputational risks if the HFEA has to cut activities to fund this. These risks need to be carefully balanced noting that the stakeholders and those affected by donor conception in this area are heavily engaged and pro active in voicing their views.

10.3. **Financial:** Due to the difficulty of predicting the actual numbers taking up the support service the contract could lead to significant more spend than expected. Given current financial constraints difficult decisions would need to be made to fund the service going forward.

10.4. **Legal:** The HFEA does not have a statutory duty to fund or provide a support service. A challenge could be made against fees charged against centres for a service which cannot be directly linked to a statutory duty. As set out above, external legal advice would need to be obtained to set out the potential risks of legal challenge to a proposed increase to licensing fees for the purpose of funding a future support service.

11. Next steps

11.1. The Authority is asked to decide whether it wishes the existing arrangements to continue (option 1). If not, the Authority is asked to provide a broad steer on the other options to inform policy development. Depending on the discussion we will need to undertake some form of public engagement before taking a final decision of those other options.

Annex A Options appraisal of support services going forward

	Advantages	Disadvantages
Option 1 – status quo	DC people and donors would continue to have access to high quality support.	If the uptake is high then the cost implications over time could severely impact on the HFEA's ability to reach its strategic goals, and possibly carry out its statutory duties.
		Cost controls (either on the number applicants and/or the amount of support per applicant) might be necessary to manage the HFEA's financial exposure but this could potentially lead to an unequitable situation leaving a number of people without support and/or a growing waiting list.
		The longer it is that the HFEA offers a support service the more it is likely to be seen as an HFEA responsibility
Option 2 – those affected by donor conception pay for any counselling support	Closing the service would release significant savings to the HFEA over time and release resources for other strategic priorities.	Stakeholders all agreed that support was vital. Removing the support service would likely be seen as detrimental for those affected by donor conception, especially with 2023 approaching. It would be unlikely any other organisation could step in and fund this service. This would be potentially damaging to the HFEA's reputation.
		A donor only receives limited compensation for their donation it may be seen as unreasonable for a donor to have to pay for a consequence of an altruistic act.
		Closure of the service would likely increase the workload of the HFEA OTR team who provide Register information, especially in dealing with those affected by donor conception who may require

		some form of support but who are unwilling or unable to pay for counselling support.
		If the service closed the future of the DCR would also need considering. Closing the service would likely be seen as detrimental for *pre*-August 1991 anonymous donors and donor-conceived individuals/siblings.
Option 3 – the clinic pays directly for any counselling support	As option 2.	Stakeholders question whether a fertility clinic is the ideal place to offer support.
	Direct link between the clinics that benefitted from providing the treatment and the consequential costs of that treatment.	Removing this service at this time could be potentially damaging to the HFEA's reputation
		Different clinic counselling services may differ in quality and provision may be patchy.
		A clinic where a donor has donated or a patient received treatment may have closed. This risk increases for DCR applicants accessing support (ie, *pre*-August 1991 anonymous donors and donor-conceived individuals/siblings) as it is more likely that the clinic may have closed.
Option 4	DC people and donors would continue to have access to high quality support	The cost of the increase will most likely be passed to those accessing treatment

	Direct link between the clinics that benefitted from providing the treatment and the consequential costs of that treatment and national insurance model would have the added benefit of ensuring a universal service.	Risk of legal challenge as the fee will be used to fund a non-statutory duty. (NB. We have yet to receive external legal advice on this issue)
	Stakeholders all agreed that support was vital. Continuing a funded service would avoid the risk of reputational damage to the HFEA.	An insurance-based model funded by a levy would take time to implement and require engagement with a number of parties.
	Support is not necessarily linked to fertility clinics.	The longer it is that the HFEA offers a support service the more it is likely to be seen as an HFEA responsibility
Option 4a & 4b – Continue the support service current model or commission a new multi-layered support services		
4a Continue with current model	As option 4	Disadvantages of existing model continue: notably limits options of support available to those affected by donor conception
4b Commission a new multi-layered support services	As option 4 In addition: Offers a multi-layered form of support that will be suitable to more people including professional counselling and peer support which we know to be valuable to donor-conceived individuals.	May be more expensive in terms of set up costs. Since this service is designed to be valuable to a wider range of people ongoing support could be high.

	May be cheaper as non-professional services such as peer support are cheaper than professional counselling	The longer it is that the HFEA offers a support service the more it is likely to be seen as an HFEA responsibility
	Support is not necessarily linked to fertility clinics.	Would take significant HFEA resource to explore further for feasibility study and business case.

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State of the Sector 2021/22 and Inspection Themes

November 2022

Sharon Fensome-Rimmer
Chief Inspector

www.hfea.gov.uk

Summary

- State of the Sector is our annual report, which summarises what we have seen through our regulatory work during the year. 2021/22 report issued 3rd October 2022
- The report is compiled from information gathered from our inspections and from other sources of information including our Register of fertility treatments, incident reports and patient feedback mechanisms
- The COVID-19 pandemic had a significant impact on the availability of fertility treatment in 2020/21 and this, combined with the changes we made to our approach to inspection during that year, means that some data provided in this report is not directly comparable with previous years and should be interpreted with caution
- The report provides a high-level overview of sector-wide compliance, reporting on the absolute number of inspections, non-compliances, incidents, and complaints
- Further insight into changes to interim inspection themes, and the data which informed these decisions, is also detailed within this report
- Detailed insight is provided to centres via the clinical Governance Quarterly Updates
- These reports on compliance are used to focus future interim inspections

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Key Findings

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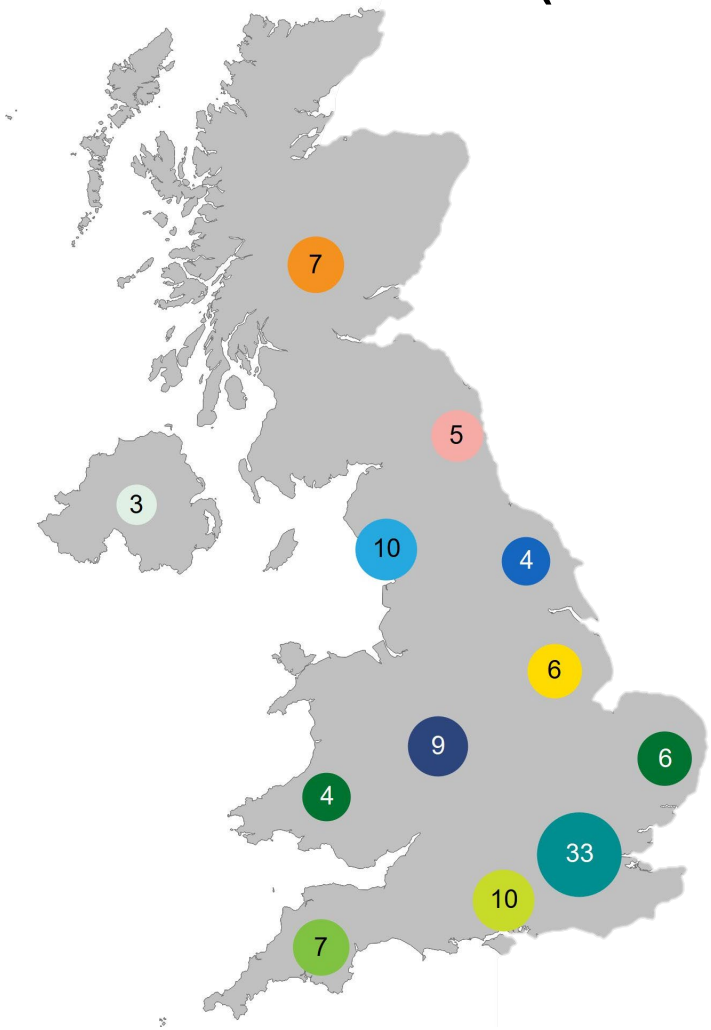
The largest concentration of clinics are in London

Number of clinics licensed to provide fertility treatment by geographical area, 2021/22 (excluding storage and research only)



- East Midlands
- East of England
- London
- North East
- North West
- Northern Ireland
- Scotland
- South East
- South West
- Wales
- West Midlands
- Yorkshire and the Humber

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Inspections

Inspections increased compared to previous years, following the COVID-19 pandemic

- 104 clinics are licensed to provide treatments
- In 2021/22 clinics were assessed using a hybrid approach involving a desk-based assessment (DBA) combined with an onsite visit to allow continued close regulatory oversight of the fertility sector
- A risk-based approach was taken in prioritising inspections due in this year with those deferred by the pandemic given priority
- There were **105 inspections** in total carried out in 2021/22, of which:
  - 63 were a combination of DBA and onsite visit
  - 20 were onsite visits only
  - 14 were a combination of DBA with virtual inspection
  - Six were a combination of DBA, onsite visit, and virtual inspection
  - Two were virtual inspections only

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Inspections

Inspections increased compared to previous years, following the COVID-19 pandemic

- A breakdown of the different types of inspection is provided below:
  - 52 (50%) were renewals
  - 38 (36%) were interim
  - 11 (10%) were additional
  - 4 (4%) were initial
- There were also 15 renewal inspections which were deferred by extension of licence, and two voluntary revocations of licence

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Incidents & complaints

No Grade A incidents since 2020/21

- There were 793 incidents (including 121 near misses) reported to the HFEA in 2021/22, compared to 548 in 2020/21
- This increase is due to the requirement for clinics to report all patient hospital admissions due to the COVID-19 pandemic
- Grade B incidents remain consistent with previous years, and no Grade A incidents occurred in 2021/22 or in 2020/21
- Severe and critical OHSS remained consistent with previous years (66 cases reported)
- Patient complaints have decreased during 2021/22 (76)

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Quarterly Clinical Governance report

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Quarterly Clinical Governance report

Report issued every quarter.

Provides the following:

- An overview of the most common non compliances for a quarter
- A review of any critical non-compliances
- A review of the most common areas of non-compliance (major and other)
- Provides an update on the number and grades of incidents reported, including a breakdown of categories
- The report also provides an update on the numbers of informal and formal complaints received

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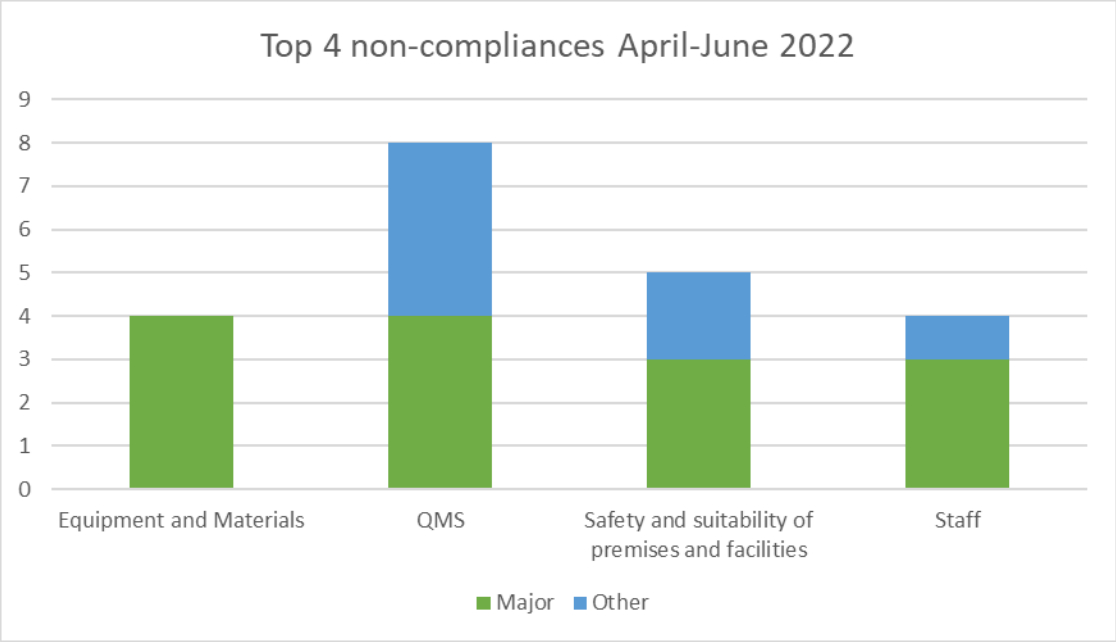
Most recent Quarterly Clinical Governance report

The four most common areas of non-compliance seen on inspections between April and June 2022

(from 12 Treatment and storage centre inspections with completed reports available in July).



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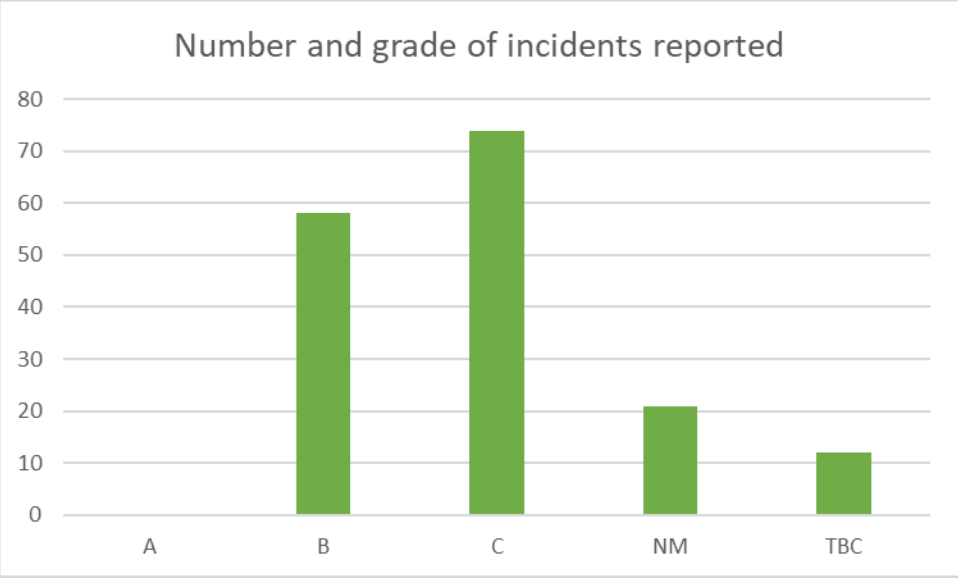
Incident findings

Number of incidents reported.



There were 198 incidents reported to the HFEA:
Grade A 0
Grade B 58
Grade C 74
Near misses 21
Grade not yet confirmed 12

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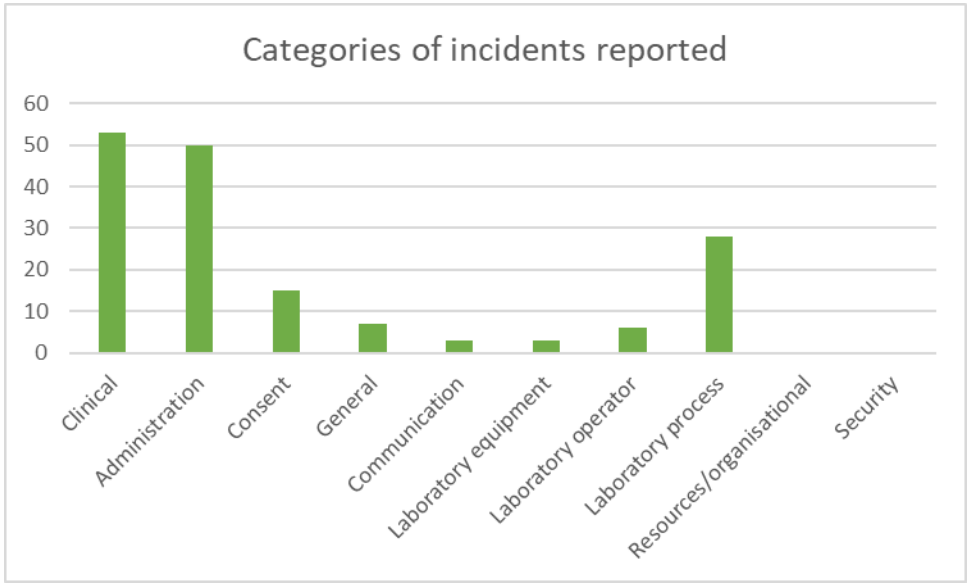
Categories of incidents

Breakdown of the categories of incidents reported

Incidents classed as ‘not an incident’ (n=33) have not been included



The largest proportion of incidents reported were:
Clinical 53
Administration 50

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Patient complaints

Provide an oversight of the numbers of informal and informal complaints seen between the period of April to June 2022

- There were 4 informal complaints referred to the HFEA. Which included the following themes, communication around number of follicles available for egg collection, complaint about clinic care and a compliant about AMH results (same results in 2022 as 2021)
- There was 1 formal complaint received whereby a patient thought she had donated an embryo to research, they were unhappy that they had not been made aware of a change of organisation holding the embryo. The embryo had not been donated to research and was still being stored at the clinic

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Changes to interim inspection themes

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Background to interim inspections

Interim inspections

- These are focused inspections based on current inspection themes, a centres previous inspection report and any incidents or complaints that have occurred (prior to Covid these were unannounced. Depending on the DBA assessment, time on site 1 day with 1 to 2 inspectors)
- Inspection notebooks are used to collate any findings and the details of evidence of compliance observed during the DBA and on inspection
- Inspection reports are written by exception only those areas of noncompliance are cited within the report

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Focus of interim inspections

The focus of Interim inspections is reviewed on a regular basis with the inspection team

- Current themes are identified by:
  - A review of inspection reports to identify areas of common non-compliance
  - Each area of noncompliance are considered on risk
  - Compare these findings to the state of the sector & incident report findings
  - Correlate these to the current HFEA strategy. Considering how the non-compliance relates to best care, right information and shaping the future

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Themes retained from the previous year

- Patient safety, feedback & emotional support
- Leadership, staffing & clinical governance
- Consent to storage, with a focus on wider consent practices
- QMS
- Audits, review of the centres own audits which include storage, legal parenthood, medicines management and infection control
- Surgical procedures
- Pre-inspection review of data quality. Currently this is on hold due to the work with PRISM
- Pre-inspection review of the centre's history of compliance, RBATs
- Patient questionnaire reports via CaFC
- Incidents and complaints and centre's websites

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Themes added

- Donor recruitment, selection, assessment and screening
- Changes to storage regulations and consent process

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Thank you