Human Fertilisation & Embryology Authority

Authority meeting held by teleconference

Date and time: 12 May 2021- 1pm to 4pm

Venue: online

Agenda items	Time
1. Welcome, apologies and declarations of interest	1.00pm
2. Minutes of the meeting held 24 March 2021 **For decision**	1.05pm
3. Chair and Chief Executive's report **For information**	1.10pm
4. Committee Chairs' report **For information**	1.20pm
5. Performance report **For information**	1.35pm
6. Covid-19 update **For information**	2.00pm
7. Strategic risk register **For information**	2.15pm
Break	2.45pm
8. Licence fee review project – timing and next steps **For decision**	2.55pm
9. Transparency and Regulation **For information**	3.25pm
10. Any other business	3.55pm
11. Close	4.00pm

Minutes of Authority meeting 24 March 2021

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	12 May 2021		
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 24 March 2021 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 24 March 2021 held via teleconference

Members present	Sally Cheshire, Chair Margaret Gilmore Anita Bharucha Anne Lampe Jason Kasraie Catharine Seddon Emma Cave	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian Tim Child
Apologies		
Observers	Julia Chain, incoming Chair Alison Marsden, Incoming Authority member Marina Pappa (Department of Health and Social Care - DHSC) Steve Pugh, DHSC Csenge Gal, DHSC	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Paula Robinson Debbie Okutubo Helen Crutcher Dina Halai

Members

There were 14 members at the meeting – nine lay and five professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present online. This was her last Authority meeting as her term of office would end on 31 March 2021. It was also Kate Brian's last meeting.

1.2. Continuing, the Chair welcomed the incoming Chair, Julia Chain, who was observing the meeting as well as Alison Marsden and informed all present that both appointments would start on 1 April 2021.

1.3. The Chair stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not able to listen in during our deliberations to hear it afterwards.

1.4. Declarations of interest were made by:

- Yacoub Khalaf (clinician at a licensed clinic)
- Tim Child (PR at a licensed clinic)
- Ruth Wilde (counsellor at licensed clinics)
- Kate Brian (working at Fertility Network UK)
- Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 27 January 2021 were an accurate record and could be signed by the Chair.

3. Chair's report

3.1. On 2 February, the Chair participated in the arms-length body (ALB) chairs roundtable discussion led by Minister of State, Edward Argar MP.

3.2. On 8 February, the Chair attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting where a number of issues were discussed. The SCAAC Chair would give a summary of this meeting later in the agenda.

3.3. The Chair thanked the committee secretaries for their hard work and support given to her during her tenure as both Chair of the Audit and Governance Committee and later Chair of the Board.

Licence Committee

3.4. Kate Brian was invited to give a summary as the outgoing chair of the Licence Committee. She reflected on her experience as Chair and stated that Jonathan Herring was now the Chair of the Committee. She sent her appreciation to the Inspection team who provided the reports and Licensing staff who supported her during her term in office.

3.5. Jonathan Herring gave a brief summary of the last Licence Committee meeting.

Audit and Governance Committee (AGC)

3.6. The AGC Chair (Anita Bharucha) gave a summary of the meeting held on 16 March. The AGC Chair welcomed the progress being made by the teams and clinics on the digital programme. Members were reminded that at the January meeting the decision had been taken to delay go live as a result of lockdown and pressures on clinics. The revised go live date was now May/June since this seemed to be the best option in order to maximise clinic engagement. Members noted that the AGC would continue to meet monthly to review progress.

3.7. An update from internal audit on completed reports was presented to the AGC and two reports had received the top rating, one on financial processes and the other on virtual inspections. The committee was very pleased to see these positive ratings.

3.8. The strategic risk register was reviewed and the committee agreed that it would be timely to review the risk policy and risk appetite statement in the near future.

3.9. An update on business continuity, resilience and cyber security was received. The committee particularly welcomed the recent update of choose a fertility clinic (CaFC) data.

Scientific and Clinical Advances Advisory Committee (SCAAC)

3.10. The SCAAC Chair (Yacoub Khalaf) summarised the items presented at the meeting held in February. He commented that the effects of Covid-19 on fertility, assisted conception and early pregnancy would continue to be monitored.

3.11. The committee agreed that the HFEA should maintain a pro-vaccine stance and update the coronavirus frequently asked questions (FAQs) as British Fertility Society (BFS) and Association of

Reproductive and Clinical Scientists (ARCS) guidance was updated. The committee suggested changes to the 2021/22 SCAAC workplan and recommended some external speakers for priority topics.

3.12. In terms of prioritisation of issues, it was noted that SCAAC had asked the Executive not to limit their horizon scanning to a previously agreed list of journals but instead use a more open, informed literature search.

3.13. Lastly, the committee's focus on embryo culture media was de-prioritised from high to medium as it did not fall within the HFEA's regulatory remit.

Statutory Approvals Committee (SAC)

3.14. The Chair of SAC (Margaret Gilmore) addressed the Authority. It was noted that monthly meetings continued to be held.

3.15. At the last meeting, the committee considered a number of PGD applications and one special direction.

3.16. The SAC Chair noted the number of items coming before the Committee continued to grow in terms of number and complexity.

Decision

3.17. Members noted all the Chairs' updates.

4. Chief Executive's report

4.1. The Chief Executive (CE) reported back on some of the engagements he had with the sector.

4.2. On 18 February the Chief Executive gave evidence to the World Health Organisation (WHO) commission on human genome editing. They were nearing the end of their evidence gathering process and were looking at regulatory aspects.

4.3. The Chief Executive gave a synopsis of progress with PRISM and explained that clinics were training their staff with their live data which should all lead to a smooth transition.

Decision

4.4. Members noted the CE's report.

5. Performance report

Strategy and Corporate Affairs

5.1. The Director of Strategy and Corporate Affairs gave a brief overview on ongoing work in the directorate.

5.2. There was a recent Association of Fertility Patient Organisations (AFPO) meeting, where the HFEA received positive feedback on our engagement and our recent response to the Covid-19 pandemic. The meeting was also informed that our website was recently updated with new treatment add-on pages and members offered to publicise this. The Authority Chair had also attended part of the meeting so that AFPO members could say their farewells to her.

5.3. On the recently published ethnic diversity in fertility treatment report, members congratulated all staff involved. Members further commented that the report showed the HFEA at its best. The report provided useful information for and from a diverse set of people. Members commented that the data gathered could be used to trigger useful conversations. There was a clarification sought about the use of term 'Black and Minority Ethnic (BAME)' and how useful it was in this context since not everyone identified as BAME.

5.4. The Director of Strategy and Corporate Affairs responded that the report had an action plan at the end and clinics, the HFEA and she would report back on progress to Authority in due course. The term 'BAME' was not being used internally or in this report, or going forward. It was noted that the findings would be presented at the Royal College of Obstetricians and Gynaecologists (RCOG) Race Equality Taskforce meeting in September.

5.5. Lastly, the Director of Strategy and Corporate Affairs noted several elements of ongoing work in the directorate: there were further EU exit related activities being carried out by teams across the HFEA; we were looking at small updates to the Code of Practice; and the HFEA @30 activities work was now live which included a series of blogs and an event scheduled for this evening.

Compliance and Information

5.6. The Director of Compliance and Information gave an overview of the work in her directorate. Members were advised that every year we have inspection themes in line with the HFEA strategy that are a focus on interim inspections. The themes for 2021-2022 are:

- Patient safety, feedback and emotional support
- Leadership, staffing and clinical governance
- Consent
- Donor recruitment, selection, assessment and screening QMS
- Audits
- Surgical procedures
- Pre-inspection review of data quality
- Pre-inspection review of the centre's history of compliance, RBATs, patient questionnaire reports, incidents and complaints and centre's websites.

5.7. On 1 April a new member of staff will start in the opening the register (OTR) team to support work clearing the backlog. Processes in the team were also being reviewed so that they can be streamlined as the team continued to receive unprecedented numbers of requests. Members commented that this was a positive step as the backlog could lead to reputational damage.

5.8. Members asked whether the current system of largely desk based inspections meant that casual conversations with junior staff on-site might not happen as they were not likely to pick up the phone to speak to the Inspector. The Director of Compliance and Information commented that we would continue to speak to a range of staff.

5.9. Members commented that it was good that on-site visits were still happening when needed. To clarify a point, the Director of Compliance and Information stated that whilst restrictions had been in place, inspections utilised virtual technology to look at specific items and this assured Inspectors. However, when necessary, Inspectors had attended the clinic in person but spent less time on-site than previously.

5.10. The Chief Executive commented that there was some assurance from the Inspectors and clinics that the hybrid system that we intend using going forward was broadly supported. During Covid

restrictions on site visits are only conducted where concerns remain. In a hybrid model going forward on-site visits would occur for each inspection but fewer hours would be spent on site.

Finance and Resources

5.11. The Director of Finance and Resources presented to the Authority. It was noted that the year-end financial position would see an underspend partly because PRISM had not been completed and we had additional funding for the project.

5.12. Regarding occupation of the new office, it was noted that the earliest we would return to the office would be in June in line with government guidance, which currently still stated that wherever possible people should work from home. In responding to a question it was noted that the office was ready for occupation.

Other issues

5.13. In response to a question on the change to a new office, it was noted that the HFEA remained a flexible employer with all Inspectors as home workers and office-based staff working from home up to two days a week. The plan was to reach an agreement on a new way of working settlement when we are able to attend the new office. The CE promised to keep members updated.

5.14. On staff wellbeing, the CE commented that there were two key performance indicators that we use to measure staff well-being: employee turnover and sickness rates, both of which were green. The third lockdown had been harder on staff and we were focusing on how best we can return to the office.

5.15. The Chair invited professional members to reflect on the situation in relation to their clinics.

5.16. Members working in the sector commented that the present situation was becoming the norm.

5.17. Clinics had started becoming busy both in the NHS and private clinics and even though there were more work pressures, they were more staff support related. There were safety rules in place and efforts were being made to reduce waiting time.

5.18. The CE stated that the importance of good communication with patients would continue to be highlighted to clinics.

5.19. The Chair congratulated clinic staff and HFEA staff and commented that the fertility sector was the first in the health sector to re-open following the first lockdown.

5.20. The Chair commented that all key performance measures were green except one which was for an invoice not paid on time.

Decision

5.21. Members noted the performance report.

6. Covid-19 update

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

6.2. Members were informed that almost all centres that had suspended treatment services in the recent lockdown had now restarted treatment.

6.3. Inspections had resumed and were risk based and where on-site visits were not conducted a clear rationale for this was documented.

6.4. As at February 2021, private centres were performing more cycles than this time last year; NHS centres were performing at c. 70% of where they were last year.

6.5. A member suggested that the presence of partners still remained an issue in some clinics, especially where bad news had been received and the patient needed support.

6.6. It was noted that there was a huge increase in the number of patients coming forward for support and advice from Fertility Network UK. FNUK had also seen anxiety from some patients who had planned to have treatment abroad but were not able to travel at present. This meant that those patients were approaching UK clinics which typically were more expensive compared than those overseas and this was causing further anxiety.

6.7. It was noted that most patients were aware of the efforts clinics' were making and were grateful for this.

Decision

6.8. Members noted the Covid-19 update.

7. Effective governance

7.1. The Chair suggested that due to time constraints, the report should be taken as read and members should focus on the changes to Standing Orders recommended.

7.2. At 5.1.1 in Standing Orders there was a proposed correction to an anomaly in the reserved matters list. It was recommended that in Annex 1, section 5.1 (p) we remove the word 'annual' and replace 'approval of' with 'consider all proposed updates to'.

- (p) Consideration of all proposed updates to the Code of Practice and general directions, while retaining the power to delegate revisions where necessary, provided this is done in accordance with paragraph 6.6 of Standing Orders.

7.3. There was a proposal to increase the delegated powers to the Chair so that decisions could be made in a more agile way. It was recommended that section 5.2.4 should read:

- The Chair of the HFEA may, alternatively, form a sub-group of members to make decisions outside the cycle of meetings in the event of urgent or business critical issues arising.

7.4. In annex A, section 2 there was a proposal to increase the membership of the Audit and Governance Committee. A member also asked if we could include the words 'if required' in relation to the two non Authority places on the committee. It was further suggested that the committee's quorum be updated to reflect that at least two Authority members should be present. The recommended changes were:

- The Audit and Governance Committee shall consist of up to six members including:
  - a Committee Chair (who shall be an Authority member)
  - a Deputy Committee Chair (who shall be an Authority member)
  - up to two other Authority members

  - two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise (if required).
- The quorum for a meeting of the Audit and Governance Committee shall be three, providing that two are Authority members, including the Committee Chair or deputy Committee Chair.

7.5. Changes to the terms of reference for the Scientific and Clinical Advances Advisory Committee (SCAAC) (Annex A, paragraph 6.3) were also recommended. The proposed changes are:

- The Scientific and Clinical Advances Advisory Committee shall consist of at least three Authority members, including:
- a Committee Chair (who shall be an Authority member)
- a Deputy Committee Chair (who shall be an Authority member), and
- up to three other Authority members.

7.6. The proposed changes to the Register Research Panel membership in Annex A, section 8 to ensure it remains fit for purpose were:

- The Register Research Panel shall consist of a Chair and Deputy Chair (or Deputy Chairs) and a pool of suitable employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a Deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.
- The quorum for a meeting of the Register Research Panel shall be five, and there shall be due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions. All decisions and minutes must be signed off by the Chair.

7.7. To correct an anomaly to the Executive Licensing Panel (ELP) delegations and make it clearer which licences ELP can vary, the following change was proposed:

- The following variations of licences on application:-
  - change of Person Responsible (under section 18A(1) of the Act)
  - changes to licensed activities (under section 18A(2) of the Act), and
  - change of a centre's premises (under section 18A(2) of the Act).

7.8. There was a request from the Chair of the Statutory Approvals Committee also to update Standing Orders to read:

- The Statutory Approvals Committee shall operate from a pool of members, with no more than five members attending each meeting.

7.9. Members were invited to ask questions.

7.10. In response to a question about the Remuneration Committee, it was noted that the Authority Chair doubled as the Remuneration Committee Chair since staff pay was governed by the pay framework set annually by the government. This limited the role of the committee to ensuring fairness and consistency rather than deciding pay rates.

Standing Orders

7.11. Members were invited to vote on the proposed changes.

Decision

7.12. Members noted the annual reviews of committee effectiveness and the action points for each committee.

7.13. Members unanimously agreed the changes to Standing Orders, effective from 1 April 2021.

8. Business plan

8.1. The Chair invited the Risk and Business Planning Manager to present this item. Members were reminded that at the November 2020 Authority meeting, they approved the draft activities section of the business plan.

8.2. The business plan for 2021-22 built on the extraordinary work during the pandemic in 2020-21 and had been developed following conversations both within teams and amongst the corporate management group. It was noted that despite the challenges of the pandemic, a lot was achieved in the preceding year as we delivered on core activities such as inspections and licensing, implementation of changes from EU exit, progressing PRISM and producing publications.

8.3. The Chair invited members to ask questions.

8.4. Members welcomed the plan and suggested that the wording could be more specific about collaborative and partnership working. Also, as it was an ambitious plan, it would be important to monitor it to ensure that it remained deliverable.

8.5. Members also commented that the work done in 2020-21 would give the HFEA a good grounding for the coming year, providing supporting evidence for discussion on the potential modernisation of the Act over the coming years. This would also feed into ongoing improvements in standards.

8.6. Members asked what clinics were required to put on their own clinic website in relation to add-ons. Staff commented that we would continue to review this and it would form part of the conversation with clinics.

8.7. In terms of the relocation to Stratford, members suggested that we change the term ‘snagging’ to ‘optimise the use of the premises’ or similar.

8.8. The Chair thanked staff and members for their contribution.

Decision

8.9. Members approved the business plan for 2021-2022 subject to incorporating the suggested comments and noted that year-end information would be added in April 2021.

9. Treatment add-ons update

9.1. An update on progress to our work on treatment add-ons since the last Authority update in November 2020 was noted. Members were reminded that addressing treatment add-ons was a key feature of our strategy for 2020 to 2024.

9.2. It was noted that the information on the website had recently been updated. The overarching aim was to ensure that add-ons were seen in the context of ‘routine’ IVF treatment.

9.3. Members were also informed that all the actions agreed at the November 2020 Authority meeting had been completed.

9.4. Members commented that clinic websites needed to be updated to ensure that there was no misleading data.

9.5. To improve patient understanding about treatment add-ons, the HFEA collaborated with the Fertility Network UK to develop a list of questions and a checklist that patients could refer to when having a discussion with their clinicians about treatment add-ons.

9.6. Members were advised that the information on complementary and alternative therapies was in draft form and would go live on the HFEA website in the coming weeks.

9.7. The Chair thanked the Scientific Policy Manager and the team for the work completed to date.

Decision

9.8. Members noted the progress made in relation to treatment add-ons.

10. HFEA response to CMA/ASA guidance

10.1. The Director of Strategy and Corporate Affairs presented this item. Members were advised that the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) had been working with the HFEA for a while now and both regulators planned to publish their guidance in the weeks ahead.

10.2. The work these regulators had undertaken had raised some important issues for us. There were some issues to note including the overall HFEA response, changes to the Code of Practice, developing a memorandum of understanding (MoU) and protocols, and training for inspectors.

10.3. There were also some issues for discussion, including further references in the Code beyond success rates, current non-compliance with the Code on publication of information about success rates and treatment add-ons, and whether text should be added to the role description for Persons Responsible (PRs).

10.4. The Chair commented that when developing the MoUs we needed to be clear on what the roles of the different regulators were. Some of the professional members who were PRs commented that PRs should already be aware of their position of overall responsibility. However, guidance might be necessary to ensure consistency across all clinics.

10.5. Members supported having written guidance from the CMA and ASA as it would ensure that all clinics understood their obligations. It would also be used for clinic engagement so as to make a tangible difference.

10.6. The Chair thanked the CMA, ASA, all staff involved and members for their contributions.

Decision

10.7. Members approved the overall HFEA response, the additions to the Code of Practice and the development of the MoU and protocols.

10.8. Members noted that there will be a further discussion with the Authority later in the year.

11. Compliance and Enforcement Policy post consultation

11.1. The Director of Compliance and Information presented this item. Members were informed that the Head of Legal had played a significant role in the development of the policy.

11.2. The new draft policy set out the Authority's regulatory aims which underpinned all our compliance and enforcement activities. The policy would apply only in circumstances that warranted regulatory action.

11.3. Members were advised that the draft policy was consulted on in January 2021 with helpful and insightful comments received from both the NHS and the private sector. These comments had been incorporated where applicable.

11.4. It was noted that once approved, the policy would come into effect in June 2021 since time was needed to train inspectors in its usage.

11.5. In response to a question, it was noted that non compliances are used to form the quarterly Governance Summary which is shared through our Clinic Focus.

11.6. Members suggested a six-month interim review/audit follow up meeting following an intervention to ensure the clinic was on track. The Director of Compliance and Information agreed to follow this up with the Director of Finance and Resources.

11.7. The Chair thanked everyone involved including the Inspectors for their work in getting this policy completed.

Decision

11.8. Members approved the final version of the Compliance and Enforcement policy and the proposed timeline for implementation.

11.9. Members agreed to delegate sign-off of the revised guidance on licensing to the Chair and Deputy Chair of the Licence Committee.

12. Any other business

12.1. The Chair, Sally Cheshire, gave some parting words and emphasised that patients were central to our work at the HFEA. She thanked everyone who had contributed to her success whilst in post over the last 15 years, since she first became involved in the HFEA.

12.2. The Chair went on to pay tribute to Kate Brian as it was also her last meeting and commented that Kate had been an effective voice for patients.

12.3. Kate thanked everyone present and stated that it was an absolute privilege and honour to work alongside all Authority members and staff, and in particular thanked the committee staff and inspection team.

12.4. Margaret Gilmore, deputy Chair, on behalf of members, thanked Kate Brian and Sally Cheshire for their outstanding dedication and contribution to the HFEA. She noted Sally's considerable achievements as Chair, in particular in putting the patient at the heart of HFEA work, ensuring scientific evidence around "add-ons" is transparent, and playing a critical role in the introduction of the licensing of Mitochondrial Transfer treatments.

12.5. The Chief Executive commented that it had been a privilege to work alongside Sally and that she had provided leadership, challenge and support throughout, ensuring that we improved as an organisation. He commented on Sally's approachability and visibility to staff.

12.6. Marina Pappa on behalf of the DHSC also thanked Sally for her work over the years and huge contribution to the work of the HFEA.

12.7. Sally responded saying that of all the places she had worked in the public sector, the HFEA was one of the best, and that she would remember her time with fondness.

Chair's signature

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

Signature

Chair: Margaret Gilmore

Date: 12 May 2021

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	
Meeting date:	12 May 2021
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 March 2021.

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 spent the last six weeks meeting Board members, executive staff and external stakeholders, as covid restrictions allowed:

- 1:1 introductory conversations with all Board members and staff throughout April
- 19 April - introductory meeting with Raj Mathur, Chair of the British Fertility Society FS
- 20 April - informal visit to the Wolfson Fertility Centre,, Hammersmith Hospital, London
- 20 and 27 April - sat in on an patient consultation evening and a partnership Q&A sessions hosted by Tim Child, Oxford Fertility
- 26 April – attended with Peter roundtable discussion hosted by Lord Bethell along with other ALB's Chair and Chief Executives on innovation and regulation.
- 27 April - introductory meeting with Mark Davies our senior sponsor at the DHSC
- 27 April - introductory meeting with Gwenda Burns, Fertility Network UK
- 27 April – introductory meeting with Veronique Berman, CHANA
- 28 April - informal visit to the Lister Fertility Clinic, London
- 29 April - observed the Statutory Approvals Committee meeting
- 29 April - observed the Professional Stakeholders Group meeting
- 4 May - introductory meeting with Sarah Norcross, Progress Educational Trust
- 5 May - introductory meeting with Lynne Berry, Chair of the Human Tissue Authority

2.2. The Chief Executive has supported the Chair during her induction and taken part in the following:

- 1 April - interview with Vivian Wu regarding UK fertility industry and consumer protection law
- 12 April - attended with members of SMT the Quarterly Accountability meeting with the DHSC
- 14 April – visited the new HFEA office at Redman Place, Stratford
- 14 April - spoke at the Progress Educational Trust event celebrating Mary Warnock
- 28 April - attended the AGC PRISM oversight meeting

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	12/05/2021
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note and comment on the latest performance report and upon the changes to the content of the report.
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

1. Latest review

1.1. The attached report is for performance up until March 2021.

1.2. Performance was reviewed by SMT at its 26 April meeting.

2. Key trends

2.1. In March performance was generally good. There were three red indicators.

Red indicators - March

2.2. The indicators classed as red are as follows:

- **C1 – Regulatory Efficiency**
- **F1 – Debt Collection**
- **II1 – Internal Incidents**

Red indicators - February

2.3. This compares with two red indicators in February:

- **R2 – Register data errors**
- **F1 – Debt Collection**

2.4. The annexes to this paper provide a scorecard giving a performance overview, high-level financial information and the monthly management accounts and more detailed information on KPIs.

3. Opening the Register (OTR) KPI

3.1. In March, Authority asked the executive to consider when we may be able to reinstate the OTR KPI. SMT has discussed this issue at length and agree that we will not be in a position to reinstate a target until the OTR service is redesigned.

3.2. The current backlog in OTR applications has two sources: the decision to temporary close the service due to the pandemic and a general increase in monthly applications. Resolving the backlog and consequential delays to OTR processing is a high priority and SMT are regularly apprised about performance. We are mindful of the impact on those awaiting a response, but we are prioritising accurate information and providing a continued high-quality service. The solution to this issue is also twofold. First, additional staffing – an additional member of staff has been appointed and is undergoing the necessary training. We are considering further appointments if necessary, though that may require savings from elsewhere in the organisation. Second, service redesign – work is underway to look at the administrative processes and underpinning IT with the aim of streamlining the service. That will take some months to complete and then any changes will have to be integrated into practice. In the meantime, the team continues to process good volumes of applications and numbers should increase as the additional member of staff becomes more productive.

Annex 1 HFEA Performance scorecard and management commentary – March 2021 data

Breakdown of total Red, Amber, Green and Neutral Indicators

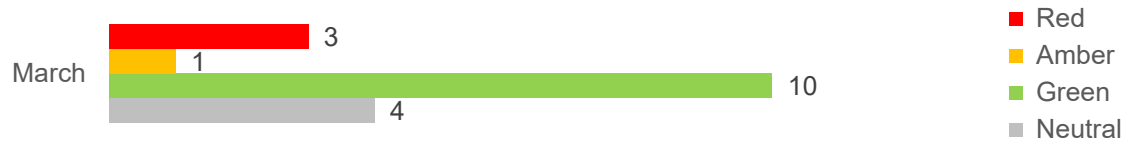

Figure 1 – One more red indicator than last month

RAG	Area	Trend and key data
Green – within target	**People -** Employee turnover Target: between 5%-15%	11.7% Turnover 0 leavers
Red – not at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	63% within target. Average of 55 wds (items beginning with an inspection)
No target – more than double last month	**Engagement -** HFEA website sessions	sessions (in same month last year)

Summary financial position – March 2021 (Figures in thousands – £'000s)

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s
Income	**7,447**	**7,211**	**(236)**
Expenditure	**(6,729)**	**(7,212)**	**483**
Total Surplus/(Deficit)	**718**	**(1)**	**719**

Commentary on financial performance to end March 2021

We have ended the year prior to any audit adjustments with a surplus against budget of £718k. This surplus includes the ring-fenced element (£228k) that can only be used to cover our non-cash costs.
The adjusted surplus is £490k which is significantly better than forecast. This was aided by stronger income levels than anticipated, the legal budget underspent and our IT costs coming more or less on budget.

Management commentary

In March performance is generally good. We had three red indicators. The publication of our Ethnic Diversity in Fertility Treatment report saw our media engagement significantly increase this month, accounting for a third of our overall coverage. The number of Licensing Officer items also increased significantly in March to 28, from an average of 10 in the preceding four months. 27 out of the 28 items were Importing Tissue Establishment (ITE) certificate applications. This increase is a direct result from EU Exit as clinics now need to have certificates in place for importing from EU countries (not just outside the EU). Many applications relate to Danish sperm banks. Despite this and the ongoing relicensing project, the Licensing team has prepared papers as quickly as ever and all licensing KPIs remain Green. Average PGD processing times rose slightly this month, due to several items being scheduled to committee later, as SAC meetings were too full for additional items. However, the increases in processing time were generally fairly small (the longest processing time was 85 working days) and therefore PGD performance is classed as Amber.

Red indicators:

Compliance

- **C1 – efficiency of the end-to-end inspection and licensing process.** Our target is for 100% of items to be processed in 70 working days, for items where minutes were sent in month. In March, our performance was 63%, with three of the eight items taking longer than 70 working days, which we count as Red. Two were over KPI due to inspector workload following the resumption of inspections and one item was over KPI due to the need for a management review meeting.

SMT has discussed this KPI and the wider issues of inspection delivery. Due to the Covid pandemic inspections were suspended between March and November 2020. Many centres had licences extended for a further 12 months which has meant now more inspections have had to be conducted in a shorter timeframe as no licence can be extended past 5 years. We also had to implement the new remote inspection methodology which has entailed greater work for inspectors (desk-based assessments – DBA - and virtual meetings). The Compliance management team are reviewing the methodology and discussing with the inspection team the appropriate levels of scrutiny when reviewing documentation to ensure a common approach to the depth of the DBA. This will ensure that the remote method, which was brought in at fairly short notice due to Covid, is optimised for ongoing use. The return to more in person inspections may also make workloads more manageable and we anticipate that compliance performance overall will settle. Looking further ahead, we need to ensure that any revised inspection methodology is sustainable for the inspection team.

Risk and business planning

- **II1 - Internal Incidents.** Our target is for the average time to close internal incidents to be 30 working days or less for those closed in the month. In March, the average was 53 working days from two items. The single item closed over the target remained open in order to undertake more in-depth analysis and learning. This incident related to an inspection booking being missed and then needing to be booked in later, so has significant wider implications and learning. Learning was communicated to the compliance team and the delay to closure has been valuable. Following an increase in focus on internal incidents and familiarising staff, we are seeing a greater number of incidents being reported, which is a good sign as it means we can extract and communicate greater learning when things go wrong. Our focus is on learning and quality rather than speed, but time to close is a proxy measure for timely actions being taken after incidents occur.

Finance

- **F1 - Debt collection.** This indicator was also red in February. Our target is 85% of debts collected within 40 working days from billing (by number of debts). In February, our performance was 73% which we count as Red and in March this had improved somewhat to 75% which is just Red rather than Amber. Collection activities are increasing and there should be a reduction in over 40-day collections going forward.

The only other red indicator from February, **R2: Register data errors** has also improved, going from Red in February (a 16% increase in errors outstanding compared with January) to Amber (a 3% increase). Our target is a greater than 5% reduction in outstanding errors in the system. We expect that the significant increase in outstanding errors in February comes from less time being able to be committed to non-CaFC errors by the Register team, since during this period we were preparing Choose a Fertility Clinic data for publication, and a change of emphasis in clinics away from working on errors as staff are at home. We are pleased to see the large increase last month has not been continued this month.

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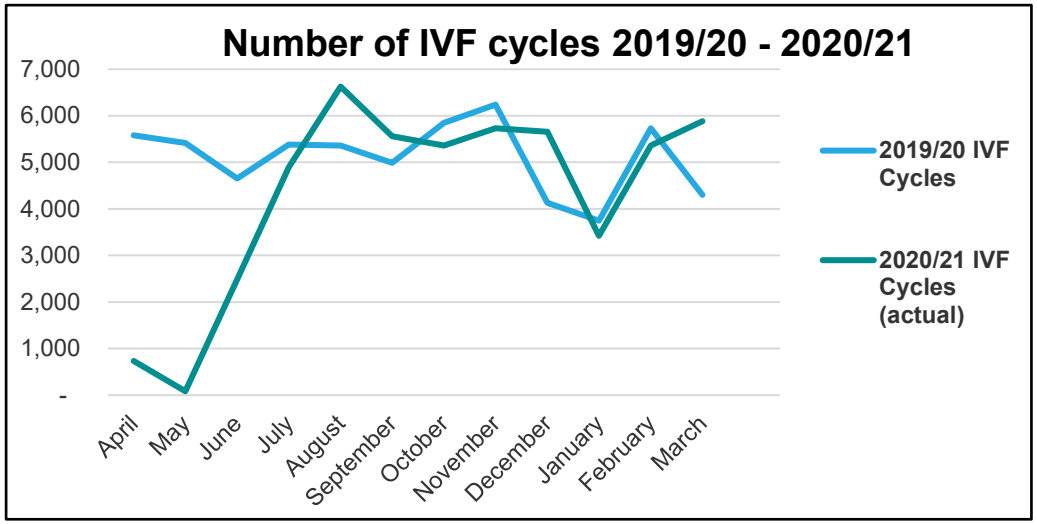
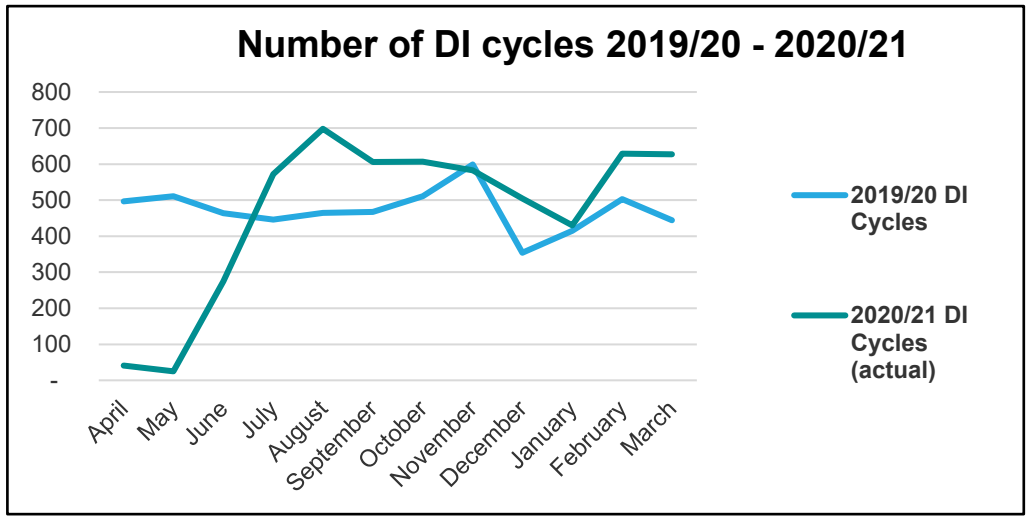
Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2019/20 IVF Cycles	61,386	4,910,880	61,386	4,910,880
2020/21 IVF Cycles (actual)	51,795	4,143,600	51,795	4,143,600
Variance	9,591	767,280	9,591	767,280

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2019/20 DI Cycles	5,676	212,850	5,676	212,850
2020/21 DI Cycles	5,598	209,925	5,598	209,925
Variance	78	2,925	78	2,925

The graph illustrates IVF treatment cycle activity over the current and previous financial year. Activity for 2020/21 is c.9,500 cycles (16%) lower than the same period (twelve months ended 31 March) in the 2019/20 financial year. Activity picked up towards the middle part of the year and ended with March 2021 figures exceeding the previous March. DI treatments ended the year lower (1%) than the 2019/20 business year. As with IVF, March volumes exceeded those of 2019/20.

To note - there is a discrepancy between the values above with the income in the management accounts. This is due to the ether calculation (the calculation we use to estimate missing treatments) which is conducted quarterly. The ether calculation makes assumptions around missing treatment forms and is not an exact science.

HFEA Income & Expenditure Mar-21

	Year to Date			
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %
Income				
Grant-in-aid	2,408	1,238	(1,170)	(95)
Non-cash (Ring-fenced RDEL)	510	510	0	0
Grant-in-aid - PCSPS contribution	100	100	0	0
Licence Fees	4,281	5,209	928	18
Interest received	1	10	9	91
Seconded and other income	147	144	(2)	-2
Total Income	7,447	7,211	(235)	-3
Revenue Costs				
Salaries (excluding Authority)	4,789	4,629	(159)	3
Staff Travel & Subsistence	4	161	156	(97)
Other Staff Costs	197	122	(75)	62
Authority & Other Committees costs	199	284	85	(30)
Facilities Costs incl non-cash	707	928	221	(24)
IT Costs	476	517	42	(8)
Legal / Professional Fees	210	387	177	(46)
Other Costs	124	184	60	(32)
Other Project Costs	23	-	(23)	
Total Revenue Costs	**6,729**	**7,212**	**483**	**(7)**
TOTAL Surplus / (Deficit)	**718**	**(1)**	**719**	
Adjusted for non-cash income/costs	**490**	**(1)**	**492**	

Management commentary

Income.
At 31 March 2021, our Licence fee income was 18% (£928k) lower than budget. This is an improvement on what was initially expected due to the restrictions that the COVID-19 Pandemic placed upon clinics. Overall our income is 3% (£235k) above budget and is in part due to the additional funding provided by DHSC.

Expenditure by exception.
Year to date we are underspent by £597k.
Salary costs - have ended the year over budget by £171k. This relates in total to expenditure on contract staff for PRISM which exceeded budget by £350k. Offsetting this overspend are underspends within staff salaries 37k, pension costs of £118k, NI contributions £23k.

Staff Travel and Subsistence - underspending by £161k due to significantly reduced site inspections and in person meetings.

Authority & Other Committee costs - underspend of £85k represented by underspends within Members fees, travel and venue costs due to remote working.

Facilities costs - underspent by £224k and include our non-cash costs of depreciation/amortisation which are under spent due to the delayed launch of PRISM. These costs are covered by Ring-fenced RDEL received from the DHSC. Provision has been made for rent costs for 2 Redman Place.

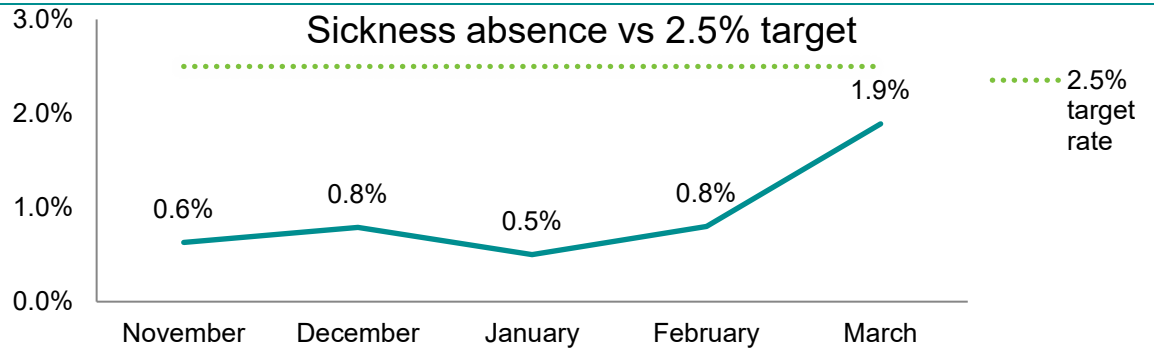
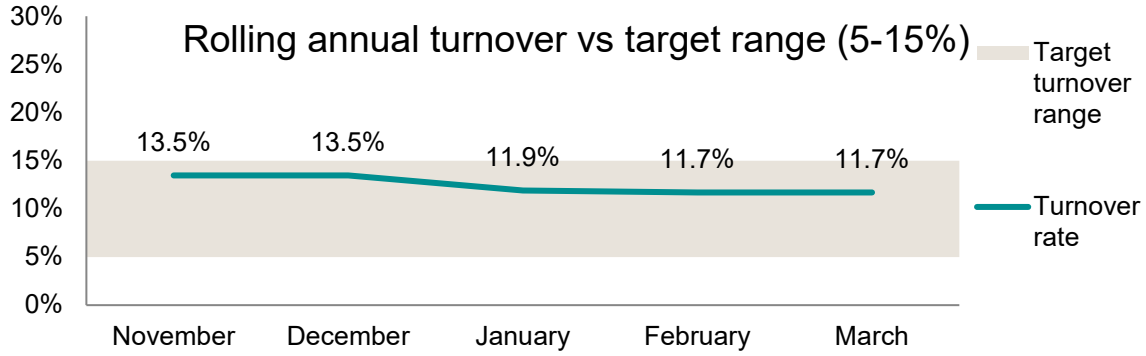
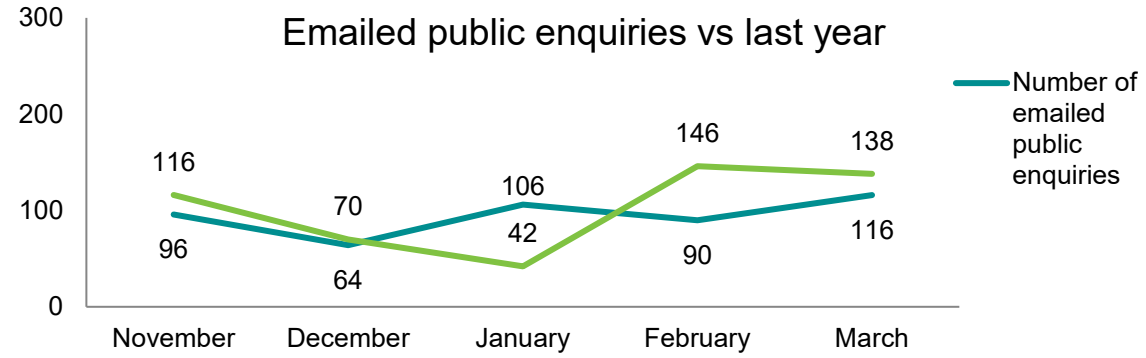
Legal/Professional Fees - under budget by £177k as a result of reduced legal activity.

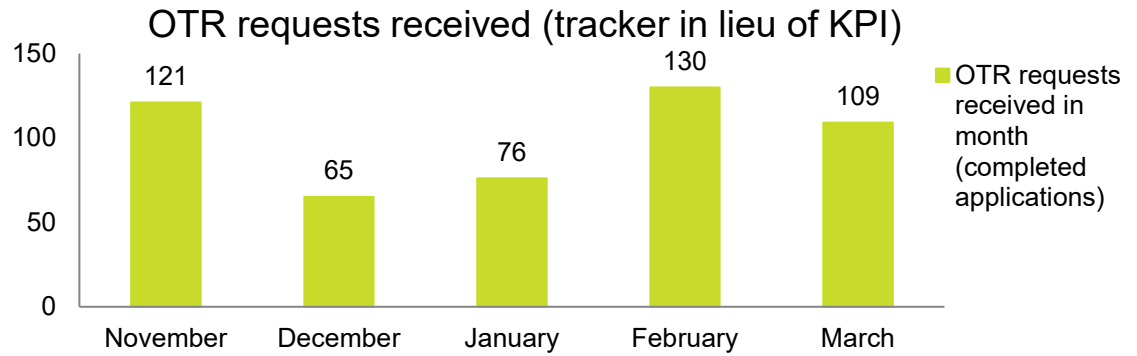
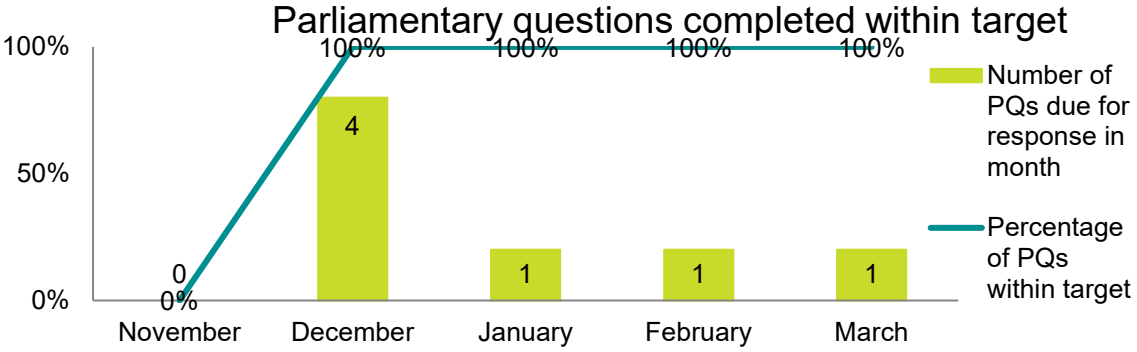
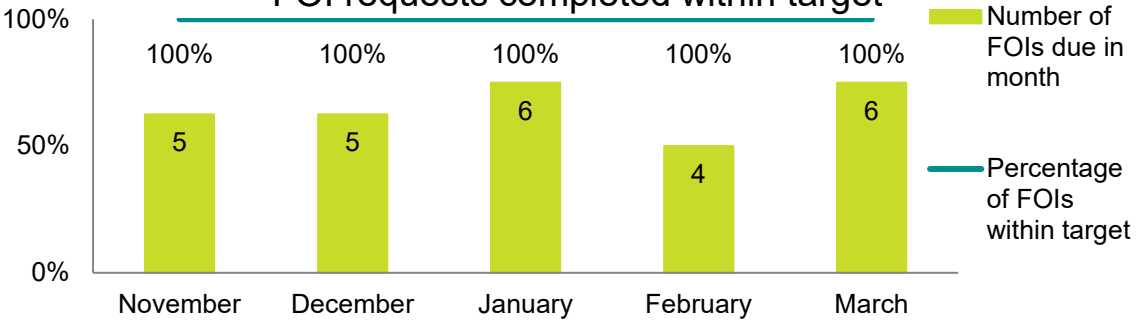
Other costs - are underspent by £68k. Most of these costs are within the Strategy and Corporate Affairs Directorate. Publications are underspent by £48k, Networking/Discretionary Training, Digital Comms are in total underspent by £75k.

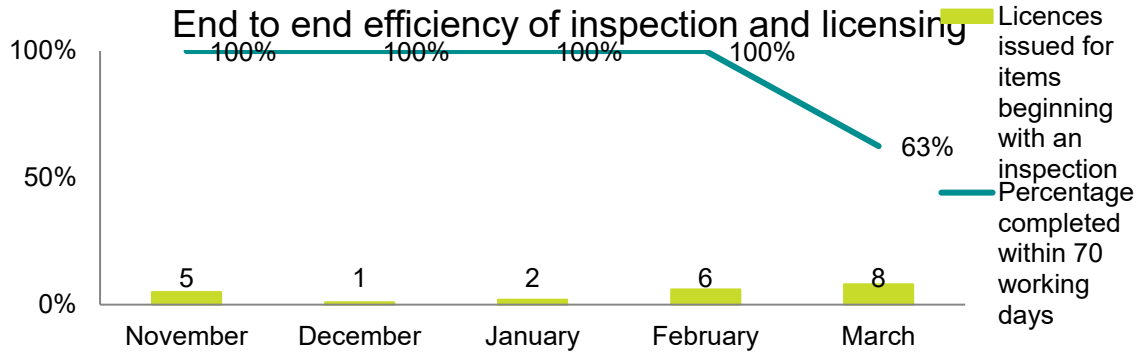
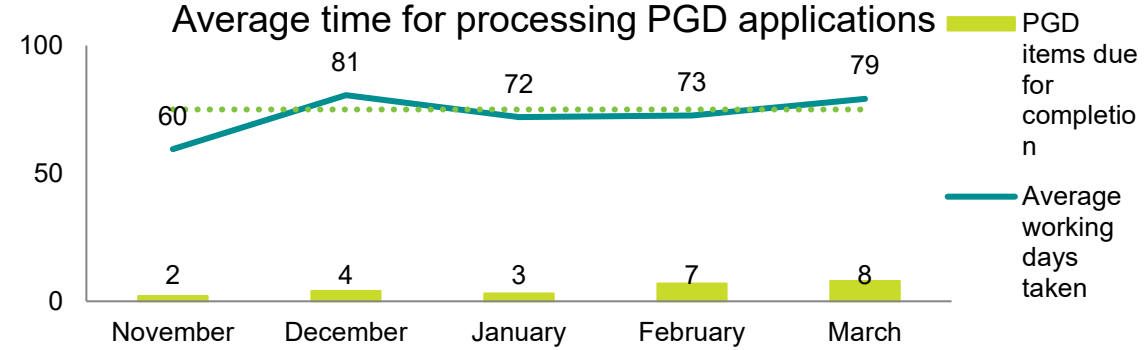
Other Project cots - this line represents the costs incurred for EU Transition which is funded by Grant in aid of £70k. Actual expenditure to date is £23k.

Outturn.
The final position before any audit adjustments is a surplus against budget of £718k which includes £228k ring fenced surplus resulting in a net surplus of £490k. This surplus is the result of higher income than anticipated, the legal budget spend was less than expected. Our IT spend appears to have come in close to budget and there are no additional charges (accruals) expected.

Annex 3 – Key performance indicators – Authority summary

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
HR1 – Sickness **Target**: less than or equal to 2.5%. Target is based upon ONS 2018 data (2.7% for the public sector)		Sickness absence is higher than normal due to one staff member suffering with long covid.	Green
HR2 - Turnover **Target**: between 5 and 15% turnover for the rolling year.		69 - Headcount 68 - Establishment (posts) We have an additional officer post in the Research team that is taking us above our budgeted headcount.	Green
Supplementary data - Public enquiries No target.			No target

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
R1 – Percentage of Opening the Register requests completed within 30 working day target. (excludes counselling time) **Target:** changed from 100% in 20wd to 95% in 30wd from April 2020. **Note: target not currently active.**		We are not currently reporting against a target this is now a tracker – as agreed at Authority October 2020. Monthly numbers remain much higher than average in previous years.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.			Green
RI2 - FOIs responded to within deadline **Target:** 100% within statutory deadlines.			Green

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
C1 - Efficiency of end-to-end inspection and licensing process. **Target:** 100% within 70 working days (wds). % processed in 70 working days, for items where minutes were sent in month. Measured from inspection date to date minutes sent.		Average working days: 55 Most days taken: 92 working days. Least days taken: 11 working days	Red
C3 – Average PGD processing **Target:** average processing time of 75 working days. Average number of working days taken for those due in month. Note: Target changed from 66 to 75 in April 2020.		Most days taken: 85 working days. Least days taken: 74 working days	Amber

Strategic risk register

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	7
Meeting date:	12 May 2021
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1 – strategic risk register 2020-2024

Output from this paper

For information or decision?	For information and comment.
Recommendation:	The Authority is asked to note and comment on the latest edition of the strategic risk register.
Resource implications:	In budget.
Implementation date:	Ongoing.
Communication(s):	The risk register is reviewed monthly by the Senior Management Team (SMT) and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 16 March and will review it again at its meeting on 22 June.
Organisational risk:	Medium.

1. Latest reviews

1.1. The strategic risk register is a live document and is reviewed on a monthly basis by SMT, with input from Heads as needed. SMT last reviewed all risks, controls and scores in the register at its meeting on 19 April.

1.2. The risk register was last discussed at AGC on 16 March. No changes were made to the risk scores at that time.

1.3. SMT and AGC's comments are summarised in the commentary for each risk and at the end of the register, which is attached at Annex 1.

1.4. One of the ten risks is above tolerance.

2. Revision of the C2 – board capability risk

2.1. AGC recommended that the board capability risk was reviewed and could potentially be recast, in the light of the current position on Board recruitment and also the related risks of turnover and knowledge loss in the Senior Management Team.

2.2. In response to this challenge, the C2 risk has been discussed with the Chair and reviewed by the Chief Executive with the Risk and Business Planning Manager. We recognise the points made by AGC and have reshaped this risk to also include risks associated with gaps at senior leadership level. Although these have different risk causes and implications, many of the mitigations are the same, as can be seen in this reframed risk.

2.3. We have also re-scored the risk to reflect the fact that we have not yet had confirmation from the Department about member reappointments. Should the three members whose first terms are due to expire in July not be reappointed, this would pose a significant problem to the management of certain committees. We also reflected upon members' concerns about executive leadership, noting areas where our controls could be strengthened, and this will be a key risk priority over the coming months, as we focus on ensuring we have specific, rigorous and ongoing controls.

2.4. We would be interested in members' views on this reframing of this risk, however, this is an initial revision and still very much a work in progress. We intend to bring a more detailed conversation about this risk back to Authority in September, at which point we can discuss particulars of the controls we are currently in the process of developing.

3. Future review of risk approach

3.1. It is good practice to confirm our organisational appetite for risk and our wider approach to risk management regularly. SMT and AGC last reviewed the organisation's risk appetite statement in June 2020, in the light of Covid-19. We last revised the wider organisational risk policy in late 2018. The related Internal Incidents process has been relaunched with staff in 2020 following Internal Audit. Since that time there have also been several contextual developments, including a revised edition of the government Orange Book guidance for risk management, which was updated in 2020. We have also launched our next strategy and had significant turnover in our Authority. This makes it a particularly good time to discuss risk appetite and our wider organisational approach to risk with members.

3.2. We want to both ensure our approach remains in line with best practice, and also, vitally, that it forms a clear basis for staff on the ground to manage risk and decision making effectively, at all levels of the organisation. To that end, we intend to bring the Risk Policy back to AGC at its October meeting, with a view to confirming the appetite statement with the Authority when the Risk Register next comes before you, in November. We would like to engage more with members on risk, so that this supports more effective delivery of the Authority's strategy.

3.3. We are already having conversations about key aspects of risk management we can strengthen, such as ensuring consistent scoring in practice across the organisation and assurance of controls and will reflect these during the review. The DHSC ALBs risk group, which has recently recommenced, and the cross-government risk improvement group will be useful sources of expertise to inform our approaches.

4. Recommendations

4.1. The Authority is asked to:

- note and comment on the latest edition of the strategic risk register, including the review of the C2 risk
- note the proposed approach to revising our risk management policy and risk approach.

Latest review date – 19/04/2021

Strategic risk register 2020-2024

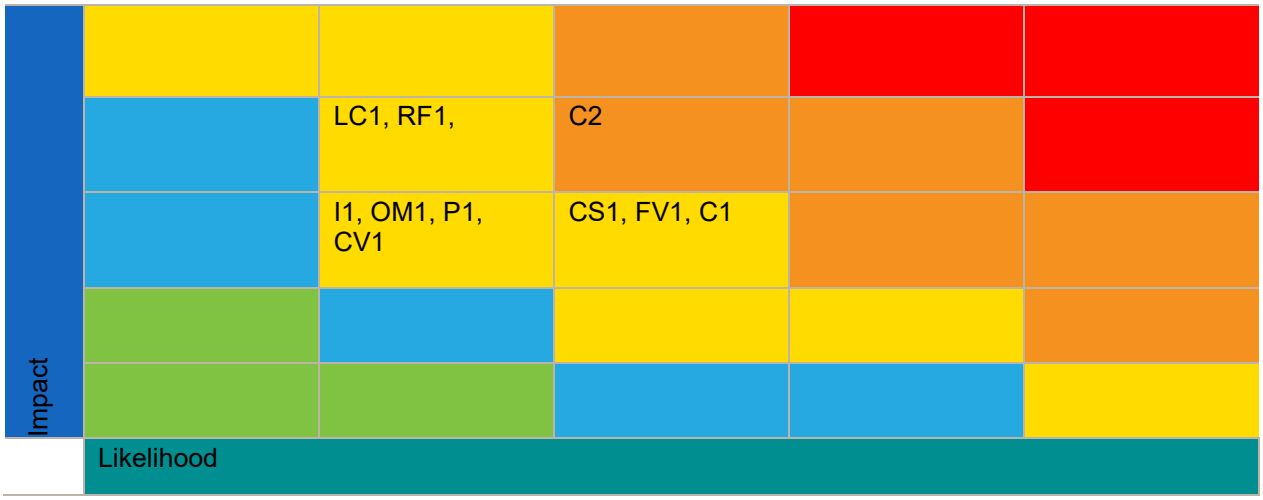
Risk summary: high to low residual risks

Risk ID	Strategy link	Residual risk	Status	Trend*
C2: Board capability	Generic risk – whole strategy	**12 - High**	Above tolerance	⇔⇩⇔⇧
FV1: Financial viability	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
C1: Capability	Generic risk – whole strategy	**9 – Medium**	Below tolerance	⇔⇔⇔⇔
RF1 – Regulatory framework	The best care (and whole strategy)	**8 - Medium**	At tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇔
OM1: Operating Model	Whole strategy	**6 – Medium**	Below tolerance	(New at 18 January SMT) - ⇩⇔⇔
I1 – Information provision	The right information	**6 - Medium**	Below tolerance	⇔⇔⇔⇔
P1 – Positioning and influencing	Shaping the future (and whole strategy)	**6 - Medium**	Below tolerance	⇔⇩⇔⇔
CV1 - Coronavirus	Whole strategy	**6 – Medium**	Below tolerance	⇔⇩⇔⇔

*This column tracks the four most recent reviews by AGC, SMT or the Authority (eg,⇧⇔⇩⇔).

Recent review points: SMT 18 January ⇨SMT 1 March⇨AGC 16 March⇨19 April SMT

Summary risk profile – residual risks plotted against each other:



RF1: There is a risk that the regulatory framework in which the HFEA operates is overtaken by developments and becomes not fit for purpose.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	5	15	**2**	**4**	**8 - Medium**
Tolerance threshold:					**8 - Medium**
Status: At tolerance					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Regulatory framework RF1: Responsive and safe regulation	Rachel Cutting, Director of Compliance and Information	The best care and whole strategy	⇔⇔⇔⇔

Commentary
As a regulator, we are by nature removed from the care and developments being offered in clinics and we must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research are safe and ethical. The result of not having an effective regulatory framework could be significant, the worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way. We reworked our inspection methodology as a result of Covid-19, to undertake remote and hybrid inspections to reduce risk, and this is bedding in as at spring 2021(reflected as a control under CV1 risk). Early insights suggest a higher resource requirement for these new processes, and we are keeping this under close review to ensure that it remains appropriate. SMT agreed in March 2021 that although this is a new source of risk for RF1, this does not yet suggest the overall risk had increased, but we will keep this under close review.

Causes / sources	**Controls**	**Timescale / owner of control(s)**
We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, the CMA in relation to pricing of treatments). We take external legal advice as relevant where developments are outside of our direct remit (eg, on an incidence of AI technology being used in the fertility sector) and utilise this to establish our legal/regulatory position. We are analysing where there are gaps in our regulatory powers so that we may be able to make	In progress - Clare Ettinghausen Ongoing - Catherine Drennan In progress - Laura Riley,

Causes / sources	Controls	Timescale / owner of control(s)
	a case for further powers if these are necessary, whenever these are next reviewed.	Joanne Anton, Catherine Drennan
We may have ineffective tools, systems, or regulatory interventions available which are too rigid and cannot be adapted to changes.	Regular review processes for all regulatory tools such as: • Code of Practice. • Compliance and enforcement policy (Final draft of revised policy signed off by Authority in March 2021 and coming into effect in June 2021) • Licensing SOPs and decision trees To enable us to revise these and prevent them from becoming ineffective or outdated.	In place, next update 2021 – Laura Riley, Joanne Anton In place but a revised version of the policy to be launched, subject to Authority agreement, in June 2021– Catherine Drennan, Rachel Cutting In place and review ongoing – Paula Robinson
The revised inspection approach (including fully remote and hybrid inspections due to Covid-19, introduced November 2020) may lead to greater resource requirements from inspection team, affecting ongoing delivery if this were to last for a sustained period. Note: risk cause arises from control under CV1.	Reviewing the new way of working and inspection approach as this continues to be embedded. Compliance management in discussion with the wider Inspection team to ensure that scrutiny is at the correct level and inspections are 'right sized' in accordance with revised methodology. Clear communication to the inspection team about appropriate level of scrutiny.	In progress – Sharon Fensome Rimmer, Rachel Cutting
Change may be too fast for us to adequately respond to if we do not understand the nature of the changes arising. Resulting in us being under-prepared or taking an insufficiently nuanced approach.	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by: • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily have to wait for some changes to be clearer in order to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing	In place – Laura Riley, Joanne Anton In place - Peter Thompson

Causes / sources	Controls	Timescale / owner of control(s)
	quick responses such as a Chair's letter, Alert or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.	
We may focus on 'pet projects' or ephemeral interests, being influenced by personal preferences or biases.	Strategic aims have been clearly articulated; all projects must be aligned to these aims to ensure that our work is focused on delivering these objectives. We ensure this by consideration at Corporate Management Group.	Ongoing – Peter Thompson
We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.	Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions. Any reprioritisation of significant Strategy work would be discussed with the Authority.	In place – Peter Thompson
We may have a lack of staffing expertise or capability in the areas developments occur in.	As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff. If a specific skills gap was identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporarily or sharing skills with other organisations.	Ongoing - Relevant Head/Director with Yvonne Akinmodun
If RITA (the register information team app – used to review submissions to the Register) is not completed in a timely way, we may not effectively use data and ensure our regulatory actions are based on the best and most current information.	Launch date of PRISM delayed due to Covid-19. Rescheduling of RITA development occurred to take advantage of this delay. Development has been split into phase 1 (essential) and phase 2 (nice-to-have). It is expected that essential phase 1 RITA development (relating to functionality to support the OTR and Register teams) will be complete before the team need to support a fully launched PRISM. If RITA is not completed in a timely way, the Register and OTR team will still be able to use manual workarounds to get access to the information they need to support clinics and / or to provide information to support our regulatory work. although these workarounds will result in a substantial delay to responding to an OTR or providing clinic support. If additional development work is required to complete RITA phase 1 development in a timely way, we will consider options for providing the necessary resource. However, this control may impact on our ability to support or develop other internal applications.	Plans in place – Dan Howard Ongoing – Dan Howard Under review as delivery continues - Dan

Causes / sources	Controls	Timescale / owner of control(s)
We may not have all the right data from the sector (from inspections or the Register) to make informed interventions, for instance on add-ons.	As part of planning and delivering the add-ons project we will look at the evidence available and consider whether we can access other information if we do not have this already. Revising our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool). Process to be established for reviewing data on the Register and adding fields when required.	In place - Laura Riley Audit tool launched in clinics from Autumn 2020 - Rachel Cutting Within 2021/2022 business year - Dan Howard
We may face barriers to adding fields to the Register, preventing us from collecting the right data to reflect changes in the sector. This might reduce the evidence available to inform regulatory interventions and maintain patient safety as the sector changes.	Process to be established for reviewing data on the Register and adding fields when required.	2021/2022 business year - Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson

I1: There is a risk that HFEA becomes an ineffective information provider, jeopardising our ability to improve quality of care and make the right information available to people.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	3	12 - High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**8 - Medium**
Status: **Below tolerance**					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Information provision I1: delivering data and knowledge	Clare Ettinghausen, Director of Strategy and Corporate Affairs	The right information	⇔⇔⇔⇔

Commentary
Information provision is a key part of our statutory duties and is fundamental to us being able to regulate effectively. We provide information to the public, patients, partners, donors, the donor conceived, their families and clinics alike. If we are not seen as relevant then we risk our information not being used, which in turn may affect the quality of care, outcomes and options available to those involved in treatment. In October 2020, the Opening the Register service reopened after being paused since clinics shut down due to Covid-19. Due to this pause, we received an influx of applications which means we are unable to meet our usual KPI for completing responses for a period. We are managing this carefully as a live issue, to ensure that applicants receive accurate data and effective support as quickly as we are able, with a focus on continuing to provide a quality, effective service. Ongoing communication with applicants and centres has been clear, to ensure they understand, and we manage expectations. We have recruited extra resource to manage the backlog but the impact of this will take some time to resolve the issue and reduce the ongoing risk.

Causes / sources	**Controls**	**Status / timescale / owner**
People don't find us/our information, meaning we are unable to get clear and unbiased information to patients, donors and others.	Knowledge of key searches and work to improve search engine optimisation to ensure that we will be found. We have a rolling bi-annual cycle to review website content and can revise website content to ensure this is optimised for search if necessary. We undertake activities to raise awareness of our information, such as using social and traditional media. We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us.	In place and ongoing - Jo Triggs

Causes / sources	Controls	Status / timescale / owner
We aren't in the places that people look for information meaning they do not find us. In some cases, this is because we have decided not to be, for instance on some social media platforms.	We are developing relationships with key influencers to ensure that we have an indirect presence on social media or forums.	In place and ongoing - Jo Triggs
We do not have effective relationships with key strategic stakeholders.	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	Early work done but development needed, future control – Clare Ettinghausen Ongoing – Paula Robinson
We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites andclinics post their own data.	Monitoring of clinic websites at the renewal inspection point to ensure that the data there is accurate and in line with guidance. A review of all centre websites undertaken during summer 2020. Ensure we maximise the information on our website and the unique features of our clinic inspection information and patient ratings. Clinics are encouraged to ask patients to use the HFEA patient rating system. We have optimised Choose a Fertility Clinic so that it is one of the top sites that patients will find when searching online.	In place and all clinic websites reviewed during summer 2020 - Rachel Cutting, Sharon Fensome Rimmer In place and ongoing - Jo Triggs
We are currently working off a snapshot of the Register and our access to live Register data is restricted. This will continue until the new Register goes live and we implement new data tools and a reporting database. This may hamper our ability to provide the right data in a timely way when responding to ad-hoc requests.	A reporting version of the Register was captured in December to enable us to do planned reporting such as the trends report, meaning there will be no impact on such standing information provision. For other requests, such as ad hoc FOIs and PQs, we also use this snapshot but there is a risk that we could receive a question about a variable that is not included in the snapshot. This would require assistance from a key staff member in the Register team and may not be possible at short notice. The implementation of these new tools and systems will be prioritised, to ensure that impact and this interim period is minimised. Teams, such as the Inspectorate, have backup plans for the gap between cutover and when the	Register snapshot captured December 2020. Understanding of potential need for cross team support in place and ongoing – Nora Cooke O'Dowd Prioritised as part of Information team delivery – Dan Howard In place - Dan Howard,

Causes / sources	Controls	Status / timescale / owner
	new register feeds into existing systems or processes (inspectors' notebooks, RBAT, QSUM etc.) to ensure relevant data is available.	Sharon Fensome-Rimmer
There is a risk that Choose a Fertility Clinic stops delivering on its unique selling point, to be a source of independent, timely, accurate information to inform patient's treatment choices, if we are unable to update it from the new Register, or provide the information in an alternative manner.	We updated the data available on CaFC ahead of the Register migration, to ensure that 2019 treatment data can be accessed, bringing this up to date. This will delay CaFC becoming out of date. Ongoing controls need to be agreed, but early conversations are underway about next steps and approaches we may take, so that we can plan any control activities into business plans for 2021-2022 as needed.	Completed February 2021 – Dan Howard Discussions about future mitigation plans underway – Peter Thompson
There are gaps in key strategic information flows on our website, for instance after treatment, resulting in missed opportunities to share information.	Digital Communications Board with membership from across the organisation in place to discuss information available and identify any gaps and what to do to fill these.	In place and ongoing - Jo Triggs
We may not signpost effectively elsewhere resulting in us trying to reinvent the wheel and stepping on other organisation's toes rather than making targeted use of our resources.	We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Links to other specialist organisations in place as relevant on the website (ie, Fertility Network UK, BICA, BFS, Endometriosis UK etc).	In place and ongoing - Jo Triggs
We may provide too much information, leading to information overload and lack of clarity about what information we provide and how.	Regular review cycle for website ensures that the information provided is relevant.	In place and ongoing - Jo Triggs
We may provide inaccurate information to the media or public enquiries. Though we have well established and effective working practices and controls, we must continue to be aware of and mitigate this risk.	Regular communication between relevant teams. Information provided in enquiries is checked within teams and by legal or at a more senior level if needed. Briefings when key reports etc are issued to ensure others know the key issues, statistics etc.	In place and ongoing - Jo Triggs, Joanne Anton In place and ongoing – Nora Cooke O'Dowd
Given the advent of increased DNA testing, we no longer hold all the keys on donor data (via our Opening the Register (OTR) service). Donors and donor conceived offspring may not	Maintain links with donor organisations to mutually signpost information and increase the chance that this will be available to those in this situation. Maintain links with DNA testing organisations to ensure that they provide information to those using	In place and ongoing - Jo Triggs In place and ongoing - Laura Riley

Causes / sources	Controls	Status / timescale / owner
have the information they need to deal with this.	direct to consumer tests about the possible implications.	
Our OTR workload will increase and change in 2021/2023 (when children born after donor anonymity was lifted begin to turn 16 and 18) and we may lack the capability to deal sensitivity with donor issues.	Plans to undertake service redesign work to review resourcing and other requirements for OTR to ensure these are fit for purpose.	Future control – scoping started in Q4 2020/2021 - Dan Howard
The OTR service may be negatively impacted by an influx of applications following reopening after being paused, with demand outstripping our ability to respond. Note, this is being managed as a live issue as at April 2021.	Our focus is on accuracy and effective support for applicants; therefore, we have temporarily ceased reporting against our usual KPI, during the period of dealing with this pent-up demand. We are continuing to clearly communicate with applicants and the sector to manage expectations. We have recruited additional temporary resource to manage demand.	New starter being trained from April 2021 – Dan Howard
Ineffective media management may mean we don't correct incorrect information available elsewhere or signpost our own.	Media monitoring service in place that is checked daily to identify items where a decision should be taken about need to correct information or not. We review the contract for our media monitoring service annually to ensure that it is fit for purpose. We would choose an alternate provider if this was not working effectively. Relationship with the media ensures that we are asked for comment and that we have internal processes in place to provide the comment in an effective way.	In place and ongoing - Jo Triggs Jo Triggs – Last reviewed January 2020 (in advance for the 2020-2021 year) In place - Jo Triggs
Risk that key regulatory information will be missed if Clinic focus, Clinic Portal or emails are not being read.	There is a statutory duty for PRs to stay abreast of updates. We duplicate essential communications by also sending via email to the centres' PR and LH (for instance, all Covid-19 correspondence). We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance when they need it regardless of additional communicated updates. We plan to implement a formal annual catch-up between clinics and an inspector. Note: that due to revised inspection approach due to Covid-19 these plans have been delayed.	In place – Rachel Cutting In place – Laura Riley, Joanne Anton Future control to consider following Covid-19 – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making.	Review of inspection reports is underway to identify future improvements to inspection reports.	Early work underway, but likely to complete late-

Causes / sources	Controls	Status / timescale / owner
	We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.	2021 – Rachel cutting In place – Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None.		

P1: There is a risk that we don't position ourselves effectively and so cannot influence and regulate optimally for current and future needs.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**2**	**3**	**6- Medium**
Tolerance threshold:					**9 - Medium**
Status: Below tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Positioning and influencing P1: strategic reach and influence	Clare Ettinghausen – Director of Strategy and Corporate Affairs	Shaping the future and whole strategy	⇔⇩⇔⇔

Commentary
This risk is about us being in a position to influence effectively to achieve our strategic aims. If we do not ensure we are, we may not be involved in key debates and developments, others will not present the HFEA perspective, meaning we may be voiceless, or our strategic impact may be limited. Discussions occurred with the Authority in January 2021 about our ongoing communications approach, including the 30th anniversary of the HFEA. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions. The response to the Covid-19 pandemic has required close working with many other organisations and professional bodies, as well as increased engagement with the sector, which has strengthened our strategic positioning and reduced the likelihood of this risk. Consequently, SMT reduced the risk score in March 2021.

Causes / sources	Controls	Status/timescale / owner
We may not engage widely enough or have the contacts and reach we need to undertake key work, meaning aspects of the strategy are too big to complete within our resources.	Ensure a stakeholder engagement plan is agreed and revisited frequently. Note: revised stakeholder plans will need to be agreed with our new Chair from April 2021. Stakeholder identification undertaken for all projects to ensure that these are clear from the outset of planning, and that we can plan communications, involvement and if necessary, consultations, appropriately.	Early work done further discussions with Authority planned– Clare Ettinghausen In place - Paula Robinson

Causes / sources	Controls	Status/timescale / owner
We may be unable to persuade partner organisations to utilise their powers/influence/resources to achieve shared aims.	Early engagement with such organisations, to build on shared interests and reduce the likelihood of this becoming an issue. For instance, the treatment add-ons working group.	In place - Clare Ettinghausen
The sector may disagree with HFEA about key strategic terms and principles, such as 'ethical care' creating negative publicity for us and reputational damage.	We have clearly communicated our intentions, to ensure that these are not misunderstood or misinterpreted and will continue to engage with our established stakeholder groups.	In place - Clare Ettinghausen
The sector may take a different view on the evidence HFEA provides in relation to Add-ons and so we may be ignored.	The working group for the add-ons project will focus on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed. SCAAC sharing evidence it receives and having an open dialogue with the sector on add-ons.	Ongoing - Laura Riley
In relation to changes, HFEA and sector interests may be in conflict, damaging our reputation. This may particularly be the case in relation to Covid-19 and the use and removal of General Directions 0014 (GD0014).	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible. Framework for decision making around removing GD0014 drawn up following Authority discussion.	In place - Peter Thompson In place – Rachel Cutting
We may not engage with early adopters or initiators of new treatments/innovations or changes in the sector.	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these. We plan to investigate holding an annual meeting with key innovators (in industry) in the future.	In place - Laura Riley/Joanne Anton In place - Laura Riley/Joanne Anton In place and ongoing – Sharon Fensome-Rimmer Future control, delayed due to Covid-19 but to be reviewed in Q3/4 2021/2022 - Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: The Department may not consider future HFEA regulatory interests or requirements when	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation.	Ongoing - Peter Thompson

Causes / sources	Controls	Status/timescale / owner
planning for any future consideration of relevant legislation which could compromise the future regulatory regime.	Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Completed - Joanne Anton
Government: Any consideration of the future legislative landscape may become politicised.	There are no preventative controls for this, however, clear and balanced messaging between us, the department and ministers may reduce the impact. Develop improved relationships with MPs and Peers to ensure our views and expertise are taken into account.	Ongoing - Peter Thompson
Government: Consideration of changes to the regulatory framework may be affected by political turbulence (for instance changes of Minister).	There are no preventative controls for this, however, we will ensure that we are prepared to effectively brief any future incumbents to reduce turbulence. We would also do any horizon scanning as the political landscape changed if needed.	Ongoing - Peter Thompson

FV1: There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16–High	**3**	**3**	**9– Medium**
Tolerance threshold:					**9 - Medium**
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Financial viability FV1: Income and expenditure	Richard Sydee, Director of Finance and Resources	Whole strategy	⇔⇔⇔⇔

Commentary
Covid-19 and the implementation of GD0014 caused reduced treatment activity during 2020-2021 meaning this risk became a live issue, although we were given assurance of cover by the Department. Close monitoring of treatments and fee income throughout the January – March 2021 lockdown, and projections for the current 2021-2022 financial year, suggest that the risk related to reduced fee income is smaller for the year ahead and we would be able to support ourselves from reserves if fees were below our projections. We have also had confirmation of our budget from the Department of Health and Social Care, which provides greater certainty. SMT agreed that this did not make a fundamental difference to the score as at April. An initial options appraisal for a fee review project was agreed with Authority in June 2020. A consultation and modelling for the new income model will follow but owing to the impact of Covid-19 there is now some uncertainty around the timing of this work. Discussions are ongoing with the Department. This review, when it occurs, should ensure that the income model is fit for purpose and reflects the changing nature of sector activity, and set the HFEA up for the future.

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending. This is a live issue as we have reduced income for as long as GD0014 (version 2) is in place, however it is a smaller risk than at the height of the pandemic. Although clinics have reopened it will take some time for activity to return to 'normal' levels.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC.	CMG monthly and Authority when required – Peter Thompson Paused due to impact of pandemic on fee income and activity levels Planning underway – Peter

Causes / sources	Controls	Timescale / owner
	We plan to undertake a fee review project (timing TBC) to ensure that the income model is fit for purpose and reflects the changing nature of sector activity. We are discussing with the Authority and Department of Health and Social Care how this will be taken forward	Thompson and Richard Sydee
Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles. As at April 2021 we have reduced income due to the deployment of GD0014 in response to Covid-19 and the subsequent reopening of the sector.	Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in October 2020. If clinics were not able to submit data and could not be invoiced for more than three months, we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.	Given the Covid-19 related drop in income, we have actively employed this control – Richard Sydee Control under quarterly review as sector reopens – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work. Note: PRISM delivery has now been delayed into 2021/2022 which will have a financial impact.	The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact. Ongoing monitoring and reporting against control totals to ensure we do not overspend. Funding was received from the Department to complete the PRISM programme. Careful consideration of ongoing cost implications of PRISM delays for 2021/2022 and discussion of approach and risk management with AGC. Additional financial cover was agreed with the Department in 2021-2022 to help cover the costs of extended delivery.	In place – Richard Sydee Ongoing, – Richard Sydee Ongoing – Richard Sydee
The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs.	Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use. The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust	Ongoing but we await confirmation of overarching procurement arrangements from central

Causes / sources	Controls	Timescale / owner
The Finance and procurement strand of the project has been delayed; we await final estimates of the cost to HFEA, though have been assured that calculations have been completed. Note: As at April 2021, although this is not yet finalised, it looks likely that the new office will be cheaper. Costs are being mapped for the next financial year.	other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed. The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens. All provided cost estimates to date suggest a material reduction in the operating costs of Redman Place when compared to Spring Gardens.	programme - Richard Sydee We await a final MOTO from DHSC which is anticipated in May 2022
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Finance staff member present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Samuel Akinwonmi
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Covid-19 impacts on HFEA income.	The final contingency for all our financial risks is to seek additional cash and/or funding from the DHSC and we are in ongoing discussions with the Department about this issue for the 2021/2022	Ongoing - Richard Sydee

Causes / sources	Controls	Timescale / owner
	business year having received confirmation from them for cover in 2020/2021.	
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to appropriate contingency level available at this point in the financial year. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model. Annual budget has been agreed with DHSC Finance team. GIA funding has been agreed through to 2021.	Quarterly accountability meetings (on-going) – Richard Sydee December/January annually, – Richard Sydee

C1: There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**3**	**9- Medium**
Tolerance threshold:					**12 - High**
Status: Below tolerance.					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Capability C1: Knowledge and capability	Peter Thompson, Chief Executive	Whole strategy	⇔⇔⇔⇔

Commentary
This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity. As at April 2021, turnover continues to be low (this was 12.2% in 2019-2020 and has remained broadly at this level). Recruitment, where it has been required, has been successfully undertaken throughout the Covid-19 pandemic, with effective remote onboarding of new starters. AGC receive 6-monthly updates on capability risks to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations. Unfortunately, this work has not progressed further due to Covid-19, although conversations about such development opportunities continue on an individual level. Management of Board and senior executive capability is captured in the separate C2 risk, below.

Causes / sources	**Mitigations**	**Status/Timescale / owner**
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps. Note: this is a more acute risk for our smaller teams.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Yvonne Akinmodun and

Causes / sources	Mitigations	Status/Timescale / owner
	CMG and managers prioritise work appropriately when workload peaks arise. Contingency: In the event of knowledge gaps, we would consider alternative resources such as using agency staff, or support from other organisations, if appropriate.	relevant managers In place – Peter Thompson In place – Relevant Director alongside managers
Poor morale could lead to staff leaving, opening up capability gaps.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of concern. Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.	In place, ongoing – Peter Thompson In place – Jo Triggs In place, staff survey undertaken June 2020 – Yvonne Akinmodun In place and review planned in 2021 - Peter Thompson
Work unexpectedly arises or increases for which we do not have relevant capabilities.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings. Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year. Oversight of projects by both the monthly Programme Board and CMG meetings. Review of project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources. Planning and prioritising data submission project delivery, within our limited resources. Skills matrix being circulated for completion by teams in 2021/2022 to enable better oversight of	In place – Paula Robinson In place – Paula Robinson In place – Paula Robinson Ongoing review in progress 2021-2022– Paula Robinson In place until project ends – Dan Howard

Causes / sources	Mitigations	Status/Timescale / owner
	organisational skills mix and deployment of resource.	In progress – Yvonne Akinmodun
Possible capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working may not be realised.	Active engagement with other organisations early on and ongoing. We are collaborating with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely, including a mentorship programme. **Note**: delayed due to Covid-19 impacts.	Early progress, ongoing – Yvonne Akinmodun
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU may have ongoing consequences for the HFEA which we would have to manage	Since December 2018, we have run an EU exit project to ensure that we have fully considered implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU. We have progressed this project through the transition period and now beyond. We continue to engage with clinics on the impacts. Authority and AGC are updated at their meetings, as appropriate. We continue to work closely across the HFEA and with the DHSC to ensure we are prepared for any further consequences of the UK leaving the EU. This includes implementing the Northern Ireland Protocol as it applies to HFEA activity across the UK.	Communications ongoing – Clare Ettinghausen/Andy Leonard
In-common risk Covid-19 (Coronavirus) may lead to high levels of staff absence leading to capability gaps or a need to redeploy staff.	Management discussion of situation as it emerges, to ensure a responsive approach to any developments. We have reviewed our business continuity plan to ensure it is fit for purpose.	Ongoing with Business continuity plan reviewed at CMG in April 2021- Peter Thompson

C2: Loss of senior leadership (whether at Board or Management level) leads to a loss of knowledge and capability which may impact formal decision-making and strategic delivery.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16- High	**3**	**4**	**12- High**
Tolerance threshold:					**4 - Low**
Status: **At tolerance**					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Estates C2: Board capability	Peter Thompson Chief Executive	Whole strategy.	⇔⇩⇔⇧

Commentary
In April 2021, the Chief Executive and Risk and Business Planning Manager reframed this risk following discussion with AGC, SMT and the Chair. This risk has been amended to now reflect both the risks related to both Board and senior executive leadership. Although the causes and impacts are different, many of the mitigations are similar, and both would have an impact on the organisation's external engagement and potentially strategic delivery. The HFEA board is unusual as members undertake quasi-judicial decision-making as part of their roles, sitting on licensing and other committees. This means that changes in Board capability and capacity may impact the legal functions of the Authority. We need to maintain sufficient members with sufficient experience to take what can be highly controversial decisions in a robust manner. As such our tolerance threshold for this risk is low. The score of this risk was reduced in March 2021 to reflect the positive effect of appointments made and the extension of key members' terms until the end of the year which provides some continuity. However, we have reviewed the overall risk score in the light to two recent developments. First, three members' first terms are due to end over summer 2021 and failure to reappoint could pose particular risks in key committees. Second, the inclusion of senior executive risks. Taken together, we have raised the overall risk. We are actively discussing controls, for instance we are in discussion with the DHSC about the reappointment of the three members and the recruitment campaign that will be needed to replace the further five members at the end of the year. Board Capability has been a key early discussion with our new Chair and proposals are with the DHSC to manage upcoming membership terms.

Causes / sources	**Mitigations**	**Status/timescale / owner**
A precipitous reduction in available members (due to member terms ending) would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and	Membership of licensing committees has been actively managed to ensure that formal decision-making can continue unimpeded by the recent board vacancies. However, there is no guarantee that this would be possible for future vacancies, especially if there were several at once and	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
research centres and authorise treatment for serious inherited illnesses.	bearing in mind that a lay/professional balance must be maintained for some committees. This is being actively discussed for upcoming possible vacancies.	
The loss of a member of the senior leadership team (for instance through retirement, leaving the organisation for a new role etc) creates a leadership/knowledge gap.	Note: We cannot mitigate the cause of this risk, since staff may choose to leave the organisation for personal reasons. However, we can mitigate the consequences. Responsibilities could be shared across SMT and Heads to cover any gaps and maintain leadership, decision-making and oversight (this would include Chairing ELP which may be delegated under Standing Orders). Good induction process to ensure that new staff are onboarded efficiently. Effective use of delegation, to build capability of less senior staff, to enable them to step up in the case of senior staff absences (either temporarily or to apply for the role permanently in the case of staff leaving). Chief Executive would discuss recommendations for cover with the Chair if he were to move on from the organisation, to ensure that responsibilities were covered during any gap before appointment. Other controls (handover, knowledge capture, processes etc) per the wider staff turnover risk above. More explicit succession planning is being considered but must be balanced with a free and fair recruitment process. Clear, documented plans to enable more straightforward management of such a situation when it occurs.	In place – Peter Thompson In place - Yvonne Akinmodun with relevant Manager for specific role In place – Relevant Director alongside managers As required – Director and staff as relevant As required – Peter Thompson, Julia Chain Future control – in discussion – Peter Thompson Future control – in discussion – Peter Thompson
Any member recruitment may take some time and therefore give rise to further vacancies and capability gaps. The recruitment process is run by DHSC meaning we have limited power to influence this risk source.	In January 2021, recruitment was successful for four Board posts. We are now focussing on streamlining induction to ensure that Members are brought up to speed as quickly as practicable (see risks below). This risk cause remains for future recruitment and we remain in discussion on the ongoing management of this.	Underway- Peter Thompson

Causes / sources	Mitigations	Status/timescale / owner
Historically, decisions on appointments have taken some time which may create additional challenges for planning (the annual report from the commission for public appointments suggests appointments take on average five months).		
Recruitment to SMT or Head post may take some time which could create a leadership gap.	Heads could temporarily act up into Director roles to manage any pre-recruitment gaps. The same would be true of manager level staff acting up for Heads.	In place, discussed as required – relevant Manager with Yvonne Akinmodun
Several current Board members are on their second terms in office, which expire within the same period (from summer 2021).	We are discussing options with the Department for managing the cycle of appointments, in order to reduce the ongoing impact of this. The targeted extension of some members extends the proximity of this issue somewhat.	In progress, ongoing - Peter Thompson
The induction time of new members (including bespoke legal training), particularly those sitting on licensing committees, may lead to a loss of collective knowledge and potentially an impact on the quality of decision-making. Evidence from current members suggests that it may take up to a year for members to feel fully confident.	The Governance team has reviewed recruitment information and member induction to ensure that this is as smooth as possible. Targeted extensions, noted above, should bridge this period of learning and therefore support new members.	In place and ongoing - Paula Robinson
Induction of new members to licensing and other committees, will require a significant amount of internal staff resource and could reduce the ability of the governance and other teams to support effective decision-making.	We have been mindful of this resource requirement when planning other work, in order to limit the impact of induction on other priorities.	In progress, - Peter Thompson, Paula Robinson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Status/timescale / owner**
Government/DHSC The Department is responsible for our Board recruitment but is	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

Causes / sources	Mitigations	Status/timescale / owner
bound by Cabinet Office guidelines.		
Government/DHSC DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA Board recruitment, it will be breaching its own legal responsibilities.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson
Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. This may impact any planned approach and risk mitigations and give rise to further risk.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

CS1: There is a risk that the HFEA is subject to a cyber-attack, resulting in data or sensitive information being compromised, or IT services being unavailable.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**
Status: At tolerance					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Cyber security CS1: Security and infrastructure weaknesses	Rachel Cutting Director of Compliance and Information	Whole strategy	⇔⇔⇔⇔

Commentary
Cyber-attacks and threats are inherently very likely. Our approach to handling these risks effectively includes ensuring we: • have an accurate awareness of our exposure to cyber risk • have the right capability and resource to handle it • undertake independent review and testing • are effectively prepared for a cyber security incident • have external connections in place to learn from others. We continue to assess and review the level of national cyber security risk and act as necessary to ensure our security controls are robust and are working effectively. Delays to PRISM delivery necessitate the continued use of EDI in clinics. Many clinics use older server technology to run our EDI gateway within their clinic or organisation resulting in an increased cyber risk while that technology is in use. Many have upgraded their infrastructure to reduce the likelihood of a cyber incident. The related cyber risk concerns an attack on the clinic's infrastructure – all have local logical and physical security controls in place. All submission data via EDI is encrypted in transit. We continue to work with clinics to support the upgrade of their server infrastructure.

Causes / sources	**Controls**	**Timescale / owner**
Insufficient board oversight of cyber security risks, resulting in them not being managed effectively.	Routine cyber risk management delegated from Authority to Audit and Governance Committee which receives reports at each meeting on cyber-security and associated internal audit reports to assure the Authority that the internal approach is appropriate and ensure they are aware of the organisation's exposure to cyber risk. The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual	In place – Dan Howard In place - Peter Thompson

Causes / sources	Controls	Timescale / owner
	and perceived cyber risks. These would be discussed with the wider board if necessary. Annual cyber security training in place to ensure that Authority are appropriately aware of cyber risks and responsibilities.	Last undertaken January 2020. We are continuing to investigate cyber security courses to identify the most appropriate one for Authority members. – Dan Howard
Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively	Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. We undertake independent review and test our cyber controls, to assure us that these are appropriate. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact. Additional online Business Continuity training for Business Continuity Group.	Undertaken by staff October/November 2020 – Dan Howard Update agreed at CMG in June 2020– Dan Howard In place, review occurred January 2021 – Dan Howard In place, CMG considered this in April 2021 – Dan Howard To be rolled out by end May 2021 – Dan Howard
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security. Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable.	Testing is undertaken regularly, last completed in January 2021 – Dan Howard In place – Dan Howard

Causes / sources	Controls	Timescale / owner
The IT support function may not provide us with the cyber security resource that we need (ie, emergency support in the case of dealing with attacks)	We have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason.	Contract in place until June 2021. We expect to take the option to extend this until June 2023 – Dan Howard
We may not effectively mitigate emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations to learn from others in relation to cyber risk.	Ongoing (such as ALB CIO network and Cyber Associates Network) – Dan Howard
We may have technical or system weaknesses which could lead to loss of, or inability to access, sensitive data, including the Register.	We undertake regular penetration testing to identify weaknesses so that we can address these. We have advanced threat protection in place to identify and effectively handle threats. Our third-party IT supplier undertakes daily checks on our server infrastructure to monitor for any errors and to monitor for any security issues or increased threats. We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software. We regularly review and if necessary, upgrade software to improve security controls for telephony	Ongoing, last test took place in January 2021 – Dan Howard In place – Dan Howard In place – Dan Howard Ongoing (Upgrade to Pulse RAS system completed during 2020) – Dan Howard Ongoing (Upgrade to Microsoft Teams system completed 2020) – Dan Howard
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) in order to implement encryption	Ongoing (regular reminders sent to staff with security best practice) – Dan Howard

Causes / sources	Controls	Timescale / owner
Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.	All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place. We have an effective permission matrix and password policy. Our web configuration limits the service to 20 requests at any one time. The new Register will be under the tightest security when this is migrated to the cloud.	In place – Dan Howard In place – Dan Howard In place – Dan Howard To be implemented – Dan Howard
The continued use of EDI by clinics during the extended delivery of PRISM means the end-of-life server version used for the EDI gateway application (which processes data from EDI or 3rd party servers into the HFEA Register) continues to be used. This may therefore be more vulnerable to attack as it becomes unsupported.	Data submitted through the EDI gateway application is encrypted in transit, which reduces the likelihood of sensitive information being accessed.	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

OM1: There is a risk that the HFEA fails to capitalise on or respond effectively to changes affecting the organisation and its ways of working (including related to office working and Covid-19) hampering strategic and statutory delivery.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 –Very High	**2**	**3**	**6- Medium**
Tolerance threshold:					**6- Medium**
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Operating Model OM1: Management of changes to HFEA operating model	Peter Thompson Chief Executive	Whole strategy.	New risk in January 2021 - ⇩⇔⇔

Commentary
In November 2020 SMT agreed to reframe the remaining risks from the previous E1 estates/office move risk, once the physical move had occurred, and instead pick these up with a new ways of working/change risk. SMT discussed this new risk in January 2021, drawing various key causes of ongoing change to the HFEA operating model into a single risk. This risk will be reviewed carefully over the coming months to ensure that it fully reflects emergent risks, and appropriate granularity, including reflecting risks arising from new ways of working brought in by PRISM once it launches. SMT reflected in March 2021 that the very active consideration of controls, engagement with staff and baseline high level of flexibility offered by the organisation meant they felt the residual risk was lower. Looking ahead, a key aspect of managing this risk will be being alert to what other organisations are doing; maintaining our relative flexibility while meeting our organisational needs is likely to be a way of attracting and retaining staff ongoing.

Causes / sources	Controls	Status/Timescale / owner
The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings. Note: Covid-19 may have altered the requirements of the HFEA and we have not yet returned to office based working, meaning that although the move has competed this risk remains.	HFEA requirements were specified up front and feedback given on all proposed designs. Outline plans were in line with HFEA needs and we had staff on the working groups set up to define the detail. Our requirements and ways of working are being revisited in the light of the changed circumstances we are in due to Covid-19. If lower-priority requirements are unable to be fulfilled, conversations will take place about	Ongoing – Richard Sydee Ongoing as part of Covid-19 management – Richard Sydee Contingency if required –

Causes / sources	Controls	Status/Timescale / owner
	alternative arrangements to ensure HFEA delivery is not adversely affected.	Richard Sydee
Stratford may be a less desirable location for some current staff due to: • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention as staff choose to leave following the move.	We will review the excess fares policy to define the length of time and mechanism to compensate those who will be paying more following the move to Stratford. Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect.	Begun but to be completed (this is now subject to Covid-19 developments) – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
There is a risk that staff views on the positives and negatives of homeworking due to Covid-19 are not taken into account, meaning we miss opportunities for factor these into planning our future operating model and alienate staff by not considering their views, for instance on flexible working.	Heads discuss impacts with teams on a regular basis and feed views into discussions at CMG. Regular communication to staff about the developing conversation and direction of travel through all staff meetings and the intranet. A further survey of staff is being planned, to inform any policy reviews.	Ongoing with survey prior to return to the office – Peter Thompson
The need to operate with revised arrangements during Covid-19 and social distancing may delay consideration of our ongoing post-covid operating model, leading to staff seeing management as extending uncertainty about arrangements, inconsistent application of temporary arrangements and inequity, causing lower morale and levels of staff retention.	Clarity provided to staff that current arrangements for working from home will continue until at least end June 2021. CMG to balance staff desire for certainty about post-Covid-19 arrangements with need for flexibility of response during a period of ongoing change. CMG to discuss likely policies that will be applicable following social-distancing arrangements to provide assurance, for instance about maximum office attendance requirements.	Discussions in progress – Peter Thompson
Current staff may not feel involved in the conversations about the new office, leading to a feeling of being 'done to' and lower morale.	Conversations about ways of working occurring throughout the office move project, to ensure that the project team and HFEA staff were an active part of the discussions and development of relevant policies and have a chance to raise questions.	Ongoing – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
	An open approach is being taken to ensure that information is cascaded effectively, and staff can voice their views and participate. We have a separate area on the intranet and Q&A functionality where all information is being shared. Staff had the opportunity to visit the site ahead of time so that they feel prepared. Staff engagement group was in place to ensure wide engagement as we approached the move. Management of ongoing ways of working tasks and engagement with staff being done through CMG as part of HFEA move project closure and post-project oversight.	
The move to a new office and Covid-19 arrangements will lead to ways of working changes that we may be unprepared for.	CMG has been discussing ways of working in the aftermath of Covid-19 and in relation the office move, to ensure that these changes happen by design rather than by default. Policies related to ways of working have been agreed and circulated significantly before the move, to ensure that there is time for these to bed in and be accepted ahead of the physical move. Staff have and will continue to be been involved and updated as appropriate.	Discussions each month at CMG until we move back to the office – Richard Sydee Done and to continue as these are reviewed in light of Covid-19 - Richard Sydee, Yvonne Akinmodun
There is some uncertainty about arrangements around meetings in Redman Place including: • availability of physical meeting spaces • AV/VC arrangements • shared desk arrangements • booking procedures and systems If these are not managed effectively or do not work well this could lead to disruption to core business.	Throughout Covid-19 remote working, the organisation has effectively run meetings remotely and could continue to do so for as long as is necessary, to ensure that required meetings can continue. Ongoing FM group in place for Redman Place, to coordinate and communicate about arrangements and ensure that these run smoothly.	Ongoing – Peter Thompson In place following central programme closure – Richard Sydee
Owing to the different cultures and working practices of the organisations moving, there may be perceived inequity about the policy changes made.	During the Redman Place Programme, a formal working group was in place including all the organisations who are moving to Stratford with us, to ensure that messaging around ways of working has been consistent across organisations, while reflecting the individual cultures and requirements	Ways of working group work completed, follow on communicatio

Causes / sources	Controls	Status/Timescale / owner
	of these. We will communicate about any differences, so that staff understand any differences in practice and that the intention is not to homogenise practices. Ongoing working groups in place following programme closure in March 2021.	ns being coordinated across all organisations – Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.	Ongoing building working groups with relevant IT and other staff such as HR. Informal relationship management with other organisations' leads.	In place – Richard Sydee, DHSC

LC1: There is a risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 – Very high	**2**	**4**	**8 - Medium**
Tolerance threshold:					**12 - High**
Status: **Below tolerance**					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Legal challenge LC 1: Resource diversion	Peter Thompson, Chief Executive	Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment	⇔⇔⇔⇔

Commentary

We accept that in a controversial area of public policy, the HFEA and its decision-making will be legally challenged. Our Act and related regulations are complex, and aspects are open to interpretation, sometimes leading to challenge. There are four fundamental sources of legal risk to the HFEA, it may be due to:

- execution of compliance and licensing functions (decision making)
- the legal framework itself as new technologies and science emerge
- policymaking approach/decisions
- individual cases and the implementation of the law (often driven by the impact of the clinic actions on patients).

Legal challenge poses two key threats:

- that resources are substantially diverted
- that the HFEA's reputation is negatively impacted by our participation in litigation.

These may each affect our ability to regulate effectively and deliver our strategy and at their most impactful they could undermine the statutory scheme the HFEA is tasked with upholding. Both the likelihood and impact of legal challenge may be reduced, but it cannot be avoided entirely. For these reasons, our tolerance for legal risk is high.

We have not been directly involved in any litigation since September 2020.

Causes / sources	Mitigations	Timescale / owner
We may face legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics	Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best possible position to defend any challenge.	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
challenging decisions taken about their licence.		
We may be legally challenged if new science, technology or wider societal changes emerge that may not be covered by the existing regulatory framework.	Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning processes. This provides the organisation with foresight and may provide more time and ability to prepare our response to developments. Case by case decisions on the strategic handling of contentious or new issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	SCAAC horizon scanning meetings annually. In place – Catherine Drennan and Peter Thompson
Our policies may be legally challenged if others see these as a threat or ill-founded. Moving to a bolder strategic stance, eg, on add-ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers.	Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed. We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law and implemented related policy and respond effectively to challenge. Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics meaning that consideration of impacts and how these will be managed is taken into account as part of the policymaking process. Stakeholder involvement and communications in place during policymaking process (for instance via regular stakeholder meetings) to ensure that clinics and others can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Laura Riley/Joanne Anton with appropriate input from Catherine Drennan Ongoing - Laura Riley, Joanne Anton In place – Richard Sydee Ongoing - Laura Riley, Joanne Anton
We may face legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases). Ongoing legal parenthood and storage consent failings in clinics and related cases are specific examples. The case-	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action.	Ongoing – Catherine Drennan In place – Catherine Drennan

Causes / sources	Mitigations	Timescale / owner
by-case nature of the Courts' approach to matters means resource demands are unpredictable when these arise.	Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly. We took advice from a leading barrister on the possible options for handling storage consent cases to ensure we take the best approach when cases arise. We also get ongoing ad hoc advice as matters arise. Some amendments were made to guidance in the Code of Practice dealing with consent to storage and extension of storage, this was launched in January 2019. This guidance will go some way to supporting clinics to be clearer about the legal requirements. Additional amendments will be made in the next update. Storage consent has been covered in the revision of the PR entry Programme (PREP).	In place – Peter Thompson Done in 2018/19 and as needed – Catherine Drennan Revised guidance will be provided where appropriate to clinics in 2021– Catherine Drennan PREP launched January 2020 – Catherine Drennan/ Laura Riley, Joanne Anton
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or Judicial Reviews. Challenge of compliance and licensing decisions is a core part of the regulatory framework and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes. Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible. The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for appropriate involvement and effective planning of work. This process has been clarified in the revised Compliance and Enforcement Policy. Panel of legal advisors in place to advise committees on questions of law and to help	In place but a revised version of the policy to be launched in June 2021– Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer In place – Sharon Fensome-Rimmer In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
	achieve consistency of decision-making processes. Measures in place to ensure consistency of advice between the legal advisors from different firms. Including: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • Regular email updates to panel to keep them abreast of any changes. Consistent and well taken decisions at licence committees supported by effective tools for committees and licensing team (licensing pack, Standard operating procedures, decision trees etc) which are regularly reviewed.	Since Spring 2018 and ongoing – Catherine Drennan In place – Paula Robinson
Any of the key legal risks may escalate into high-profile legal challenges which may result in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime.	Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public. The default HFEA position is to conduct litigation in a way which is not confrontational, personal or aggressive. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement with them means that challenge is more likely to be focused on matters of law than on the HFEA. Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Catherine Drennan, Joanne Triggs In place – Peter Thompson, Catherine Drennan In place – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: HFEA could face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime.	If this risk was to become an issue, then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
	necessary, this would include agreeing any associated implementation budget. Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	
DHSC: The Department may be a co-defendant for handling legal risk when cases arise.	We work closely with colleagues at the Department to ensure that the approach of all parties is clear and is coordinated wherever possible. We also pre-emptively engage on emerging legal issues before these become formal legal matters.	In place – Peter Thompson

CV1: There is a risk that we are unable to undertake our statutory functions and strategic delivery because of the impact of the Covid-19 Coronavirus.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**2**	**3**	**6- Medium**
Tolerance threshold:					**12 - High**
Status: **Below tolerance**					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Business Continuity CV1: Coronavirus	Peter Thompson Chief Executive	Whole strategy.	⇔⇩⇔⇔

Commentary
Risk management of these risk causes has been our organisational priority since the beginning of the pandemic. All staff are working from home and a strategy to manage inspections is in place. Communications to the sector and patients are in place and ongoing. A business continuity group meets regularly to consider risks and ensure an effective response is developed and maintained. Our revised inspection processes are effective and include comprehensive risk assessment and controls; we are assured that we can effectively maintain this regulatory function. Licensing has continued effectively remotely. SMT considered the risk score in March and decided that the effective inspection methodology reduced the impact of this risk, as the controls ensured we are able to continue to undertake this statutory function, bringing the score down. The implementation of the methodology has caused a secondary risk, while it beds in, but that is being managed and is captured under RF1.

Causes / sources	**Controls**	**Status/Timescale / owner**
Risk of providing incorrect, inconsistent or non-responsive advice to clinics or patients as guidance and circumstances change (ie, not updating our information in a timely manner) and this leading to criticism and undermining our authoritative position as regulator.	Business continuity group (including SMT, Communications, HR and IT) meeting frequently to discuss changes or circumstances and planning timely responses to these. Out of hours media monitoring being undertaken, to ensure that we respond to anything occurring at weekends or evenings in a timely manner. Close communication with key sector professional organisations to ensure we are ready to react to any developments led by them (such as guidance updates). Proactive handling of clinic enquiries and close communication with them.	In place, ongoing – Richard Sydee In place - SMT and communications team In place and ongoing – Clare Ettinghausen In place and ongoing – Sharon

Causes / sources	Controls	Status/Timescale / owner
	Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth and this is up to date. Enquiries team have additional support from Managers and Directors. We have reviewed our approach regularly to ensure that this is fit for purpose. Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.	Fensome-Rimmer, Rachel Cutting Joanne Triggs – in place In place and under regular review – Laura Riley In place – Jo Triggs
Risk of being challenged publicly or legally about the HFEA response, resulting in reputational damage or legal challenge. (This risk also therefore relates directly to LC1 above)	As above – ensuring approach is appropriate. As above – continuing to liaise with professional bodies. We may choose to put out a press release in case of public challenge. Legal advice has been sought to ensure that HFEA actions are in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Joanne Triggs Done – Peter Thompson If required – Peter Thompson, Catherine Drennan
Gaps in HFEA staffing due to sickness, caring responsibilities etc	Possible capability gaps have been reviewed by teams to ensure that these are identified and managed. Other mitigations as described under the C1 risk.	In place – Yvonne Akinmodun
Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds. Note: we do not have evidence of this being an issue within the HFEA.	Decision taken to delay routine return to the office subject to government guidance, reducing work-related risk. We are engaging with other similar organisations to consider possible approaches to managing this risk. We have considered the impact as part of planning for the return to inspections and office working, including individual risk assessments for inspection staff, performed before each inspection.	In progress – Yvonne Akinmodun In place – Sharon Fensome-Rimmer

Causes / sources	Controls	Status/Timescale / owner
Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.	Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.	In place - Paula Robinson
Ineffective oversight of those clinics that are continuing to practice, as clinics may not abide by professional body and HFEA guidance. Since GD0014 version 2 was issued, clinics have been able to reopen where it is safe to do so.	HFEA restarted physical inspections from November which reduces the potential oversight gap, although during third national Covid-19 lockdown, from 5 January 2021, in-person inspections have been kept to a minimum to manage risk, in line with our revised inspection methodology. We put in place a new General Direction for clinics to follow. Clinics who do not follow General Directions 0014 would be subject to serious regulatory action. Inspection team are in active communication with all of their clinics to ensure oversight and understanding of risks. Activity of centres is being monitored through the Register submission system. Effective desk-based approach to oversight of clinics. Those clinics (who have resumed treatment services and/or are open) where Interim inspections were due during the period of no inspections were asked to complete the Self-Assessment Questionnaire, in the same way that they would have done before an inspection. This gives us oversight of all areas of practice. A methodology for a wholly virtual inspection is in place. Agreed approach with the Department for managing any exceptional breaches in statutory duty to physically visit licensed premises every two years if this were impossible (for instance if future Covid-19 restrictions make this unworkable), to ensure that centres remain appropriately inspected and licensed.	In place – Rachel Cutting In place – Sharon Fensome-Rimmer In place – Sharon Fensome-Rimmer, Rachel Cutting Agreed November 2020 – Rachel Cutting, Catherine Drennan
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: as per FV1 this is a live issue, although treatment volumes recovered somewhat since spring 2020. Note: this risk may be both short and longer-term if clinics close down as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity. The final contingency would be to seek additional cash and/or funding from the Department. We have agreed support for the remainder of 2020/21, and we will resume discussions about the likely impact on us in 2021/22 in the coming months.	In place – Richard Sydee Ongoing discussions as impact becomes clearer – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity.	Provided equipment for staff who have to WFH without suitable arrangements in place. Ability of staff unable to work from home to work in Covid-19 secure office. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance.	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing – Yvonne Akinmodun
Inability of staff to return to office working may negatively impact organisational culture, reduce collaboration, or hamper working dynamics and productivity. Note: This risk will affect the organisation for some time including when we return to the office, while social distancing is in place and office working is significantly reduced due to Covid-19 restrictions. The ongoing consideration of this risk is reflected within the OM1 risk.	Discussion about return to office working at CMG to ensure that this is planned effectively, and impacts considered. This is occurring on a month-by-month basis in the run up to returning to the office. Online solutions to maintain collaboration and engagement, such as informal team engagement and 'teas', Microsoft Teams etc.	Ongoing – Peter Thompson In place – Heads
Risk that we miss posted financial, OTR or other correspondence.	Arrangement in place to securely store, collect and distribute post. Updated website info to ask people to contact us via email and phone. We notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.	In place– Richard Sydee In place – Jo Triggs In place – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
In common risk		

Causes / sources	Controls	Status/Timescale / owner
DHSC: HFEA costs exceed annual income because of reduced treatment volumes. Live issue as at April – captured under FV1	Use of cash reserves, up to appropriate contingency level available. The final contingency would be to seek additional cash and/or funding from the Department. (additional Grant in Aid has been provided for the 2020/2021 business year).	Richard Sydee

Reviews and revisions

19/04/2021 – SMT review – April 2021

SMT reviewed all risks, controls and scores and made the following points in discussion:

- SMT noted there were no substantive changes to the CS1, C1, RF1, LC1, I1 or P1 risks.
- FV1: Financial viability – The Director of Finance and Resources noted that we had had confirmation of our budget from the Department and finance team monitoring suggested the income risk for this business year was small. SMT agreed that the Risk and Business Planning Manager and Director of Finance and Resources should review the commentary to reflect updates, but there was no change in the score.
- C2: Board capability – SMT discussed the upcoming conversation with the Chair about plans for handling of Board member recruitment. SMT agreed that following that meeting, a full revision could be done to this risk by the Risk and Business Planning Manager and the Chief Executive to reflect these plans and AGC's earlier comments. On review, following discussion with the Chair the risk was revised per AGC's suggestion to include senior executive leadership risks and the score was raised.
- OM1: Operating Model – SMT discussed some updates from the central DHSC Office Move Programme which was coming to an end. The Director of Finance and Resources noted an update would be given to the Corporate Management Group on the remaining actions in May.
- CV1: Coronavirus – Given we are operating very well with virtual meetings, the inability of running in-person events was not causing risk to current strategic delivery so this risk cause was removed. There was no change to the score.

16/03/2021 - AGC review - March 2021

AGC reviewed all risks, controls and scores and made the following points:

- AGC noted the four risks that had been reduced and that this seemed appropriate given the status of controls.
- Members suggested reframing the C2 risk now that there was more stability on Board recruitment, to reflect the key concern of managing knowledge retention and consistency. The risks associated with possible turnover within the Senior Management Team should also be reflected.
- Members raised questions about the OTR risk, DNA testing and the hybrid inspection regime.
- AGC noted the proposal to review the risk management policy, approach, and register, with this returning to AGC in October before going to the Authority in November. Members suggested a more dynamic approach could add value for the Strategic Risk Register.

01/03/2021 – SMT review – March 2021

SMT reviewed all risks, controls and scores and made the following points in discussion:

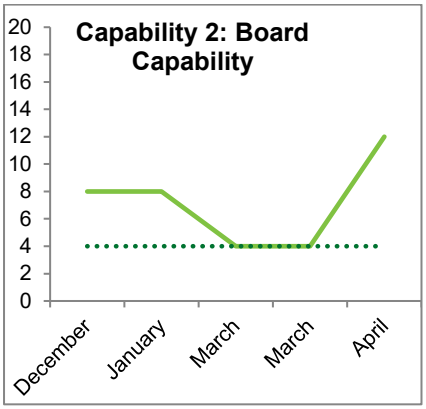
- SMT discussed the aggregate view of residual strategic risk and noted the clustering of risks as 'medium'. SMT agreed that they would recalibrate the risk scores when reviewing each risk, to ensure that risks with the same scores were of comparable significance.
- RF1 – SMT discussed the new inspection methodology and noted that it was effective in providing oversight of clinics, but the Compliance team were currently finding that it required additional resource. The new methodology was developed as a rapid response to the pandemic and inspectors had to adapt to change very quickly. As with any new process issues will emerge during the embedding phase and the problem of increased resource demand is in part due to the lack of consensus among the inspection team about the appropriate degree of remote oversight of clinic policies and procedures. The new methodology will be monitored to ensure workload returns to manageable levels, so this does not have a substantive impact on the overall risk. Unmanaged increased resource requirements could lead to burnout and ineffective ongoing delivery.
- I1 – SMT reflected that OTR as a live issue was the key cause of present risk. Balanced with the controls in place and developing to address this, alongside the good position for the rest of the risk, SMT decided not to raise the score. A new risk cause was added related to accessing Register data post-PRISM launch, controls were being actively discussed in this area to ensure they were appropriate.

- P1 – SMT discussed the impact of our recent collaborative work on this risk and agreed that this reduced the risk at this time. SMT discussed possible health regulatory changes and noted that these were not directly related to HFEA and so were not deemed a source of a positioning risk for us.
- FV1 - RS noted that there was no change, conversations were ongoing about 2RP costs and would be resolved shortly for the coming financial year. Wider financial viability discussions were ongoing, per January discussion, but there was no change to the score of this risk. It was unlikely to be as impactful in 2021-2022 as during 2020.
- C1 - This risk had been reviewed in full, with a few minor control updates, by the Head of HR, who believed no change to the score was indicated. SMT noted the main unknown related to capability would be the impact of returning to the office; we were already engaging staff in these discussions about ways of working (for which there is now a separate OM1 risk), which would help us to understand possible impacts. SMT considered that if the turnover level remained as low as now, we may wish to review the likelihood score of this risk at the end of the next quarter.
- OM1 – SMT reflected that the high importance being placed on the controls for this risk and regular engagement about the future meant the residual likelihood score could be lowered at the current time.
- L1 – had been reviewed with Head of Legal, no significant changes impacting the score.
- CS1 – SMT noted that the CIO had been asked for an update on controls. SMT asked about the general position on cyber risk, what would enable us to reduce this? SMT noted that full penetration was due to occur later in the year and this would provide a key opportunity for a reassessment of effectiveness of controls.
- CV1 – SMT reflected that our approaches to managing Coronavirus risk had proven effective, we were able to maintain our regulatory functions. Key strategic delivery continued. Financial risks related to Covid-19 were in hand and the organisation was working effectively. Given this, SMT agreed that the residual impact was less than indicated and reduced this to 3, bringing the overall risk score down.

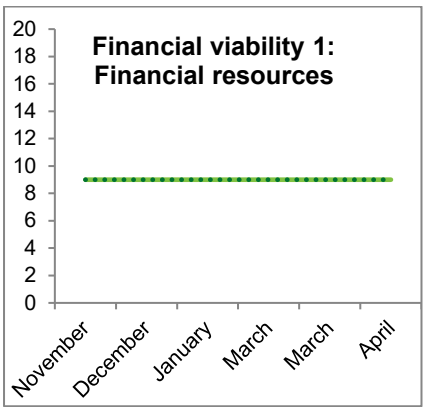
Risk trend graphs (last updated April 2021)

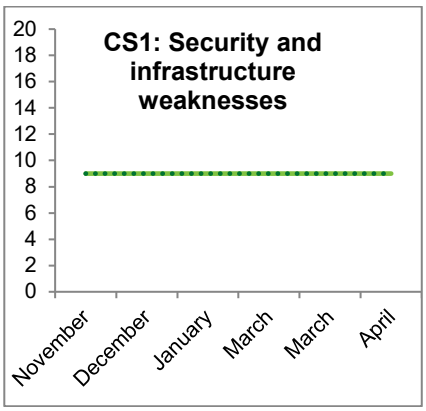
High and above tolerance risks

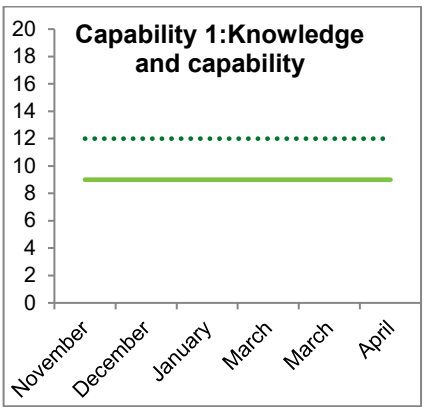
Key:

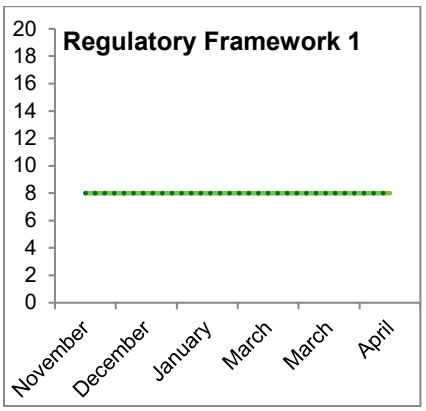


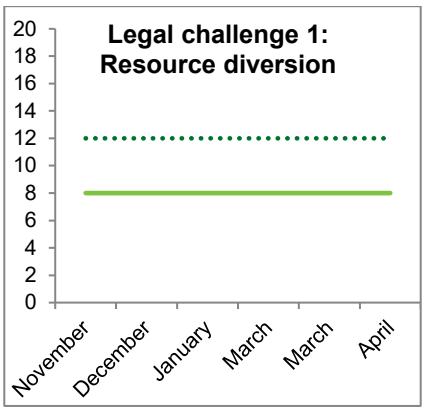
Lower and below tolerance risks

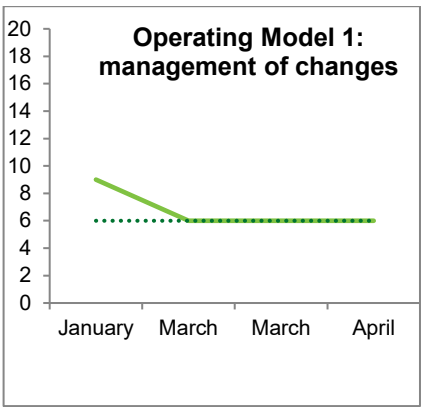


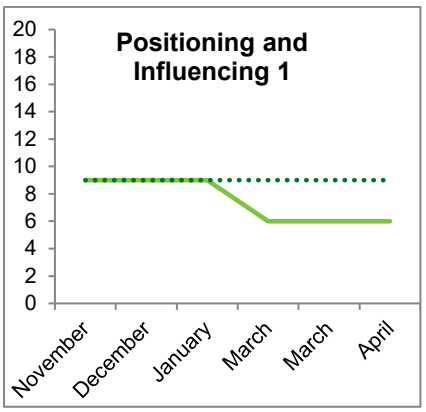


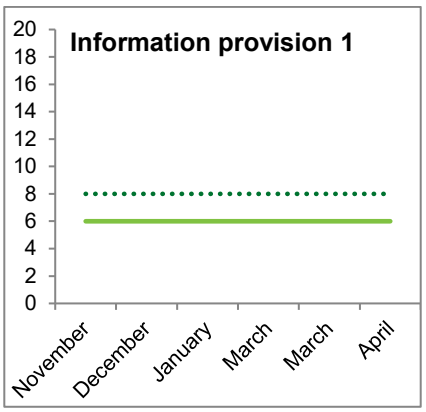


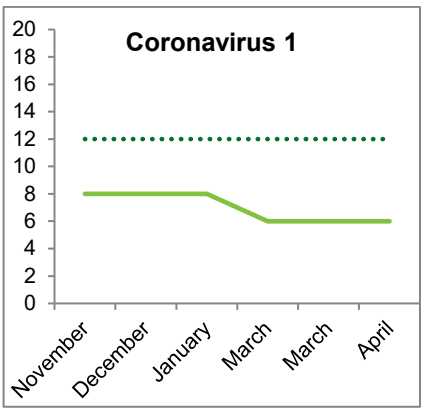












Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.

Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in rank order according to the severity of the current residual risk score.

Risk trend

The risk trend shows whether the threat has increased or decreased recently. The direction of the arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system

We use the 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=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥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
	Likelihood				

Risk Score = Impact x Likelihood

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlike to change, unless the organisation's role or environment changes dramatically.

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it 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. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed

Assessing inherent risk

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define 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.'

System-wide risk interdependencies

We explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. There is a distinct section beneath each risk to record any such interdependencies, so we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC or auditors as required.

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve 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.

When a risk exceeds its tolerance threshold, or when the risk translates into 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.

Licence fee review project – timing and next steps

Details about this paper

Area(s) of strategy this paper relates to:	
Meeting:	Authority
Agenda item:	7
Meeting date:	12 May 2021
Author:	Richard Sydee, Director of Finance and Resources
Annexes	N/a

Output from this paper

For information or decision?	For decision
Recommendation:	That members agree the next steps in reviewing HFEA's licence fees and the proposal to delay this work until 2022.
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	None
Organisational risk:	High

1. Introduction

1.1. The Authority last received a paper updating on the fees review work at its meeting in June 2020. Following that meeting the Executive took the decision to postpone further work whilst the sector worked through the impact of the COVID19 pandemic. The purpose of this paper is to clarify the point at which activity was paused and to seek agreement on next steps to restart this work.

2. Background

2.1. As with a number of Government regulators across numerous sectors the HFEA is expected to recover the majority of its operating funds (currently 80% of total income, with the remainder from the DHSC in the form of grant-in-aid) through charging fees to the sector it regulates. In doing this the HFEA must look to ensure that it recovers the full cost of regulation through a mechanism that is fair, transparent and that ensures there is no cross subsidisation, for example that private and public funded clinics are charged consistently.

2.2. Historically it has been felt the cost of regulation is evenly distributed amongst licenced establishments based on the level of activity that they undertake, and that therefore a fee per IVF/DI cycle performed is used as the basis for licence fees. As ever it is important to be clear that HFEA licence fees are charged to licenced establishments and not patients, although some clinics choose to list the activity based licence fee on patient's bills the HFEA does not and will not charge patients.

2.3. Until 2019 we had seen consistent year on year growth in treatment activity across the sector. Since the HFEA last reviewed its fees in April 2016 growth had been approximately 2% per annum, which is broadly in line with inflation across the same period. As a result, the HFEA has been able to hold fees at the 2016 rate for the past 4 years (currently £80 per IVF treatment and £37.50 for DUI).

2.4. During the 2019/20 business year we saw, for the first time, a reduction in the number of chargeable cycles, leading to drop in income for the HFEA. Further analysis of this data highlighted some key changes:

- within the private sector activity was increasing, but the number of cycles that met the threshold for charging was falling – partly due to changes in clinic practice
- that although overall activity levels were increasing there was a material drop in activity within NHS clinics.

2.5. This was the background against which the Authority last considered the licence fee model in January 2020. The agreement then was that a licence fees review project should be undertaken to consider whether the current charging mechanism remains a fair and equitable recovery of the cost of regulation. The Authority discussed a further paper in June 2020, setting out the further analysis and the proposed options that would be taken forward for more detailed modelling and consultation with the sector.

3. Activity since June 2020

3.1. Following the June Authority meeting further work was undertaken on modelling the potential impacts of the agreed options, this included an initial consultation with the Licence Centres Panel and some discussion with the Department. Although these initial consultations and other internal

discussions through the summer were fruitful, it became apparent that it would be difficult to continue this work to a successful conclusion with the full engagement of the sector given the pressures of operating through the ongoing COVID19 pandemic. The impact on the sector and the HFEA of the fees work would be a significant distraction when resources would be better employed concentrating on recovering and operating services across the sector. The Executive took the decision to pause this work for the 2020/21 business year in August 2020.

3.2. Since the resumption of fertility treatment in June 2020 we have seen activity quickly recover and on the whole monthly activity since July 2020 has been near or consistently above 2019/20 levels. It is difficult to suggest with any certainty whether this is catch up from treatments delayed or indicative of the likely activity levels for the next financial year. This uncertainty around future activity levels will make the modelling of the impact of fee changes more difficult in the short term.

3.3. Our budget for the 2021/22 financial year is based on pre pandemic activity levels, affordable this financial year due to savings generated from our office relocation and the impact of the Government pay freeze for public sector workers. This budget is unlikely to be sufficient in future years as we enter a demanding strategic programme and face the resourcing challenges that will arise from new challenges like the increased eligibility to access data from our register from donor conceived people.

3.4. We have undertaken work previously to model future activity using both historic activity and to include wider socio demographic and economic conditions. Although these latter factors provide data that would support a general trend for increased sector activity in the future it is historic data that has proven a more reliable indicator of activity over a shorter-term planning window. Given the very different activity levels we have seen over the past 15 months our modelling, of which we will share more at the meeting, provides more variable outcomes and does not carry the usual level of confidence we would have in our forecasting.

4. Proposals for the timing of a fees review

4.1. Our dilemma then is whether to allow a further year for the sector to recover, allow for activity to reach a new equilibrium and then restart our fees review; or, to press ahead using data from 2019/20 as a basis for modelling fees with the intent of announcing revised fees for the start of the 2022/23 financial year.

4.2. In calculating our fees, we must look to recover only what we need to operate. As an NDPB we must cover our operating costs and not enter a deficit position whilst also looking to minimise any operating surplus, as we cannot access historic cash reserves without agreement of our sponsor Department. Ideally, we would establish any new fee, or fee regime, with the intent of maintaining this for a 3 to 5 year period.

4.3. We have not revised our fees for 5 years and the most consistent feedback we received from initial consultation with the sector is that they value stability and certainty in our approach. Most understand the need to fund the HFEA appropriately and would not resist in principle a fee increase; however, they indicate a strong preference for a simple charging model and some certainty in terms of fee levels for the foreseeable future.

4.4. Our concern in setting a new fee now, using older data, is that we could materially over or under recover fees requiring further remodelling in the short term. In not acting now we face a possible shortfall in 2022/23 that would impact on our ability to deliver against our strategic and operational objectives. This could be alleviated if we were granted permission to access our cash reserves in

the short term to balance our position whilst we undertook our fee review, although as stated earlier that would require sponsor department approval.

4.5. On balance, and subject to the agreement of our sponsor department, we would opt to delay this work through to 2022 with the intent of introducing any new fees from the start of the 2023/24 financial year.

5. For discussion

5.1. Members are asked to:

- consider and agree the proposal to delay the HFEA fees review until 2022.

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Transparency and Regulation

Clare Ettinghausen
Director of Strategy and Corporate Affairs
12 May 2021

www.hfea.gov.uk

Transparency and Regulation

Outline of discussion

1. Background – what are the issues and why are we discussing them today?
2. Current HFEA approach – key principles revisited
3. Issue 1 – publications coming from our compliance regime and publicity as a regulatory incentive
4. Issue 2 – other regulators publishing non-compliances of HFEA licensed clinics
5. What do other regulators do?
6. For discussion – to agree direction going forward

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Background 1

What are the issues?

- Can transparency be used as a regulatory incentive in a more powerful way than we use today?
- What do we do if other regulators publish non-compliances about HFEA regulated clinics?
- We have a generally good relationship with the sector we regulate – with an emphasis on working *with* licensed clinics to improve standards. Any change might impact on this relationship.
- We publish all non-compliances through our inspection reports – but they are not easy to find
- Choose a Fertility Clinic – inspection ratings are not nuanced – part of a longer-term discussion

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Background 2

Why are we discussing this now?

- Appropriate time to revisit underlying principles previously agreed by Authority:
  - No ‘Name and shame’ (primary issue)
  - League tables (secondary issue)
- Enforcement action maybe taken against HFEA licensed clinics
- Other regulators publish enforcement action or non-compliances in more explicit ways – are we now out of step?
- NB. Whatever direction we decide to move in we need to ensure consistency with Compliance and Enforcement Policy

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Current HFEA approach

Previously agreed principles

1. ‘Name and shame’

Clinics should not be ‘named and shamed’ because:

- Potentially lead to patient concerns
- Potential implication for clinic in financial terms
- Does not support the approach of collaborative regulation we have adopted

2. No league tables

League tables should not be produced by the HFEA because:

- Patients should be encouraged to look at more than success rates
- Success rates themselves may not vary much from one year to next
- Many patients have little choice of which clinic to use
- How would patients of a clinic at the lower end feel?

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Issue 1

Publications coming from our compliance regime and publicity as a regulatory incentive

- Inspection reports and licensing committee minutes are published for every clinic on Choose a Fertility Clinic (CaFC) but they are hard to find and are written for PRs to state where improvements are needed and for the purposes of making licensing decisions
- We have transparency in our decision-making process
- Given our current regulatory powers, should we be using a more public airing of non-compliances to draw greater attention to poor areas of practice?
- We plan to review the cover page of the inspection report later this year to make it more public facing/patient friendly – is this enough?

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Issue 2

Other regulators publishing non-compliances of HFEA clinics

- The CMA and ASA both publish on their websites when enforcement action has been taken.
- If, in the future, enforcement action has been taken against a HFEA licensed clinic, should we also publish this information for patients to find easily?

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What do other regulators do?

Examples of where clearer attention is given to non-compliance

- There are examples from the CQC of a system of highlighting compliance in relation to five key areas of inspection
- The Electoral Commission – monthly updates plus press announcements of investigations
- OFCOM – publish details of cases and those being monitored for compliance
- SART (US) – will start to publicise when clinics do not comply with display of success rates
- CMA – pages relating to investigations and enforcement action
- ASA – publish weekly when their Code has been broken and details of enforcement activity

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Care Quality Commission (CQC)

CQC homepage

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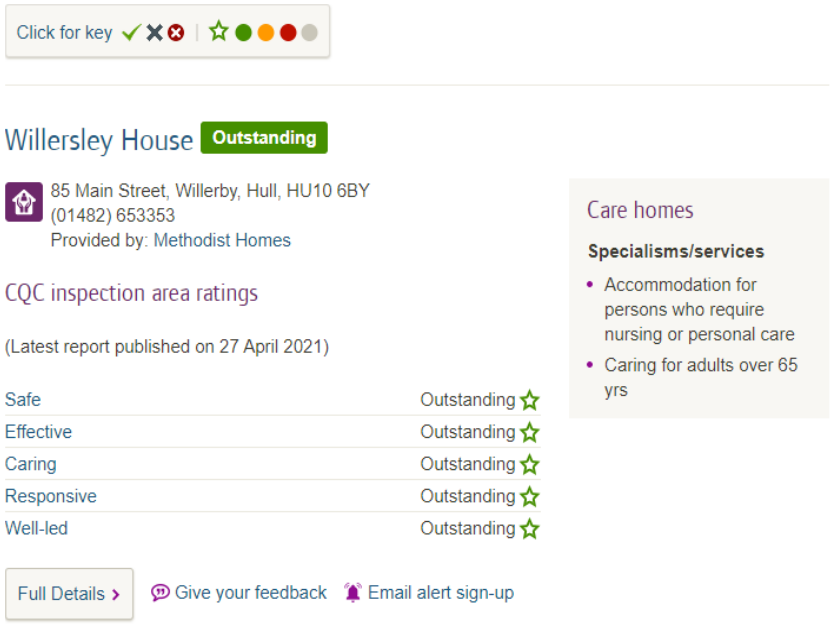
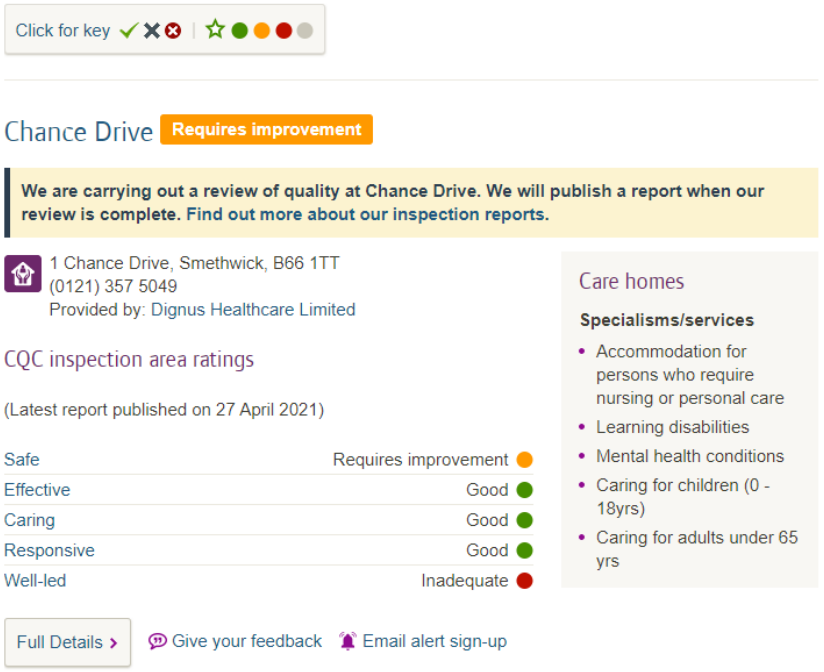
CQC examples

Examples of an outstanding and needs improvement ratings





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The Electoral Commission

Monthly updates plus other announcements

Details of the investigation concluded in the last month have been published today by the Electoral Commission. This is an important part of delivering transparency in political finance in the UK.

First published: 20 April 2021
Last updated: 20 April 2021

Name and type of regulated entity	What was investigated	Offences found	Decision taken
British National Party (registered political party)	Late delivery of campaign spending return for 2019 UKPGE	Late delivery of campaign spending return for 2019 UKPGE	£300 variable n penalty impose payment by 6 M

Commenting on the concluded investigation, Louise Edwards, Director of Regulation, said:

"The reporting requirements are clear, so it is always disappointing when they are not met. It is vital that voters have the opportunity to see timely data on how parties spend their money at elections and can then see the information as soon as possible.

"The Commission will continue to enforce these requirements to ensure that voters have the information they need."

Ends

For more information contact the Electoral Commission press office on 020 7271 0704, out of office hours 07789 920 414 or press@electoralcommission.org.uk

It has also issued press statements when it is starting an investigation – for example it was announced that it would start an investigate on the basis that "reasonable grounds to suspect that an offence or offences may have occurred".

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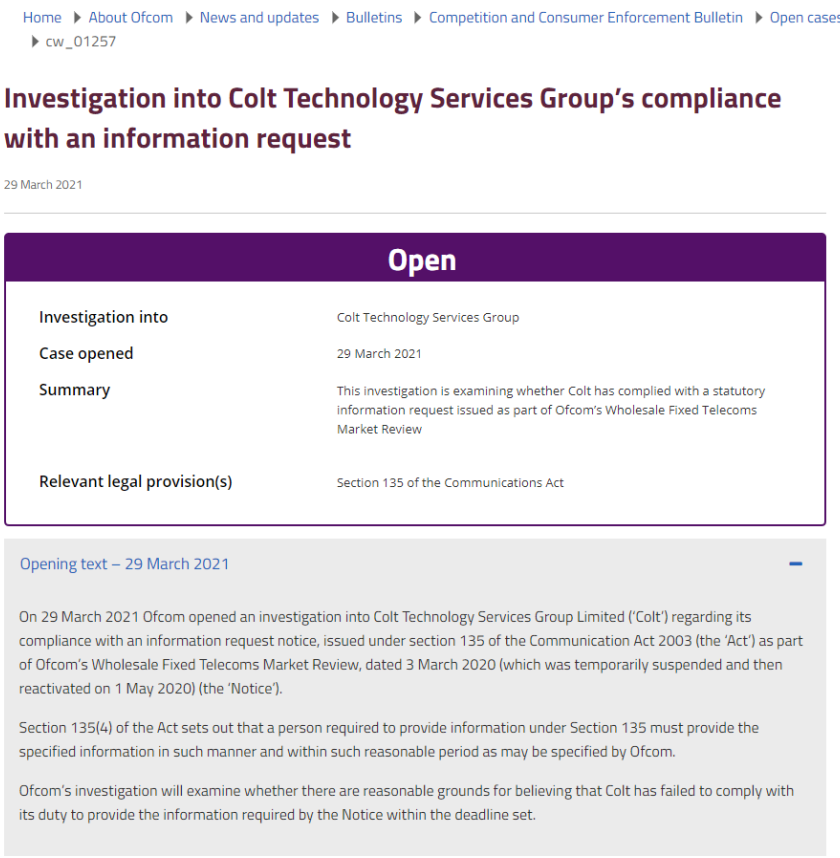
Ofcom

Publish details of investigations – open and closed cases and those being monitored for compliance



Home ▸ About Ofcom ▸ News and updates ▸ Bulletins ▸ Competition and Consumer Enforcement Bulletin ▸ Open cases ▸ cw_01257

Investigation into Colt Technology Services Group's compliance with an information request

29 March 2021

Open

Investigation into	Colt Technology Services Group
Case opened	29 March 2021
Summary	This investigation is examining whether Colt has complied with a statutory information request issued as part of Ofcom's Wholesale Fixed Telecoms Market Review
Relevant legal provision(s)	Section 135 of the Communications Act

Opening text – 29 March 2021 −

On 29 March 2021 Ofcom opened an investigation into Colt Technology Services Group Limited ('Colt') regarding its compliance with an information request notice, issued under section 135 of the Communication Act 2003 (the 'Act') as part of Ofcom's Wholesale Fixed Telecoms Market Review, dated 3 March 2020 (which was temporarily suspended and then reactivated on 1 May 2020) (the 'Notice').

Section 135(4) of the Act sets out that a person required to provide information under Section 135 must provide the specified information in such manner and within such reasonable period as may be specified by Ofcom.

Ofcom's investigation will examine whether there are reasonable grounds for believing that Colt has failed to comply with its duty to provide the information required by the Notice within the deadline set.

Example of details of an open case

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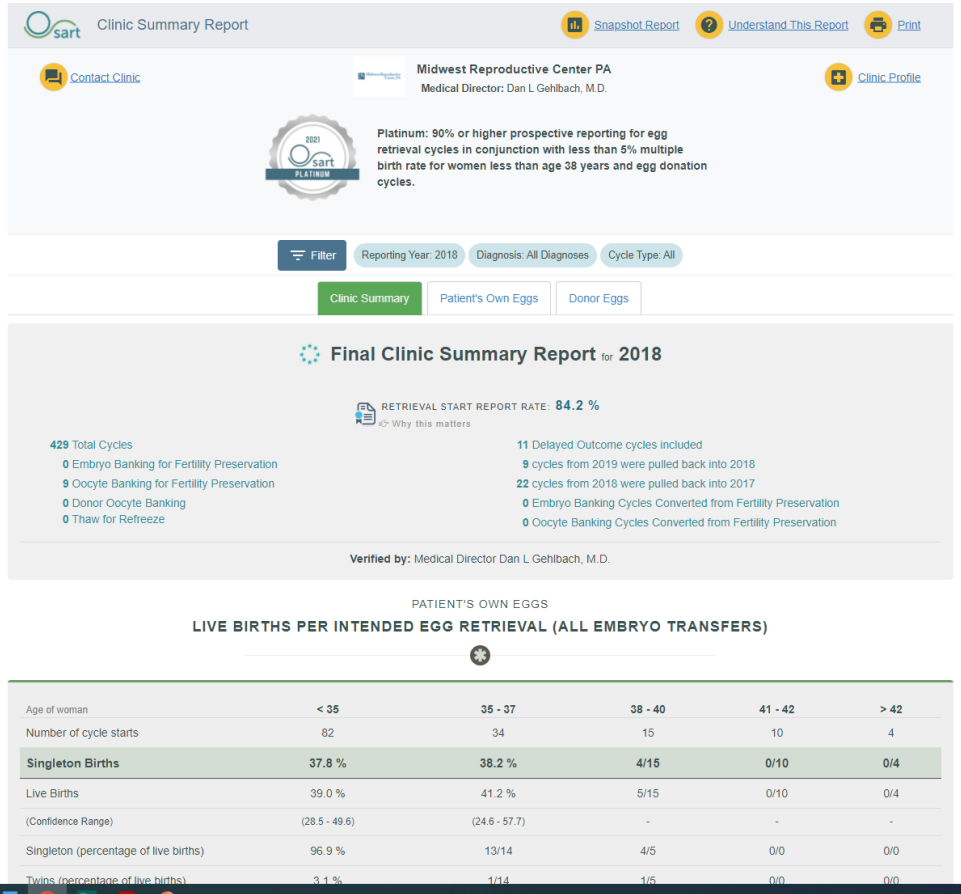
Society for Assisted Reproductive Technology (SART) – USA based

New guidelines for clinics publishing success rates



Clinic Summary Report

Snapshot Report | Understand This Report | Print

Contact Clinic

Midwest Reproductive Center PA
Medical Director: Dan L Gehlbach, M.D.

Clinic Profile

Platinum: 90% or higher prospective reporting for egg retrieval cycles in conjunction with less than 5% multiple birth rate for women less than age 38 years and egg donation cycles.

Filter | Reporting Year: 2018 | Diagnosis: All Diagnoses | Cycle Type: All

Clinic Summary | Patient's Own Eggs | Donor Eggs

Final Clinic Summary Report for 2018

RETRIEVAL START REPORT RATE: 84.2 %
Why this matters

429 Total Cycles
0 Embryo Banking for Fertility Preservation
9 Oocyte Banking for Fertility Preservation
0 Donor Oocyte Banking
0 Thaw for Refreeze

11 Delayed Outcome cycles included
9 cycles from 2019 were pulled back into 2018
22 cycles from 2018 were pulled back into 2017
0 Embryo Banking Cycles Converted from Fertility Preservation
0 Oocyte Banking Cycles Converted from Fertility Preservation

Verified by: Medical Director Dan L Gehlbach, M.D.

PATIENT'S OWN EGGS

LIVE BIRTHS PER INTENDED EGG RETRIEVAL (ALL EMBRYO TRANSFERS)

Age of woman	< 35	35 - 37	38 - 40	41 - 42	> 42
Number of cycle starts	82	34	15	10	4
Singleton Births	**37.8 %**	**38.2 %**	**4/15**	**0/10**	**0/4**
Live Births	39.0 %	41.2 %	5/15	0/10	0/4
(Confidence Range)	(28.5 - 49.6)	(24.6 - 57.7)	-	-	-
Singleton (percentage of live births)	96.9 %	13/14	4/5	0/0	0/0
Twins (percentage of live births)	3.1 %	1/14	1/5	0/0	0/0

If clinics do not comply then various levels of public recognition of this will apply e.g. statement placed on the SART page of the clinic – up to the membership of SART being revoked.

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Competition and Markets Authority

Examples of enforcement action

Care homes: consumer protection case

The CMA is investigating concerns that some care homes may be breaching consumer law.

From: Competition and Markets Authority
Published: 14 June 2017
Last updated: 5 November 2020, see all updates

Case type: **Consumer enforcement**
Case state: **Open**
Market sector: **Healthcare and medical equipment**
Opened: **13 June 2017**

Contents

Related content

- Care homes: consumer law advice for providers
- Care homes market study
- Care homes: short guide to consumer rights for residents
- Consumer law advice sets out obligations for care homes
- CMA launches court action against Care UK

Brexit

Check what you need to do

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Competition and Markets Authority

Examples of details published

Care UK gives refunds and undertaking for NHS Continuing Healthcare (CHC) residents

8 October 2020: The CMA has secured more than £1 million in refunds for those NHS funded residents at Care UK's premium care homes who paid an unfair additional fee towards essential care. Care UK has also formally committed to stop charging this additional fee to current and future CHC residents at its homes.

- Final undertakings (8.10.20)
- Press release: More than £1m in refunds secured for care home residents (8.10.20)

CMA launches court action against Barchester

24 March 2020: The CMA has now issued court proceedings against Barchester Healthcare Limited and Barchester Healthcare Homes Limited, (together 'Barchester'). This action, taken under section 217 of the Enterprise Act 2002, comes after Barchester's failure to address the concerns set out in a letter before action which the CMA sent to Barchester in July 2019.

Barchester issued with letter before action

25 July 2019: After a period of consultation under the Enterprise Act 2002 (EA02), a letter before action has been issued to Barchester Healthcare Limited, Barchester Healthcare Homes Limited, Grove Limited and

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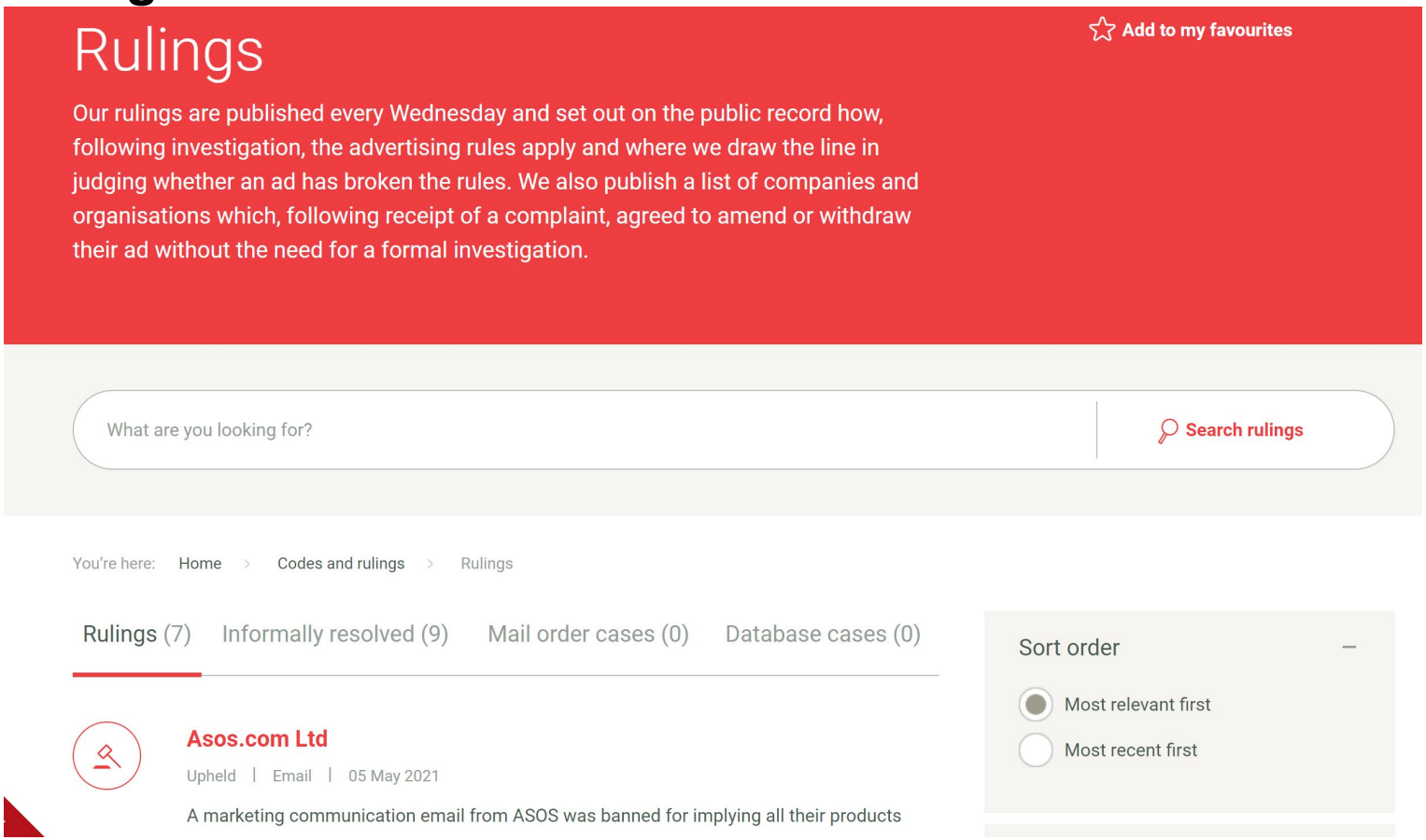
Advertising Standards Authority

Weekly publication of when rules have been broken – can click through on each to find details



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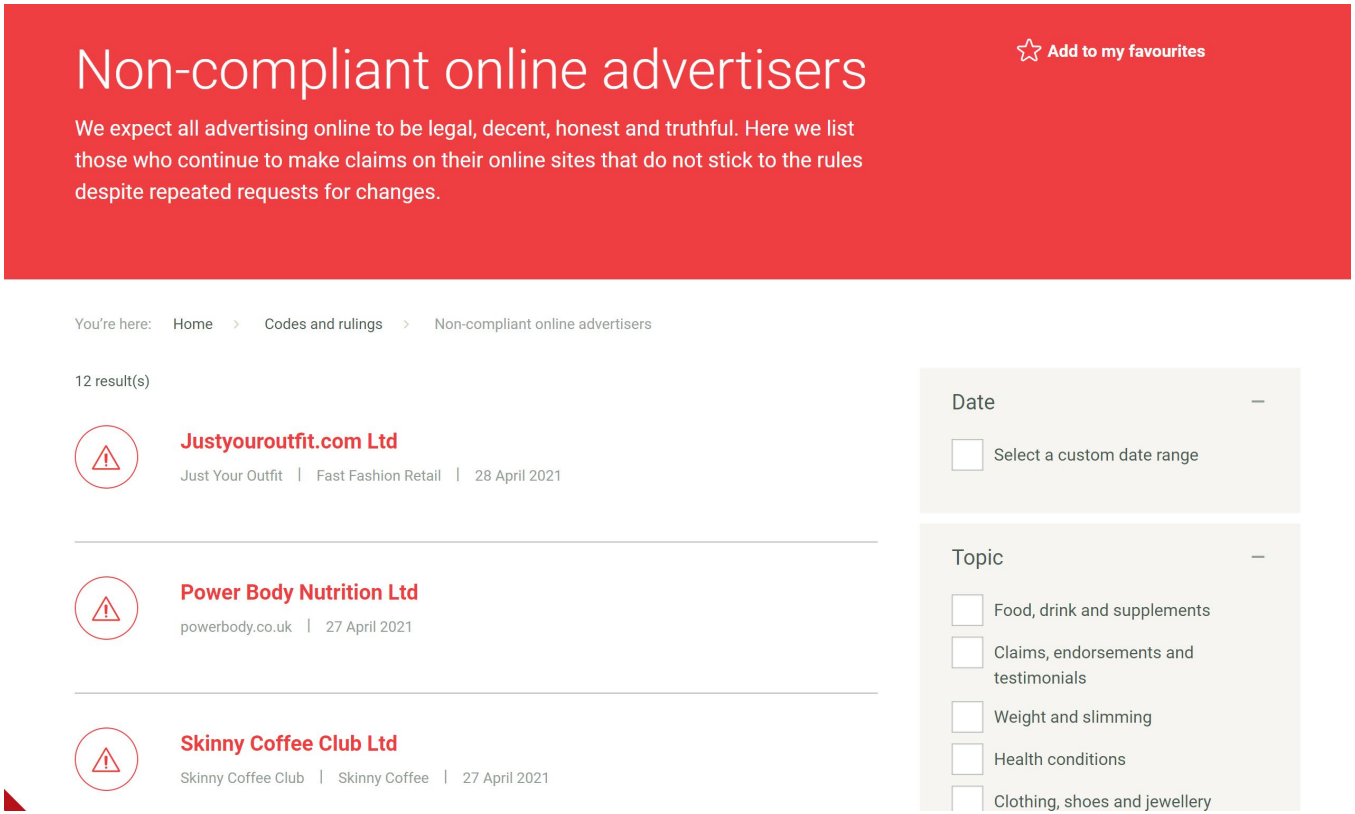
Enforcement activity – can click through on each to find details



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For discussion

For Authority to consider

1. Are there any issues outlined above that you would like more detailed information or review?
2. Are the two principles outlined above still applicable?
3. Is the planned review of the inspection report cover sufficient to tackle the issues discussed?
4. Should any further consideration be given to use of publication as a regulatory tool of incentive?
5. What should we consider and come back to you with in relation to the specific question of the CMA and ASA?
6. Are there other questions in relation to Choose a Fertility Clinic etc that we need to discuss further?

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