

Audit and Governance Committee meeting - agenda



06 Oct 2020

Online

Agenda item		Time
1.	Welcome, apologies and declaration of interests	10.00am
2.	Minutes of 23 June 2020 [AGC (06/10/2020) DO]	For Decision 10.05am
3.	Matters Arising [AGC (06/10/2020) MA]	For Information 10.10am
4.	Digital Programme Update [AGC (06/10/2020) DH]	For Information 10.15am
5.	Internal Audit a) Progress report [AGC (06/10/2020) TS]	For Information 10.45am
6.	Implementation of Recommendations [AGC (06/10/2020) MA]	For information 11.00am
7.	Strategy & Corporate Affairs management [AGC (06/10/2020) CE]	For Information 11.20am
8.	Reserves Policy [AGC (06/10/2020) RS]	For Information 11.35am
9.	Estates Update [AGC (06/10/2020) RS]	Verbal update 11.45am
10.	Resilience, Business Continuity Management Cyber Security training [AGC (06/10/2020) DH]	For Information 11.55am
11.	Legal risks [AGC (06/10/2020) RS]	Verbal update 12.15pm
12.	Strategic Risk Register [AGC (06/10/2020) HC]	For Comment 12.25pm
13.	AGC Forward Plan [AGC (06/10/2020) MA]	For Decision 12.40pm
14.	Gifts and Hospitality [AGC (06/10/2020) MA]	For Information 12.45pm

15.	Whistle Blowing and Fraud [AGC (06/10/2020) MA]	Verbal update	12.50pm
16.	Contracts and Procurement [AGC (06/10/2020) MA]	Verbal update	1.00pm
17.	Any other business		1.05pm
18.	Close		1.10pm
19.	Session for members and auditors only		1.15pm

Next Meeting: Tuesday, 8 December 2020, Online

Minutes of Audit and Governance Committee meeting 23 June 2020

Details:

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Agenda item	2
Meeting date	6 October 2020
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Annexes

Minutes of the Audit and Governance Committee meeting on 23 June 2020 held online

Members present	Anita Bharucha - Chair Margaret Gilmore Mark McLaughlin Geoffrey Podger
Apologies	None
External advisers	Mike Surman, National Audit Office – External auditor Tony Stanley, Internal Auditor – GIAA
Observer	Steve Pugh (Department of Health and Social Care - DHSC)
Staff in attendance	Peter Thompson, Chief Executive Richard Sydee, Director of Finance and Resources Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cutting, Director of Compliance and Information Morounke Akingbola, Head of Finance Dan Howard, Chief Information Officer Yvonne Akinmodun, Head of Human Resources Kevin Hudson, Programme Manager Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager Debbie Okutubo, Governance Manager

1. Welcome and declarations of Interest

- 1.1. The Chair welcomed everyone present online.
- 1.2. There were no declarations of interest.

2. Minutes of 3 March 2020

- 2.1. The minutes of the meeting held on 3 March 2020 were agreed as a true record.

3. Matters arising

- 3.1. The committee noted the progress on actions from previous meetings and agreed that all matters arising be removed as they had either been dealt with or overtaken by events.

4. Internal audit – annual opinion, draft plan

- 4.1. The internal auditor presented this item.
- 4.2. It was noted that the internal audit report on records management had been sent to management for comments and this would be presented at the next committee meeting.

- 4.3.** The final report on external information requests was presented to the committee. The Internal Auditor commented that the arrangements in place for each type of information request had appropriate controls in place for handling as well as effective performance in respect of clearing these within timescales. He highlighted that there were risks to continued effective performance due to issues associated with resilience in relevant teams.
- 4.4.** The Director of Finance and Resources commented that there was a need to tolerate the resilience risk, since in a small organisation, key roles were often held by one person, with no deputies available.
- 4.5.** The Director of Strategy and Corporate Affairs gave a management view stating that Freedom of Information (FOI) requests were always responded to on time and the team had missed only one Parliamentary Question (PQ) deadline in the last two years. It was also noted that there was backup built in to cover staff absences when this was required.
- 4.6.** Regarding the 2019/20 annual assurance statement, the Internal Auditor commented that some improvements were required to enhance the adequacy and effectiveness of the framework of governance, risk management and control. A 'Moderate' overall assurance rating was therefore deemed appropriate for 2019/20 and that was consistent with last year's opinion.
- 4.7.** Members commented that a 'Moderate' overall assurance rating was acceptable to them because of the controls in place in the organisation, for example the use of shared drives, documented processes that were accessible by others and handover notes. These gave them some form of assurance even though there was always room for improvement.
- 4.8.** Members queried the overspend on the current digital programme as it had incurred significant time and budget overspends and asked if this had put us in a risky position.
- 4.9.** The Director of Finance and Resources responded that we now have a grip on the overall overspend in the organisation, but we would revisit the recommendations in the report.

Decision

- 4.10.** Members noted the 2020/21 revised internal audit plan.
- 4.11.** Members noted the 'Moderate' overall assurance rating.
- 4.12.** Members requested that the recommendations be prioritised and brought back to the next meeting.

5. Progress with audit recommendations

- 5.1.** The Head of Finance presented this item. It was noted that of the 25 recommendations, five were complete. There were nine recommendations that had completion dates after the June AGC meeting and the remainder were either due or overdue.
- 5.2.** The Head of Finance highlighted the points below:
- Strengthening audit trails in Content Manager (CM) – it was agreed that this would be addressed and brought back to the next meeting
 - External information requests – Standard Operating Procedures (SOPs) – the schedule stating the review dates and named individuals was still outstanding. It was agreed that this would be addressed and brought back to the next meeting.

- External information requests - knowledge generated by responding to FOIs and PQs to be captured by creating detailed guidance for the processes, including worked examples to be implemented and brought back to the next meeting.
- Business continuity - formal training to be provided to those individuals with a responsibility in delivering the plans and addressing potentially disruptive incidents, with the training formally recorded. The record of the training to be brought back to the next meeting.
- Data loss – the Senior Inspector role to include responsibility over clinics' governance arrangements in managing data loss. This recommendation to be implemented and reported back to a future meeting.

Decision

- 5.3.** Members noted the progress on each recommendation and noted all actions including those highlighted above that would be brought back to the October meeting.
-

6. Senior Information Risk Officer's (SIRO) report

- 6.1.** The Director of Finance and Resources presented the SIRO's annual report to the committee. It was noted that we had an effective information governance framework in place and that the report formed part of the consideration of the Annual Governance Statement (AGS).
- 6.2.** The Director of Finance and Resources commented that we had a low tolerance to breaches of information risk and to mitigate this, information security awareness and training formed part of the induction of all staff. There were also data security and information security controls in place.
- 6.3.** Members asked about the controls to be put in place at Stratford. Staff responded that the level of security that we need to have would be in place as this was part of the discussions being held by all organisations moving in and that we all had similar information security needs.
- 6.4.** Members commented that the report provided assurance but wanted to know if breaches via portable devices or information sent to personal emails could lead to breaches.
- 6.5.** Staff commented that controls were in place to limit access to information, but breaches could not be eradicated completely.

Decision

- 6.6.** Members noted the SIRO report.
-

7. Annual report and accounts

- 7.1.** The annual report and accounts was presented by the Director of Finance and Resources. It was noted that the impact of the Covid-19 pandemic had led to a suspension of all fertility treatments for 2 months. This in turn had a major impact as the majority of the HFEA's income came from licence fees charged to clinics undertaking fertility treatments.
- 7.2.** Members commented that the Department had recognised that additional Grant in Aid funding for the 2020/21 financial year would be needed to support the reduction in licence fee income. The Committee were content that this provided assurance and therefore that the statement on HFEA being a 'going concern' be left in the report.

- 7.3.** Members asked if other arms-length bodies (ALBs) had received notification from the DHSC as a number of ALBs would be in similar positions of needing assistance from the department.
- 7.4.** The DHSC representative commented that that was the case in a broader sense.
- 7.5.** Members suggested that we were particularly vulnerable due to our reliance on treatment in the private sector but were assured by the action of the DHSC and noted that the sector was now restarting.
- 7.6.** Members suggested that in the Chief Executive's (CE) foreword where it was mentioned that almost all treatment was suspended in the UK fertility sector, it could go into a little more detail as to why this was necessary. The CE agreed with the suggestion.
- 7.7.** The Director of Finance and Resources thanked the Head of Finance and National Audit Office (NAO) colleagues and suggested that whilst it was not a complicated set of accounts, working virtually had its challenges which were unprecedented, but despite this all deadlines were met.
- 7.8.** The committee echoed this and extended their appreciation to all staff.

Decision

- 7.9.** Members delegated authority to the CE to sign the accounts subject to the auditors sign off.

8. External audit – completion report

- 8.1.** Mike Surman from the NAO presented to the committee. He noted that his colleague Jill Hearne who as a direct impact of the Covid-19 pandemic had moved wholly to one of her other portfolios.
- 8.2.** He stated that the NAO intended to recommend to the Comptroller and Auditor General (C&AG) that he should certify the 2019/20 financial statements with an unqualified audit opinion, without modification in respect of both regularity and the true and fair view on the financial statements.
- 8.3.** The external auditor stated that the continued engagement during the audit process, particularly following the move to homeworking and the additional challenges that had presented in undertaking the required work was worthy of mention and that HFEA colleagues had greatly supported the process.
- 8.4.** The NAO also agreed that the HFEA was a going concern and the communication from the DHSC provided sufficient assurance on this point.
- 8.5.** The committee was advised that audit adjustments were spotted by the HFEA which meant that the unadjusted misstatements stood at £7,000. This would have been deemed immaterial but due to the size of the HFEA, this figure should be addressed.
- 8.6.** As part of the actions that needed to be resolved, it was noted that the auditors were awaiting letters from the bank confirming the completeness and existence of cash held in commercial bank accounts. Also, that the accruals testing was in progress, as some queries remained outstanding.

Decision

- 8.7.** Members noted the report and agreed that once the NAO work was complete, the CE could sign off the accounts.

9. Resilience, business continuity management, cyber security

- 9.1. The Chief Information Officer presented the report to the committee. Members were advised that the business continuity group continued to meet to review HFEA IT issues resulting from the Covid-19 pandemic including changes to support homeworking.
- 9.2. The committee noted that additional IT and office equipment had been provided to staff to support homeworking and the IT team were responding to IT support issues as they were raised.
- 9.3. Members were also informed of the planned upgrades to the accounting and business intelligence systems, and the review of the network security policy. There were also recent improvements to the electronic document management system.
- 9.4. In response to a question on teleconferencing, staff commented that Zoom had a few advantages compared to Microsoft Teams but security on the latter was more sophisticated.
- 9.5. Regarding IT failures, staff commented that there were controls in place to mitigate this, and the recent upgrade to new Pulse VPN and moving files to the cloud also mitigated potential IT failures.
- 9.6. Members thanked the IT team for getting everyone, both Authority members and staff, online successfully.

Decision

- 9.7. Members noted the update.

10. Digital programme update

- 10.1. The Programme Manager gave the committee an update following the PRISM Overview meeting held on 5 June 2020.
- 10.2. It was noted that clinics had been contacted and none had indicated that they were unable to take on the new system or raised any major issues.
- 10.3. The committee received an update on staffing issues in the team including a key staff member who was retiring.
- 10.4. In response to a question it was noted that there would be a handover period and the staff member to lead on the PRISM project had been identified and would get the required support.
- 10.5. The committee discussed in detail the update it had received on the programme, and in particular focussed on issues and risks in relation to staffing, programme timetable and resourcing.
- 10.6. Members noted the update and the monthly catch-up scheduled meeting.

11. Strategic risk register

- 11.1.** The Risk and Business Planning Manager presented the revised version of the strategic risk register. The register had been revised to align with the new strategy which would be launched later in the year, and three new strategic risks had been captured, to replace those aligned to the last strategy. Existing strategic risks had been reviewed and reframed.
- 11.2.** It was noted that there were three risks above tolerance:
- Board capability
 - Financial viability
 - Coronavirus
- 11.3.** Board capability. It was noted that forthcoming issues with members' terms of office ending had been escalated and discussions were happening with the DHSC. Staff advised that the DHSC were looking at targeted extensions so as not to lose expertise as changes in Board capability and capacity could impact the legal functions of the Authority and as such our tolerance threshold for this risk was low.
- 11.4.** The CE commented that the DHSC would issue the advert for four member vacancies very soon and the recruitment of a new Chair would begin in September.
- 11.5.** Financial viability. It was noted that a paper went to the Authority's June meeting. Due to the Covid-19 pandemic and the suspension of clinic treatment activities there was limited income for as long as GD0014 (version 2) was in place. Furthermore, although some clinics were now resuming treatment, it could take some time for activity to return to normal levels which meant that our income would be lower than planned.
- 11.6.** Members were advised that the fees project was underway and that we were looking to have identified a workable model (or models) over the summer. However, forecasting over the next 18 months would be difficult because of the impact of coronavirus. There were also ongoing discussions with the DHSC.
- 11.7.** Coronavirus. It was noted that the coronavirus risk which has been on the register since March has had a cascading effect across the whole risk register and this would be the case for the foreseeable future. Following comments at the last meeting, the Risk and Business Planning Manager informed the committee that the register had been updated to contain the strategic risks and the more operational content has been pushed down to team operational risk registers.
- 11.8.** Members commented that a direct impact of the coronavirus was homeworking and that there could be a downside to people working from home as they could start to depend more on their own initiative and lose out on collaborative working with colleagues. Members also suggested

that a greater risk was when new people joined the organisation and due to everyone working from home it was more difficult to instill a collaborative working culture.

- 11.9.** Staff commented that lessons learned would be captured and findings reported to AGC. Members agreed that this needed to be kept as a live document. The Chair suggested that the report on this be brought to the December meeting.
- 11.10.** Members noted that compared to June 2019 there were a higher number of risks that were above tolerance.

Decision

- 11.11.** Members noted the latest edition of the risk register.
- 11.12.** A report will be brought to the December meeting on the lessons learned from the risk management of coronavirus.

12. Human resources – bi-annual report

- 12.1.** The Head of Human Resources presented a paper providing a broad overview of work that had taken place in the last six months within the organisation.
- 12.2.** In April, a short survey was launched to find out how staff were feeling about working at home during lockdown, 85% of staff responded. Of those, 93% felt connected to their teams and the work of the HFEA. Overall, it was a positive response from staff.
- 12.3.** The Head of Human Resources stated that other ALB Human Resource departments had been meeting online and HFEA were in line with what they were doing to check on staff wellbeing.
- 12.4.** It was noted that there was still some outstanding issues including the effect of the Covid-19 pandemic on Black and Minority Ethnic (BAME) staff and concerns raised by staff about not wanting to work virtually. It was noted that Occupational Health resources were available to staff. The effect of virtual working on staff with caring responsibilities was also being explored.
- 12.5.** In response to a question, it was noted that no staff were furloughed, and that staff will continue to work from home until at least September when a review will take place.
- 12.6.** Regarding annual leave, the Head of Human Resources commented that staff were being advised to take their holidays, even if they couldn't travel away. It was important to rest and look after staff wellbeing.
- 12.7.** Members asked if staff were working overtime and if so, how was it being addressed. Staff responded that other than the Senior Management Team, there was no overtime being reported and where it was happening, the policy in HFEA was to take time off in lieu (TOIL).
- 12.8.** It was noted that the annual full staff survey closed on 12 June. 83% of staff responded and an action plan would be put in place to support the findings from the survey with a detailed report brought back to the committee.
- 12.9.** Members were informed that there had been a significant decline in staff turnover in recent months. This was probably due to a range of factors including the effect of the Covid-19 pandemic and being able to offer opportunities for internal promotion and development.

- 12.10.** Members were also advised that the planned office move to Stratford was still set to take place later on in the year and that government guidance on coronavirus would be adhered to before, during and after our move to Stratford.
- 12.11.** Members asked if staff in key roles had been identified that might not be moving with us and what contingency was in place for such positions.
- 12.12.** The CE responded that they were not aware of any although some degree of turnover may be inevitable. But on a positive note flexible working remained a plus for HFEA and staff had confirmed this during the recent staff surveys. The conversation would continue with staff.

Decision

- 12.13.** The Committee noted the content of the report.
-

13. Audit and governance committee forward plan

- 13.1.** The Head of Finance presented the AGC forward workplan to the committee.
- 13.2.** Members requested that the Director of Strategy and Corporate Affairs present to the meeting in October and the Director of Compliance and Information in December.

Decision

- 13.3.** Members noted the forward plan.
-

14. Register of gifts and hospitality

- 14.1.** The register of gifts and hospitality was presented to the committee. There were no changes.
-

15. Whistle blowing and fraud

- 15.1.** The Director of Finance and Resources stated that there was nothing to report.
-

16. Contracts and procurement

- 16.1.** There were no contracts signed for this period.
-

17. Estates update

- 17.1.** The Director of Finance and Resources stated that the office move was moving faster than had been anticipated and it was looking likely we would have a move-in date in October.
- 17.2.** Most issues had been resolved but the use of meeting rooms and desk space was still under consideration.

Decision

- 17.3.** Members to be kept updated.
-

18. Any other business

- 18.1.** There was no other business to discuss.

19. Chair's signature

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

Signature

A handwritten signature in black ink, appearing to read 'A Bharucha', written in a cursive style.

Name

Anita Bharucha

Date

6 October 2020

Matters arising from previous AGC meetings

Strategic delivery:	<input type="checkbox"/> Safe, ethical, effective treatment	<input checked="" type="checkbox"/> Consistent outcomes and support	<input type="checkbox"/> Improving standards through intelligence
Details:			
Meeting	Audit and Governance Committee		
Agenda item	3		
Paper number	HFEA (06/10/2020) MA		
Meeting date	6 October 2020		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each AGC		
Implementation date	2020/21 business year		
Communication(s)			
Organisational risk	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> High

Numerically:

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 23 June 2020			
4.12 Internal audit recommendations to be prioritised and tabled at the October meeting	Chief Information Officer	Oct-20	Update – Records Management report has been amended by GIAA and has been updated in the Audit Tracker
11.2 Lessons learned report from the risk of management of COVID-19 to be brought to the December meeting	Director of Finance and Resources	Dec-20	Update – not due till December



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PRISM update

Dan Howard

Chief Information Officer

6 October 2020

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Recap on our launch approach

- As agreed with AGC on 18 September:
 - *the launch of PRISM is effectively a process rather than an event*
 - *the release candidate, clinic training, data migration, PRISM go live.*
- ‘PRISM reprofiling plan’ developed:
 - *‘clinic engagement, integrated testing and data cutover, and RITA development - with a CaFC verification running in parallel underpinned by EDI migration’*
- PRISM launch
 - commence with the sharing of the Release Candidate of clinics on 12 October 2020
 - Data ‘go-live’ will be on 25 January 2021

The Release Candidate

- At the end of September, both PRISM homepage and API reporting were completed. **This completes the PRISM build.**
- Release candidate will be shared with 'standalone (non-API) clinics' on 12 October along with their basic training package.
- The final bulk package of APIs will be sent to system suppliers during week commencing 12 October.
- Peter Thompson will then write to PRs at all clinics, advising of PRISM launch and our expectations of the system.

Clinic engagement and training

- We have a four stage process for ensuring that clinics maximise their PRISM expertise by 25 January 21 (our data 'go live' date):
 - From 12 Oct: **Basic training** on the Release Candidate
 - Mid Nov: **Advanced training** on complex fertility scenarios
 - Early Dec: **Specialist training** on functions not offered by all clinics (e.g. surrogacy)
 - Early Jan 21: **Live training** on the clinics' own data before go-live
- Kevin Hudson will lead the PRISM familiarisation and training with weekly video conference sessions with support from the inspectors.
- For API clinics we will work closely with the three system suppliers (Ideas, CARE, Meditex) to ensure they are on track for go-live

Data migration and integrated testing

- PRISM has already passed its functional tests
- We have already imported data into PRISM and conducted tests.
- Initial data tests have identified no major issues, although have shown some refinements in data migration we would like to make.
- Our extension of integrated testing will test the following:
 - That functional tests can be repeated in a live environment
 - Extend legacy data testing to confirm our initial results
 - Check automatic validation rules and how they present to clinics
- Integrated testing will finish on 30 November and all data migration adjustments will be complete by 23 December.
- From 4 January 2021, A 'live data' Release Candidate will be shared with clinics to support their final stage of training.

RITA development

- RITA stands for Register Information Team Administration System
- There are two Phases for RITA:
 - Phase 1: Staff functionality felt essential for launch
 - Phase 2: Other functionality that staff believe is needed
- We will proceed immediately to develop RITA phase 1. Developers will start work on this after Release Candidate and API release.
- We anticipate RITA Phase 1 will complete by 23 December.
- We will take more time to develop the requirements for Phase 2 and allow these to be informed by the actual experiences of PRISM by both staff and clinics once the system goes live.
- Alongside this, we also need to confirm the new HFEA reporting structure that will drive functions such as the 2021 CaFC process.

CaFC verification and EDI migration

- In parallel to the PRISM launch process we will be running a full CaFC verification process and migrating EDI out of Spring Gardens
- CaFC verification reports will go out to clinics on 12 October.
- Thereafter there is a clearly laid out timetable of deadlines for clinic responses to ensure completion of 2020 CaFC by Christmas.
- With Alscient, we have worked out the details of the EDI migration and expect this to happen on 2 and 3 November.
- Clinics manually entering data to EDI will need to make a small manual IT change at their end at this time.
- We will communicate this through the 'technical' leads already established by PRISM launch to ensure it happens smoothly.

Data cutover and 'go-live'

- All work on final PRISM testing and RITA Phase 1 will complete by Christmas. CaFC verification will also complete by this time.
- From January the organisational focus will be on data cutover and a PRISM 'go-live'. Iergo will help HFEA safely navigate this process.
- Iergo have a detailed data cutover and system retirement plan:
 - 13 Jan: Close EDI to data entry after HFEA finance runs.
 - 15 Jan: Commence cutover and check the results.
 - 25 Jan: All checks complete, open to clinics for live data entry.
- From 25 January we will need to closely support clinics to ensure they are bedded in and help resolve any data quality or backlog issues.
- We also need to track system supplier deployment of new API user interfaces.
- PRISM will be embedded by 31 March 2021.



Financial review and affordability

- Reprofiting brings forward certain work and results in additional costs of **£230,380** during 2020/21
 - PRISM build and cutover
 - Cover for early retirement of PRISM Development Manager
 - Clinical Engagement
 - Developing RITA
 - EDI migration from Spring Gardens
- Around **£160k** identified through underspends
- Around **£70k** outstanding – to be identified during finance reviews by end October

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Strategy and Corporate Affairs update

Clare Ettinghausen

Director of Strategy and Corporate Affairs

October 6 2020

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The 'Stratcad' directorate

Planning and Governance

Head: Paula Robinson

- Licensing
- Corporate governance
- Strategic and Business planning
- Risk management
- Programme management
- Performance Monitoring

Research and Intelligence

Head: Nora Cooke O'Dowd

- Information access
- Data analysis
- Intelligence reports
- Data research governance
- FOIs and PQs

Engagement and Communications

Head: Jo Triggs

- Patient information/enquiries
- Internal communications
- Media, campaigns, reports
- Digital and social media
- Communications with clinics
- Stakeholder engagement

Policy

Head: Laura Riley/Joanne Anton

- Standards and guidance
- Public enquiries
- Stakeholder engagement
- Scientific horizon scanning
- Policy project across and outside organisation

Directorate risks: trends

2016 risks

- CaFC litigation
- Vacancies in Governance
- PQ/FoI resilience
- Capacity issues in Comms
- Stakeholder acceptance of website

2017 risks

- Appeal and CaFC litigation
- Staff turnover
- Capacity in Governance
- Comms impact
- Capitalising on data opportunities

2018 risks

- Appeal and CaFC litigation
- Staff turnover/Capacity of key staff
- Comms impact
- Capitalising on data opportunities
- Code implementation - realising changes in Clinic practice

Directorate risks: 2019/20

- Resilience within directorate – one person/one role
- Staff turnover/impact of office move
- Poor internal comms by leading to miscommunication
- Capacity to achieve strategic objectives and BAU
- Capitalising on data opportunities
- Processing around Register Research Panel requirements
- Capacity of other teams to support our work e.g. IT
- Realising changes in Clinic practice e.g. treatment add-ons
- Matching ambition with resource – having a joined up approach across the organisation
- Core standards and processes being adhered to across the organisation
- Other data providers and our response



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Clare Ettinghausen

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Reserves policy

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting AGC

Agenda item 8

Paper number HFEA (06/10/2020) RS

Meeting date 6 October 2020

Author Richard Sydee, Director of Finance and Facilities

Output:

For information or decision? For information

Recommendation The AGC is requested to approve the unamended Reserves Policy.

Resource implications

Implementation date 2020/21 business year

Communication(s)

Organisational risk Low Medium High

Background

1. Prior to 2016 the HFEA routinely declared surplus income in its annual accounts and this had led to a considerable cash reserve. In recent years, due to increased expenditure on development projects and by not increasing the licence fees we charge clinics we have been able to limit further increases in our reserves
2. The committee last reviewed the HFEA reserves policy in 2019, although the better management of in year funds was noted the committee agreed with the executive and HFEA auditors that efforts should continue to be made to reduce the existing reserve levels, and agreed a new baseline levels for cash reserves. The Authority and AGC agree that the preferred method for reducing this balance would be investment in priority projects, but that the resulting accounting impact (reporting a deficit in year) would not comply with DHSC and HMT guidance.
3. At the end of the 2019/20 financial year the HFEA had maintained cash reserves at the same level as the previous year (£2.6m). However, the impact of COVID19 on the sector and HFEA licence fee income has had a considerable impact on our cash holdings..
4. The temporary cessation of treatments across the sector between March and June 2020 has had a negative impact on our cash reserves. With effectively no income the HFEA were forecasting that without additional support it would exhaust its cash reserves in quarter 3 of the 2020/21 financial year.
5. We have now reached agreement with the Department to provide additional Grant In Aid (GIA) of £2.4m; in conjunction with sector activity restarting we now believe that we have sufficient funding to meet all our liabilities this financial year, albeit we may still report a small deficit which will require the use of our cash reserves. We continue to monitor clinic activity and our cash expenditure closely and expect to provide an update to the Board following our full quarter 2 review of finances, which will complete in October
6. Although this has been an unprecedented year in terms of our finances, we propose no material change to our reserves policy. The reserve limits we set were sufficient to allow the organisation to take stock of the emerging situation and enter into negotiations with the Department for additional funding, as such we remain confident that the limits as set are robust and appropriate for an organisation our size.
7. Our overall reserves will likely be reduced by the end of the 2020/21 financial year, but this is manageable and should not result in our reserves falling below the £1.4m we set out in the policy.
8. The committee are asked to review and approve the enclosed Reserves policy

Reserves Policy

Introduction

The purpose of this policy is to ensure that both the Executive and Authority of the HFEA are aware of the minimum level at which reserves are maintained and the reasons for doing so. The minimum level of reserves set out in this policy has been agreed with the Department of Health.

Principles

An organisation should maintain enough cash reserves to continue business operations on a day-to-day basis and in the event of unforeseen difficulty and commitments that arise. It is best practice to implement a reserves policy in order to guide key decision-makers.

Reserves Policy

1. The Authority has decided to maintain a reserves policy as this demonstrates:
 - Transparency and accountability to its licence fee payers and the Department of Health
 - Good financial management
 - Justification of the amount it has decided to keep as reserves
2. The following factors have been taken into account in setting this reserves policy:
 - Risks associated with its two main income streams - licence fees and Grant-in-aid - differing from the levels budgeted
 - Likely variations in regulatory and other activity both in the short term and in the future
 - HFEA's known, likely and potential commitments
3. The policy requires reserves to be maintained at least at a level that ensures the HFEA's core operational activities continue on a day-to-day basis and, in a period of unforeseen difficulty, for a suitable period. The level should also provide for potential commitments that arise.

Cashflow

4. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes account of when receipts are expected, and payments are to be made. Most receipts come from treatment fees - invoices are raised monthly and on average take 60 days to be paid. Cash reserves are needed to ensure sufficient working capital is available to make payments when they become due throughout the year.
5. The HFEA experiences negative cashflow (more payments than receipts) in some months but overall there is a net positive position. Based on a review of our cashflows over the last few years we see on average net cash outflows over the last quarter of c£300k, with the range being between £100k and £400k. In order to ensure that there is always a positive cash balance we would wish to maintain a working capital cash balance of £400k, based on our most unfavourable outflow in the last 4 years.

Contingency

6. The certainty and robustness of HFEA's key income streams, the predictability of fixed costs and the relationship with the Department of Health would suggest that HFEA would be unlikely to enter a prolonged period of financial uncertainty that would result in it being unable to meet its financial liabilities.
7. However, it is clearly prudent for an organisation to retain a sufficient level of reserves to ensure it could meet its immediate liabilities should an extraordinary financial incident occur.
8. In arriving at a reserve requirement for unforeseen difficulty we have considered the likely period that the organisation might need to cover and whilst discussions are undertaken to secure the situation, the immediate non-discretionary spend that would have to be met over that period.
9. We believe that a prudent assumption would be to ensure a minimum of two months of fixed expenditure is maintained as a cash reserve; in terms of the costs that would need to be met we consider the following to be non-discretionary spend that would be required to ensure the HFEA could maintain its operations:
 - a. salaries (including employer on-costs);
 - b. the cost of accommodation.; and,
 - c. Sundry costs related to IT contracts, outsourced services and other essential services.

10. These fixed costs would have to be paid in times of unforeseen difficulty, salaries and accommodation costs alone represent 69% of the HFEA's total annual spend.
11. Based on the HFEA's current revenue budget, the combined monthly cost of salaries and accommodation is £407k, accommodation costs have increased since the relocation to Spring Gardens in 2016. A reserve of two months for these two elements would therefore be £814k.
12. A further reserve for other commitments for two months is estimated to be £150k.

Minimum reserves

13. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£400k), provides £964k for contingency. The minimum level of cash reserves required is therefore £1.4m. These reserves will be in a readily realisable form at all times.
14. Each quarter the level of reserves will be reviewed by the Director of Finance and Resources as part of the HFEA's ongoing monitoring of its cash flow.
15. Each autumn as part of the HFEA's business planning and budget setting process, the required level of reserves for the following financial year will be reassessed.
16. In any assessment or reassessment of its reserves policy the following will be borne in mind.
 - The level, reliability and source of future income streams.
 - Forecasts of future planned expenditure.
 - Any change in future circumstances - needs, opportunities, contingencies, and risks – which are unlikely to be met out of operational income.
 - An identification of the likelihood of such changes in these circumstances and the risk that the HFEA would not be able to meet them.
17. HFEA's reserves policy will be reviewed annually by the Audit and Governance Committee.

Document name	Reserves Policy
Original release date	October 2014
Author	Head of Finance
Approved by	CMG
Next review date	September 2021
Total pages	3

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created	DoF	AGC	Feb 2015
2.0	Branded/amended	HoF	AGC	Dec 2016
2.1	Cashflow figures amended	HoF	AGC	Oct 2017
2.2	Reviewed	HoF	AGC	Oct 2018
2.3	Reviewed by DoF and amended	HoF	AGC	Dec 2019
2.4	Reviewed by DoF	Hof	AGC	Oct 2020

1. Introduction and background

- 1.1. In recent months, AGC has received regular and detailed updates on Resilience, Business Continuity Management and Cyber Security, in line with the strategic risk register.
- 1.2. Our Business Continuity group continues to meet regularly to consider the IT impact and emerging issues as a result of the Covid-19 pandemic.
- 1.3. We continue to make IT infrastructure improvements and decommission redundant hardware and systems ahead of the move to the new office.
- 1.4. Following AGC agreement earlier this month to the reprofiling of PRISM launch our Choose a Fertility Clinic (CaFC) refresh has started. The timeline is set out below.
- 1.5. We will be submitting a Data Security and Protection Toolkit assessment later in the current financial year to provide both provide assurance against this standard and continually improve data security resilience.
- 1.6. Teams have made good progress with respect to records management document retention and an update is below.

2. Responding to Covid-19 and supporting remote working

- 2.1. Our Business Continuity group (SMT plus IT, HR and Communications) has continued to meet regularly to take necessary action as a result of the Covid-19 pandemic.
- 2.2. We have continued to monitor the Microsoft Teams / Pulse upgrades and the systems remain stable and are working well.
- 2.3. Over the coming months and following UK government guidance some HFEA staff may work from the CQC / HTA offices at Buckingham Palace Road. We will be providing 4G hotspots to support staff working from this location to ensure continuation of system access and data security.

3. Infrastructure improvements

- 3.1. Planning continues to support the move to our new build to ensure systems and network are available. The systems and hardware test strategy has been agreed. The IP (Internet Protocol) address range has been agreed between DHSC and our network provider. We have agreed the scope for the additional on-site IT service. We are now awaiting readiness of the computer suite and for the network to be installed by third party suppliers.
- 3.2. Our work continues to decommission IT hardware at Spring Gardens. Epicentre was successfully moved to the Microsoft Azure cloud along with several production databases in early September 2020.
- 3.3. Following AGC agreement earlier this month, work has started to migrate the EDI application to Microsoft Azure.
- 3.4. Other system upgrades have taken place recently including Tableau (business intelligence and analytics software used by the Intelligence team) and upgrading Sage (finance system).

4. Choose a Fertility Clinic refresh

- 4.1. Following AGC agreement earlier this month to the reprofiling of PRISM launch, we have started the CaFC update process.
- 4.2. In early October we will provide PRs with the usual CaFC verification reports. From then, the register team will be available to support clinics with any queries from those reports.
- 4.3. To allow CaFC verification we will be undertaking maintenance work on EDI and the Register during the next eight weeks, as mentioned in section 3.3 above. All clinics will be required to undertake a minor IT change (updating the IP address) to enable their systems to communicate with the EDI application in its new location to allow continued data submission.
- 4.4. The deadline for data submission and resolving data errors is 4 December 2020, after which PRs will be asked, as usual, to sign off their reports. We will provide a breakdown of CaFC performance information to AGC in due course for information. Following PR sign-off and Corporate Management Group approval to proceed, we will then refresh the CaFC information on our website.

5. Data Security and Protection Toolkit (DSPT)

- 5.1. We have agreed with the DHSC and NHSX that we will complete a Data Security and Protection Toolkit (DSPT) annual assessment. The next one is due before 31 March 2021.
- 5.2. The Data Security and Protection Toolkit is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards. It is typically completed by organisations that process NHS data.
- 5.3. The requirements for the DSPT are tailored to each organisation type, ours being the DHSC ALB type.
- 5.4. The 10 data security standards are
 - Keep personal confidential data secure, and only share it lawfully.
 - Staff understand their responsibilities.
 - Annual staff training (including passing a mandatory test).
 - Access to personal confidential data on a 'need to know' basis only.
 - Annual process reviews.
 - Identify and immediately respond to cyber attacks and data breaches.
 - Have an annually tested data security continuity plan.
 - No unsupported IT systems or software are used.
 - Have a cyber security strategy based on best practice (e.g. Cyber Essentials).
 - Suppliers are held accountable for protecting confidential data via contracts
- 5.5. There are up to 146 evidence items for ALBs to provide. We will confirm the scope of our return with NHSX shortly.
- 5.6. We will keep AGC updated on progress and ask AGC to sign off our DSPT assessment ahead of its submission.

6. Information Governance and Document Management

- 6.1.** Information Champions continue to review and delete electronic records. Steady progress has been made in recent months by the finance and communication teams. The Inspectorate have set up weekly meetings to review records deletion as well as the creation of records/folders within the Content Manager system. The HR team have electronic files outside of the Content Manager system to review and their work is scheduled to complete by February 2021.
- 6.2.** Planning has started to develop a digital archive within Content Manager to temporarily hold records marked for permanent retention to form our corporate memory.
-

7. Recommendation

The Committee is asked to note:

- That our Business Continuity group has continued to meet to review HFEA IT issues resulting from Covid-19
- The IT infrastructure work taking place ahead of the move to the new office and the upgrade to business intelligence and finance systems
- The details and timeline relating to the next Choose a Fertility Clinic refresh
- That we will be submitting an assessment against the Data Security and Protection Toolkit (DSPT) before 31 March 2021.
- Recent improvements and progress made in relation to electronic document management

Strategic risk register 2020-2024

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Audit and Governance Committee
Agenda item:	12
Paper number:	HFEA (06/10/2020) HC
Meeting date:	6 October 2020
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:	AGC is asked to note the latest edition of the risk register, set out in the annex.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from AGC will inform the next SMT review later in October. Authority will next review the strategic risk register at its meeting on 11 November.
Organisational risk:	Medium

1. Latest reviews

- 1.1. SMT reviewed the register at its meeting on 7 September. SMT reviewed all risks, controls and scores.
- 1.2. SMT's comments are summarised in the commentary for each risk and at the end of the register, which is attached at Annex 1. The annex also includes a graphical overview of residual risk scores plotted against risk tolerances.
- 1.3. Two of the ten risks are above tolerance.

2. Recommendation

- 2.1. AGC is asked to note the above, and to comment on the strategic risk register

Strategic risk register 2020-2024

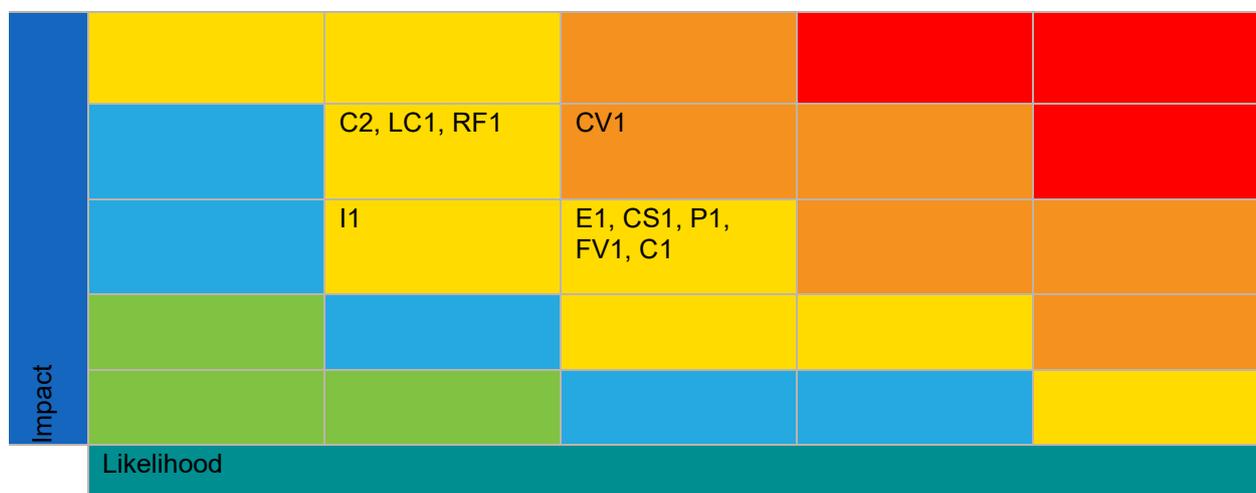
Risk summary: high to low residual risks

Risk ID	Strategy link	Residual risk	Status	Trend*
CV1 - Coronavirus	Whole strategy	12 – High	At tolerance	↔↔↔↔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	9 – Medium	Above tolerance	↔↔↔↔
FV1: Financial viability	Generic risk – whole strategy	9 – Medium	At tolerance	↔↔↔↓
P1 – Positioning and influencing	Shaping the future (and 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	↔↔↔↔
C2: Board capability	Generic risk – whole strategy	8 – Medium	Above 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	↔↔↔↔
I1 – Information provision	The right information	6 - Medium	Below tolerance	↔↔↔↔

*This column tracks the four most recent reviews by AGC, SMT or the Authority (eg, ↑↔↓↔).

Recent review points: SMT 10 June 2020 ⇔ AGC 23 June ⇔ SMT 20 July 2020 ⇔ SMT 7 September 2020

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 at a remove 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 is 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.

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).	<p>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).</p> <p>We take external legal advice as relevant where developments are outside of our direct remit (ie, on an incidence of AI technology being used in the fertility sector) and utilise this to establish our legal/regulatory position.</p> <p>We are analysing where there are gaps in our regulatory powers so that we may be able to make a case for further powers if these are necessary, whenever these are next reviewed.</p>	<p>In progress - Clare Ettinghausen</p> <p>Ongoing - Catherine Drennan</p> <p>In progress as at September - Laura Riley, Joanne Anton, Catherine Drennan</p>

Causes / sources	Controls	Timescale / owner of control(s)
<p>We may have ineffective tools, systems, or regulatory interventions available which are too rigid and cannot be adapted to changes.</p>	<p>Regular review processes for all regulatory tools such as:</p> <ul style="list-style-type: none"> • Code of Practice (we are considering the timing of the next review and any risks related to delay). • Compliance and enforcement policy • Licensing SOPs and decision trees <p>To enable us to revise these and prevent them from becoming ineffective or outdated.</p>	<p>In place, last update December 2019 – Laura Riley, Joanne Anton</p> <p>Currently under review as at September (delivery extended due to Covid-19) – Catherine Drennan, Rachel Cutting</p> <p>In place and review ongoing – Paula Robinson</p>
<p>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.</p>	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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 immediate responses such as a Chair’s letter or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.</p>	<p>In place – Laura Riley, Joanne Anton</p> <p>In place - Peter Thompson</p>
<p>We may focus on ‘pet projects’ or ephemeral interests being influenced by personal preferences or biases.</p>	<p>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.</p>	<p>Ongoing – Peter Thompson</p>
<p>We have limited capacity, which may reduce our ability to respond quickly to new work,</p>	<p>Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions.</p>	<p>In place – Peter Thompson</p>

Causes / sources	Controls	Timescale / owner of control(s)
since we may need to review and stop doing something else.	Any reprioritisation of significant Strategy work would be discussed with the Authority.	
We may have a lack of staffing expertise or capability in the areas developments occur in.	<p>As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff.</p> <p>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 temporary or sharing skills with other organisations.</p>	Ongoing - Relevant Head/Director with Yvonne Akinmodun
<p>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.</p> <p>Note: as at September 2020 we are actively discussing risk management, as we continue to plan RITA delivery.</p>	<p>Launch date of PRISM delayed due to Covid-19. RITA will be built sequentially after PRISM and while RITA development has not started, it is expected that RITA will be complete before the team need to support a fully launched PRISM.</p> <p>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.</p> <p>If additional development work is required to complete RITA 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.</p>	<p>Plans in place – Dan Howard</p> <p>Ongoing – Dan</p> <p>Under review as plans develop - Dan</p>
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.	<p>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.</p> <p>Revising our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool).</p> <p>Process to be established for reviewing data on the Register and adding fields when required.</p>	<p>In place - Laura Riley</p> <p>Audit tool being tested and launched in clinics from Autumn 2020 - Rachel Cutting</p> <p>Within 2020/2021 business year - Dan Howard</p>
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.	Within 2020/2021 business year - Dan Howard

Causes / sources	Controls	Timescale / owner of control(s)
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
<p>DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.</p>	<p>Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation.</p> <p>Provided a considered response to the Department's storage consent consultation to give the HFEA position.</p>	<p>Ongoing - Peter Thompson</p>

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 regulatory duties and it 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.

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.	<p>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.</p> <p>We undertake activities to raise awareness of our information, such as using social and traditional media.</p> <p>We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us.</p>	In place and ongoing - Jo Triggs
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

Causes / sources	Controls	Status / timescale / owner
We might undermine our own role as an information provider by partnering with too many others to provide information or doing so in an ad hoc and non-strategic way.	<p>Ensure a stakeholder engagement plan is agreed and revisited frequently.</p> <p>Stakeholder engagement plans considered as part of project planning to ensure this is effective.</p>	<p>Early work done but development needed, future control – Clare Ettinghausen</p> <p>Ongoing – Paula Robinson</p>
We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites, or clinics post their own data.	<p>Monitoring of clinic websites at the renewal inspection point to ensure that the data there is accurate and in line with guidance.</p> <p>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.</p>	<p>In place and being reviewed during Covid-19 period - Rachel Cutting, Sharon Fensome Rimmer</p> <p>In place and ongoing - Jo Triggs</p>
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 targeting our resources.	<p>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.</p> <p>Links to other specialist organisations in place as relevant on the website (ie, Fertility Network UK, BICA, BFS, endometriosis UK etc).</p>	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
<p>We may provide inaccurate information to the media or public enquiries.</p> <p>Though we have well established and effective working practices and controls,</p>	<p>Regular communication between relevant teams. Information provided in enquiries is checked within teams and by legal or at a more senior level if needed.</p> <p>Briefings when key reports etc are issued to ensure others know the key issues, statistics etc.</p>	In place and ongoing - Jo Triggs, Joanne Anton

Causes / sources	Controls	Status / timescale / owner
we must continue to be aware of and mitigate this risk.		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. Donors and donor conceived offspring may not have the information they need to deal with this.	<p>Maintain links with donor organisations to mutually signpost information and increase that chance that this will be available to those in this situation.</p> <p>Developed links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications.</p>	<p>In place and ongoing - Jo Triggs</p> <p>In place and ongoing - Laura Riley</p>
Our OTR workload will increase in 2021/2023 (when children born after anonymity was lifted 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 – to be undertaken in Q3/4 2020/2021 - Dan Howard
Ineffective media management may mean we don’t correct incorrect information available elsewhere or signpost our own.	<p>Good 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.</p> <p>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.</p> <p>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.</p>	<p>In place and ongoing - Jo Triggs</p> <p>In place - Jo Triggs</p> <p>Jo Triggs – Last reviewed January 2020</p>
We may not get our information out to clinics if they do not use the Clinic Portal.	<p>We duplicate essential communications by also sending via email to the centres’ PR and LH (for instance, all Covid-19 correspondence).</p> <p>We actively encourage all PRs to make full use of the Clinic Portal.</p>	In place - Rachel Cutting
Risk that key regulatory information will be missed if Clinic focus, Clinic Portal or emails are not being read.	<p>As above, there is a statutory duty for PRs to stay abreast of updates.</p> <p>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.</p> <p>We are considering implementing a formal annual catch-up between clinics and an inspector.</p>	<p>In place – Rachel Cutting</p> <p>In place – Laura Riley, Joanne Anton</p> <p>Possible future control, TBC – Rachel Cutting</p>
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.	In place – Rachel Cutting

Causes / sources	Controls	Status / timescale / owner
	We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.	
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	3	3	9 - Medium
Tolerance threshold:					9 - Medium
Status: At 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.

Although we have not yet publicly launched our new strategy, the decisions taken over the next months prior to its launch will have an impact on these strategic risk areas, so we are already beginning to think about these risks and controls in order to manage them effectively.

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. 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 but development needed, future control – Clare Ettinghausen In place - Paula Robinson
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

Causes / sources	Controls	Status/timescale / owner
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 will clearly communicate our intentions, to ensure that these are not misunderstood or misinterpreted and 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 are investigating holding an annual meeting with key innovators (in industry).	In place - Laura Riley/Joanne Anton In place - Laura Riley/Joanne Anton In place and ongoing – Sharon Fensome-Rimmer Future control, to review in autumn - Rachel Cutting
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
DHSC: The Department may not consider future HFEA regulatory interests or requirements when planning for any future consideration of relevant legislation which could compromise the future regulatory regime.	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 Completed - Joanne Anton

Causes / sources	Controls	Status/timescale / owner
<p>Government: Any consideration of the future legislative landscape may become politicised.</p>	<p>There are no preventative controls for this, however, clear and balanced messaging between us, the department and ministers may reduce the impact.</p> <p>Develop improved relationships with MPs and Peers to ensure our views and expertise are taken into account.</p>	<p>Ongoing - Peter Thompson</p>
<p>Government: Consideration of changes to the regulatory framework may be affected by political turbulence (for instance changes of Minister).</p>	<p>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.</p>	<p>Ongoing - Peter Thompson</p>

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
<p>Due to Covid-19 and the suspension of clinic treatment activities this is a live issue for 2020/2021 since we have limited income for as long as GD0014 (version 2) is in place. Although almost all clinics have now resumed treatment, it is clear that it will take many months for activity to return to normal levels. Moreover, capacity constraints with GPs mean that many potential patients are not being referred to fertility clinics. Taken together, this means that our income will be lower than planned for the remainder of this business year at least.</p> <p>We have had assurance of financial cover from the Department for the remainder of this financial year. There remains significant uncertainty about the 2021/2022 financial year. We will continue to monitor sector activity very closely. SMT reduced the score of this risk from 15 to 8 in September 2020 to reflect this, but noted that given wider uncertainties (about grant-in-aid and treatment volumes) for the 2021/2022 financial year, this risk score may rise over the coming months, the risk would need to be carefully managed and monitored.</p> <p>An initial options appraisal for a fee review project went to the Authority in May. A consultation and modelling for the new income model will follow, with the intention to launch this in 2021/2022, subject to Authority agreement. This should ensure that the income model is fit for purpose and reflects the changing nature of sector activity, and the set the HFEA up for the future.</p>

Causes / sources	Controls	Timescale / owner
<p>There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.</p> <p>This is no longer a risk – this is a live issue for 2020/2021 as we have reduced income for as long as GD0014 (version 2) is in place and furthermore we expect that when clinics reopen it will</p>	<p>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.</p> <p>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</p>	<p>CMG monthly and Authority when required – Peter Thompson</p> <p>Quarterly, ongoing, with AGC model review at least</p>

Causes / sources	Controls	Timescale / owner
<p>take some time for activity to return to 'normal' levels.</p>	<p>quarterly internally and review at least annually with AGC.</p> <p>We are undertaking a fee review project in 2020/2021 to ensure that the income model is fit for purpose and reflects the changing nature of sector activity.</p> <p>We are discussing with the Department of Health and Social Care how this issue will be managed.</p>	<p>annually - Richard Sydee</p> <p>Planning underway – Peter Thompson and Richard Sydee</p>
<p>Our monthly income can vary significantly as:</p> <ul style="list-style-type: none"> 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. <p>As at September 2020 we have reduced income due to the deployment of GD0014 in response to Covid-19 and the subsequent reopening of the sector.</p>	<p>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 June 2019.</p> <p>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. Note: we have decided not to employ this control in the light of the significant impact of Covid-19 on the sector (clinics are not working at historic levels). We will look to review this risk and controls on a quarterly basis depending on the level of activity underway across the sector.</p>	<p>Given the Covid-19 related drop in income, we have actively employed this control – Richard Sydee</p> <p>Control under quarterly review as sector reopens – Richard Sydee</p>
<p>Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.</p>	<p>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.</p> <p>All project business cases are approved through CMG, so any financial consequences of approving work are discussed.</p>	<p>Quarterly meetings (ongoing) – Morounke Akingbola</p> <p>Ongoing – Richard Sydee</p>
<p>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.</p> <p>This may not be sufficient to complete the work if it is delayed due to Covid-19.</p>	<p>The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact.</p> <p>Ongoing monitoring and reporting against control totals to ensure we do not overspend.</p> <p>Funding was received from the Department to complete the PRISM programme.</p>	<p>In place – Richard Sydee</p> <p>Ongoing – Richard Sydee</p>
<p>Inadequate decision-making leads to incorrect financial</p>	<p>Within the finance team there are a series of formalised checks and reviews, including root and</p>	<p>In place and ongoing - Richard Sydee</p>

Causes / sources	Controls	Timescale / owner
forecasting and insufficient budget.	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.	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) – Olaide Kazeem
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 Department and we are in active discussion with the Department about this issue.	Ongoing - Richard Sydee
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 provisionally 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
<p>This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity.</p> <p>For 2019/2020 Turnover was 12.2% (in 2018/19 this was 26.8%). This reduction in turnover suggests that we are currently in a more stable situation and this will naturally strengthen our capabilities as staff develop more experience in their roles. We have also often been able to recruit internally which has assisted in reducing turnover as staff have been able to develop their careers within the HFEA. We have taken active steps. We have taken steps to improve retention, focussing on things that we can control like learning and development.</p> <p>AGC receive 6-monthly updates on capability risk 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 further. 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.</p> <p>We have two Authority member vacancies which create Board capability gaps, these risks are captured in the separate C2 risk, below.</p> <p>Although we reduced our assessment of this risk score in May 2020, we are aware that ongoing impacts of Covid-19 may affect capability in future months, and we are considering approaches to manage this as the situation develops.</p>

Causes / sources	Mitigations	Status/Timescale / owner
<p>High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.</p>	<p>Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement.</p> <p>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.</p>	<p>In place – Yvonne Akinmodun</p> <p>Checklist in use – Yvonne Akinmodun</p>
	<p>Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.</p> <p>CMG and managers prioritise work appropriately when workload peaks arise.</p> <p>Contingency: In the event of knowledge gaps we would consider alternative resources such as using agency staff if appropriate.</p>	<p>In place – Yvonne Akinmodun</p> <p>In place – Peter Thompson</p> <p>In place – Relevant Director alongside managers</p>
	<p>Poor morale could lead to staff leaving, opening up capability gaps.</p>	<p>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.</p> <p>The staff intranet enables regular internal communications.</p> <p>Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of concern.</p> <p>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.</p>
<p>Work unexpectedly arises or increases for which we do not have relevant capabilities.</p>	<p>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.</p> <p>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.</p>	<p>In place – Paula Robinson</p> <p>In place – Paula Robinson</p> <p>In place – Paula Robinson</p>

Causes / sources	Mitigations	Status/Timescale / owner
	<p>Oversight of projects by both the monthly Programme Board and CMG meetings.</p> <p>Review of project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources.</p> <p>Planning and prioritising data submission project delivery, within our limited resources.</p>	<p>Ongoing review in progress 2020-2021 – Paula Robinson</p> <p>In place until project ends – Dan Howard</p>
<p>The future office move, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.</p>	<p>See separate E1 risk for full assessment of risk causes and controls.</p>	<p>Engagement with staff and other organisations underway and ongoing – Richard Sydee</p>
<p>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.</p>	<p>Active engagement with other organisations early on.</p> <p>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 mentorship programme.</p>	<p>Ongoing – Richard Sydee</p> <p>Early progress, ongoing – Yvonne Akinmodun</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
<p>Government/DHSC</p> <p>The UK leaving the EU may have unexpected operational consequences for the HFEA for which we do not have the relevant capabilities.</p>	<p>We continue to work closely with the Department to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector.</p> <p>Since December 2018, we have run an EU exit project to ensure that we fully consider 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.</p> <p>We continue to engage with DHSC and clinics to prepare for the end of the transition period. Actions will depend on the progress of the UK/EU talks. Authority and AGC are also updated at their meetings, as appropriate.</p>	<p>Communications ongoing – Peter Thompson</p>
<p>In-common risk</p> <p>Covid-19 (Coronavirus) may lead to high levels of staff absence leading to capability gaps or need to redeploy staff.</p>	<p>Management discussion of situation as it emerges, to ensure a responsive approach to any developments.</p> <p>We have reviewed our business continuity plan to ensure it is fit for purpose.</p>	<p>Ongoing - Peter Thompson</p>

C2: Failure to appoint new or reappoint current Authority members within an appropriate timescale leads to loss of knowledge and may impact formal decision-making.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	4	12- High	2	4	8 - Med
Tolerance threshold:					4 - Low
Status: Above tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates C2: Board capability	Peter Thompson Chief Executive	Whole strategy.	↔ ↔ ↔ ↓

Commentary

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.

Out of a current Board membership of 14, we have two vacancies. In addition, one members' term ends on 11 November 2020, bringing the Board membership down to eleven. The Chair's term expires on 31 March 2021. Four other senior Authority members' terms also end on that date. If we are not able to recruit to all these positions, the membership would be reduced to six. This would pose a significant challenge to robust statutory decision-making and knowledge management. The extension of the Chair's term to 2021 is helpful, however recruitment is still underway for the other posts.

We anticipate that the Department's recruitment to four posts will be completed by autumn 2020. We do not yet have clarity on the timing of Chair recruitment, but we understand that an advert will issue this autumn. We remain in contact with the Department on these matters. SMT reduced the risk score from 16 to 8 in September to reflect the progress made on recruitment, although the risk remains above tolerance.

Causes / sources	Mitigations	Status/timescale / owner
As at September 2020, we have two member vacancies. The reduction of available members that is possible by March 2021, including the Chair, would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and research centres and	Membership of licensing committees has been actively managed to ensure that formal decision-making can continue unimpeded by the current board vacancies. However, there is no guarantee that this would be possible for future vacancies, especially if there were several at once and bearing in mind that a lay/professional balance must be maintained for some committees.	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
authorise treatment for serious inherited illnesses.		
<p>The uncertainty about Chair reappointment may result in a gap in leadership and direction for the Authority.</p> <p>The Chair's term has been extended until March 2021, which gives more time to consider controls, though it only changes the proximity of this risk.</p>	The Department is actively considering extending certain Board appointments to ensure a smooth transition.	Further controls to be considered - Peter Thompson
<p>Any member recruitment may take some time and therefore give rise to further vacancies and capability gaps.</p> <p>The recruitment process is run by DHSC meaning we have limited power to influence this risk source.</p> <p>Historically, decisions on appointments have taken some time which may create additional challenges for planning. Meanwhile, the annual report from the commission for public appointments suggests appointments take on average five months.</p>	Recruitment is underway for four Board posts. This is being run by the Department of Health and Social Care (DHSC) and is expected to complete in the autumn.	In progress as at September, with plan to appoint Autumn 2020- Peter Thompson
Several current Board members are on their second terms in office, which expire within the same period (six Members of the Board by March 2021, in addition to the two pre-existing vacancies).	We are discussing options with the Department for managing the cycle of appointments, in order to reduce the impact of this.	In progress, ongoing - Peter Thompson
<p>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.</p> <p>Evidence from current members suggests that it may take up to a year for members to feel fully confident.</p>	The Governance team are reviewing recruitment information and member induction to ensure that this will be as smooth as possible once it starts.	In progress, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
<p>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.</p>	<p>We will be mindful of this resource requirement when planning other work, in order to limit the impact of induction on other priorities.</p>	<p>In progress, as timescales become clear - Peter Thompson, Paula Robinson</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Status/timescale / owner
<p>Government/DHSC The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines.</p>	<p>CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register. Recruitment, led by the Department, is in progress as at September.</p>	<p>Raised December 2019 - Peter Thompson</p>
<p>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.</p>	<p>CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register. Recruitment, led by the Department, is in progress as at September.</p>	<p>Raised December 2019 - Peter Thompson</p>
<p>Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. We are unsure of the intended approach of any future government. This may impact any planned approach and risk mitigations and give rise to further risk.</p>	<p>CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register. Recruitment, led by the Department, is in progress as at September.</p>	<p>Raised December 2019 - Peter Thompson</p>

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
<p>Cyber-attacks and threats are inherently very likely. Our approach to handling these risks effectively includes ensuring we:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>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. We are supporting many to upgrade their infrastructure to reduce the likelihood of a cyber incident. The related cyber risk concerns an attack on the clinic’s infrastructure – and all have local logical and physical security controls in place. We are aware of the related cyber risk. All submission data is encrypted in transit. We continue to work with clinics to support the upgrade of their server infrastructure.</p>

Causes / sources	Controls	Timescale / owner
Insufficient board oversight of cyber security risks, resulting in them not being managed effectively.	<p>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.</p> <p>The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual</p>	In place – Dan Howard

Causes / sources	Controls	Timescale / owner
	<p>and perceived cyber risks. These would be discussed with the wider board if necessary.</p> <p>Annual cyber security training in place to ensure that Authority are appropriately aware of cyber risks and responsibilities.</p>	<p>In place - Peter Thompson</p> <p>Last undertaken January 2020 – Dan Howard</p>
<p>Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively</p>	<p>Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities.</p> <p>Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance.</p> <p>We undertake independent review and test our cyber controls, to assure us that these are appropriate.</p> <p>Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact.</p>	<p>Last undertaken by all staff June 2019 reminder being sent to staff September 2020 – Dan Howard</p> <p>Update agreed at CMG in June 2020– Dan Howard</p> <p>In place, review last undertaken March 2019 – Dan Howard</p> <p>In place, review last undertaken May 2019 – Dan Howard</p>
<p>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.</p>	<p>Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security.</p> <p>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.</p>	<p>Done – Dan Howard</p> <p>In place – Dan Howard</p>
<p>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)</p>	<p>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.</p>	<p>Contract in place until May 2021 with option to extend until May 2023 – Dan Howard</p>

Causes / sources	Controls	Timescale / owner
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) – Dan Howard
We may have technical or system weaknesses which could lead to loss of, or inability to access, sensitive data, including the Register.	<p>We undertake regular penetration testing to identify weaknesses so that we can address these.</p> <p>We have advanced threat protection in place to identify and effectively handle threats.</p> <p>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.</p> <p>We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software.</p> <p>We regularly review and if necessary, upgrade software to improve security controls for telephony</p>	<p>Ongoing (last test May 2019) – Dan Howard</p> <p>In place – Dan Howard</p> <p>In place – Dan Howard</p> <p>Ongoing (Last review and upgrade to Pulse RAS system April 2020) – Dan Howard</p> <p>Ongoing (Last review and upgrade to Microsoft Teams system April 2020) – Dan Howard</p>
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	<p>Hardware is encrypted, which would prevent access to data if devices were misplaced. (corrective control)</p> <p>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 (corrective control).</p>	Ongoing (regular reminders sent to staff with security best practice) – Dan Howard
Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.	<p>All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place.</p> <p>We have an effective permission matrix and password policy.</p> <p>Our web configuration limits the service to 20 requests at any one time.</p> <p>The new Register will be under the tightest security when this is migrated to the cloud.</p>	<p>In place – Dan Howard</p> <p>In place – Dan Howard</p> <p>In place – Dan Howard</p> <p>To be implemented – Dan Howard</p>

Causes / sources	Controls	Timescale / owner
<p>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.</p>	<p>Data submitted through the EDI gateway application is encrypted in transit, which reduces the likelihood of sensitive information being accessed. (corrective control)</p>	<p>In place – Dan Howard</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
<p>None. Cyber-security is an 'in-common' risk across the Department and its ALBs.</p>		

E1: There is a risk that the HFEA’s office relocation in 2020 leads to disruption to operational activities and delivery of our strategic objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16	3	3	9 - Medium
Tolerance threshold:					8 - Medium
Status: Above tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates E1: Relocation of HFEA offices in 2020	Richard Sydee Director of Finance and Resources	Whole strategy.	↔ ↔ ↔ ↔

Commentary
<p>An internal project is in place to prepare for the office move, handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks. This feeds into a larger programme managed by DHSC.</p> <p>We have made progress in reviewing working practices and policies and have launched several of these. Several cross-ALB working groups have been established and are actively defining requirements and solutions and these are feeding into the HFEA internal project.</p> <p>Covid-19 has had significant impacts on the office move. SMT raised the risk score in April to reflect this emerging risk. Delays have been managed proactively by the overall DHSC programme which has reduced the overall impact. We do not yet have a date for the HFEA move, but will ensure that we are able to continue to operate if the move is delayed.</p> <p>As at September 2020 delays have emerged at programme level, with the handover of the building to DHSC affected by construction issues. The HFEA project team is considering the impact of this on organisational preparations and is also considering contingency arrangements (for instance for housing our servers) if these are required, for instance if dilapidations must begin at 10 Spring Gardens before we can access 2 Redman Place.</p>

Causes / sources	Controls	Status/Timescale / owner
<p>The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings.</p> <p>Note: Covid-19 may have altered the requirements of the HFEA.</p>	<p>HFEA requirements were specified up front and feedback given on all proposed designs. Outline plans are in line with HFEA needs and we have staff on the working groups set up to define the detail.</p> <p>We will revisit our requirements and ways of working in the light of the changed circumstances we are in due to Covid-19.</p>	<p>Ongoing – Richard Sydee</p> <p>Future control as part of Covid-19 management</p>

Causes / sources	Controls	Status/Timescale / owner
	<p>If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected.</p> <p>Arrangements need to be put in place to ensure that costs and access are shared equitably.</p>	<p>– Richard Sydee</p> <p>Contingency if required – Richard Sydee</p> <p>Discussions still underway as at September – Richard Sydee</p>
<p>We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation.</p> <p>Note: Move to Stratford noted in all job adverts. Recruitment data to date suggests we are not seeing an impact on recruitment. We will continue to monitor this to consider whether other mitigations are needed/possible.</p>	<p>We will continue to offer desirable staff benefits and policies, such as flexible working, and have reviewed and updated these to ensure that they support staff recruitment and retention.</p> <p>Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.</p>	<p>Completed (however as per above control we may need to revisit in the light of Covid-19) – Yvonne Akinmodun</p>
<p>Stratford may be a less desirable location for some current staff due to:</p> <ul style="list-style-type: none"> • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, <p>leading to lower morale and lower levels of staff retention as staff choose to leave before the move.</p>	<p>Work underway to 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.</p> <p>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.</p> <p>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.</p>	<p>Begun but to be completed (this is now subject to Covid-19 developments) – Yvonne Akinmodun, Richard Sydee</p> <p>Done - Yvonne Akinmodun,</p>
<p>The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs.</p>	<p>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.</p> <p>The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust</p>	<p>Ongoing but we await confirmation of overarching procurement arrangements from central</p>

Causes / sources	Controls	Status/Timescale / owner
<p>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.</p>	<p>other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed.</p> <p>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.</p>	<p>programme - Richard Sydee</p>
<p>The move to a new office will lead to ways of working changes that we may be unprepared for.</p>	<p>CMG will be 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.</p> <p>Policies related to ways of working have been agreed and circulated significantly before the move, to ensure that there is time for these to be in and be accepted ahead of the physical move. Staff have been involved and updated as appropriate.</p>	<p>September 2020 and ongoing – Richard Sydee</p> <p>Done and to continue as these are reviewed following Covid-19 - Richard Sydee, Yvonne Akinmodun</p>
<p>Owing to the different cultures and working practices of the organisations moving, there may be perceived inequity about the policy changes made.</p>	<p>A formal working group is in place including all the organisations who are moving to Stratford with us, to ensure that messaging around ways of working is consistent across organisations, while reflecting the individual cultures and requirements of these.</p> <p>The ways of working group will communicate on these differences, so that staff understand any differences in practice and that the intention is not to homogenise practices.</p>	<p>Ongoing – Richard Sydee</p> <p>Future control – Richard Sydee</p>
<p>Current staff may not feel involved in the conversations about the move, leading to a feeling of being ‘done to’ and lower morale.</p>	<p>Conversations about ways of working occurring throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions.</p> <p>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.</p> <p>Staff have had the opportunity to visit the site ahead of time so that they feel prepared.</p> <p>Staff engagement group established to ensure wide engagement as we approach the move.</p>	<p>Ongoing – Richard Sydee</p>

Causes / sources	Controls	Status/Timescale / owner
<p>The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.</p>	<p>Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed.</p> <p>Assurance will be provided by regular reporting to AGC and Authority.</p> <p>The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance.</p> <p>Dedicated part-time external project manager brought in to undertake ongoing project management, to ensure sufficient and effective resourcing of this as the project moves into a more advanced phase of delivery.</p> <p>Other key staff such as HR and representatives from other teams involved in the internal HFEA Project team.</p>	<p>In place – Richard Sydee</p>
<p>Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.</p>	<p>Communications between HFEA and other organisations' IT teams to determine IT requirements, allowing more time to resolve these.</p> <p>Infrastructure has largely been migrated to the cloud, which will facilitate the move and reduce related risk to IT systems. It will also mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.</p>	<p>In place - Steve Morris, Dan Howard</p> <p>Ongoing - Steve Morris, Dan Howard</p>
<p>The physical move may cause short-term disruption to HFEA activities and delivery, if necessary resources, such as meeting rooms or physical assets, are not available to staff.</p> <p>We may move to Redman Place later which could increase the chance of this disruption or extend it.</p>	<p>Careful planning of the move to reduce the likelihood of disruption. We will increase our focus on planning as we move closer to the move date and reprioritise as required.</p> <p>Staff would be able to work from home in the short-term if there was disruption to the physical move which would reduce the impact.</p> <p>Implementation of enhanced remote access security arrangements in advance of the move.</p> <p>Contingency plan for locating IT kit being explored to ensure smooth running in the case of further delays to building access.</p>	<p>Ongoing - Richard Sydee</p> <p>In place – Dan Howard</p> <p>Done - Dan Howard</p> <p>Planning underway – Steve Morris</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>British Council – lead on physical build – may not understand or take HFEA needs into account.</p>	<p>DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.</p>	<p>In place – Richard Sydee, DHSC</p>

Causes / sources	Controls	Status/Timescale / owner
<p>DHSC – Lead on the whole overarching project, entering into contracts on behalf of HFEA and others – HFEA requirements may not be considered/met.</p>	<p>Regular external programme meetings attended by the Director of Finance and Resources as HFEA Project Sponsor and other HFEA staff when delegation required.</p>	<p>In place – Richard Sydee</p>
<p>NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.</p>	<p>Regular DHSC programme meeting involving all regulators.</p> <p>Sub-groups with relevant IT and other staff such as HR.</p> <p>Informal relationship management with other organisations' leads.</p>	<p>In place – Richard Sydee, DHSC</p>

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
<p>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:</p> <ul style="list-style-type: none"> • 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 by clinics (often driven by the impact of the clinic actions on patients). <p>Legal challenge poses two key threats:</p> <ul style="list-style-type: none"> • that resources are substantially diverted • that the HFEA’s reputation is negatively impacted by our participation in litigation. <p>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.</p> <p>We have not been directly involved in any litigation since October 2018.</p>

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 or technology emerges that may not be covered by the existing regulatory framework.	<p>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.</p> <p>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.</p>	<p>SCAAC horizon scanning meetings annually.</p> <p>In place – Catherine Drennan and Peter Thompson</p>
<p>Our policies may be legally challenged if others see these as a threat or ill-founded.</p> <p>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.</p>	<p>Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed.</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>In place – Laura Riley/Joanne Anton with appropriate input from Catherine Drennan</p> <p>Ongoing - Laura Riley, Joanne Anton</p> <p>In place – Richard Sydee</p> <p>Ongoing - Laura Riley, Joanne Anton</p>
<p>We may face legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases).</p> <p>Ongoing legal parenthood and storage consent failings in clinics and related cases are specific ongoing examples. The</p>	<p>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.</p> <p>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.</p>	<p>Ongoing – Catherine Drennan</p> <p>In place – Catherine Drennan</p>

Causes / sources	Mitigations	Timescale / owner
<p>case by case nature of the Courts' approach to matters means resource demands are unpredictable when these arise.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Storage consent has been covered in the revision of the PR entry Programme (PREP).</p>	<p>In place – Peter Thompson</p> <p>Done in Q1 2018/19 – Catherine Drennan</p> <p>Revised guidance will be provided where appropriate to clinics – Catherine Drennan</p> <p>PREP launched January 2020 – Catherine Drennan/ Laura Riley, Joanne Anton</p>
<p>Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or Judicial Reviews.</p> <p>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.</p>	<p>Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.</p> <p>Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.</p> <p>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.</p> <p>Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes.</p>	<p>In place but a review of the Compliance and Enforcement policy underway, due for completion Autumn 2020 – Rachel Cutting, Catherine Drennan</p> <p>In place – Sharon Fensome-Rimmer</p> <p>In place – Sharon Fensome-Rimmer</p> <p>In place – Peter Thompson</p>

Causes / sources	Mitigations	Timescale / owner
	<p>Measures in place to ensure consistency of advice between the legal advisors from different firms. Including:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>	<p>Since Spring 2018 and ongoing – Catherine Drennan</p> <p>In place – Paula Robinson</p>
<p>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.</p> <p>We are aware of endeavours to put some test storage consent cases to the courts which may make HFEA involvement more likely.</p>	<p>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.</p> <p>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.</p> <p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.</p>	<p>In place – Catherine Drennan, Joanne Triggs</p> <p>In place – Peter Thompson, Catherine Drennan</p> <p>In place – Peter Thompson</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
<p>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.</p>	<p>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.</p>	<p>In place – Peter Thompson</p>
<p>DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.</p>	<p>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 necessary, this would include agreeing any associated implementation budget.</p>	<p>In place – Peter Thompson</p>

Causes / sources	Mitigations	Timescale / owner
	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.	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	3	4	12 - High
Tolerance threshold:					12 - High
Status: At 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 necessarily become our organisational priority. All staff are working from home and a strategy to manage inspections has been put in place until September. 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.

The Coronavirus risk has had a cascading effect across the whole risk register and will do for the foreseeable future. Where there are specific risk causes related to other core risks these are signposted as relevant. The organisation has been incredibly flexible to rapidly adapt to changed ways of working, the next step is to ensure this is sustainable and we take a flexible and appropriate response as restrictions loosen and life returns to a ‘new normal’.

A Covid-19 risk management review is being undertaken in September 2020 to reflect on lessons learned during the first phase of the pandemic response. These lessons will be used to consider effectiveness of controls and a report will be presented to AGC in December.

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).	In place, ongoing – Richard Sydee In place - SMT and communications team In place and ongoing – Clare Ettinghausen

Causes / sources	Controls	Status/Timescale / owner
	<p>Proactive handling of clinic enquiries and close communication with them.</p> <p>Careful monitoring of the need to update information and proactive handling of updates.</p> <p>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 will review our approach regularly to ensure that this is fit for purpose.</p> <p>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.</p>	<p>In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting</p> <p>Joanne Triggs – in place</p> <p>In place and under regular review – Laura Riley</p> <p>In place – Jo Triggs</p>
<p>Risk of being challenged publicly or legally about the HFEA response, resulting in reputational damage or legal challenge.</p> <p>(This risk also therefore relates directly to LC1 above)</p>	<p>As above – ensuring approach is appropriate.</p> <p>As above – continuing to liaise with professional bodies.</p> <p>We may choose to put out a press release in case of public challenge.</p> <p>Legal advice has been sought to ensure that HFEA actions are in line with legislative powers. Further advice available for future decisions.</p> <p>Ability to further engage legal advisors from our established panel if we are challenged.</p>	<p>In place – Richard Sydee</p> <p>Ongoing - Rachel Cutting</p> <p>If required - Joanne Triggs</p> <p>Done – Peter Thompson</p> <p>If required – Peter Thompson, Catherine Drennan</p>
<p>Gaps in HFEA staffing due to sickness, caring responsibilities etc</p>	<p>Possible capability gaps have been reviewed by teams to ensure that these are identified and managed.</p> <p>Other mitigations as described under the C1 risk.</p>	<p>In place – Yvonne Akinmodun</p>
<p>Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds.</p>	<p>Decision taken not to return to Spring Gardens site so no office-working will occur until at least November 2020, reducing work-related risk.</p> <p>We will consider the impact as part of planning for a return to inspections and office working.</p>	<p>In progress – Yvonne Akinmodun</p>

Causes / sources	Controls	Status/Timescale / owner
	We are engaging with other similar organisations to consider possible approaches to managing this risk.	
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
<p>Ineffective oversight of those clinics that are continuing to practice as clinics may not abide by professional body and HFEA guidance.</p> <p>Since GD0014 version 2 was issued, clinics have been able to reopen where it is safe to do so. Meanwhile, HFEA do not plan to restart physical inspections until September. This creates a potential oversight gap.</p>	<p>We put in place a new General Directions for clinics to follow. Clinics who do not follow General Directions 0014 would be subject to serious regulatory action.</p> <p>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.</p> <p>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 will still be 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.</p>	<p>In place – Rachel Cutting</p> <p>In place – Sharon Fensome-Rimmer</p> <p>Approach agreed and in place – Sharon Fensome-Rimmer, Rachel Cutting</p>
Inability to run representations hearing due to restrictions/inability of staff/others to meet.	Plan in place to run this via teleconference.	In place– Paula Robinson
<p>Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus.</p> <p>Note: as per FV1 this is a live issue.</p> <p>Note: this risk may be both short and longer-term if clinics close down as a result.</p>	<p>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 (contingency).</p> <p>The final contingency would be to seek additional cash and/or funding from the Department, and we are in conversation with them about the likely impact on us (further contingency).</p>	<p>In place – Richard Sydee</p> <p>Ongoing discussions as impact becomes clearer – Richard Sydee</p>
We have had to cancel events and meetings and cannot run them as planned which may delay some strategic delivery.	<p>Conversations ongoing with Authority and Corporate Management about options for management of individual risk impacts and review key milestones where needed.</p> <p>Routine stakeholder meetings occurring virtually and revised arrangements to allow for virtual meetings and committees.</p>	In place – Peter Thompson

Causes / sources	Controls	Status/Timescale / owner
<p>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.</p>	<p>Provided equipment for staff who have to WFH without suitable arrangements in place.</p> <p>Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources.</p> <p>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.</p> <p>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.</p>	<p>In place – Richard Sydee</p> <p>In place – Yvonne Akinmodun</p> <p>In place – Yvonne Akinmodun</p> <p>In place and ongoing – Yvonne Akinmodun</p>
<p>Inability of staff to return to office working may negatively impact organisational culture, reduce collaboration, or hamper working dynamics and productivity.</p> <p>Note: This risk is linked to the E1 risk due to inability to return to Spring Gardens and delay to accessing Redman Place. 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.</p>	<p>Discussion about return to work at CMG to ensure that this is planned effectively, and impacts considered.</p> <p>Online solutions to maintain collaboration and engagement, such as informal team engagement and 'teas', Microsoft teams etc.</p> <p>Staff creating opportunities to meet in person within the limits of covid-19 restrictions, to maintain effective working relationships.</p>	<p>September CMG meeting – Peter Thompson</p> <p>In place – Heads</p> <p>Ad-hoc, ongoing -</p>
<p>Risk that we miss posted financial, OTR or other correspondence.</p>	<p>While the office remains open, we have an arrangement to securely store, collect and distribute post. Though we would need to reconsider this control should the office be closed.</p> <p>Updated website info to ask people to contact us via email and phone.</p> <p>We have notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.</p> <p>OTR service paused which removes OTR related risks.</p>	<p>In place – Richard Sydee</p> <p>In place – Jo Triggs</p> <p>In place – Morounke Akingbola</p> <p>In place – Dan Howard</p>

Causes / sources	Controls	Status/Timescale / owner
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
In common risk		
<p>DHSC: HFEA costs exceed annual income because of reduced treatment volumes.</p> <p>Live issue as at September – captured under FV1</p>	<p>Use of cash reserves, up to appropriate contingency level available.</p> <p>The final contingency would be to seek additional cash and/or funding from the Department.</p>	Richard Sydee

Reviews and revisions

07/09/2020 – SMT review – September 2020

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

- SMT agreed that the following risks and their scores remained appropriate, IP1, RF1, I1. Authority discussions to follow would prompt further reconsideration.
- FV1 – SMT discussed the recent assurance provided for financial cover through to the end of this financial year. SMT reflected that the score had therefore decreased in the short to medium term. However, future treatment volumes were uncertain and there was also significant uncertainty for 2021/2022. The risk would need careful monitoring over the coming months.
- C2 – as recruitment was now in hand and discussions were underway regarding targeted extensions to terms, SMT agreed to reduce this risk, although it remains above tolerance.
- E1 – SMT discussed current delays to the project and noted that this does not increase this risk further at the current time, since the organisation had proven effective ways of working remotely.
- CV1 – SMT reflected that a further risk source emerged the longer the organisation worked entirely from home, negative impacts on organisational culture and close working. CMG would discuss further control options shortly.
- CS1 – clarity on progress of some controls being sought from the Chief Information Officer.
- LC1 – no matters of strategic significance, no change to this risk.

20/07/2020 – SMT review - July 2020

SMT discussed points raised by AGC, reviewed all risks, controls and scores and made the following points:

- CV1 – Following a discussion with AGC, SMT discussed how lessons would be captured in relation to Covid-19 risk management. SMT discussed the approaches taken and success of these and agreed that a lessons learned workshop should be held in early September to capture these and agree any further risk management actions.
- SMT discussed the score of this risk and agreed that the inherent risk of Covid-19 had reduced somewhat due to reduced levels of infection and emerging from lockdown. The organisation had adapted well to ensure that it could continue to undertake its statutory duties while working from home, however, SMT felt that it was too soon to reduce the residual risk, as we did not yet have an agreed inspection resumption strategy in place. We could reassess the score once inspections were successfully resumed.
- I1 – SMT agreed that we would be in a better position to reassess this score in September.
- P1 – SMT discussed the score of this risk and agreed that it had not changed. SMT noted however that this may change once a new Chair was in post.
- FV1 – SMT noted that to date we had not had formal confirmation of cover from the Department, though we had had informal assurances – consequently, there was no additional risk at this time, but no progress or formal assurance had been made. AGC and the NAO were satisfied that this informal assurance covers going concerns. Cashflow in Q3 would be biggest concern and this risk would be reassessed and escalated at the end of the Summer.
- C2 – SMT agreed that this should be reassessed once progress was made on Chair recruitment.
- E1 – SMT noted that until the building had been effectively handed over, this risk would be above tolerance. RS noted that the delay to the finance and procurement strand did not have a substantive impact on the score of the risk.

23/06/2020 – AGC review – June 2020

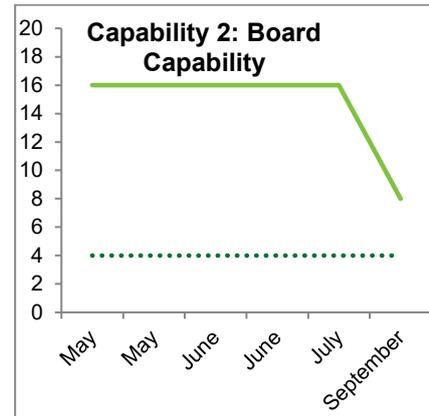
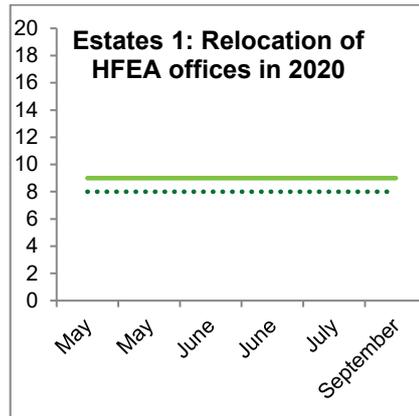
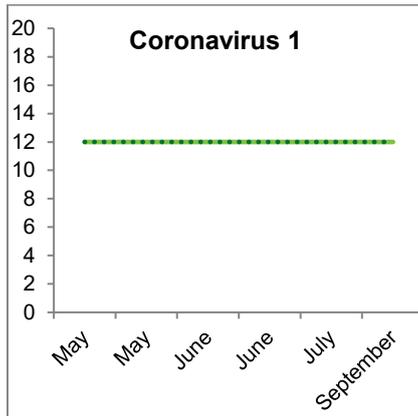
AGC received the full new Strategic Risk Register for the first time, reviewed all risks, controls and scores and made the following points:

- Members commented that homeworking as a direct impact of the coronavirus could mean staff depend more on their own initiative and lose out on collaborative working with colleagues. There was a risk to establishing a collaborative culture when new starters joined while home working.

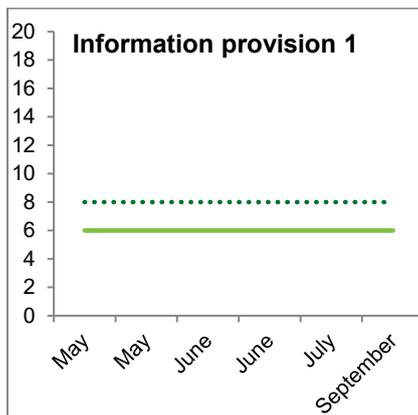
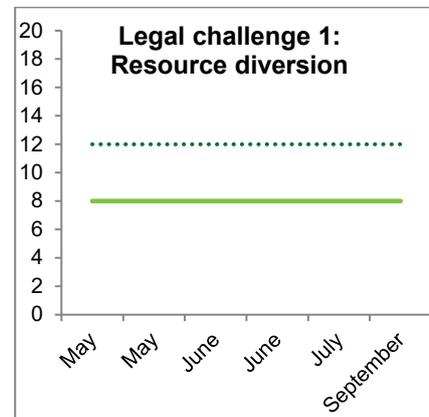
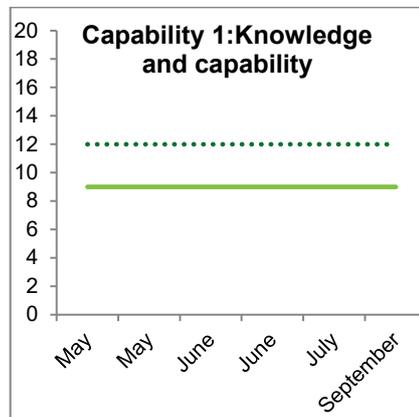
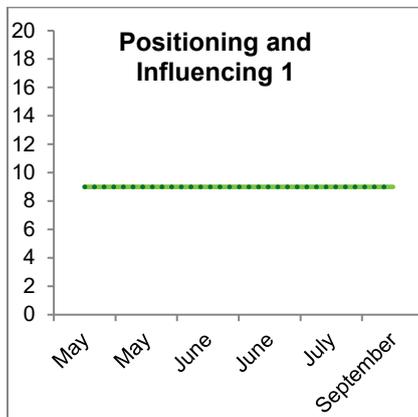
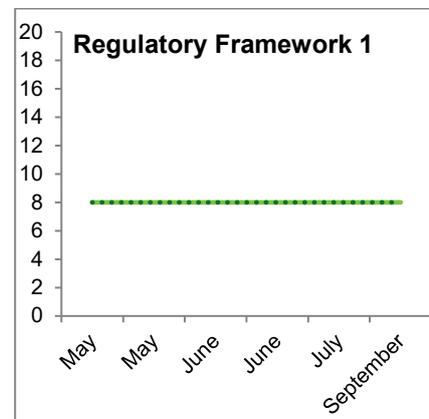
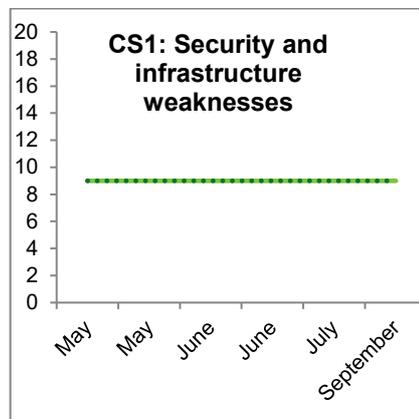
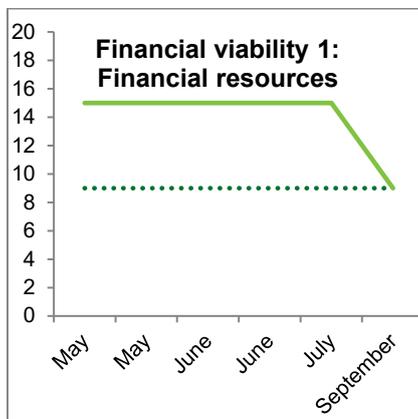
- The NAO and AGC members confirmed that the actions being taken to escalate the FV1 risk and proceed at risk felt appropriate.
- Members agreed that lessons learned captured for risk managing Covid-19 needed to be kept as a live document. The Chair suggested that the report on this be brought to the December meeting.

Risk trend graphs (last updated September 2020)

High and above tolerance risks



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

Audit and Governance Committee Forward Plan

Strategic delivery:

Safe, ethical,
effective treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting Audit & Governance Committee Forward Plan

Agenda item 13

Paper number AGC (06/10/2020) MA

Meeting date 6 October 2020

Author Morounke Akingbola, Head of Finance

Output:

For information or
decision? Decision

Recommendation The Committee is asked to review and make any further suggestions and
comments and agree the Forward Plan

Resource implications None

Implementation date N/A

Organisational risk Low Medium High

Not to have a plan risks incomplete assurance, inadequate coverage
or unavailability key officers or information

Annexes N/A

Audit & Governance Committee Forward Plan

AGC Items Date:	10 Mar 2020	23 Jun 2020	6 Oct 2020	8 Dec 2020
Following Authority Date:	18 Mar 2020	2 July 2020	11 Nov 2020	TBC
Meeting 'Theme/s'	Finance and Resources	Annual Reports, Information Governance, People	Register and Compliance, Business Continuity	Strategy & Corporate Affairs, AGC review
Reporting Officers	Director of Finance & Resources	Director of Finance & Resources	Director of Compliance and Information	Director of Strategy & Corporate Affairs
Strategic Risk Register	Yes	Yes	Yes	Yes
Digital Programme Update	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)	Draft Annual Governance Statement	Yes – For approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report		Audit Planning Report
Information Assurance & Security		Yes, plus SIRO Report		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Update	Results, annual opinion approve draft plan	Update	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Public Interest Disclosure (Whistleblowing) policy	Reviewed annually thereafter			

AGC Items Date:	10 Mar 2020	23 Jun 2020	6 Oct 2020	8 Dec 2020
Anti-Fraud, Bribery and Corruption policy	Reviewed and presented annually thereafter GovS: 013 Counter Fraud			
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes		Yes Including bi-annual HR report		Bi-annual HR report
Strategy & Corporate Affairs management			Yes	
Regulatory & Register management	Yes			Yes
Cyber Security Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Estates	Yes	Yes	Yes	Yes
Review of AGC activities & effectiveness, terms of reference				Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes

Register of Gifts and Hospitality

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting	AGC
Agenda item	14
Paper number	HFEA (063/10/2020) MA
Meeting date	6 October 2020
Author	Morounke Akingbola (Head of Finance)

Output:

For information or decision?	For information
Recommendation	Attached is the latest Gifts and Hospitality Register. Since the last meeting, no items have been added no doubt due to COVID-19. Members are asked to note.
Resource implications	
Implementation date	2020/21 business year
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

