# Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

## 16 March 2021

## Online

| Agenda item | | Page No | Time |
|---|---|---|---|
| 1. | Welcome, apologies and declaration of interests | | 9.30am |
| 2. | Minutes of 08 December 2021<br>**[AGC (16/03/2021) DO]** | for decision | 9.35am |
| 3. | Matters arising<br>**[AGC (16/03/2021) MA]** | for information | 9.40am |
| 4. | Digital programme update<br>**[AGC (16/03/2021) DH]** | for information | 9.45am |
| 5. | 2020/21 Internal audit delivery update and 2021/22 proposed internal audit plan<br>**[AGC (16/03/2021) JC]** | for information | 10.00am |
| 6. | Implementation of recommendations<br>**[AGC (16/03/2021) MA]** | for information | 10.15am |
| 7. | External audit interim feedback<br>**[AGC (16/03/2021) MS]** | verbal update | 10.30am |
| 8. | Resilience, business continuity management cyber security training<br>**[AGC (16/03/2021) DH]** | for information | 10.40am<br>12.05pm |
| 9. | Strategic risk register<br>**[AGC (16/03/2021) HC]** | for comment | 10.55pm |
| 10. | Policies<br>• Public Interest Disclosure (Whistleblowing)<br>• Counter Fraud Strategy<br>• Anti-Fraud, Bribery and Corruption policy<br>**[AGC (16/03/2021) RS]** | for approval | 11.15pm |
| 11. | AGC forward plan<br>**[AGC (16/03/2021) MA]** | for decision | 11.30pm |
| 12. | Items for noting<br>• Gifts and hospitality<br>• Whistle blowing and fraud<br>• Contracts and Procurement | for information | 11.35pm |

| | | |
|---|---|---|
| | **[AGC (16/03/2021) MA]** | |
| **13.** | Any other business | 11.40pm |
| **14.** | Close | 11.45pm |
| **15.** | Session for members and auditors only | 12noon |

**Next Meeting**: Tuesday, 22 June 2021, Online

# Minutes of Audit and Governance Committee meeting 8 December 2020

| **Details:** | | | |
|---|---|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society | | |
| Agenda item | 2 | | |
| Meeting date | 16 March 2021 | | |
| Author | Debbie Okutubo, Governance Manager | | |
| **Output:** | | | |
| For information or decision? | For decision | | |
| Recommendation | Members are asked to confirm the minutes of the Audit and Governance Committee meeting held on 8 December 2020 as a true record of the meeting | | |
| Resource implications | | | |
| Implementation date | | | |
| Communication(s) | | | |
| Organisational risk | ☒ Low | ☐ Medium | ☐ High |
| Annexes | | | |

# Minutes of the Audit and Governance Committee meeting on 8 December 2020 held via teleconference

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

## 1. Welcome and apologies

**1.1.** The Chair welcomed everyone present online.

**1.2.** There were no declarations of interest.

## 2. Minutes of the meeting held 6 October 2020

**2.1.** The minutes of the meeting held on 6 October were agreed as a true record and signed by the Chair.

## 3. Matters arising

**3.1.** The committee noted the progress on actions from previous meetings and the updates presented at the meeting.

## 4. Digital programme update

**4.1.** The digital programme update was presented to members. Members were advised of the intention to communicate to clinics by Christmas that EDI will be switched off in the early part of January

with a provisional date of 13 January. The caveat to this being the subsequent assessment of clinic feedback on their own data.

**4.2.** Members questioned why the date was provisional. The Programme Manager responded that there were a few 'unknowns' and consequently, we were not in a position to commit to final dates, but we were progressing steadily towards achieving that outcome. An example was given of clinics seeing their own data before 'go live' which was a new feature and needed to be tested.

**4.3.** Members were also advised that there were interdependencies between PRISM and other teams across the organisation, for example billing which could happen on an estimated basis with a reconciliation happening later if necessary and the development of staff functionality which was not happening as quickly as planned due to conflicting priorities on key staff.

**4.4.** Staff commented that the communication with clinics would happen once the PRISM programme board were confident that all issues arising out of the integrated testing were resolved. This communication was likely to take place in the week before Christmas.

**4.5.** The Chief Executive (CE) remarked that dates in the paper were achievable, even though there were unknowns as mentioned above.

**4.6.** Members were informed that integrated testing of the migrated data for all types of fertility treatment had been completed at the end of November.

**4.7.** Issues logged by clinics as prioritised by the programme board was now being reviewed by our data migration and PRISM development team.

**4.8.** Members were advised that we were not expecting data to flow immediately from clinics after go-live, as it was expected that it would be a gradual increase in data flows into HFEA over the weeks following launch.

**4.9.** Members questioned what would happen if clinics did not submit required data or if they did not engage with PRISM.

**4.10.** The Chief Executive responded that there is a general direction for submission of data which could be enforced but we will work to get a consensus. Members commented that they agreed with the consensus approach.

**4.11.** The Director of Compliance and Information commented that in addition, all clinics have relationships with their Inspectors, we will therefore involve the Inspectors should such a situation arise.

**4.12.** Members congratulated the team and commented that we were very close to go live and we were in a very good position.

### Decision

**4.13.** Members approved the approach to formally communicate the EDI switch off date to clinics.

**4.14.** Members noted the approach being taken for clinic and supplier readiness and agreed that we should be cautious should we get a request from clinics to extend or change the date of go-live.

**4.15.** Members agreed to receive an update at the 11 January 2021 PRISM meeting.

## 5. Internal audit progress report

**5.1.** The Internal Auditor presented a progress update to the committee. It was noted that the accounts payable and account receivable reviews will start in December 2020, the other three audit reviews will be delivered in quarter 4. These are:

- the review of key performance indicators and internal performance measurement
- consistency in the inspection process and
- the review of implementation and ongoing management of the digital programme (in particular PRISM)

**5.2.** A member questioned if it was too early to audit the consistency of inspections given the restrictions of Covid-19. The Director of Compliance and Information responded that they were currently doing a follow up questionnaire to clinics and we might need to reconsider the timing.

**5.3.** The Internal Auditor commented that work can be done by looking at the effectiveness of the changes implemented rather than the output from the consistency of inspections.

**5.4.** In response to a question about the feasibility of the three audits given other business pressures, Members were advised that staff were in agreement with the timings.

Decision

**5.5.** Members noted the progress updates.

## 6. Implementation of recommendations

**6.1.** The Head of Finance presented this item. There are currently 14 recommendations, 3 were complete but evidence needs to be provided to GIAA before they can be removed. There are 11 with completion dates on or after the December AGC meeting including 3 which were overdue.

**6.2.** It was noted that some of the recommendations due at the end of December 2020 were on track while others will be closed in January 2021.

**6.3.** The Committee noted that recommendation 2 (Annual Budgeting Process – Contingency plan) was complete in that the plan would be to recruit to the senior positions and use of SOPs would ensure continuity of the budgetary planning process. The Head of Finance requested that the annual budget training item be postponed to the end of the financial year.

**6.4.** The Chair suggested that in light of the Internal Auditor stating that evidence of outstanding recommendations was outstanding, the recommendations showing as complete should be provided to the Internal Auditor.

Decision

**6.5.** Members noted the progress of the recommendations.

## 7. External audit planning report

**7.1.** The External Auditor presented the report detailing the proposed approach for the audit of 2020-21 financial statements to members.

**7.2.** Members were advised that the office relocation to Stratford was increased to a significant audit risk. The external auditor explained that it was anticipated that the office move would give rise to a significant accounting judgement about the treatment of the new lease.

**7.3.** In response to Members' questions, it was noted that we had now changed our address to Redman Place, Stratford and that staff continued to work from home. Staff who were using the CQC office will continue to do so at no extra cost to the HFEA.

**7.4.** The Director of Finance commented that there might be an overlap of a two-week period from when the lease ends at Spring Gardens and begins at Redman Place, Stratford but the cost would be negligible.

**7.5.** The Chief Executive responded to the questions on Covid-19 and EU exit. It was confirmed that remote working was going well with no immediate concerns about staff falling ill at the same time. In relation to EU exit, we were in dialogue with clinics and had assurance that there were no current concerns regarding supply chains.

**7.6.** The Director of Strategy and Corporate Affairs advised members that in a fortnight guidance would be issued to clinics in relation to EU exit and relevant staff would be available to answer any questions arising.

Decision

**7.7.** Members considered the actions in the NAO's report and stated that they had no matters to bring to the NAO's attention and were content with the audit plan to address the risks.

## 8. Lessons learned from Covid-19 management

**8.1.** The Director of Finance presented this item to the committee.

**8.2.** Members were advised that two internal meetings were held to discuss how the organisation had handled Covid-19 in terms of the impact on the organisation and on the sector we regulate.

**8.3.** Following a discussion, members commented on the quality of the lessons learned exercise and the very positive findings in it. Turning to some points of detail, members noted the scenario planning and suggested that there was a lot of Authority and Chair involvement and the Board felt that that part was handled well.

**8.4.** Members commented that an area that could have been handled better was in respect of hybrid meetings, held just before the first lockdown in March, where some members were in the office and others were online, and there were a few organisational mishaps.

**8.5.** Another area that could have been better handled was to formalise the meetings between the Chair, Deputy Chair and the Chair of the AGC as fewer of them were held during the pandemic period.

**8.6.** In terms of responding to social media engagement, members commented that they believed that social media helped with our credibility as a regulator.

**8.7.** Members also felt that the private sector's voice was heard from Board members who worked in the private sector alongside their NHS roles.

**8.8.** The Director of Finance commented that being able to prioritise remains crucial as the Covid-19 response exposed the extent to which there was very little spare capacity in the HFEA. Future readiness is therefore important.

Decision

**8.9.** Members agreed that the report be tabled at an Authority meeting to give members insight into the lessons learned and that future lessons were likely as the pandemic continues.

**8.10.** Members also recognized some positive changes to working practices are emerging as a result of the pandemic, including unprecedented progress in the use of technologies for remote working.

## 9. Estates update

**9.1.** The Director of Finance presented this item to the committee. Members were advised that we had officially left Spring Gardens and that all paper files were securely stored. It was noted that officially our address had been changed to Redman Place, Stratford and all stakeholders had been advised.

**9.2.** It was noted that in compliance with Covid-19 restrictions, the office was fitted out with 12 desks for HFEA staff. Staff had been advised of this and the wellbeing of staff remained crucial.

**9.3.** In response to a question, it was noted that until Covid-19 restrictions were lifted, we would be occupying up to 50% of the new office capacity allocated to us.

**9.4.** Members asked how home working was going. The Director of Finance responded that his team were working well. The Director of Compliance and Information responded that the Compliance team were traditionally home workers, so to them there was no difference. In terms of working collaboratively with office-based staff, this was also working well as there has always been an established pattern. The Director of Strategy and Corporate Affairs commented that staff in the directorate were office based and while some staff were thriving working from home, there were some that were struggling.

**9.5.** The CE commented that no one anticipated that working from home would be for this long. In the long term, we would find a flexible balance for when staff need to return to the office. The CE also commented that it was worthy of mention that the output had not diminished even though more work needed to be done with some staff members.

Decision

**9.6.** Members noted the estates update.

## 10. Resilience, business continuity management, cyber security training

**10.1.** The Chief Information Officer (CIO) presented this item to the committee. The infrastructure upgrade work associated with the move to the new office had concluded and IT services was running from our new office in Redman Place, Stratford.

**10.2.** Members were advised that a contract with no extra cost had been agreed with Stone Computers for the destruction of our redundant hardware including servers, laptops and other data-bearing

items. In response to a question, Members were assured that all confidential information would be disposed of properly.

**10.3.** Also, in early October, persons responsible (PRs) were provided with the usual Choose a Fertility Clinic (CaFC) verification report. Clinics had until Friday, 11 December to submit any missing data or to resolve errors and the deadline for PRs to sign off their reports was Friday 18 December 2020.

**10.4.** Members were reminded that at the October 2020 meeting, NHSX and DHSC had decided that the HFEA should complete a data security and protection toolkit (DSPT) for the first time. NHSX have confirmed that the 2020/2021 DSPT self-assessment was due by 30 June 2021.

**10.5.** The Internal Auditor commented that should an audit review be required they would be ready to do this ahead of submission.

Decision

**10.6.** The committee would be updated on progress and they would sign off the DSPT assessment ahead of its submission.

## 11. Regulatory and register management

**11.1.** The Director of Compliance and Information presented this item and gave an overview of the sector in relation to treatment numbers and licenced centres taken from the state of the sector report 2019/2020.The team structure and the strategic and operational risks facing the directorate, including the new draft compliance and enforcement policy was presented.

**11.2.** Members were reminded of the managed process following the first national lockdown to shut clinics and how centres responded to the requirement to develop and put in place a treatment commencement strategy to ensure clinics could resume safe working during the pandemic.

**11.3.** Following a detailed discussion, members commented that the compliance and enforcement policy was a sensible way forward, in particular members endorsed it being risk based and the clarity that the mitigating and aggravating factors provided when deciding on proportionate regulatory action.

**11.4.** Members questioned why clinics were not handling their complaints themselves initially to assist with the process. The Director of Compliance and Information commented that at the initial stages when the HFEA received a complaint, Inspectors get involved and encourage clinics to follow up using their internal processes to resolve issues. It is only where complaints are escalated that they come to us as the regulator.

**11.5.** Members asked about the provision of service during the ongoing pandemic. The Director of Compliance and Information responded that some clinics were concerned that referrals may decrease due to delays in fertility investigations which are conducted in secondary care prior to IVF. Treatment numbers are being carefully monitored and regular meetings are held with NHS England.

Decision

**11.6.** Members noted the regulatory and register management review.

## 12. Bi-annual HR report

**12.1.** The Head of Human Resources presented some of the key activities the organisation had been working on since the last human resource presentation in December 2019.

**12.2.** Members noted that many of the activities had taken place against a backdrop of Covid-19 restrictions and changes to ways of working.

**12.3.** Members were advised that the HFEA benchmarked more widely with other public sector organisations and this gave an insight about how we were faring. Areas we were not so strong on included working across teams and because we were now working remotely this remained an issue.

**12.4.** Another area where the organisation scored on the low side was career aspirations and to try to mitigate this there was an Arms-Length Body (ALB) mentoring scheme which the HFEA was part of.

**12.5.** Members questioned what could be done about career aspirations against the backdrop of the size of the organisation and the inspirational work that HFEA was involved in. It was suggested that an honest conversation needed to be held with staff explaining the different options open to them.

**12.6.** The Head of Human Resource agreed and commented that that moving across ALBs might be an option.

**12.7.** In terms of organisational health, there were a low number of cases of long-term absence as well as the lowest rate of turnover. Despite this, it was noted that turnover would continue to be monitored and exit interviews conducted with those who were leaving the organisation to understand what lessons could be learned to help us continually improve engagement in the workplace.

**12.8.** Members were advised that mandatory online training for all staff had been set up and this included unconscious bias, and equality and inclusion training for new starters as part of their induction.

**12.9.** Members were reminded that staff had now been working from home since March 2020. Measures have been put in place over the last few months to support staff and the evidence pointed towards majority coping well with working from home. However, there were a number of staff who had stated that they would like to return to an office setting as soon as possible.

### Decision

**12.10.** Members noted the bi-annual HR report.

## 13. Strategic risk register

**13.1.** The Risk and Business Planning Manager presented this item to the committee. It was noted that C2 - board capability remained above tolerance. Because the physical office move had been successfully completed the E1 - relocation of HFEA offices in 2020 risk score had been reduced and this was now below tolerance. SMT had discussed the need to retain some of the risk causes, but there would now be a change in focus, to a ways of working/culture change risk which will be revisited in the new year. The CV1 - Covid-19 risk had also been reduced, owing to the effective implementation of a revised inspection process, which managed risks to ensure ongoing regulatory delivery.

**13.2.** Members observed that board capability was a risk that needed to be managed due to the expertise required of HFEA members who undertook quasi-judicial decision-making as part of their roles. The CE agreed with this comment.

**13.3.** The DHSC representative commented that they were aware of the concerns over this issue.

**13.4.** Members commented that regarding C2 – Board capability, the board was functioning well with fewer members, as they had the right skills. It was felt that the concern could also be around the risk of loss of a member of the Senior Management Team (SMT) or the CE as this would pose more of a worry as there is the risk of disruption to service delivery.

**13.5.** Members also commented on the finances for 2021/22 and felt that it seemed to be more unpredictable than this year's picture. The Director of Finance and Resources responded that we have had assurance of financial cover from DHSC for the remainder of this financial year. We will continue to monitor sector activity very closely and in 2021/22 we are considering whether to undertake a fee review project in to ensure that the income model is fit for purpose and reflects the changing nature of sector activity, subject to approval by the Authority. The Director of Finance and Resources also provided an update on ongoing discussions with representatives from DHSC Finance about our budget for 2021/22, which gave some assurance.

**13.6.** Members thanked the Risk and Business Planning Manager for the report and that it formed the basis of a good discussion.

Decision

**13.7.** Members noted the strategic risk register.

## 14. AGC forward plan

**14.1.** The Head of Finance presented this item. It was noted that PRISM will remain on the forward plan until further notice.

**Decision**

**14.2.** Members noted the current position of the forward plan.

## 15. Gift and hospitality

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

## 16. Whistle blowing and fraud

**16.1.** There were no cases of whistle blowing or fraud cases to report.

## 17. Contracts and procurement

**17.1.** There were no new contracts or procurements to report.

## 18. Any other business

**18.1.** There was no other business.

## 19. AGC committee effectiveness

**19.1.** The Head of Planning and Governance serviced this part of the meeting with members only.

## Chair's signature

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

Signature

Chair: Anita Bharucha

Date: 16 March 2021

# AGC Matters Arising

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science, and society |

| | | | |
|---|---|---|---|
| Meeting | Audit and Governance Committee | | |
| Agenda item | 3 | | |
| Paper number | HFEA (16/03/2021) MA | | |
| Meeting date | 16 March 2021 | | |
| 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 | ☐ Low | X Medium | ☐ High |

| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|---|---|---|---|
| **Matters Arising from the Audit and Governance Committee – actions from 6 October 2020** | | | |
| **13.4** Cyber security training to be confirmed to members | Head of Finance | Dec-20 | **Update** – training was provided using the Astute training platform which was not adequate. New training to be sourced. |
| **Matters Arising from the Audit and Governance Committee – actions from 8 December 2020** | | | |
| **8.9** Lessons learned report to be tabled at an Authority meeting | Director of Finance and Resources | ? | **Update –** to be circulated to Members asap |
| **10.6** Data Security and Protection toolkit (DSPT) self-assessment progress update prior to committee sign-off ahead of its submission | Chief Information Officer | Jun-21 | **Update –** an interim assessment conducted 24/2/21 following CMG approval. Committee to be updated at meeting on DSPT. Decision as to whether to accept GIAAs offer to conduct an audit prior to 21 June submission date. |

# Resilience, Business Continuity Management and Cyber Security

| | | | |
|---|---|---|---|
| **Strategic delivery:** | ☒ Setting standards | ☐ Increasing and informing choice | ☒ Demonstrating efficiency economy and value |

| **Details:** | |
|---|---|
| Meeting | Audit and Governance Committee (AGC) |
| Agenda item | 8 |
| Paper number | AGC (16/03/2021) DH |
| Meeting date | 16 March 2021 |
| Author | Dan Howard, Chief Information Officer |
| **Output:** | |
| For information or decision? | For information |
| Recommendation | The Committee is asked to note that:<br>• Our laptop replacement programme will commence shortly and we have reviewed our Microsoft Azure agreement in light of recent changes resulting in a cost saving of around 13% per annum<br>• CMG will be prioritising IT software development work to be completed post-PRISM<br>• The Choose a Fertility Clinic section on our website was updated in February 2021 with up to data performance data<br>• Following CMG approval our interim Data Security Protection Toolkit submission was completed on 24 February 2021 |
| Resource implications | Within budget |
| Implementation date | Ongoing |
| Communication(s) | Regular, range of mechanisms |
| Organisational risk | ☐ Low ☒ Medium ☐ High |
| Annexes: | Annex A – Data Security and Protection Toolkit interim assessment |

## 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.** This paper provides an update on IT infrastructure and software development; that we will be deploying replacement laptops shortly in line with our refresh programme.

**1.3.** We have agreed a new Microsoft Azure tenancy agreement which will result in savings of around 13% per annum.

**1.4.** A piece of work has been commissioned to upgrade our website content management system, explore an industry standard system to replace our 'online apps' system and investigate a new licensing system.

**1.5.** Following a lengthy and very detailed piece of work by the Register team, we refreshed the Choose a Fertility Clinic section on our website in February 2021, as planned.

**1.6.** Demand on the Opening the Register team has increased significantly in recent months We have recruited to a fixed term post to help reduce waiting times for applicants and will be commencing a service redesign project shortly.

**1.7.** Our Data Security and Protection Toolkit interim submission was made in February 2021. See section 6 and Annex A for details of the interim assessment.

## 2. Infrastructure improvements and software development

**2.1.** We have reviewed our laptop estate along with support calls associated with hardware issue. A laptop replacement programme will commence shortly and will replace around 35 devices over the coming months. Once complete, no laptop in use will be older than 3.5 years and staff will benefit from faster devices and less downtime. We will replace the remaining laptops in time as part of a rolling programme.

**2.2.** Following the server changes in 2020 when we moved our systems from physical servicers to the Azure cloud, we have considered our Microsoft Azure 'tenancy' agreement. We have been able to take advance of a new contract which will result in a annual cost-reduction of around 13%. Our new three year contract is expected to commence from 1 April 2021.

**2.3.** We have commissioned a one-off piece of work with our third party IT and software development supplier to

- Upgrade our website content management system to the latest version
- Develop a proof of concept for a potential replacement of our 'Online apps' system used to capture forms based information from clinics
- Complete a short research piece of work to investigate a potential replacement for our bespoke licensing system

**2.4.** We recognise that the PRISM programme has consumed internal IT resource for several years and there is subsequently a backlog of demand for development of our bespoke systems. We have recently had detailed discussions with business 'system owners' to prioritise requests for work. The requests include system changes, maintenance and support. The prioritised list and associated workplan will be reviewed and approved by

CMG in spring 2021. That will mean that work can progress once associated development and handover for PRISM has concluded later in 2021.

## 3. Choose a Fertility Clinic refresh

**3.1.** The HFEA routinely updates performance information on the Choose a Fertility Clinic section of our website. This provides invaluable information on treatment types, pregnancy rates and success rates to support decision making by patients.

**3.2.** The last refresh of the CaFC data took place in late 2019 and constituted treatment and pregnancy data up to 2018 and outcome data up to 2017.

**3.3.** Before new data is uploaded to the website it is processed through a detailed verification process to ensure data issues and errors are resolved. Following verification, the final position was:

| Year | Number of data issues identified | Number of data issues following verification |
|---|---|---|
| 2018 | 612 | 8 |
| 2019 | 5751 | 3 |
| **Totals** | **6363** | **11** |

**3.4.** A final set of reports is run on this data to allow clinics to view their success rates to ensure they match with their expectations. Once the PRs have checked these reports, they are asked to sign off the data by completing a confirmatory document which is returned to the Register team.

**3.5.** A small number of clinics are unable to resolve their errors and sign-off their data, for reasons of workload or in some cases, technical issues. It is usual that we agree caveats to be displayed on the CaFC website for the clinics who are unable to sign off their data.

**3.6.** All PRs have signed off their data and we agreed caveats for six clinics who were not able to do so. The number of caveats Ais typical of CaFC refreshes undertaken in previous years.

**3.7.** Ahead of publication, a number of spot checks are undertaken on different treatment types and patient profiles to compare the new success rate data against what is displayed on the current CaFC website. All displayed results in line with what have been published in the last year.

**3.8.** The new CaFC data was published during the week commencing 22 February 2021 and we communicated the update through our usual channels which includes social media, Clinic Focus and on our website.

**3.9.** To support future updates with the new Register, we will need to create new linkages between the new Register and the CaFC website. Our planning for this work has started.

## 4. Data Security and Protection Toolkit (DSPT)

**4.1.** AGC will recall that the Data Security and Protection Toolkit (DSPT) is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards.

**4.2.** The DSPT is completed on an annual basis with a baseline assessment mid year to evidence interim compliance. We have agreed to complete the 21/22 and future DSPT assessments to show our compliance with the data security standards. The completed annual DSPT submission for each organisation is made available online to the public via the NHS Digital website.

**4.3.** The DSPT sets both mandatory and non-mandatory requirements. There are 42 requirements and 37 of them are mandatory. We will complete the 37 mandatory requirements only.

**4.4.** Each requirement has multiple questions for which we need to provide evidence and explanation, the total number of evidence items across the 37 mandatory requirements is therefore 89 of which we have met 69 so far.

**4.5.** Assessment is in two stages; a mid-year baseline assessment, this year in February 2021, and a final submission in June 2021 (extended from March 2021 due to the Covid pandemic).

**4.6.** See Annex A for our interim assessment:

- Completed items are already complete and we will collate the evidence and store centrally
- Pending items are due to be completed before the end of June 2021
- 'Not met' items are ones where we will be unable to fully meet the requirement by end June 2021

**4.7.** CMG considered and approved our interim submission on 24 February 2021. The interim assessment sets out:

- Out of the 37 mandatory requirements we met 31 of these requirements for our baseline assessment at the end of February 2021.
- For our final submission in June 2021 we expect to have met 35 out of 37 mandatory requirements. **That means our final submission will be "Not met" and we will not be compliant with the DSPT.** If our submission is classed as 'not met' it is required that we agree an improvement plan.
- It is optional for evidence to be submitted to the DSPT website. CMG agreed that we will not submit evidence to the external website and instead store it locally to be shared on request, for example with our auditors or NHS Digital.
- We expect that we will not be compliant with the following two requirements in June 2021:

| | |
|---|---|
| **1.6.4**<br><br>**Provide the overall findings of the last data protection by design audit (Should be from last 12 months - covering access control, encryption, computer port control, pseudonymisation and physical control)** | We will not meet this requirement because we will not be carrying out a network penetration test until after the June submission deadline. While we have the results of other security tests over the past 12 months none cover the requirements for this requirement in full. We don't pseudonymise data held on the HFEA server as it is either deleted according to our Retention Schedule or we need to identify data subjects for access to information requests (OTR). We will provide results from our |

| | |
|---|---|
| | network penetration test when the audit has been completed later in 2021 and this will be used as evidence for our 2022 submission. |
| **6.2.11**<br>**You have implemented on your email, Domain-based Message Authentication Reporting and Conformance (DMARC), Domain Keys Identified Mail (DKIM) and Sender Policy Framework (SPF) records in place for their domain to make email spoofing difficult** | We will not meet this requirement because this level of enforcement is not currently in place and we do not have the capacity to complete it before June 2021. We expect to put this in place by the end of September 2021 and so this will be available as evidence for our 2022 submission. |

**4.1.** To complete the above two requirements by June (and therefore be fully compliant) would a have significant impact on the operational IT service as the IT team is just two people. The consequence of completing the two actions above at this time would mean that IT and server issues are not resolved in a timely way and staff receive a very poor standard of service.

**4.2.** We have considered temporary backfill support to increase capacity within the team to complete the work internally to satisfy the DSPT and / or outsource the DSPT work to meet the requirements above.

- Complete DSPT work internally: We considered that the time taken to pass on knowledge about our EDI system, laptop software builds and other bespoke systems would be significant. We concluded the time and resource needed over an extended period of time would outweigh the benefits. It would also provide us with a significant operation support issue and would impact on our PRISM launch given our reliance on key technical HFEA staff at the time of launch.
- Complete DSPT work externally: We carefully considered outsourcing the work to complete the two items above to our outsourced IT support partner. We concluded that they would need continual access to our staff to complete the data by design audit and to implement domain based messaging controls and the impact on consequences on our very small team would be similar to completing the work in-house.

**4.3.** We will continue to review the situation in light of the quantity of EDI support issues reported, our laptop rollout programme and support issues relating to other bespoke systems.

**4.4.** Following approval by CMG the interim assessment was submitted electronically on 24 February 2021

**4.5.** We will be discussing the requirements, our workload and size of organisation with NHS Digital as some leniency with compliance may be possible given the circumstances.

**4.6.** As part of the submission, it is required that our internal audit function assess the suitability of our evidence. GIAA have offered to audit our submission later this year.

**4.7.** We will continue to provide AGC with progress updates and we will ask AGC to sign off our final submission in June 2021.

## 5. Recommendation

The Committee is asked to note:

- Our laptop replacement programme will commence shortly and we have reviewed our Microsoft Azure agreement in light of recent changes resulting in a cost saving of around 13% per annum
- CMG will be prioritising IT software development work to be completed post-PRISM
- The Choose a Fertility Clinic section on our website was updated in February 2021 with up to data performance data
- Following CMG approval our interim Data Security Protection Toolkit submission was completed on 24 February 2021

# 6. Annex A – Data Security and Protection Toolkit interim assessment

| Assertion | Progress |
|---|---|
| 1.1.1 Has SIRO responsibility for data security been assigned? | Completed |
| 1.1.2 List the names and job titles of your key staff with responsibility for data protection and/or security | Completed |
| 1.1.3 Are there clear lines of responsibility and accountability to named individuals for data security? | Completed |
| 1.1.4 Is data security direction set at board level and translated into effective organisational practices? | Completed |
| | |
| 1.2.1 Are there board approved data security and protection policies in place that follow relevant guidance | Completed |
| 1.2.3 How are data security and protection policies made available to the public | Completed |
| | |
| 1.3.1 What is your ICO registration number? | Completed |
| 1.3.2 How is transparency information (e.g. privacy notice) published and available to the public? | Completed |
| 1.3.5 Have there been any ICO actions taken against the organisation in the last 12 months, such as fines, enforcement notices or decision notices? | Completed |
| | |
| 1.4.1 Provide details of the record or register that details each use or sharing of personal information | Completed |
| 1.4.2 When did your organisation last review both the list of all systems/information assets holding or sharing personal information and data flows? | Completed |
| 1.4.4 Provide a progress update on your compliance with the national data opt-out | Completed |
| | |
| 1.5.2 Does your organisation carry out regular data protection spot checks? | Completed |
| | |
| 1.6.1 There is an approved procedure that sets out the organisation's approach to data protection by design and by default, which includes pseudonymisation requirements | Pending |
| 1.6.2 There are technical controls that prevent information from being inappropriately copied or downloaded | Completed |
| 1.6.3 Briefly describe the physical controls your buildings have that prevent unauthorised access to personal data | Completed |
| 1.6.4 Provide the overall findings of the last data protection by design audit (Should be from last 12 months - covering access control, encryption, computer port control, pseudonymisation and physical control) | Not met |
| 1.7.2 Was the scope of the last data quality audit in line with guidelines (In accordance to Service User Data Audit) | Pending |
| 1.7.4 Has a records retention schedule been produced? | Completed |
| 1.7.5 Provide details of when personal data disposal contracts were last reviewed/updated | Pending |
| 1.8.1 Does your organisation operate and maintain a data security risk register (including risks from supply chain) which links to the corporate risk framework providing senior visibility? | Completed |
| 1.8.3 What are your top three data security and protection risks? | Completed |

| | |
|---|---|
| 2.2.1 Is there a data protection and security induction in place for all new entrants to the organisation? | Completed |
| 2.2.2 Do all employment contracts contain data security requirements? | Completed |
| 3.1.1 Has an approved organisation-wide data security and protection training needs analysis been completed after 1 April 2020? | Pending |
| 3.2.1 Have at least 95% of all staff, completed their annual data security awareness training in the period 1 April 2019 to 30 Sep 2020 | Completed |
| 3.3.1 Provide details of any specialist data security and protection training undertaken | Completed |
| 3.3.2 The organisation has appropriately qualified technical cyber security specialist staff and/or service | Completed |
| 3.3.3 The organisation has nominated a member of the cyber associates network | Completed |
| 3.4.1 Have your SIRO and Caldicott Guardian received appropriate data security and protection training? | Pending |
| 3.4.2 What percentage of Board Members have completed appropriate data security and protection training? | Not met |
| 4.1.1 Your organisation maintains a record of staff and their roles | Completed |
| 4.1.2 Does the organisation understand who has access to personal and confidential data through your systems, including any systems which do not support individual logins? | Completed |
| 4.2.1 When was the last audit of user accounts held? | Completed |
| 4.2.5 Are unnecessary user accounts removed or disabled | Completed |
| 4.3.1 All system administrators have signed an agreement which holds them accountable to the highest standards of use | Completed |
| 4.3.2 Are users, systems and where appropriate, devices, always identified and authenticated prior to being provided access to information or system? | Completed |
| 4.4.1 Has the Head of IT, or equivalent, confirmed that IT administrator activities are logged and those logs are only accessible to appropriate personnel? | Pending |
| 4.4.3 The organisation does not allow users with wide ranging or extensive system privilege to use their highly privileged accounts for high-risk functions, in particular reading email and web browsing | Completed |
| 4.5.4 Passwords for highly privileged system accounts, social media accounts and infrastructure components shall be changed from default values and shall not be easy to guess. Passwords which would on their own grant extensive system access, should have high strength | Completed |
| 5.1.1 Root cause analysis is conducted routinely as a key part of your lessons learned activities following data security incident | Pending |
| 5.1.2 Provide summary details of process reviews held to identify and manage problem processes which cause security breaches | Completed |
| 6.1.1 A data security and protection breach reporting system is in place | Completed |
| 6.1.4 How is the Board or equivalent notified of the action plan for all data security and protection breaches? | Completed |
| 6.1.5 Individuals affected by a breach are appropriately informed | Completed |
| 6.2.2 Number of alerts recorded by the anti virus tool in the last 3 months | Pending |
| 6.2.3 Has antivirus/anti-malware software been installed on all computers that are connected to or capable of connecting to the Internet | Completed |
| 6.2.11 You have implemented on your email, Domain-based Message Authentication Reporting and Conformance (DMARC), Domain Keys Identified Mail (DKIM) and Sender Policy Framework (SPF) records in place for their domain to make email spoofing difficult | Not met |
| 6.2.12 You have implemented spam and malware filtering, and enforce DMARC on inbound email | Completed |
| 6.3.1 If you have had a data security incident, was it caused by a known vulnerability? | Completed |

| | |
|---|---|
| 6.3.2 The organisation has responded to high severity CareCERT alerts within 48 hours over the last 12 months | Completed |
| 6.3.3 The organisation has a proportionate monitoring solution to detec cyber events on systems and services | Completed |
| 6.3.5 Are all new Digital services that are attractive to cyber criminals for the purposes of fraud, implementing transactional monitoring techniques from the outset? | Pending |
| 7.1.1 Organisations understand the health and care services they provide | Completed |
| 7.1.2 Do you have well defined processes in place to ensure the continuity of services in the event of a data security incident, failure or compromise? | Completed |
| 7.2.1 Explain how your data security incident response and management plan has been tested to ensure all parties understand their roles and responsibilities as part of the plan | Pending |
| 7.2.4 From the business continuity exercise which issues and actions were documented, with names of actionees listed against each item | Pending |
| 7.3.1 On discovery of an incident, mitigating measures shall be assessed and applied at the earliest opportunity, drawing on expert advice where necessary | Pending |
| 7.3.2 All emergency contacts are kept securely, in hardcopy and are up-to-date | Pending |
| 7.3.4 Suitable backups of all important data and information needed to recover the essential service are made, tested, documented and routinely reviewed | Completed |
| 8.1.1 Provide evidence of how the organisation tracks and records all software assets and their configuration? | Completed |
| 8.1.2 Does the organisation track and record all end user devices and removeable media assets? | Completed |
| 8.2.1 List of unsupported software prioritised according to business risk, with remediation plan against each item | Completed |
| 8.2.2 The SIRO confirms that the risks of using unsupported systems are being treated or tolerated | Completed |
| 8.3.1 How do your systems receive updates and how often? | Completed |
| 8.3.2 How often, in days, is automatic patching typically being pushed out to remote endpoints? | Completed |
| 8.3.3 There is a documented approach to applying security updates (patches) agreed by the SIRO | Completed |
| 8.3.4 Where a security patch has been classed as critical or high-risk vulnerability it is applied within 14 days, or the risk has been assessed, documented, accepted and signed off by the SIRO with an auditor agreeing a robust risk management process has been applied. | Completed |
| 8.4.1 Is all your infrastructure protected from common cyber-attacks through secure configuration and patching? | Completed |
| 8.4.2 All infrastructure is running operating systems and software packages which are patched regularly, and as a minimum in vendor support. | Completed |
| 9.1.1 The Head of IT, or equivalent role confirms all networking components have had their default passwords changed | Completed |
| 9.2.1 The annual IT penetration testing is scoped in negotiation between the SIRO, business and testing team including checking that all networking components have had their default passwords changed | Completed |
| 9.2.2 The date the penetration test was undertaken | Pending |
| 9.3.1 All web applications are protected and not susceptible to common security vulnerabilities, such as described in the top ten Open Web Application Security Project (OWASP) vulnerabilities | Completed |
| 9.3.3 The organisation uses the UK Public Sector DNS Service to resolve internet DNS queries | Pending |
| 9.3.4 The organisation ensures that changes to your authoritative DNS entries can only be made by strongly authenticated and authorised administrators | Completed |
| 9.3.5 The organisation understands and records all IP ranges in use across your organisation | Completed |

| | |
|---|---|
| 9.3.6 The organisation is protection data in transit (including email) using well configured TLS v1.2 or better | Completed |
| 9.3.7 The organisation has registered and uses the National Cyber Security Centre (NCSC) Web Check service for your publicly visible applications | Pending |
| 9.4.4 Security deficiencies uncovered by assurance activities are assessed, prioritised and remedied when necessary in a timely and effective way | Completed |
| 9.4.6 What level of assurance did the independent audit of your data security and protection toolkit provide to your organisation | Pending |
| 9.6.1 All devices in your organisation have technical controls which manage the installation of software on the device | Completed |
| 9.6.2 Confirm all data is encrypted at rest on all mobile devices and removeable media and you have the ability to remotely wipe and/or revoke access from an end user device | Completed |
| 9.6.10 You have a plan for protecting devices that are natively unable to connect to the Internet, and the risk has been assessed, documented, accepted and signed off by the SIRO | Completed |
| 9.7.1 Have one or more firewalls (or similar network device) been installed on all the boundaries of the organisation's internal network(s) | Completed |
| 10.1.1 The organisation has a list of its suppliers that handle personal information, the products and services they deliver, their contact details and the contract duration | Completed |
| 10.2.1 Organisations ensure that any supplier of IT systems that could impact on the delivery of care, or process personal identifiable data, has the appropriate certification | Completed |
| 10.2.2 Organisations should, as part of their risk assessment, determine whether the supplier certification is sufficient assurance | Completed |
| 10.2.4 Where services are outsourced (for example by use of cloud infrastructure or services), the organisation understands and accurately records which security related responsibilities remain with the organisation and which are the supplier's responsibility | Completed |

# Strategic risk register 2020-2024

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society |
| Meeting: | Audit and Governance Committee |
| Agenda item: | 9 |
| Paper number: | HFEA (16/03/2021) HC |
| Meeting date: | 16 March 2021 |
| Author: | Helen Crutcher, Risk and Business Planning Manager |
| Annexes | Annex 1: Strategic risk register 2020-2024 |

## Output from this paper

| | |
|---|---|
| For information or decision? | For information and comment |
| Recommendation: | 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 in April. |
| Organisational risk: | Medium |

## 1. Latest reviews

**1.1.** SMT reviewed the register at its meeting on 1 March 2021. 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.** None of the ten risks are above tolerance.

**1.4.** A key consideration during the March SMT discussion was to look across the total risk picture and review the scores comparatively, to ensure these were properly calibrated. Their discussion on the current status of controls has led to reductions to the scores of four risks. Two of the key considerations are outlined below in addition to the commentary in the Register.

**1.5.** The reduction of the Board Capability (C2) risk at this time reflects the much-improved position in terms of appointments, key recruitment is completed and onboarding is well underway. Targeted extensions to terms also provide further stability and knowledge retention and reduce the present inherent risk. We are, however, very mindful that board capability will be a key consideration for any new Chair and that this risk will fluctuate as we approach further member term endings. The key consideration is the ongoing administration of the cycle of membership management, though we have limited power over this control and remain in close discussion with the Department on this matter.

**1.6.** On Coronavirus, our assessment of risk has taken account of our ongoing review of the effectiveness of our revised inspection processes which has assured us that we are able to continue to effectively deliver our statutory duties. More generally, we have replanned where appropriate to enable us to continue to deliver strategic work, such as the add-ons project.

## 2. Next steps for risk management review

**2.1.** It has been some time since we last brought the HFEA risk management policy to AGC, which we did last in December 2018. We last confirmed the risk appetite statement section with you in June 2020. Rather than bringing the risk appetite statement separately, we think it would be most helpful for us to undertake a full review of the risk policy and appetite statement and present these to you together.

**2.2.** We are keen to ensure that our approach remains in line with best practice, such as the Orange Book, and also, vitally, that it forms a clear basis for staff on the ground to manage risk effectively at all levels of the organisation. To that end, we intend to bring the Policy back to AGC at its October meeting, with a view to confirming the appetite statement with the Authority when the Risk Register goes to them in November.

**2.3.** Meanwhile, we are already having conversations about some key aspects or risk management we can strengthen, such as ensuring consistent scoring across the organisation and assurance of controls and will reflect these during the review. The DHSC ALBs risk group, which has recently recommenced will also be a useful source of knowledge to inform our approaches.

## 3. Recommendation

**3.1.** AGC is asked to note the above and comment on the strategic risk register and plans for the next review of the risk policy and appetite statement.

Latest review date – 01/03/2021

# Strategic risk register 2020-2024

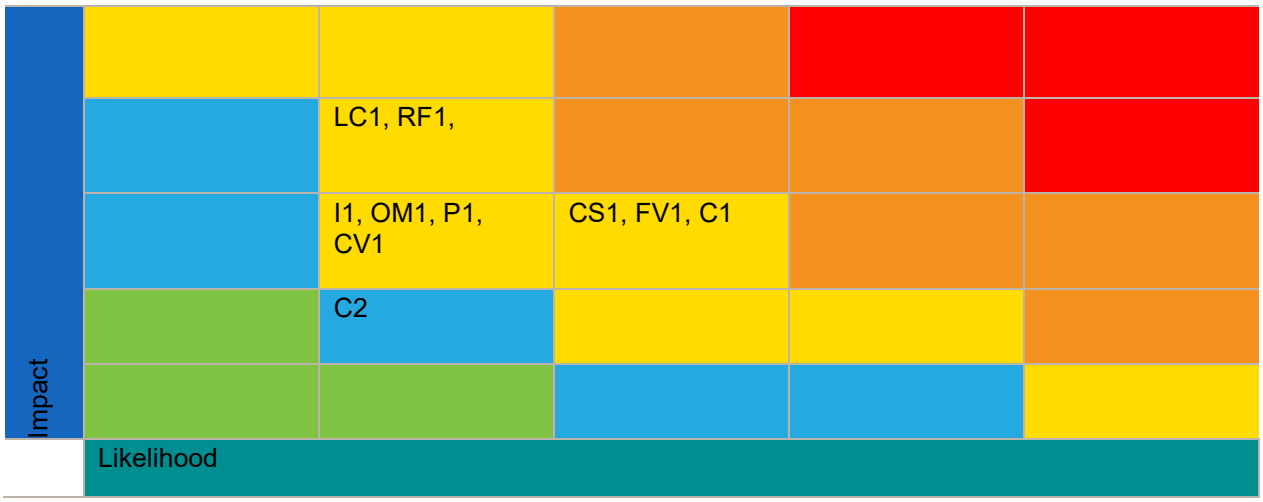
## Risk summary: high to low residual risks

| Risk ID | Strategy link | Residual risk | Status | Trend* |
|---|---|---|---|---|
| FV1: Financial viability | Generic risk – whole strategy | **9 – Medium** | At tolerance | ⇔⇔⇔⇔ |
| CS1: Cyber security | Generic risk – whole strategy | **9 – Medium** | At tolerance | ⇔⇔⇔⇔ |
| C1: Capability | Generic risk – whole strategy | **9 – Medium** | Below tolerance | ⇔⇔⇔⇔ |
| RF1 – Regulatory framework | The best care (and whole strategy) | **8 - Medium** | At tolerance | ⇔⇔⇔⇔ |
| LC1: Legal challenge | Generic risk – whole strategy | **8 – Medium** | Below tolerance | ⇔⇔⇔⇔ |
| OM1: Operating Model | Whole strategy | **6 – Medium** | Below tolerance | (New at 18 January SMT) -⇩ |
| I1 – Information provision | The right information | **6 - Medium** | Below tolerance | ⇔⇔⇔⇔ |
| P1 – Positioning and influencing | Shaping the future (and whole strategy) | **6 - Medium** | Below tolerance | ⇔⇔⇔⇩ |
| CV1 - Coronavirus | Whole strategy | **6 – Medium** | Below tolerance | ⇩⇔⇔⇩ |
| C2: Board capability | Generic risk – whole strategy | **4 – Low** | At tolerance | ⇔⇔⇔⇩ |

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

**Recent review points:** SMT 25 November 2020⇨AGC 8 December 2020 ⇨ SMT 18 January ⇨SMT 1 March

**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**<br>RF1: Responsive and safe regulation | Rachel Cutting, Director of Compliance and Information | The best care and whole strategy | ⇔⇔⇔⇔ |

| Commentary |
|---|
| As a regulator, we are by nature removed from the care and developments being offered in clinics and we must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research are safe and ethical.<br><br>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.<br><br>We reworked our inspection methodology as a result of Coronavirus, to undertake remote and hybrid inspections to reduce risk, and this is bedding in as at spring 2021(reflected as a control under CV1 risk). Early insights suggest a higher resource requirement for these new processes, and we are keeping this under close review to ensure that it remains appropriate. SMT agreed in March 2021 that although this is a new source of risk for RF1, this does not yet suggest the overall risk had increased, but we will keep this under close review. |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

| Risk area | Risk owner | Links to which strategic objectives? | Trend |
|---|---|---|---|
| **Positioning and influencing**<br>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.<br><br>Discussions occurred with the Authority in January 2021 about our ongoing communications approach, including the 30th anniversary of the HFEA. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions.<br><br>The response to the Covid-19 pandemic has required close working with many other organisations and professional bodies, as well as increased engagement with the sector, which has strengthened our strategic positioning and reduced the likelihood of this risk. Consequently, SMT reduced the risk score in March 2021. |

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

| Causes / sources | Controls | Status/timescale / owner |
|---|---|---|
| We may be unable to persuade partner organisations to utilise their powers/influence/resources to achieve shared aims. | Early engagement with such organisations, to build on shared interests and reduce the likelihood of this becoming an issue. For instance, the treatment add-ons working group. | In place - Clare Ettinghausen |
| The sector may disagree with HFEA about key strategic terms and principles, such as 'ethical care' creating negative publicity for us and reputational damage. | We have clearly communicated our intentions, to ensure that these are not misunderstood or misinterpreted and will continue to engage with our established stakeholder groups. | In place - Clare Ettinghausen |
| The sector may take a different view on the evidence HFEA provides in relation to Add-ons and so we may be ignored. | The working group for the add-ons project will focus on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed.<br>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.<br>Framework for decision making around removing GD0014 drawn up following Authority discussion. | In place - Peter Thompson<br>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.<br>Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way.<br>Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these.<br>We are investigating holding an annual meeting with key innovators (in industry). | In place - Laura Riley/Joanne Anton<br>In place - Laura Riley/Joanne Anton<br>In place and ongoing – Sharon Fensome-Rimmer<br>Future control, delayed due to Covid-19 but to be reviewed in Q4 - 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 | Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. | Ongoing - Peter Thompson |

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

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

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

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

| Commentary |
|---|
| Reduced treatment activity owing to Covid-19 and the implementation of GD0014 during 2020-2021 meant this was a live issue, with treatment income lower than planned for the year, although we were given assurance of cover by the Department.<br><br>There remains significant uncertainty about the 2021-2022 financial year. We continue to monitor sector activity very closely. Analysis by the Finance team suggests that if there were a deficit in 2021-2022, we would likely be able to support ourselves from reserves, meaning that the risk was unlikely to be the same existential threat as it had been towards the beginning of the pandemic. However, the detail of arrangements for Grant in Aid and how any deficit would be funded are still under discussion.<br><br>An initial options appraisal for a fee review project was agreed with Authority in June 2020. A consultation and modelling for the new income model will follow but owing to the impact of Covid-19 there is now some uncertainty around the timing of this work. Discussions are ongoing with the Department. This review, when it occurs, should ensure that the income model is fit for purpose and reflects the changing nature of sector activity, and set the HFEA up for the future. |

| Causes / sources | Controls | Timescale / owner |
|---|---|---|
| There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.<br><br>This is a live issue for 2020/2021 as we have reduced income for as long as GD0014 (version 2) is in place. Although clinics have reopened it will take some time for activity to return to 'normal' levels. | Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed.<br><br>We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC. | CMG monthly and Authority when required – Peter Thompson<br><br>Quarterly, ongoing, with AGC model review at least annually (conversation planned in |

| Causes / sources | Controls | Timescale / owner |
|---|---|---|
| | We plan to undertake a fee review project (timing TBC) to ensure that the income model is fit for purpose and reflects the changing nature of sector activity. We are discussing with the Department of Health and Social Care how this issue will be managed from 2021-2022. | March) - Richard Sydee<br>Planning underway – Peter Thompson and Richard Sydee |
| Our monthly income can vary significantly as:<br>• it is linked directly to level of treatment activity in licensed establishments<br>• we rely on our data submission system to notify us of billable cycles.<br>As at March 2021 we have reduced income due to the deployment of GD0014 in response to Covid-19 and the subsequent reopening of the sector. | Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in October 2020.<br>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. | Given the Covid-19 related drop in income, we have actively employed this control – Richard Sydee<br>Control under quarterly review as sector reopens – Richard Sydee |
| Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend. | Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements.<br>All project business cases are approved through CMG, so any financial consequences of approving work are discussed. | Quarterly meetings (on-going) – Morounke Akingbola<br>Ongoing – Richard Sydee |
| Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work.<br>Note: PRISM delivery has now been delayed into 2021/2022 which will have a financial impact. Controls for this ongoing financial risk are being discussed to minimise the impact. | The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact.<br>Ongoing monitoring and reporting against control totals to ensure we do not overspend. Funding was received from the Department to complete the PRISM programme.<br>In 2020/2021, additional funding was allocated from underspends elsewhere in order to cover budget needed to complete the project following impact of Covid-19 delays, while minimising the impact on the wider organisation.<br>Careful consideration of ongoing cost implications of PRISM delays for 2021/2022 and discussion of approach and risk management with AGC. | In place – Richard Sydee<br>Ongoing, – Richard Sydee<br>October 2020 – Richard Sydee<br>Ongoing – Richard Sydee |

| Causes / sources | Controls | Timescale / owner |
|---|---|---|
| The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs.<br><br>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.<br><br>Note: As at March 2021, although this is not yet finalised, it looks likely that the new office will be cheaper. Costs are being mapped for the next financial year. | 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.<br><br>The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed.<br><br>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. | Ongoing but we await confirmation of overarching procurement arrangements from central programme - Richard Sydee |
| Inadequate decision-making leads to incorrect financial forecasting and insufficient budget. | Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations.<br><br>The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making. | In place and ongoing - Richard Sydee<br><br>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.<br><br>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<br><br>Monthly (on-going) – Samuel Akinwonmi |
| Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding. | The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community.<br><br>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<br><br>Annually and as required – Morounke Akingbola |
| **Risk interdependencies (ALBs / DHSC)** | **Control arrangements** | **Owner** |

| Causes / sources | Controls | Timescale / owner |
|---|---|---|
| **DHSC:** Covid-19 impacts on HFEA income. | The final contingency for all our financial risks is to seek additional cash and/or funding from the DHSC and we are in ongoing discussions with the Department about this issue for the 2021/2022 business year having received confirmation from them for cover in 2020/2021. | 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.<br>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.<br>Annual budget has been agreed with DHSC Finance team. GIA funding has been agreed through to 2021. | Quarterly accountability meetings (on-going) – Richard Sydee<br>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**<br>C1: Knowledge and capability | Peter Thompson, Chief Executive | Whole strategy | ⇔⇔⇔⇔ |

| **Commentary** |
|---|
| This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity.<br><br>As at March 2021, turnover continues to be low (this was 12.2% in 2019-2020 and has remained broadly at this level). Recruitment, where it has been required, has been successfully undertaken throughout the Covid-19 pandemic, with effective remote onboarding of new starters.<br><br>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. 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.<br><br>Management of Board capability is captured in the separate C2 risk, below. |

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

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

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

## 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** |
| 2 | 4 | 8- Med | **1** | **4** | **4 - Low** |
| **Tolerance threshold:** | | | | | **4 - Low** |
| **Status:** **At tolerance** | | | | | |

| Risk area | Risk owner | Links to which strategic objectives? | Trend |
|---|---|---|---|
| **Estates**<br>C2: Board capability | Peter Thompson<br>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.<br><br>As at March 2021, several appointments have been made, and onboarding is underway, reducing the inherent risk likelihood for a time. Several existing members' terms were also extended to enable management of possible capability gaps. Although this means that the residual risk has currently reduced to low, this risk may fluctuate as terms of office end, and new members are appointed. The possible impact is high, and we have limited influence over some of the controls (timing and duration of recruitment), making this an ongoing risk. Board Capability will be a key discussion with a new Chair, once appointed. |

| Causes / sources | Mitigations | Status/timescale / owner |
|---|---|---|
| A precipitous reduction in available members would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and research centres and authorise treatment for serious inherited illnesses. | 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 |
| The uncertainty about Chair appointment may result in a gap in leadership and direction for the Authority. | The Department has extended both the Deputy Chair and Chair of Audit and Governance Committee, to ensure a smooth transition. | In place - Peter Thompson |

| Causes / sources | Mitigations | Status/timescale / owner |
|---|---|---|
| Any member recruitment may take some time and therefore give rise to further vacancies and capability gaps.<br><br>The recruitment process is run by DHSC meaning we have limited power to influence this risk source.<br><br>Historically, decisions on appointments have taken some time which may create additional challenges for planning (the annual report from the commission for public appointments suggests appointments take on average five months). | In January 2021, recruitment was successful for four Board posts. We are now focussing on streamlining induction to ensure that Members are brought up to speed as quickly as practicable (see risks below).<br><br>This risk cause remains for future recruitment and we remain in discussion on the ongoing management of this. | Underway- Peter Thompson |
| Several current Board members are on their second terms in office, which expire within the same period<br><br>Note: this is a live issue. | We are discussing options with the Department for managing the cycle of appointments, in order to reduce the ongoing impact of this.<br><br>The targeted extension of some members extends the proximity of this issue somewhat. | In progress, ongoing - Peter Thompson |
| The induction time of new members (including bespoke legal training), particularly those sitting on licensing committees, may lead to a loss of collective knowledge and potentially an impact on the quality of decision-making.<br><br>Evidence from current members suggests that it may take up to a year for members to feel fully confident. | The Governance team has reviewed recruitment information and member induction to ensure that this will be as smooth as possible.<br><br>Targeted extensions, noted above, should bridge this period of learning and therefore support new members. | In place and ongoing - Paula Robinson |
| Induction of new members to licensing and other committees, will require a significant amount of internal staff resource and could reduce the ability of the governance and other teams to support effective decision-making. | We have been mindful of this resource requirement when planning other work, in order to limit the impact of induction on other priorities. | In progress, - Peter Thompson, Paula Robinson |
| **Risk interdependencies (ALBs / DHSC)** | **Control arrangements** | **Status/timescale / owner** |
| **Government/DHSC**<br><br>The Department is responsible for our Board recruitment but is | Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control. | Ongoing - Peter Thompson |

| Causes / sources | Mitigations | Status/times cale / owner |
|---|---|---|
| bound by Cabinet Office guidelines. | Recruitment, led by the Department, has led to the successful appointment of new members in January 2021, but is in progress for a new Chair as at March. | |
| **Government/DHSC**<br>DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA Board recruitment, it will be breaching its own legal responsibilities. | Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.<br>Recruitment for a new Chair, led by the Department, is in progress as at March. | Ongoing - Peter Thompson |
| **Government/DHSC**<br>HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. This may impact any planned approach and risk mitigations and give rise to further risk. | Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.<br>Recruitment, led by the Department, has led to the successful appointment of new members in January 2021, but is in progress for a new Chair as at March. | Ongoing - Peter Thompson |

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

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

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

**Commentary**

Cyber-attacks and threats are inherently very likely. Our approach to handling these risks effectively includes ensuring we:

- have an accurate awareness of our exposure to cyber risk
- have the right capability and resource to handle it
- undertake independent review and testing
- are effectively prepared for a cyber security incident
- have external connections in place to learn from others.

We continue to assess and review the level of national cyber security risk and act as necessary to ensure our security controls are robust and are working effectively.

Delays to PRISM delivery necessitate the continued use of EDI in clinics. Many clinics use older server technology to run our EDI gateway within their clinic or organisation resulting in an increased cyber risk while that technology is in use. Many have upgraded their infrastructure to reduce the likelihood of a cyber incident. The related cyber risk concerns an attack on the clinic's infrastructure – all have local logical and physical security controls in place. All submission data via EDI is encrypted in transit. We continue to work with clinics to support the upgrade of their server infrastructure.

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

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

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

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

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

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

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

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

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

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

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

| Causes / sources | Controls | Status/Timescale / owner |
|---|---|---|
| | differences, so that staff understand any differences in practice and that the intention is not to homogenise practices.<br>Ongoing working groups will be established following programme closure in March 2021. | coordinated across all organisations – Richard Sydee |
| **Risk interdependencies (ALBs / DHSC)** | **Control arrangements** | **Owner** |
| **NICE/CQC/HRA/HTA** – IT, facilities, ways of working interdependencies. | Regular DHSC programme meeting involving all regulators.<br>Sub-groups with relevant IT and other staff such as HR.<br>Informal relationship management with other organisations' leads. | In place until the end of the Redman Place Programme in March 2021 with ongoing groups to be established as part of closure – Richard Sydee, DHSC |

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

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

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

**Commentary**

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

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

Legal challenge poses two key threats:

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

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

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

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

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

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

| Causes / sources | Mitigations | Timescale / owner |
|---|---|---|
| | Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes.<br><br>Measures in place to ensure consistency of advice between the legal advisors from different firms. Including:<br>• Provision of previous committee papers and minutes to the advisor for the following meeting<br>• Annual workshop<br>• Regular email updates to panel to keep them abreast of any changes.<br><br>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. | In place – Peter Thompson<br><br>Since Spring 2018 and ongoing – Catherine Drennan<br><br>In place – Paula Robinson |
| Any of the key legal risks may escalate into high-profile legal challenges which may result in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime. | Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public.<br><br>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.<br><br>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary. | In place – Catherine Drennan, Joanne Triggs<br><br>In place – Peter Thompson, Catherine Drennan<br><br>In place – Peter Thompson |
| **Risk interdependencies (ALBs / DHSC)** | **Control arrangements** | **Owner** |
| **DHSC:** HFEA could face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime. | If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it. | In place – Peter Thompson |
| **DHSC:** We rely upon the Department for any legislative changes in response to legal risks or impacts. | Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as | In place – Peter Thompson |

| Causes / sources | Mitigations | Timescale / owner |
|---|---|---|
| | needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget.<br><br>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.<br><br>We also pre-emptively engage on emerging legal issues before these become formal legal matters. | In place – Peter Thompson |

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

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

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

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

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

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

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

| Causes / sources | Controls | Status/Timescale / owner |
|---|---|---|
| We have had to cancel events and meetings and cannot run them as planned which may delay some strategic delivery. | Conversations ongoing with Authority and Corporate Management about options for management of individual risk impacts and review key milestones where needed.<br>Routine stakeholder meetings occurring virtually and revised arrangements to allow for virtual meetings and committees. | In place – Peter Thompson |
| Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity. | Provided equipment for staff who have to WFH without suitable arrangements in place. Ability of staff unable to work from home to work in Covid-19 secure office.<br>Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources.<br>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.<br>Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance. | In place – Richard Sydee<br>In place – Yvonne Akinmodun<br>In place – Yvonne Akinmodun<br>In place and ongoing – Yvonne Akinmodun |
| Inability of staff to return to office working may negatively impact organisational culture, reduce collaboration, or hamper working dynamics and productivity.<br>Note: This risk will affect the organisation for some time including when we return to the office, while social distancing is in place and office working is significantly reduced due to Covid-19 restrictions. The ongoing consideration of this risk is reflected within the OM1 risk. | Discussion about return to office working at CMG to ensure that this is planned effectively, and impacts considered. This is occurring on a month by month basis in the run up to returning to the office.<br>Online solutions to maintain collaboration and engagement, such as informal team engagement and 'teas', Microsoft Teams etc. | Ongoing – Peter Thompson<br>In place – Heads |
| Risk that we miss posted financial, OTR or other correspondence. | Arrangement in place to securely store, collect and distribute post.<br>Updated website info to ask people to contact us via email and phone. | In place– Richard Sydee<br>In place – Jo Triggs |

| Causes / sources | Controls | Status/Timescale / owner |
|---|---|---|
| | We notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems. | In place – Morounke Akingbola |
| **Risk interdependencies (ALBs / DHSC)** | **Control arrangements** | **Owner** |
| **In common risk** | | |
| **DHSC:** HFEA costs exceed annual income because of reduced treatment volumes.<br>Live issue as at March – captured under FV1 | Use of cash reserves, up to appropriate contingency level available.<br>The final contingency would be to seek additional cash and/or funding from the Department. (additional Grant in Aid has been provided for the 2020/2021 business year). | Richard Sydee |

## Reviews and revisions

### 01/03/2021 – SMT review – March 2021

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

- SMT discussed the aggregate view of residual strategic risk and noted the clustering of risks as 'medium'. SMT agreed that they would recalibrate the risk scores when reviewing each risk, to ensure that risks with the same scores were of comparable significance.
- RF1 – SMT discussed the new inspection methodology and noted that it was effective in providing oversight of clinics, but the Compliance team were currently finding that it required additional resource. The new methodology was developed as a rapid response to the pandemic and inspectors had to adapt to change very quickly. As with any new process issues will emerge during the embedding phase and the problem of increased resource demand is in part due to the lack of consensus among the inspection team about the appropriate degree of remote oversight of clinic policies and procedures. The new methodology will be monitored to ensure workload returns to manageable levels, so this does not have a substantive impact on the overall risk. Unmanaged increased resource requirements could lead to burnout and ineffective ongoing delivery.
- I1 – SMT reflected that OTR as a live issue was the key cause of present risk. Balanced with the controls in place and developing to address this, alongside the good position for the rest of the risk, SMT decided not to raise the score. A new risk cause was added related to accessing Register data post-PRISM launch, controls were being actively discussed in this area to ensure they were appropriate.
- P1 – SMT discussed the impact of our recent collaborative work on this risk and agreed that this reduced the risk at this time. SMT discussed possible health regulatory changes and noted that these were not directly related to HFEA and so were not deemed a source of a positioning risk for us.
- FV1 - RS noted that there was no change, conversations were ongoing about 2RP costs and would be resolved shortly for the coming financial year. Wider financial viability discussions were ongoing, per January discussion, but there was no change to the score of this risk. It was unlikely to be as impactful in 2021-2022 as during 2020.
- C1 - This risk had been reviewed in full, with a few minor control updates, by the Head of HR, who believed no change to the score was indicated. SMT noted the main unknown related to capability would be the impact of returning to the office; we were already engaging staff in these discussions about ways of working (for which there is now a separate OM1 risk), which would help us to understand possible impacts. SMT considered that if the turnover level remained as low as now, we may wish to review the likelihood score of this risk at the end of the next quarter.
- OM1 – SMT reflected that the high importance being placed on the controls for this risk and regular engagement about the future meant the residual likelihood score could be lowered at the current time.
- L1 – had been reviewed with Head of Legal, no significant changes impacting the score.
- CS1 – SMT noted that the CIO had been asked for an update on controls. SMT asked about the general position on cyber risk, what would enable us to reduce this? SMT noted that full penetration was due to occur later in the year and this would provide a key opportunity for a reassessment of effectiveness of controls.
- CV1 – SMT reflected that our approaches to managing Coronavirus risk had proven effective, we were able to maintain our regulatory functions. Key strategic delivery continued. Financial risks related to Covid-19 were in hand and the organisation was working effectively. Given this, SMT agreed that the residual impact was less than indicated and reduced this to 3, bringing the overall risk score down.

### 18/01/2021 – SMT review – January 2021

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

- RF1 – due to the delay to PRISM we may be in a better position with completing RITA and managing associated risks, but it was still too soon to assess if this made a difference to reducing the risk score.
- FV1 – RS gave an overview of the position for the remainder of the year and into 2021/2022 and SMT agreed that although there was uncertainty, the score still feels the same. Projections for the next financial year were that if there were a deficit we would likely be able to support ourselves from reserves, meaning that the risk was unlikely in 2021/2022 to be the same existential threat as it had

been towards the beginning of the pandemic. However, the detail of arrangements for Grant in Aid and how any deficit would be funded were still under discussion.

- C2 – SMT discussed the impact that pending successful Board appointments had on this risk but agreed to retain the current score given the impact of induction and the fact that length of time to address appointments was still a substantial risk as further members' terms come to an end in coming months.
- CV1 – SMT discussed the extent to which the ongoing effective use of the new Covid-19 risk-based inspection model reduced this risk. They agreed that we could reconsider this once further validation had taken place.
- OM1: SMT discussed a new risk related to the need for a new operating model to respond to impacts of a new office and Covid-19 on organisational ways of working and gave an indicative score for the risk. SMT noted that the risk required some reshaping over the coming weeks as these issues were discussed with CMG.

### 8/12/2020 – AGC review – December 2020

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

- AGC discussed board member recruitment, noting that interviews had taken place for four new Authority members and we were waiting for these appointments to be completed by the DHSC. The DHSC representative confirmed that the advert for the appointment of the Chair position was progressing.
- AGC discussed the ongoing FV1 risk and noted that discussions were underway about 2021/2022.

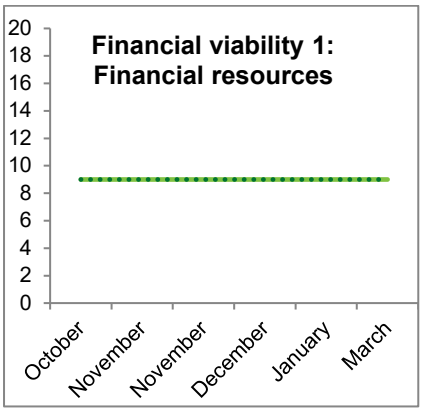
# Risk trend graphs (last updated March 2021)

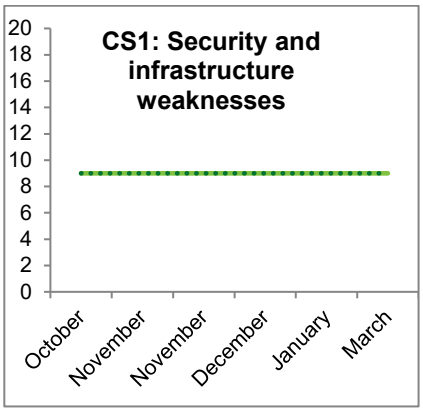
## High and above tolerance risks

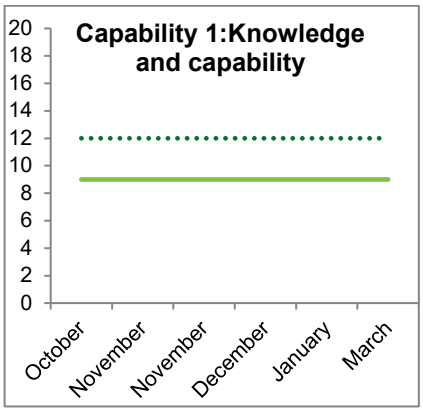
None

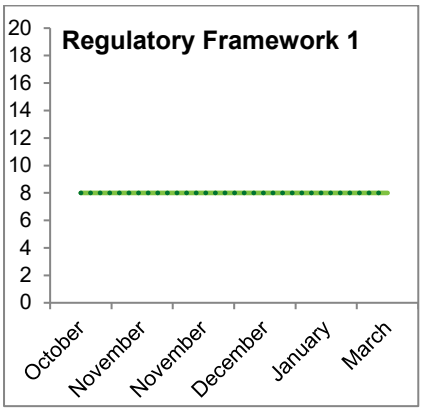
Key:

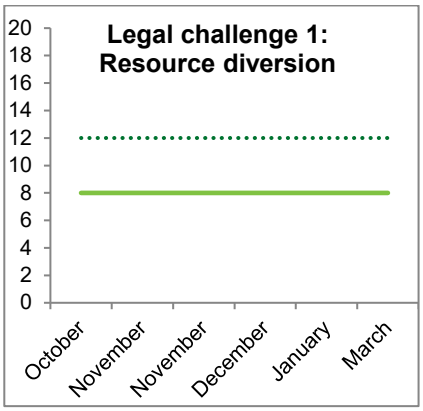

## Lower and below tolerance risks

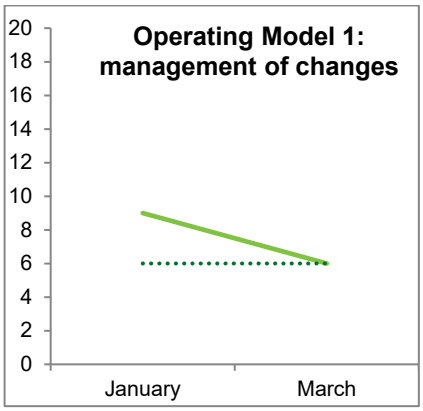


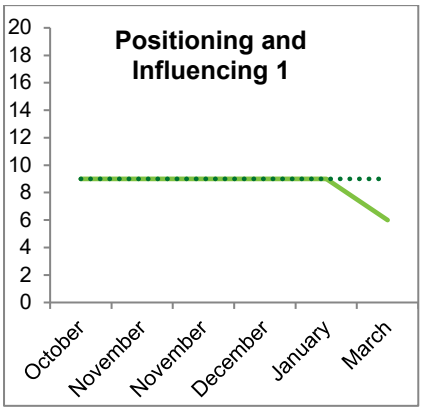



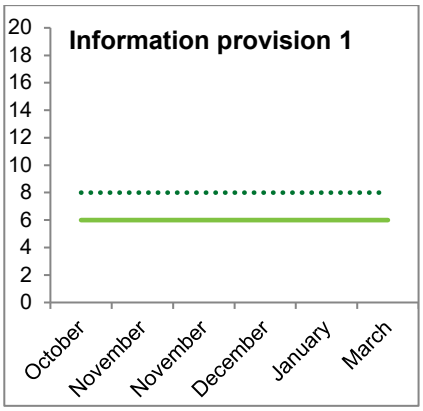



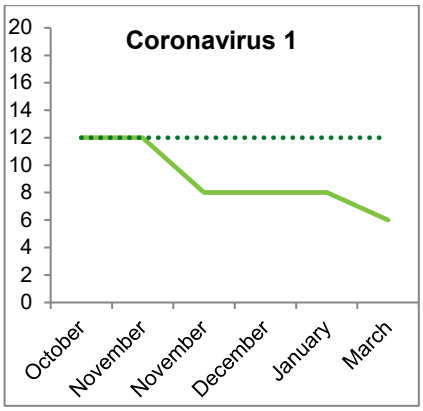



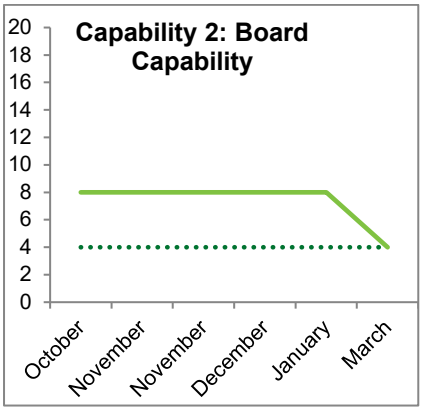



## Criteria for inclusion of risks

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

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

### Rank

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

### Risk trend

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

### Risk scoring system

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

| | | | | | |
|---|---|---|---|---|---|
| Likelihood: | 1=Very unlikely | 2=Unlikely | 3=Possible | 4=Likely | 5=Almost certain |
| Impact: | 1=Insignificant | 2=Minor | 3=Moderate | 4=Major | 5=Catastrophic |

Risk scoring matrix

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

Risk Score = Impact x Likelihood

## Risk appetite and tolerance

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

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed

## Assessing inherent risk

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

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

## System-wide risk interdependencies

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

## Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.

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

# Public Interest Disclosure Policy

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society |
| Meeting: | AGC |
| Agenda item: | 10 |
| Paper number: | HFEA (16/03/2021) |
| Meeting date: | 16 March 2021 |
| Author: | Morounke Akingbola, Head of Finance |
| Annexes | Annex 1: Public Interest Disclosure Policy |

## Output from this paper

| | |
|---|---|
| For information or decision? | For information |
| Recommendation: | AGC are requested to review/comment |
| Resource implications: | None |
| Implementation date: | Ongoing |
| Communication(s): | Share with staff via the 'Hub' |
| Organisational risk: | ~~Low~~/Medium/~~High~~ |

## 1. Purpose

**1.1.** The Public Interest Disclosure Policy generally referred to as the “Whistleblowing” Policy was implemented to ensure people working for the HFEA were aware of the channels available t report inappropriate behaviour.

**1.2.** This paper also confirms that a review of the HFEA Whistleblowing Policy has been undertaken and to set out the updated policy which includes a few minor amendments for the committee’s agreement

## 2. Policy

**2.1.** The policy was brought to AGC in March 2020. Since then, a review has been undertaken to ensure the policy is still fit for purpose.

**2.2.** There have been no amendments to this policy.

**2.3.** The Committee are requested to provide any comments or additions to this policy.

# Public Interest Disclosure ("Whistleblowing") Policy

## 1. Introduction

1.1 In accordance with the Public Interest Disclosure Act 1998, and the corporate values of integrity, impartiality, fairness and best practice, this policy intends to give employees a clear and fair procedure to make disclosures which they feel are in the public interest ("whistleblowing") and will enable the HFEA to investigate these disclosures promptly and correctly.

## 2. Aim

2.1 To outline what constitutes a Public Interest disclosure, and to provide a procedure within the HFEA to deal with such disclosures

## 3. Scope

3.1 This policy applies to all employees, both permanent and fixed term and also Authority members

## 4. Responsibility

4.1 The HR department is responsible for ensuring that all staff have access to this policy. Managers and Senior Executives are responsible for ensuring that any public interest disclosure is dealt with immediately, and sensitively, and confidentially.

## 5. Principles

5.1 Employees who raise their concerns within the HFEA, or in certain circumstances, to prescribed external individuals or bodies will not suffer detriment as a result of their disclosure, this includes protection from subsequent unfair dismissal, victimisation or any other discriminatory action.

5.2 The Public Interest Disclosure Act 1998, (more widely known as the 'Whistleblowers' Act) protects 'workers' from suffering any detriment where they make a disclosure of information while holding a reasonable belief that the disclosure tends to show that:

(a) a criminal offence has been committed, is being committed or is likely to be committed,
(b) a person has failed, is failing or is likely to fail to comply with any legal obligation to which he is subject,
(c) A miscarriage of justice has occurred, is occurring or is likely to occur,
(d) The health and safety of any individual has been, is being or is likely to be endangered,
(e) The environment has been, is being or is likely to be damaged, or
(f) Information tending to show any matter falling within any one of the preceding paragraphs has been, is being or is likely to be deliberately concealed.

5.3 It should be noted that disclosures which in themselves constitute an offence are not protected.

**5.4** HFEA's policy is intended to ensure that where a member of staff, including temporary or contractual staff, have concerns about criminal activity and/or serious malpractice e.g. fraud, theft, or breaches of policy on health and safety, they can be properly raised and resolved in the workplace. Such matters **must be raised internally** in the first instance. Please refer to the paragraph on gross misconduct in the Authority's Disciplinary Policy, and also the Authority's counter-fraud and anti-theft policy.

**5.5** HFEA seeks to foster a culture that enables staff who witness such malpractice to feel confident to raise the matter in the first instance in the knowledge that, once raised, it will be dealt with effectively and efficiently. The HFEA will not tolerate the victimisation of individuals who seek to bring attention to matters of potentially serious public concern and will seek to reassure any individual raising a concern that he or she will not suffer any detriment for doing so. If an individual is subject to a detriment for raising a concern the HFEA will seek to pursue an appropriate sanction.

**5.6** Frivolous or vexatious claims which fall outside the protection of the Act or such other provisions as may be held to protect them (e.g. HFEA's codes of conduct, confidentiality clause etc.) may be considered acts of misconduct and subject to disciplinary action.

## 6. Legal overview

**6.1** Protection for whistleblowers was first introduced in the Public Interests Disclosure Act 1998 the Employment Rights Act 1986 (ERA). This act made it unlawful for an employer to dismiss or subject a worker to detriment on the grounds that they have made a protected disclosure.

## 7. Procedure

### Internal Disclosure

**7.1** HFEA staff who become concerned about the legitimacy or public interest aspect of any HFEA activity or management of it should raise the matter initially with their line manager. If a member of staff feels unable to raise the matter through their line manager, they may do so through the HR Department.

**7.2** It will be the responsibility of the line manager to record and pursue the concerns expressed; consulting such other parts of the Authority; (e.g. HR, SMT) as may be necessary, including where appropriate consideration as to whether external expert assistance is required.

**7.3** The identity of the individual making the disclosure will be kept confidential if the staff member so requests unless disclosure is required by law.

**7.4** In other than serious cases, the line manager will normally be responsible for responding to the individual's concern. They must maintain appropriate records and ensure that they provide the individual raising the concern with:

- An explanation of how and by whom the concern will be handled
- An estimate of how long the investigation will take
- Where appropriate, the outcome of the investigation

- Details of who he/she should report to if the individual believes that he/she is suffering a detriment for having raised the concern
- Confirmation that the individual is entitled to independent advice.

**7.5** Should a member of staff feel that they are not satisfied that their concern has been adequately resolved, they may raise the matter more formally with the Chief Executive.

**7.6** Any member of staff wishing to make a disclosure of significant importance may approach the Chief Executive in the first instance. Matters of significant importance include, but are not restricted to, criminal activity e.g. fraud or theft, or other breaches of the law; miscarriage of justice; danger to health and safety; damage to the environment; behaviour or conduct likely to undermine the Authority's functions or reputation; breaches of the *Seven Principles of Public Life* (Annex A) and attempts to cover up such malpractice.

**7.7** The matter of significant importance may have taken place in the past, the present, or be likely to take place in the future.

**7.8** Concerns may be raised either in writing or at a meeting convened for the purpose. A written record of meetings must be made and agreed by those present. In serious cases or in any case where a formal investigation may be required, line managers concerned should consult the Head of HR and SMT, unless they are implicated, when they should speak to the Chair. Line managers must not take any action which might prejudice any formal investigation, or which might alert any individual to the need to conceal or destroy any material evidence.

**7.9** Where an individual has reason to believe that the concerns about which he / she intends to make a disclosure are condoned or are being concealed by the line manager to whom they would ordinarily be reported, the matter may be referred directly to the Head of HR who will determine in conjunction with the Chief Executive the need for, and the means of, investigation. In exceptional circumstances, the Head of HR may take the disclosure directly to the HFEA Chair. Any such approach should be made in writing, clearly stating the nature of the allegations.

**7.10** Unless inappropriate in all the circumstances, investigations will normally be undertaken by the following posts:

| *Allegation against* | *Investigated by* |
|---|---|
| Directors | Chief Executive |
| Chief Executive | Chair |
| Member | Chair |
| Audit Committee Member | Audit Committee Chair |
| Chair | Department of Health and Social Care* |
| Deputy Chair | Chair |

*Via Senior Sponsor at the DHSC (currently Mark Davies, Director, Health Science and Bioethics (tel. 0207 210 6304 / mark.davies@dhsc.gov.uk)

**7.11** Individuals under contract to the HFEA for the delivery of services should raise any issues of concern in the same way, via the appropriate line manager.

**7.12** Once investigations and follow up actions as appropriate have been concluded, a written summary of the matter(s) reported and concluding actions taken should be forwarded to the Chair of the Authority (the Chair) for inclusion in the central record of issues reported under this policy. The anonymity of the individual who made the disclosure should be preserved as far as possible.

## External Disclosure

**7.13** The HFEA recognises that there are circumstances where the matters raised cannot be dealt with internally and in which an individual may make the disclosure externally and retain the employment protection of the Act. Ordinarily such disclosure will have to be to a person or regulatory body prescribed by an order made to the Secretary of State for these purposes.

**7.14** Prescribed bodies under the Act include the Comptroller and Auditor General of the National Audit Office (NAO), who are the external auditors to the Authority. The Act states that disclosure to the NAO should relate to "the proper conduct of public business, fraud, value for money and corruption in relation to the provision of centrally-funded public services."

**7.15** The NAO have a designated whistle blowing hotline which can be used in confidence on 020 7798 7999. Further information about this service and other bodies prescribed under the Act is available via the NAO's website: http://www.nao.org.uk/contact-us/whistleblowing-disclosures/

**7.16** In these circumstances the worker will be obliged to show that the disclosure is made in good faith and not for personal gain, that he or she believed that the information provided and allegation made were substantially true, and that they reasonably believed that the matter fell within the description of matters for which the person or regulatory body was prescribed.

**7.17** Unless the relevant failure of the employer is of an exceptionally serious nature, the worker **will not** be entitled to raise it publicly unless he/she has already raised it internally, and/or with a prescribed regulatory body and, in all the circumstances, it is reasonable for him / her to make the disclosure in public.

**7.18** If a member of staff is unsure of their rights or obligations and wishes to seek alternative independent advice***,*** Public Concern at Work is an independent organisation that provides confidential advice, free of charge, to people concerned about wrongdoing at work but who are not sure whether or how to raise the concern (telephone 020 7404 6609 or 020 3117 2520, email: whistle@pcaw.org.uk), or visit their website at http://www.pcaw.org.uk/. HFEA staff may also use the **Whistleblowing Helpline**, which offers free, confidential and anonymous advice to the health sector: https://speakup.direct/

**7.19** Where matters raised from external disclosure procedures are (as appropriate) subsequently investigated and resolved internally, a written record of the matters raised and actions taken should be forwarded to the Chair for inclusion in the central record of issues referred under this

policy. The anonymity of the individual who made the disclosure should be preserved as far as possible.

## 8. Protected disclosures

Certain conditions must be met for a whistleblower to qualify for protection under the Public Interest Disclosure Act 1998 (PIDA), depending on to whom the disclosure is being made and whether it is being made internally or externally.

**8.1** Workers are encouraged to raise their concerns with the employer (an internal disclosure) with a view that the employer will then have an opportunity to address the issues raised. If a worker makes a qualifying disclosure internally to an employer (or another reasonable person) they will be protected.

**8.2** No worker should submit another worker to a detriment on the grounds of them having made a protected disclosure.

**8.3** Any colleague or manager (provided that they and the whistleblower have the legal status of employee / worker) can personally be liable for subjecting the whistleblower to detriment for having made a protected disclosure.

**8.4** If a disclosure is made externally, there are certain conditions which must be met before a disclosure will be protected. One of these conditions must be met if a worker is considering making an external disclosure (this does not apply to disclosures made to legal advisors).

**8.5** If the disclosure is made to a prescribed person, the worker must reasonably believe that the concern being raised I one which is relevant to the prescribed person.

**8.6** A worker can also be protected if they reasonably believe that the disclosure is substantially true, the disclosure is not made for personal gain i.e. is in the public interest, it is reasonable to make the disclosure and one of the following conditions apply:

- At the time the disclosure is made, the worker reasonably believes that s/he will be subjected to a detriment by their employer if the disclosure is made to the employer; or
- The worker reasonably believes that it is likely that evidence relating to the failure/wrongdoing will be concealed or destroyed if the disclosure is made to the employer; or
- The worker has previously made a disclosure to his/her employer.

**8.7** Additional conditions apply to other wider disclosures to the police, an MP or the media. These disclosures can be protected if the worker reasonably believes that the disclosure is substantially true, the disclosure is of an exceptionally serious nature, and it is reasonable to make the disclosure.

## 9. Prescribed persons/organisations

**9.1** Special provision is made for disclosures to organisations prescribed under PIDA. Such disclosures will be protected where the whistleblower meets the tests for internal disclosures and additionally, honestly and reasonable believes that the information and any allegation contained in it are substantially true. Contact details can be found here.

The HFEA is not a prescribed organisation under PIDA and as such can only take limited action in relation to whistleblowing concerns in respect of other external organisations.

## 10. Information held on the HFEA Register

Under Section 31 of the Human Fertilisation and Embryology Act 1990 ("the Act"), the HFEA is required to keep a register containing certain categories of information. The Act prohibits disclosure of data held on the HFEA register, subject to a number of specified exceptions. Disclosure of information which is not permitted by an exception may constitute a criminal offence.

## 11. Notes

**11.1** This policy will be reviewed by the Audit and Governance Committee annually.

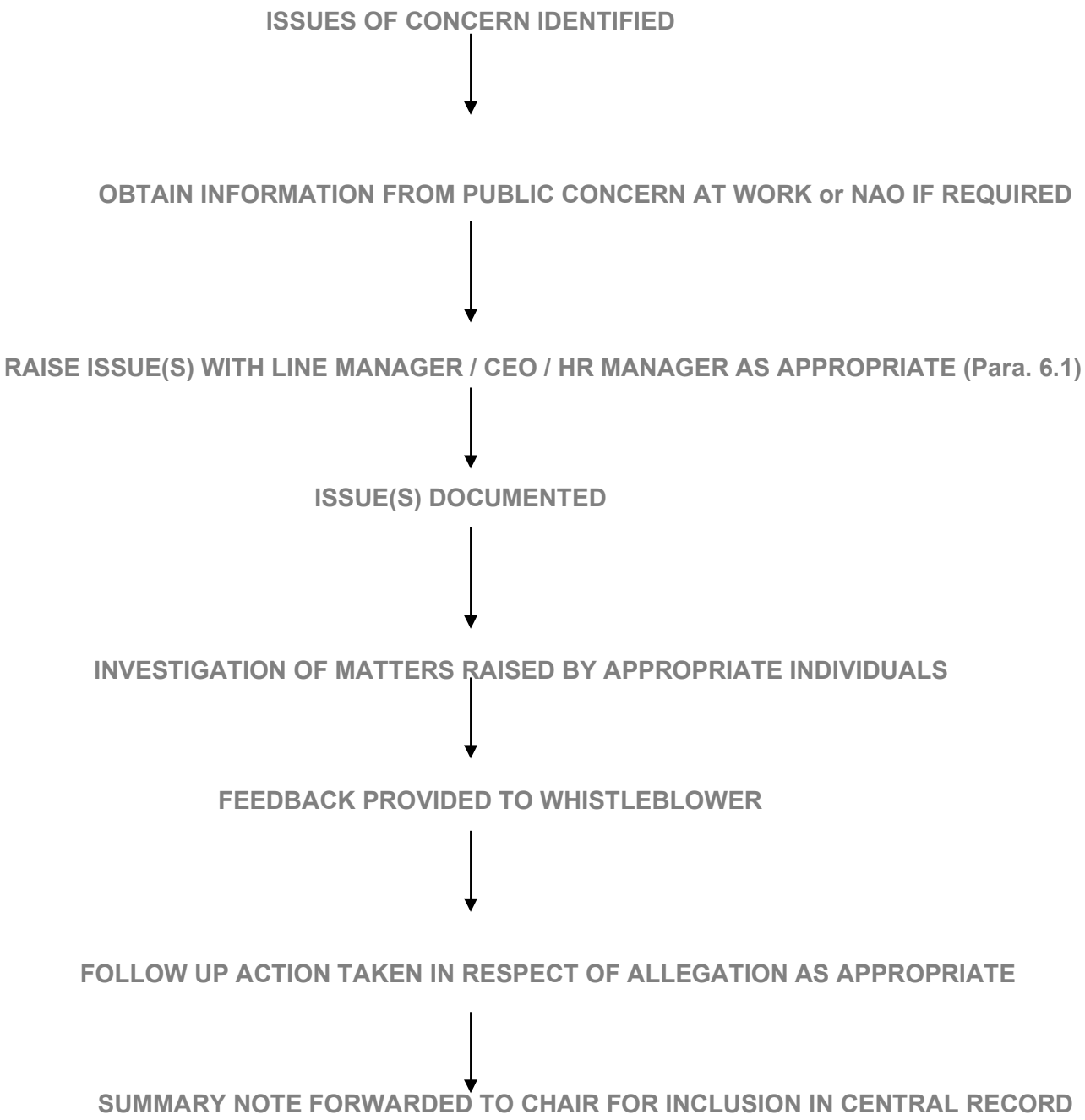
**11.2** An anonymised summary of issues raised under this whistleblowing policy and remedial actions taken will be forwarded annually to the Authority for information.

**11.3** The role of the HFEA as a regulatory body:

Under the provisions of the Public Interest Disclosure Act 1998 employees of an organisation are able to disclose publicly (under certain circumstances) their concerns about legitimacy or public interest aspects of the organisation within which they work. Although the Act requires that concerns be raised internally in the first instance, there are provisions for disclosure to be made to a regulatory body. The HFEA is itself one such regulatory body.

The procedure for dealing with a public interest disclosure from a member of staff of one of the licensed centres for which the HFEA is the regulatory body is not covered by this policy and prior to any separate procedure being issued, guidance must be sought from the Director of Compliance and Information.

## Procedure Diagram




Procedures for **external disclosures** will depend upon the procedures of the body to whom disclosures are made. **Public Concern at Work** or the **NAO** will be able to provide information in this respect. Where matters raised from external disclosure procedures are (as appropriate) subsequently investigated and resolved internally, a written record of the matters raised and actions taken should be forwarded to the Chair for inclusion in the central record of issues referred under this policy.

**The identity of the individual making the disclosure will be kept confidential if the staff member so requests unless disclosure is required by law.**

# Seven Principles of Public Life
# (As recommended by the Committee on Standards in Public Life)

## Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family or their friends.

## Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations which might influence them in the performance of their official duties.

## Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards or benefits, holders of public office should make choices on merit.

## Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

## Openness

Holders of public office should be as open as possible about all decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

## Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

## Leadership

Holders of public office should promote and support these principles by leadership and example.

These principles apply to all aspects of public life.

| | |
|---|---|
| **Document name** | Public Interests Disclosure |
| **Doc Ref No.** | 2014/021228 |
| **Release date** | January 2019 |
| **Author** | Head of HR |
| **Approved by** | CMG/AGC |
| **Next review date** | March 2022 |
| **Total pages** | 10 |

**Version/revision control**

| Version | Changes | Updated by | Approved by | Release date |
|---|---|---|---|---|
| **0.1** | Created | Head of Finance | Head of HR | July 2010 |
| **0.2** | Revisions and updates | Head of Finance | CMG/AGC/ Staff Forum | May 2012 |
| **0.3** | Revisions and updated | Head of HR | Staff Forum/CMG/ AGC | December 2014 |
| **0.4** | Minor clarification in 6.8 omitted at time of (0.3 above) | Head of HR | As above | February 2015 |
| **0.5** | Reviewed/updated prior to AGC | Head of Finance and Head of HR | | *December 2016* |
| **0.6** | Reviewed/updated prior to AGC | Head of Finance and Head of HR | N/a | January 2019 |
| **0.7** | Reviewed/updated prior to AGC | Head of Finance | N/a | March 2020 |
| **0.8** | Reviewed prior to AGC | Head of Finance | N/a | March 2021 |

# Counter Fraud Strategy

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society |
| Meeting: | AGC |
| Agenda item: | 10 |
| Paper number: | HFEA (16/03/2021) |
| Meeting date: | 16 March 2021 |
| Author: | Morounke Akingbola, Head of Finance |
| Annexes | Annex 1: Counter Fraud Strategy |

## Output from this paper

| | |
|---|---|
| For information or decision? | For information |
| Recommendation: | AGC are requested to review/comment |
| Resource implications: | None |
| Implementation date: | Ongoing |
| Communication(s): | Share with staff via the 'Hub' |
| Organisational risk: | ~~Low~~/Medium/~~High~~ |

## 1. Purpose

**1.1.** The Counter-fraud Strategy was developed as part of the HFEA's commitment to tackling fraud, bribery and corruption and is a key aspect of the Government Functional Standard GovS 013 Counter Fraud. The strategy was developed in October 2019 when it was shared with the Committee at the 8 October 2019 meeting.

**1.2.** The strategy has been reviewed and updates provided against actions as detailed in the strategy.

## 2. Strategy

**2.1.** Amendments to the strategy have been made in blue for ease.

**2.2.** The Committee are requested to provide any comments and note the updated strategy.

# Counter-Fraud Strategy

## Purpose of the Counter Fraud Strategy

1. The HFEA is a small organisation with a less public-facing role than some other regulators; nevertheless, our activities can expose us to inherent risk of fraud from both external and internal sources. Our commissioning and procurement of goods and services also presents inherent risks of corruption and bribery.

2. As well as financial loss, fraud and corruption also detrimentally impacts service provision, morale and undermines confidence in the HFEA and public bodies more generally.

3. There is little evidence that these risks ('fraud risk') are a material risk for the HFEA. This may be due to the established counter fraud arrangements as set out in the 'Counter Fraud Policy and Procedures', although such evidence can, of course, only be based on what is known. There is, however, strong evidence that overall, fraud risk in the public sector is increasing, due to more sophisticated methods of fraud but also different ways of delivering service and revised management arrangements.

4. It is therefore essential that the HFEA regularly assesses its exposure to fraud risk and ensures that its counter fraud arrangements and the resources allocated to managing the risks – the controls are effective and aligned to best practice. Overall, the Counter Fraud Policy commits the HFEA to achieving an anti-fraud and theft culture that promotes honesty, openness, integrity and vigilance in order to minimise fraud, theft and its cost to the HFEA.

5. This Strategy therefore sets out what the HFEA will need to do over the period 2019 to 2022 to successfully fulfil this commitment.

6. Many controls to manage fraud risk are already in place but these need to be maintained and where necessary, improved to help keep pace with the risk. There are also other controls which either are needed or may be needed, depending on the overall assessment of fraud risk and the resources available.

7. Implementation of the Strategy will help the HFEA to achieve its strategic objective of 'improving standards through intelligence and meet the Cabinet Office Functional Standards released in 2018.

## Scope – What is covered by this Strategy

8. All references to fraud within this Strategy include all types of fraud-related offence, i.e., theft, corruption and bribery.

9. The Strategy covers all business, activities and transactions undertaken by the HFEA or on its behalf, and therefore applies to all Members and all who work for the HFEA[1].

## Basis – What has informed this Strategy

10. The HFEA's counter-fraud arrangements are based on the Cabinet Office Government Functional Standard for Counter Fraud. These Standards set the expectations for the management of Fraud, bribery and corruption risk in all government organisations.

11. This standard sets out key principles:

| | |
|---|---|
| **Strategic Governance** | Accountabilities and responsibilities for managing fraud, bribery and corruption risks are defined across all levels of the organisation |
| **Inform and Involve** | Staff have the skills, awareness and capability to protect the organisation against fraud |
| **Prevent and deter** | Policies, procedures and controls are in place to mitigate fraud, bribery and corruption risks and are regularly reviewed to meet evolving threats |
| **Investigate and sanction** | Thoroughly investigate allegations of fraud and seek redress |
| **Continuously review and hold to account** | Systems in place to record all reports of suspected fraud, bribery and corruption are reviewed; intelligence feeds into the wider landscape |

12. This Strategy has been informed by a detailed assessment against these principles using the Functional Standards Maturity model. The HFEA assessed itself as being non-compliant against the standard at this time.

13. The basis of this Strategy is therefore to address those areas of the standard that must be met and developed in order that the HFEA can move towards embedding the counter-fraud culture envisaged by the functional standards.

14. Not all areas of the standard are relevant to the HFEA as the standard applies to organisations of varying sizes and type within the UK, and not all recommendations are therefore proportionate to the risks faced.

[1] Employees including casual staff and agency staff, consultants, contractors and partners.

## Key risks and challenges

15. In an effort to understand and mitigate areas of fraud, bribery and corruption, a risk assessment was conducted prior to development of this strategy.

16. The result of this assessment highlighted the following fraud risks
    - Travel and subsistence fraud;
    - Procurement fraud and
    - Inappropriate use/sharing of data.

17. Cyber fraud whilst not listed above is still a risk and is held within the operational and strategic risk registers and managed.

## Objectives – Where the HFEA needs to be

18. Based on the five principles of the Counter Fraud Functional Standards (11 above), the objectives below set out what the HFEA will need to be achieving by 2020 in order to fully have met the basic standard.

    - Conduct fraud risk assessment of existing and new fraud threats to ensure appropriate actions are taken to mitigate identified risks;
    - Creation of a counter-fraud culture across the organisation through training and communication;
    - Maintain effective systems, controls and procedures to facilitate the prevention and detection of fraudulent and corrupt activity;
    - Effective response and investigation of suspected cases of fraud and corruption and pursue redress and effective sanctions, including legal action against people committing fraud;
    - Implement reporting of counter-fraud performance by establishing key metrics for reporting on counter-fraud activity and fraud cases.

**Update** – Fraud risk assessments were conducted three times since this strategy was presented to the committee. The last assessment was undertaken with the Corporate Management Group (CMG) in December 2020. No new risks were identified.
Staff are due to undertake re-fresher fraud awareness training before the end of the financial year. This may be delayed as we currently do not have access to the revamped Civil Service Learning platform used last year. We do have a new platform (Astute) that we hope will be able to provide relevant online courses.
We continue to maintain an effective suite of policies and controls in the prevention and detection of fraud. These include our policies on ant-fraud, bribery and corruption, declaration of interests. Spot-checks of expense submissions are carried out periodically as part of the system for detection. The Head of Finance attends the Counter Fraud Liaison Group meetings where ideas are shared.
There has been no incidences of fraud and therefore no investigation have been conducted.
Reporting of counter-fraud performance is on-going. We currently report quarterly in arrears to Cabinet Office the Consolidated Data Return that includes detected and prevented errors and incidences of fraud; recovered errors and fraud.
Metrics for reporting on counter-fraud activity and fraud cases

## Implementation

19. Implementation of this Strategy takes account of the controls that are already in place to mitigate fraud risk. Actions (high-level) to achieve the above objectives are at Annex A.

## Accountability

20. The Director of Finance and Resources is the SMT member responsible for counter fraud and has delegated responsibility for maintaining, reviewing and implementing this Strategy to the Head of Finance.

21. Additionally, all other Directors and Heads of Directorates are responsible for ensuring that the Strategy is applied within their areas of accountability and for working with the Head of Finance in its implementation. All employees and Authority Members have a responsibility to work in line with this strategy and support its effective implementation. Details of responsibilities are set out in the Counter-Fraud Policy.

22. Progress on implementing this Strategy will be provided to the Audit and Governance Committee (AGC) in addition to the Department of Health and Social Care Anti-Fraud Unit (DHSC AFU).

23. The effectiveness of counter fraud controls is assessed in part by Internal Audit reviews, and an overview of the effectiveness of our mitigating controls are contained in the Internal Audit reports submitted to AGC. Any strategic concerns could be raised in these reports.

## Measures of success

24. The successful implementation of this strategy will be measured by:

- successful implementation of the actions contained within the strategy;
- increased awareness of fraud and corruption risks amongst members, managers and employees;
- evidence that fraud risks are being actively managed across the organisation;
- increased fraud risk resilience across the organisation to protect the HFEA's assets and resources;
- an anti-fraud culture where employees feel able to identify and report concerns relating to potential fraud and corruption.

## Reporting and review

25. The HFEA's approach to suspected fraud can be demonstrated in its Fraud Response Plan contained in the Counter-fraud and Anti-theft Policy

26. The responsibility for the prevention and detection of fraud rests with all staff, but Directors and Managers have a primary responsibility given their delegated contractual and financial authority. If anyone believes that someone is committing a fraud, or suspects corrupt practices, these concerns should be raised in the first instance directly with line management or a member of SMT then the Chair of the Audit and Governance Committee.

27. The Chief Executive and the Director of Finance and Resources has responsibility for ensuring the HFEA has a robust anti-fraud and corruption response.

28. The Audit and Governance Committee will ensure the continuous review and amendment to this Strategy and the Action Plan contained within it, to ensure that it remains compliant with good practice national public sector standards, primarily Cabinet Office Functional Standards: Counter-fraud.

## Annex A: Strategic Action plan 2019-21

| Strategic Governance | | | | | | |
|---|---|---|---|---|---|---|
| **Action** | **Description** | **Core Discipline** | **Due date** | **Outcome** | **Owner** | **Update** |
| Roles and responsibilities | Assign accountable individual responsible for delivery of counter-fraud strategy, senior lead for counter-fraud activity | Leadership, Management and Strategy | June 2019 | Director of Finance and Resources assigned as accountable individual | Head of Finance | Accountable individual was assigned at the June AGC meeting |
| Strategy | Detail our arrangements for managing fraud, bribery and corruption. | Leadership, Management and Strategy | July 2019, reviewed annually | A shared understanding of the management of the risk of fraud, bribery and corruption | Director of Finance and Resources | N/a |
| Action Plan | Develop annual action plan which details the activities needed to manage areas of fraud risk | Prevent | July 2019 then annually | Increased awareness; additional controls implemented | Head of Finance | Action plan was created in July 2019 and has been updated. |

| Inform and Involve | | | | | | |
|---|---|---|---|---|---|---|
| **Action** | **Description** | **Core Discipline** | **Due date** | **Outcome** | **Owner** | **Update** |
| Risk Assessment | Identify and assess HFEA's fraud risk exposure affecting principle activities in order to fully understand changing patterns in fraud and corruption threats and potential harmful consequences to the authority | Risk Assessment | Complete August 2019 then annually | Controls implemented for fraud risks identified | Head of Finance | Fraud Risk Assessment was created and shared with CMG on: 17/07/19 & 16/12/20 No new risks were added |
| Awareness | Raise awareness of fraud and corruption by running awareness campaigns | Culture | Ongoing throughout the duration of the strategy | Improved staff awareness | Head of Finance | Plan to create page on the Hub for all thing's fraud! Q4 2020 |
| Training | Actively seek to increase the HFEA's resilience to fraud and corruption through fraud awareness by ensuring that all existing and new employees in all directorates undertake a fraud and corruption e-learning course | Culture | July annually | All staff have undertaken fraud awareness training via CSL | Head of Finance/Head of HR | Staff undertook fraud awareness training: Nov 2019 and plan to in Q4 2020 |

| Prevent and Deter | | | | | | |
|---|---|---|---|---|---|---|
| **Action** | **Description** | **Core Discipline** | **Due date** | **Outcome** | **Owner** | **Update** |
| Policies | Refresh and promote the HFEA's suite of anti-fraud related policies and procedures to ensure that they continue to be relevant to current guidance. | Leadership, Management and Strategy | Annually, each April | Updated policies. | Head of Finance | Anti-Fraud policy reviewed Jan-21 |
| Internal Audit | Use of Internal Audit review to identify further weaknesses | Prevent | TBC | Assurance to AGC | Director of Finance and Resources | TBC |
| Intelligence | Use of information and intelligence from external sources to identify anomalies that may indicate fraud | Prevent | TBC | Increased awareness; additional controls implemented | Head of Finance | Discussion with DHSC Fraud Liaison Group 24/11/20. Agreed ALBs can on-board to NFI at cost of £1500. Data submitted to be checked. |

| Investigate and sanction | | | | | | |
|---|---|---|---|---|---|---|
| **Action** | **Description** | **Core Discipline** | **Due date** | **Outcome** | **Owner** | **Update** |
| Reporting | Produce fraud investigation outcome reports for management which highlight the action taken to investigate the fraud risks, the outcome of investigations e.g. sanction and recommendations to minimise future risk of fraud | Leadership, Management and Strategy | November, then quarterly as standing item on AGC agenda | Management feel assured and sighted on any actual fraud and resulting investigations | Director of Finance and Resources | No investigations have been conducted. |
| Recording | System for recording of and progress of cases of fraud to be utilised where practicable | Leadership, Management and Strategy | On-going, HFEA has access to DHSC AFU | Database of intelligence that feeds into DHSC AFU's benchmarking data | Director of Finance and Resources | No cases to update |

| Review and held to account | | | | | | |
|---|---|---|---|---|---|---|
| **Action** | **Description** | **Core Discipline** | **Due date** | **Outcome** | **Owner** | **Update** |
| Embedding the standard (GovS 013) | Maintaining staff awareness through consistent sharing of information. | Culture | On-going | 100% of staff complete fraud training | Head of Finance | Training scheduled for Q4 2020 |
| Sharing | Reporting quarterly to Cabinet Office' Consolidated Data Requests | Leadership, Management and Strategy | September 2019 and quarterly | Basic to maturing standard met | Director of Finance and Resources | CDR reports shared with DHSC quarterly in arrears. Last report shared 25/01/2021 |

# Counter-Fraud and Anti-Theft Policy

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society |
| Meeting: | AGC |
| Agenda item: | 10 |
| Paper number: | HFEA (16/03/2021) |
| Meeting date: | 16 March 2021 |
| Author: | Morounke Akingbola, Head of Finance |
| Annexes | Annex 1: Ant-Fraud, Bribery and Corruption Policy |

## Output from this paper

| | |
|---|---|
| For information or decision? | For information |
| Recommendation: | AGC are requested to review/comment |
| Resource implications: | None |
| Implementation date: | Ongoing |
| Communication(s): | Share with staff via the 'Hub' |
| Organisational risk: | Low/~~Medium~~/~~High~~ |

## 1. Purpose

**1.1.** The Counter Fraud and Anti- Theft Policy was implemented to ensure people working for the HFEA are aware that fraud can exist and how to respond if fraud is suspected.

**1.2.** This paper also confirms that a review of the HFEA Anti-Fraud Policy has been undertaken and to set out the updated policy which includes a few minor amendments for the committee's agreement.

## 2. Policy

**2.1.** The policy was brought to AGC in March 2020. Since then, a review has been undertaken to ensure the policy is still fit for purpose. The policy was revied by CMG on 24 February 2021.

**2.2.** There have been a few additions to this policy, please see the following paragraphs headed

- Sanction and Redress (sections 13-14)
- Recovery of monies lost through fraud (sections 15-16)
- DHSC Anti-Fraud Unit (section 42)
- Information Management and Technology (section 43-44)
- Training requirements (sections 45-46) and
- Monitoring and Compliance (sections 47-48)

**2.3.** The Committee are requested to provide any comments or additions to this policy.

# Counter fraud and anti-theft policy

## Introduction

1. This strategy has been produced in order to promote and support the framework within which the HFEA tackles fraud and theft and makes reference to the Bribery Act 2010. It sets out the aim and objectives of the Authority with respect to countering fraud and theft, whether it is committed externally or from within. Awareness of, and involvement in, counter-fraud and anti-theft work should be a general responsibility of all, and the support of all staff is needed. With clear direction from the CEO that there will be a zero-tolerance attitude to fraud within the HFEA.

## Aim

2. It is the Authority's aim to generate an anti-fraud and theft culture that promotes honesty, openness, integrity and vigilance in order to minimise fraud and theft and its cost to the Authority.

## Objectives

3. In respect of the risk of fraud and theft, the Authority seeks to:

    - promote and support an anti-fraud and theft culture;
    - deter, prevent and discover fraud and theft effectively;
    - carry out prompt investigations of suspected fraud and theft;
    - take effective action against individuals committing fraud and theft;
    - support the core values and principles set out in the Civil Service Code

## Protecting the Authority from the risk of fraud and theft

**Promoting and supporting an anti-fraud and theft culture**

4. The Authority seeks to foster an anti-fraud and theft culture in which all staff are aware of what fraud and theft are, and what actions constitute fraud and theft. Staff should know how to report suspicions of fraud and theft with the assurance that such suspicions will be appropriately investigated, and any information supplied will be kept in confidence.

5. This policy aims to promote good practice within the HFEA through the following:

    - zero tolerance to fraud;
    - a culture in which bribery is never accepted;
    - any allegations of fraud, anonymous or otherwise, will be investigated;
    - consistent handling of cases without regard to position held or length of service
    - consideration of whether there have been failures of supervision. Where this has occurred, disciplinary action may be initiated against those responsible;

- any losses resulting from fraud will be recovered, if necessary, through civil actions
- publication of the anti-fraud policy on the HFEA intranet site;

all frauds will be reported to the Audit and Risk Assurance Committee.

## Deterring, preventing, and discovering fraud and theft

6. The preferred way of minimising fraud and theft is to deter individuals from trying to perpetrate a fraud or theft in the first place. An anti-fraud and anti - theft culture whereby such activity is understood as unacceptable, combined with effective controls to minimise the opportunity for fraud and theft, can serve as a powerful deterrent. The main deterrent is often the risk of being caught and the severity of the consequences. One of the most important aspects about deterrence is that it derives from perceived risk and not actual risk.
7. If it is not possible to deter individuals from committing frauds and thefts, then the next preferable course of action is to prevent them from succeeding before there is any loss. Potential/possible frauds and thefts will be identified and investigated through:
    - a defined counter-fraud and anti-theft assurance programme addressing the areas where the Authority is most vulnerable to fraud and theft. Any gaps in control or areas where controls are not being applied properly that are identified by this work will be addressed accordingly; and;
    - routine use of Computer Assisted Audit Techniques (CAATs) as a standard part of the internal auditor's toolkit, to identify transactions warranting further investigation.
8. It is the responsibility of managers to ensure that there are adequate and effective controls in place. Internal Audit will provide assurance on the adequacy and effectiveness of such controls. In addition to the annual programme of internal audits (which provide assurance on the controls identified in the Strategic Risk Register), Internal Audit will also carry out advisory work on request and seek to ensure appropriate controls are built into new systems and processes through its project assurance role.
9. It will not always be possible to prevent frauds and thefts from occurring. Therefore, the Authority must have the means to discover frauds and thefts at the earliest opportunity. All staff should be vigilant and aware of the potential for fraud and theft and report any suspicions in accordance with the Authority's Whistleblowing Policy

## Prompt investigation of suspected frauds and thefts

10. All suspected and actual frauds will be investigated promptly in line with the Whistleblowing Policy. The effective investigation of suspected and actual frauds depends upon the capability of the appropriate staff or internal auditors conducting these investigations.
11. All thefts should be reported to the relevant line manager for action to be taken in line with the Authorities policies.

## Taking effective action

12. In the case of a proven allegation of fraud or theft, effective action will be taken in respect of those investigated in accordance with the Authority's Disciplinary Policies and Procedures. The Authority will always seek financial redress in cases of losses to fraud and theft and legal action will be taken where appropriate.

## Sanction and Redress

13. This section outlines the sanctions that can be applied and the redress that can be sought against individuals who commit fraud, bribery and corruption against the Authority and should be read in conjunction with the HFEA's Disciplinary Policy. Where staff are believed to be involved in any fraud, the Director of Finance and Resources will be informed and will follow the HR Protocol.

14. The type of sanction which the HFEA may apply when an offence has occurred are as follows:

- Civil – civil sanctions can be taken against those who commit fraud, bribery or corruption, to recover money and/or assets which have been fraudulently obtained;
- Criminal – the Local Counter Fraud Specialist will work in partnership with the DHSC Anti-Fraud Unit, the Police, and the Crown Prosecution Service, to bring a case to court against an offender;
- Outcomes – if found guilty, can include fines, a community order or imprisonment and a criminal record;
- Disciplinary procedures will be initiated when an employee is suspected of being involved in fraudulent or illegal activity.
- Professional body disciplinary – an employee may be reported to their professional body as a result of an investigation or prosecution.

## Recovery of monies lost through fraud

15. One of the key aims of the HFEA's Anti-Fraud Strategy is to protect public funds, thus where there is evidence that fraud has occurred, it will seek to recover this. This will limit the financial impact; help deter others form committing fraud and minimise any reputational damage to the HFEA.
16. Recovery can take place in a number of ways:

- Through the Criminal Court by means of a Compensation Order;
- Through the Civil Courts or a local agreement between the HFEA and the offender to repay monies lost;
- In cases of serious fraud, the DHSC Anti-Fraud Unit can apply to the courts to make an order concerning the restraint and confiscation of proceeds of criminal activity. The purpose is to prevent the disposal of assets e.g., abroad which may be beyond the reach of the UK criminal system.

## Policy Statement

17. The HFEA requires all staff at all times to act honestly and with integrity and to safeguard the public resources for which they are responsible. The Authority will not accept any level of fraud, corruption or theft. Consequently, any suspicion or allegation of fraud or theft will be investigated thoroughly and dealt with appropriately. The Authority is committed to ensuring that opportunities for fraud, corruption or theft are reduced to the lowest possible level.

18. Staff should have regard to related policy and procedures including:

a. HFEA Standing Financial Instructions and Financial Procedures
b. Disciplinary and Whistleblowing Policies

19. This Policy applies to all staff including contractors, temporary staff and third parties delivering services to and on behalf of the Authority.

20. The circumstances of individual frauds and thefts will vary. The Authority takes fraud and theft very seriously. All cases of actual or suspected fraud or theft against the Authority will be thoroughly and promptly investigated and appropriate action will be taken.

## Definitions of Fraud and Theft, Bribery and Corruption

21. The Fraud Act 2006 created the general offence of fraud which can be committed in three ways. These are by false representation, by failing to disclose information where there is a legal duty to do so, and by abuse of position. It also created offences of obtaining services dishonestly and of possessing, making and supplying articles for use in frauds.

22. A person is guilty of theft if he dishonestly appropriates property belonging to another with the intention of permanently depriving the other of it.

23. A bribe is an inducement or reward offered, promised or provided in order to gain any commercial, contractual, regulatory or personal advantage. The advantage sought or the inducement offered does not have to be financial or remunerative in nature and may take the form of improper performance of an activity or function.

24. The Bribery Act 2010 includes the offences of:

    a) Section 1 – bribing another person;
    b) Section 2 – offences relating to being bribed.

25. Further guidance is at http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf

26. Corruption is defined as “The offering, giving, soliciting or acceptance of an inducement or reward which may influence the action of any person”. In addition, “the failure to disclose an interest in order to gain financial or other pecuniary gain”.

27. The HFEA’s responsibilities in relation to fraud are set out in Annex 4.9 of Managing Public Money https://www.gov.uk/government/publications/managing-public-money

## Avenues for reporting Fraud and Theft

28. The Authority has a Whistleblowing Policy that sets out how staff should report suspicions of fraud, including the process for reporting thefts. All frauds, thefts, or suspicions of fraud or theft, of whatever type, should be reported in accordance with the Whistleblowing Policy. All matters will be dealt with in confidence and in strict accordance with the terms of the Public Interest Disclosure Act 1998. This statute protects the legitimate personal interests of staff.

## Responsibilities

29. The responsibilities of Authority staff in respect of fraud and theft are determined by the Treasury publication “Managing Public Money” (MPM), supplemented by the Authority’s policies and procedures for financial and corporate governance. These documents include Standing Financial Instructions, Financial Procedures; Standing Orders, the Financial Memorandum, and the Management Statement

## Accounting Officer (Chief Executive)

30. As “Accounting Officer”, the Chief Executive is responsible for managing the organisation’s risks, including the risks of fraud and theft, from both internal and external sources. The risks of fraud or theft are usually measured by the probability of them occurring and their impact in monetary and reputational terms should they occur. In broad terms, managing the risks of fraud and theft involves:

    a. assessing the organisation’s overall vulnerability to fraud and theft;
    b. identifying the area’s most vulnerable to fraud and theft;
    c. evaluating the scale of fraud and theft risk;
    d. responding to the fraud and theft risk;
    e. measuring the effectiveness of managing the risk of fraud and theft;
    f. reporting fraud and theft to the Treasury;
    g. In consultation with the Chair, Director of Finance and Resources, and Legal Services, reporting any thefts against the Authority to the police.

31. In addition, the Chief Executive must:

    a. be satisfied that the internal control applied by the Authority conforms to the requirements of regularity, propriety, and good financial management;
    b. ensure that adequate internal management and financial controls are maintained by the Authority, including effective measures against fraud and theft.

32. The Chief Executive will be responsible for making a decision as to whether:

    a. an individual who is under suspicion of fraud or theft should be suspended;
    b. criminal or disciplinary action should be taken against an individual who is found to have committed a fraud or theft.

33. Such decisions should be taken in conjunction with the relevant Director, HR Manager and Internal Audit, with advice from Legal Services and Finance where appropriate, to ensure consistency across the organisation. Should there be any disagreement over the appropriate action to be taken, the Chief Executive will be the final arbiter in deciding whether criminal or disciplinary action should be taken against an individual.

## Director of Finance and Resources

34. Responsibility for overseeing the management of fraud and theft risk within the Authority has been delegated to the Director of Finance and Resources, whose responsibilities include:

    b. ensuring that the Authority’s use of resources is properly authorised and controlled;
    c. developing fraud and theft risk profiles and undertaking regular reviews of the fraud and theft risks associated with each of the key organisational objectives in order to ensure the Authority can identify, itemise and assess how it might be vulnerable to fraud and theft;
    d. evaluating the possible impact and likelihood of the specific fraud and theft risks the Authority has identified and, from this, deducing a priority order for managing the Authority’s fraud and theft risks;
    e. designing an effective control environment to prevent fraud and theft commensurate with the fraud and theft risk profiles. This will be underpinned by a balance of preventive and detective controls to tackle and deter fraud, corruption and theft;
    f. ensuring that appropriate reporting of fraud and theft takes place both within the organisation and to the Audit and Governance Committee, and to the Assurance Control and Risk (ACR) team within H M Treasury, to which any novel or unusual frauds must be

reported, as well as preparing the required annual fraud return of the Authority to H M Treasury which also includes a requirement to report actual or attempted thefts;

g. forward to the Department of Health and Social Care an annual report on fraud and theft suffered by the Authority; notify any unusual or major incidents as soon as possible; and notify any changes to internal audit's terms of appointment, the Audit and Governance Committee's terms of reference or the Authority's Fraud and Anti – Theft Policy.

h. measuring the effectiveness of actions taken to reduce the risk of fraud and theft. Assurances about these measures will be obtained from Internal Audit, stewardship reporting, control risk self-assessment and monitoring of relevant targets set for the Authority;

i. establishing the Authority's response to fraud and theft risks including mechanisms for:

- developing a counter-fraud and anti-theft policy, a fraud response plan and a theft response plan;
- developing and promoting a counter-fraud and anti-theft culture;
- allocating responsibilities for the overall management of fraud and theft risks and for the management of specific fraud and theft risks so that these processes are integrated into management generally;
- establishing cost-effective internal controls to detect and deter fraud and theft, commensurate with the identified risks;
- developing skills and expertise to manage fraud and theft risk effectively and to respond to fraud and theft effectively when it arises;
- establishing well publicised avenues for staff and members of the public to report their suspicions of fraud and theft;
- responding quickly and effectively to fraud and theft when it arises using trained and experienced personnel to investigate where appropriate;
- establishing systems to monitor the progress of investigations;
- using Internal Audit to track all fraud cases and drawing on their experience to strengthen control to reduce the risk of recurrence of frauds and thefts;
- reporting thefts to the policy in accordance with the theft response plan;
- seeking to recover losses;
- continuously evaluating the effectiveness of counter-fraud and anti-theft measures in reducing fraud and theft respectively;
- working with stakeholders to tackle fraud and theft through intelligence sharing, joint investigations and so on.

j. as Director of Finance and Resources, enforcing financial compliance across the organisation while guarding against fraud and theft and delivering continuous improvement in financial control.

k. In consultation with the Chief Executive, Chair and legal services, reporting any thefts against the Authority to the police.

## Management

35. Managers are responsible for:

a. ensuring that an adequate system of internal control exists within their areas of responsibility and that controls operate effectively, in order to assist in their role of preventing and detecting fraud and theft;

b. assessing the types of risk involved in the operations for which they are responsible;

c. reviewing and testing the control systems for which they are responsible regularly;

d. ensuring that controls are being complied with and their systems continue to operate effectively;

e. implementing new controls to reduce the risk of similar frauds and thefts taking place;

f. ensuring that all expenditure is legal and proper;

g. authorising losses of cash including theft and fraud in accordance with Financial Delegation limits;

h. reporting any fraud, or suspicion of fraud in accordance with the Whistleblowing Policy;

## Staff

36. All staff, individually and collectively, are responsible for avoiding loss and for:

a. acting with propriety in the use of official resources and the handling and use of public funds whether they are involved with cash or payments systems, receipts or dealing with suppliers;

b. conducting themselves in accordance with the seven principles of public life set out in the first report of the Nolan Committee "Standards in Public Life". These are:

- Selflessness: Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends;
- Integrity: Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties;
- Objectivity: In carrying out public business, including making public appointments or recommending individuals for rewards and benefits, holders of public office should make choices on merit;
- Accountability: Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office;
- Openness: Holders of public office should be as open as possible about all the decisions and action that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands it;
- Honesty: Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest (CCE 4);
- Leadership: Holders of public office should promote and support these principles by leadership and example.

c. being alert to the possibility that unusual events or transactions could be indicators of fraud or theft;

d. reporting details immediately through the appropriate channel if they suspect that a fraud or theft has been committed or see any suspicious acts or events;

e. co-operating fully with whoever is conducting internal checks or reviews, or investigations of fraud or theft.

37. Staff are specifically not responsible for investigating any allegations of fraud or theft. These are to be undertaken in accordance with the Authority's Public Interest Disclosure ("Whistleblowing" Policy).

## Board Members

38. The Authority's Board Members have a responsibility to:

a. comply at all times with the Code of Conduct that is adopted by the Authority and with the rules relating to the use of public funds and to conflicts of interest, and declare any interests which are relevant and material to the board:

b. not misuse information gained in the course of their public service for personal gain or for political profit, nor seek to use the opportunity of public service to promote their private interests or those of connected persons or organisations:

c. comply with the Authority's rules on the acceptance of gifts and hospitality and of business appointments.

## Internal Audit

39. Matters in relation to fraud and/or corruption will involve the Authority's Internal Auditors.
Internal Audit's primary responsibilities in relation to fraud are:

a. delivering an opinion to the Chief Executive on the adequacy of arrangements for managing the risk of fraud and ensuring that the Authority promotes an anti-fraud culture;

b. assisting in the deterrence and prevention of fraud by examining and evaluating the effectiveness of control commensurate with the extent of the potential exposure/risk in the various segments of the Authority's operations;

c. ensuring that management has reviewed its risk exposures and identified the possibility of fraud as a risk;

d. assisting management by conducting fraud investigations;

40. Under its approved terms of appointment, the Internal Auditors may be tasked with responsibility for investigating cases of discovered fraud and corruption within, or operated against, the Authority.

## Audit and Governance Committee

41. The Audit and Governance Committee is responsible for:

a. Receiving reports on losses and compensations, and overseeing action in response to these;

b. Ensuring that the Authority has in place an appropriate fraud policy and fraud response plan.

## DHSC Anti-Fraud Unit

42. The services of the DHSC Anti-Fraud Unit are available to the HFEA on request. The unit provides advice, training about fraud prevention and investigation services. The Director of Finance and Resources or the Chief Executive will make the decision as to whether to call on this unit.

## Information Management and Technology

43. The Computer Misuse Act 1990 makes activities illegal, such as hacking into other people's systems, misusing software, or helping a person to gain access to protected files of someone else's computer a criminal offense.

44. The Chief Information Officer will contact the Counter Fraud Lead in all cases where there is suspicion that IT is being used for offences under the Act or fraudulent purposes. HR will also need to be informed if there is a suspicion that an employee is involved.

## Training Requirements

45. Training will be provided, as appropriate, to new members of staff as part of the induction process. The existence and scope of this policy will be brought to the attention of all staff via the intranet (the Hub) and any other method considered relevant, i.e., dedicated workshops/on-line training or individual discussions.
46. Where possible, specific training will also be provided for managers to ensure they have the knowledge, skills and awareness necessary to operate this policy efficiently and effectively and to communicate it to staff.

## Monitoring and Compliance

47. The HFEA will monitor policy effectiveness, which is essential to ensure that controls are appropriate and robust enough to prevent or reduce fraud, bribery and corruption. Arrangements will include reviewing system controls on an on-going basis and identifying any weaknesses in processes.
48. Where deficiencies are identified as a result of monitoring, appropriate recommendations and action plans will be implemented and taken into consideration when this policy is reviewed.

## Review

49. This policy will be reviewed every two years or when there are changes in the law that significantly affect this policy.

## References

Managing Public Money – Chapter 4 and Annex 4.7 (HM Treasury);

Managing the Risk of Fraud (HM Treasury): www.hm-treasury.gov.uk

Core Values and the Civil Service Code: www.civilservice.gov.uk/about/values/index.aspx

Related Authority Corporate Documents

Financial Memorandum

Management Statement

Standing Financial Instructions

Standing Orders

Disciplinary Policy & Procedure

Whistleblowing Policy

Audit and Governance Committee Terms of Reference

| | |
|---|---|
| **Document name** | Counter Fraud and Anti-Theft Policy |
| **Release date** | May 2019 |
| **Author** | Head of Finance |
| **Approved by** | CMG |
| **Next review date** | March 2023 |
| **Total pages** | 14 |

**Version/revision control**

| Version | Changes | Updated by | Approved by | Release date |
|---|---|---|---|---|
| **2.0** | Revisions/update | Head of Finance | CMG | May 2012 |
| **2.1** | Revision/updates | Head of Finance | AGC | March 2015 |
| **2.2** | Minor clarification under staff para | Head of Finance | | |
| **2.3** | Reviewed/re-branded | Head of Finance | CMG/AGC | March 2019 |
| **2.4** | Sections added: Sanction and Redress; Recoveries of monies lost through fraud, DHSC AFU, Information Management and Technology; Training requirements; Monitoring and Compliance | Head of Finance | CMG/AGC | March 2021 |

# Appendix: *(Suggested)* Fraud response plan

## Introduction

1. The fraud response plan provides a checklist of actions and a guide to follow in the event that fraud is suspected. Its purpose is to define authority levels, responsibilities for action and reporting lines in the event of suspected fraud, theft or other irregularity. It covers:
   a) notifying suspected fraud;
   b) the investigation process;
   c) liaison with police and external audit;
   d) initiation of recovery action;
   e) reporting process;
   f) communication with the Audit and Risk Assurance Committee.

## Notifying suspected fraud

2. It is important that all staff are able to report their concerns without fear of reprisal or victimisation and are aware of the means to do so. The Public Interest Disclosure Act 1998 (the "Whistleblowers Act") provides appropriate protection for those who voice genuine and legitimate concerns through the proper channels.

3. In the first instance, any suspicion of fraud, theft or other irregularity should be reported, as a matter of urgency, to your line manager. If such action would be inappropriate, your concerns should be reported upwards to one of the following:
   a) your head;
   b) your director;
   c) Chief Executive;
   d) Audit and Governance Committee Chair;
   e) Authority Chair.

4. Additionally, all concerns must be reported to the Director of Finance and Resources.

5. Every effort will be made to protect an informant's anonymity if requested. However, the HFEA will always encourage individuals to be identified to add more validity to the accusations and allow further investigations to be more effective. In certain circumstances, anonymity cannot be maintained. This will be advised to the informant prior to release of information.

6. If fraud is suspected of the Chief Executive or Director of Finance and Resources, notification must be made to the Audit and Governance Committee Chair who will use suitable discretion and coordinate all activities in accordance with this response plan, appointing an investigator to act on their behalf.

7. If fraud by an Authority Member is suspected, it should be reported to the Chief Executive and the Director of Finance and Resources who must report it to the Chair to investigate. If fraud by the Chair is suspected, it should be reported to the Chief Executive and Director of Finance and Resources who must report it to the Chair of the Audit and Governance Committee to investigate.

## The investigation process

8. Suspected fraud must be investigated in an independent, open-minded and professional manner with the aim of protecting the interests of both the HFEA and the suspected individual(s). Suspicion must not be seen as guilt to be proven.

9. The investigation process will vary according to the circumstances of each case and will be determined by the Chief Executive in consultation with the Director of Finance and Resources. The process is likely to involve the DHSC Anti-Fraud Unit, who have expertise and resources to undertake investigations. An "Investigating Officer" will be appointed to take charge of the investigation on a day-to-day basis.

10. The Investigating Officer will appoint an investigating team. This may, if appropriate, comprise staff from within the Finance Directorate but may be supplemented by others from within the HFEA or from outside.

11. Where initial investigations reveal that there are reasonable grounds for suspicion, and to facilitate the ongoing investigation, it may be appropriate to suspend an employee against whom an accusation has been made. This decision will be taken by the Chief Executive in consultation with the Director of Finance and Resources, the Head of HR and the Investigating Officer. Suspension should not be regarded as disciplinary action nor should it imply guilt. The process will follow the guidelines set out in HFEA Disciplinary policy relating to such action.

12. It is important, from the outset, to ensure that evidence is not contaminated, lost or destroyed. The investigating team will therefore take immediate steps to secure physical assets, including computers and any records thereon, and all other potentially evidential documents. They will also ensure, in consultation with the Director of Finance and Resources, that appropriate controls are introduced in prevent further loss.

13. The Investigating Officer will ensure that a detailed record of the investigation is maintained. This should include chronological files recording details of all telephone conversations, discussions, meetings and interviews (with whom, who else was present and who said what), details of documents reviewed, tests and analyses undertaken, the results and their significance. Everything should be recorded, irrespective of the apparent insignificance at the time.

14. All interviews will be concluded in a fair and proper manner and as rapidly as possible and will include a note-taker.

15. The findings of the investigation will be reported to the Chief Executive and Director of Finance and Resources. Having considered, with the Head of HR, the evidence obtained by the Investigating officer, the Chief Executive and Director of Finance and Resources will determine what further action (if any) should be taken.

## Liaison with police and external audit

16. Some frauds will lend themselves to automatic reporting to the police (such as theft by a third party). For other frauds the Chief Executive, following consultation with the Director of Finance and Resources and the Investigating Officer will decide if and when to contact the police.

17. The Director of Finance and Resources will report suspected frauds to the police and external auditors at an appropriate time.

18. All staff will co-operate fully with any police or external audit enquiries, which may have to take precedence over any internal investigation or disciplinary process. However, wherever possible, teams will co-ordinate their enquiries to maximize the effective and efficient use of resources and information.

## Initiation of recovery action

19. The HFEA will take appropriate steps, including legal action if necessary, to recover any losses arising from fraud, theft or misconduct. This may include action against third parties involved in the fraud or whose negligent actions contributed to the fraud.

## Reporting process

20. Throughout any investigation, the Investigating Officer will keep the Chief Executive and the Director of Finance and Resources informed of progress and any developments. These reports may be oral or in writing.

21. On completion of the investigation, the Investigating Officer will prepare a full written report to the Chief Executive and Director of Finance and Resources setting out:
    a) background as to how the investigation arose;
    b) what action was taken in response to the allegations;
    c) the conduct of the investigation;
    d) the facts that came to light and the evidence in support;
    e) recommended action to take against any party where the allegations were proved (see policy on disciplinary action where staff are involved);
    f) recommended action to take to recover any losses;
    g) recommendations and / or action taken by management to reduce further exposure and to minimise any recurrence.

22. In order to provide a deterrent to other staff a brief and anonymous summary of the circumstances will be communicated to staff.

## Communication with the Audit and Governance Committee

23. Irrespective of the amount involved, all cases of attempted, suspected or proven fraud must be reported to the Audit and Governance Committee by the Chief Executive or Director of Finance and Resources.

24. The Audit and Governance Committee will notify the Authority.

25. In addition, the Department requires returns of all losses arising from fraud together with details of:
    a) all cases of fraud perpetrated within the HFEA by members of its own staff, including cases where staff acted in collusion with outside parties;
    b) all computer frauds against the HFEA, whether perpetrated by staff or outside parties;
    c) all cases of suspected or proven fraud by contractors arising in connection with contracts placed by the HFEA for the supply of goods and services.

26. The Director of Finance and Resources is responsible for preparation and submission of fraud reports to the Audit and Risk Assurance Committee and the Department.

# 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 | | | |
| Paper number | AGC (16/03/2021) MA | | |
| Meeting date | 16 March 2021 | | |
| 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: | 8 Dec 2020 | 16 Mar 2021 | 22 Jun 2021 | 5 Oct 2021 |
|---|---|---|---|---|
| Following Authority Date: | 27 Jan 2021 | 24 Mar 2021 | 7 July 2021 | 17 Nov 2021 |
| Meeting 'Theme/s' | Register and Compliance, Business Continuity | Finance and Resources (deferred to June) | Annual Reports, Information Governance, People | Strategy & Corporate Affairs, AGC review |
| Reporting Officers | Director of Compliance and Information | Director of Finance & Resources | Director of Finance & Resources | Director of Strategy and Corporate Affairs |
| Strategic Risk Register | Yes | Yes | Yes | Yes |
| Digital Programme Update | Yes | Yes | Yes | |
| Annual Report & Accounts (inc Annual Governance Statement) | | Draft Annual Governance Statement – sent via email for approval/comment | Yes – For approval | |
| External audit (NAO) strategy & work | Audit Planning Report | Interim Feedback | Audit Completion Report | |
| Information Assurance & Security | | | Yes, plus SIRO Report | |
| Internal Audit Recommendations Follow-up | Yes | Yes | Yes | Yes |
| Internal Audit | Update | Update | Results, annual opinion approve draft plan | Update |
| Whistle Blowing, fraud (report of any incidents) | Update as necessary | Update as necessary | Update as necessary | Update as necessary |

| AGC Items Date: | 8 Dec 2020 | 16 Mar 2021 | 22 Jun 2021 | 5 Oct 2021 |
|---|---|---|---|---|
| Public Interest Disclosure (Whistleblowing) policy | | Reviewed annually thereafter – sent via email for approval/comment | | |
| Anti-Fraud, Bribery and Corruption policy | | Reviewed and presented annually thereafter GovS: 013 Counter Fraud – sent via email for approval/comment | | |
| Contracts & Procurement including SLA management | Update as necessary | Update as necessary | Update as necessary | Update as necessary |
| HR, People Planning & Processes | Bi-annual HR report | | Yes Including bi-annual HR report | |
| Strategy & Corporate Affairs management | | | | Yes |
| Regulatory & Register management | Yes | | | |
| Cyber Security Training | | | | Yes – update on whether annual training undertaken |
| Resilience & Business Continuity Management | Yes | Yes | Yes | Yes |
| Finance and Resources management | | Yes | | |
| Reserves policy | | | | Yes |
| Estates | Yes | Yes | Yes | Yes |

| AGC Items Date: | 8 Dec 2020 | 16 Mar 2021 | 22 Jun 2021 | 5 Oct 2021 |
|---|---|---|---|---|
| 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 |

# Gifts and Hospitality Register

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society |

| | | | |
|---|---|---|---|
| Meeting | AGC | | |
| Agenda item | 12 | | |
| Paper number | HFEA (16/03/2021) MA | | |
| Meeting date | 16 March 2021 | | |
| 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. Members are asked to note. | | |
| Resource implications | | | |
| Implementation date | 2020/21 business year | | |
| Communication(s) | | | |
| Organisational risk | ☐ Low | X Medium | ☐ High |

## Register of Gifts / Hospitality Received and Provided/Declined

Version: HFEAG0001
Mar-21

**DIVISION / DEPARTMENT:** HFEA
**FINANCIAL YEAR:** 2019/20

| | Details of the Gift or Hospitality | | | | | | Provider Details | | | Recipient Details | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type** | **Brief Description of Item** | **Reason for Gift or Hospitality** | **Date(s) of provision** | **Value of Item(s)** | **Location where Provided** | **Action on Gifts Received** | **Name of Person or Body** | **Contact Name** | **Relationship to Department** | **Name of Person(s) or Body** | **Contact Name** |
| *Either 'Provision' or 'Receipt'* | *Give a brief description of the gift or hospitality recorded* | *Summarize the reason or occasion for the gift or hospitality* | *Give the date(s) on which it was provided or offered* | *Give the known or estimated value - if unknown then state 'unknown' and explain further under the 'Reason for Gift' column.* | *Give the name of the venue or location at which the gift or hospitality was provided* | *For Gifts Received only, specify what happened to the item(s) after it was received* | *Give the name of the individual or organization providing or offering the gift / hospitality* | *Give a contact name if an individual is not specified as the provider - otherwise leave blank* | *Specify the relationship of the provider to the Department (e.g. 'supplier', 'sponsor', etc.) - if the Department is the provider then leave blank* | *Give the name of the individual(s) or organisation receiving the gift / hospitality - if there are multiple recipients, specify each on a separate line* | *Give a contact name if an individual is not specified as the recipient - otherwise leave blank* |
| Receipt | Lunch invitation | To introduce to Legal Trainers | 10/08/2017 | £ - | Not known | Lunch accepted | Old Square Chambers | Eleena Misra | Legal Consultancy | HFEA | C Drennan |
| Receipt | Lunch invitation | Introduce Clients to new lawyers | 01/11/2017 | £ - | Not known | Lunch accepted | Blackstone Chambers | Catherin Callaghan | Legal Consultancy | HFEA | C Drennan |
| Receipt | Breakfast invitatoin | Breakfast meeting | 08/02/2018 | £ - | Not known | Breakfast accepted | Fieldfisher | Mathew Lohn | Legal Consultancy | HFEA | P Thompson |
| Receipt | Invitation to Silk Party | Informing Clients of a change (to QC) | 22/03/2018 | £ - | Not known | Invitation accpeted | Blackstone Chambers | Catherin Callaghan | Legal Consultancy | HFEA | C Drennan |
| Receipt | Lunch provided | Lunch provided prior to a review meeting | 24/07/2019 | £ 20.00 | Not known | Lunch accepted | Alsicent | | IT Support supplier | HFEA | D Howard |
| Receipt | Chocolates | Recruitment agency meeting | 16/12/2019 | £ - | Not known | Shared in office | Covent garden Bureau | Charlotte Saberter | Recruitment agency | HFEA | J Hegarty |
| Receipt | Lunch invitation | Interactive Workshops | 11/12/2019 | £ | Central London | Lunch accepted | Interactive Workshop | Anna Beer | Training | HFEA | Y Akinmodun |
| Receipt | Cheque received | Book Review conducted | 14/02/2020 | £ 50.00 | Not known | Cheque cashed donated to charity | Literary Review | | None | HFEA | M Gilmore |
| | | | | | | | | | | | |
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