Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

15 March 2022

Online

10am – 1.05pm

	Agenda item		Time
1.	Welcome, apologies and declaration of interests		10.00am
2.	Minutes of 09 December 2021 **[AGC (15/03/22) DO]**	for decision	10.05am
3.	Matters arising **[AGC (15/03/22) MA]**	for information	10.10am
4.	Internal audit report **[AGC (15/03/22) JC]**	for information	10.20am
5.	Implementation of recommendations **[AGC (15/03/22) MA]**	for information	10.40am
6.	External audit interim feedback - Verbal update **[AGC (15/03/22) MS/DG]**	for information	10.50am
7.	Digital Projects / PRISM update **[AGC (15/03/22) KH]**	for information	11.05am
8.	Draft Annual Governance Statement **[AGC (15/03/22) RS]**	for information	11.15am
9.	Strategic risk register **[AGC (15/03/22) PR/SQ]**	for comment	11.30am
10.	Resilience & business continuity Management and Cyber Security **[AGC (15/03/22) RC]**	for comment	11.45am 12.00noon
	Break		12noon
11.	Items for discussion • Public Interest Disclosure (Whistleblowing) policy • Counter-Fraud and Anti-theft policy **[AGC (15/03/22) MA]**	for comment	12.10pm

12.	Strategic risk deep dive - Finance **[AGC (15/03/22) RS]**	for comment	12.20pm
13.	Implementation of IFRS16 – Leases **[AGC (15/03/22) MA]**	for comment	12.40pm
14.	AGC forward plan **[AGC (15/03/22) MA]**	for decision	12.50pm
15.	Items for noting • Gifts and hospitality • Contracts and Procurement **[AGC (15/03/22) RS]**	for information	12.55pm
16.	Any other business		1.00pm
17.	Close		1.05pm
18.	Session for members and auditors only		

Next Meeting: Tuesday, 28 June 2022, Venue TBD.

Minutes of Audit and Governance Committee meeting 09 December 2021

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	15 March 2022		
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 9 December 2021 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 9 December 2021 held via teleconference

Members present	Catharine Seddon – Chair Anita Bharucha Margaret Gilmore Geoffrey Podger
Apologies	Mark McLaughlin (present for item 7)
External advisers	Mike Surman, National Audit Office – External auditor Joanne Charlton, Internal Auditor – GIAA Dean Gibbs, KPMG – Audit Director/lead
Observers	None
Staff in attendance	Peter Thompson, Chief Executive Richard Sydee, Director of Finance and Resources Morounke Akingbola, Head of Finance Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cutting, Director of Compliance and Information Paula Robinson, Head of Planning and Governance Yvonne Akinmodun, Head of Human Resources Steve Morris, Head of IT Neil McComb, Head of information Debbie Okutubo, Governance Manager Shabbir Qureshi, Risk and Business Manager

1. Welcome, apologies and declarations of interest

1.1. The Chair welcomed everyone present and extended a warm welcome to Shabbir Qureshi as this was his first meeting as the new Risk and Business Planning Manager.

1.2. Mark McLaughlin was unable to join the entire meeting but had sent his questions and comments before the meeting and joined for item 7 only.

1.3. There were no declarations of interest.

2. Minutes of the meeting held on 5 October 2021

2.1. The minutes of the meeting held on 5 October 2021 were agreed as a true record and signed by the Chair subject to item 8 – Reserves policy being amended to reflect that there is an ongoing discussion with the Department of Health and Social Care (DHSC), who had reiterated that we could not go into deficit by utilising our cash reserves. We were therefore proceeding with the proposed fee increases for 2022/23 but we would need to await HM Treasury's final agreement.

3. Matters arising

3.1. The Head of Finance introduced this item.

Cyber security

3.2. It was noted that the cyber security training for members remained outstanding.

3.3. Members expressed their concern about the delay of this training and commented that this needed to be resolved particularly in light of the known increased risks in this area arising from the pandemic. The Head of Planning and Governance commented that we now had access to the civil service training platform and we were in the process of looking through it to see if there is an information security training module for members or non-executive directors. Cyber security training would be a different and more specialist subject. An alternative might be to bring in a cyber security expert to come and speak to the committee.

3.4. The NAO external auditor commented that a fact sheet had previously been circulated and he would speak to the team who published the fact sheet to see what they could offer.

3.5. The KPMG Audit lead stated that there were people within his organisation who could provide this training. It was agreed that the Director of Finance and Resources should take this forward with the KPMG Audit lead.

3.6. It was noted that although cyber security training was not mandatory for members it was still good practice for this committee to have an understanding of cyber security issues, as well as receiving the annual information security training, which covers keeping data and information safe in the course of normal working. Therefore, the committee asked for a report on progress back to the next meeting.

PRISM

3.7. The Chair invited the Chief Executive to give a brief synopsis of what to expect from the meeting scheduled for 17 December 2021 to discuss the lessons learned on PRISM.

3.8. The Chief Executive commented that members should receive the report by Monday, 13 December 2021 and the scope of what they could expect was what was discussed at the meeting in October which included: leadership, management, disconnect with people on the frontline, feedback, costs, staffing and relationships. Members agreed that the following questions should be addressed, as suggested in the paper:

- The circumstances that led staff to erroneously advise AGC in late 2019 that PRISM was ready to launch, and how we would make sure we avoid such a governance breach with any future projects.
- Other viable alternatives to an in-house development of PRISM (if any)
- How in the future we could avoid reliance on single individuals for important pieces of work.

3.9. Members commented that the running total of spend in date order needed to be included as this would enable members align the spend with AGC decisions.

3.10. In response to a question, it was noted that internal audit had not been involved in the lessons learned report.

3.11. The Chief Executive commented that it was hard to find discussions at a smaller scale of IT projects as most discussions were about large projects for larger organisations. The NAO external auditor commented that other similar sized or smaller organisations might benefit from the report.

3.12. Members commented that in the concluding section in the report, lessons that are pertinent and applicable across the organisation should be pulled out.

3.13. The report should also be shared with the internal and external auditors.

Decision

3.14. Director of Finance and Resources to pursue suggestions from NAO and IA regarding options for Board cyber-security training.

3.15. CEO to share PRISM "lessons learned" report with Internal and external auditors and consider incorporating any additional suggestions.

3.16. Members noted the actions from matters arising.

4. Internal audit update

4.1. The Chair invited the internal auditor to present this item.

4.2. It was noted that as at 26 November 2021, 33% of the 2021/22 audit plan had been delivered to final report stage.

4.3. The fieldwork on the release of data audit had been completed and the internal auditors were working on issuing the draft report.

4.4. Members were advised that the planning and scoping work was underway on the reviews into the effectiveness of the inspection process (Q4) and the operational risk management review, which was a Q2 review but got delayed due to key staff attrition within the Authority.

4.5. It was noted that the planning and scoping activity on the financial management: budgeting review was due to commence before Christmas 2021.

4.6. Lastly, there was noticeable improvement in the level of outstanding audit recommendations. There was ongoing work with the Authority to mitigate the associated risks with the four recommendations still outstanding.

4.7. In response to a question the internal auditor commented that the draft report on release of the data audit overall had been concluded with a moderate risk rating, as it was felt that the length of time used to keep evidence needed to be extended and an end date for receipt of complaints on FOI requests should be provided.

4.8. Members asked why the Authority was featuring in the Covid-19 inquiry as it was felt and believed that the HFEA had managed this situation well. The Chief Executive responded that the DHSC had written to us formally, and that we now had to collate documents, as we have been put on notice. It was explained that fortnightly meetings were being held with other arms-length bodies (ALBs) in the department but the terms of reference had not yet been published.

4.9. Members commented that, that being the case, it was good practice to pull documents together but until the terms of reference were known, our limited resources should not be overly diverted to it.

4.10. In response to a question, the internal auditor confirmed but there were contingency plans in place and timescales for internal audits were flexible enough to accommodate a few delays especially as there were a few new staff joining the organisation.

4.11. Finally, the internal auditor commented that the GIAA supplementary report – an audit committee hub cross government paper - would be published in the week commencing 13 December 2021 and would be shared with the Chair and Chief Executive.

Decision

4.12. Members noted the internal audit update.

5. Progress with current audit recommendations

5.1. The Head of Finance introduced this item.

DSP Toolkit

5.2. It was noted that the submission date was June 2022. The Internal Auditor commented that specialist auditors would be working with the Authority and would give deeper insight. Also, that they were experienced in working with similar sized organisations, which meant that they would tailor their requests to the size of the Authority.

5.3. Members commented that it would be useful to see a summary of other ALBs' experiences with the DSP toolkit, especially smaller ALBs.

5.4. Also, that there was a role for the specialist auditor but they had to adhere to the notion of proportionality and ensure that there was shared understanding of what a reasonable ask was and be encouraged to stick to scale.

Staff wellbeing

5.5. The Head of Human Resources commented that work to revise the People strategy would be completed by January 2022.

5.6. In response to a question, the Head of Human Resources stated that the staff sickness levels would be a concern if it was in the human resource team as they had very limited staff but this was not the case.

5.7. Members commented that the Authority had done very well in ensuring that people were working well together online but that the Executive should not lose sight of the potential for depression and loneliness to be an issue for some staff over the Christmas period.

Key performance indicators (KPIs)

5.8. The Chair commented that the review should be completed by March 2022 and value for money should be built into the key performance indicators.

5.9. The Head of Planning and Governance commented that the remaining audit recommendations would soon be taken forward, now that the new Risk and Business Planning Manager had joined the organisation. As part of this work, it would be necessary to check with all heads of service to

ensure that all standard operating procedures (SoPs) relating to the KPIs had been kept up to date and maintained. A process could then be developed for performing periodic dip-checks to test the quality and accuracy of data submitted by teams.

Records management

5.10. The Chair commented that the goodwill letters was a recurring theme that did not seem to be urgent to staff. The Chief Executive responded that this was not the case, and that all letters were safe in a secure location, and would be digitalised, time and space permitting.

5.11. The Director of Compliance and Information commented that in the opening the register (OTR) team they were prioritising reducing the backlog and responding to applications but the goodwill letters was still very much on their radar.

External information requests

5.12. The Director of Strategy and Corporate Affairs agreed to discuss this with the Head of Finance.

Decision

5.13. Members requested that they receive a summary of other ALBs' experiences with the DSP toolkit, especially smaller ALBs.

5.14. The committee noted progress on several outstanding recommendations. The committee supported the decision to prioritise front-facing patient protection during the pandemic but expressed concern lest there be any further slippage particularly in relation to recommendations on KPIs, business continuity planning and the knowledge and skills gap.

6. External audit planning report

6.1. The NAO External Auditor presented this item. The change in the audit fee was discussed, it was noted that the audit fee for 2021/22 was £36,000. Compared to £29,500 in the previous financial year, this was an increase of £6,500 (22 per cent). The rationale for the increase in the fee was also explained.

6.2. It was noted that one element of the increase was an additional non-recurring fee of £5,000, which related to the additional work required in 2020/2021 to address the audit risks associated with the PRISM transition. It was explained that the work required specialist skills and the additional work could not be absorbed.

6.3. Members were informed that subject to sufficient assurance being obtained, this element of the fee should not recur beyond 2021/22.

6.4. The KPMG audit lead gave the summary of the audit risks. It was noted that the risks which had the most significant impact on the audit were:

- presumed risk of management override of controls
- presumed risk of fraud in revenue recognition
- prism system migration.

6.5. In response to a question the Chief Executive commented that the data quality on PRISM was looking very promising as the system had been built to identify poor quality data, and the error rates were therefore now appeared much lower for most clinics.

6.6. In response to a question on IFRS 16, the Director of Finance and Resources commented that this was an outstanding medium-term risk which was being escalated through our sponsor team.

Decision

6.7. Members noted the audit planning report.

7. Human resources bi-annual report

7.1. The Head of Human Resources presented this item. It was noted that the all staff survey was conducted in October 2021 and that an external provider was used. In terms of how we compare with other organisations, Members were advised that the external provider would now be adding other similar sized arms-length bodies (ALBs) to our comparators.

7.2. Areas of concern raised were:

- reward
- people returning to work and
- autonomy.

7.3. Members were advised that a small focus group had been formed and would put together an action plan. Members requested a means to monitor the impact and effectiveness of the actions proposed by the focus group. It was noted that some areas might be out of our remit, for instance reward and pay freeze.

7.4. Also, the Head of Human Resources commented that an area we scored low on and were looking into was on Wellbeing. On issues raised relating to career progression we are looking at opportunities for mentoring.

7.5. Members commented that online discussions were not the same as face to face and asked what could be done in terms of bonuses as some staff were feeling undervalued. The Head of Human Resources responded that in terms of home working we were in the process of offering home working contracts. We also changed our policy and suggested that staff only need to attend the office one day a week subject to government restrictions and that we would continue to try to get the balance right.

7.6. Members were reminded that as a public body we could not offer bonuses but we would continue to look at ways of rewarding staff for instance last year all staff received one extra annual leave day.

7.7. The KPMG lead commented that one way their organisation worked on this was to look beyond reward and look at recognition, by giving thank you cards to staff was an impactful way of recognising hard work and commitment.

7.8. Members commented that a pathway the organisation needed to recognise was that people got a promotion by leaving the organisation and this needed to be accepted as a good springboard to other greater things.

7.9. In response to a question, the Chief Executive commented that people did have a sense of what they did mattered and at our weekly all staff meetings, SMT used the opportunity to recognise staff and we would continue to try and keep people connected.

7.10. The Chief Executive continued that we do not want to become a virtual organisation, so there was increased flexibility for staff but also increased description of what needed to be done and achieved.

7.11. Members commented that there was a need for caution in ensuring the right balance was struck between working from home and being flexible. Members commented that they were impressed with the results of the survey and in particular the increased staff satisfaction and the united senior management team (SMT).

7.12. The Chair welcomed the collective action to improve offerings to staff and noted that there was a proportionality issue there and that the balance should be kept in a workable way.

7.13. In terms of the finding that some respondents do not feel that all colleagues are treated fairly or equally, the Chair asked for evidence of corporate culture/values/inclusivity being probed further, either through regular pulse surveys or the next iteration of the staff survey.

Action

7.14. The Head of Human Resources (HR) to incorporate considerations regarding corporate culture into the proposed action plan and future iterations of the annual survey.

7.15. The Head of HR to update AGC at Oct 22 meeting on progress and effectiveness of the action plan.

Decision

7.16. Members supported the proposed action plan and the involvement of staff.

7.17. The committee to be sent the timetable for the roll out of the plan.

8. Strategic risk register

8.1. The Head of Planning and Governance introduced this item. Members were reminded that the departure of the previous Risk and Business Planning Manager had left a gap in the team which meant a delay in the review of our risk system. The broad plan for the review was set out in the covering paper. A summary was then given of recent changes to risks.

8.2. Risk C1 – Capability had now been partially written and OM1 – Operating Model had been merged into it. It was noted that OM1 had been discontinued but not closed as some elements of OM1 was still live.

8.3. Risk I1 – Information provision has been raised slightly which has now put it above tolerance. Members asked if we needed to include the communication strategy in the risk description.

8.4. Risk C2 – Leadership capability has had commentary added to it in the event of senior managers leaving. In general responsibilities will be reallocated to the most relevant available person.

8.5. For risk CS1 – cyber security, a full review is being planned, and the IT team is in the process of rolling out further measures to protect us against any data loss. This would include staff not being able to use personal devices. For members we have proposed to communicate almost entirely using members' HFEA email accounts.

8.6. Members commented that horizon scanning was now an important matter to reflect on as part of the review of strategic risks.

8.7. Following further discussion it was agreed that the plans for the review of risk management should come to the committee in March 2022 with an outline describing the plans for the risk register and the risk policy. There was a further comment that the internal audit report recommendations, if concluded by then, could also be reflected in the plan.

8.8. Members commented that from next year the risk register should continue to be kept under review especially with new members joining, as there are too many key risks at or above tolerance level.

8.9. Members also felt that having matters above tolerance could mean everything was collapsing therefore was the register capturing what was necessary. The internal auditor asked if the risk appetite for members had changed considering the discussion.

8.10. Regarding RF1 – Regulatory framework, members asked if it needed to be reframed since the Authority was starting a piece of work on the Act which may result in seeking new powers. Members also asked whether the new inspection regime necessitated by Covid had resulted in any breach of the law or putting clinics at risk of not being able to operate. The Director of Compliance and Information commented that it was a statutory duty to inspect clinics every two years and that while this had not been possible, other methods had been adopted to ensure patients were not at risk.

8.11. For P1 - Strategic reach and influence, members asked if we need to increase the ratings because if we fail to keep up the momentum we would need to think of the consequences.

Decision

8.12. Horizon-scanning to be added as a regular feature of risk register review at each AGC.

8.13. Members noted the strategic risk register.

9. Resilience & business continuity management

9.1. The Head of IT and the Head of Information presented this item.

DSPT

9.2. The Data Security and Protection Toolkit (DSPT) an online self-assessment tool that allowed organisations to measure their performance against the National Data Guardian's ten data security standards was explained in detail to members.

9.3. Members were reminded that the mid-year interim assessment was submitted in February 2021 and at the time it was forecasted that we would not be fully compliant with the mandatory DSPT requirements for the annual submission in June 2021.

9.4. The final DSPT report found the HFEA to have an overall rating of 'unsatisfactory' as not enough evidence was provided even though no security issues were found. The Head of Information commented that a lot of recommendations had been completed.

9.5. It was noted that due to the newness of this toolkit and the limited knowledge we have been able to gain from the last submission, it was not yet known whether we would meet all the requirements in the Toolkit for 2022.

IT

9.6. The Head of IT commented that changes to infrastructure would make our information technology more secure. These changes would provide greater protection for the HFEA from cyber-attacks such as ransomware, the changes were:

- HFEA staff will no longer be able to access HFEA's instance of O365 (inc email) from non-HFEA laptops
- Access to IT resources in HFEA (the Register for example) will only be possible from within the UK (temporary exceptions can be made)
- A basic net nanny will be installed to prevent unintentional access by HFEA staff to web sites that present technical risks (i.e. those known to carry malware)
- Emails to and from Authority members will only be exchanged using their HFEA email accounts.

9.7. Members commented that there should be guidance sent to Authority and non-Authority members about safeguards required for using their personal devices. Also, that staff needed to bear in mind that vulnerabilities change all the time so proportionality is needed to be built into the guidance and security for all devices.

Action

9.8. Head of IT to send guidance to Authority and committee advisory members about safeguards required when using personal devices.

9.9. Head of Planning and Governance to add IT guidance to induction material for all Authority and committee advisory members.

Decision

9.10. The IT guidance should form part of the induction for new Authority and non-Authority members joining us.

9.11. Members noted the report.

10. Regulatory and register management

10.1. The Director of Compliance and Information presented this item. The changes to the team structure and directorate risks were explained.

10.2. With regard to inspections, it was noted that due to the pandemic, 67 inspections were deferred by 12 months which meant that the number of inspections decreased compared to previous years. In total in 2020/21, 77 inspections were carried out, of which:

- 17 were completely desk-based
- 32 were a combination of desk-based assessment and onsite visit
- 23 were onsite visits with informal desk-based assessment
- 5 were risk-assessed with no onsite visit

10.3. To assess the robustness of the process the new inspection methodology was audited by our internal auditors, the Government Internal Audit Agency (GIAA) in January and February 2021. Their overall finding was 'substantial'.

10.4. Members asked if the compliance and enforcement policy was introduced as a result of a general review of the old policy and what the plans were for its review. The Director of Compliance and Information responded that due to the previous policy needing significant improvement a new policy was written. The new policy is more robust and leads to greater consistency. The current policy was consulted on, and approved by the Authority in June 2021 and would be reviewed for its effectiveness by June 2022.

OTR

10.5. The Director of Compliance and Information commented that there is a continued increase in the number of OTR applications compared to previous years. The resilience in the team previously was not enough, and therefore to meet demand and to help work through the backlog two temporary staff members had been recruited.

10.6. On the IT helpdesk, members asked if BCC would provide a service outside working hours. The Director of Compliance and Information responded that for now it was a nine to five service.

10.7. Members commented that there are internal dependencies on the IT and information plans for 2022 but not a lot of contingency was planned into this.

Decision

10.8. Members noted the Regulatory and Register management report.

11. AGC forward plan

11.1. The Internal Auditor commented that the internal audit report would be coming to the March 2022 meeting rather than the June 2022 meeting.

11.2. The Chair requested periodic deep dives at future AGC meetings, to explore one particular area of business risk and the effectiveness of current and planned mitigations. The Executive agreed to consider this in more detail after the meeting.

Decision

11.3. The forward plan to be updated following a discussion with the Chair and the Director of Finance and Resources.

11.4. Members noted the requested changes to the forward plan.

12. Items for noting

12.1. Gifts and hospitality

- There were no changes to the register. Members **agreed** that this would only be presented when there are updates.

12.2. Whistle blowing and fraud

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

12.3. Contracts and procurement

- There were no new contracts or procurements to report.

13. Any other business

13.1. Catharine Seddon, the incoming Chair paid tribute to Anita Bharucha the outgoing Chair for all she had achieved during her leadership of the committee, and in particular for overseeing the launch and deployment of PRISM.

13.2. Margaret Gilmore, the deputy Chair of AGC also thanked Anita and commented that over the years she had been inspirational and her style was inclusive.

13.3. The Chief Executive thanked Anita on behalf of staff for being able to offer challenge and support in an inclusive way.

13.4. Anita thanked everyone for their comments including the independent members and the staff team and commented that there were disagreements at times but it was all handled in a good and transparent way.

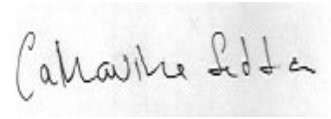
13.5. Members were reminded that the PRISM lessons learned meeting was on Friday 17 December 2021.

13.6. It was noted that for now meetings will remain online and will be reviewed when possible.

Chair's signature

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

Signature



Chair: Catharine Seddon

Date: 15 March 2022

AGC Matters Arising

Details about this paper

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

Meeting	Audit and Governance Committee		
Agenda item	3		
Meeting date	15 March 2022		
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	2021/22 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/Governance Manager	Dec-20	**Update** – training was provided using the Astute training platform. **Update** – Civil Service Learning is now being used – Responsible for Information link sent to Authority members and reminders sent out.
Matters Arising from the Audit and Governance Committee – actions from 5 October 2021			
4.20 A lessons learned from PRISM meeting to be held in December (special AGC meeting)	Chief Executive/Director of Compliance and Information	Dec-21	**Update** – Lessons learned paper was shared with AGC in December.
6.2 Outstanding audit recommendations that are overdue to have their target dates reviewed and presented to committee	Head of Finance	Dec-21	**Update –** Audit recommendations are on the agenda
Matters Arising from the Audit and Governance Committee – actions from 9 December 2021			
3.14 Pursue suggestions from NAO and GIAA for Board Cyber Security training	Director of Finance and Resources	Mar-22	**Update** – training to be facilitated by NAO at March meeting
5.13 Committee to receive a summary of other ALBs' experiences with DSP Toolkit	Director of Compliance and Information	Mar-22	**Update** – Report on the agenda
7.14/15/16 Head of HR to incorporate considerations regarding corporate culture into the proposed action plan and update AGC at October 2022 meeting on progress and effectiveness of the action plan being created from the Staff survey results.	Head of HR	Oct-22	**Update** – This will be given at the October meeting.

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
The time-table for the roll-out of the action plan to be shared with the Committee			
9.8 Head of IT to send guidance to the Authority and committee advisory members about safeguards required when using personal devices.	Head of IT	Jan-22	**Update** – Done and attached
9.9 Head of Planning and Governance to add IT guidance to induction material for all new Authority and committee advisory members.	Head of Planning and Governance	Jan-22	**Update -** Completed

Digital Projects / PRISM Update February 2022

Details about this paper

Area(s) of strategy this paper relates to:	The right information – to ensure that people can access the right information at the right time
Meeting:	AGC
Agenda item:	7
Meeting date:	15 March 2022
Author:	Kevin Hudson, PRISM programme manager
Annexes	

Output from this paper

For information or decision?	For information
Recommendation:	
Resource implications:	
Implementation date:	PRISM already live
Communication(s):	
Organisational risk:	Medium

1. Introduction and summary

1.1. PRISM went live on 14th September 2021. Since then, the system has been in its deployment period.

1.2. In October 2021 we updated AGC on the cutover to PRISM and early results from PRISM use. In December 2021, Peter Thompson presented a Lessons Learned document that was reviewed and discussed in detail at a special AGC meeting on 17th December 2021. It was agreed at that meeting that this signalled to conclusion of AGC's detailed programme oversight. Thereafter the focus for AGC would be on seeking assurance that the risks to the delivery of the remaining work were being effectively managed.

1.3. As of the end of February, 68,794 units of activity have been submitted into PRISM from 73 standalone (direct entry) and API (third-party system supplier) clinics.

1.4. There remain 25 clinics that have so far not used PRISM. These are all API clinics still awaiting deployment from their third-party system supplier. In late November 2021 we set clinics a target of completing deployment by the end of March 2022.

1.5. The purpose of this paper is to update AGC on:

1. The progress of PRISM deployment and latest use of PRISM by clinics.
2. The ongoing plan for post-PRISM technical work, particularly the re-establishment of the reports and processes necessary to conduct a first CaFC through PRISM during 2022.
3. Ongoing challenges for PRISM, both for clinics and technical staff.
4. The handover to employed staff so that the system becomes part of the ongoing operational framework for HFEA.

2. Progress on PRISM deployment

Standalone Clinics (entering information directly to PRISM)

2.1. By the end of February 2022, 32,278 units of activity have been submitted by 37 standalone clinics. These clinics commenced on 14th September 2021 and have been using PRISM continuously since that date.

2.2. The quality of data submissions from standalone clinics continues to be extremely good. As of the end of February, these clinics had only 234 outstanding validation errors, 0.7% of all activity. Clinics using the legacy system, EDI, generated around 10% error rate on forms submitted, concerning which the HFEA Register Team then had to contact the clinic for corrections.

2.3. We believe the reason for this exceptionally low error rate is that in PRISM, data errors are automatically presented in the clinic's PRISM Homepage. This serves as a strong and visible prompt to the clinic to fix the error there and then.

2.4. There are 12 standalone clinics that report zero error rates (i.e., no outstanding validation errors), and a further 17 with less than 10 errors on their Homepages. This clearly sets the expected quality standard for the sector as a whole.

2.5. Since go-live, we have been supporting standalone clinics through a weekly conference-call with programme and register team staff. Clinics can discuss and share their experiences on PRISM, and the teams also respond directly to email queries between those calls. A strong 'PRISM user group' of clinic staff is emerging from these calls and contact with this group continue on an ongoing basis (although less frequently - first fortnightly, then monthly).

API clinics (submitting information automatically through a third-party system)

2.6. **Mellowood:** 28 clinics using the IDEAS system have submitted 32,238 units of activity into PRISM. As the IDEAS system requires a physical upgrade in each clinic (unlike PRISM which is web-based and can be launched at once to all users), Mellowood have deployed clinics sequentially. No data is lost, as all data between the start of September 2021 and the date of clinic deployment is stored up by the IDEAS system and then clinics work through submitting their backlog over the days following deployment.

2.7. There are 9 Mellowood clinics yet to deploy: CRGW Wales, Belfast Royal, Inovo Belfast, Glasgow Royal Infirmary, and the 5 clinics of the CREATE group. The delay to the latter group is due to technical work that is required by Mellowood to split their shared database for individual clinic submissions. Clinics and Mellowood are reporting that the delays in the former group are due to it taking longer than expected for IT departments in the clinics to install the IDEAS upgrade. We have used the HFEA inspectors to give these clinics a 'nudge' towards completing as quickly as possible.

2.8. Before go-live and during deployment we have continued to have weekly calls with Mellowood management and their implementation teams. Whilst there were issues with Mellowood in May 2021, it is the view of the programme that the Mellowood deployment has progressed well.

2.9. **CARE Group:** 6 clinics from this group have submitted 6,501 units of activity to PRISM. All deployments from the group are controlled and checked by their central IT team. The full backlog for each clinic is submitted when it is deployed.

2.10. There are 6 CARE clinics yet to deploy. We are advised by CARE that they expect to complete this deployment on target by the end of March.

2.11. **Meditex:** As reported in previous AGC updates, the programme team have encountered challenges with the Meditex API solution. In December, we accredited their submissions using test data. Thereafter, Meditex undertook a pilot with 0030 Herts and Essex to ensure their solution also worked with real clinic data, particularly to ensure it synchronised with legacy data and that no duplicate records were submitted to the Register.

2.12. The Meditex pilot incurred a number of technical and data synchronisation issues. During January and February, the programme team liaised closely with Meditex. As of the end of February, 0030 Herts and Essex have submitted 785 units of activity, which HFEA staff have fully tested. We are therefore confident in the quality of these submissions to progress to a full Meditex deployment.

2.13. There are 10 Meditex clinics yet to deploy. Whilst Meditex had originally been working to complete this work by March, additional time taken on their pilot means we have agreed a new deployment plan with them that completes current clinic deployment by the end of April.

2.14. **Error rates from API clinics:** The average validation error rate API clinics is 8.4%. In general, we are not observing the very low error rates that are being achieved by standalone clinics.

2.15. We believe this is because with an API solution, clinics do not have direct access to the PRISM Homepage – instead PRISM submissions are managed through third party system screens. This could lead to a 'fire and forget' approach in clinics. We have issued guidance to API clinics on how they can access their validation errors through the PRISM Homepage, and we initiated a pilot with the HFEA Register Team to work with selected API clinics with particularly high error rates to endeavour to address errors.

2.16. As part of that Register Team pilot, one clinic (TFP Oxford) reduced its validation errors from 344 errors (34%) at the end of November to just 20 errors (0.7%) at the end of February. We are working with the clinic to write up the processes used to achieve this result so it can serve as a template for other API clinics.

Deadline for completing deployment / recommencing data submission standard

2.17. We have written to clinics that deployment is due to finish at the end of March. From 1st April 2022, data submissions standards for clinics (General Direction 0005) will once again be in place. As the old General Direction document has multiple references to the legacy system, EDI, we have created a version of the current standards that is 'PRISM complaint' which has been reviewed by HFEA legal team and inspectors. We have also updated the General Direction to include requirements for all clinics to review their PRISM Homepage.

2.18. We expect to share the updated General Direction 0005 with clinics during March. At the same time, we will communicate to clinics through Clinic Focus on best practice for PRISM including the learning from TFP Oxford on achieving low error rates, and other points for best practice, particularly on movements. (See section 4 below).

2.19. Clinics will also be able to monitor 'live' their performance against these standards through a statistical dashboard on their PRISM Homepage.

2.20. We expect 85 – 90% of all clinics to be deployed on PRISM by the end of March. For the reasons described above, there will be a small number of Mellowood and Meditex clinics that will overrun this deadline. We will deal with these by exception, and in general we will aim for a 'soft introduction' of the new standards.

3. Post-PRISM planning - re-establishing reporting including 2022 Choose a Fertility Clinic

3.1. We have developed a detailed programme plan for the activities and objectives that are required after PRISM go-live including:

1. Re-establishing billing, a new reporting database for the HFEA Intelligence team and re-establishing Inspectors' Books.
2. Re-establishing the processes for a 2022 CaFC – including analytics and verifications reports, a clinic verification exercise (the first-time clinics will use PRISM in this regard) and final calculations, reconciliation and sign off.
3. Ongoing PRISM maintenance and responding to bugs identified by clinics through PRISM use.

4. Delivering RITA Phase 2: Further development and reports required for HFEA Register and OTR teams.
5. Developing functionality for Mitochondrial Donation Therapy (MDT) submissions, and bulk-backport functionality so clinics can change their submissions methods from standalone to API, and new system suppliers can establish new API solutions.
6. Stabilising the Epicentre system, which reports clinic information for a number of HFEA teams, including inspectors.
7. Handover of PRISM activities from contracted to employed staff.

3.2. The anticipated timescales for data and reporting activities (including CaFC) are as follows:

1. The first reporting activity to be re-established was billing. This was completed in November. The new reporting database for the Intelligence Team is also now complete.
2. Since January our data analysts have been working on re-establishing Inspectors' Books. This will be completed in the first week of March and serves as a springboard to completing the remaining reports (over 40 reports) required in order to start a CaFC clinic verification exercise.
3. We are provisionally forecasting that clinic verification will take place between June and October 2022. Instead of the traditional one-year verification, to catch up after PRISM, clinics will be asked to verify two years of data (treatment data for 2020 and 2021, outcome data for 2019 and 2020), and clinics will be given four months to complete the exercise which is twice the amount of time normally given.
4. Once clinics have completed verification, we are provisionally forecasting a CaFC publication date in November 2022. However, our CAFC dates are subject to a large number of risks that are detailed in section 4.
5. The HFEA Communications Team are working on a communications plan for all stakeholders to address any risks or issues arising from this delay for CaFC.
6. The 2022 CaFC requires a significant period for clinic verification because it is referencing EDI submitted data. However, the very low error rates for PRISM submissions from a large number of clinics, point to a future time when sector-wide clinic verification exercises may not be required, if this current clinic performance can be extended to the sector as a whole.
7. Once he has completed all the PRISM verification reports, and whilst clinics are undertaking a the CaFC verification exercise, our PRISM data developer will be undertaking the work to stabilise the Epicentre system.

3.3. The anticipated timescales for PRISM development and handover activities are as follows:

1. Both our developers are addressing queries from third-party system suppliers as they continue with their deployments.

2. Our contracted developer is continuing to address PRISM bugs that are being reported by clinics. The number of bugs is at a level that would be expected with a complex system being used in high volumes by a large number of clinics.
3. Since January our employed system developer has been working on the RITA Phase 2 requirements for the HFEA Register and OTR Team. This work will continue until August 2022 at the earliest, although there will be a break in this work to address the handover (see section 5).
4. During late March and April, our contacted developer will undertake work to develop functionality for bulk backport and MDT.
5. The months of May and June will be devoted entirely to handover from contacted to employed staff (see section 5).
6. Contracted PRISM staff (PRISM, programme manager, PRISM developer, PRISM co-ordinator and system expert) are due to leave on 1st July 2022.
7. There will remain one contacted IT member of staff until March 2023. This is the 'back-end' data developer who has significant experience of HFEA's register structure and IT infrastructure.

4. Ongoing PRISM challenges

4.1. Whilst PRISM has gone live, and deployment is soon to complete, there still remain a number of ongoing challenges for HFEA:

4.2. **Validation Errors:** As previously reported, some clinics are reporting exceptionally good error rates, but there is further work required to ensure the whole sector achieves this standard.

4.3. **Reporting Gamete Movements:** Whereas with EDI, reporting movements was the least accurate area of clinic submissions, with PRISM it is now an essential part of the process. A sending clinic must complete a Gamete Out return before a receiving clinic can complete a Gamete In and report on any subsequent treatments. Clinics are reporting a number of treatments they cannot report on because of inaction at the sending clinic. This will be addressed after deployment and the March Clinic Focus update will be the start of that engagement.

4.4. **Quality Metrics:** The whole of HFEA reporting in EDI was based on a bespoke system of Quality Metric flags which was developed by our Intelligence Team analyst who has since left. These need to be rebuilt in PRISM, and the external Stalis Report did not offer any alternatives to this process. Therefore, and essentially from a 'standing start', our HFEA data analyst, is restoring the Quality Metrics into PRISM, first for billing, then for inspectors' books, and then for CaFC and RBAT. He is now up to speed on these metrics and achieving good progress.

4.5. **Legacy Data Issues:** It is likely that during the construction of the 40+ reports required for CaFC verification, a number of data issues will emerge which will need to be fixed before clinics can start to verify. Time has been allocated for this, but if any issues are substantial then the date of clinic verification may be delayed.

4.6. **Impact on OTR:** Currently, the OTR process requires checking both in PRISM and EDI. We are undertaking further work to scope what technical data work might be required to eliminate the requirement for a double-check.

4.7. **Clinic verification:** In all previous CaFC verification exercises, clinics have requested an extension to the verification period. These requests have generally been accepted by HFEA. Even though HFEA will be offering double the normal verification time, it is likely that clinics will ask for a further extension to their verification periods, particularly as they are using a new system for the first time. This would delay any CaFC publication until 2023.

4.8. **Technical Resources**: As a result of PRISM go-live, detailed post go-live planning, and the request from HFEA senior management to DSHC for additional resources, plans are in place to recruit additional staff as follows:

1. **Additional Employed System Developer:** To work alongside our current system developer on PRISM support and maintenance, RITA, and other HFEA development requirements. As this is critical to the handover, the advert for this role closed at the end of February and interviews are ongoing.
2. **Additional Employed Data Developer:** To work alongside our current data analyst on Register maintenance, report generation and data analysis. Recruitment activity will start imminently on this role.

4.9. **Single Points of Failure:** The recruitment of these roles significantly mitigates the single point of failure risk that was discussed in the lessons learned report in December 2021.

5. PRISM Handover to employed HFEA staff

5.1. The handover of PRISM from contracted to employed staff is a critical element of the programme:

5.2. A dedicated handover window has been identified to take place during May and June for the development and clinic support activities. No other development work is scheduled during this time, although work on CaFC is outside the scope of the handover and will continue without interruption.

5.3. The handover is being ‘employee led’. The current Head of IT who retires at the end May, is leading the planning of this process and engagement and support of HFEA employees.

5.4. The key points of handover are as follows:

1. Handover of PRISM system management from contracted PRISM programme manager to the newly appointed Head of IT who commences in early May.
2. Handover of PRISM support activities from contracted PRISM co-ordinator and system expert to the newly appointed Register Team Manager who starts in April.
3. A full development handover of the PRISM code from the contracted PRISM developer to the employed system developer. Depending on the speed of recruitment, it is hoped that any newly appointed additional system developer will also be able to partake in this handover.

5.5. There will need to be a further ‘analytical handover’ when our contracted ‘back-end’ developer leaves in March 2023 to the HFEA data analyst and the new employed data developer.

6. AGC recommendations

6.1. AGC are asked to note:

1. The progress with PRISM use and API deployment since go-live
2. The ‘re-establishment plan’ for 2022.
3. The ongoing challenges that are likely to PRISM and CaFC
4. The approach to handover to employed staff

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 The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Audit and Governance Committee
Agenda item:	9
Meeting date:	15 March 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager Paula Robinson, Head of Planning and Governance
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. The Authority is due to receive the Strategic Risk Register at its meeting next week. We will report verbally on any feedback from today's AGC discussion.

1.2. Following earlier feedback from AGC, the senior management team have done an in-depth review over the preceding two months resulting in a number of changes.

1.3. In summary:

- RF1 (regulatory framework) has been updated to reflect the latest position related to the ongoing effects of earlier Covid impacts. The risk score remains the same.
- I1 (information provision) has been updated slightly, pending further work on our communications strategy. In the longer term, this risk will need to be reframed, to focus more on the risks to us achieving the desired impact and reach with our information. For the time being, it seems appropriate to leave this risk slightly above tolerance, given that further work is still needed. We will update this risk further before June AGC.
- P1 (positioning and influencing) has been updated, but as with the above risk, may need to be updated further as we progress the work on our communications strategy. This would include reference to AGC's previous point about the added risk if we were to gain no traction regarding updating the Act.
- FV1 (financial viability) has been comprehensively updated in light of the Q3 position and following the approval of HMRC for our fees increase this year.
- C1 (capability) has had minor updates throughout, including the addition of an 'in common' risk affecting all ALBs, relating to recruitment in the current job market.
- C2 (leadership capability) has been revised to update the position on Board appointments. The risk score has been lowered. We have also raised the tolerance threshold a little, since on reflection (and consistent with wider comments about tolerances at the December AGC meeting) it was felt that a tolerance of 4 was unrealistically low for this risk. This risk is therefore now at tolerance.
- CS1 (cyber security) has been updated significantly following a planned review. The update reflects recent steps taken to improve our resilience to cyber attacks and data loss.
- LC1 (legal challenge) – no significant changes have been made on this occasion.
- CV1 (business continuity and covid) – the text has been updated to reflect the current position. It is proposed that this risk be retired (with AGC's permission) in June, at which point any remaining elements could instead be fed into the ongoing capability risk.

1.4. 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.

1.5. One of the ten risks (I1) is currently above tolerance.

2. Plan for risk management review

2.1. Since the departure of the previous Risk & Business Planning Manager delayed the intended review of our risk management policy and associated processes in 2021, the committee requested that a plan be brought to this meeting.

2.2. The plan will include a review of the risk register itself, a review of the risk policy, and consideration of risk appetite and risk tolerances. In addition, an internal audit of our risk system is now in progress, which will also inform the plan once the report is available.

2.3. Plan for the coming months:

March	Support the internal audit of our risk systems and begin to consider recommendations once the report is ready.
April	Review of best practice guidance and other organisational approaches with reference to the revised Orange Book and risk improvement groups (DHSC and Cross-government). Consideration of how to feed latest best practice into a revised version of our risk policy.
May	Commence review of operational risk management practices and identification and mitigation of weaknesses, in line with recommendations arising from the current audit, and our own observations about current team practices. Redrafting of policy to begin. Consideration of content/structure changes in the strategic risk register, to surface the most active issues and improve presentation. Feedback for AGC on progress to date to be drafted in readiness for the June meeting.
June-September	Design and implementation of rolling improvement plans for operational risk management. Ongoing work on the revised risk policy and risk register. Consideration of how to frame the discussion on our overall risk appetite and the setting of tolerances for individual risks. Design of a horizon scanning methodology.
October	Revised draft of risk policy and risk register completed and presented to AGC for consideration. Discussion on risk appetite and tolerance levels.
November	Agreement of risk appetite with Authority alongside their periodic review of the risk register.
December	Finalisation and launch of the revised risk policy and feedback to AGC on the Authority's discussion on risk appetite.

2.4. AGC's previous comments on these topics will be taken into consideration during the review, as well as additional input from our internal auditors. For instance, we will consider how we might make the risk register, and our consideration of controls, more dynamic, and review our approach to setting individual risk tolerances. We will consider how we can develop the new 'deep dives' approach to incorporate risk assurance mapping and a more thorough assessment of the effectiveness of mitigations. We will develop a way of incorporating periodic horizon scanning into our risk conversations, to anticipate upcoming areas of risk.

3. Recommendation

3.1. AGC is asked to note the above and comment on the strategic risk register.

3.2. AGC is also asked to agree that the Coronavirus risk, CV1, be discontinued from June 2022 onwards, with any residual elements that still present an ongoing risk being integrated into the capability risk (C1) or other risks as appropriate.

Latest review date – 21/02/2022

Annex 1

Strategic risk register 2020-2024

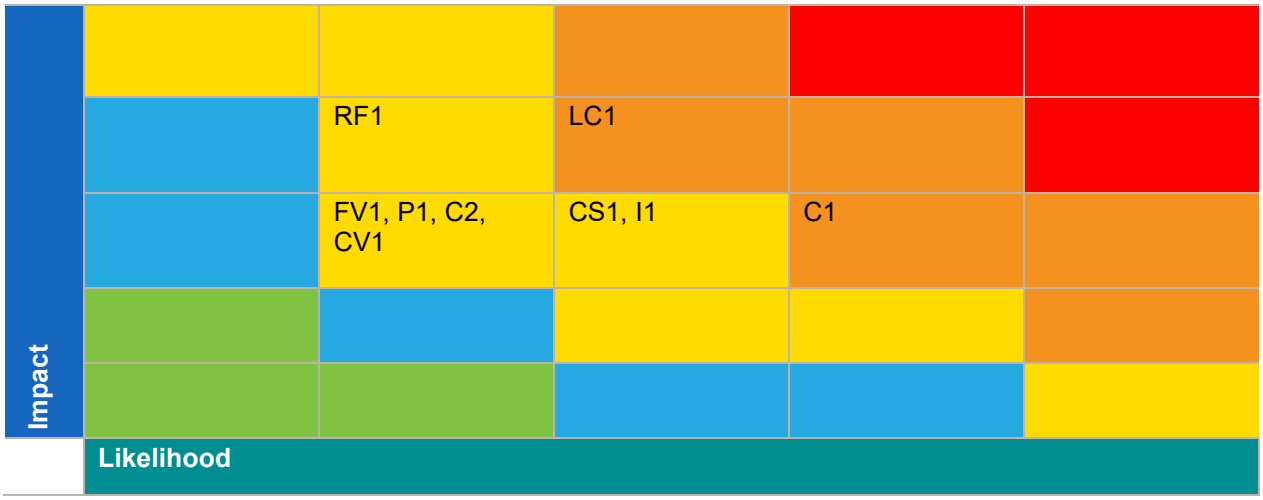
Risk summary: high to low residual risks

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

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

Recent review points: SMT 1 November ⇨ AGC 9 December ⇨ SMT 10 January ⇨ SMT 21 February

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 - High	**2**	**4**	**8 - Medium**
Tolerance threshold:					**8 - Medium**
Status: At tolerance					

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

Commentary
As a regulator, we are by nature removed from the care and developments being offered in clinics and must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research are safe and ethical. The result of not having an effective regulatory framework could be significant. The worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way. We reworked our inspection methodology because of Covid-19, to undertake remote and hybrid inspections to reduce risk. Post Covid restrictions lifting, the hybrid methodology will continue to be used for renewal inspections and will be integrated into interim inspections for those starting to be scheduled from April 2022. We are now undertaking more on-site inspections as part of a more balanced steady state between desk-based assessments and on-site inspections, balancing workloads and risk. In September 2021 Authority received an update on the revised regime including a review of the effectiveness of the changes. The Authority endorsed this approach. There is a higher resource requirement for these new processes as they bed down, and we have kept this under close review to ensure that it remains appropriate. There is still a degree of risk – for example the licence extensions implemented in 2020/21 meant there was an inspection scheduling issue in January 2022, with a bottleneck of inspections due at that point. To manage this, we will need to continue to breach the two-yearly visit rule for some clinics and extend licences where this is possible.

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 advertising or artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, we collaborated on the CMA and ASA's work in this area to strengthen the information and advertising provision for patients). Working with other expert	In progress - Clare Ettinghausen

Causes / sources	Controls	Timescale / owner of control(s)
	regulators is effective in areas where we do not have effective powers We take external legal advice as relevant where developments are outside of our direct remit (eg, on an incidence of AI technology being used in the fertility sector) and utilise this to establish our legal/regulatory position. We are analysing where there are gaps in our regulatory powers so that we may be able to make a case for further powers if these are necessary, whenever these are next reviewed. We will initiate the first stage of a multi-year project in 2022-2023.	Ad hoc ongoing - Catherine Drennan Pre-business case project planning in progress - Joanne Anton, Catherine Drennan
Developments occur which our regulatory tools, systems and interventions have not been designed to address and they are unable to adapt to.	Regular review processes for all regulatory tools such as: • Code of Practice. • Compliance and enforcement policy • Licensing SOPs and decision trees Regular reviews enable us to revise these and prevent them from becoming ineffective or outdated. Regular liaison with DHSC and other health regulators to raise issues.	In place - Joanne Anton Revised version of the policy launched 1 June 2021– Catherine Drennan, Rachel Cutting In place and ongoing – Paula Robinson In place - Peter Thompson
The revised inspection approach (including a period of fully remote and hybrid inspections due to Covid-19, introduced November 2020) requires greater resources from the inspection team. This affects ongoing delivery. Note: risk cause arises from control under CV1.	Reviewing the new way of working and inspection approach as this continues to be embedded. Moving towards a steady state balance between desk-based elements and on-site inspections. 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. Review of documentation required for DBA undertaken in July 2021 to ensure this is proportionate. Clear communication to the inspection team about appropriate level of scrutiny. Continued extensions to some licences where appropriate (ie, low risk clinics with good compliance) to manage the pressure on inspection delivery workload.	Plan in place, agreed by Authority September 2021 – Sharon Fensome Rimmer, Rachel Cutting

Causes / sources	Controls	Timescale / owner of control(s)
Some changes can be very fast meaning our understanding of the implications is limited, affecting our ability to adequately prepare, respond and take a nuanced approach	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by: • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily must wait for some changes to be clearer to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing 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.	In place – Joanne Anton In place - Peter Thompson
We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.	Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions. Any reprioritisation of significant Strategy work would be discussed with the Authority.	In place – Peter Thompson
Developments occur in areas where we have a lack of staffing expertise or capability.	As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff. If a specific skills gap was identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporarily or sharing skills with other organisations.	Ongoing - Relevant Head/Director with Yvonne Akinmodun
RITA (the register information team app – used to review submissions to the Register) has been built but some reporting issues still need to be resolved. If this 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. As of February 2022, development work is in progress and this risk is decreasing.	If RITA is not completed in a timely way, the Register and OTR team will still be able to use manual workarounds to get access to the information they need to support clinics and / or to provide information to support our regulatory work. although these workarounds will result in a substantial delay to responding to an OTR request or providing clinic support. RITA Phase 2 has been prioritised against other development work. A new group to prioritise and oversee development was established in October 2021.	Ongoing – Rachel Cutting (pending recruitment to Chief Technology Officer post) Prioritisation of remaining development as delivery continues – Kevin Hudson
We don't hold all the data from the sector (beyond inspection or	As part of planning and delivering the add-ons project we have looked at the evidence available	In place – Joanne Anton

Causes / sources	Controls	Timescale / owner of control(s)
Register data) to inform our interventions, for instance on add-ons.	and considered whether we can access other information if we do not have this already. We revise our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool). Process to be established for reviewing the data dictionary which will allow for internal and external stakeholders to suggest that we collect more/less data, review impact assessments on the HFEA and the sector as a whole of those changes and plan for any development that will be needed (both internally and externally) to make them possible.	Audit tool launched in clinics from Autumn 2020 - Rachel Cutting Detailed planning to follow – Neil McComb
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 the HFEA's position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson

I1: There is a risk that the 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	**3**	**3**	**9 - Medium**
Tolerance threshold:					**8 - Medium**
Status: **Above tolerance**					

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

Commentary

Information provision is a key part of our statutory duties and is fundamental to us being able to regulate effectively. We provide information to the public, patients, partners, donors, the donor conceived, their families and clinics alike. If we are not seen as relevant then we risk our information not being used, which in turn may affect the quality of care, outcomes, and options available to those involved in treatment.

In October 2020, the Opening the Register service reopened after being paused since clinics shut down due to Covid-19. Due to this pause, we received an influx of applications which means we are unable to meet our usual KPI for completing responses for a period. We have managed 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. New performance reporting KPIs are being developed to give the Authority a clear picture of progress. Ongoing communication with applicants and centres has been clear to ensure they understand the position 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. While training has occurred over summer 2021 processing rates have dropped, but we expect this to increase again in the coming months.

As at Autumn 2021, development work is outstanding to enable us to update CaFC from the new Register. A review has been undertaken but we need to discuss the implications of this, set against other developments, before agreeing a full plan. It is now likely to be Autumn 2022 before we can update CaFC, and the management of this gap is being discussed. Given the centrality of CaFC to our services, this will require a communications plan as well.

The residual risk level was raised slightly after discussion at SMT in November, in recognition of earlier points raised at AGC about CaFC uncertainties.

There are a number of external challenges which impact on our information provision, for example the rise of social media and online groups as competing information sources, as well as clinics' own websites and other publicly available information. Working on our wider profile raising and media and social media reach may help to address these challenges.

Causes / sources	Controls	Status / timescale / owner
People don't find us/our information, meaning we are unable to get clear and unbiased information to patients, donors, and others.	Knowledge of key searches and work to improve search engine optimisation to ensure that we will be found. We have a rolling bi-annual cycle to review website content and can revise website content to ensure this is optimised for search if necessary. We undertake activities to raise awareness of our information, such as using social and traditional media. We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us. We are also assessing this from the 2021 patient survey.	In place and ongoing – Clare Ettinghausen
Our information is not used by our key stakeholders	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. New Patient Organisation Stakeholder Group launched in 2021. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	In place with ongoing review – Clare Ettinghausen . Ongoing – Clare Ettinghausen
We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites and clinics post their own data.	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 and will be able to evaluate this from the outcomes of the 2021 patient survey. Review our information and distribution mechanisms on an ongoing basis to ensure relevance. (Also see below about CaFC.)	In place and ongoing - Clare Ettinghausen In place and ongoing - Clare Ettinghausen
The new Register is now live, but there is still a considerable amount of work to be undertaken to develop, test and implement new data tools. This may hamper our ability to provide the right data in a timely way across the whole organisation.	The implementation of these new data tools and systems will be prioritised, to ensure that the impact in the interim period is minimised. Teams, such as the Inspectorate, have backup plans for the gap between cutover and when the new register feeds into existing systems or processes (inspectors' notebooks, RBAT, QSUM, OTR etc.) to ensure relevant data is available. A reporting version of the Register was captured in August 2021 before EDI was switched off. This will allow the intelligence team to continue to respond to FOIs and enquiries. A reporting database has been	In place - Rachel Cutting (pending recruitment to Chief Technology Officer (CTO) post), Sharon Fensome-Rimmer Interim arrangement in

Causes / sources	Controls	Status / timescale / owner
	built in the new Register and is being tested with the team.	place - Nora Cooke O'Dowd
The data in the new Register is not yet complete or validated.	While some data can be accessed, the information is not yet of sufficient quality to be used. For Intelligence, this means that it is not possible to publish Fertility Trends in 2022 and therefore a Covid report is being published instead. The intelligence team cannot provide information based on updated data until validation has been completed (expected November 2022). All responses to FOIs, PQs and enquiries will point to unvalidated 2020 treatments and unvalidated 2019 outcomes throughout 2022 and into early-mid 2023.	Interim arrangement in place - Nora Cooke O'Dowd
Pending planned post-PRISM development to re-enable the reporting of verified data from the new Register, we will be unable to update Choose a Fertility Clinic for some months. It therefore risks losing or reducing its unique selling point, which is to be an authoritative source of independent, timely, accurate information to inform patients' treatment choices.	As above - We updated the data available on CaFC ahead of the Register migration, to ensure that 2019 treatment data can be accessed, and have a reporting version of the Register captured in August 2021. This delays CaFC becoming out of date but does not close the risk. Discussions about communicating this necessary gap in updating CaFC to the sector and our stakeholders are in progress.	Completed February 2021 and August 2021 – Neil McComb In progress – Peter Thompson
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 have the information they need to deal with this.	Maintain links with donor organisations to mutually signpost information and increase the chance that this will be available to those in this situation. Maintain links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications. Raise this in any review of the Act.	In place and ongoing – Clare Ettinghausen In place and ongoing – Laura Riley Future measure – Peter Thompson
Our OTR workload has increased and will change again in 2023 (when children born after donor anonymity was lifted begin to turn 18) and we may lack the capability to deal sensitivity with donor issues.	Service development work to review resourcing and other requirements for OTR to ensure these are fit for purpose. Service development project in progress. Temporary additional resource in place (from April and July 2021) to help mitigate increasing demands on the service in the short-term.	Future control – project in progress - Neil McComb
The OTR service may be negatively impacted by an influx of applications following reopening after being paused,	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	Additional resource in place (from April and July

Causes / sources	Controls	Status / timescale / owner
with demand outstripping our ability to respond. Note, this is being managed as a live issue as of September 2021.	continuing to clearly communicate with applicants and the sector to manage expectations. We have recruited additional temporary resource to manage demand, however during training processing of applications has again been limited.	2021) – Neil McComb
Risk that key regulatory information will be overlooked by stakeholders owing to the number of different communication channels and information sources.	There is a statutory duty for PRs to stay abreast of updates, and we provide key information via Clinic Focus. We duplicate essential communications by also sending via email to each centre's PR and LH (for instance, all Covid-19 correspondence). We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance on the Portal when they need it regardless of additional communicated updates. We plan to implement a formal annual catch-up between clinics and an inspector. Note: that due to revised inspection approach due to Covid-19 these plans have been delayed.	In place – Rachel Cutting In place – Joanne Anton Future control to consider following Covid-19 – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making; because of this, we could be seen as less transparent than other modern regulators.	Review of inspection reports is underway to identify future improvements to inspection reports. This will be delivered alongside other transparency work. Consideration of further changes to the information we publish in discussions on 'regulation and transparency' at Authority meetings. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics. Further work on transparency and regulation was planned for 2022 but may need to be delayed.	Early work underway, but likely to complete 2022 – Rachel Cutting In place – Rachel Cutting Clare Ettinghausen
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None.		

P1: There is a risk that we do not 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 - High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**9 - Medium**
Status: Below tolerance					

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

Commentary
This risk is about us being able to influence effectively to achieve our strategic aims. If we do not ensure we are well placed to do this, we may not be involved in key debates and developments, and our strategic impact may be limited. We have a communications approach, agreed with the Authority in January 2021. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions. The response to the Covid-19 pandemic required close working with many other organisations and professional bodies, as well as increased engagement with the sector, which has strengthened our strategic positioning. In 2021 we have changed our patient stakeholder organisation group to broaden it's membership and have also established a patient forum to support greater patient involvement in our work. Wider political developments mean that the HFEA has been incorporated into the DHSC 'health family' in a closer way than previously. This has likely improved our connections with the DHSC and other ALBs and enabled us to have greater influence on specific issues.

Causes / sources	Controls	Status/timescale / owner
We do not currently have the range of influence we need to secure our position.	Maintaining and updating our stakeholder engagement plan.	In place, agreed with the Chair and reviewed regularly ongoing – Clare Ettinghausen In place but will need to

Causes / sources	Controls	Status/timescale / owner
	Chair and Authority members acting as ambassadors to expand the reach and influence of the organisation's messages and work. 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.	continue to engage on this as Board membership changes. Authority members - Peter Thompson and Clare Ettinghausen In place – Project Sponsors and Project Managers
We lack some of the required influencing capacity and skills for strategic delivery.	Oversight on public affairs from senior staff and good individual external relationships with key stakeholders. As we move towards the later stages of strategic delivery, we will need to assess our capacity and capabilities in this area, alongside our strategic plans, to ensure we can engage on key issues such as legislative changes and new technologies. Senior Management to keep need for this under review.	In place – Peter Thompson and Clare Ettinghausen In place – Peter Thompson and Clare Ettinghausen, Paula Robinson
We are 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 can take a different view on the evidence HFEA provides (for instance in relation to Add-ons) and so our information may be overlooked.	The working group for the add-ons project has focused on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed. SCAAC sharing evidence it receives more widely and having an open dialogue with the sector on add-ons. Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed.	Ongoing - Joanne Anton
When there are policy and strategic changes, HFEA and sector interests can be in conflict, damaging our reputation.	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible.	In place - Peter Thompson

Causes / sources	Controls	Status/timescale / owner
We lack opportunities to engage with early adopters or initiators of new treatments/innovations or changes in the sector.	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these. We plan to investigate holding an annual meeting with key innovators (in industry) in the future and in advance of this are continuing informal contact.	In place - Joanne Anton In place - Joanne Anton Delayed due to Covid – future control – Sharon Fensome-Rimmer Future control, delayed due to Covid-19 but to be reviewed in Q4 2021/2022 - Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: The Department may not consider future HFEA regulatory interests or requirements when planning for any future consideration of relevant legislation which could compromise the future regulatory regime.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson Completed - Joanne Anton
Government: Any consideration of the future legislative landscape may become politicised.	There are no preventative controls for this, however clear and balanced messaging between us, the department and ministers may reduce the impact. Develop improved relationships with MPs and Peers to ensure our views and expertise are considered.	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**
3	4	12 - High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**9 - Medium**
Status: Below tolerance					

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

Commentary
The in-year income position remains uncertain as actual activity data has not been available since August 2021 when clinics began the move to the HFEA's new reporting system, PRISM. Invoices have been raised and issued to clinics based on historic activity in previous years and a full reconciliation will be undertaken once clinics have entered backlog data and are submitting data in line with HFEA requirements. It is unlikely that a reconciliation for all clinics will be complete this business year, although we remain confident that most data will be reconciled ahead of the final accounts. In January 2022 the HFEA received approval from HMT and DHSC to increase the IVF licence fee by £5. A Chair's letter has been issued advising that the increase will take effect from 1 April 2022.

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. This has been the basis for invoicing since August 2021 and provides significant confidence that the reconciliation process will not result in material variances between the current forecast and final outturn position. The agreement to a £5 increase in the IVF licence fee for 2022/23 onwards will provide additional income to meet the emerging and acknowledged operational pressures the HFEA faces.	CMG monthly and Authority when required – Peter Thompson

Causes / sources	Controls	Timescale / owner
Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles.	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. 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.	Policy in place October 2021 – Richard Sydee Control under quarterly review as sector reopens – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed. The ten-year lease at Redman Place (from 2020-2030) provides 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.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee A moto is in place for Stratford confirming details of arrangements – 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. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Project assurance Group is chaired by the Director of Resources and a finance staff member is also present at PAG. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at PAG and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Samuel Akinwonmi
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of	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.	Continuous - Richard Sydee

Causes / sources	Controls	Timescale / owner
financial autonomy or goodwill for securing future funding.	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).	Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to appropriate contingency level available at this point in the financial year. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model. GIA funding for the SR21 period is yet to be finalised, discussions are underway with the department and expected to conclude ahead of the 2022/23 business year	Quarterly accountability meetings (on-going) – Richard Sydee December/ January annually, – Richard Sydee

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

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

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

Commentary

This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity. There are also links with organisational change (such as hybrid working or the advent of PRISM), and risk elements that were formerly captured under a separate risk, OM1, which has now been discontinued, have been added to this risk accordingly.

Turnover remains above tolerance putting strain on staff generally while covering gaps, inducting new starters, and managing knowledge transfer. Moreover, recruitment has been more difficult for some individual posts, with typically fewer high-quality applicants per post advertised, which increases the risk of a post not being appointed to or taking more than one recruitment round to fill. The civil service pay freeze has not helped, although pay is an issue throughout the wider public sector, not just for the HFEA. Though overall high turnover has cumulative effects across the whole organisation, high turnover at team level can feel particularly acute. Regular conversations about resources at CMG ensure that we are aware of and can, where possible, plan mitigations.

High turnover is made more problematic in the context of expanding BAU work, reducing the opportunity to prioritise. As a consequence, discussions are ongoing with the DHSC about the need to increase the headcount of the organisation, funded from the modest fee increase that has been agreed (see FV1).

Where we have met recruitment challenges, we have considered the needs of the post and designed our response accordingly, to identify other means to cover capability gaps and redeploy skills. For example, we extended an existing contractor and asked another staff member to act up to cover pending recruitment to the Chief Technology Officer post. Anecdotal evidence is that the turnover is in line with trends in the wider public sector, though we plan to review data from exit interviews to understand this further. We are aware that some organisations have reviewed terms and conditions to attract high-quality applicants; CMG is considering ongoing arrangements for flexible and homeworking, and this should help to ensure that we continue to attract a wide range of candidates to our roles.

We are working to maintain our relative flexibility while meeting our organisational needs. Recruitment has been generally successful. Discussions with CMG are advancing and proposals on homeworking are being finalised. More engagement with staff on these issues is in progress following on from the staff survey conducted at the end of October 2021.

AGC receive 6-monthly updates on capability risks to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations. Unfortunately, this work has not progressed further due to Covid-19, although conversations about such development opportunities continue on an individual level.

Management of Board and senior executive capability is captured in the separate C2 risk, below.

Causes / sources	Mitigations	Status/Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps. Note: this is a more acute risk for our smaller teams.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise. Contingency: In the event of knowledge gaps, we would consider alternative resources such as using agency staff, or support from other organisations, if appropriate. This has been required for certain posts.	In place – Yvonne Akinmodun and relevant managers In place – Peter Thompson In place – Relevant Director alongside managers
Inability to quickly appoint to key posts is extending the duration of capability gaps.	Taking an alternative approach to covering the Chief Technology Officer role in the interim. We also reviewed our approach to longer-term recruitment. Looking for alternative ways to allocate skills and resources for hard-to-fill roles to cover gaps.	In place Rachel Cutting Ongoing – hiring managers, Yvonne Akinmodun
Poor morale leading to staff leaving, opening up capability gaps.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable	In place, ongoing – Peter Thompson In place – Clare Ettinghausen In place - staff survey October

Causes / sources	Mitigations	Status/Timescale / owner
	management responses where there are areas of concern.	2021 with wellbeing pulse survey September 2021 and quarterly thereafter– Yvonne Akinmodun
	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 - 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, and periodic planning workshops.	In place – Paula Robinson
	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.	In place – Paula Robinson
	Oversight of projects by both the monthly Project Assurance Group and CMG.	In place – Paula Robinson
	Project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources.	In place– Paula Robinson
	Planning and prioritising data submission project delivery, within our limited resources.	In place until project ends – Rachel Cutting (pending CTO recruitment)
	Skills matrix completed by teams to enable better oversight of organisational skills mix and deployment of resource. Plans being drawn up in relation to findings.	Analysis completed February 2022 – Yvonne Akinmodun
Not putting actions in place to realise the capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working.	Active engagement with other organisations early on and ongoing (HR group). 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
	Future control – use of Redman Place intranet to enable cross-organisational communications.	Planned but not yet in place

Causes / sources	Mitigations	Status/Timescale / owner
		– Richard Sydee
Stratford is a less desirable location for some current staff due to: • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention (resulting in knowledge loss and capacity and capability gaps) as staff choose to leave because of the office location.	We have an agreed excess fares policy to compensate those who will be paying more following the move to Stratford (those in post before December 2019). Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect. Reduction in number of days in the office following Covid-19 is likely to have reduced the risk of loss of staff.	In place – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
There is a risk that staff views on the positives and negatives of homeworking due to Covid-19 are not considered, meaning we miss opportunities for factoring these into planning our future operating model and alienate staff by not considering their views, for instance on flexible working. This could lead to staff leaving.	Heads discuss impacts with teams on a regular basis and feed views into discussions at CMG. Regular communication to staff about the developing conversation and direction of travel through all staff meetings and the intranet. A further survey of staff was conducted in late October, to inform any policy reviews.	Ongoing with survey in October – Peter Thompson
The need to operate with revised arrangements during the ongoing pandemic 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 the current arrangement of working in the office one day per week will continue unless Government advice changes. 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 is discussing policies, to provide assurance, for instance about maximum office attendance requirements.	Discussions in progress Ongoing with specific culture discussion in September – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC	Funding in place for additional resource to manage EU Exit workload in 2021-2022.	Communications ongoing – Clare

Causes / sources	Mitigations	Status/Timescale / owner
The UK leaving the EU has ongoing consequences for the HFEA which we must manage.	We continue to work closely with the DHSC on any arising issues and work towards implementing the impacts of the Northern Ireland Protocol as it applies to HFEA activity across the UK. NB unless any further funding is secured for future years then this work will need to be absorbed within existing activity.	Ettinghausen/ Andy Leonard
In-common risk Covid-19 (Coronavirus) may at times lead to high levels of staff absence leading to capability gaps or a need to redeploy staff.	Management discussion of situation as it emerges, to ensure a responsive approach to any developments. We reviewed our business continuity plan in April 2021 to ensure it is fit for purpose.	Ongoing - Peter Thompson
NICE/CQC/HRA/HTA – IT, facilities, meeting rooms, ways of working interdependencies.	Ongoing building working groups with relevant IT and other staff such as HR. Informal relationship management with other organisations' leads.	In place – Richard Sydee, DHSC
In-common risk The general jobs market and the so-called 'great resignation' may lead to capability gaps where recruitment takes some time to complete.	Management discussion when needed to agree how to deal with recruitment gaps.	Ongoing – Peter Thompson

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

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

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

Commentary
This risk reflects both the risks related to Board and senior executive leadership. Although the causes and impacts are different, many of the mitigations are similar, and both would have an impact on the organisation's external engagement and potentially strategic delivery. The HFEA board is unusual since 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 fairly low. However, we have raised the tolerance level from 4 to 6 (February 2022) to reflect the current operational reality, which is that an unusually high proportion of new Board members are being appointed this year. Seven new Board members have now been recruited to replace the three members whose terms have already finished, and four members whose terms will finish at the end of March and the end of April 2022. Three members' terms of office were extended by three months, which was helpful in managing committee quoracy in the interim. New members have relatively long onboarding times at the HFEA owing to the need for specialist training for the licensing committees, and the need to then accumulate experience and knowledge. However, the seven new appointments reduce this risk considerably. The Board is now at full strength which provides a stable basis for some time to come. Were a member of the senior executive team to leave the appropriate mitigations would depend on the role, but mitigations include delegating some responsibilities to remaining members of SMT and/or the relevant Head(s) and the appointment of an interim, where professional skills allow. Recruitment to a senior role will usually take longer than the 3 months contractual notice and so there will inevitably be a gap to manage.

Causes / sources	Mitigations	Status/timescale / owner
The induction time of new members (including bespoke legal training) can be significant, particularly for those	There is some degree of continuity of membership, which will help new members to acclimatise and learn.	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
sitting on licensing committees, which may experience an initial loss of collective knowledge and potentially an impact on the quality or ease of decision-making. Evidence from current members suggests that it can take up to a year for members to feel fully confident. Depending on new members to ensure committee quoracy means that their legal training must be arranged prior to their start date, and that there will be no opportunity for them to observe a meeting prior to participating as a decision-maker.	Legal training is available and is being improved to focus more on the decision-making process as well as the requirements and powers in the Act. The Governance team and the Chief Executive have reviewed recruitment information and member induction to ensure that this is as smooth as possible. A set of briefings on key issues has been introduced. All members have access to the standard licensing pack containing key documents to aid the committee in its decision-making. The guidance on licensing in the standard licensing pack is being updated, to align with the current compliance and enforcement policy and to give committee members and Chairs more support, particularly when decisions are challenging or finely balanced.	
Induction of new members to licensing and other committees, requires a significant amount of internal staff resource and could reduce the ability of Governance and other teams to support effective decision-making in other ways.	We have been mindful of this resource requirement when planning other work, to limit the impact of induction on other priorities.	In progress - Peter Thompson, Paula Robinson
Any member recruitment often takes some time and can therefore give rise to further vacancies and capability gaps. The recruitment process is run by DHSC meaning we have limited power to influence this risk source. Historically, decisions on appointments can create additional challenges for planning (the annual report from the commission for public appointments suggests appointments take on average five months).	We have focused on streamlining induction to ensure that the members who joined the HFEA this year are brought up to speed as quickly as practicable. This risk cause remains for all future recruitment.	Under way- Peter Thompson
The loss of a member of the senior leadership team (for instance through retirement, leaving the organisation for a new role etc) creates a leadership/knowledge gap.	Note: We cannot mitigate the cause of this risk, since staff may choose to leave the organisation for personal reasons. However, we can mitigate the consequences. Responsibilities could be shared across SMT and Heads to cover any gaps and maintain leadership, decision-making and oversight (this would include	

Causes / sources	Mitigations	Status/timescale / owner
	Chairing ELP which may be delegated under Standing Orders). Good induction process to ensure that new staff are onboarded efficiently. Effective use of delegation, to build capability of less senior staff, to enable them to step up in the case of senior staff absences (either temporarily or to apply for the role permanently in the case of staff leaving). Chief Executive would discuss recommendations for cover with the Chair if he were to move on from the organisation, to ensure that responsibilities were covered during any gap before appointment. Other controls (handover, knowledge capture, processes etc) per the wider staff turnover risk above. Clear, documented plans to enable more straightforward management of such a situation when it occurs.	In place – Peter Thompson In place - Yvonne Akinmodun with relevant Manager for specific role In place – Relevant Director alongside managers As required – Director and staff as relevant As required – Peter Thompson, Julia Chain As required – Peter Thompson
Recruitment to SMT or Head post often takes some time which could create a leadership gap.	Heads could temporarily act up into Director roles to manage any pre-recruitment gaps. The same would be true of manager-level staff acting up for Heads. Control employed to manage Chief Technology Officer recruitment gap.	In place, discussed as required – relevant Manager with Yvonne Akinmodun
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Status/timescale / owner**
Government/DHSC The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson
Government/DHSC DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA Board recruitment, it will be	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

Causes / sources	Mitigations	Status/timescale / owner
breaching its own legal responsibilities.		
Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. This may impact any planned approach and risk mitigations and give rise to further risk.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

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

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

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

Commentary
Cyber-attacks and threats are inherently 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.

Causes / sources	Controls	Timescale / owner
Insufficient board oversight of cyber security risks, resulting in them not being managed effectively.	Routine cyber risk management delegated from Authority to Audit and Governance Committee which receives reports at each meeting on cyber-security and associated internal audit reports to assure the Authority that the internal approach is appropriate and ensure they are aware of the organisation's exposure to cyber risk. The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual and perceived cyber risks. These would be discussed with the wider board if necessary. Cyber security training needs to be included in a standard induction process for Authority members. A new induction process will be introduced by the end of March 2022.	In place – Steve Morris In place - Peter Thompson Last undertaken January 2020. New course for Authority

Causes / sources	Controls	Timescale / owner
		members to be implemented Autumn 2021. – Steve Morris
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. Further training including lunch and learn sessions planned for Q1 2022. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. Policies currently under review, for completion by end of 2021-2022.. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact.	Undertaken by staff October/ November 2020 – Steve Morris Update agreed at CMG in June 2020– Steve Morris In place and ongoing process – Steve Morris
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. We undertake penetration testing regularly but a full network penetration test will cover access control, encryption, computer port control, pseudonymisation and physical control 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, – next cycle of testing for completion by March 2022– Steve Morris In place, reviewed in summer 2020 and fit for purpose – Neil McComb
The IT support function is small so 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. The support arrangement will be reviewed in 2022.	Contract in place until June 2023 – Steve Morris
We cannot mitigate effectively for emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations (such as ALB CIO network and NHS Digital Cyber Associates Network) to learn from others in relation to cyber risk. We receive regular security alerts and action the high priority ones when they arrive.	Ongoing– Steve Morris
Technical or system weaknesses could lead to loss of, or inability to access,	We undertake regular penetration testing to identify weaknesses so that we can address these.	Ongoing, next round of testing to

Causes / sources	Controls	Timescale / owner
sensitive data, including the Register.	We have advanced threat protection in place to identify and effectively handle threats. We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software.	complete by March 2022– Steve Morris In place – Steve Morris Ongoing (Upgrade to Pulse RAS system completed during summer 2021) – Steve Morris
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) to implement encryption. Conditional access being put in place for remote access by HFEA staff. This will reduce the risk of attack by devices that are not owned by HFEA.	Ongoing (regular reminders sent to staff with security best practice) – Steve Morris Conditional access should be complete by April 2022.
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.	In place – Steve Morris
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**
Status: **At tolerance**					

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

Commentary

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

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

Legal challenge poses two key threats:

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

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

In May, we were served with a Judicial Review claim. We filed our summary grounds of resistance and both the claim, and our summary grounds were considered by a judge, who refused permission to proceed with the Judicial Review claim. The Civil Procedure rules make provision for the claimant to renew their application by way of an oral hearing. At a hearing on 12 October the claim for Judicial Review was rejected. We now understand that the claimant has applied for permission in the Appeal Court.

Causes / sources	Mitigations	Timescale / owner
Legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics challenging decisions taken about their licence.	At every Licence Committee there is a legal advisor present and where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best possible position to make out a robust case and defend any challenge.	In place – Peter Thompson
Legal challenge if new science, technology, or wider societal changes emerge that are not covered by the existing regulatory framework.	Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning processes. This provides the organisation with foresight and may provide more time and ability to prepare our response to developments. Case by case decisions on the strategic handling of contentious or new issues to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	SCAAC horizon scanning meetings annually. In place – Catherine Drennan and Peter Thompson
Legal challenge to policies when others see these as a threat or ill-founded. Moving to a bolder strategic stance, eg, on add-ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Note: the current challenge as of September 2021 relates to this risk source.	Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed. Reviewing and updating existing policy on contentious issues if required. We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law and implemented related policy and respond effectively to challenge. Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics meaning that consideration of impacts and how these will be managed is considered as part of the policymaking process. Stakeholder involvement and communications in place during policymaking process (for instance via regular stakeholder meetings) to ensure that clinics and others can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Joanne Anton with appropriate input from Catherine Drennan Ongoing - Joanne Anton In place – Richard Sydee Ongoing - Joanne Anton

Causes / sources	Mitigations	Timescale / owner
Legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases). Ongoing legal parenthood and storage consent failings in clinics and related cases are specific examples. The case-by-case nature of the Courts' approach to matters means resource demands are unpredictable when these arise. Note: we are in dialogue with the Department on the proposed changes to the statutory storage period and the impact that it will have on consent for gametes and embryos currently in storage.	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action. Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly. We took advice from a leading barrister on the possible options for handling storage consent cases to ensure we take the best approach when cases arise. We also get ongoing ad hoc advice as matters arise. Significant amendments have been made to guidance in the Code of Practice dealing with consent to storage and this will be published in October 2021. This guidance will go further to supporting clinics to be clearer about the legal requirements. Storage consent has been covered in the revision of the PR entry Programme (PREP).	Ongoing – Catherine Drennan In place – Catherine Drennan In place – Peter Thompson Done in 2018/19 and we continue to apply this advice and take further ad hoc advice as required – Catherine Drennan Revised guidance– Catherine Drennan PREP in place – Catherine Drennan/ Joanne Anton
Committee decisions or our decision-making processes being contested. ie, Licensing appeals and/or Judicial Reviews. Challenge of compliance and licensing decisions is a core part of the regulatory framework, and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure	Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes. Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible. The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to	In place new version launched June 2021– Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer

Causes / sources	Mitigations	Timescale / owner
consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	ensure that it is clear if legal involvement is required, to allow for appropriate involvement and effective planning of work. Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes. Measures in place to ensure consistency of advice between the legal advisors from different firms. Including: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • Regular email updates to panel to keep them abreast of any changes. Consistent and well taken decisions at licence committees supported by effective tools for committees and licensing team (licensing pack, Standard operating procedures, decision trees etc) which are regularly reviewed.	In place – Peter Thompson Since Spring 2018 and ongoing – Catherine Drennan In place – Paula Robinson
Any of the key legal risks escalating into high-profile legal challenges resulting in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime.	Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public. The default HFEA position is to conduct litigation in a way which is not confrontational, personal, or aggressive. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement with them means that challenge is more likely to be focused on matters of law than on the HFEA. Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Catherine Drennan, Clare Ettinghausen In place – Peter Thompson, Catherine Drennan In place – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: If HFEA 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

Causes / sources	Mitigations	Timescale / owner
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. We highlight when science and medicine are changing so that they can consider whether to make changes to the regulatory framework. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson
DHSC: The Department may be a co-defendant for handling legal risk when cases arise.	We work closely with colleagues at the Department to ensure that the approach of all parties is clear and is coordinated wherever possible. We also pre-emptively engage on emerging legal issues before these become formal legal matters.	In place – Peter Thompson

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

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

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

Commentary
Risk management of these risk causes has been our organisational priority since the beginning of the pandemic. All staff were working from home (and returned to the office at least one day per week, from October 2021, followed by a return to working from home in December 2021 and January 2022). We remain able to operate on either basis. A strategy to manage inspections is in place. Communications to the sector and patients have been in place throughout and are ongoing as and when needed. We would revisit and revise our plans as circumstances change, as is possible in the autumn and winter. 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 2021 and decided that the effective inspection methodology reduced the impact of this risk, as the controls ensured we can 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. While the implementation has now bedded in well, any increase in infection rates later in the year is likely to impact the inspection team so we will monitor the effects on our delivery approach and review this if required. Preparations for the Covid public inquiry are under way, with relevant documents being catalogued. The extent of the HFEA's involvement in the inquiry is not yet known. **It is proposed that this risk be discontinued in June, and any residual elements (such as those relating to capacity) integrated into other risks as appropriate.**

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	Business continuity group (including SMT, Communications, HR, and IT) meeting frequently to discuss changes or circumstances and planning timely responses to these.	In place, ongoing – Richard Sydee In place - SMT and

Causes / sources	Controls	Status/Timescale / owner
undermining our authoritative position as regulator.	Out of hours media monitoring being undertaken, to ensure that we respond to anything occurring at weekends or evenings in a timely manner. Close communication with key sector professional organisations to ensure we are ready to react to any developments led by them (such as guidance updates). Proactive handling of clinic enquiries and close communication with them. Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth, and this is up to date. Enquiries team have additional support from Managers and Directors. We have reviewed our approach regularly to ensure that this is fit for purpose. Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.	Communic-ations team In place and ongoing – Clare Ettinghausen In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting Clare Ettinghausen – in place In place and under regular review – Joanne Anton In place – Clare Ettinghausen
Risk of being challenged publicly (eg during the Covid public inquiry) or legally about the HFEA response, resulting in reputational damage or legal challenge. (This risk also therefore relates directly to LC1 above)	As above – ensuring approach is appropriate. As above – continuing to liaise with professional bodies. We may choose to put out a press release in case of public challenge. Legal advice was sought to ensure that HFEA actions were in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged. Framework for decision making around removing GD0014 in place and Directions kept under periodic review.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Clare Ettinghausen Done – Peter Thompson If required – Peter Thompson, Catherine Drennan In place – Rachel Cutting and

Causes / sources	Controls	Status/Timescale / owner
	Preparations for the Covid inquiry are under way to ensure we are ready to respond as needed.	Catherine Drennan In progress – Clare Ettinghausen
Gaps in HFEA staffing due to sickness, caring responsibilities etc	Possible capability gaps have been reviewed by teams to ensure that these are identified and managed. Other mitigations as described under the C1 risk.	In place – Yvonne Akinmodun
Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds. Note: we do not have evidence of this being an issue within the HFEA.	Decision taken to delay routine return to the office subject to government guidance, reducing work-related risk. We are engaging with other similar organisations to consider possible approaches to managing this risk. We have considered the impact as part of planning for the return to inspections and office working, including individual risk assessments for inspection staff, performed before each inspection.	In progress – Yvonne Akinmodun In place – Sharon Fensome-Rimmer
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
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: this risk may be both short and longer-term if clinics close as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity. The final contingency would be to seek additional cash and/or funding from the Department.	In place – Richard Sydee Ongoing discussions if needed as ongoing impact becomes clearer – Richard Sydee
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 must WFH without suitable arrangements in place. Ability of staff unable to work from home to work in Covid-19 secure office. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing –

Causes / sources	Controls	Status/Timescale / owner
	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. Pulse wellbeing survey to assess impact.	Yvonne Akinmodun September 2021 and reoccurring quarterly – Yvonne Akinmodun
Inability of staff to return to office working may negatively impact organisational culture, reduce collaboration, or hamper working dynamics and productivity. Note: This risk will affect the organisation for some time including when we return to the office, while social distancing is in place and office working is significantly reduced due to Covid-19 restrictions. The ongoing consideration of this risk is reflected within the OM1 risk.	Discussion about return to office working at CMG to ensure that this is planned effectively, and impacts considered. This is occurring on a month-by-month basis in the run up to returning to the office. Online solutions to maintain collaboration and engagement, such as informal team engagement and 'teas', Microsoft Teams etc.	Ongoing – Peter Thompson In place – Heads
Risk that we miss posted financial, OTR or other correspondence.	Arrangement in place to securely store, collect and distribute post. Updated website info to ask people to contact us via email and phone. We notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.	In place– Richard Sydee In place – Clare Ettinghausen 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.	Use of cash reserves, up to appropriate contingency level available. The final contingency would be to seek additional cash and/or funding from the Department. (Additional Grant in Aid was provided for the 2020/2021 business year).	Richard Sydee

Reviews and revisions

SMT review – 21 February 2022:

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

- RF1 updated to reflect the latest position related to the ongoing effects of earlier Covid impacts.
- I1 will need further work when our new communications strategy is more advanced. This risk will then be reframed, to focus more on the risks to us achieving the desired impact and reach with our information.
- P1 updated, but as with the above risk, may need to be updated further as we progress the work on our communications strategy.
- FV1 comprehensively updated following the approval of HMRC for our fees increase this year.
- C1 updated slightly throughout, including the addition of an 'in common' risk affecting all ALBs relating to recruitment in the current job market.
- C2 revised to update the position on Board appointments. The risk score has been lowered. The tolerance threshold has also been raised.
- CS1 updated significantly following a planned review.
- LC1 no significant changes have been made on this occasion.
- CV1 updated to reflect the current position. It is proposed that this risk be retired (with AGC's permission sought in March) in or around June, at which point any remaining elements could be fed into the ongoing capability risk.

SMT review – 14 January 2022:

SMT reviewed all risks, controls and scores and made the following points in discussion:
SMT reviewed the risks and agreed to review several of the risks in more detail after the meeting, as follows:

- RF1 to be reviewed in light of comments at AGC.
- I1 to be reviewed in light of our latest thinking on the communications strategy and the forthcoming paper to the Authority about this.
- P1 to be reviewed to include the possibility of the Act not being reviewed in the next few years.
- FV1 to be reviewed in light of latest Q3 position and to update the commentary to reference the covid inquiry, storage regulations, PRISM handover and the latest position on fees and funding.
- CS1 to be referred to the Head of IT for review following recent work on device security.

SMT considered the point raised at AGC about risk tolerances, but felt that the tolerances set remain appropriate for the time being. While it is not ideal that several risks remain above or at tolerance, there are no further controls to add at the present time, and it remains very unlikely that all of the risks would become live issues simultaneously. While risks are running above tolerance, this tends to create more strain in the system, rather than making the risk unmanageable. It will likely mean increased effort and possibly some resource diversion at times, and so we would seek to implement any further controls we can identify in order to bring the risk back within tolerance. There will be occasions, however, when there are no more actions we can take. It is worth noting that the intended future control of obtaining additional resources would make a positive difference, if achieved, to the tolerability of a number of the risks.

AGC review – 9 December 2021:

AGC noted a report and presentation including an update on all risks, controls and scores and made the following points in discussion:

- The plan for reviewing the risk system in line with earlier input was noted. An outline plan and timetable should come to the next AGC meeting.
- RF1 – may need to be reframed to reflect that our work on the Act may see us seeking new powers. A question was also raised about whether the impact of the Covid restrictions on inspection meant that we had been in breach of the law – it was confirmed that it was a statutory duty to inspect clinics every two years, and that while this had not been possible, other methods had been adopted to ensure that clinics were safe and patients were not at risk.
- C1 – changes were noted.
- I1 – it was noted that this risk was now slightly over tolerance. It was suggested that the communications strategy should be incorporated into the risk description.

- C2 – the update on leadership capabilities and succession planning was noted.
- CS1 – noted the current work being done to improve our resilience against ransomware and hacking attacks, and that this risk would be reviewed shortly.
- P1 – members asked if we needed to increased the rating for this risk. If we failed to keep up the momentum, we would need to consider the consequences.
- The Committee was keen to see more horizon scanning incorporated into the risk register, to anticipate upcoming areas of risk.
- Members questioned whether having so many risks above tolerance was factually correct, as this implied that everything was collapsing, and this evidently wasn't the case. It was worth considering whether the tolerances, or the overall risk appetite, may have changed.

SMT review – 1 November 2021:

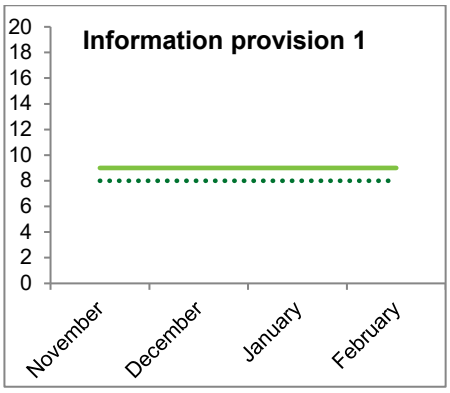
SMT reviewed all risks, controls and scores and made the following points in discussion:

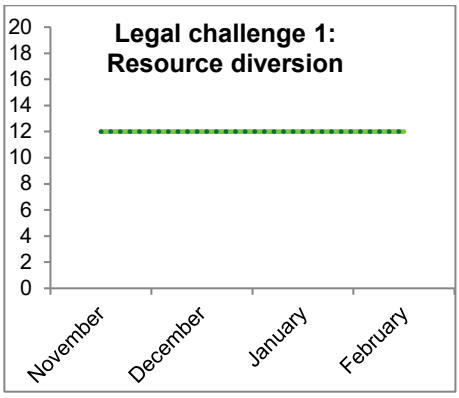
- RF1 - Risk sources relating to general capacity and capability challenges should be reflected in risk C1, since they were not linked to the regulatory framework itself.
- I1 – The residual risk likelihood score was increased slightly, in recognition of points raised at AGC. The next CMG meeting would need to discuss managing the gap in CAFC reporting (until Autumn 2022). Discussions about this are ongoing. New performance measures are being developed to enable reporting to the Authority on the OTR backlog.
- C1 – SMT reflected on discussions at AGC, and agreed that the points about upcoming risks and new areas of work should be reflected in this risk. Our 'business as usual' work continues to expand, and this is a risk without additional resources to meet the new requirements.
- C2 – There was no news at the time of this review about the possibility of extending members' terms of office (three extensions were subsequently agreed). The November Authority meeting would be the last for some members, so we did need to know the outcome. Extensions would help us to manage licensing quoracy in the new year. Were a member of the senior executive team to leave, the appropriate mitigations would depend on the role, but mitigations include delegating some responsibilities to remaining members of SMT and/or the relevant Head(s) and the appointment of an interim, where professional skills allow. Recruitment to a senior role will usually take longer than the 3 months contractual notice and so there will inevitably be a gap to manage.
- CS1 – SMT agreed this risk should be reviewed following recent discussions at CMG about cybersecurity, especially in relation to the use of personal devices and members' personal email accounts.
- OM1 – SMT considered that this risk had changed. Some elements were dealt with, and others related relating mainly to capacity and capability issues. It was therefore agreed that this risk would be merged into C1, removing those elements that were now out of date.
- LC1 – this risk has potentially reduced somewhat, since the recent JR proceedings had been rejected by a court. However, there may yet be an appeal, and so the residual risk score has not been reduced at this time.
- CV1 – SMT considered whether this risk was still pertinent at this stage in the pandemic, but agreed that it was. Infection rates were currently high again, and factors around vaccinations could still potentially affect clinic on-site visits. The inherent risk score was lowered. We will continue to monitor this risk.

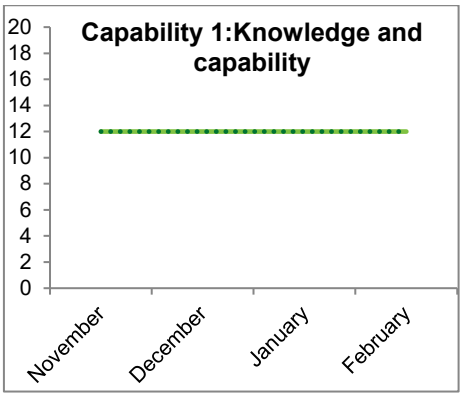
Risk trend graphs (February 2022)

Key:

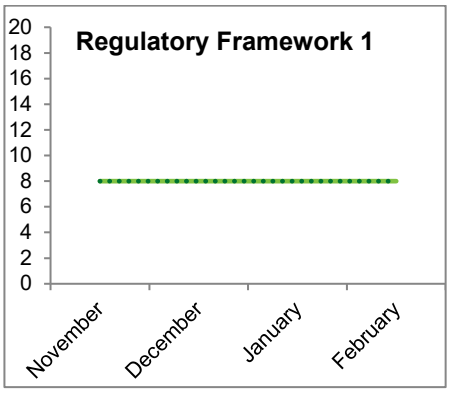
High and above tolerance risks

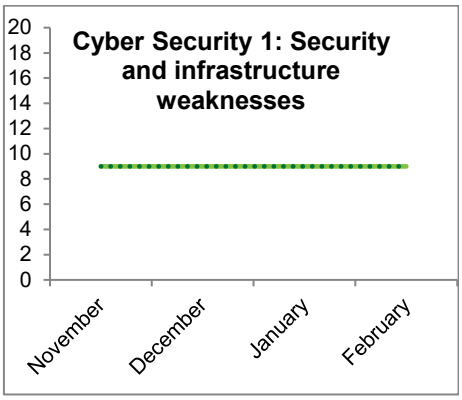


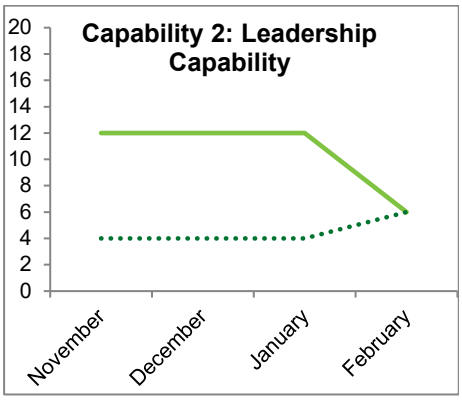


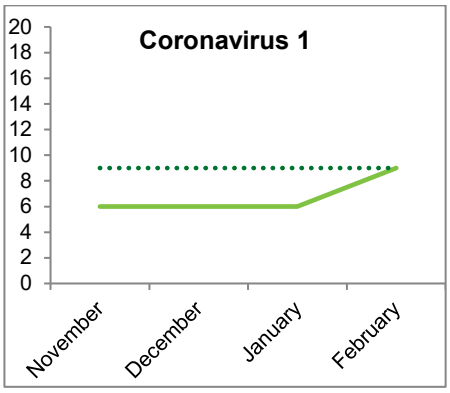


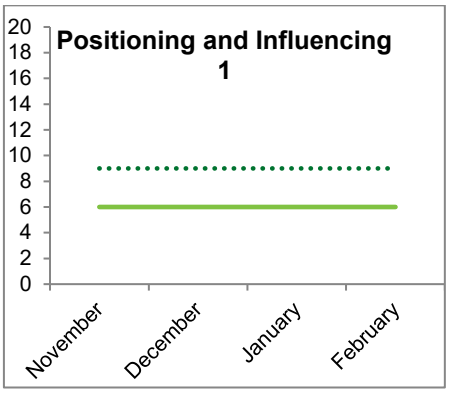
Lower and below tolerance risks

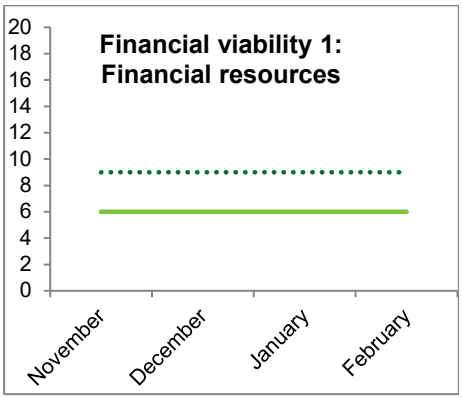












Criteria for inclusion of risks

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

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

Rank

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

Risk trend

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

Risk scoring system

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

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

Risk scoring matrix

Impact	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
Risk Score = Impact x Likelihood	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.

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	10
Meeting date	15 March 2022
Authors	Steve Morris, Head of IT and Neil McComb, Head of Information
Output:	
For information or decision?	For information

Recommendation	The Committee is asked to note:
	• Infrastructure improvements
	  ◦ Improvements to IT security that have been implemented and those yet to be completed.
	  ◦ Immediate actions requested by DHSC of Arm's-Length Bodies (ALBs) as a result of the UK stance on the escalating war in Ukraine
	  ◦ Business continuity policy update
	  ◦ Progress on upgrade of electronic document management system
	• Current position on Data Security and Protection Toolkit

Resource implications	Within budget
Implementation date	Ongoing
Communication(s)	Regular, range of mechanisms
Organisational risk	☐ Low ☒ Medium ☐ High

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 cyber security in a number of areas.

1.3. It also includes an update on our current approach to submitting evidence for next year's Data Security and Protection Toolkit

2. Infrastructure improvements

IT security changes

2.1. At CMG on 20th October a number of changes to IT security arrangements were proposed and agreed. These changes will provide greater protection for HFEA from cyber-attacks such as ransomware. Most of these changes have now been implemented

- HFEA staff are no longer be able to access HFEA's instance of O365 (inc email) from non-HFEA laptops
- Access to IT resources in HFEA (the Register for example) is only possible from within the UK (temporary exceptions can be made)
- It is not possible to auto-forward emails from HFEA accounts. Individual emails can be forwarded.
- Emails to and from Authority members are only be exchanged using their HFEA email accounts. This and more, is explained in a new Authority IT induction document.

2.2. Two pieces of work agreed by CMG have not yet been completed.

- Changes to how HFEA email can be accessed from personal mobile phones. Work on this has not yet commenced.
- Implementation of web filtering (aka 'net nanny') to prevent access from HFEA laptops to known malware and phishing web sites. We expect this to be implemented by 11th March.

Increased threat as a result of the war in Ukraine

2.3. DHSC emailed all ALBs week commencing 28th February, to request a number of immediate actions to mitigate possible risks arising from the Russia/Ukraine conflict. It is possible that cyber-attacks will be directed at UK Gov IT. The response from HFEA is summarised below.

- Patching – All our production servers are in Azure and are automatically patched via Azure Update Services. We will bring the dev/test servers into the same regime asap, they are currently managed automatically by Windows. We will also implement exception reporting, ie get reports on any updates that fail.
- Access control – We have MFA on all accounts.
- Monitoring – NCSC alerts are sent to the itsupport@hfea.gov.uk account where they can be accessed by all support personnel.

- Backups – Everything is backed up every night. We have successfully restored all the databases for our reporting infrastructure. We have also restored the data warehouse from deep archive. We need to restore a copy of the principal Register database onto the reporting server for data comparison purposes, so we'll be sure that recovers fine. Beyond that we will restore an example server and the fileshare. There is little more we can test in respect of recovery.

  NB, all backups are done in Azure and are safe from ransomware attacks that encrypt production services.

- Incident response and Business continuity planning – We have updated the BC policy this week.
- Awareness – We email staff frequently on risks and these were re-iterated by our Chief Executive at an All Staff call on 1st March. We will communicate again next week after we put in place web filtering.

Business continuity policy update

2.4. This has been updated in draft form by the IT team and, at the time of writing, awaits sign-off by senior management.

EDRM upgrade (electronic document and records management system)

2.5. It has taken longer than expected to complete all pre-requisites. The upgrade of the EDRM server is now planned for 4th to 7th March. Staff have been informed of the change and the expected downtime.

3. Data Security and Protection Toolkit (DSPT)

Background

3.1. 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. It was the first time we have submitted an end of year annual DSPT return.

3.2. The DSPT sets both mandatory and non-mandatory requirements. There are 42 detailed requirements and 37 of them are mandatory. We chose to assess ourselves against the 37 mandatory requirements only.

3.3. 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 88.

3.4. AGC will recall that we submitted our mid-year interim assessment in February 2021 and at the time we forecast that we would not be fully compliant with the mandatory DSPT requirements for the annual submission in June 2021.

Final Report

3.5. The final DSPT report found the HFEA to have an overall rating of 'unsatisfactory'.

3.6. They noted that:

"HFEA do not have a structured evidence submission process or the benefit of experience from previous years to draw upon and have not had sufficient time to develop one. HFEA have been transparent in their decision to focus on mandatory assertions

only however, documentary evidence to support the assertions have not been uploaded into the toolkit by HFEA and we have not been provided with the suite of off-line evidence on which we can provide assurance that assertions are accurate and fully supported."

3.7. They also provided a number of recommendations to accelerate knowledge and experience to avoid future evidence provision weaknesses and to offer greater assurance that data security and protection controls are operating and are effective.

Recommendation 1	HFEA should develop a structured approach to future Toolkit population with a nominated Toolkit lead and line of business representatives specifically tasked with acquiring tangible evidence of the actual controls employed to manage data security and protection.
Recommendation 2	HFEA to re-examine the evidential needs of the Toolkit and use this to re-evaluate and re-design where appropriate all of their information and security management processes.
Recommendation 3	Conduct a lessons-learned exercise to support the development of the framework described in recommendation 1.
Recommendation 4	To reach out to similar organisations deemed more mature in the process of the Toolkit completion to learn from their experience, process and techniques.

Follow up

3.8. The HFEA have already conducted a lessons learned review during a meeting with the SIRO, Director of Compliance and Information and the new Head of Information.

- It was agreed that the recommendations should be actioned.
- It was noted that the failings in the Toolkit submission was due to staff inexperience with the process rather the quality of security practices.
- It was noted that the failings mentioned in the report were not linked to failings in HFEA data security, but rather in the evidencing of them.
- It was agreed to quickly reach out to colleagues in the HRA to learn from their experiences

3.9. On meeting with representatives from the HRA it became clear that they had a much more robust process to address all the necessary assertions in the toolkit, clear lines of responsibility for evidencing those assertions and processes by which that documentation could be collected.

3.10. Since the last paper to AGC, CMG has agreed our new approach to collecting evidence for submission to the toolkit. A new panel consisting of the SIRO, the Head of I.T, the head of information and the IG manager has been created and has already met for the first time.

3.11. This panel has assigned owners to each of the requirements in the toolkit and the IG manager has set up meetings with these owners to explain the documentation they need to provide as evidence. This will be kept in a log and presented at further meetings of the panel with the SIRO having the final say on whether the supplied information is sufficient for the toolkit requirement.

3.12. The next meeting of this panel will take place on 6th April.

3.13. Due to the newness of this approach and the lack of knowledge we have been able to gain from the last submission it is unlikely we will meet all the requirements in the Toolkit for 2022. We will however be able to show evidence of improvement and a desire to continue that improvement until we can meet all necessary requirements in future submissions.

Public Interest Disclosure (Whistleblowing) Policy

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	AGC
Agenda item:	11
Meeting date:	15 March 2022
Author:	Morounke Akingbola, Head of Finance
Annexes	Annex 1: Whistleblowing Policy Annex 2: N/a

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 2021. Since then, a review has been undertaken to ensure the policy is still fit for purpose.

2.2. There have been some small amendments to this policy as detailed below:

- Para 5.2, item (b);
- Para 7.1, the last sentence has been added;
- Para 7.11, referring to section 2-15 within the fraud policy and finally
- Para 12 – review period of bi-annually or if changes in law

2.3. The Committee are requested to comment and agree the changes in particular the review period.

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) there is possible fraud and corruption
(c) a person has failed, is failing or is likely to fail to comply with any legal obligation to which he is subject,
(d) a miscarriage of justice has occurred, is occurring or is likely to occur,
(e) the health and safety of any individual has been, is being or is likely to be endangered,
(f) the environment has been, is being or is likely to be damaged, or
(g) 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.

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

6.4 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. This procedure should also be used where there is suspected fraud, bribery, or corruption.

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/they should report to if the individual believes that he/she/they is/are 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[1]
Deputy Chair	Chair

[1] 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 In cases of suspected fraud, the above process in conjunction with the Counter Fraud Policy (sections 2 – 15) should be followed. All cases should be reported to the Director of Finance and Resources in the first instance.

7.12 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.

7.13 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

7.14 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.

7.15 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."

7.16 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/

7.17 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.

7.18 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.

7.19 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/

7.20 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

11.2 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:

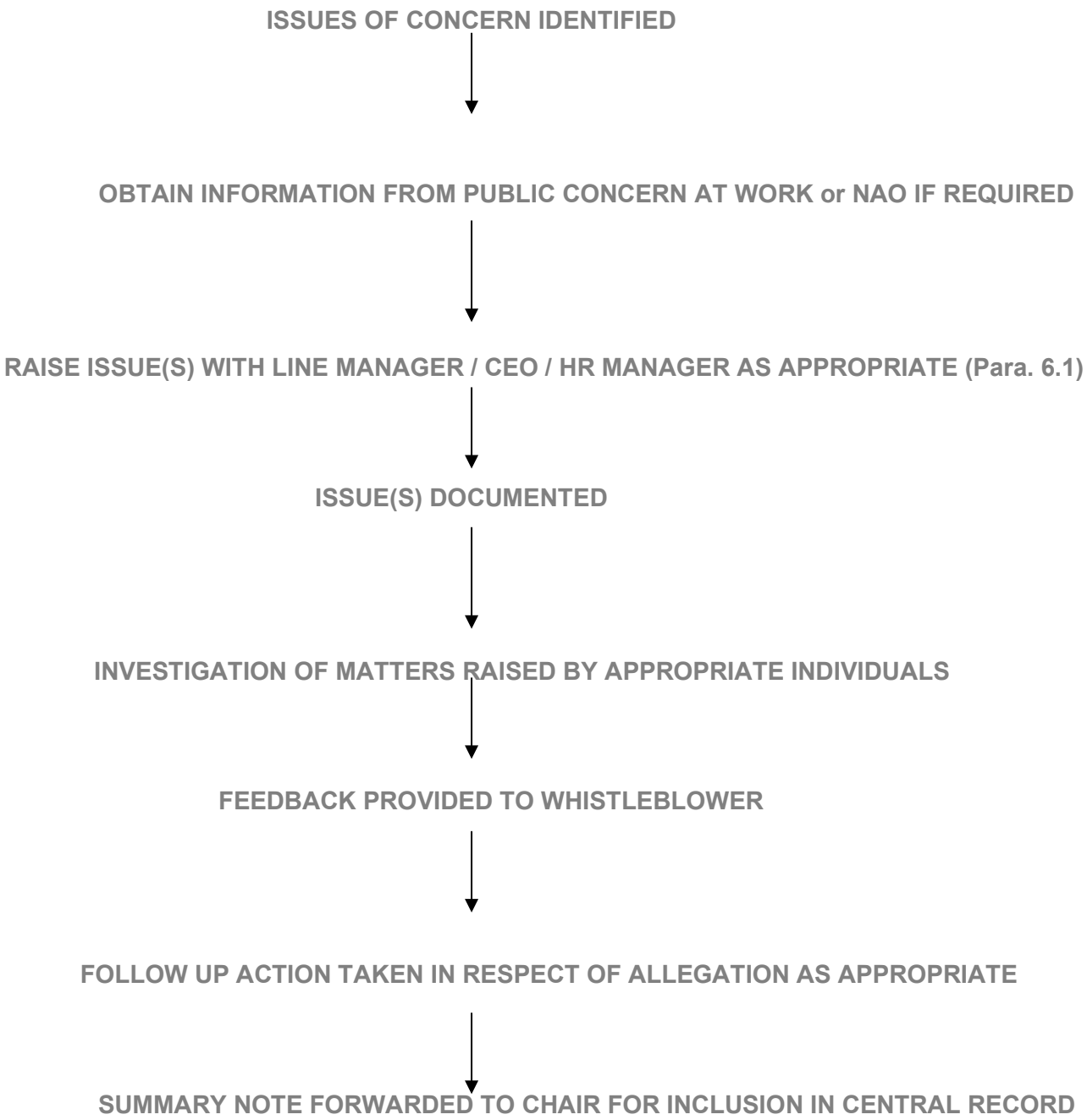
11.4 Under the provisions of the Public Interest Disclosure Act 1998 employees of an organisation are able to disclose publicly (under certain circumstances) their concerns about legitimacy or public interest aspects of the organisation within which they work. Although the Act requires that concerns 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.

12. Review

12.1 This policy will be reviewed by the Audit and Governance Committee bi-annually or earlier if there are changes in the law that significantly impacts this policy.

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.

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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/section added for Fraud investigation	Head of Finance	AGC	December 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 The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	AGC
Agenda item:	11
Meeting date:	15 March 2022
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 2021. Since then, a review has been undertaken to ensure the policy is still fit for purpose. The policy was revied in on 24 November 2021.

2.2. There have been no changes to this policy.

2.3. The Committee are requested to provide any comments or additions to this policy, note that there have been no changes.

2.4. The Committee are also requested to consider that this policy be brought every 2 years or earlier if there are changes in law that may affect 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. does 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

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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
2.5	No changes	Head of Finance	AGC	March 2022

Appendix: 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.

Human Fertilisation & Embryology Authority

Strategic Risk Deep Dive - Finance

Details about this paper

Area(s) of strategy this paper relates to:	
Meeting:	Audit & Governance Committee
Agenda item:	
Meeting date:	22 March 2022
Author:	Richard Sydee, Director of Resources
Annexes	Risk Assurance Map – FV1

Output from this paper

For information or decision?	For information
Recommendation:	The committee note a first pass on assurance mapping for the HFEA's Finance risk and the current material issues being managed within the Finance & Resources Directorate
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	High

1. Introduction

1.1. Following discussion at the last AGC meeting this paper outlines an approach to "Deep dive" into particular risks within the HFEA risk register, providing more information on specific risks and placing Directorate updates in the context of strategic risk management.

1.2. Also attached is a fist draft at providing an assurance map on the financial risk, outlining controls and mitigations in more detail as well as the recent activities undertaken to provide assurance to the Executive and AGC that mitigation is live

2. Background

2.1. The HFEA's financial management risk focuses on the volatility in income, given the reliance on sector activity and the inherent risk that it falls below budgeted expectations, and across a broad range of financial controls and management overview of financial performance.

2.2. Although we accept that there are potential factors outside of our direct control, sector activity as mentioned above and the medium-term risk of falling Grant in Aid (GiA) funding from DHSC, overall, the risk is mitigated through routine management accounts production and review as well as trend analysis of sector activity.

2.3. We also retain several levers that can control in year expenditure to mitigate income risks. Through business case submission for projects and a clearance process for any staff recruitment we can, on the whole, manage expenditure within year and address longer term funding needs through our modelling and annual budgeting process

2.4. Annex A presents a first cut of an assurance map for the finance risk, highlighting causal factors as well as current controls and mitigations. The committee are invited to discuss the content and indicate whether there is sufficient granularity and assurance provided within the annex

3. Material issues

3.1. There are a number of areas to note that will impact on either our year end position or will require regular monitoring in the next financial year.

2021/22 Income position

3.2. As the committee are aware the HFEA have been invoicing licensed establishment based on average historic activity since August 2021. We have taken a prudent approach to expenditure to ensure we provide a reasonable buffer ahead of the reconciliation process we expect to conclude at year end, but it is possible that activity in the sector has been materially higher that currently invoiced.

3.3. We do expect most clinics to have caught up with data submission by the end of this business year, with the expectation that 2022/23 will begin with invoicing to most clinics based on submitted activity

Spending Review 21

3.4. At the point of writing, we still await confirmation of the HFEA's GiA settlement for the three-year SR21 period. GiA is approximately 15% of our 2022/23 income budget, but a material reduction would place pressure on some planned areas of expenditure. Our submission to the Department also includes a request for additional funds to support preparations for the end of Donor anonymity in 2023.

Fees model review

3.5. The HFEA recognise the need to evaluate our current approach to licence fees in order to better reflect the types of activity undertaken across our sector and to ensure that we recover the cost of regulation fairly based on the regulatory burden.

3.6. This work will require considerable internal resource to review activity data, consider and evaluate the regulatory and information provisions now being placed on the HFEA before developing and consulting with stakeholders on possible new models. Although we retain the ambition to do this work this will have to be considered in the light of other business priorities and could extend beyond the next business year.

4. Directorate risks

4.1. The Resources Directorate continues to manage a number of operational risks that could impact on the delivery of strategic aims.

4.2. Although a Directorate in name the function is delivered by a team of 4 people equating to 3 FTE. All positions therefore represent single points of failure, with the pending loss of 1 staff member to an internal promotion posing a short-term risk to processing and reporting tasks. We have detailed processes and procedures documented that will facilitate new postholders, and plans are in place to mitigate the immediate loss through agency staff

4.3. Finance systems are a key component of our control regime. Although our core system has recently been migrated to the cloud our purchase order system should be considered for upgrading. Linked to paragraph 4.2 we will look to begin work on commissioning a single financial system for both the HFEA and HTA, with whom senior staff are shared, to introduce an updated financial management system that can meet future needs and we hope add resilience to a small function through further integration of the 2 finance teams.

4.4. At the

5. For discussion

5.1. Members are asked to:

- Note the risks as outlined in the paper and detailed in the risk assurance map
- Note the material issues highlighted
- Note the direction of travel outlined for managing the Directorate's internal risks

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY L	INHERENT RISK PRIORITY I	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY L	RESIDUAL RISK PRIORITY I	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
FV1	*There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims* *Risk Owner:* *Richard Sydee, Director of Finance & Resources*	***Cause*** • *There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.* • *Our monthly income can vary significantly as:* • *it is linked directly to level of treatment activity in licensed establishments* • *we rely on our data submission system to notify us of billable cycles.* • *Management fail to set licence fees at a level that recover sufficient income to meet resource requirements* • *Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.* • *Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.* • *Project scope creep leads to increases in costs beyond the levels that have been approved.* • *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.* • *Fraudulent activity detected too late* • *DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.* • *DHSC: GIA funding could be reduced due to changes in Government/policy.* ***Effect*** • *Payments to suppliers and/or staff delayed* • *Compensatory reductions in staff and other expenditure budgets* • *Increased licence fees* • *Requests for further public funding* • *Draw on reserves* • *Failure to adhere to Cabinet Office Functional Standards* ***Leading to:*** • *Inability to deliver operations and carry out statutory remit* • *Reputational damage and breach of HMT Accountong Officer principles*	*3*	*4*	Ongoing	Budget management framework to control and review spend and take early action	2	3		9	X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Revised version reviewed by SMT
						Financial projections, cash flow forecasting and monitoring					X			Monitoring	Monthly finance reports to SMT and to each Authority. Quarterly reports to DHSC	Last quarterly report to Board in November 2021
						Licence fee modelling								Preventative	Annual update to fees model	No change to fees agreed by the Board November 2021 meeting
						Rigorous debt recovery procedure					X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of outstanding debt is being reduced. Older debt are being collected. Although we maintain a tight grip on our position, the overall environment is more uncertain than normal.
						Reserves policy and levels reserves					X			Monitoring	Reserves policy reviewed annually and agreed by AGC	Last agreed by AGC October 2020
						Delegation letters set out responsibilities					X	X		Preventative	Delegation letters issued annually	Issued in April 2021
						Fees model provides cost/income information for planning					X			Preventative	Annual review of fees modelling, reported to SMT and Authority	Went to the Board November 2021
						Annual external audit							X	Detective	NAO report annually	Unqualified Accounts produced June 2021
									Monitoring of income and expenditure (RS) **Ongoing**				X	Detective	Monthly finance reports to Directors, discussed at SMT and to each Authority. Quarterly reports to DHSC	Last quarterly report January 2022
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) **Ongoing**		X	X		Detective	Quarterly Finance Directors and Accountability meetings	DHSC DG Finance holds monthly meetings with DHSC ALB FDs. FD from NHS Resolution, HRA, NICE and CQC maintain contact over common issues monthly. Quarterly meetings with DHSC, which cover finance and non-finance issues/risks.
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards		X	X		Preventative	Counter fraud Strategy and Action Plan developed and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office - CDR submissions made quarterly last submission April 2021 (Q4 2020/21). Counter-fraud activities now part of BAU.

Implementation of IFRS 16: Leases. Impact on the Statement of Financial Position

Details about this paper

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

Meeting	AGC		
Agenda item	13		
Meeting date	15 March 2022		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	The Committee are requested to note the update		
Resource implications			
Implementation date	2022/23 business year		
Communication(s)			
Organisational risk	☐ Low	**X** Medium	☐ High

Leases

Overview of Leases

1. IFRS 16 is applicable to most public sector organisations and for the HTA, and other ALBs, is effective from 1 April 2022. This new standard amends the accounting for leases, removing the distinction between recognising an operating lease (off balance sheet) and a finance lease (on balance sheet).

2. This new standard requires recognition of most leases, which last more than 12 months, to be recognised on the balance sheet.

3. There are exceptions where a lease need not be recognised and these are:

    a. Where the lease is of low value £5,000 has been used as a guide (i.e., tablet, personal computers, telephones, photo copiers)
    b. Where the lease term ends within 12 months of initial application of the standard (short term leases i.e., software licences, some property leases).

Definition of a lease

4. The standard defines a lease as a contract that 'conveys the right to control the use of an identified asset for a period of time in exchange for consideration'.

    - Software as a service (SaaS) – licensing and delivery model in which software is licenced on a subscription basis.
    - Licence agreements renewable annually
    - Contracts for service – such as Internal Audit
    - Contracts for support/maintenance

5. The HFEA has 8 contracts in total, of which one meets the definition of a lease as per the standard. The remaining contracts were also of a low value and expire within 12 months, and therefore would not be included on the Statement of Financial Position (Balance Sheet).

6. The contract relating to the HFEA's occupation of the second floor at 2 Redman Place meets the definition of a lease. Due to the continued delay in implementing IFRS 16, the lease is currently being treated under IAS17 as an operating lease therefore expensing the rent costs.

7. The new lease was signed by the DHSC on the 27 January 2021. For the accounting year ending 31 March 2022, the HFEA will be required to disclose the expected impact of introducing IFRS 16 from April 2022 onwards within its accounting policies.

8. From 1 April 2022, the HFEA's Statement of Financial Position will be impacted by the numbers below:

   Lease term - 10 years

   Annual Rent - £138k (this figure is taken from the latest signed MOTO with DHSC, and whilst invoices have been received for quarters 1 and 2 of 2021/22) we are still awaiting confirmation on how the rent-free period will be factored into the invoiced rent costs).

   Discount rate used is per HMT PES paper 0.95%

9. IFRS 16 requires all lessee leases (with two exemptions noted at paragraph 12 below) to be accounted for as finance leases, recognising the rights to use an asset i.e., accounted for as though the Authority had purchased the asset.

10. These changes to IFRS16 do not apply where the HFEA is acting as the lessor.

11. To account for a leased asset as though we had purchased it requires us to determine three things to support the initial recognition of the asset:

    - The value of the asset being leased;
    - How much to charge to the income and expenditure account each year for the amount of the assets value used; and
    - How the asset will be financed.

12. Impact on the balance sheet would be:

    - Increase in non-current assets £1,380k (Present value of lease payments over 10 years (Right of Use Asset).
    - Increase in long term liabilities £1,380k (Lease Liability)

13. Impact on the I&E (Profit and Loss account)
    - Annual Depreciation charge £131k
    - Annual Interest charge will vary however first year would be £12k. The rental payment of £138k will be eliminated and the net impact on the income and expenditure account would be £6k in the first year, reducing through out the period of the lease.

14. For the 2021/22 business year, reporting bodies are only required to disclose how the standard would have impacted on the accounts were it applied in that year.

15. Committee members are requested to note the impact.

Audit and Governance Committee Forward Plan

Strategic delivery:	☐The best care – effective and ethical care for everyone	☐The right information – to ensure that people can access the right information	☐Shaping the future – to embrace and engage with changes in the law, science and society
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	12		
Paper number	AGC (15/30/2022) MA		
Meeting date	15 March 2022		
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. *Receive confirmation of bi-annual review of Fraud/Whistleblowing policies.*		
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:	15 Mar 2022	28 Jun 2022	5 Oct 2022	8 Dec 2022
Following Authority Date:	23 Mar 2022	6 July 2022	16 Nov 2022	TBC
Meeting 'Theme/s'	Finance and Resources (Deep dive)	Annual Reports, Information Governance, People	Strategy & Corporate Affairs (Deep dieve), AGC review	Register and Compliance, Business Continuity (Deep dive)
Reporting Officers	Director of Finance & Resources	Director of Finance & Resources	Director of Strategy and Corporate Affairs	Director of Compliance and Information
Strategic Risk Register	Yes	Yes	Yes	Yes
Risk Management Policy[1]		*Confirm*	*Confirm*	
Digital Programme Update	Yes	Yes		
Annual Report & Accounts (inc Annual Governance Statement)	Draft Annual Governance Statement –	Yes – For approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report		Audit Planning Report
Information Assurance & Security		Yes, plus SIRO Report		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Results, annual opinion approve draft	Update	Update	Update

[1] Policy will have been reviewed by the Executive, including updated appetite statement for Authority approval.

AGC Items Date:	15 Mar 2022	28 Jun 2022	5 Oct 2022	8 Dec 2022
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Public Interest Disclosure (Whistleblowing) policy	Reviewed and presented every 2 years			
Anti-Fraud, Bribery and Corruption policy	Reviewed and presented every 2 years thereafter			
Counter-fraud Strategy and progress of Action Plan	*Moved to June*	Counter Fraud Strategy; Action Plan and FRA		
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		Bi-annual HR report
Strategy & Corporate Affairs management			Yes	
Regulatory & Register management				Yes
Cyber Security Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes – deep dive			
Reserves policy			Yes	
Estates	Yes	Yes	Yes	Yes
Review of AGC activities, terms of reference				Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes

AGC Items Date:	15 Mar 2022	28 Jun 2022	5 Oct 2022	8 Dec 2022
Session for Members and auditors	Yes	Yes	Yes	Yes