Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

23 June 2020

Online

Agenda item			Time
1.	Welcome, apologies and declaration of interests		10.00am
2.	Minutes of 3 March 2020 **[AGC (23/06/2020) DO]**	For decision	10.05am
3.	Matters arising **[AGC (23/06/2020) MA]**	For information	10.10am
4.	Internal audit – annual opinion, draft plan **[AGC (23/06/2020) TS]**	For decision	10.15am
5.	Progress with internal audit recommendations **[AGC (23/06/2020) MA]**	For information	10.30am
6.	Information security – SIRO report **[AGC (23/06/2020) RS]**	For Information	10.40am
7.	Annual report and accounts **[AGC (23/06/2020) RS]**	For information	10.50am
8.	External audit – audit completion report **[AGC (23/06/2020) MS]**	For information	11.10am
9.	Resilience, business continuity management cyber security **[AGC (23/06/2020) DH]**	For information	11.25am
10.	Digital programme update **[AGC (23/06/2020) HC]**	Verbal update	11.35pm
11.	Strategic risk register **[AGC (23/06/2020) HC]**	For information	11.45pm
12.	Human resources – bi-annual report **[AGC (23/06/2020) YA]**	For information	12.00pm
13.	AGC forward plan **[AGC (23/06/2020) MA]**	For information	12.15pm
14.	Gifts and hospitality register **[AGC (23/06/2020) MA]**	For information	12.20pm

15.	Whistle blowing, fraud **[AGC (23/06/2020) RS]**	Verbal update	12.25pm
16.	Contracts and procurement **[AGC (23/06/2020) MA]**	Verbal update	12.35pm
17.	Estates update **[AGC (23/06/2020) RS]**	Verbal update	12.40pm
18.	Any other business		12.55pm
19.	Close		1.00pm
20.	Session for members and auditors only		

Next Meeting: 10am Tuesday, 6 October 2020, Online

Minutes of Audit and Governance Committee meeting 10 March 2020

Details:			
Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence		
Agenda item	2		
Meeting date	23 June 2020		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Minutes of the Audit and Governance Committee meeting on 10 March 2020 held at Chartered Institute of Arbitrators, 12 Bloomsbury Square, London WC1A 2LP

Members present	Anita Bharucha Margaret Gilmore Mark McLaughlin
Apologies	Geoffrey Podger
External advisers	Mike Surman, NAO Jill Hearne, NAO Tony Stanley, Audit Manager – GIAA Karen Holland, Group Internal Auditor - GIAA
Observer	Dafni Moschidou (Department of Health and Social Care - DHSC)
Staff in attendance	Peter Thompson, Chief Executive Richard Sydee, Director of Finance and Resources Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cutting, Director of Compliance and Information Morounke Akingbola, Head of Finance Dan Howard, Chief Information Officer Kevin Hudson, Programme Manager Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager Moya Berry, Committee Officer Debbie Okutubo, Governance Manager

1. Welcome and declarations of Interest

1.1. The Chair welcomed everyone present, including those who joined online. The Chair also gave a special welcome to Karen Holland, GIAA, attending her first meeting and Moya Berry, Committee Officer who was also in attendance as an observer.

1.2. There were no declarations of interest.

2. Minutes of 3 December 2019

2.1. The minutes of the meeting held on 3 December 2019 were agreed as a true record and signed by the Chair subject to 4.23 to be changed to:

> "Colleagues from the NAO asked whether the funds requested would be treated as revenue expenditure in the financial statements. Officers confirmed this would be the case".

3. Matters arising

3.1. The committee noted the progress on actions from previous meetings. Some items were on the agenda and others were planned for the future.

3.2. It was noted that 4.7 was still outstanding - committee to be kept updated on the outcome of the meeting with the Cabinet Office in relation to fraud standards.

4. Digital Programme update

4.1. The Programme Manager presented an update to the committee.

4.2. The Chair commented that it was an excellent paper. She suggested the committee should focus on the budget and understand how the planned spend would be met in the new financial year. Members also requested more clarity on the timeline. Lastly, members asked for more information on the completion plan and the milestones at the end of March and 23 April.

4.3. It was noted that the external assurance draft report had been received and no major issues had been highlighted in relation to the completion plan.

4.4. In response to a question, it was noted that, being a draft report, staff needed to send a response back and that this would be finalised by Friday 13 March 2020. Also, that the main risk identified in the report was the risk we had already identified, which was the reliance on a sole developer.

4.5. The Programme Manager commented that the Patient Register Information System (PRISM) as at 10 March 2020 was 88% built which indicated that it was progressing in accordance with the plan. In response to a question it was noted that data quality in the new system would be at par with the current system and its historical data and if it could be improved that would be an advantage.

4.6. Members asked staff to confirm if all historical data would be transferred. It was confirmed that this would be the case. However, on the issue of the data being cleaned up, this would only apply to the critical aspects of the data. Also, reconciliation tests were being carried out and these were looking positive.

4.7. Staff further commented that resource planning would be taken on board as it was an operational decision.

4.8. In terms of oversight, staff explained that the plan was tracked every week by the Senior Management Team (SMT) and every other week by the Programme Board. Therefore, any slippages would come to light when they occurred, and before the 23 April second milestone date.

4.9. The Department of Health and Social Care (DHSC) representative commented that they as the sponsor were also waiting on the 23 April 2020 date. This therefore made the date quite critical. They were aware that a lot of the contingency had been used up.

Decision

4.10. Members noted the progress to date and stated that a decision about the completion plan would be taken after 23 April 2020.

4.11. In terms of budgetary requirements, members agreed that it was sensible for expenditure to continue up to 23 April and that a decision in relation to the funds would be taken after that date.

4.12. Members commented that communications to clinics should be sent in late summer.

4.13. Lastly that the Chief Executive should alert AGC members if there were any significant issues.

5. Internal audit

5.1. Karen Holland, Group Internal Auditor introduced herself and handed over to the Internal Auditor to give an update on the plan.

5.2. It was noted that good progress had been made on records management and external information requests audits and that the reports would be released by the end of March.

5.3. With the annual budgeting process audit, a moderate opinion had been given overall because it was believed that some improvements were required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.

5.4. The Director of Finance and Resources gave a management update and it was noted that there was a need to tolerate the resilience risk, since in a small organisation, key roles were often held by one person, with no deputies available.

5.5. Members agreed that the management position was the right approach, reiterating the size of the organisation. They further commented that it was about finding the balance and documenting as much as they could and ensuring that financial governance procedures were upheld.

5.6. Members commented on why the PRISM overspend was not reflected in the internal audit report.

5.7. The internal audit plan for 2020-21 was discussed with the scope and timing. Members commented that it felt like a comprehensive plan and that it was appropriate but needed to be kept under review.

Decision

5.8. Members noted the moderate assurance and recommendation.

5.9. They also noted the internal audit plan for 2020-21.

6. Progress with audit recommendations

6.1. The Head of Finance presented this item. It was noted that a number of recommendations had now been implemented but of the nine remaining on the schedule:

- Four were new and would not be due for completion until the 2020/21 business year
- Two were complete but required further evidence
- The remaining three were still in progress with delays.

Action

6.2. Members noted the progress on each recommendation.

7. External audit – interim feedback

7.1. Mike Surman and Jill Hearne from the NAO presented to the committee.

7.2. They noted that they were in the middle of the interim audit and testing was in progress.

7.3. Members would be sent an update if there were significant changes.

7.4. The external auditors stated that they had attended a visit at a licensed clinic.

Decision

7.5. Members noted the feedback.

8. Resilience, business continuity management, cyber security

8.1. The Chief Information Officer reported to the Committee.

8.2. An update was given on incidents that had occurred since the last meeting.

8.3. In response to a question, it was noted that there would be fewer incidents once the move happened.

8.4. In terms of the update on infrastructure, members asked if Authority members needed to be doing anything different especially as they used their own equipment.

8.5. Members also asked if Authority members were sent reminders about updating the anti-virus on their systems.

8.6. Staff responded that this did not occur at present but that it could be implemented going forward. It would be done when reminders are sent for the annual security training.

Action

8.7. Members noted the updates on resilience, business continuity management and cyber security, in line with the strategic risk register.

9. Strategic risk register

9.1. An update on the coronavirus pandemic was given. It was noted that the business continuity plan had been enacted, with checks carried out, and all staff were taking their assigned work Surface Pros home every day in case the office was closed.

9.2. Frequently asked question (FAQs) were communicated to all staff and on the hub (intranet) that all staff had access to.

9.3. Home working procedures had also been communicated to staff.

9.4. Regarding clinics, there were updates on the website. Members were reminded that we had a statutory requirement to inspect clinics every two years and that contingency plans were being put in place for imminent inspections.

9.5. Members commented that they were aware that we were following government advice but asked what advice was being given to staff who were feeling anxious or concerned. The

committee was assured that all these areas were addressed in the FAQs. Also that individuals with specific concerns had been advised to speak to their line managers.

9.6. Regarding fees income from fertility treatment should patients decide to put it on hold due to the coronavirus pandemic, members were advised that the HFEA had sufficient reserves, and that it would be kept under review. After three months of fewer or no fertility treatments and consequently less fees income, we would speak to the DHSC.

9.7. The external auditor asked if there had been any situations where clinics had asked inspectors not to visit due to the coronavirus pandemic. Staff responded that this had not happened so far. However, if the situation escalated and we could not inspect, the Senior Management Team (SMT) would take some administrative decisions and the Executive Licencing Panel (ELP) and Licence Committee would be able to take any necessary licensing decisions.

9.8. The Risk and Business Planning Manager presented an overview of the strategic risk register. It was noted that this was last reviewed by the Authority at their November meeting.

9.9. In terms of board capability, it was noted that the Chair's term of office had been extended for a further year. There were currently two board vacancies and there were members whose term would end in the autumn. This remained our highest risk and that it was above tolerance.

9.10. The DHSC representative commented that work was ongoing in the department to ensure that these positions were covered.

9.11. Members commented that we have a mature board with no new recruitments recently so renewal could be a refresh. However, the risk of losing three committee Chairs at the same time might be above tolerance.

9.12. Other members agreed that for continuity purposes, renewal needed to be gradual rather than having too many members' terms come to an end at the same time.

9.13. Members were advised that the regulatory effectiveness risk which related to PRISM had been increased.

9.14. Members were also advised that the HFEA's new strategy was agreed at the January Authority meeting and high-level risks to delivering the strategy were being developed, along with their controls.

9.15. It was noted that the new risk register would be signed off in May at the Authority meeting and that it would be reviewed at the June AGC meeting.

9.16. Members commented that it was a sensible approach and that risk management at the HFEA was a model worth emulating, furthermore that it was the right direction.

9.17. Members were advised that the financial risk would be discussed as a separate agenda item.

Decision

9.18. Members noted the latest edition of the risk register.

10. Finance and resources management

10.1. The Director of Finance and Resources gave an update.

10.2. In terms of historic licence fee activity, it was noted that NHS activity had decreased in absolute terms over recent years and that it was no longer offset by increased activity in the privately funded sector. Also, that a future income model was being looked into.

10.3. It had been agreed with DHSC that work would be undertaken during 2020/21 to consider whether the existing licence fee structure remained the appropriate mechanism for recovering the cost of regulation.

10.4. Members commented that short term issues were manageable but work needed to start on the medium term financial planning to ensure that the mix between fees and grants was resolved to have a sustainable structure going forward.

10.5. Staff commented that the way fees were charged no longer matched the reality in society as we only charged for embryo transfers and patients now had a higher tendency to freeze eggs which was not a chargeable activity.

10.6. Furthermore, that grant in aid (GIA) received from DHSC had reduced over the years. Also, we had been asked to submit GIA reduction plans for 2020/21 through to 2023/24.

10.7. Staff suggested that a paper would be taken to Authority in May giving options available to us.

10.8. Regarding the office relocation project, members were informed that the programme was on track and that we were engaging with the workstreams.

10.9. The IT activity was also progressing well.

10.10. It was noted that communication to staff was a continuous process and that there was a resourcing risk for some internal activities including project management support.

Decision

10.11. Members noted the update.

11. Audit and governance committee forward plan

11.1. The Head of Finance presented the AGC forward workplan to the committee.

11.2. It was noted that the Strategy and Corporate Affairs report would be presented to the June 2020 committee meeting. Also, that the audit planning report would be taken to the December meeting.

Action

11.3. Members noted the forward plan.

12. Register of gifts and hospitality

12.1. The register of gifts and hospitality was presented to the committee.

12.2. It was noted that there was only one update since the last meeting.

Action

12.3. Members noted the entries in the register.

13. Anti-fraud, bribery and corruption policy

13.1. The Director of Finance and Resources presented the reviewed policy to the committee.

13.2. Members were given an update on a case that had now been resolved. The committee were satisfied with the outcome.

13.3. Regarding the policy members commented that the policy appeared to have the right balance.

Decision

13.4. Members approved the updated policy.

14. Public interest disclosure (whistle blowing policy)

14.1. The Director of Finance and Resources presented this to the committee

14.2. Members approved the updated policy.

15. Contracts and procurement

15.1. There were no contracts signed for this period.

16. Regulatory and register management

16.1. The Director of Compliance and Information presented this item to the committee.

16.2. It was noted that incidents reported were less than 1% and that the sector had become more compliant, as the number of non-compliances (NCs) per inspection had been decreasing since 2015/16.

16.3. In the team there was a need to review capacity.

16.4. In response to a question regarding the opening the register facility (OTR), it was noted that this risk would need to be managed as any new postholder would have a long induction.

16.5. The revamped compliance and enforcement policy would be presented to the Authority in September. The Chief Executive clarified that we had an existing policy but that it needed to be updated.

Decision

16.6. The committee noted the presentation.

17. Draft annual governance statement

17.1. The Director of Finance and Resources presented the draft statement to the committee.

17.2. The committee were advised that this was the first amended draft.

17.3. There was a challenge from the external auditor as to whether it may be worth reflecting the PRISM scenario and the effects it was having on finances in the annual statements.

17.4. The Director of Finance and Resources commented that programmes and projects were not usually reflected in the statements but that it might be considered for future annual statements.

17.5. Members agreed to receive via email any amendments made prior to the June meeting at which the statement should be signed off.

Decision

17.6. Members noted the draft annual governance statement.

18. Estates update

18.1. The Director of Finance and Resources noted that there was nothing else to add as he had given the update minuted in section 10 above.

19. Any other business

19.1. There was no other business to discuss.

20. Chair's signature

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

Signature

Name

Anita Bharucha

Date

23 June 2020

Matters arising from previous AGC meetings

Strategic delivery:	☐Safe, ethical, effective treatment	☒Consistent outcomes and support	☐Improving standards through intelligence
Details:			
Meeting	Audit and Governance Committee		
Agenda item	3		
Paper number	HFEA (23/06/2020) MA		
Meeting date	23 June 2020		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each AGC		
Implementation date	2020/21 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Numerically:

- 4 items carried over from earlier meetings, 1 ongoing
- 7 items added from October 2018 meeting, 1 ongoing
- 10 items added from June 2019 meeting, 4 ongoing
- 9 Items removed: 4.9 (5 Mar-19), 4.20,5.6,6.6,7.7,7.8,7.9,7.11,13.2 (18 June-19)
- Item 9.10 from June 18 combined with 10.6 June 19, item 3.8, 4.10,7.6 (8 Oct-19) removed
- 9 Items removed: 4.7 (12 Jun-18), 4.26, 4.28,4.29,4.31,6.10,11.9,13.5 and 15.8

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 12 June 2018 and 18 June 2019 meeting			
10.6 Chief Information Officer to give monthly updates on the progress of the Digital Programme	Chief Information Officer	On-going	**Update –** an item on the agenda
Matters Arising from the Audit and Governance Committee – actions from 8 October 2019 meeting			
5.6 A reminder is to be sent to members about IT security training.	Committee Secretary	Jan-2021	**Update –** Reminder sent. Discussion took place on 29 Jan Authority meeting - 7/12 Members have completed the training. Reminder sent but was overtaken by the onset of Covid-19.
Matters Arising from the Audit and Governance Committee – actions from 3 December 2019 meeting			
4.30 AGC to continue to receive monthly updates	Chief Executive	On-going	**Update -** Updates are being provided – this is part of 10.6 request to remove
Matters Arising from the Audit and Governance Committee – actions from 10 March 2020 meeting			
There were no outstanding actions			

SIRO Report

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	AGC		
Agenda item	6		
Paper number	HFEA (23/06/2020) RS		
Meeting date	23 June 2020		
Author	Richard Sydee, Director of Resources		
Output:			
For information or decision?	For information		
Recommendation	N/A		
Resource implications	N/A		
Implementation date	N/A		
Communication(s)	N/A		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

1. Background

1.1. The Senior Information Risk Officer's (SIRO) holds responsibility to manage the strategic information risks that may impinge on our ability to meet corporate objectives, providing oversight and assurance to the Executive and Authority of the HFEA. It is a Cabinet Office (CO) requirement that Boards receive regular assurance about information risk management. This provides for good governance, ensures that the Board is involved in information assurance and forms part the consideration of the Annual Governance Statement (AGS).

1.2. This report is my annual report to the Accounting Officer and AGC.

1.3. The Security Policy Framework (SPF) provides a suitable format for the HFEA's report. ALBs are also asked to assess themselves and report against the 10 Steps to Cyber Security, the guidance issued as part of the Government's Cyber Security strategy. The HFEA has made such an assessment and recorded relevant actions and risks as part of the operational risk register, which is reviewed monthly by the HFEA Management Group.

2. Report

2.1. The HFEA routinely assess the risks to information management across the organisation, through its assessment of the risk of data loss, cyber security and the inclusion of guidance on creating and managing records throughout its Standard Operating Procedures (SOPS) and policies.

2.2. The HFEA has historically held and processed personal data and records and maintained robust controls and security protocols around all data relating to fertility treatments,, which it is required to hold under the HFE Act.

2.3. In recent years we have also responded to changes in legislation relating to the broader personal data we hold on our staff, clinic staff and members of the pubic who may have contacted us. We have introduced a number of changes to our policies and procedures to ensure we comply with the General Data Protection Regulation and the Data Protection Act.

2.4. Throughout the year we undertake scheduled activity to ensure we comply with our policies, this work Is overseen by the HFEA;s Information Governance Manager who makes periodic reports to the Corporate Management Group. In particular:

- During the year we have finalised and published a revised document retention policy.

- We have introduced regular reviews of our Information asset register, ensuring all assets have owners who are reviewing the assets held, there purpose and use. We have also introduced protocols to ensure documents that have reached the end of their retention period are reviewed and either deleted or the retention period extended.
- We have updated the information risk training we are using and have made this mandatory across the organisation

2.5. This provides an overview of our approach to RM and specifically the roles and responsibilities of staff across the organisation as well as our approach to record retention and deletion.

2.6. We continue to review our process for assessing our approach to capturing the level of information risk and out=r tolerance of it. Given the size of the HFEA there is limited resource to provide continuous oversight of this issue, as such our approach is proportionate and looks to embed the consideration of information risks within the broader assessment of organisational risks.

2.7. Overall, we have a low tolerance of risk for information on our Register database, that which falls within the auspices of GDPR and is commercially sensitive or business critical. The focus of our resource will continue to be the secure and compliant storage of these records.

2.8. In terms of the security of our data the HFEA has appropriate cyber security polices in place. AGC regularly receive updates on cyber security and I am assured that the HFEA's approach to cyber security provides significant protection of our information assets and that there is active monitoring of cyber security with appropriate action taken to improve the level of protection against new and emerging cyber threats.

2.9. I have considered the HFEAs compliance with the mandatory requirements set out in the SPF, see Security policy framework - Publications - GOV.UK. The requirements were last updated in July 2014 and focus on eight areas (governance, culture, risk management, information, technology, personnel, physical security, responding to incidents) with three types of consideration for each of those (information, physical and people). The requirements have been applied proportionately and matched to the HFEA's organisational risks. Not all of the areas apply to the HFEA. This is contained at Appendix A to this document.

2.10. In line with the Office of the Government SIRO handbook I have also considered a number of the factors that underpin the management of the HFEA's information risks.

- I believe the HFEA have an effective Information Governance framework in place and that the HFEA complies with all relevant regulatory, statutory and organisation information security policies and standards.

- I am satisfied that the HFEA has introduced and maintains processes to ensure staff are aware of the need for information assurance and the risks affecting corporate information.

- The HFEA has appropriate and proportionate security controls in place relating to records and data and that these are regularly assessed.

2.11. In conclusion I believe the HFEA has progressed in its approach to data, information and records management over the past year and is in a stronger position in terms of its governance in this area as a consequence. As SIRO I believe the HFEA takes issues relating to information risk seriously and has appropriate processes in place to assess and minimise these risks. We will continue to maintain and improve processes over the coming year and ensure we consider how we can maximise the use of our information as a business asset.

Annex A - Assessment of the HFEAs compliance with the Security Policy Framework 2014 (As at 31 March 2020)

	Mandatory Requirement	Compliance	Further actions required
1	Departments and Agencies must establish an appropriate security organisation (suitably staffed and trained) with clear lines of responsibility and accountability at all levels of the organisation. This must include a Board-level lead with authority to influence investment decisions and agree the organisation's overall approach to security.	Director of Resources is SIRO, Chief Information Officer has day to day responsibility of information security.	Ongoing review and refresher training as required.
2	Departments and Agencies must: * Adopt a holistic risk management approach covering all areas of protective security across their organisation. * Develop their own security policies, tailoring the standards and guidelines set out in this framework to the particular business needs, threat profile and risk appetite of their organisation and its delivery partners.	Risks identified as part of routine operational and strategic risk management as well as detailed on the information asset register Policies are in place and reviewed annually.	Ongoing review and development of the information asset register.
3	Departments and Agencies must ensure that all staff are aware of Departmental security policies and understand their personal responsibilities for safeguarding assets and the potential consequences of breaching security rules.	All staff and Authority members are informed of policies and given guidance. Annual training is undertaken by all	Ongoing reminders and awareness raising with staff.

		through Civil Service Learning.	
4	Departments and Agencies must have robust and well tested policies, procedures and management arrangements in place to respond to, investigate and recover from security incidents or other disruptions to core business.	System in place for detecting security breaches and business continuity arrangements in place.	None.
5	Departments and Agencies must have an effective system of assurance in place to satisfy their Accounting Officer / Head of Department and Management Board that the organisation's security arrangements are fit for purpose, that information risks are appropriately managed, and that any significant control weaknesses are explicitly acknowledged and regularly reviewed.	System in place and SIRO reports annually - any weaknesses identified in Governance Statement (none). Response to GDPR and Records management audits during 2018/19 have also been reflected in HFEA processes	None.
6	Departments and Agencies must have an information security policy setting out how they and any delivery partners and suppliers will protect any information assets they hold, store or process (including electronic and paper formats and online services) to prevent unauthorised access, disclosure or loss. The policies and procedures must be regularly reviewed to ensure currency.	Policies and procedures are in place and reviewed annually.	None.
7	Departments and Agencies must ensure that information assets are valued, handled, shared and protected in line with the standards and procedures set out in the Government Security Classifications	The HFEA's assets are all classified OFFICIAL and are appropriately controlled.	None.

	Policy (including any special handling arrangements) and the associated technical guidance supporting this framework.		
8	All ICT systems that handle, store and process HMG classified information or business critical data, or that are interconnected to cross-government networks or services (e.g. the Public Services Network, PSN), must undergo a formal risk assessment to identify and understand relevant technical risks; and must undergo a proportionate accreditation process to ensure that the risks to the confidentiality, integrity and availability of the data, system and/or service are properly managed.	ICT systems are risk assessed as part of the overall operational risk register. IT security was reviewed by Internal Audit in 2017/18	None
9	Departments and Agencies must put in place an appropriate range of technical controls for all ICT systems, proportionate to the value, importance and sensitivity of the information held and the requirements of any interconnected systems.	Patching and firewalls in place. Assurance reports received and reviewed regularly with suppliers. Portable devices and removable media is secured.	None.
10	Departments and Agencies must implement appropriate procedural controls for all ICT (or paper-based) systems or services to prevent unauthorised access and modification, or misuse by authorised users.	Policies and staff induction in place, to clarify proper use and implications of breaches.	None.
11	Departments and Agencies must ensure that the security arrangements among their wider family of delivery partners and third-	Contracts include required conditions and where appropriate third	None.

	party suppliers are appropriate to the information concerned and the level of risk to the parent organisation. This must include appropriate governance and management arrangements to manage risk, monitor compliance and respond effectively to any incidents. Any site where third party suppliers manage assets at SECRET or above must be accredited to List X standards.	parties are given copies of the HFEA's system policies. Changes to arrangements and incident monitoring and results are reviewed at quarterly meetings with suppliers.	
12	Departments and Agencies must have clear policies and processes for reporting, managing and resolving Information Security Breaches and ICT security incidents.	Policies have been revised and are in place.	None.
13	Departments must ensure that personnel security risks are effectively managed by applying rigorous recruitment controls, and a proportionate and robust personnel security regime that determines what other checks (e.g. national security vetting) and ongoing personnel security controls should be applied.	Recruitment and references provide assurance. No vetting in place as very little sensitive data.	None.
14	Departments and Agencies must have in place an appropriate level of ongoing personnel security management, including formal reviews of national security vetting clearances, and arrangements for vetted staff to report changes in circumstances that might be relevant to their suitability to hold a security clearance.	N/a.	
15	Departments must make provision for an internal appeal process for existing employees wishing to challenge National Security Vetting	N/a.	

	decisions and inform Cabinet Office Government Security Secretariat should an individual initiate a legal challenge against a National Security Vetting decision.		
16	Departments and Agencies must undertake regular security risk assessments for all sites in their estate and put in place appropriate physical security controls to prevent, detect and respond to security incidents.	Assessment and sufficient controls provided by building management.	None.
17	Departments and Agencies must implement appropriate internal security controls to ensure that critical, sensitive or classified assets are protected against both surreptitious and forced attack and are only available to those with a genuine “need to know". Physical security measures must be proportionate to the level of threat, integrated with other protective security controls, and applied on the basis of the “defence in depth" principle.	Visitor and entry controls provided by building management. Lockable furniture provided for storage. Clear desk and clear screen requirements reinforced through training, checks and reminders.	None.
18	Departments and Agencies must put in place appropriate physical security controls to prevent unauthorised access to their estate, reduce the vulnerability of establishments to terrorism or other physical attacks, and facilitate a quick and effective response to security incidents. Selected controls must be proportionate to the level of threat, appropriate to the needs of the business and based on the “defence in depth" principle.	Sufficient controls around access and mail provided by building management.	None.

19	Departments and Agencies must ensure that all establishments in their estate put in place effective and well tested arrangements to respond to physical security incidents, including appropriate contingency plans and the ability to immediately implement additional security controls following a rise in the Government Response Level.	Building management provide the lead on incidents. HFEA have contingency plans in place that are reviewed annually, and incident management processes were utilised in 2018 in relation to a power outage	None.
20	Departments and Agencies must be resilient in the face of physical security incidents, including terrorist attacks, applying identified security measures, and implementing incident management contingency arrangements and plans with immediate effect following a change to the Government Response Level.	Building management provide the lead on incidents. HFEA have contingency plans in place that are reviewed annually, and incident management processes were utilised in 2018 in relation to a power outage	

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
Agenda item	9
Paper number	AGC (23/06/2020) DH
Meeting date	23 June 2020
Author	Dan Howard, Chief Information Officer
Output:	
For information or decision?	For information
Recommendation	The Committee is asked to note: • That our Business Continuity group has continued to meet to review HFEA IT issues resulting from Covid-19 including changes to support homeworking • The upgrades to telephony and security connection software which took place in March 2020 • The work taking place to provide network and server infrastructure and migrate services ahead of the office move • Planned upgrades to the accounting, business intelligence systems and review of the Network Security policy, and • The recent improvements to electronic document management
Resource implications	Within budget
Implementation date	Ongoing
Communication(s)	Regular, range of mechanisms
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes:	None

1. Introduction and background

1.1. In recent months, AGC has received regular and detailed updates on Resilience, Business Continuity Management and Cyber Security, in line with the strategic risk register.

1.2. Our Business Continuity group has continued to meet frequently to consider the IT impact or emerging issues as a result of Covid-19

1.3. Several immediate changes have been implemented to support increased homeworking - Microsoft Teams and an upgrade to our Virtual Private Network (VPN) system.

1.4. Improvements continue to be made to our electronic Document Management System (Content Manager) to include retention schedules. A planned upgrade to our system will take place later in 2020.

2. Responding to Covid-19 and supporting remote working

2.1. Our Business Continuity group (the SMT plus IT, HR and Comms) has continued to meet frequently to take necessary action including reviewing IT provision as a result of the Covid-19 pandemic.

2.2. We have provided additional IT and office equipment to staff to support homeworking and our IT team continues to respond to IT support issues as they are raised.

2.3. Ahead of lockdown, several immediate changes were made to support homeworking in March. These changes included:

- upgrading our instant messaging and telephony system to Microsoft Teams
- upgrading our Virtual Private Network (VPN) system to be more reliable, easier to use and more secure

2.4. CMG considered the necessary changes to both Microsoft Teams and Pulse VPN at its March meeting and agreed to proceed.

2.5. The Teams and VPN infrastructure changes were made at pace and so there were inevitably some minor teething issues (relating to usability) as the systems were implemented.

2.6. Microsoft Teams was an upgrade to Skype for Business; with increased functionality, is cloud based and has been reliable since its implementation.

2.7. Zoom is used for some meetings, such as Authority, because of additional functionality such as the ability to view more than 9 participants. A review was undertaken before it was approved for use.

2.8. Our Pulse VPN system uses an additional layer of authentication to be more secure (something you know, something you have). The new version is cloud based and so removes a dependency on old hardware in Spring Gardens. The old hardware has since been decommissioned.

3. Infrastructure improvements

3.1. Planning is underway to provide the necessary network and server infrastructure (including mounting equipment and switches) at our new build location to support the applications we use. This includes the core network connection to the building which

provides the internet backbone to our new server room. This work includes migrating services and databases away from physical servers to improve resilience.

3.2. Our Sage accounting system will be upgraded in August 2020. Work is underway for implementing Tableau server which provides business intelligence and analytics functionality. This will provide our intelligence team with the ability to better manipulate and work collaboratively on Register data, supporting better decision making for regulation, research and sector-wide improvements.

3.3. As part of our regular policy review cycle, the Network Security Policy has been updated and will be reviewed by CMG at its meeting on 24 June 2020.

4. Information Governance and Document Management

Document Management System (Content Manager)

4.1. **Retention Schedule:** As previously reported, we have assigned information champions to assist departmental heads to review and delete records for each business area. This has been effective where the reviewing of records is done by two people ensuring we do not delete records which may have further historical or corporate value. While good progress has been made within Legal, IT, Corporate Governance, Clinical Governance and Licensing areas, further progress is required for many areas. We will consider this work becoming a project for monitoring purposes.

4.2. **Offline audit logs:** We are required to keep a record of records deleted for audit purposes. We have enabled offline audit logs to be recorded in Content Manager on a daily basis. The offline audit logs keep track of all the changes made to individual records which includes creation, editing and deletion, covering the lifecycle of a record which is in line with records management best practice.

4.3. **Document Management training:** Earlier this year we provided four extra training sessions for users; we used a new CM competency training document. This document has been made available on the Information Governance page on the intranet and users are asked to make use of it when they are unsure on how to use CM. Ad hoc training for users continues to be provided as support issues are raised.

4.4. **System upgrade:** We plan to upgrade the system to the latest version towards the end of 2020 once other IT infrastructure priorities are complete.

5. Recommendation

The Committee is asked to note:

- That our Business Continuity group has continued to meet to review HFEA IT issues resulting from Covid-19 including changes to support homeworking
- The upgrades to telephony and security connection software which took place in March 2020
- The work taking place to provide network and server infrastructure and migrate services ahead of the office move
- Planned upgrades to the accounting, business intelligence systems and review of the Network Security policy, and
- The recent improvements to electronic document management

Human Fertilisation & Embryology Authority

Resilience, Business Continuity and Cyber Security: June 2020

Dan Howard
Chief Information Officer
23 June 2020

www.hfea.gov.uk

Covid-19 and remote working

- Business Continuity group review (inc IT) - systems, IT support, upgrades and building access.
- Additional equipment provided to support homeworking
- Upgraded to Microsoft Teams and new Pulse VPN
- Zoom used for key meetings where appropriate

Human Fertilisation & Embryology Authority

Infrastructure

- Work continues to ensure new office is IT-ready
  - Core network connection
  - Some new physical servers
- Sage accounting system upgrade due in August
- Tableau upgrade to be complete shortly
- Network Security policy review

Human Fertilisation & Embryology Authority

Information Governance and Document Management

- Heads and Information champions reviewing and marking records for deletion in many areas although more progress needed in other areas
- Audit logs now activated for offline records
- Additional training provided in response to support issues

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Strategic risk register 2020-2024

Details about this paper

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Meeting:	Audit and Governance Committee
Agenda item:	11
Paper number:	HFEA (23/06/2020) HC
Meeting date:	23 June 2020
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: Strategic risk register 2020-2024

Output from this paper

For information or decision?	For information and comment
Recommendation:	AGC is asked to note the latest edition of the risk register, set out in the annex.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from AGC will inform the next SMT review in July.
Organisational risk:	Medium

1. Latest reviews

1.1. Authority reviewed and signed off the new strategic risk register at its meeting on 1 June.

1.2. SMT reviewed the register at its meeting on 10 June. SMT reviewed all risks, controls and scores.

1.3. 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.

1.4. Three of the six risks are above tolerance.

2. Ongoing changes to the strategic risk context

2.1. The new strategic risk register is aligned to our strategic goals for 2020-2024, although Authority took the decision to delay publication of the new strategy until later in the year. Meanwhile, the strategic context of the organisation has changed significantly, with the emergence of Covid-19 and our response to it, including suspension of almost all treatment and the subsequent reopening of the fertility sector, and revised ways of HFEA and sector working. This change is ongoing. What this demands from the organisation is a responsive and engaged approach to risk management.

2.2. Early indications are that Covid-19 may reduce some risks for at least a time. For instance, the C1 risk of staff leaving the organisation has reduced significantly in recent months and may continue to do so since there may be fewer opportunities elsewhere. However, we are aware that interdependent considerations, such as our future office operating model for Stratford, may also have an impact on staff decision-making on this issue. The Corporate Management Group are keen to take decisions on our future ways of working in a proactive way and have begun to discuss these. This will be done in a way that reflects staff and business needs, risks and our wider operating context. Other risks, such as FV1, have been made more acute by the impact of Covid-19.

2.3. We will be reviewing our approach to managing Covid-19 business continuity and risks and intend to bring a paper to AGC to discuss lessons learned. At that point we might want to return again to the issue of whether a wider business continuity risk would add ongoing value on the strategic register.

Organisational risk appetite and tolerance

2.4. Authority noted our current exposure to risk. We are dealing with high risks on a number of fronts. SMT discussed this, and the possible impact on our statement of risk appetite. On balance, SMT agree with the appetite statement; we are a regulator, with a naturally conservative appetite for risk. However, they were minded that in response to Covid-19, we had to take bold decisions which were inherently risky; likewise certain strategic approaches to, say, treatment add-ons, are riskier. In those circumstances we have chosen to knowingly increase our tolerance for particular risk rather than change our overall appetite. SMT agreed that we should return to reviewing risk appetite with the Authority when we launch the strategy, in case these ongoing changes have a substantive impact on our appetite and approach.

2.5. Separate, but related to this discussion, is the need to be clear about our capacity for risk, which is a different issue than our general appetite or tolerance levels. How much risk can we actually

sustain? For those risks where we are currently above tolerance we have asked for support from outside the organisation as necessary, for example in respect of FV1 or C2, which reflects that these risks exceed our capacity to tolerate or mitigate them.

3. Recommendation

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

Latest review date – 10/06/2020

Strategic risk register 2020-2024

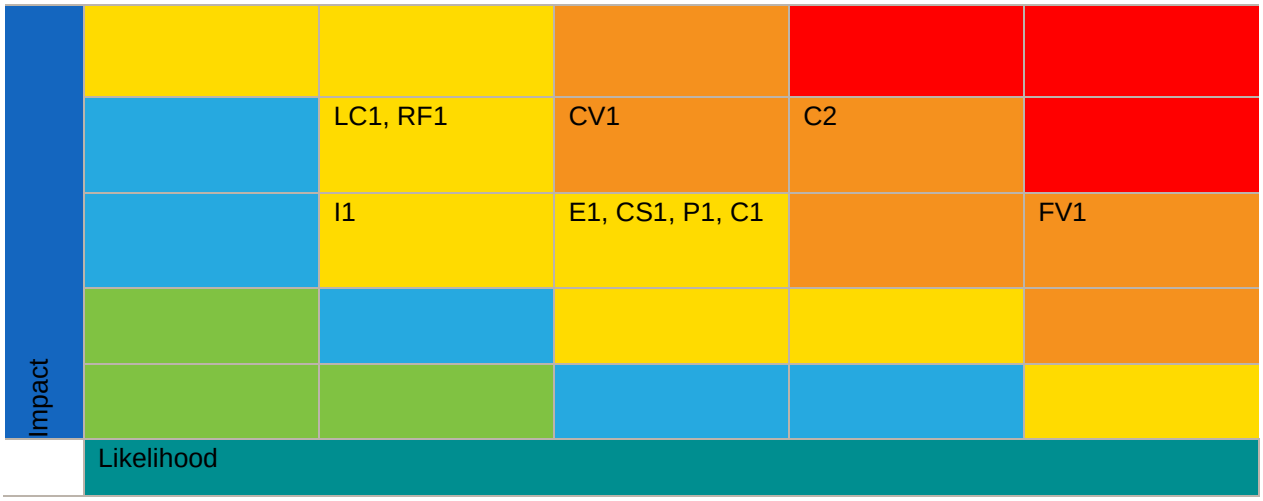
Risk summary: high to low residual risks

Risk ID	Strategy link	Residual risk	Status	Trend*
C2: Board capability	Generic risk – whole strategy	**16 – High**	Above tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	**15 – High**	Above tolerance	⇔⇔⇔⇔
CV1 - Coronavirus	Whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
P1 – Positioning and influencing	Shaping the future (and whole strategy)	**9 - Medium**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
C1: Capability	Generic risk – whole strategy	**9 – Medium**	Below tolerance	⇔⇩⇔⇔
RF1 – Regulatory framework	The best care (and whole strategy)	**8 - Medium**	At tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇔
I1 – Information provision	The right information	**6 - Medium**	Below tolerance	⇔⇔⇔⇔

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

Recent review points are: CMG 22 April 2020 ⇨ SMT 20 May 2020 ⇨Authority 1 June 2020 ⇨ SMT 10 June 2020

Summary risk profile – residual risks plotted against each other:



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

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

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

Commentary
As a regulator, we are by nature at a remove from the care and developments being offered in clinics and we must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research is safe and ethical. The result of not having an effective regulatory framework could be significant, the worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way.

Causes / sources	**Controls**	**Timescale / owner of control(s)**
We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, the CMA in relation to pricing of treatments). We take external legal advice as relevant where developments are outside of our direct remit (ie, 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.	In progress - Clare Ettinghausen Ongoing - Catherine Drennan In progress as at June - Laura Riley, Joanne Anton, Catherine Drennan

Causes / sources	Controls	Timescale / owner of control(s)
We may have ineffective tools, systems, or regulatory interventions available which are too rigid and cannot be adapted to changes.	Regular review processes for all regulatory tools such as: • Code of Practice (we are considering the timing of the next review and any risks related to delay). • Compliance and enforcement policy • Licensing SOPs and decision trees To enable us to revise these and prevent them from becoming ineffective or outdated.	In place, last update December 2019 – Laura Riley, Joanne Anton Currently under review as at June – Catherine Drennan, Rachel Cutting In place and review ongoing – Paula Robinson
Change may be too fast for us to adequately respond to if we do not understand the nature of the changes arising. Resulting in us being under-prepared or taking an insufficiently nuanced approach.	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by: • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily have to wait for some changes to be clearer in order to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing immediate responses such as a Chair's letter or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.	In place – Laura Riley, Joanne Anton In place - Peter Thompson
We may focus on 'pet projects' or ephemeral interests being influenced by personal preferences or biases.	Strategic aims have been clearly articulated; all projects must be aligned to these aims to ensure that our work is focused on delivering these objectives. We ensure this by consideration at Corporate Management Group.	Ongoing – Peter Thomson
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

Causes / sources	Controls	Timescale / owner of control(s)
We may have a lack of staffing expertise or capability in the areas developments occur in.	As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff. If a specific skills gap was identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporary or sharing skills with other organisations.	Ongoing - Relevant Head/Director with Yvonne Akinmodun
If RITA (the register information team app – used to review submissions to the Register) is not completed in a timely way, we may not effectively use data and ensure our regulatory actions are based on the best and most current information.	Launch date of PRISM delayed due to Covid-19. RITA will be built sequentially after PRISM and while RITA development has not started as at June 2020, it is expected that RITA will be complete before the team need to support a fully launched PRISM later in 2020. 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. If additional development work is required to complete RITA in a timely way, we will consider options for providing the necessary resource. However, this control may impact on our ability to support or develop other internal applications.	Plans in place – Dan Howard Ongoing – Dan Under review as plans develop - Dan
We may not have all the right data from the sector (from inspections or the Register) to make informed interventions, for instance on add-ons.	As part of planning the add-ons project we will look at the evidence available and consider whether we can access other information if we do not have this already. Revising our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool). Process to be established for reviewing data on the Register and adding fields when required.	In place - Laura Riley Audit tool being tested and launched in clinics from Autumn 2020 - Rachel Cutting Within 2020/2021 business year - Dan Howard
We may face barriers to adding fields to the Register, preventing us from collecting the right data to reflect changes in the sector. This might reduce the evidence available to inform regulatory interventions and maintain patient safety as the sector changes.	Process to be established for reviewing data on the Register and adding fields when required.	Within 2020/2021 business year - Dan Howard

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

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

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

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

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

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

Causes / sources	Controls	Status / timescale / owner
We might undermine our own role as an information provider by partnering with too many others to provide information or doing so in an ad hoc and non-strategic way.	Ensure a stakeholder engagement plan is agreed and revisited frequently. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	Early work done but development needed, future control – Clare Ettinghausen Ongoing – Paula Robinson
We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites, or clinics post their own data.	Monitoring of clinic websites at the renewal inspection point to ensure that the data there is accurate and in line with guidance. Ensure we maximise the information on our website and the unique features of our clinic inspection information and patient ratings. Clinics are encouraged to ask patients to use the HFEA patient rating system. We have optimised Choose a Fertility Clinic so that it is one of the top sites that patients will find when searching online.	In place and being reviewed during Covid-19 period - Rachel Cutting, Sharon Fensome Rimmer In place and ongoing - Jo Triggs
There are gaps in key strategic information flows on our website, for instance after treatment, resulting in missed opportunities to share information.	Digital Communications Board with membership from across the organisation in place to discuss information available and identify any gaps and what to do to fill these.	In place and ongoing - Jo Triggs
We may not signpost effectively elsewhere resulting in us trying to reinvent the wheel and stepping on other organisation's toes rather than targeting our resources.	We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Links to other specialist organisations in place as relevant on the website (ie, Fertility network UK, BICA, BFS, endometriosis UK etc).	In place and ongoing - Jo Triggs
We may provide too much information, leading to information overload and lack of clarity about what information we provide and how.	Regular review cycle for website ensures that the information provided is relevant.	In place and ongoing - Jo Triggs
We may provide inaccurate information to the media or public enquiries. Though we have well established and effective	Regular communication between relevant teams. Information provided in enquiries is checked within teams and by legal or at a more senior level if needed. Briefings when key reports etc are issued to ensure others know the key issues, statistics etc.	In place and ongoing - Jo Triggs, Joanne Anton

Causes / sources	Controls	Status / timescale / owner
working practices and controls, we must continue to be aware of and mitigate this risk.		In place and ongoing – Nora Cooke O'Dowd
Given the advent of increased DNA testing, we no longer hold all the keys on donor data. Donors and donor conceived offspring may not have the information they need to deal with this.	Maintain links with donor organisations to mutually signpost information and increase that chance that this will be available to those in this situation. Developed links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications.	In place and ongoing - Jo Triggs In place and ongoing - Laura Riley
Our OTR workload will increase in 2021/2023 (when children born after anonymity was lifted turn 16 and 18) and we may lack the capability to deal sensitivity with donor issues.	Plans to undertake service redesign work to review resourcing and other requirements for OTR to ensure these are fit for purpose.	Future control – to be undertaken in Q3/4 2020/2021 - Dan Howard
Ineffective media management may mean we don't correct incorrect information available elsewhere or signpost our own.	Good media monitoring service in place that is checked daily to identify items where a decision should be taken about need to correct information or not. We review the contract for our media monitoring service annually to ensure that it is fit for purpose. We would choose an alternate provider if this was not working effectively. Relationship with the media ensures that we are asked for comment and that we have internal processes in place to provide the comment in an effective way.	In place and ongoing - Jo Triggs In place - Jo Triggs Jo Triggs – Last reviewed January 2020
We may not get our information out to clinics if they do not use the clinic portal.	We duplicate essential communications by also sending via email to the centres' PR and LH (for instance, all Covid-19 correspondence). We actively encourage all PRs to make full use of the clinic portal.	In place - Rachel Cutting
Risk that key regulatory information will be missed if Clinic focus, Clinic Portal or emails are not being read.	As above, there is a statutory duty for PRs to stay abreast of updates. We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance when they need it regardless of additional communicated updates. We are considering implementing a formal annual catch-up between clinics and an inspector.	In place – Rachel Cutting In place – Laura Riley, Joanne Anton Possible future control, TBC – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making.	Review of inspection reports is underway to identify future improvements to inspection reports.	In place – Rachel Cutting

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

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

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

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

Commentary
This risk is about us being in a position to influence effectively to achieve our strategic aims. If we do not ensure we are, we may not be involved in key debates and developments, others will not present the HFEA perspective, meaning we may be voiceless, or our strategic impact may be limited. Although we have not yet publicly launched our new strategy, the decisions taken over the next months prior to its launch will have an impact on these strategic risk areas, so we are already beginning to think about these risks and controls in order to manage them effectively.

Causes / sources	Controls	Status/timescale / owner
We may not engage widely enough or have the contacts and reach we need to undertake key work, meaning aspects of the strategy are too big to complete within our resources.	Ensure a stakeholder engagement plan is agreed and revisited frequently. Stakeholder identification undertaken for all projects to ensure that these are clear from the outset of planning, and that we can plan communications, involvement and if necessary, consultations, appropriately.	Early work done but development needed, future control – Clare Ettinghausen In place - Paula Robinson
We may be unable to persuade partner organisations to utilise their powers/influence/resources to achieve shared aims.	Early engagement with such organisations, to build on shared interests and reduce the likelihood of this becoming an issue. For instance, the treatment add-ons working group.	In place - Clare Ettinghausen

Causes / sources	Controls	Status/timescale / owner
The sector may disagree with HFEA about key strategic terms and principles, such as 'ethical care' creating negative publicity for us and reputational damage.	We will clearly communicate our intentions, to ensure that these are not misunderstood or misinterpreted and engage with our established stakeholder groups.	In place - Clare Ettinghausen
The sector may take a different view on the evidence HFEA provides in relation to Add-ons and so we may be ignored.	The working group for the add-ons project will focus on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed. SCAAC sharing evidence it receives and having an open dialogue with the sector on add-ons.	Ongoing - Laura Riley
In relation to changes, HFEA and sector interests may be in conflict, damaging our reputation. This may particularly be the case in relation to Covid-19 and the use and removal of General Directions 0014 (GD0014).	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible. Framework for decision making around removing GD0014 drawn up following Authority discussion.	In place - Peter Thompson In place – Rachel Cutting
We may not engage with early adopters or initiators of new treatments/innovations or changes in the sector.	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and devlopments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE so that the wider organisation can consider the impact of these. We are investigating holding an annual meeting with key innovators.	In place - Laura Riley/Joanne Anton In place - Laura Riley/Joanne Anton In place and ongoing – Sharon Fensome-Rimmer Future control - Clare Ettinghausen/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 Underway, Spring 2020 - Joanne Anton

Causes / sources	Controls	Status/timescale / owner
Government: Any consideration of the future legislative landscape may become politicised.	There are no preventative controls for this, however, clear and balanced messaging between us, the department and ministers may reduce the impact. Develop improved relationships with MPs and Peers to ensure our views and expertise are taken into account.	Ongoing - Peter Thompson
Government: Consideration of changes to the regulatory framework may be affected by political turbulence (for instance changes of Minister).	There are no preventative controls for this, however, we will ensure that we are prepared to effectively brief any future incumbents to reduce turbulence. We would also do any horizon scanning as the political landscape changed if needed.	Ongoing - Peter Thompson

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	5	25–Very High	**5**	**3**	**15 – High**
Tolerance threshold:					**9 - Medium**
Status: Above 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
Due to Covid-19 and the suspension of clinic treatment activities this is a live issue for 2020/2021 since we have limited income for as long as GD0014 (version 2) is in place. Furthermore, although clinics can now resume treatment, even for those that do, it may take some time for activity to return to normal levels which means that our income will be lower than planned. We have sufficient cash reserves to meet all liabilities due until the end of August. We are in discussion with the Department of Health and Social Care to provide additional funding and cash, to ensure that we can operate until normal activity resumes. An initial options appraisal for a fee review project went to the Authority in May. A consultation and modelling for the new income model will follow, with the intention to launch this in 2021/2022, subject to Authority agreement. This should ensure that the income model is fit for purpose and reflects the changing nature of sector activity, and the set the HFEA up for the future.

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending. This is no longer a risk – this is a live issue for 2020/2021 as we have reduced income for as long as GD0014 is in place and furthermore we expect that when clinics reopen it will take some time for activity to return to 'normal' levels.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC. We are undertaking a fee review project in 2020/2021 to ensure that the income model is fit for	CMG monthly and Authority when required – Peter Thompson Quarterly, ongoing, with AGC model review at least annually - Richard Sydee

Causes / sources	Controls	Timescale / owner
	purpose and reflects the changing nature of sector activity. We are discussing with the Department of Health and Social Care how this issue will be managed.	Planning underway – Peter Thompson and Richard Sydee
Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles. As at June 2020 we have very limited income due to the deployment of GD0014 in response to Covid-19 and the limited reopening of the sector.	Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in June 2019. If clinics were not able to submit data and could not be invoiced for more than three months, we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted. **Note**: we have decided not to employ this control in the light of the significant impact of Covid-19 on the sector (clinics are not working at historic levels). We will look to review this risk and controls on a quarterly basis depending on the level of activity underway across the sector.	Given the Covid-19 related drop in income, we are now actively employing this control – Richard Sydee Control under quarterly review as sector reopens – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work. This may not be sufficient to complete the work if it is delayed due to Covid-19.	The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact. Ongoing monitoring and reporting against control totals to ensure we do not overspend. Funding has now been received from the Department to complete the PRISM programme.	Procurement underway – Richard Sydee Ongoing – 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

Causes / sources	Controls	Timescale / owner
Project scope creep leads to increases in costs beyond the levels that have been approved.	Finance staff member present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Olaide Kazeem
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Covid-19 impacts on HFEA income.	The final contingency for all our financial risks is to seek additional cash and/or funding from the Department and we are in active discussion with the Department about this issue.	Ongoing - Richard Sydee
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to appropriate contingency level available at this point in the financial year. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model. Annual budget has been agreed with DHSC Finance team. GIA funding has been provisionally agreed through to 2021.	Quarterly accountability meetings (on-going) – Richard Sydee December/January annually, – Richard Sydee

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

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

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

Commentary
This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity. For 2019/2020 Turnover was 12.2% (in 2018/19 this was 26.8%). This reduction in turnover suggests that we are currently in a more stable situation and this will naturally strengthen our capabilities as staff develop more experience in their roles. We have also often been able to recruit internally which has assisted in reducing turnover as staff have been able to develop their careers within the HFEA. We have taken active steps. We have taken steps to improve retention, focussing on things that we can control like learning and development. AGC receive 6-monthly updates on capability risk to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing further. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations. Unfortunately this work has not progressed further due to Covid-19, although conversations about such development opportunities continue on an individual level. We have two Authority member vacancies which create Board capability gaps, these risks are captured in the separate C2 risk, below. Although we reduced our assessment of this risk score in May 2020, we are aware that ongoing impacts of Covid-19 may affect capability in future months, and we are considering approaches to manage this as the situation develops.

Causes / sources	Mitigations	Status/Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	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 if appropriate.	In place – Yvonne Akinmodun In place – Peter Thompson In place – Relevant Director alongside managers
Inability to recruit due to Coronavirus leads to capability gaps in the Policy and other teams.	Reprioritisation of workload due to Coronavirus has led to some work being delayed, which reduces the impact of any capability gaps, especially in the Policy team. Pause in OTR workload to ensure that the service can be effectively manned. Will reopen following recruitment to Manager post. Planning to develop a clear internal methodology for return to BAU workload following Covid-19. This will ensure that capability and capacity is sufficient and effectively managed.	Reprioritisation undertaken April 2020 - Laura Riley and Joanne Anton In place - Dan Howard Future control, being developed and considered by CMG in June - Yvonne Akinmodun
Poor morale could lead to staff leaving, opening up capability gaps.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of concern. Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider	In place, ongoing – Peter Thompson In place – Jo Triggs In place but staff survey due May 2020 – Yvonne Akinmodun

Causes / sources	Mitigations	Status/Timescale / owner
	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. Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year. Oversight of projects by both the monthly Programme Board and CMG meetings. Review of project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources. Planning and prioritising data submission project delivery, within our limited resources.	In place – Paula Robinson In place – Paula Robinson In place – Paula Robinson Ongoing review in progress 2020-2021– Paula Robinson In place until project ends – Dan Howard
The future office move, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.	See separate E1 risk for full assessment of risk causes and controls.	Engagement with staff and other organisations underway and ongoing – Richard Sydee
Possible capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working may not be realised.	Active engagement with other organisations early on. We are collaborating with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely, including mentorship programme.	Ongoing – Richard Sydee Early progress, ongoing – Yvonne Akinmodun
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA for which we do not have the relevant capabilities.	We continue to work closely with the Department to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. Since December 2018, we have run an EU exit project to ensure that we fully consider implications and are able to build enough	Communications ongoing – Peter Thompson

Causes / sources	Mitigations	Status/Timescale / owner
	knowledge and capability to handle the effects of the UK's exit from the EU. We will progress this project through the transition period. We continue to engage with DHSC and clinics to prepare for EU exit. Actions will depend on the progress of the UK/EU talks. Authority and AGC are also updated at their meetings, as appropriate.	
In-common risk Covid-19 (Coronavirus) may lead to high levels of staff absence leading to capability gaps or need to redeploy staff.	Management discussion of situation as it emerges, to ensure a responsive approach to any developments. We have reviewed our business continuity plan to ensure it is fit for purpose.	Ongoing - Peter Thompson

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 - Very High	**4**	**4**	**16 - High**
Tolerance threshold:					**4 - Low**
Status: **Above tolerance**					

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

Commentary
The HFEA board is unusual as members undertake quasi-judicial decision-making as part of their roles, sitting on licensing and other committees. This means that changes in Board capability and capacity may impact the legal functions of the Authority. We need to maintain sufficient members with sufficient experience to take what can be highly controversial decisions in a robust manner. As such our tolerance threshold for this risk is low. Out of a current Board membership of 14, we have two vacancies. In addition, two members' terms end on 11 November 2020, bringing the Board membership down to ten. The Chair's term expires on 31 March 2021.Three other senior Authority members' terms also end on that date. If we are not able to recruit to all these positions, the membership would be reduced to six. This would pose a significant challenge to robust statutory decision-making and knowledge management. The extension of the Chair's term to 2021 is helpful, however recruitment is not yet underway for any of these posts. It is unclear how and when recruitment will be handled in the light of Covid-19. We remain in contact with the department on these matters.

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

Causes / sources	Mitigations	Status/timescale / owner
The uncertainty about Chair reappointment may result in a gap in leadership and direction for the Authority. The Chair's term has been extended until March 2021, which gives more time to consider controls, though it only changes the proximity of this risk.	Given the Deputy Chair will also be leaving the organisation in 2021, our previous controls, for the Deputy Chair to take over on a temporary basis, subject to approval, will no longer be fit for purpose.	Further controls to be considered - Peter Thompson
Any member recruitment may take some time and therefore give rise to further vacancies and capability gaps. The recruitment process is run by DHSC meaning we have limited power to influence this risk source. Historically, decisions on appointments have taken some time which may create additional challenges for planning. Meanwhile, the annual report from the commission for public appointments suggests appointments take on average five months.	The Chair/CEO are in close contact with the Department to press for an early decision.	In progress, timescale TBC - Peter Thompson
Several current Board members are on their second terms in office, which expire within the same period (six Members of the Board by March 2021, in addition to the two pre-existing vacancies).	We are discussing options with the Department for managing the cycle of appointments, in order to reduce the impact of this.	In progress, ongoing - Peter Thompson
The induction time of new members (including bespoke legal training), particularly those sitting on licensing committees, may lead to a loss of collective knowledge and potentially an impact on the quality of decision-making. Evidence from current members suggests that it may take up to a year for members to feel fully confident.	The Governance team are reviewing recruitment information and member induction to ensure that this will be as smooth as possible once it starts.	In progress, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
Induction of new members to licensing and other committees, will require a significant amount of internal staff resource and could reduce the ability of the governance and other teams to support effective decision-making.	We will be mindful of this resource requirement when planning other work, in order to limit the impact of induction on other priorities.	In progress, as timescales become clear - Peter Thompson, Paula Robinson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Status/timescale / owner**
Government/DHSC The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register.	Raised December 2019 - 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 breaching its own legal responsibilities.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register.	Raised December 2019 - Peter Thompson
Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. We are unsure of the intended approach of any future government. This may impact any planned approach and risk mitigations and give rise to further risk.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register.	Raised December 2019 - Peter Thompson

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

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

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

Commentary

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

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

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

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

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 (preventative control).	In place – Dan Howard

Causes / sources	Controls	Timescale / owner
	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 (preventative control). Annual cyber security training in place to ensure that Authority are appropriately aware of cyber risks and responsibilities (preventative control).	In place - Peter Thompson Last undertaken January 2020? – Dan Howard
Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively	Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities (preventative control). Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. We undertake independent review and test our cyber controls, to assure us that these are appropriate (preventative control). Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact (corrective control).	Last undertaken by all staff June 2019 Due June 2020 – Dan Howard Update to go to CMG in June 2020– Dan Howard In place, review last undertaken March 2019 – Dan Howard In place, review last undertaken May 2019 – Dan Howard
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security. Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable.	In place and further testing planned before going live – Dan Howard In place – Dan Howard
The IT support function may not provide us with the cyber security resource that we need (ie, emergency support in the case of dealing with attacks)	We have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason.	Contract in place until May 2021 with option to extend until

Causes / sources	Controls	Timescale / owner
		May 2023 – Dan Howard
We may not effectively mitigate emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations to learn from others in relation to cyber risk.	Ongoing (such as ALB CIO network) – Dan Howard
We may have technical or system weaknesses which could lead to loss of, or inability to access, sensitive data, including the Register.	We undertake regular penetration testing to identify weaknesses so that we can address these. We have advanced threat protection in place to identify and effectively handle threats. Our third-party IT supplier undertakes daily checks on our server infrastructure to monitor for any errors and to monitor for any security issues or increased threats. We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software. We regularly review and if necessary, upgrade software to improve security controls for telephony	Ongoing (last test May 2019) – Dan Howard In place – Dan Howard In place – Dan Howard Ongoing (Last review and upgrade to Pulse RAS system April 2020) – Dan Howard Ongoing (Last review and upgrade to Microsoft Teams system April 2020) – Dan Howard
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. (corrective control) Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) in order to implement encryption (corrective control).	Ongoing (regular reminders sent to staff with security best practice) – Dan Howard
Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.	All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place. We have an effective permission matrix and password policy.	In place – Dan Howard In place – Dan Howard

Causes / sources	Controls	Timescale / owner
	Our web configuration limits the service to 20 requests at any one time. The new Register will be under the tightest security when this is migrated to the cloud.	In place – Dan Howard To be implemented – Dan Howard
The continued use of EDI by clinics during the extended delivery of PRISM means the end of life server version used for the EDI gateway application (which processes data from EDI or 3rd party servers into the HFEA Register) continues to be used. This may therefore be more vulnerable to attack as it becomes unsupported.	Data submitted through the EDI gateway application is encrypted in transit, which reduces the likelihood of sensitive information being accessed. (corrective control)	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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

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

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

Commentary
An internal project is in place to prepare for the office move, handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks. This feeds into a larger programme managed by DHSC. We have made progress in reviewing working practices and policies and have launched several of these. Several cross-ALB working groups have been established and are actively defining requirements and solutions and these are feeding into the HFEA internal project. Covid-19 has had significant impacts on the office move. SMT raised the risk score in April to reflect this emerging risk. Delays have been managed proactively by the overall DHSC programme which has reduced the overall impact. We do not yet have a date for the HFEA move, but will ensure that we are able to continue to operate if the move is delayed.

Causes / sources	Controls	Status/Timescale / owner
The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings. Note: Covid-19 may have altered the requirements of the HFEA.	HFEA requirements were specified up front and feedback given on all proposed designs. Outline plans are in line with HFEA needs and we have staff on the working groups set up to define the detail. We will revisit our requirements and ways of working in the light of the changed circumstances we are in due to Covid-19. If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected.	Ongoing – Richard Sydee Future control as part of Covid-19 management – Richard Sydee Contingency if required – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
	Arrangements need to be put in place to ensure that costs and access are shared equitably.	Discussions underway – Richard Sydee
We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation. Note: Move to Stratford noted in all job adverts. Recruitment data to date suggests we are not seeing an impact on recruitment. We will continue to monitor this to consider whether other mitigations are needed/possible.	We will continue to offer desirable staff benefits and policies, such as flexible working, and have reviewed and updated these to ensure that they support staff recruitment and retention. Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.	Completed (however as per above control we may need to revisit in the light of Covid-19) – Yvonne Akinmodun
Stratford may be a less desirable location for some current staff due to: • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention as staff choose to leave before the move.	Work underway to review the excess fares policy to define the length of time and mechanism to compensate those who will be paying more following the move to Stratford. Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect.	Begun but to be completed (this is now subject to Covid-19 developments) – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs. The Finance and procurement strand of the project has been delayed; we await final estimates of the cost to HFEA, though have been assured that calculations have been completed.	Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use. The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed. The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens.	Ongoing but we await confirmation of overarching procurement arrangements from central programme - Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
The move to a new office will lead to ways of working changes that we may be unprepared for.	HFEA will be discussing ways of working in the aftermath of Covid-19 and in relation the office move, to ensure that these changes happen by design rather than by default. Policies related to ways of working have been agreed and circulated significantly before the move, to ensure that there is time for these to bed in and be accepted ahead of the physical move. Staff have been involved and updated as appropriate.	Timing to be confirmed but beginning Q1 – Richard Sydee Done and to continue as these are reviewed following Covid-19 - Richard Sydee, Yvonne Akinmodun
Owing to the different cultures and working practices of the organisations moving, there may be perceived inequity about the policy changes made.	A formal working group is in place including all the organisations who are moving to Stratford with us, to ensure that messaging around ways of working is consistent across organisations, while reflecting the individual cultures and requirements of these. The ways of working group will communicate on these differences, so that staff understand any differences in practice and that the intention is not to homogenise practices.	Ongoing – Richard Sydee Future control – Richard Sydee
Current staff may not feel involved in the conversations about the move, leading to a feeling of being 'done to' and lower morale.	Conversations about ways of working occurring throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions. An open approach is being taken to ensure that information is cascaded effectively, and staff can voice their views and participate. We have a separate area on the intranet and Q&A functionality where all information is being shared. Staff have had the opportunity to visit the site ahead of time so that they feel prepared.	Ongoing – Richard Sydee
The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.	Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed. Assurance will be provided by regular reporting to AGC and Authority. The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance. Dedicated part-time external project manager brought in to undertake ongoing project management, to ensure sufficient and effective	In place – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
	resourcing of this as the project moves into a more advanced phase of delivery. Other key staff such as HR and representatives from other teams involved in the internal HFEA Project team.	
Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.	Communications between HFEA and other organisations' IT teams to determine IT requirements, allowing more time to resolve these. Infrastructure has largely been migrated to the cloud, which will facilitate the move and reduce related risk to IT systems. It will also mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.	In place - Ongoing - Steve Morris, Dan Howard Ongoing - Steve Morris, Dan Howard
The physical move may cause short-term disruption to HFEA activities and delivery, if necessary resources, such as meeting rooms or physical assets, are not available to staff. We may move to Redman Place later which could increase the chance of this disruption or extend it.	Careful planning of the move to reduce the likelihood of disruption. We will increase our focus on planning as we move closer to the move date and reprioritise as required. Staff would be able to work from home in the short-term if there was disruption to the physical move which would reduce the impact. Implementation of enhanced remote access security arrangements in advance of the move.	Ongoing - Richard Sydee In place – Dan Howard Done - Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
British Council – lead on physical build – may not understand or take HFEA needs into account.	DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.	In place – Richard Sydee, DHSC
DHSC – Lead on the whole overarching project, entering into contracts on behalf of HFEA and others – HFEA requirements may not be considered/met.	Regular external programme meetings attended by the Director of Finance and Resources as HFEA Project Sponsor and other HFEA staff when delegation required.	In place – Richard Sydee
NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.	Regular DHSC programme meeting involving all regulators. Sub-groups with relevant IT and other staff such as HR. Informal relationship management with other organisations' leads.	In place – Richard Sydee, DHSC

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

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

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

Commentary

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

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

Legal challenge poses two key threats:

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

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

We have not been directly involved in any litigation since October 2018.

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

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

Causes / sources	Mitigations	Timescale / owner
case by case nature of the Courts' approach to matters means resource demands are unpredictable when these arise.	Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly. 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. Some amendments were made to guidance in the Code of Practice dealing with consent to storage and extension of storage, this was launched in January 2019. This guidance will go some way to supporting clinics to be clearer about the legal requirements. Additional amendments will be made in the next update. Storage consent has been covered in the revision of the PR entry Programme (PREP).	In place – Peter Thompson Done in Q1 2018/19 – Catherine Drennan Revised guidance will be provided where appropriate to clinics – Catherine Drennan PREP launched January 2020 – Catherine Drennan/ Laura Riley, Joanne Anton
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or Judicial Reviews. Challenge of compliance and licensing decisions is a core part of the regulatory framework and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes. Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible. The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for appropriate involvement and effective planning of work. Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes.	In place but a review of the Compliance and Enforcement policy underway, due for completion Autumn 2020 – Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer In place – Sharon Fensome-Rimmer In place – Peter Thompson

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

Causes / sources	Mitigations	Timescale / owner
	Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	
DHSC: The Department may be a co-defendant for handling legal risk when cases arise.	We work closely with colleagues at the Department to ensure that the approach of all parties is clear and is coordinated wherever possible.	In place – Peter Thompson

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	5	25 – Very High	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**
Status: At tolerance					

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

Commentary
Risk management of these risk causes has necessarily become our organisational priority. All staff are working from home and a strategy to manage inspections has been put in place until September. Communications to the sector and patients are in place and ongoing. A business continuity group meets regularly to consider risks and ensure an effective response is developed and maintained. The Coronavirus risk has had a cascading effect across the whole risk register and will do for the foreseeable future. Where there are specific risk causes related to other core risks these are signposted as relevant. The organisation has been incredibly flexible to rapidly adapt to changed ways of working, the next step is to ensure this is sustainable and we take a flexible and appropriate response as restrictions loosen and life returns to a 'new normal'.

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

Causes / sources	Controls	Status/Timescale / owner
	Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth and this is up to date. Enquiries team have additional support from Managers and Directors. We will review 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.	Rimmer, Rachel Cutting Joanne Triggs – in place In place and under regular review – Laura Riley In place – Jo Triggs
Risk of being challenged publicly or legally about the HFEA response, resulting in reputational damage or legal challenge. (This risk also therefore relates directly to LC1 above)	As above – ensuring approach is appropriate. As above – continuing to liaise with professional bodies. We may choose to put out a press release in case of public challenge. Legal advice has been sought to ensure that HFEA actions are in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Joanne Triggs Done – Peter Thompson If required – Peter Thompson, Catherine Drennan
Gaps in HFEA staffing due to sickness, caring responsibilities etc	Possible capability gaps have been reviewed by teams to ensure that these are identified and managed. Other mitigations as described under the C1 risk.	In place – Yvonne Akinmodun
Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.	Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.	In place - Paula Robinson
Ineffective oversight of those clinics that are continuing to practice as clinics may not abide by professional body and HFEA guidance.	We have put in place a new General Direction for clinics to follow. Clinics who do not follow General Direction 14 would be subject to serious regulatory action. Inspection team are in active communication with all of their clinics to ensure oversight and	In place – Rachel Cutting In place – Sharon

Causes / sources	Controls	Status/Timescale / owner
Since GD0014 version 2 was issued, clinics have been able to reopen where it is safe to do so. Meanwhile, HFEA do not plan to restart physical inspections until September. This creates a potential oversight gap.	understanding of risks. Activity of centres is being monitored through the register submission system. Effective desk-based approach to oversight of clinics. Those clinics (who have resumed treatment services and/or are open) where Interim inspections were due during the period of no inspections will still be asked to complete the Self-Assessment Questionnaire, in the same way that they would have done before an inspection. This gives us oversight of all areas of practice.	Fensome-Rimmer Approach agreed and in place – Sharon Fensome-Rimmer, Rachel Cutting
Inability to run representations hearing due to restrictions/inability of staff/others to meet.	Plan in place to run this via teleconference. Finer points of arrangements being agreed.	In place and developing – Paula Robinson
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: as per FV1 this is a live issue. Note: this risk may be both short and longer-term if clinics close down as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity (contingency). The final contingency would be to seek additional cash and/or funding from the Department, and we are in conversation with them about the likely impact on us (further contingency)	In place – Richard Sydee Ongoing discussions as impact becomes clearer – Richard Sydee
We have had to cancel events and meetings and cannot run them as planned which may delay some strategic delivery.	Conversations ongoing with Authority and Corporate Management about options for management of individual risk impacts and review key milestones where needed. Routine stakeholder meetings occurring virtually and revised arrangements to allow for virtual meetings and committees.	In place – Peter Thomson
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity.	Provided equipment for staff who have to WFH without suitable arrangements in place. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing – Yvonne Akinmodun

Causes / sources	Controls	Status/Timescale / owner
	in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance.	
Risk that we miss posted financial, OTR or other correspondence.	While the office remains open, we have an arrangement to securely store, collect and distribute post. Though we would need to reconsider this control should the office be closed. Updated website info to ask people to contact us via email and phone. We have notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems. OTR service paused which removes OTR related risks.	In place – Richard Sydee In place – Jo Triggs In place – Morounke Akingbola In place – Dan Howard
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.	Richard Sydee

Reviews and revisions

10/06/2020 - SMT review – June 2020

SMT discussed comments from Authority, reviewed all risks, controls and scores and made the following points:

- FV1, C2 – discussions ongoing, no further updates to reflect.
- E1 – RS to provide updates.
- CV1 – SMT agreed that this needed to be updated to reflect that some risks were no longer applicable given the current context and others could now be referred down to operational registers. SMT reflected on the risk score now that our desk-based approach is in place. The organisation had gone a long way to mitigate risks but given the circumstances we needed to stay vigilant and not reduce this too soon.
- P1 – SMT discussed controls around understanding and reacting to innovation and agreed to reflect these further in the register.
- IP1 – SMT discussed risks related to information provision and agreed that although the HFEA has very effective mitigations and takes great care, any organisation that provides detailed information to the public via a variety of sources should manage provision of inaccurate data as an active risk.
- Risk appetite – SMT agreed that this still felt appropriate at the current time.

01/06/2020 - Authority review – June 2020

Authority reviewed the strategic risk register for the first time. Members reviewed all risks, controls and scores and made the following points:

- The Chair commented that it was a sensible risk register but there were concerns around the above tolerance risks. Regarding the board capability risk, the Chair stated that we were working with DHSC to try and stagger finishing dates for purposes of continuity.
- CV1 - Members discussed the coronavirus risk and whether the risk appetite for the board was appropriate for the current situation.
- Members felt that it was an excellent risk register. In particular, members welcomed the approach taken, responsiveness to information provision and how the register aligned with the strategy.
- Members suggested that some of the causes, sources and controls in the risk register be revisited so that they reflected strategic high-level points.
- Regarding Heads of service considering what work to prioritise if income fell below projected expenditure, members asked staff to ensure the Authority was sighted on the proposals.

20/05/2020 - SMT review – May 2020

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

- RF1 – SMT noted that the Head of Planning and Governance had proposed that the inherent risk was actually higher (the controls already in place were bringing the residual likelihood down). SMT agreed with this change.
- C1 – SMT noted that the Head of HR had reviewed this risk and suggested that given the current reduced level of turnover this risk was now below tolerance. SMT agreed with this and noted that we would need to monitor this carefully as things could change in future months following Covid-19.
- CV1 - A few updates were needed to the Covid-19 risk to reflect recent developments in controls.

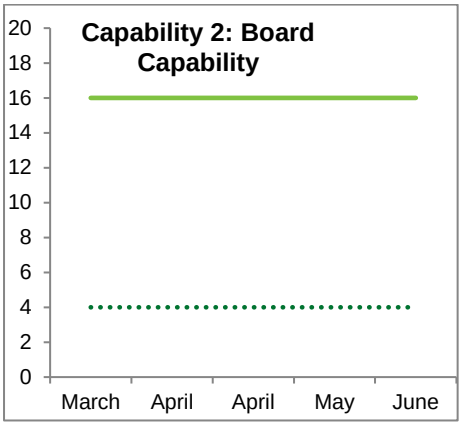
22/04/2020 - CMG review of draft register – April 2020

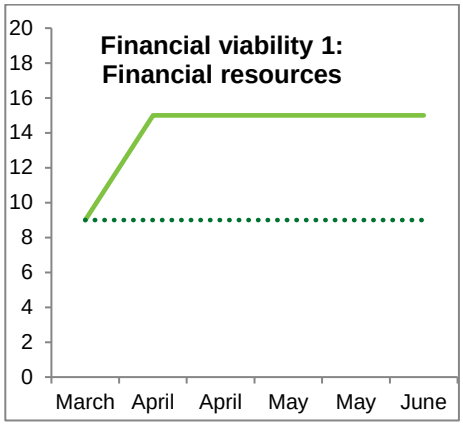
CMG reviewed all risks, controls and scores and made the following points:

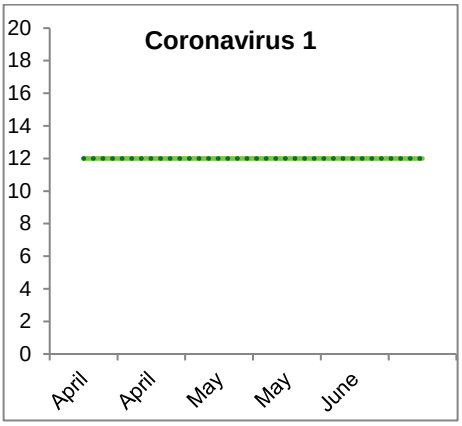
- They agreed the scores seemed appropriate and the new strategic risks captured the core risk to the new strategy.
- Members agreed to further review to ensure controls in their areas were correct.

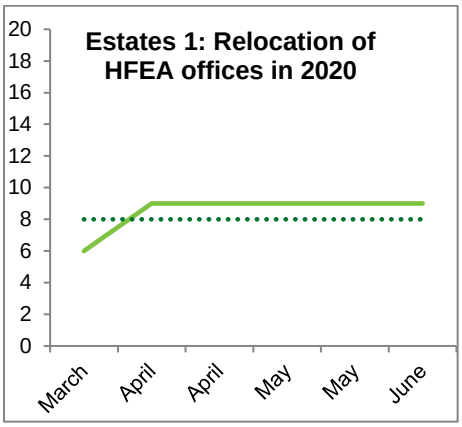
Risk trend graphs

High and above tolerance risks

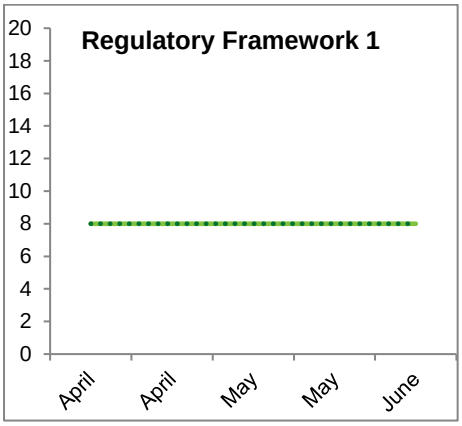


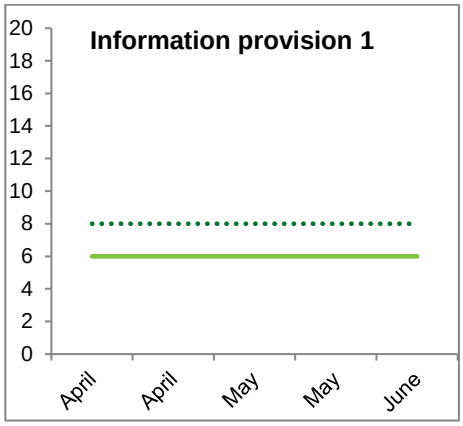


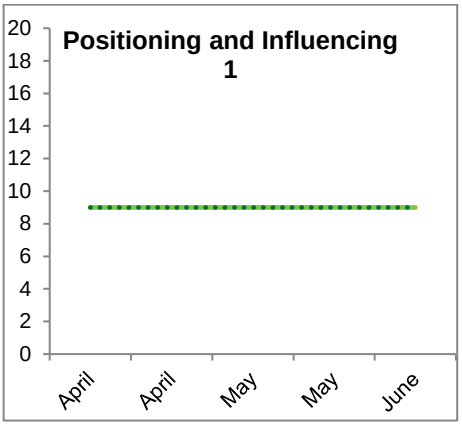


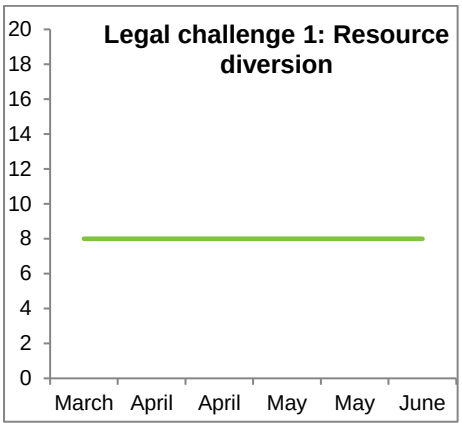


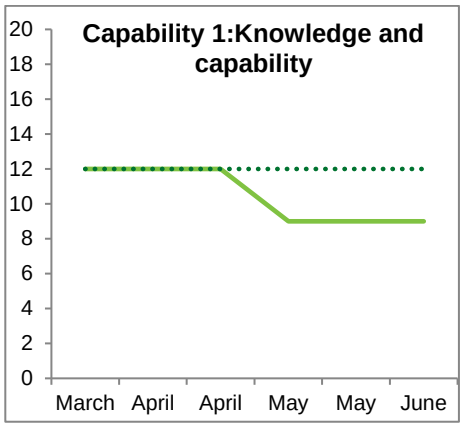
Lower and below tolerance risks

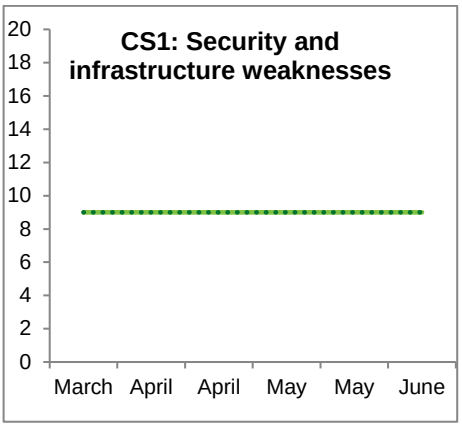












Criteria for inclusion of risks

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
	Likelihood				

Risk Score = Impact x Likelihood

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

System-wide risk interdependencies

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

Contingency actions

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

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

Human Resources update 2020

Details about this paper

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Meeting:	Audit and Governance Committee
Agenda item:	12
Paper number:	HFEA (23/06/2020) YA
Meeting date:	23 June 2020
Author:	Yvonne Akinmodun, Head of Human Resources Peter Thompson, Chief Executive
Annexes	

Output from this paper

For information or decision?	For information and comment
Recommendation:	The Committee is asked to note the content of this report:
Resource implications:	
Implementation date:	Ongoing
Communication(s):	
Organisational risk:	

1. Introduction

1.1. This paper provides a broad overview of work that has taken place in the last six months (particularly the last three) within the organisation. The main focus in on the support that has been provided to staff since the lockdown and their views of that support. Although the lockdown is beginning to be lifted it is likely that HFEA staff will continue to work from home for some time to come. We would particularly welcome AGC's views on the adequacy of our actions to date and in identifying any issues we ought to consider over the coming six months.

2. Impact of COVID-19

2.1. Following the Government decision to impose a lockdown in March, the HFEA moved all of its activities online. Board meetings and committee business have been held virtually and all staff now work from home. The transition to virtual working was undertaken at great speed and the IT team deserve praise for their work at the time and since.

2.2. We have put a number of measures in place to support staff during this period of remote working, including:

- Weekly team meetings between heads of department and team members
- Weekly all staff meetings, hosted by the Chief Executive
- Bi-weekly staff quizzes
- Monthly wellness sessions led by the Mental Health First Aiders
- Weekly virtual tea/coffee sessions for small groups of staff

2.3. In April, we launched a short 'pulse' survey to find out how staff were feeling about working at home during lockdown.

2.4. We had a response rate of 85% (57 responses from across the business). Below is a summary of the responses.

(i) I feel well informed about mattters that affect me during this COVID crisis – 88%

(ii) I feel that the HFEA is a caring employer who understands and supports the needs of its workforce in this difficult time – 88%

(iii) I feel that the HFEA is well led and that the leadership team has a clear plan for this period – 73%

(iv) I feel senior leaders are visible - 79%

(v) I feel the HFEA has manaaged this period of change well - 82%

(vi) I feel connected to my team and the work of the HFEA – 93%

2.5. This positive response is supported by a range of written comments from staff, with many feeling the communication and approach taken by the leadership team in this period has been the right one. Staff were very appreciative of the weekly catch up. Several also commented on the other forms of communication such as the Mental Health First Aiders briefing along with the quizzes and team meetings.

2.6. However, a small number of staff also expressed anxiety about the impact that Covid-19 has had on their own personal work tasks. In part, such views reference a desire for certainty and clarity in an environment which is inherently uncertain. These staff are asking for a clear plan of how work is allocated and what projects and work they can get involved with. Further work to help provide support to staff on work allocation has since taken place.

2.7. Since the survey, CMG have continued to work with team members to monitor workload and staff wellbeing.

3. Staff survey

3.1. We usually conduct a wider annual staff survey, although this was postponed this year because of the disruption of Covid-19. The postponed survey was conducted in late May early June and we are presently analysing the results. The overall response rate for the survey stands at 83%, which is similar to previous years (87% in 2018 and 86% in2017). Given the unusual circumstances at present we are pleased with response rate.

3.2. We will put in place an action plan to support the findings from the survey.

4. Staff turnover

4.1. We have seen a significant decline in staff turnover in recent months. The current level of turnover stands at 13.7% This compares very favourably with the figure of 27% in June last year.

4.2. The figure of 13.7% is also below the target of 15% set out in our business plan

4.3. The lower level of turnover is clearly welcome and is probably due to a range of factors. Covid-19 has undoubtedly had an impact as it has reduced the number of opportunities elsewhere. More positively, we also believe that the fact that we have been able to offer opportunities for internal promotion and development has helped.

4.4. Although we cannot say with certainty, we also believe the new pay and grading system introduced last year, may have provided greater clarity for staff on progression routes within the organisation.

4.5. We have plans in place to continue to provide management development opportunities for staff in junior to mid manager grades within the organisation through a range of management development workshops in the coming months

5. Office move

5.1. The planned office move to Stratford is still set to take place in November. Whether the move to Stratford marks a return to office based working is a separate question and one which will be taken later in the year in the light of Government guidelines. Regardless of when that decision is taken, the impact of Covid-19 has required us to consider what changes, if any, we need to put in place to encourage more flexibility around home working.

5.2. As noted above, we have been able to adapt our ways of working to allow staff to work from home on a full-time basis, with very little disruption to day to day service provision. We do not know how long the lockdown arrangements will last, but the injunction to work from home if you are able remains in place and may do so for many months to come. It is therefore important that we revisit those working arrangements to see whether they are still fit for purpose. In short, we need to determine how long the current arrangements needs to be in place, and what impact, if any, it has on work performance.

5.3. We also need to ensure that for those who may be carrying out caring responsibilities alongside the day job, we ensure that they are able to balance the demands of their work with their home life, whilst minimising the impact their dual roles might have on their personal health and wellbeing .

5.4. One of the ways in which we have supported staff over the lockdown, has been to be flexible with their working hours so that they do not feel under too much pressure to meet a demanding workload at this time. This situation will continue to remain under review and senior managers have been encouraged to speak with any of their team member who might be affected to ensure their continued wellbeing remains at the fore

6. Recommendations

The Committee is asked to note and comment on the actions taken to date

Audit and Governance Committee Forward Plan

Strategic delivery:	☐Safe, ethical, effective treatment	☐Consistent outcomes and support	☒Improving standards through intelligence
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	13		
Paper number	AGC (23/06/2020) MA		
Meeting date	23 June 2020		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to note that the update from the Director of Strategy and Corporate Affairs has been deferred till October and are asked to review and make any further suggestions and comments and agree the Forward Plan		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low	☐ Medium	☐ High
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information		
Annexes	N/A		

Audit & Governance Committee Forward Plan

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

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

Register of Gifts and Hospitality

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	14		
Paper number	HFEA (23/06/2020) MA		
Meeting date	23 June 2020		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	Attached is the latest Gifts and Hospitality Register. Since the last meeting, no items have been added. Members are asked to note.		
Resource implications			
Implementation date	2020/21 business year		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High

Register of Gifts / Hospitality Received and Provided/Declined

Version: HFEAG0001
Jun-20

DIVISION / DEPARTMENT: HFEA
FINANCIAL YEAR: 2020/21

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