Audit and Governance Committee meeting - agenda

09 December 2021

Online

10am – 1.00pm

Agenda item			Time
1.	Welcome, apologies and declaration of interests		10.00am
2.	Minutes of 05 October 2021 [AGC (09/12/2021) DO]	for decision	10.05am
3.	Matters arising [AGC (09/12/2021) MA]	for information	10.10am
4.	Internal audit update [AGC (09/12/2021) JC]	for information	10.20am
5.	Progress with current recommendations [AGC (09/12/2021) MA]	for information	10.40am
6.	External audit planning report [AGC (09/12/2021) MS/DG]	for information	10.50am
7.	Human Resource bi-annual report [AGC (09/12/2021) YA]	for information	11.10am
8.	Strategic risk register [AGC (09/12/2021) PR]	for comment	11.25pm
	Break		11.45pm
9.	Resilience & business continuity management [AGC (09/12/2021) RC]	for comment	12.00noon
10.	Regulatory and Register management [AGC (09/12/2021) RC]	for comment	12.20pm
11.	AGC forward plan [AGC (09/12/2021) MA]	for decision	12.40pm
12.	Items for noting • Gifts and hospitality • Whistle blowing and fraud • Contracts and Procurement	for information	12.50pm

	[AGC (09/12/2021) RS]	
13.	Any other business	12.55pm
14.	Close	1.00pm
15.	Session for members and auditors only	

Next Meeting: Tuesday, 15 March 2022, Online.

Minutes of Audit and Governance Committee meeting 05 October 2021

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	9 December 2021		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Audit and Governance Committee meeting held on 5 October 2021 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Audit and Governance Committee meeting on 5 October 2021 held via teleconference

Members present	Margaret Gilmore – Chair Catharine Seddon Mark McLaughlin Geoffrey Podger
Apologies	Anita Bharucha
External advisers	Mike Surman, National Audit Office – External auditor Joanne Charlton, Internal Auditor – GIAA Rebecca Jones, GIAA Dean Gibbs, KPMG – Audit lead
Observers	Csenge Gal, Department of Health and Social Care – DHSC Amy Parsons, 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 Paula Robinson, Head of Planning and Governance Kevin Hudson, Programme Manager Debbie Okutubo, Governance Manager Samuel Akinwonmi, Finance Manager Helen Crutcher, Risk and Business Manager

1. Welcome, apologies and declarations of interest

1.1. The Chair welcomed everyone present online.

1.2. There was one apology from Anita Bharucha (Chair AGC); Margaret Gilmore (Deputy Chair) had agreed to chair in Anita's absence.

1.3. There were no declarations of interest.

2. Minutes of the meeting held on 22 June 2021

2.1. The minutes of the meeting held on 22 June 2021 were agreed as a true record and signed by the Chair.

3. Matters arising

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

3.2. Members commented that this was a matter of concern that needed to be resolved. The Chief Executive commented that it would be treated as being urgent.

3.3. A member commented that at another organisation, Board member training which included cyber security was carried out as a short workshop and that it might be worth considering a similar approach rather than sourcing an online package.

4. Digital programme update

4.1. A detailed account of the current situation with PRISM was presented by the Programme Manager.

4.2. Members were advised that the cutover from EDI to PRISM had been enacted:

- EDI was switched off on Friday 27 August 2021
- a detailed cutover exercise was conducted which was tested both internally and with selected clinics
- the cutover was successful, and PRISM went live on Tuesday 14 September.

4.3. The Programme Manager commented that they were pleased with the performance of PRISM to date and that the focus was to now support clinics and the API deployments.

4.4. Members were also advised on the progress of the EPRS suppliers. It was noted that work was ongoing with Mellowood and there was an expectation that they would complete deployment by the end of November. CARE were on track to deploy within the deployment window. There were concerns with Meditex, but at this stage the practical solution was to put further pressure on them through their clinics.

4.5. Members noted that the date when all clinics were expected to have completed deployment was 10 December 2021 which was three months after launch.

4.6. Members congratulated the team on achieving the launch of PRISM and noted the post go-live work still to be done.

4.7. The Programme Manager commented that interactions with clinics were lower than we were expecting and that this was a positive.

4.8. Members asked how errors were detected and how soon assurance could be given that PRISM was working as expected.

4.9. The Programme Manager explained the workings of PRISM and commented that errors were detected and recorded on the PRISM homepage as part of the inbuilt programme. HFEA staff monitored all errors recorded.

4.10. Members were advised that currently queries are sent directly to the Programme Manager and the end-to-end process for how they were resolved was being documented to help train other register staff.

4.11. Members asked about the data dictionary. The Chief Executive explained the history, which dates from a review of the HFEA and HTA which recommended that we should collect less data in an effort reduce the regulatory burden on licensed clinics. The data dictionary was developed with sector representatives, and we now collected fewer data items than previously.

4.12. Continuing, the Chief Executive said that there was perhaps some confusion between the amount of data collected and the process of data submission. PRISM was a much more efficient data submission system and once clinics were confident in using it there was an opportunity to reopen

discussions with clinics about whether there were additional data we ought to collect, in particular, data that would aid research.

4.13. In response to a question, members were advised that 'reasons for infertility' was one of the data points no longer collected. Members suggested that this was a pertinent question and that this information should be revisited for research purposes.

4.14. Members asked how we would ensure that Meditex and other ERPS system suppliers were able to deploy by the agreed date. The Programme Manager responded that at first we would ensure that their systems were working properly and then look to apply measures at our disposal.

4.15. In terms of post go-live development, it was noted that to consider options for the production of CaFC from the new Register, Stalis, an external business intelligence company, was commissioned to conduct an assessment of future options.

4.16. Members asked if the deadlines for the early post PRISM work on billing, inspectors books and the reporting database were realistic. Staff responded that we were confident that we would meet them. For re-establishing CaFC, members noted that a lot of work was needed including taking our clinics through the validation process.

4.17. In response to a question, it was noted that CaFC publication dates could be changed at the HFEA's discretion and that a planning meeting was being organised at which the aim was to assess the resources needed and timescales of all post PRISM IT work, including CaFC.

4.18. Members asked about the costs associated with the extension of contracts and where the funding for this would come from. The Director of Finance and Resources responded that we were looking at sourcing it from our reserves and if we were not allowed to do that, it would be funded from additional income realised from increased activity.

4.19. Members agreed that a separate meeting to consider the lessons learned from PRISM should be held in December. It was agreed that the Chief Executive should lead on drafting the lessons learned report.

4.20. Members agreed that in addition to the suggested questions in the paper it was also important to consider additional points on leadership, management, disconnect with people on the frontline, feedback, costs, staffing and relationships. Members agreed that the following questions should be addressed, as suggested in the paper:

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

4.21. Members commented that optimism bias should also be included as a factor in the report and asked whether members could, at some stages, have asked more searching questions.

Decision

4.22. Members noted

- the cutover to PRISM and the level of activity currently being experienced
- the work still required to complete the deployment of PRISM

- the ongoing work for post go-live development and re-establishing reporting
- the additional costs of extending key contracts
- our approach to agreeing a long-term development plan for HFEA IT and information.

4.23. Members agreed the approach for reporting lessons learned from PRISM, and that this should be delivered at a special AGC meeting during December.

5. Internal audit update

5.1. The Chair invited the Internal Auditor to present the 2021/22 internal audit progress report.

5.2. It was noted that as at 24 September 2021, 33% of the plan to final report stage had been completed. The review of the Data Security & Protection Toolkit (DSPT) submission for 21/22 was amended to June 2022 which meant that it would be a 2022/23 quarter one audit going forward.

5.3. The Internal Auditor requested that the customer satisfaction questionnaire sent to the executive should be completed as it assisted the GIAA work with clients more effectively.

5.4. Members were advised that two final reports had been issued, the Staff Wellbeing report which was given a 'moderate' assurance rating and the DSP Toolkit which was rated as 'unsatisfactory'.

5.5. Members commented on the insight provided for data governance and in particular that data protection impact assessments (DPIAs) should be carried out early in all projects. Staff responded that this already formed part of our tools for managing projects.

5.6. In response to a question on why DSPT was given an 'unsatisfactory' assurance rating, the internal auditor acknowledged that this was the first time that the HFEA had completed the toolkit and the executive had probably underestimated the amount of time and resource work required. This led, in the opinion of the GIAA, that there was insufficient evidence provided by the Authority to support their conclusions.

5.7. The Chief Executive responded that the DSPT was new to us and we would carry out the work required and ensure that we were able to articulate how we store and record data, in the format required. The Chief Executive reassured members that although the DSPT rating was disappointing it did not mean that the HFEA did not handle data securely - we had never had a data loss from the Register in our 30 year history,

5.8. Members asked if this was a process or a data management problem, as we could not afford a breach. Also, that this type of audit which supported the compliance with legal and regulatory requirements was not going to go away. It therefore needed to be addressed and resources allocated to it.

5.9. In response to a question, the internal auditor commented that the DSPT was one of several mechanisms in place to support Health and Social Care organisations in their ongoing journey to manage data security and data protection risk. Also, that some other small sized DHSC ALBs were compliant.

5.10. The Director of Finance and Resources commented that we were in conversation with some other ALBs including the Health Research Authority (HRA) to learn how they became compliant over time. Members were advised that a lot of the evidence sat in various parts of HFEA and it needed to be collated and documented, which we had started working on. The plan was to become

compliant. It was also noted that the ALBs which were compliant had been using the online self-assessment for two to three years.

5.11. Members commented that it looked like a large proportion of staff time needed to be dedicated to matters like these and asked what the opportunity cost was to such a small organisation with limited staff resources. There was a suggestion that a worthwhile exercise might be to ask NHS Digital what had been achieved from the exercise.

5.12. Other members commented that the resource implication and benefits to us were valid statements but what such exercises also did was to force us to address our defects with the added assurance of us adhering to legal and regulatory requirements.

Decision

5.13. Members discussed the content of the progress update and ratified the deletion of the Data Security & Protection Toolkit for 21/22 from the audit plan.

6. Implementation of recommendations

6.1. The Finance and Accounting Manager presented this item. It was noted that a number of completion targets had not been met including the knowledge and skills gap exercise and staff being aware of the business continuity plans.

6.2. It was stated that all overdue tasks would be the focus and that revised timelines would be presented at the next meeting.

6.3. Members asked how SMT were sure that staff did not feel overwhelmed with working from home, the extra work and or difficulties with communication as an effect of the pandemic.

6.4. The Chief Executive responded that a short staff wellbeing survey was done a couple of months ago and the responses were generally positive. Most staff had started to attend the office actively once a week and this was assisting with communication and generally staff had coped well working from home even though there have been some drawbacks.

6.5. It was noted that staff had worked at pace and as a response we changed our ways of working which would be kept under review.

6.6. Members thanked staff for their hard work to date.

Decision

6.7. Members noted the progress of the recommendations.

7. External audit update

7.1. The External Auditor gave a verbal update. Members were advised that the NAO had a long-standing commitment to contract-out 20% of its financial audit work. After many years of keeping the HTA and HFEA audits in-house, the NAO had decided to contract-out the audits for at least the next three years.

7.2. Audits of the HFEA and the HTA have been contracted out to KPMG and Dean Gibbs, KPMG's Audit Director would be the audit lead.

7.3. Members were advised that the plan was to continue to have one seamless audit team as there would be interaction between the National Audit Office and KPMG which would be reflected in their presentations at meetings.

7.4. Dean Gibbs introduced himself and commented that there was a paper setting out the proposed approach and timetable to transition which would be shared with the committee.

Decision

7.5. Members noted the update.

8. Reserves policy

8.1. The Director of Finance and Resources presented this item to the committee. Members were reminded that enough cash reserves were required to continue business operations on a day-to-day basis and in the event of unforeseen difficulty and commitments that might arise.

8.2. Going forward, it was felt that the minimum level of cash reserves required was £1.3m (rounded) and that the reserves would be in a readily realisable form.

8.3. Members were informed that discussions had been held with DHSC Finance team and a soft agreement had been reached that we could not go into deficit by utilising our cash reserves. We were therefore proceeding with the proposed fee increases for 2022/23 but we would need to await HM Treasury's final agreement.

8.4. Members asked why in our minimum reserve we did we not have an allocation for judicial reviews. The Director of Finance and Resources responded that it was included in the Finance budget as a subsection for general reserve.

Decision

8.5. Members approved the updated Reserves policy.

9. Strategy & Corporate Affairs directorate update

9.1. The Director of Strategy and Corporate Affairs presented this item to the committee.

9.2. Members were advised of the risks faced in the directorate and some of the ways the risks would be mitigated during this business year. Members were advised that the risks in the directorate were representative of the wider risks across the organisation and particularly in the Covid recovery period, where staff were tired and capacity stretched, which increased the risk of mistakes being made.

9.3. Members commented that there were grounds to make a case for more resources. Members went on to ask if there were other creative ways of encouraging staff to stay in roles in the absence of a pay rise, in terms of flexibility around benefits.

9.4. The Chief Executive commented that we were in discussion with the DHSC regarding the cap on our head count particularly highlighting that in fulfilling our statutory functions, we often relied on a single person responsible and if that one person was unavailable it remained a single point of failure. It was also believed that we could fund these extra posts without increasing our grant in aid.

9.5. Members commented that they supported the Chief Executive's argument and that the point should continue to be made that growth could be sourced through other means.

9.6. The Director of Strategy and Corporate Affairs commented that our wider strategic ambition would not be compromised. It was the detail of the business plan that we would need to continue to work with to ensure that we have the capacity to realise and deliver the business plan.

Decision

9.7. Members noted the update and thanked the Strategy and Corporate Affairs team through the Director.

10. Legal risks

10.1. The Chief Executive presented this item.

10.2. Members noted the position of the Authority.

11. Strategic risk register

11.1. The Risk and Business Planning Manager presented the strategic risk register. There were ten risks in the register with one above tolerance.

11.2. C2: Loss of senior leadership both at board or management level, leading to a loss of knowledge and capability which could impact formal decision-making and strategic delivery was above tolerance. It was noted that board vacancies not being filled was not sustainable in the long run.

11.3. Members were also advised that staff turnover (C1) was increasing and would soon be above tolerance putting strain on staff generally while covering gaps, inducting new starters, and managing knowledge transfer.

11.4. It was noted that it had become common to scope the work that needed to be covered to ensure that we met our regulatory requirements.

11.5. In response to a question, the Risk and Business Planning Manager commented that data risk and cyber risk were on the radar of the new Head of IT who was looking at having a review of the cyber security risk. This would first be presented to the Corporate Management Group (CMG).

11.6. Members asked if SMT were looking at other ways to market roles and offers to staff. The Chief Executive responded that currently salaries were caught by the Government's pay freeze for the civil service. However, other offers including more flexibility in working patterns were being discussed.

11.7. Members were advised that when staff leave, we were experiencing recruitment challenges and it was becoming harder to get good quality replacements. This was a reflection of the tight labour market conditions which was affecting both the public and private sectors.

11.8. Members commented on I1: the risk that HFEA could become an ineffective information provider, jeopardising our ability to improve quality of care and make the right information available to people, and asked If the risk rating was right, due to the uncertainty around opening the register (OTR) requests, and choose a fertility clinic (CaFC).

11.9. The Risk and Business Planning Manager commented that SMT would look again at I1 once the controls had been reviewed and better articulated.

11.10. Members commented on horizon scanning and suggested that it felt like there should be an additional risk relating to workload and business as usual. The impact on staff morale and the potential for exhaustion could impact on whether we had the resources to gather the evidence needed to underpin future legislative reform and change.

11.11. The Chief Executive reiterated that core statutory tasks could not be ignored and that they would be covered but we would also need to prioritise other tasks. This would be discussed in the context of upcoming business planning work.

11.12. The Chair thanked the Risk and Business Planning Manager for all she had done whilst working at the Authority as this was her last meeting.

Decision

11.13. Members noted the strategic risk register.

12. Resilience & business continuity management

12.1. The Director of Compliance and Information presented this item. Members were updated on the interim structure and management of the IT team that would allow the team to function effectively in the short term.

12.2. Members were also advised on the CM upgrade which required a client rollout to all laptops and would be completed by end of October 2021. The Director of Compliance and Information commented that the IT security review provided reassurance that the method used by the HFEA to back up IT systems meant that we could recover from a ransomware attack with minimal data loss.

12.3. To address the recent increase in demand in the OTR service and to prepare for applications in 2023, members were informed that there would be a service redesign project. Short term measures had been put in place to start to clear the backlog of applications and reduce waiting times.

12.4. Members expressed concern about the backlog and the time it was taking to reduce it.

12.5. In response to a question, it was noted that part of the measures put in place to clear the backlog of applications and reduce waiting time was the recruitment of two additional members of staff on fixed term contracts in the OTR team. Staff are currently undergoing training.

Decision

12.6. Members noted the recommendations,

13. AGC forward plan

13.1. The Finance and Accounting Manager presented this item.

13.2. Members noted the current position of the forward plan.

14. Items for noting

14.1. Gifts and hospitality

- The register of gifts and hospitality was presented to the committee. There were no changes. Members **agreed** that this would only be presented when there are updates.

14.2. Whistle blowing and fraud

- There were no cases of whistle blowing or fraud to report. Members **noted** the assessment provided by DHSC Anti-Fraud Unit (AFU).
- Members **agreed** the Fraud Risk Assessment (FRA).

14.3. Contracts and procurement

- There were no new contracts or procurements to report.

15. Any other business

15.1. There was no other business.

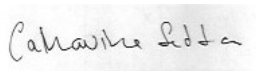
16. AGC committee effectiveness

16.1. The Governance Manager and the Head of Planning and Governance serviced this part of the meeting with members only.

Chair's signature

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

Signature



Chair: Catharine Seddon

Date: 9 December 2021

AGC Matters Arising

Details about this paper

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

Meeting	Audit and Governance Committee		
Agenda item	3		
Meeting date	9 December 2021		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each AGC		
Implementation date	2021/22 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 6 October 2020			
13.4 Cyber security training to be confirmed to members	Head of Finance	Dec-20	**Update** – training was provided using the Astute training platform. Reminder to be sent to members before the Christmas break. **Update** – we are still trying to source a training platform
Matters Arising from the Audit and Governance Committee – actions from 5 October 2021			
4.20 A lessons learned from PRISM meeting to be held in December (special AGC meeting)	Chief Executive/Director of Compliance and Information	Dec-21	**Update**
6.2 Outstanding audit recommendations that are overdue to have their target dates reviewed and presented to committee	Head of Finance	Dec-21	**Update**

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HFEA Staff Survey 2021 overview

www.hfea.gov.uk

Overview of the survey areas

The survey is split into the following themes:

- Overall experience – the extent to which I am committed and enjoy working for the HFEA
- Autonomy
- Enablement
- Reward
- Leadership
- Purpose

- Questions relating to staff views on to return to office working were also explored

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Comparators

Our survey results were compared with other around 200 public sector bodies. Below is a selection of the types of organisations which form comparators

- HSIB (Healthcare safety bereau)
- UKAR
- Various universities (e.g. Open University)
- Multiple fire & rescue services
- British Business Bank
- Inland homes
- GPhC – General pharmaceutical council
- Royal college of surgeons
- Francis Crick Institute
- NHS improvement and NHS England
- St John's ambulance
- VSO – voluntary service overseas
- UK supreme court

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Technical notes

Below is a key to the how the data from the survey is presented

	Positive responses to the questions
	Neutral responses – neither agree nor disagree
	Negative responses to the questions
	The extent to which our data compares favourably above public sector comparators
	The extent to which our data compare less favourably against public sector comparators

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Headline Indicators

- Response rate 72% (83% 2020) (Above sector average of 70%)
- Our engagement scores, i.e. the extent to which staff feel happy at work stands at 80% – this is above the average for our public sector comparators of 75% and above last years score of 77%
- We have a higher percentage of staff, 67% who see themselves remaining with the organisation 2 years from now. Although this is still 2% below the average for the sector of 69%, it is significantly higher than the 55% response rate from last year
- Perception of senior management is higher than last year and stands at 64%, compared with 62% last year and is 16% higher than the sector average .
- We have a lower-than-average favourable response to questions about pay, 14% which is 21% below the sector average
- Responses on wellbeing also fall 15% below the sector average however responses in this area were gathered prior to the introduction of the wellbeing portal

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Theme Headlines
(Data compared against 2020)

Focal point	Response favourability	Comparison
Engagement	80% 12% 8%	+3

Theme headlines

Themes	Response favourability	Comparison
Purpose	77% 12% 10%	-3
Enablement	62% 17% 21%	0
Autonomy	71% 13% 16%	-1
Reward	49% 24% 27%	-5
Leadership	64% 18% 18%	+2

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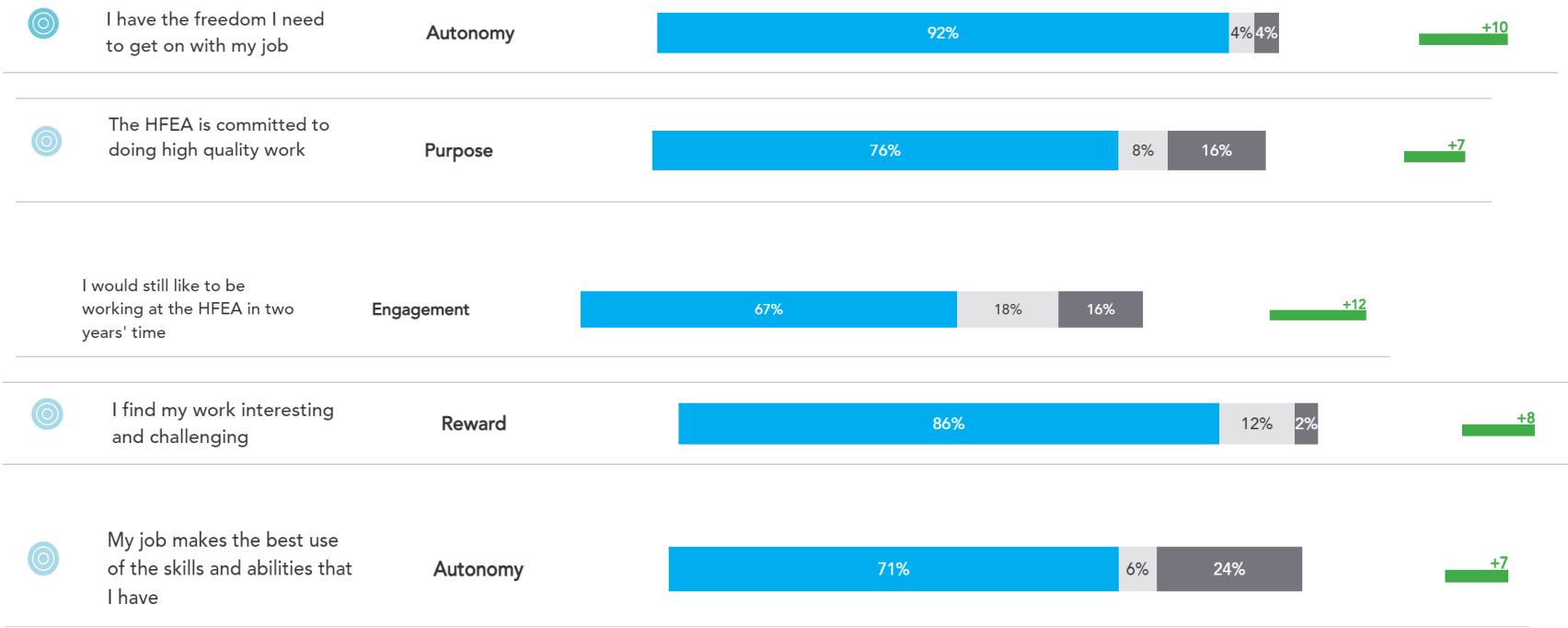
Top 5 high performing questions against sector average



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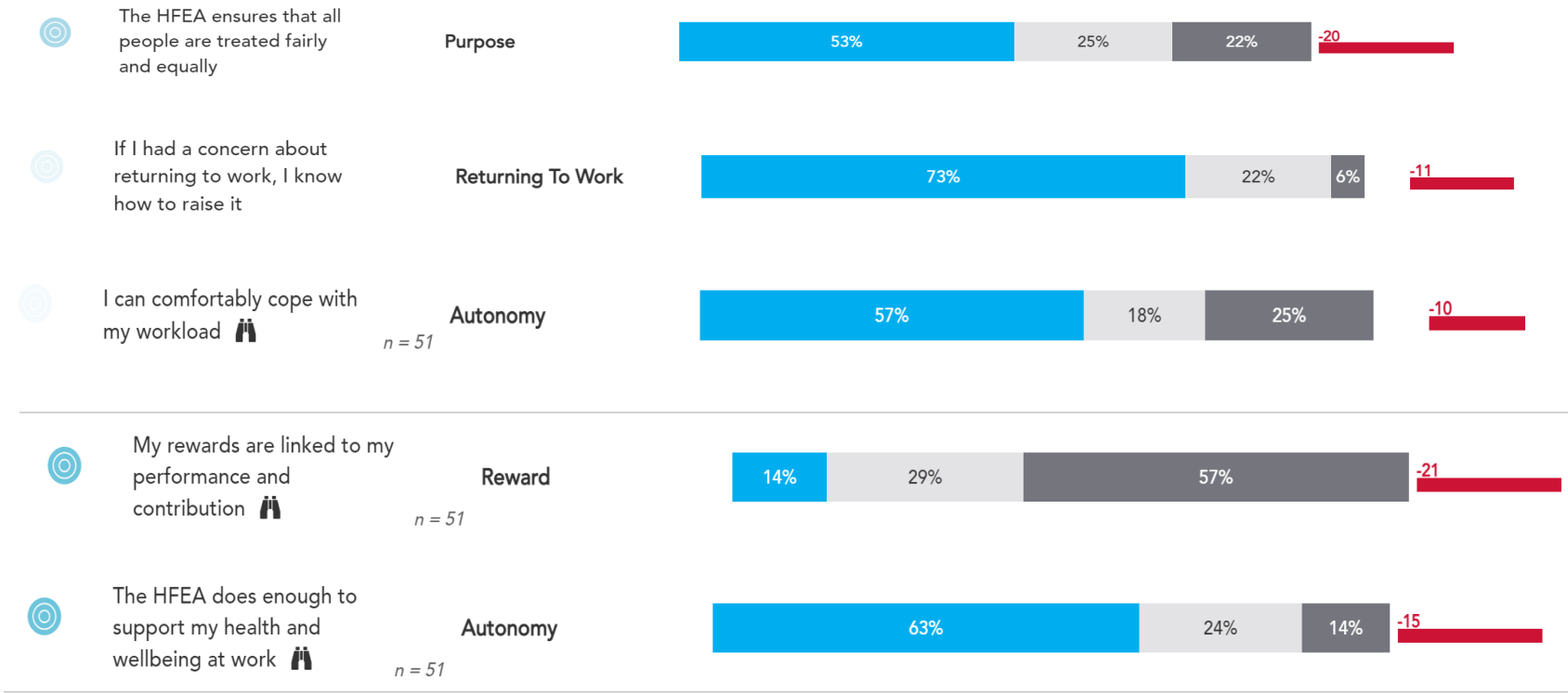
Low scores compared with the sector norms



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Overall experience – the extent to which I am committed and enjoy working for the HFEA compared with 2020

Impact	Question	Theme	Response favourability	Comparison
	I am proud to say I work for the HFEA	Engagement	84% 12% 4%	-1
	I care about the future of the HFEA	Engagement	92% 6% 2%	-4
	I would still like to be working at the HFEA in two years' time	Engagement	67% 18% 16%	+12
	If asked, I would recommend to friends and family that the HFEA is a good place to work	Engagement	73% 16% 12%	+3
	Working here makes me want to do the best work I can	Engagement	82% 10% 8%	+4

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Key Driver questions

In the survey, some questions have more of an impact on our engagement score than others.

They are called key drivers

The responses to these key drivers will help in putting together our action plan. If a question has a high score, we want to make sure we do what we can to maintain it;

if it's a low score, consider this an action area for improvement.

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The top 5 questions which impact on engagement compared with 2020

5 questions most impacting Engagement

Impact	Question	Theme	Response favourability	Comparison
	The purpose of the HFEA makes me feel good about my work	Purpose	86% 10% 4%	+13
	I believe action will be taken as a result of this survey	Leadership	41% 29% 29%	-5
	I feel valued and recognised for the work that I do	Reward	57% 24% 20%	-5
	I have the freedom I need to get on with my job	Autonomy	92% 4% 4%	+15
	People help and support each other here	Enablement	69% 16% 16%	-3

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Key themes from the open text responses

Summary responses included:

- Staff like the fact that the organisation offers good work-life balance
- Many felt that relationships within teams is good, but not cross teams
- Some expressed concern about returning to the office and expressed a desire to see the organisation be flexible with its approach
- A number of staff said they liked the option of being able to work in the office and to collaborate with others
- Some staff expressed concerns about pay in relation to workload
- The lack of opportunities for progression was mentioned by some
- Clarity about the work on diversity and inclusion was also raised

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Next steps

What will we do next

- Present findings to staff
- Heads to discuss survey results with their teams
- Put together a small group to help pull together an action plan
- Present action plan to CMG and staff prior to implementation
- Monitor and feedback on action plan on a quarterly basis
- Results will be shared on the Hub

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Staff Key Data Overview

www.hfea.gov.uk

Sickness absence

Overview

- Sickness absence is high again this month. We had two employees on long term sick, one has returned. Our sickness absence rate of 3.87% is above the average for the public sector which stood at 2.7% in 2021 and the average of 1.8% across all UK sectors

- Only workers working in public health recorded a higher rate (3.6%) than the previous year (3.4%).

- We will continue to monitor our sickness rates and offer support to staff through occupational health referrals, employee assistance programs and our recently launch wellness portal

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Staff turnover

Overview

- The UK job market across all sectors has seen a steady increase in job vacancies over the last 12 months, the decision not to award most public sector workers a pay rise has also had an impact with a number of our leavers moving into better paid private sector jobs

- Turnover at 17.5% is, 2.6% higher than our target of not higher than 15% With two leavers in the last month, turnover may now be slowing down and recruitment is now at a more steady, manageable pace.

- Median turnover within the public sector currently stands at 13.4%

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Staff turnover

Overview

- We will continue to conduct exit interviews and use the findings from our recent staff survey to help improve engagement across all areas within the organisation. We however recognise that our powers are limited in areas such as pay.

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Strategic risk register 2020-2024

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Audit and Governance Committee
Agenda item:	8
Meeting date:	9 December 2021
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex 1: Strategic risk register 2020-2024

Output from this paper

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

1. Latest reviews

1.1. SMT reviewed the register at its meeting on 1 November 2021. SMT reviewed all risks, controls and scores.

1.2. SMT's comments are summarised in the commentary for each risk and at the end of the register, which is attached at Annex 1. The annex also includes a graphical overview of residual risk scores plotted against risk tolerances.

1.3. Two of the nine risks are above tolerance.

2. Risk management system – future plans

2.1. AGC will recall that we had been hoping to begin a review of our risk system in the past few months, and that this work has been delayed by the departure of the Risk and Business Planning Manager. At the time of writing, we are still managing a gap, and so capacity for this area is severely limited. However recruitment has been in progress, and we are now hopeful that we have found a candidate for the role – it may be possible to give a verbal update on this at the meeting.

2.2. Prior to leaving, the outgoing Risk and Business Planning Manager reviewed the existing risk policy (agreed in November 2018) against guidance and updated our internal supportive processes as well as briefing an internal auditor on the HFEA risk system. When we have filled this important role, the postholder (after a period of induction and any necessary training) will focus on the following areas as a priority:

- Supporting a risk audit and considering the recommendations that emerge from that process.
- Reviewing the format and content of our strategic risk register, in line with previous suggestions from AGC. This will include an enhanced focus on risk assurance in our control framework and a way of displaying live issues more clearly and dynamically.
- Further work on embedding risks and incidents into the organisational culture internally.
- Work to improve the consistency of scoring of operational risks across teams.
- Assisting in the development of interactive training on internal incidents and data breaches.
- Reviewing our risk management policy, in light of all of the above.

2.3. The review of the policy, as the final step in the process, will come to AGC for approval – most likely in Autumn 2022.

3. Recommendation

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

Annex: Strategic risk register

Latest review date – 1/11/2021

Strategic risk register 2020-2024

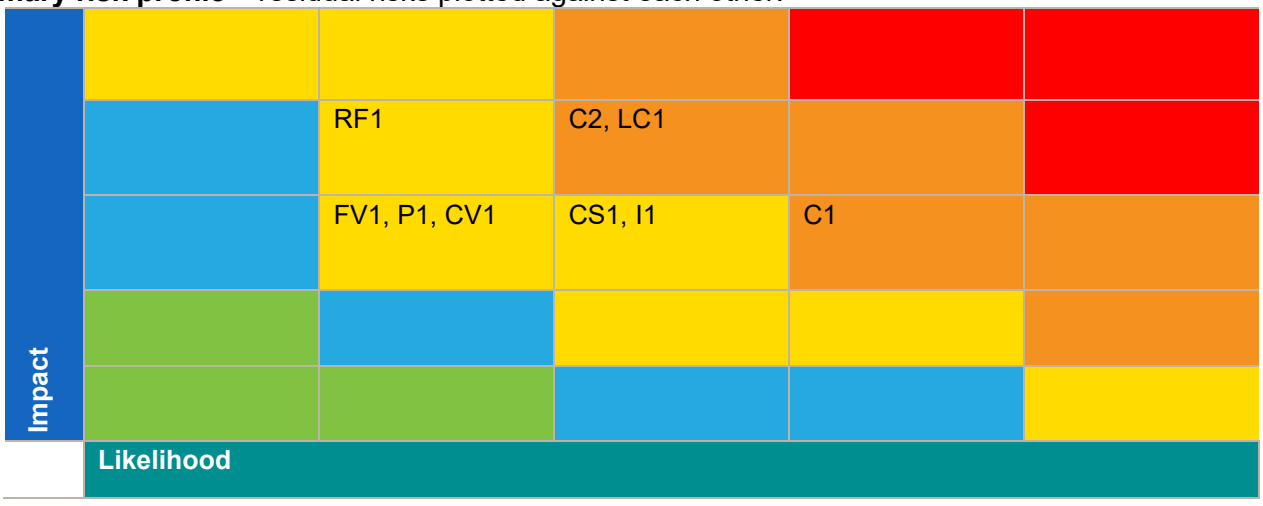
Risk summary: high to low residual risks

Risk ID	Strategy link	Tolerance	Residual risk	Status	Trend*
C2: Leadership capability	Generic risk – whole strategy	4 - Low	**12 – High**	Above tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	12 – High	**12 – High**	At tolerance	⇔⇔⇔⇔
C1: Capability	Generic risk – whole strategy	12- High	**12 – High**	At tolerance	⇔⇧⇔⇔
CS1: Cyber security	Generic risk – whole strategy	9 – Medium	**9 – Medium**	At tolerance	⇔⇔⇔⇔
RF1 – Regulatory framework	The best care (and whole strategy)	8 – Medium	**8 – Medium**	At tolerance	⇔⇔⇔⇔
OM1: Operating Model	Whole strategy	6 – Medium	**6 – Medium**	Risk now discontinued	⇔⇔⇔x
FV1: Financial viability	Generic risk – whole strategy	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇩⇔
I1 – Information provision	The right information	8 – Medium	**9 – Medium**	Above tolerance	⇔⇔⇔⇧
P1 – Positioning and influencing	Shaping the future (and whole strategy)	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔
CV1 - Coronavirus	Whole strategy	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔

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

Recent review points: SMT 2 August ⇨ SMT 20 September ⇨ AGC 5 October ⇨ SMT 1 November

Summary risk profile – residual risks plotted against each other:



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

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

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

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

Causes / sources	Controls	Timescale / owner of control(s)
We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance advertising or artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, we collaborated on the CMA and ASA's work in this area to strengthen the information and advertising provision for patients). Working with other expert regulators is effective in areas where we do not have effective powers	In progress - Clare Ettinghausen

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

Causes / sources	Controls	Timescale / owner of control(s)
	Continued extensions to some licences where appropriate (ie, low risk clinics with good compliance) to manage the pressure on inspection delivery workload.	
Some changes can be very fast meaning our understanding of the implications is limited, affecting our ability to adequately prepare, respond and take a nuanced approach	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by: • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily must wait for some changes to be clearer to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing quick responses such as a Chair's letter, Alert or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.	In place – Joanne Anton In place - Peter Thompson
We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.	Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions. Any reprioritisation of significant Strategy work would be discussed with the Authority.	In place – Peter Thompson
Developments occur in areas where we have a lack of staffing expertise or capability.	As developments occur, Heads consider what the gaps are in our expertise are and whether there is training available to our staff. If a specific skills gap was identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporarily or sharing skills with other organisations.	Ongoing - Relevant Head/Director with Yvonne Akinmodun
RITA (the register information team app – used to review submissions to the Register) has been built but some reporting issues still need to be resolved. If it is not completed in a timely way, we may not effectively use data and ensure our regulatory actions are based on the best and most current information. As of September 2021, development on the first phase	If RITA is not completed in a timely way, the Register and OTR team will still be able to use manual workarounds to get access to the information they need to support clinics and / or to provide information to support our regulatory work. although these workarounds will result in a substantial delay to responding to an OTR request or providing clinic support. RITA Phase 2 needs to be prioritised against other development work. We will set up a new group to prioritise and oversee development from October 2021.	Ongoing – Rachel Cutting (pending recruitment to Chief Technology Officer post) Prioritisation of remaining development as delivery

Causes / sources	Controls	Timescale / owner of control(s)
has completed and this risk is decreasing.		continues – Kevin Hudson
We don't hold all the data from the sector (beyond inspection or Register data) to inform our interventions, for instance on add-ons.	As part of planning and delivering the add-ons project we have looked at the evidence available and considered whether we can access other information if we do not have this already. We revise our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool). Process to be established for reviewing the data dictionary which will allow for internal and external stakeholders to suggest that we collect more/less data, review impact assessments on the HFEA and the sector as a whole of those changes and plan for any development that will be needed (both internally and externally) to make them possible.	In place – Joanne Anton Audit tool launched in clinics from Autumn 2020 - Rachel Cutting Detailed planning to follow and first meeting likely to be held in Q4 2021/2022 – Neil McComb
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	3	12 - High	**3**	**3**	**9- Medium**
Tolerance threshold:					**8- Medium**
Status: **Above tolerance**					

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

Commentary

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

In October 2020, the Opening the Register service reopened after being paused since clinics shut down due to Covid-19. Due to this pause, we received an influx of applications which means we are unable to meet our usual KPI for completing responses for a period. We have managed this carefully as a live issue, to ensure that applicants receive accurate data and effective support as quickly as we are able, with a focus on continuing to provide a quality, effective service. New performance reporting KPIs are being developed to give the Authority a clear picture of progress. Ongoing communication with applicants and centres has been clear to ensure they understand the position and we manage expectations. We have recruited extra resource to manage the backlog but the impact of this will take some time to resolve the issue and reduce the ongoing risk. While training has occurred over summer 2021 processing rates have dropped, but we expect this to increase again in the coming months.

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

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

Causes / sources	Controls	Status / timescale / owner
People don't find us/our information, meaning we are unable to get clear and unbiased information to patients, donors, and others.	Knowledge of key searches and work to improve search engine optimisation to ensure that we will be found. We have a rolling bi-annual cycle to review website content and can revise website content to ensure this is optimised for search if necessary. We undertake activities to raise awareness of our information, such as using social and traditional media. We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us. We will be able to assess this in the 2021 patient survey.	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 and widening our presence on social media channels.	In place and ongoing - Jo Triggs
We do not have effective relationships with key strategic stakeholders and so cannot tailor our information to them.	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. Active work taking place to expand our regular stakeholder contacts (patient organisation stakeholder group, formerly AFPO). This will be evaluated a year after launching. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	In place with ongoing review – Clare Ettinghausen Recruitment underway – plan to launch revised group in Autumn 2021. 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 and clinics post their own data.	Ensure we maximise the information on our website and the unique features of our clinic inspection information and patient ratings. Clinics are encouraged to ask patients to use the HFEA patient rating system. We have optimised Choose a Fertility Clinic so that it is one of the top sites that patients will find when searching online and will be able to evaluate this as part of the 2021 patient survey. Review our information and distribution mechanisms on an ongoing basis to ensure relevance.	In place and ongoing - Jo Triggs In place and ongoing - Jo Triggs

Causes / sources	Controls	Status / timescale / owner
We are currently working off a snapshot of the Register and our access to live Register data is restricted. This will continue until the new Register goes live and we implement new data tools and a reporting database. This may hamper our ability to provide the right data in a timely way when responding to ad-hoc requests.	A reporting version of the Register was captured in December 2020 to enable us to do planned reporting such as the trends report, meaning there will be no impact on such standing information provision. For other requests, such as ad hoc FOIs and PQs, we also use this snapshot but there is a risk that we could receive a question about a variable that is not included in the snapshot. This would require assistance from a key staff member in the Register team and may not be possible at short notice. The implementation of these new tools and systems will be prioritised, to ensure that impact and this interim period is minimised. Teams, such as the Inspectorate, have backup plans for the gap between cutover and when the new register feeds into existing systems or processes (inspectors' notebooks, RBAT, QSUM etc.) to ensure relevant data is available.	Register snapshot captured December 2020. Understanding of potential need for cross team support in place and ongoing – Nora Cooke O'Dowd In place - Rachel Cutting (pending recruitment to Chief Technology Officer (CTO) post), Sharon Fensome-Rimmer
Until more development is done on reporting from the new Register, we will be unable to update data on Choose a Fertility Clinic. Over time it will stop delivering on its unique selling point, to be a source of independent, timely, accurate information to inform patients' treatment choices.	We updated the data available on CaFC ahead of the Register migration, to ensure that 2019 treatment data can be accessed, bringing this up to date. This will delay CaFC becoming out of date but does not close the risk. Ongoing controls need to be agreed, but conversations are underway about next steps and approaches we may take, so that we can plan any control activities into business plans for 2021/22 or 2022/23 as needed.	Completed February 2021 – Neil McComb Discussions about future mitigation plans underway item at CMG scheduled September 2021 – Peter Thompson
There are gaps in key strategic information flows on our website, for instance after treatment, resulting in missed opportunities to share information.	Digital Communications Board with membership from across the organisation in place to discuss information available and identify any gaps and what to do to fill these.	In place and ongoing - Jo Triggs
Given the advent of increased DNA testing, we no longer hold all the keys on donor data (via our Opening the Register (OTR) service). Donors and donor conceived offspring may not have the information they need to deal with this.	Maintain links with donor organisations to mutually signpost information and increase the chance that this will be available to those in this situation. Maintain links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications. Raise this in any review of the Act.	In place and ongoing - Jo Triggs In place and ongoing – Joanne Anton Future measure –

Causes / sources	Controls	Status / timescale / owner
		Peter Thompson
Our OTR workload will increase and change in 2021/2023 (when children born after donor anonymity was lifted begin to turn 16 and 18) and we may lack the capability to deal sensitivity with donor issues.	Service development work to review resourcing and other requirements for OTR to ensure these are fit for purpose. Business case for service development project approved July 2021. Delivery to begin Autumn 2021. Temporary additional resource in place (April and July 2021) to help mitigate increasing demands on the service in the short-term. Training is underway.	Future control – project will begin delivery Autumn - Neil McComb
The OTR service may be negatively impacted by an influx of applications following reopening after being paused, with demand outstripping our ability to respond. Note, this is being managed as a live issue as of September 2021.	Our focus is on accuracy and effective support for applicants; therefore, we have temporarily ceased reporting against our usual KPI, during the period of dealing with this pent-up demand. We are continuing to clearly communicate with applicants and the sector to manage expectations. We have recruited additional temporary resource to manage demand, however during training processing of applications has again been limited.	Additional resource in place (from April and July 2021) and being trained– Neil McComb
Risk that key regulatory information will be overlooked by stakeholders owing to the number of different communication channels and information sources.	There is a statutory duty for PRs to stay abreast of updates, and we provide key information via Clinic Focus. We duplicate essential communications by also sending via email to the centres' PR and LH (for instance, all Covid-19 correspondence). We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance on the Portal when they need it regardless of additional communicated updates. We plan to implement a formal annual catch-up between clinics and an inspector. Note: that due to revised inspection approach due to Covid-19 these plans have been delayed.	In place – Rachel Cutting In place – Joanne Anton Future control to consider following Covid-19 – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making; because of this, we could be seen as less transparent than other modern regulators.	Review of inspection reports is underway to identify future improvements to inspection reports. This will be delivered alongside other transparency work. Consideration of further changes to the information we publish in discussions on 'regulation and transparency' at Authority meetings. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.	Early work underway, but likely to complete 2022 – Rachel Cutting In place – Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None.		

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

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

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

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

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

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

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

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 – High	**2**	**3**	**6 – Medium**
Tolerance threshold:					**9 - Medium**
Status: Below tolerance					

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

Commentary
Covid-19 and the implementation of GD0014 caused reduced treatment activity during 2020-2021 meaning this risk became a live issue. We are now assured about our budget for 2021-2022, and in September SMT reduced the risk score accordingly, however uncertainty remains about resources in future years. In September 2021 the Authority agreed that the Executive should pursue additional resources for 2022-23. This would either take the form of access to reserves, or an increase to our licence fees. The Executive returned to the Authority in November with further recommendations, and it was agreed that we should now approach the Treasury regarding a fee increase.

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. Following agreement by Authority, options for access to additional resources in 2022-23 (through access to reserves or an increase to fees) being explored as of September. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC.	CMG monthly and Authority when required – Peter Thompson Discussions underway – Peter Thompson and Richard Sydee Regular review to resume following outcomes of discussions for 2022-23 – Richard Sydee

Causes / sources	Controls	Timescale / owner
Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles.	Our reserves policy takes account of monthly fluctuations in treatment activity, and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. If clinics were not able to submit data and could not be invoiced for more than three months, we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.	Policy in place review October 2021 – Richard Sydee Control under quarterly review as sector reopens – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed. The ten-year lease at Redman Place (from 2020-2030) provides greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee A moto is in place for Stratford confirming details of arrangements – Richard Sydee
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Project assurance Group is chaired by Director of Resources and a finance staff member is also present at PAG. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at PAG and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Samuel Akinwonmi
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is	Continuous - Richard Sydee

Causes / sources	Controls	Timescale / owner
reputational risk and a loss of financial autonomy or goodwill for securing future funding.	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).	Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Further Covid-19 impacts on HFEA income. As of September 2021, this is considered a small risk but there is uncertainty about autumn/winter covid impacts.	The final contingency for all our financial risks is to seek additional cash and/or funding from the DHSC.	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 agreed through to 2021 and discussions about SR21 are underway to set out funding for the next three years.	Quarterly accountability meetings (on-going) – Richard Sydee December/ January annually, – Richard Sydee

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

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

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

Commentary

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

As of September 2021, turnover is increasing above tolerance putting strain on staff generally while covering gaps, inducting new starters, and managing knowledge transfer. Moreover, recruitment is getting more difficult for some posts, with typically fewer high-quality applicants per post advertised, which increases the risk of a post not being appointed to. The civil service pay freeze is not helping and the increase for the NHS increases the likelihood that HFEA staff might choose to move to those health ALBs on NHS T&Cs. Though overall high turnover has cumulative effects across the whole organisation, high turnover at team level can feel particularly acute. This has been the case in the Policy team particularly. Regular conversations about resources at CMG ensures that we are aware of and can, where possible, plan mitigations for both.

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

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

We are working to maintain our relative flexibility while meeting our organisational needs. Discussions with CMG are advancing and proposals on homeworking and principles for using the office space are

being finalised. More engagement with staff on these issues is planned both through and following the recent staff survey, conducted at the end of October 2021.

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

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

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

Causes / sources	Mitigations	Status/Timescale / owner
	management responses where there are areas of concern.	survey occurring October 2021 with wellbeing pulse survey September and quarterly thereafter– Yvonne Akinmodun
	Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.	In place and review planned in 2021 - Peter Thompson
Work unexpectedly arises or increases for which we do not have relevant capabilities.	Careful planning and prioritisation of both business plan work and business flow through our committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings.	In place – Paula Robinson
	Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year.	In place – Paula Robinson
	Oversight of projects by both the monthly Programme Board and CMG meetings.	In place – Paula Robinson
	Project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources.	In place– Paula Robinson
	Planning and prioritising data submission project delivery, within our limited resources.	In place until project ends – Rachel Cutting (pending CTO recruitment)
	Skills matrix completed by teams to enable better oversight of organisational skills mix and deployment of resource. Plans to be drawn up in relation to findings.	Analysis underway as of September 2021 – Yvonne Akinmodun
Not putting actions in place to realise the capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working.	Active engagement with other organisations early on and ongoing (HR group). We are collaborating with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely, including a mentorship programme. **Note**: delayed due to Covid-19 impacts.	Early progress, ongoing – Yvonne Akinmodun
	Future control – use of Redman Place intranet to enable cross-organisational communications.	Planned but not yet in place – Richard Sydee

Causes / sources	Mitigations	Status/Timescale / owner
Stratford is a less desirable location for some current staff due to: • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention (resulting in knowledge loss and capacity and capability gaps) as staff choose to leave because of the office location.	We have an agreed excess fares policy to compensate those who will be paying more following the move to Stratford (those in post before December 2019). Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect. Reduction in number of days in the office following Covid-19 is likely to have reduced the risk of loss of staff.	In place – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
There is a risk that staff views on the positives and negatives of homeworking due to Covid-19 are not considered, meaning we miss opportunities for factoring these into planning our future operating model and alienate staff by not considering their views, for instance on flexible working. This could lead to staff leaving.	Heads discuss impacts with teams on a regular basis and feed views into discussions at CMG. Regular communication to staff about the developing conversation and direction of travel through all staff meetings and the intranet. A further survey of staff was conducted in late October, to inform any policy reviews.	Ongoing with survey in October – Peter Thompson
The need to operate with revised arrangements during the ongoing pandemic may delay consideration of our ongoing post-covid operating model, leading to staff seeing management as extending uncertainty about arrangements, inconsistent application of temporary arrangements and inequity, causing lower morale and levels of staff retention.	Clarity provided to staff that the current arrangement of working in the office one day per week will continue unless Government advice changes. CMG to balance staff desire for certainty about post-Covid-19 arrangements with need for flexibility of response during a period of ongoing change. CMG is discussing policies, to provide assurance, for instance about maximum office attendance requirements.	Discussions in progress Ongoing with specific culture discussion in September – Peter Thompson
Current staff may not yet feel informed about the facilities in the new office, leading to anxiety and lower morale.	Conversations about ways of working occurred throughout the office move project, to ensure that the project team and HFEA staff were an active part of the discussions and development of relevant policies and have a chance to raise questions, information was cascaded, and staff could visit the site.	Ongoing – Richard Sydee

Causes / sources	Mitigations	Status/Timescale / owner
	Staff engagement group was in place to ensure wide engagement as we approached the move. Management of ongoing ways of working tasks and engagement with staff being done through CMG as part of HFEA move project closure and post-project oversight. As the situation relating to the pandemic evolves, we are seeking clarity on the availability of facilities, so that this can be communicated to staff.	
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU has ongoing consequences for the HFEA which we must manage.	Funding in place for additional resource to manage EU Exit workload in 2021-2022. We continue to work closely with the DHSC on any arising issues and work towards implementing the impacts of the Northern Ireland Protocol as it applies to HFEA activity across the UK. NB unless any further funding is secured for future years then this work will need to be absorbed within existing activity.	Communications ongoing – Clare Ettinghausen/ Andy Leonard
In-common risk Covid-19 (Coronavirus) may lead to high levels of staff absence leading to capability gaps or a need to redeploy staff.	Management discussion of situation as it emerges, to ensure a responsive approach to any developments. We reviewed our business continuity plan in April 2021 to ensure it is fit for purpose.	Ongoing - Peter Thompson
NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.	Ongoing building working groups with relevant IT and other staff such as HR. Informal relationship management with other organisations' leads.	In place – Richard Sydee, DHSC

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

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

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

Commentary
This risk reflects both the risks related to Board and senior executive leadership. Although the causes and impacts are different, many of the mitigations are similar, and both would have an impact on the organisation's external engagement and potentially strategic delivery. The HFEA board is unusual 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. Between now and April 2022 we need to recruit seven new Board members. The public appointments timetable is tight and unpredictable. Three members' terms of office have been extended by three months, which is helpful. Wholly new members have long onboarding times and plans to bridge any gaps will necessarily rely on existing members' flexibility and goodwill. This will not be sustainable longer-term and may make maintaining effective licensing and governance challenging in 2022. Were a member of the senior executive team to leave the appropriate mitigations would depend on the role, but mitigations include delegating some responsibilities to remaining members of SMT and/or the relevant Head(s) and the appointment of an interim, where professional skills allow. Recruitment to a senior role will usually take longer than the 3 months contractual notice and so there will inevitably be a gap to manage.

Causes / sources	**Mitigations**	**Status/timescale / owner**
A precipitous reduction in available members (due to member terms ending) would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and 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 recent 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. This is	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/times cale / owner
	being actively discussed for upcoming possible vacancies.	
The loss of a member of the senior leadership team (for instance through retirement, leaving the organisation for a new role etc) creates a leadership/knowledge gap.	Note: We cannot mitigate the cause of this risk, since staff may choose to leave the organisation for personal reasons. However, we can mitigate the consequences. Responsibilities could be shared across SMT and Heads to cover any gaps and maintain leadership, decision-making and oversight (this would include Chairing ELP which may be delegated under Standing Orders). Good induction process to ensure that new staff are onboarded efficiently. Effective use of delegation, to build capability of less senior staff, to enable them to step up in the case of senior staff absences (either temporarily or to apply for the role permanently in the case of staff leaving). Chief Executive would discuss recommendations for cover with the Chair if he were to move on from the organisation, to ensure that responsibilities were covered during any gap before appointment. Other controls (handover, knowledge capture, processes etc) per the wider staff turnover risk above. Clear, documented plans to enable more straightforward management of such a situation when it occurs.	In place – Peter Thompson In place - Yvonne Akinmodun with relevant Manager for specific role In place – Relevant Director alongside managers As required – Director and staff as relevant As required – Peter Thompson, Julia Chain As required – Peter Thompson
Any member recruitment often takes 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 (the annual report from the commission for public appointments suggests appointments take on average five months).	We have focused on streamlining induction to ensure that the members who joined the HFEA this year are brought up to speed as quickly as practicable (see risks below). This risk cause remains for future recruitment, and we remain in discussion on the ongoing management of this.	Under way- Peter Thompson

Causes / sources	Mitigations	Status/timescale / owner
Recruitment to SMT or Head post often takes some time which could create a leadership gap.	Heads could temporarily act up into Director roles to manage any pre-recruitment gaps. The same would be true of manager-level staff acting up for Heads. Control employed to manage Chief Technology Officer recruitment gap.	In place, discussed as required – relevant Manager with Yvonne Akinmodun
Several current Board members are on their second and third terms in office, which expire within the same period (December 2021- April 2022).	Contingency plan in place for managing committees when the upcoming members' terms end in case we are carrying vacancies however this control relies heavily on the goodwill of other members and ability to maintain quoracy.	In progress, ongoing - Peter Thompson, Paula Robinson
The induction time of new members (including bespoke legal training) can be significant, particularly for those sitting on licensing committees, which 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 can take up to a year for members to feel fully confident.	The Governance team has reviewed recruitment information and member induction to ensure that this is as smooth as possible. Targeted extensions to some existing members, bridged the period of learning for those members who joined in Spring 2021 and provided support new members.	In place and ongoing - Paula Robinson
Induction of new members to licensing and other committees, requires a significant amount of internal staff resource and could reduce the ability of the governance and other teams to support effective decision-making.	We have been mindful of this resource requirement when planning other work, to limit the impact of induction on other priorities.	In progress, - Peter Thompson, Paula Robinson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Status/timescale / owner**
Government/DHSC The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson
Government/DHSC DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

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

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

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

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

Commentary
Cyber-attacks and threats are inherently 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.

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

Causes / sources	Controls	Timescale / owner
	investigate cyber security courses to identify the most appropriate one for Authority members.	members to be implemented Autumn 2021. – Steve Morris
Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively	Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. Policies currently under review, for completion by end of 2021-2022. Further review of cyber security scheduled to CMG in October 2021. We undertake independent review and test our cyber controls, to assure us that these are appropriate. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact. Additional online Business Continuity training for Business Continuity Group.	Undertaken by staff October/November 2020 – Steve Morris Update agreed at CMG in June 2020– Steve Morris In place, next full review to be complete by December 2021 – Steve Morris In place, CMG considered this in April 2021 – Steve Morris In place and being completed by end July 2021 – Steve Morris
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security. We undertake penetration testing regularly but a full network penetration test will cover access control, encryption, computer port control, pseudonymisation and physical control Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable.	Testing is undertaken regularly, – next cycle of testing for completion by December 2021– Steve Morris In place, reviewed in summer 2020 and fit for purpose – Neil McComb

Causes / sources	Controls	Timescale / owner
The IT support function is small so may not provide us with the cyber security resource that we need (ie, emergency support in the case of dealing with attacks)	We have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason. The support arrangement will be reviewed in 2022.	Contract in place until June 2023 – Steve Morris
We cannot mitigate effectively for emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations (such as ALB CIO network and NHS Digital Cyber Associates Network) to learn from others in relation to cyber risk. We receive regular security alerts and action the high priority ones when they arrive.	Ongoing– Steve Morris
Technical or system weaknesses could lead to loss of, or inability to access, 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. 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. We are also currently reviewing whether to redevelop our centres database, Epicentre, in the coming year, since some elements of it are old and out of support.	Ongoing, next round of testing to complete by December 2021– Steve Morris In place – Steve Morris Ongoing (Upgrade to Pulse RAS system completed during summer 2021) – Steve Morris Ongoing – Steve Morris
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) to implement encryption.	Ongoing (regular reminders sent to staff with security best practice) – Steve Morris
Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.	All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place. We have an effective permission matrix and password policy. Our web configuration limits the service to 20 requests at any one time. The new Register is under the tightest security in the cloud.	In place – Steve Morris To be decided Autumn 2021 – Steve Morris

Causes / sources	Controls	Timescale / owner
	Proposals will be brought to CMG in October 2021 to further reduce risks from remote access	
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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

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

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

Commentary

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

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

Legal challenge poses two key threats:

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

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

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

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

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

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

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

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

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

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

Commentary
Risk management of these risk causes has been our organisational priority since the beginning of the pandemic. All staff were working from home (and have now returned to the office at least one day per week, from October 2021. A strategy to manage inspections is in place. Communications to the sector and patients have been in place throughout and are ongoing as and when needed. We would revisit and revise our plans as circumstances change, as is possible in the autumn and winter. Our revised inspection processes are effective and include comprehensive risk assessment and controls; we are assured that we can effectively maintain this regulatory function. Licensing has continued effectively remotely. SMT considered the risk score in March 2021 and decided that the effective inspection methodology reduced the impact of this risk, as the controls ensured we can continue to undertake this statutory function, bringing the score down. The implementation of the methodology has caused a secondary risk, while it beds in, but that is being managed and is captured under RF1. While the implementation has now bedded in well, any increase in infection rates later in the year is likely to impact the inspection team so we will monitor the effects on our delivery approach and review this if required.

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

Causes / sources	Controls	Status/Timescale / owner
	Proactive handling of clinic enquiries and close communication with them. Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth, and this is up to date. Enquiries team have additional support from Managers and Directors. We have reviewed our approach regularly to ensure that this is fit for purpose. Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.	Clare Ettinghausen In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting Joanne Triggs – in place In place and under regular review – Joanne Anton 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 was sought to ensure that HFEA actions were in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged. Framework for decision making around removing GD0014 in place and Directions kept under periodic review.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Joanne Triggs Done – Peter Thompson If required – Peter Thompson, Catherine Drennan In place – Rachel Cutting and 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

Causes / sources	Controls	Status/Timescale / owner
Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds. Note: we do not have evidence of this being an issue within the HFEA.	Decision taken to delay routine return to the office subject to government guidance, reducing work-related risk. We are engaging with other similar organisations to consider possible approaches to managing this risk. We have considered the impact as part of planning for the return to inspections and office working, including individual risk assessments for inspection staff, performed before each inspection.	In progress – Yvonne Akinmodun In place – Sharon Fensome-Rimmer
Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.	Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.	In place - Paula Robinson
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: this risk may be both short and longer-term if clinics close as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity. The final contingency would be to seek additional cash and/or funding from the Department.	In place – Richard Sydee Ongoing discussions if needed as ongoing impact becomes clearer – Richard Sydee
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity.	Provided equipment for staff who must WFH without suitable arrangements in place. Ability of staff unable to work from home to work in Covid-19 secure office. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance. Pulse wellbeing survey to assess impact.	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing – Yvonne Akinmodun September 2021 and reoccurring quarterly –

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

Reviews and revisions

SMT review – November 2021

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

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

05/10/2021 – AGC review – October 2021

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

- AGC noted the reduced resourcing for risk management due to the Risk and Business Planning manager leaving the organisation. Risk management review actions were now on hold until more resource was in place.
- AGC noted the improved position in relation to financial risk, but that there were longer term considerations about resource (which had been discussed at length earlier in the meeting).
- AGC noted the particularly high risks related to resources and the strain this put the organisation under – there was both a high residual and inherent risk. These were discussed at length under other agenda items. AGC discussed senior succession planning and heard that plans would be made but were not yet in place.
- A member queried whether the risk rating for I1 was correct given the uncertainties about plans for CaFC. The executive noted that SMT had discussed raising the score but wished to consider risks in the round and what controls were possible before doing so. The score would be considered at the next SMT review.
- Horizon scanning - Members noted that risks on the horizon were noted around Covid uncertainty and CaFC. A member raised an additional risk related to resource and its impact on capacity for key work, most notably the review of the Act and preparation to gather evidence for legislative change. Staff

exhaustion and negative impact on staff morale could impact the HFEA's strategic ambitions. The Chief Executive noted that providing evidence around legislative reform would be a priority of senior management, and this would not be compromised. However, he agreed to review the general risk raised and where and how this was reflected in the register.

20/09/2021 – SMT review – September 2021

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

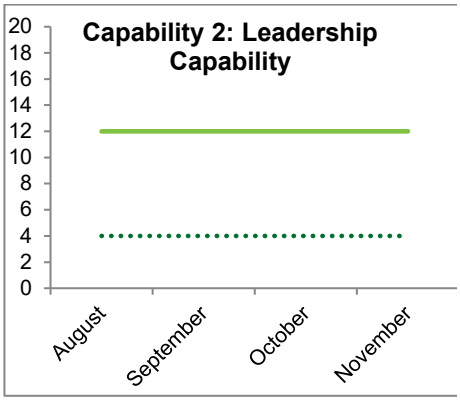
- SMT noted some updates to control owners because of staff leaving the HFEA.
- RF1 depending on the outcome of a discussion with Authority on the effectiveness of the revised inspection regime, this risk is likely to reduce.
- I1 – SMT noted that discussions were still underway regarding plans for updating CaFC. If it were not able to be updated by July 2022 (more than a year since the previous data) this risk would rise.
- P1 – No significant updates.
- FV1 – SMT agreed that the immediate pressure on HFEA finances had reduced and agreed to reduce the risk score. Discussions were underway with Authority and DHSC about controls for future years.
- C1 – SMT noted that the risk had been reviewed with the Head of HR and discussed the impact of turnover and management thereof. Further work would be done to understand the causes and possible further controls. Though 20% may be the performance point that turnover became particularly problematic, the pain of this could be much more acute at a team level and needs careful management.
- C2 – SMT noted that though early indications on recruitment were positive, Board recruitment and the process around appointments had seemed to become more politicised. Contingency plans were in place to manage potential gaps but relied on current members' goodwill to enable core regulatory functions.
- CS1 – SMT noted this risk should be reviewed by the staff covering the role of CTO. An initial update took place, though this risk will need a full review in the light of IT prioritisation and work planned in the autumn.
- OM1 – SMT noted the upcoming conversation with CMG and agreed that this risk should reflect the work underway with CMG on developing principles for using the office strategically.
- LC1 - SMT noted that the Head of Legal had reviewed the risk in full and agreed no change to the score was required.
- CV1 – no major updates but this risk would be under close review over the autumn and winter, especially in relation to Covid approach.

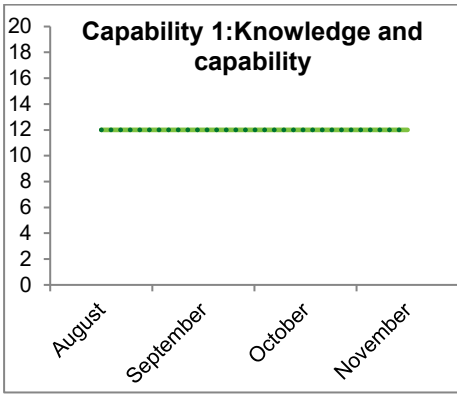
Risk trend graphs (last updated November 2021)

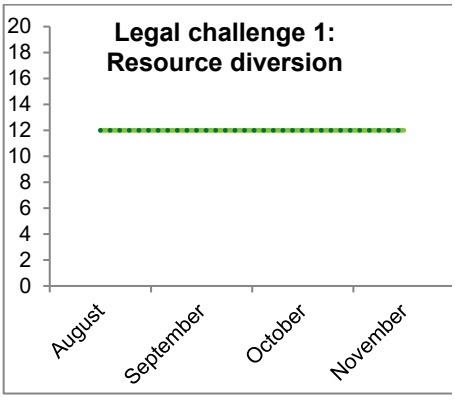
Key:

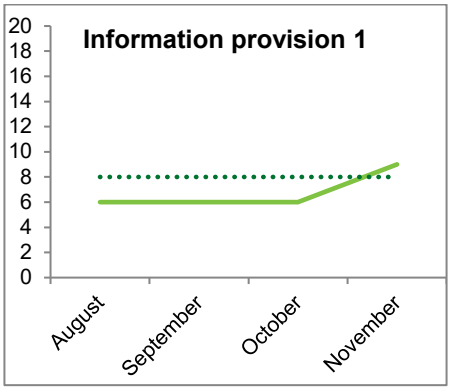
Residual Risk
Tolerance

High and above tolerance risks

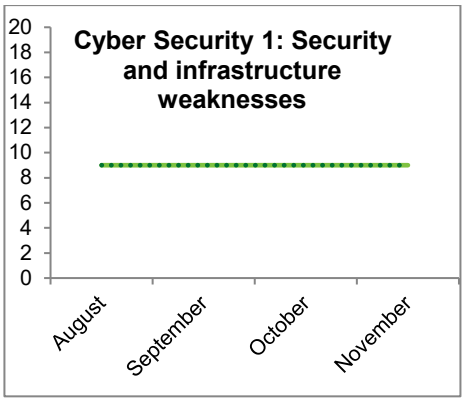


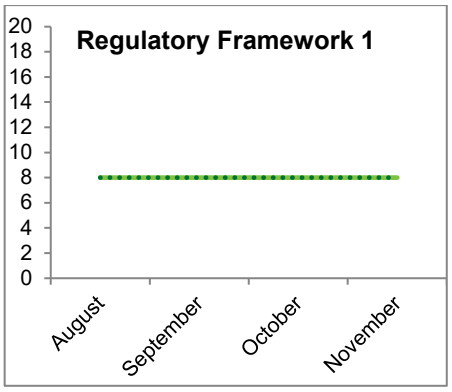


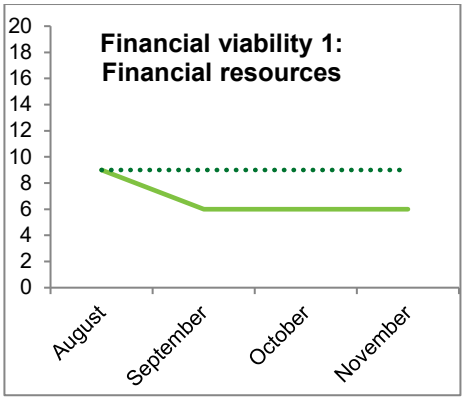


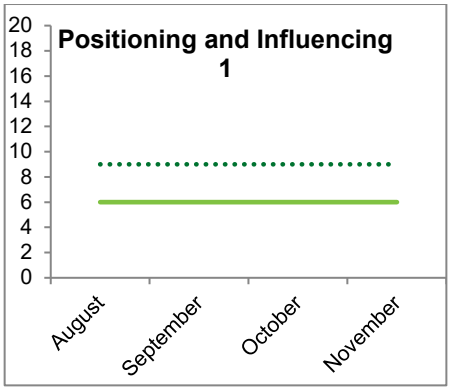


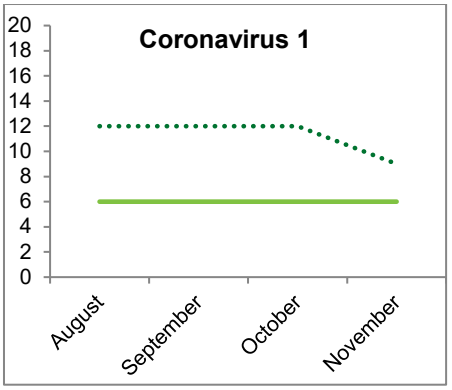
Lower and below tolerance risks











Criteria for inclusion of risks

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

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

Rank

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

Risk trend

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

Risk scoring system

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

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

Risk scoring matrix

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

Risk Score = Impact x Likelihood

Likelihood

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

System-wide risk interdependencies

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

Contingency actions

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

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

Resilience, Business Continuity Management and Cyber Security

Strategic delivery:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Details:			
Meeting	Audit and Governance Committee (AGC)		
Agenda item	9		
Meeting date	9 December 2021		
Authors	Steve Morris, Head of IT and Neil McComb, Head of Information		
Output:			
For information or decision?	For information		

Recommendation	The Committee is asked to note:
	• Infrastructure improvements
	  • Completion of laptop replacement programme
	  • Improvements to IT security that have been agreed by CMG
	  • Progress on upgrade of electronic document management system
	  • IT services at 2 Redman Place
	• Current position on Data Security and Protection Toolkit		

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

1. Introduction and background

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

1.2. This paper provides an update on IT infrastructure and cyber security in a number of areas.

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

2. Infrastructure improvements

Replacement laptops

2.1. HFEA staff were experiencing problems with older laptops, screens were coming adrift and internal batteries overheating. Over 30 laptops have been replaced during 2021, none of the laptops currently deployed are more than 3 years old.

IT security review

2.2. At CMG on 20th October a number of changes to IT security arrangements were proposed and agreed. These changes will provide greater protection for HFEA from cyber attacks such as ransomware

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

2.3. Testing and rehearsal of these changes is currently underway, it is expected this will be complete and the changes implemented before the end of 2021.

2.4. One of the proposals taken to CMG was that access to HFEA's instance of O365 (inc email) from personal mobile phones be blocked. After discussion it was decided this functionality would be retained, but that changes will be made to improve security. It is expected this will be implemented in early 2022.

EDRM upgrade (electronic document and records management system)

2.5. This was due to be completed in October, but the date has slipped. Completion expected before the end of 2021. In the meantime a fix has been applied for the most serious problem experienced by a number of staff: the add-in for Outlook and Word has been re-instated.

IT services in Redman Place

2.6. Most HFEA staff have now worked at Redman Place for at least one day. The numbers vary daily from zero (common on Fridays) to over 20 (when CMG is on for example). All IT services including printers and audio-video in meeting rooms are now running.

3. Data Security and Protection Toolkit (DSPT)

Background

3.1. AGC will recall that the Data Security and Protection Toolkit (DSPT) is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards. It was the first time we have submitted an end of year annual DSPT return.

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

3.3. Each requirement has multiple questions for which we need to provide evidence and explanation, the total number of evidence items across the 37 mandatory requirements is 88.

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

Final Report

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

3.6. They noted that:

"HFEA do not have a structured evidence submission process or the benefit of experience from previous years to draw upon and have not had sufficient time to develop one. HFEA have been transparent in their decision to focus on mandatory assertions only however, documentary evidence to support the assertions have not been uploaded into the toolkit by HFEA and we have not been provided with the suite of off-line evidence on which we can provide assurance that assertions are accurate and fully supported."

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

Recommendation 1	HFEA should develop a structured approach to future Toolkit population with a nominated Toolkit lead and line of business representatives specifically tasked with acquiring tangible evidence of the actual controls employed to manage data security and protection.
Recommendation 2	HFEA to re-examine the evidential needs of the Toolkit and use this to re-evaluate and re-design where appropriate all of their information and security management processes.
Recommendation 3	Conduct a lessons-learned exercise to support the development of the framework described in recommendation1.
Recommendation 4	To reach out to similar organisations deemed more mature in the process of the Toolkit completion to learn form their experience, process and techniques.

Follow up

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

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

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

3.10. Since the last paper to AGC on this topic the HFEA have recruited a new Head of Information and a new Information and Governance Manager who will take responsibility for this area.

3.11. A draft paper, written by the Head of Information, has been circulated for comment between the SIRO and Head of IT for comment. Its purpose is to create a new panel which aims to create clear lines of responsibility for each business area relevant in the Toolkit, set priorities and bring together documentation. The new IG manager will be responsible for submitting this data in the Toolkit.

3.12. This paper will go to CMG and if agreed, will be quickly actioned with the aim of completing another DSPT submission in June 2022.

3.13. Due to the newness of this approach and the limited knowledge we have been able to gain from the last submission it is not yet known whether we will meet all the requirements in the Toolkit for 2022. It is our aim to show evidence of improvement and a desire to continue that improvement until we can meet all necessary requirements.

Audit and Governance Committee Forward Plan

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

Meeting	Audit & Governance Committee Forward Plan
Agenda item	11
Meeting date	9 December 2021
Author	Morounke Akingbola, Head of Finance
Output:	
For information or decision?	Decision
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the Forward Plan. *Receive confirmation of bi-annual review of Fraud/Whistleblowing policies.*
Resource implications	None
Implementation date	N/A
Organisational risk	☒ Low ☐ Medium ☐ High Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information
Annexes	N/A

Audit & Governance Committee Forward Plan

AGC Items Date:	9 Dec 2021	15 Mar 2022	28 Jun 2022
Following Authority Date:	9 Feb 2022	23 Mar 2022	6 July 2022
Meeting 'Theme/s'	Register and Compliance, Business Continuity	Finance and Resources	Annual Reports, Information Governance, People
Reporting Officers	Director of Compliance and Information	Director of Finance & Resources	Director of Finance & Resources
Strategic Risk Register	Yes	Yes	Yes
Risk Management Policy[1]	Yes (moved from Nov)		
Digital Programme Update	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)		Draft Annual Governance Statement –	Yes – For approval
External audit (NAO) strategy & work	Audit Planning Report	Interim Feedback	Audit Completion Report
Information Assurance & Security			Yes, plus SIRO Report
Internal Audit Recommendations Follow-up	Yes	Yes	Yes
Internal Audit	Update	Results, annual opinion approve draft plan	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary

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

AGC Items Date:	9 Dec 2021	15 Mar 2022	28 Jun 2022
Public Interest Disclosure (Whistleblowing) policy		Reviewed bi-annually thereafter	
Anti-Fraud, Bribery and Corruption policy		Reviewed and presented bi-annually thereafter	
Counter-fraud Strategy and progress of Action Plan		Presented annually Functional Standards:GovS: 013 Counter Fraud	
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes	Bi-annual HR report		Bi-annual HR report
Strategy & Corporate Affairs management			
Regulatory & Register management	Yes		
Cyber Security Training	Yes – update on whether annual training undertaken		
Resilience & Business Continuity Management	Yes	Yes	Yes
Finance and Resources management		Yes	
Reserves policy			
Estates	Yes	Yes	Yes
Review of AGC activities & effectiveness, terms of reference			

AGC Items Date:	9 Dec 2021	15 Mar 2022	28 Jun 2022
Legal Risks			
AGC Forward Plan	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes