Audit and Governance Committee meeting - agenda

08 Oct 2019

Chartered Institute of Arbitrators, Old Library Room (Lower Ground Floor) 12 Bloomsbury Square, London, WC1A 2LP.

	Agenda item		Time
1.	Welcome, apologies and declaration of interests		10.00am
2.	Minutes of 18 June 2019 **[AGC (08/10/2019) 686 DO]**	For Decision	10.05am
3.	Matters Arising **[AGC (08/10/2019) 687 MA]**	For Information	10.10am
4.	Internal Audit a) Progress report **[AGC (08/10/2019) 688 TS]**	For Information	10.15am
5.	Progress with Audit Recommendations **[AGC (08/10/2019) 689 MA]**	For information	10.25am
6.	External Audit – Planning work **[Oral NAO]**	Verbal update	10.40am
7.	Reserves Policy **[AGC (08/10/2019) 690 RS]**	For Information	10.50am
8.	Estates Update **[Oral RS]**	Verbal update	11.00am
9.	Senior Information Risk Officer (SIRO) Report **[AGC (08/10/2019) 691 RS]**	For Information	11.05am
10.	Digital Programme Update **[AGC (08/10/2019) 692 DH]**	For Information	11.15am
11.	Resilience, Business Continuity Management Cyber Security training **[AGC (08/10/2019) 693 DH]**	For Information	11.30am
12.	Legal risks **[Oral RS]**	Verbal update	11.40am
13.	Strategic Risk Register **[AGC (08/10/2019) 694 HC]**	For Comment	11.50am
14.	AGC Forward Plan **[AGC (08/10/2019) 695 MA]**	For Decision	12.05pm

15.	Gifts and Hospitality register **[AGC (08/10/2019) 696 MA]**	For Information	12.15pm
16.	Whistle Blowing and Fraud – Counter Fraud Strategy **[AGC (08/10/2019) 697 RS]**	For Information	12.20pm
17.	Contracts and Procurement **[Oral MA]**	Verbal update	12.35pm
18.	Any other business		12.40pm
19.	Close (Refreshments & Lunch provided – in the **Garden Meeting room**)		12.45pm
20.	Session for members and auditors only		12.50pm

Next Meeting: 10am Tuesday, 3 December 2019, Chartered Institute of Arbitrators, 12 Bloomsbury Square, London, WC1A 2LP

Audit and Governance

Committee meeting minutes

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Audit and Governance Committee
Agenda item	2
Paper number	AGC (08/10/2019) 686 DO
Meeting date	8 October 2019
Author	Debbie Okutubo, Governance Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	

Minutes of Audit and Governance Committee (AGC) meeting held on 18 June 2019

Chartered Institute of Arbitrators, 12 Bloomsbury Square, London, WC1A 2LP

Members present	Anita Bharucha (Chair) Mark McLaughlin Geoffrey Podger
Apologies	Margaret Gilmore
External advisers	Tony Stanley – Audit Manager, Internal Audit George Smiles - External Audit - National Audit Office (NAO) Jill Hearne – National Audit Office (NAO)
Observers	Sandrine Oakes, Clinical Inspector Nicola Lawrence, Clinical Inspector
Staff in attendance	Peter Thompson, Chief Executive Morounke Akingbola, Head of Finance Richard Sydee, Director of Finance and Resources Clare Ettinghausen, Director of Strategy Yvonne Akinmodun, Head of Human Resources Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager Dan Howard, Chief Information Officer Debbie Okutubo, Governance Manager

1. Welcome and declarations of interests

1.1 The Chair welcomed everyone present.

1.2 There were no declarations of interest.

2. Minutes of meetings held on 5 March 2019 and 8 May 2019

2.1 Minutes of meetings held on 5 March and 8 May 2019 were agreed as a true record of the meeting and approved for signature.

3. Matters arising

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

4. Audit plans for 2018/19 and 2019/20

4.1 Since the March meeting, final audit reports had been issued for anti-fraud controls, business continuity planning and GDPR reviews. The reports were presented to the committee.

Anti-fraud controls

4.2 The objective of the review was to assess the robustness, effectiveness and adequacy of anti-fraud controls. Areas for improvement were identified and the need for strengthening internal controls as a result of the government counter fraud standards reviewed in 2018 were explained.

4.3 The review was given a limited opinion as significant weaknesses were identified in the framework of governance, risk management and control.

4.4 Following a discussion regarding proportionality, it was noted that the recommendations could be difficult to implement due to the size of the organisation.

4.5 Members suggested that lessons learned needed to form part of the training to be put in place.

4.6 The Director of Finance and Resources commented that a proportionate response would be sent to the Cabinet Office.

Action

4.7 Members requested that they be kept updated on the outcome of the meeting with the Cabinet Office.

Business continuity report

4.8 The objective of the review was to assess the processes relating to business continuity (BC), including improvements implemented over the last 12 months.

4.9 Recommendations were made to improve the control framework.

4.10 The review was given a moderate opinion. As it was felt that there was still one area that required strengthening, which was ‘arrangements for longer term business disruption’.

4.11 The Chief Information Officer commented that a test was carried out with all staff and members and the response was deemed satisfactory.

4.12 Lessons learned had also been noted and four out of the five actions had been implemented. The last one would be implemented by August 2019.

4.13 In response to a question, it was noted that many staff did not log on speedily, but those who did, logged on with ease and were able to get on to the SharePoint business continuity site. Appropriate training would be put in place for the Disaster Recovery Group members. Follow-up with staff about log-in difficulties and other obstacles encountered had taken place.

4.14 Members commented that it was a good story to tell and noted that the plan had been updated following BC testing and to align with other Arm’s Length Bodies (ALBs) and industry standards.

GDPR

4.15 This review was a continuation of internal audit’s engagement in relation to GDPR following the audit work undertaken in relation to preparedness, in 2018.

4.16 The objective of the audit was to provide assurance that there were arrangements in place to demonstrate GDPR compliance.

4.17 The overall opinion given was 'moderate' as there were some areas which could still expose us to both financial and reputational risk because of noncompliance to GDPR requirements.

4.18 Members noted that there were numerous areas of good practice, and that there had been significant progress made towards ensuring GDPR compliance.

4.19 Members commented that the report seemed to be appropriate and the opinion given was proportionate.

Action

4.20 The Director of Finance and Resources to present the Senior Information Risk Officer (SIRO) report at the next meeting.

Progress on 2019/20 audit plan

4.21 For the 2019/20 audit plan, it was noted that the initial scoping had taken place for the capability risk audit, and a draft terms of reference had been issued. This would be discussed after the meeting.

4.22 The AGC confirmed that they were content with the draft 2019/20 internal audit plan.

Government Functional standards: Counter Fraud (GovS 13)

4.23 Members were advised that anti-fraud audit recommendations would be addressed in line with GovS 13. The Committee noted the assessment conducted and the rating of non-compliant. Steps to achieve compliance by 2 September were shared with the Committee. Members agreed that the Director of Finance and Resources would be the Accountable Individual responsible for counter fraud.

5. Progress with audit recommendations

5.1 The Head of Finance presented the item to the committee and stated that there were 25 audit recommendations of which 15 remained open.

5.2 In response to a question, it was noted that the anti-fraud audit recommendations were aligned with the Government Functional Standards: Counter Fraud and were time-critical in that some had to be achieved by September 2019.

5.3 Also, that the procure to pay system used for expenses, known as WAP, whilst being a robust system did not currently mitigate the issue of duplication of expense claims. In the longer term we were looking to move to a digital finance system.

5.4 The Head of Finance got agreement from the committee that completed audits would be removed on confirmation from internal audit that adequate evidence had been provided.

5.5 In response to a question, the Chief Information Officer commented that regarding business continuity and individuals with a responsibility in delivering the plans and addressing potentially disruptive incidents, that an appropriate method of training would be considered and duly recorded.

5.6 Members suggested that the summary table needed to be updated as the business continuity plan was not yet complete but had been marked so.

5.7 Members were advised that on a quarterly basis, review meetings would take place with Alscient as a measure of ensuring appropriate cyber security.

Action

5.8 Members noted the progress made with audit recommendations.

6. Draft Annual Report and Accounts

6.1 The draft Annual Report and Accounts 2018/19 was presented to the Committee.

6.2 It was noted that the total operating income was higher than the previous year with the majority of the increase from treatment fees. Also, that the grant in aid income was not incorporated in the accounts due to the way government accounting works.

6.3 The Committee was advised that the Accounting Officer sign-off would be delayed until such time that confirmation and definite timelines had been received from NAO. This was to ensure that the accounts were reviewed and took into account any material developments prior to sign-off.

6.4 There was a brief discussion regarding the attendance recording of Authority and external members at formal meetings and whether a breakdown could be shown within the report.

6.5 Following the discussion, Members requested that the Director of Finance and Resources should look into the approach adopted to record attendance of members in the Annual Report.

Action

6.6 AGC Members considered the External Auditors' annual statement and ISA 260 reports and recommended the Accounting Officer signs the HFEA 2018/19 Annual Report and Accounts subject to any further changes that arose from the audit.

6.7 The Director of Finance and Resources agreed with the committee that significant changes and updates would be shared with the committee.

7. External Audit – Audit Completion report

a) 2019/20 audit plan

7.1 The external auditors presented to the committee and noted that subject to the clearance of outstanding matters they anticipated recommending to the Comptroller and Auditor General (C&AG) that he should certify the 2018-19 financial statements with an unqualified audit opinion, without modification.

7.2 The NAO reported that no significant risks had been identified in relation to the presumed risk of management override of controls and the risk of fraud in revenue recognition. There were no adjusted misstatements.

7.3 The NAO identified that the net effect of adjustments on the accounts was £24.5k. It was noted that these were mainly due to accrual errors.

7.4 Members were advised that the audit of the financial statements was substantially complete subject to completion of the areas detailed below:

- Intangible asset additions
- Accruals and expenditure
- Review of the Annual Report and financial statement disclosures

- NAO internal review of audit file.

It was noted that actions needed to be resolved prior to completion of the audit.

7.5 Members requested the status of previous recommendations. The external auditors confirmed that they had been resolved and closed.

7.6 Regarding accruals, the Head of Finance explained that information provided by staff was not always accurate thereby causing issues with accruals.

Action

7.7 Incorporate suggested amendments to the report, including the draft letter of representation and audit certificate at Appendix 1 and 2 respectively.

7.8 Consider whether the unadjusted misstatements identified so far, set out in the identified misstatements section (page 10), should be corrected.

7.9 The Audit Committee minutes should provide written endorsement of management's reasons for not adjusting misstatements.

7.10 Subject to all outstanding work, the Financial statement was agreed in principle as long as they were not material changes.

7.11 CE foreword to be sent to Authority and AGC members- Accountability letter to DHSC will be circulated for comment.

8. Human Resource update 2019

8.1 The Chief Executive presented a paper responding to organisational capability from a broader overview since it was last reported in December 2018. The report also focused on staff opinion, turnover, and the work that was underway on a potential new pay framework designed to enable clearer and easier development.

8.2 It was noted that over the last 12 months turnover stood at 27%. Members commented that being a flat organisation, staff movement after 4 years should not be deemed out of place.

8.3 Members also suggested that moving to new premises away from Central London could have the effect of staff looking at their options.

8.4 Members found it encouraging that confidence in leadership was higher than it previously was.

8.5 At exit interviews, the three top reasons given by staff for leaving were (1) pay, (2) lack of opportunity for progression (3) poor relationship with line manager/senior managers.

8.6 Members commented that with no reported specific bullying and harassment cases, this could be looked at as poor working relationships. This being the case, members suggested that a 'Respect at Work' policy should be considered.

8.7 The Head of Human Resources confirmed that there was ongoing work around the corporate values and respect was a word that was being considered for inclusion.

Action

8.8 The committee noted the report.

9. Estates update

9.1 An update was given by the Director of Finance. It was noted that a full report was going to the Authority meeting of 3 July 2019.

9.2 There was ongoing work with Human Resources (HR) in relation to the flexible working policy and related policies.

9.3 Staff turnover had been flagged as a risk and mitigating measures were being put in place.

9.4 Members commented that access to transport was a shifting pattern in East London which could be a positive once it was finalised and the organisation moved to East London.

Action

9.5 Members noted the update on Estates.

10. Digital Programme update

10.1 A report providing an update on progress relating to system development, data migration, the implementation of the new register and the associated transitional activities was presented to the committee by the Chief Information officer.

10.2 The PRISM launch timeline was posted for the end of November 2019. Members noted that data migration work was progressing well.

10.3 A Choose a Fertility Clinic (CaFC) data refresh would take place in October 2019. Members commented that communication with clinics remained important and also the need to verbalise the tolerance levels that were acceptable.

10.4 The Chair reiterated that the extra cost incurred from the delay in delivering the digital programme had consequences for other spends this financial year and consequently the budget had been set conservatively.

10.5 The Director of Finance and Resources confirmed that we would continue to closely monitor our financial position against the agreed capital and revenue budget.

Action:

10.6 The committee agreed to receive monthly updates in-between meetings from the Chief Information Officer.

11. Resilience, business continuity management and cyber security

11.1 In line with the strategic risk register, the committee had received regular and detailed updates on resilience, business continuity management and cyber security.

11.2 In March 2019 AGC received an update on our IT infrastructure and IT development support arrangements. The Chief Information Officer had signalled an intention to secure a longer-term support arrangement in 2019.

11.3 The associated procurement work had concluded and the contract had been awarded. Members were advised that the winning bid met the quality and price threshold set.

11.4 The results of the business continuity arrangements tested in March 2019 were presented to the committee.

11.5 An update was also given on the improvements to the telephone system and video-conferencing facilities.

Action:

11.6 Members noted:

- The contract award relating to the procurement to secure a supplier for essential IT infrastructure and development support
- The results of the business continuity plan test undertaken in March 2019
- The update on work to upgrade our telephone system, network and video-conferencing facilities.

12. Strategic risk register

12.1 The Risk and Business Planning Manager presented the strategic risk register. Members noted that one risk remained above tolerance level which was the capability risk. Mitigations related to this risk had been discussed under the HR item.

12.2 The committee noted that SMT reviewed the register on 20 May 2019 and had reviewed all risks, controls and scores. Key discussions included the impacts of the ongoing Director of Compliance and Information vacancy and the implications of the ongoing work on digital projects for financial viability. The score for the financial viability risk had been raised as a result.

12.3 There was also a correction to the financial viability risk, that it was reviewed in May and not March.

12.4 The committee noted that a strategic risk around the office move had been drafted and would be considered by SMT next month. In response to a question, the Director of Finance and Resources commented that this was still work in progress and would be presented at the next AGC meeting.

12.5 The AGC Chair queried whether the score and tolerance level of the legal risk had been considered in the round. The Chief Executive noted that, given the ethical and legal context, the inherent risk relating to HFEA being legally challenged remained high. However, there were mitigations in place to reduce the likelihood. The executive confirmed that it would continue to consider this risk to avoid complacency.

Action:

12.6 The committee noted the latest edition of the risk register and commented that it was a robust risk register.

13. AGC forward plan

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

13.2 It was noted that the gift and hospitality register will be added to the forward plan and brought to the October 2019 meeting.

13.3 The Senior information Risk Officer (SIRO) report on GDPR will also be presented at the October 2019 AGC meeting.

Action:

13.4 The items above to be added to the forward plan.

14. Whistle blowing and fraud policies – counter fraud

14.1 In January 2019 the Cabinet Office launched a revised Functional Standards for Counter Fraud (GovS 013) and announced its extension to all Arms-Length Boards (ALBs). Assessment against these standards formed part of our recent internal audit review of the HFEA's counter fraud processes.

14.2 The Director of Finance and Resources commented that compliance with these standards was a significant element of our response to the recent audit recommendations and would provide the organisation with a benchmark against which we would assess our counter fraud activities and approach.

14.3 There were no items of fraud to report.

Action:

14.4 Members noted the update.

15. Contracts and procurement

15.1 The Head of Finance gave the committee an update on existing contracts. It was noted that since the last meeting, only one contract had been let in relation to our IT support and infrastructure..

15.2 In response to a question, it was confirmed that the data migration contract had been reported and agreed at AGC prior to commencement of the contract.

16. Any other business

16.1 There was no other business.

16.2 Members and auditors retired for their confidential session.

16.3 The next meeting will be held on Tuesday, 8 October 2019 at 10am.

17. Chair's signature

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

Signature

Name

Anita Bharucha

Date

8 October 2019

Matters arising from previous AGC meetings

Strategic delivery:	☐Safe, ethical, effective treatment	☒Consistent outcomes and support	☐Improving standards through intelligence
Details:			
Meeting	AGC		
Agenda item	3		
Paper number	HFEA (08/10/2019) 687 MA		
Meeting date	8 October 2019		
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	2019/20 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Numerically:

- 4 items carried over from earlier meetings, 1 ongoing
- 7 items added from October 2018 meeting, 1 ongoing
- 10 items added from June 2019 meeting, 4 ongoing
- Items removed: 4.9 (5 Mar-19)

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 12 June 2018 meeting			
9.10 The Committee to receive monthly updates highlighting any variances and increased risk.	Chief Information Officer	On-going	**Update** - on the three identified risks and issues concerning data migration, additional development work and loss of key staff to be given in the meeting
Matters Arising from the Audit and Governance Committee – actions from 9 October 2018 meeting			
3.8 The Committee Secretary to contact members regarding availability for training after the meeting on 4 December 2018 or 5 March 2019	Committee Secretary		**Update** – Training to take place in the autumn
Matters Arising from the Audit and Governance Committee – actions from 5 March 2019 meeting			
~~**4.9** Discussion at future Authority workshop on whether licences could be issued for 5 years for centres with a good compliance record~~			~~**Update** – this was a suggestion for future Authority meetings and if logged elsewhere this should be removed~~
Matters Arising from the Audit and Governance Committee – actions from 18 June 2019 meeting			
4.7 Committee to be kept updated on the outcome of the meeting with the Cabinet Office – Fraud standards	Director of Finance and Resources	On-going	**Update –** Meeting has not yet taken place as we are waiting for feedback from 2 Sept submission.
4.20 The SIRO Annual Report to be presented to Committee at the next meeting	Director of Finance and Resources	October 2019	**Update -** an agenda item
5.6 Summary table of Audit Recommendations to be amended	Head of Finance	October 2019	**Update –** Complete. Actions to complete item have been taken. Evidence to be provided to Internal Audit.

(Business Continuity Plan) as not complete			
6.6 Share with the Committee any significant changes that arise from the final audit	Director of Finance and Resources		**Update -** Complete. Audit Completion report was submitted to Committee on 18/7/19. There were no significant changes.
7.7 Incorporate suggested amendments to the Annual Report including draft letter of representation	Head of Finance		**Update –** Complete
7.8 Consider whether the unadjusted misstatements identified so far, set out in the identified misstatements section (page 10) should be corrected.	Head of Finance		**Update -** Complete. All errors identified were adjusted prior to finalisation of the accounts.
7.9 The Audit Committee minutes should provide written endorsement of managements reasons for not adjusting misstatements	Committee Secretary		**Update -** TBC
7.11 CEO forward to be sent to AGC members prior to inclusion in the Annual Report	Director of Finance and Resources	June 2019	**Update -** Complete
10.6 Chief Information Officer to give monthly updates on the progress of the Digital Programme	Chief Information Officer		**Update –** an item on the agenda
13.2 The Gifts and Hospitality Register to be added to the Forward Plan and		October 2019	**Update -** Complete. Register of Gifts and Hospitality is included in pack

presented at the next meeting and thereafter.			

Reserves policy

Strategic delivery:	☐ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	AGC		
Agenda item	7		
Paper number	HFEA (08/10/2019) 690 RS		
Meeting date	8 October 2019		
Author	Richard Sydee, Director of Finance and Facilities		
Output:			
For information or decision?	For information		
Recommendation	A review of our reserves position has taken place and there are no significant changes. In December 2018 the AGC were furnished with a detailed look at HFEA historic cashflows and three options as how best to reduce its cash balance. The option to invest n our infrastructure was taken. The effect of this has resulted in a reduction in our cash balance by 18% to £2.6m at March 2019. The AGC is requested to approve the unamended Reserves Policy.		
Resource implications			
Implementation date	2019/20 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Reserves Policy

Introduction

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

Principles

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

Reserves Policy

1. The Authority has decided to maintain a reserves policy as this demonstrates:

    - Transparency and accountability to its licence fee payers and the Department of Health
    - Good financial management
    - Justification of the amount it has decided to keep as reserves

2. The following factors have been taken into account in setting this reserves policy:

    - Risks associated with its two main income streams - licence fees and Grant-in-aid - differing from the levels budgeted
    - Likely variations in regulatory and other activity both in the short term and in the future
    - HFEA's known, likely and potential commitments

3. The policy requires reserves to be maintained at least at a level that ensures the HFEA's core operational activities continue on a day-to-day basis and, in a period of unforeseen difficulty, for a suitable period. The level should also provide for potential commitments that arise.

Cashflow

4. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes account of when receipts are expected and payments are to be made. Most receipts come from treatment fees - invoices are raised monthly and on average take 60 days to be paid. Cash reserves are needed to ensure sufficient working capital is available to make payments when they become due throughout the year.

5. The HFEA experiences negative cashflow (more payments than receipts) in some months. Based on a review of our cashflows over the last few years, the total of all the months where we experienced shortfalls is around £520k. Reserves should be maintained so that there is always a positive cash balance.

Contingency

6. The certainty and robustness of HFEA's key income streams, the predictability of fixed costs and the relationship with the Department of Health would suggest that HFEA would be unlikely to enter a prolonged period of financial uncertainty that would result in it being unable to meet its financial liabilities.

7. However, it is clearly prudent for an organisation to retain a sufficient level of reserves to ensure it could meet its immediate liabilities should an extraordinary financial incident occur.

8. In arriving at a reserve requirement for unforeseen difficulty we have considered the likely period that the organisation might need to cover and whilst discussions are undertaken to secure the situation, the immediate non-discretionary spend that would have to be met over that period.

9. We believe that a prudent assumption would be to ensure a minimum of two months of fixed expenditure is maintained as a cash reserve; in terms of the costs that would need to be met we consider the following to be non-discretionary spend that would be required to ensure the HFEA could maintain it's operations:

    a. salaries (including employer on-costs);

    b. the cost of accommodation.; and,

    c. Sundry costs related to IT contracts, outsourced services and other essential services.

10. These fixed costs would have to be paid in times of unforeseen difficulty, salaries and accommodation costs alone represent 71% of the HFEA's total annual spend.

11. Based on the HFEA's current revenue budget, the combined monthly cost of salaries and accommodation is £354k, accommodation costs have increased since the relocation to

Spring Gardens in 2016. A reserve of two months for these two elements would therefore be £710k.

12. A further reserve for other commitments for two months is estimated to be £150k.

Minimum reserves

13. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£520k), provides £710k for contingency. The minimum level of cash reserves required is therefore £1.4m. These reserves will be in a readily realisable form at all times.

14. Each quarter the level of reserves will be reviewed by the Director of Finance and Resources as part of the HFEA's ongoing monitoring of its cash flow.

15. Each autumn as part of the HFEA's business planning and budget setting process, the required level of reserves for the following financial year will be reassessed.

16. In any assessment or reassessment of its reserves policy the following will be borne in mind.

    - The level, reliability and source of future income streams.
    - Forecasts of future, planned expenditure.
    - Any change in future circumstances - needs, opportunities, contingencies, and risks – which are unlikely to be met out of operational income.
    - An identification of the likelihood of such changes in these circumstances and the risk that the HFEA would not able to be able to meet them.

17. HFEA's reserves policy will be reviewed annually by the Audit and Governance Committee.

Document name	Reserves Policy
Original release date	October 2014
Author	Head of Finance
Approved by	CMG
Next review date	September 2018
Total pages	3

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created	DoF	AGC	Feb 2015
2.0	Branded/amended	HoF	AGC	Dec 2016
2.1	Cashflow figures amended	HoF	AGC	Oct 2017

SIRO Report

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	AGC		
Agenda item	9		
Paper number	HFEA (08/10/2019) 691 RS		
Meeting date	08 October 2019		
Author	Richard Sydee, Director of Resources		
Output:			
For information or decision?	For information		
Recommendation	N/A		
Resource implications	N/A		
Implementation date	N/A		
Communication(s)	N/A		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

1. Background

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

1.2. This report is my annual report to the Accounting Officer and AGC. The SMT have also reviewed this report.

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

2. Report

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

2.2. Although the HFEA has historically held, and processed, data and records effectively the introduction of General Data Protection Regulation (GDPR) and changes to the Data Protection Act have necessitated a review of our processes and procedures to ensure ongoing compliance with relevant legislation.

2.3. The recent internal audit of our response to the introduction of GDPR provided "Moderate" assurance, with an overall positive assessment of the process undertaken to achieve compliance. As a result of this audit we have undertaken a number of additional activities to bolster our approach to information risk management. In particular:

- During the year we have made the previously fixed term IG and Records Manager post full time and successfully recruited to that role – signifying the importance we have placed on IG and RM.
- We have updated the information risk training we are now using and will be looking to ake this mandatory cross the organisation
- We have reviewed our Information asset register, ensuring all assets have owners and linking records through to the relevant documentation on the assets purpose and use. This has provided a good level of assurance to me as SIRO that our current IAR is up to date.

2.4. Our draft Retention Policy is at an advanced stage of development and will be reviewed by the Corporate Management Group before being published and enacted. This provides an overview of our approach to RM and specifically the roles and responsibilities of staff across the organisation as well as our approach to record retention and deletion.

2.5. Moving through in to the next business year information asset owners (IAOs) now have a specific objective in the personal development plans to ensure they undertake regular review of their assets to ensure compliance with our policies on retention. They will provide assurance to the SIRO that they have undertaken this review on an annual basis. IAOs will be provided with guidance and training on their responsibilities as part of the introduction of this process.

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

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

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

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

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

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

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

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

Annex A - Assessment of the HFEAs compliance with the Security Policy Framework 2014 (As at 30 September 2019)

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

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

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

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

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

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

Digital Programme Update: October 2019

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Audit and Governance Committee		
Agenda item	10		
Paper number	AGC (08/10/2019) 692 DH		
Meeting date	08 October 2019		
Author	Dan Howard, Chief Information Officer		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note: • Data migration progress, including EggBatchID resolution • PRISM and API development • Choose a Fertility Clinic (CaFC) data refresh progress • Communications, engagement and budget review • Approval to proceed proposed approach • Remaining timeline • Risk assessment		
Resource implications	Early December 2019 go-live within budget. Additional budget to support a go live later in December not yet agreed (see section 6)		
Implementation date	Winter 2019		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes:	None		

1. Introduction

1.1. In August 2019 AGC received an interim update on data migration, system development, the implementation of the new register the associated transitional activities and our plans for updating Choose a Fertility Clinic (CaFC) performance data on our website.

1.2. This update provides an overview of:

- Data migration progress, including the resolution of the EggBatchID issue
- PRISM and API development, including User Acceptance Testing (UAT), Preview launch and transitional activities
- Updating Choose a Fertility Clinic (CaFC) performance data on our website
- Communications / engagement and budget review
- 'Approval to proceed' approach, including the expected metrics, impact, and business consequence
- Detailed timeline, including an outline of the work that will be completed prior to the approval to proceed meeting, the work completed between approval to proceed and launch, and the work that will be completed thereafter (see section 7.3), and
- Risk Assessment

1.3. Since the last update in August, a substantial amount of work has been completed and most areas of the programme (with the exception of PRISM development) have progressed well. We have experienced slippage on PRISM development which is forecast to have a direct impact of 2 weeks on our launch date because without other components ready, we cannot launch the new Register and submission system. There have been ongoing challenges relating to the quantity of work and we believe these will continue over the coming weeks. Further information is available below.

1.4. We are pleased to report good progress on CaFC verification with clinics, EggBatchID, User Acceptance Testing (UAT) and the launch of the PRISM preview system.

2. Summary

2.1. Good progress has been made relating to data migration and EggBatchID resolution. The EggBatchIDs linkage rate was 58% in June 2019 and is currently at 89%. It is predicted to further increase to 94% at the point of go-live and further increase to 99.5% by February 2020.

2.2. PRISM User Acceptance Testing (UAT) was completed on 11 September with positive results. We released the PRISM preview system on 2 October. Given the proximity of the preview launch date and AGC meeting we will provide a verbal update feedback from the sector. The preview launch was released around 2 weeks later than planned due to additional bugs identified in PRISM relating to the code that tracks gametes and developing validation rules. Both areas relate to core system functionality and must be correct before launch. This means that it is not now possible to go live in early December and we will need to go live in mid-December. Further information is available in section 4 (PRISM) and section 6 (budget).

2.3. Work on our CaFC refresh continues at pace and we continue to make good progress supporting clinics as they update and verify their data ahead of the CaFC refresh planned for later this year. Clinics have responded well over the summer and data errors relating to the historical data used for CaFC have reduced dramatically from 21,916 in June 2019 to 192 in September 2019. Further details are available below.

2.4. We have communicated frequently with the sector and suppliers to keep them updated on progress, our expectations of them in relation to suppliers' development using our API, and how to access additional support.

2.5. We have carefully considered business processes for our internal teams in their support of the new Register in the short and medium term post go-live. There will need to be workarounds in place immediately following go-live. Further details are available below.

2.6. As work progresses, there is more clarity on the metrics, impact and business consequence for any data discrepancies following data migration. This paper sets out the expected metrics and tolerances. These will be further refined ahead of the Approval to Proceed AGC meeting on 8 November 2019.

2.7. This paper provides further detail on all aspects of section 1.2 and provides clarity on

- What will be complete ahead of the AGC go-live decision (8 November 2019)
- What will be complete between the go live decision and PRISM launch, expected in December 2019
- What will be complete after go-live in respect of workarounds or supporting systems and the resultant impact on business processes (such as internal teams such as our Register team, Opening the Register service and providing risk information to clinics as part of the inspection process)

2.8. Our programme risk register is regularly reviewed and the top three risks are outlined below in section 8. We are actively reviewing our top three risks relating to ongoing PRISM development support and handover post go live, the loss of key staff (risk reducing due to proximity to the end of the programme) and the development of PRISM enhancements to allow internal teams the ability to easily access and interrogate register data and associated reports. A full risk update is available in section 8 below.

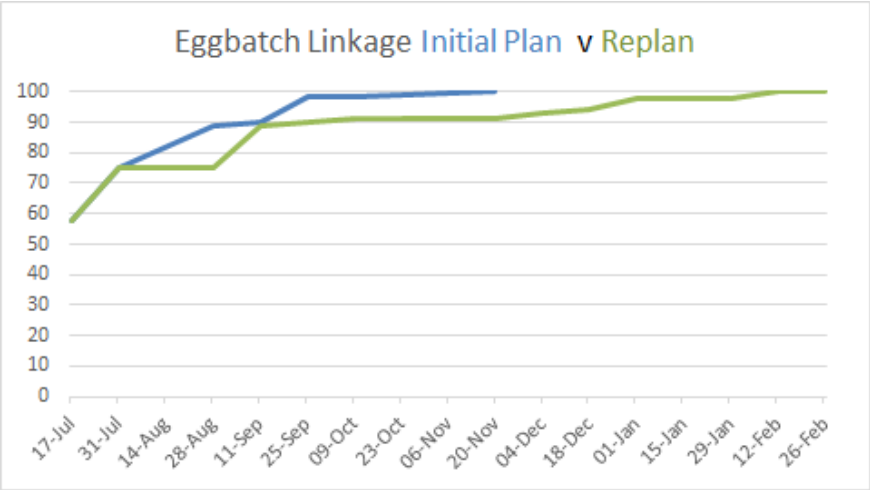
3. Data Migration

3.1. Iergo, the data migration specialists have made good progress and continue to work on all areas of data migration including resolving the EggBatchID linkages using dedicated additional resource.

3.2. Data Migration consists of several discrete activities; the resolution of data errors (namely EggBatchID), technical data transfer, associated testing and development of reporting, and detailed fallback and fallout planning should an issue occur at the point of data migration.

3.3. All data migration tasks have been identified, scrutinised and categorised as ones which will be completed ahead of data migration or soon after go-live, ensuring we are at an acceptable level of resolution for EggBatchID at go-live.

3.4. The current data readiness graph is below. The EggBatchID linkage rate in June 2019 was 58%. The forecast is that the EggBatchID linkage rate will continue to increase and we will reach 94% by the time we go-live, and after go-live this will increase further to around 99.5% by February 2020. The HFEA data analyst was on planned leave for around 3 weeks in August and has also been involved in the data review work ahead of the CaFC refresh.



3.5. Some errors relating to unresolved EggBatchID linkages will remain at go-live which will have a minor impact on clinics. In practice some data will require re-entering for a small number of individuals who return to clinics. As outlined in the graph above, this number will further reduce over a short period of time after go-live. This approach will not need more iergo resource or an increase in the Iergo data migration contract cost.

3.6. We believe the impact will be acceptable to clinics and we will be clear on the impact of the unresolved linkages (on different clinics types and quantity of treatment cycles) before the AGC Approval to proceed meeting on 8 November. The measurement of this will form a key part of the approval to proceed assessment.

3.7. We considered moving back the date we publish CaFC to free resource to allow more progress to be made increasing the EggBatch linkage rate at go-live. In practise, because of the small team this wouldn't give a material advantage and may in turn create an issue with support for the new Register post go-live due to lack of resource in the future.

3.8. It expected that the next Trial Load will take place w/c 30 September, following which data acceptance testing resulting from the trial load will take place. The Trial Load takes a snapshot of all Register data and moves it into the new register and is undertaken for testing purposes.

3.9. Detailed planning continues relating to fallback and fallout planning. This will form a key part of the data migration section of the report provided to AGC ahead of the 8 November sign-off meeting.

4. PRISM

4.1. Since the last update, PRISM development has continued at pace. We have worked relentlessly to address several issues as they have arisen which have required additional resource, resulting in an unavoidable delay to go-live of around 2 weeks. The impact on our go live estimate of early December is unavoidable given the core functionality issues we faced and are addressing.

4.2. PRISM development:

- Our development and testing work has been focused on UAT preparation, and bug-fixing (e.g. on gamete source, inventory and role change features). These bugs were serious issues affecting core functionality rather than typical bugs which may be classed as minor issues affecting visual features. Some work has also been undertaken on the implementation of validation rules.
- Six clinics staff took part in User Acceptance Testing during on 11 September. There was a positive reception scoring over 8/10 for first impression, ease of use and look and feel. It scored 7/10 on responsiveness. Responsiveness is simple to address given our ability to increase server performance to increase system speed as required. We received feedback relating to around eleven known system issues.

4.3. Clinic users of submission (third party) systems:

- We have been in regular contact with clinics users of submission systems and system providers. We provided a newsletter update to PRISM users and third party system users in August. The Newsletter discussed UAT, the release of a second preview / beta version of PRISM, the technical requirements needed for PRISM, the need for clinics to resolve errors and address omissions, and for completeness, an outline of our ‘go-live’ decision making process.
- We released the second preview / beta version of PRISM on 2 October. Use of the preview system will give users the opportunity to experience more of the functionality of the new system and provide feedback to help us make refinements before we release the final version later this year.

4.4. Third party system suppliers

- We continue to work proactively with system suppliers to assess their readiness ahead of system launch. We are in regular dialogue to capture any issues hindering progress. We have indicated that we will monitor progress more closely requiring more frequent updates until system launch. We will shortly be agreeing our approach for how we manage those suppliers who are not ready by December 2019. It is expected that we will give some clinics (who use third party systems) a short grace period of up to two months to update their systems and commence data input into the new Register via their third party system. Our approach will be confirmed over the coming weeks, taking into account the balance we must strike between supporting clinics during a significant data entry change, and ensuring they provide data to us within a reasonable timeframe.
- The team recently met on-site with the biggest third party supplier providing systems to around 40% of all clinics to discuss cut-over, UAT, API extension and deployment and communication plans. While our review of their preparedness will continue, there is a good level of assurance they will be ready in time.

4.5. RITA

- We originally planned to develop a separate system (RITA) to provide internal teams, such as the Register support team (used by clinics to provide support for data entry queries) and Opening the Register team (which responds to OTR queries) the ability to interrogate the data and produce detailed reports.

- We now plan to provide only essential functionality, such as the ability for the Register team to check submissions across multiple clinics, and the ability to delete data (deleted data always includes an audit trail that it has been deleted, so it never truly deleted).

4.6. The remaining work to complete development includes:

- Incorporation of validation rules and reporting
- Testing and release of the final update of the API to system suppliers, scheduled for 16 October
- Enhancements to PRISM to allow the Register and Donor Information Teams to access and report on data on a sector wide basis (RITA update above provides more detail).

4.7. The validation work provides the ability to check and inform the user of the validity of the data at the point of data entry (as opposed to the current system where data is checked and reported on in retrospect). In practise this provides a prompt to the user if a value is entered which the system is not expecting.

There are three weeks scheduled to undertake the validation work. It is difficult to predict how long this will take as each rule is variable in its complexity. By the end of October we expect to complete the work associated with coding the validation rules.

4.8. Our plans for training are advanced. We are developing a user guide for PRISM which will cover not only how to use PRISM but frequently used tasks such as how to log on, where to get help (telephone and email support). Video tutorials for certain tasks are being developed. There will be an FAQ available which will be updated as questions are raised. In addition we will be running half day training courses which will take place after we switch off EDI and before we switch on the new one – when we feel clinics may have time to attend. We are continuing to encouraging clinics to familiarise themselves with the preview system using scenarios we've created.

4.9. Our plans for launch involve a soft launch around the middle of December. A big-bang launch is likely to put significant pressure on the small supporting team in the first few days post launch. We plan to allow clinics one month to familiarise themselves with the system and start submitting data.

4.10. The third and final penetration test on the cloud infrastructure is scheduled for mid October and the results will inform the 8 November AGC go live decision.

5. Choose and Fertility Clinic (CaFC) update

5.1. We continue to work with clinics to support them updating their data. The CaFC data we will be publishing is treatment data relating to 2015 and 2018 and clinics are rectifying errors in their submissions which will ensure the highest quality of data. Once checked each PR signs off their clinics' completed forms for that period. We are actively targeting our effort towards the issues that affect headline performance rates within CaFC, rather than focussing on more minor errors which have a limited influence on the headline figure.

5.2. We have extended the deadline for submission on a number of occasions over the summer and are pleased to report that the overall error rate has reduced substantially from 21,916 errors to 192. To date we have responded to around 1000 queries from clinics.

5.3. By the time we publish CaFC, we expect this rate will reach around 150 and at that point we plan to stop. At that point, the remaining errors (around 150 spread over 4 years) relate to missing forms rather than missing data within forms.

5.4. Around eight clinics have expressed difficulty accessing reports because they use both a third party system to submit data and a standalone version of our EDI (current data submission system) to access reports. Our Register team have worked very closely with the affected clinics and we have again extended to deadline to allow sufficient time for them to update and review their data. The extensions do not impact on the CaFC refresh date.

5.5. Progress made to date is as follows:

Year	Number of data issues identified (before any removals and corrections)	Number of data issues (02/07/2017)	Number of data issues (17/07/2019)	Number of data issues (26/09/2019)
2015	2581	356	348	19
2016	3932	1422	1276	44
2017	6277	2931	2434	68
2018	9126	3676	2857	61
Totals	**21916**	**8385**	**6915**	**192**

5.6. We expect PRs to sign off their data w/c 7 October 2019. A final review will then take place and the data will be processed in readiness for publishing the updated CaFC in early December.

6. Budget

6.1. Our budget forecast aligned to an early December launch, and without the post go-live support is below.

Budget	£437k
Planned and Actual Spend	£431k
Surplus/Deficit	£6k

6.2. We are actively managing the issue relating to the additional budget needed for post go-live support / handover along with the associated costs to support the 2 week delay in December. We will provide an oral update at the 8 October AGC meeting.

7. 'Approval to proceed' approach

7.1. This section outlines our approach for project sign-off to provide approval to proceed with:

- Authorising use of our new cloud Register environment
- Data Migration - moving our old Register into the new Register
- Turning the existing data submission system (EDI) off
- Authorising the use of the PRISM system and APIs

7.2. We have set out a clear process for approval and governance. This takes into account the assurances AGC have requested relating to impact, consequence and risk, along with an internal sign off by HFEA business owners before the AGC review meeting. The internal review meeting will consider both the Readiness Assessment (section 7.3) and the Transition to Business as Usual Assessment (section 7.4).

7.3. When we reach the approval to proceed meeting we will have full clarity on remaining development, available budget, and impact of progress on the resolution of EggBatchID linkages.

7.4. **Readiness Assessment**

The 'readiness assessment' will include a review of PRISM development, API development, Data Migration readiness, Infrastructure readiness, Comms/engagement readiness, and readiness of the 'cutover' process.

This section provides an overview of the current status, projected status on 8 November 19 and the business owner who will provide assurance that the work is complete and delivered to an acceptable standard.

	Current Status (27 Sept 19)	Projected Status (8 Nov 19)	Confirmation Complete
PRISM	• UAT of system successfully completed • Beta version released to clinics for familiarisation and feedback • Validation and Reporting outstanding • Bug fixing currently being undertaken is outstanding (inc. gamete sources, inventory, and change of user role (inc. swap role) • Frontend changes outstanding (inc. basic homepage/ dashboard) • Enhancement to allow cross centre support to Register Information Team and Donor Information Team	• PRISM Development complete including validation rules to an acceptable level. • Enhancements to support the Register and Donor Information Teams will be completed after the 8 November meeting and before go-live. • Future enhancements will include: - Soft deletion of records - Ability to attach scanned images to records - Mitochondrial Donation - Extended reporting suite - Extended Dashboard (inc. graphical	Chris Hall (Interim Head of Information)

		representation of data to aid rapid assimilation, trend analysis and sector benchmarking)	
API	• Fourth API update released to third party system suppliers on 25th June 19 • Final API update planned for 16 October 19 • Suppliers are continuing their system development based on the API	• We will have confirmation by suppliers that their system development is complete (although they are unlikely to have updated their clients' systems by this date)	Chris Hall (Interim Head of Information)
Data Migration	• More development needed to resolve additional EggBatchID linkages – as outlined in section 3. • Software (routines) to perform the automatic data transfer for data migration is outstanding and needs to be written • A final data quality review is required to ensure all is in order ahead of data migration.	• Routines have been written and testing • Data Quality acceptable for go live (EggBatchID reaches an acceptable level)	Johny Morris (Data Migration Lead)
Infrastructure	• A final Penetration test is scheduled for w/c 14 October to assure the security and safety of the data and system • Performance test to be completed for PRISM • Synchronisation with Billing and EPICENTRE (internal workflow system) to be tested	• Penetration test completed and environment secure • Performance test results acceptable • Synchronisation works as expected	Steve Morris (Systems Manager)
Engagement (including directions)	• Comms to clinics (PRs) of go-live process and timetable not yet written and finalised • Amended directions complete and ready for issue. This relates to extending the timeline for submitting data after launch of PRISM and APIs.	• PRs have confirmed readiness for go-live	David Crook (Programme Manager)
Cutover Process	• The outline cutover process is complete and detailed planning is underway	• A detailed cutover process will be in place	Johny Morris (Data Migration Lead)

7.5. Transition to Business as Usual Assessment

The Transition to Business as Usual Assessment includes several additional checks that are needed ahead of system launch, specifically a review of any gaps in delivery along with a review of any impact on business process. In addition to the readiness assessment we will also review clinic readiness, along with any business impact or potential reputational impact. We will review the impact on finance (our billing processes relating to HFEA income from treatment cycles), impact on inspection team, Register team, Donor Information (OTR) team, Intelligence team and the proposed decommissioning of key data submission system and supporting infrastructure). The table below shows how that will be measured and assurance will be sought from those responsible for business processes.

	Status based on projected development at time of assessment	Impact of any gaps	Mitigation/Contingency to overcome any gaps	Agreement to Proceed
Clinic Readiness	Clinics will be able to enter data using the API and PRISM	We will be certain the validation rules are working correctly	Not applicable	David Crook (Programme Manager)
Finance	Finance processes for clinic billing can be supported	We will be certain we can bill clinics correctly – taking into account rate of use of the new system	Not applicable	Richard Sydee (Director of Finance and Resources)
Inspections	Information from multiple data sources is used for clinic inspections. Inspection Notebooks will be produced ahead of cutover for several months supporting inspections to continue during and after go-live. A new process will be in place to produce Inspection Notebooks post go-live. The process of delivering Risk Based Alerts will be will need	We will be certain the Inspection Notebooks can be produced to support the inspection process – an effective workaround will be in place	The Chief Inspector has indicated that this acceptable.	Sharon Fensome-Rimmer (Chief Inspector)

	to developed post go-live (within 2 months, the Inspection team have confirmed 6 months is acceptable).			
Register Management	PRISM enhancements will to support the Register Information Team will be in development.	There is a risk that the enhancements will not be complete by go-live	Register Team will use clinic logins, but support will be limited until the enhancement is available	Neil McComb (Register Information Manager)
Donor Information	PRISM enhancements to support the Donor Information Team will be in development The team will not be able to attach images to files	There is a risk that the enhancements will not be complete by go-live	The Donor Information Team will be able to use the legacy Register pending the enhancement	Sumrah Chohan (Donor Information Manager)
Intelligence	Data will be tested as adequate and available to the Intelligence team	No gaps	N/A	Nora Cooke-O'Dowd (Head of Intelligence)
Legacy Decommissioning	Decommissioning plan will be in place	No gaps	N/A	Steve Morris (Systems Manager)

8. Risks

8.1. Our risks remain broadly unchanged since the previous programme update in August 2019:

- We are actively managing the risk relating to extending the contract of the PRISM developer to provide support post go live.
- The likelihood of the risk relating to the loss of key staff has been reduced from 4 to 3 as we are nearing the end of the programme.
- Enhancements to PRISM to provide essential functionality to support the Register and Donor teams (see section 4.5) have been reduced to 15 days development and there are workarounds in place for the period immediately after go-live.

8.2. The top three programme risks are below:

Risk	Likelihood (post mitigation)	Impact (post mitigation)	Score (post mitigation)	Mitigation	Contingency
The programme is completed before the Lead Developer (or internal development team) is appointed to allow for handover, meaning contractors leave losing knowledge and handover of new processes.	4	5	20	Extend contract of PRISM developer along with a handover to a third party support company (Alscient). Risk mitigation involves retention and handover.	If we cannot mitigate this risk, our contingency is retaining the external developer for longer until the Development team is in place.
Loss of key staff: The programme is heavily dependent upon a few key staff. The loss of any one will have a severe impact on the plan and quality of deliverables. The ongoing issue of EggBatch linkages relies heavily on one person. This crucial element of the programme is therefore at risk.	3	5	15	There is no real mitigation for this. One of the outcomes of the project is that the data and processes are less opaque and skills and knowledge can be shared.	Loss of key staff will necessarily mean the project will take longer as new staff will need to learn and understand processes.

Enhancements to PRISM to allow the Register and Donor Information Teams takes longer than expected delaying the go-live.	3	5	15	Review of the development requirements indicated the required changes should be fairly light (15 days development)	Support will be undertaken using individual clinic log ins and access to old Register data for a short period until the new functionality is ready.

9. Recommendation

The Committee is asked to note:

- Data migration progress, including EggBatchID resolution
- PRISM and API development
- Choose a Fertility Clinic (CaFC) data refresh progress
- Communications, engagement and budget review
- Approval to proceed proposed approach
- Remaining timeline (within section 7.3)
- Risk assessment

Resilience, Business Continuity Management and Cyber Security

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☒ Improving standards through intelligence

Details:	
Meeting	Audit and Governance Committee (AGC)
Agenda item	11
Paper number	AGC (08/10/2019) 693 DH
Meeting date	08 October 2019
Author	Dan Howard, Chief Information Officer
Output:	
For information or decision?	For information
Recommendation	The Committee is asked to note: • The implementation of our new Electronic Document management system and associated policies / procedures; • The IT incident on 3 September including action taken and our ongoing work to minimise the risk or a recurrence; and • The update on work to upgrade our telephone and video-conferencing facilities.
Resource implications	Within budget
Implementation date	Ongoing
Communication(s)	Regular, range of mechanisms
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes:	None

1. Introduction and background

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

1.2. We have completed the implementation of Content Manager, our new Electronic Document Management system (replacing TRIM). The development work on the associated information governance and records management policies and procedures is progressing well. An update is below.

1.3. On 3 September we experienced an IT incident relating to the failure of one of the hard drives in a server in Spring Gardens. This resulted in a short term outage for some IT services. An update is below.

1.4. The third and final penetration test due on our new Register cloud infrastructure will take place later in October 2019. The results of which will be one element used to support the go-live decision on 8 November.

1.5. AGC have regularly received details on our plan to make improvements to our telephone system and video-conferencing facilities. An update is below.

2. Electronic Document Management system upgrade

2.1. Our work to implement Content Manager (an upgrade to our previous system, TRIM) has been ongoing for several months and is now complete.

2.2. This project set out to replace an unstable system which had been in use for 14 years. Use of the previous system did not adequately support compliance with electronic documentation retention and with wider information governance and data protection legislation such as GDPR and e-privacy.

2.3. The project had two aims, to implement a modern fit for purpose electronic document management system and a new retention policy that would meet legislative requirements

2.4. The system was implemented and data transferred successfully from TRIM. A training programme was initiated and most staff received training at the point of go-live. Further training sessions post go-live have taken place, along with hand-on support from the Information Governance / Records Manager.

2.5. While the project took six weeks longer than planned, benefits have been measured and the project has delivered on all objectives. Content Manager is faster and more stable than TRIM, there is less demand on IT staff resource, and it is easier to use than the previous system. Lastly, we have developed and published an interim retention policy; this will be further improved over the next two months, and then regularly reviewed thereafter.

2.6. Alongside the new system we are making several improvements to records management policies and procedures. During the next two months CMG (Corporate Management group) will review the following updated documents:

- Information Governance Policy
- Records Retention Policy
- Information Asset Register and Data mapping spreadsheet

2.7. Over the coming months we will work with staff across the organisation to make the most of the new system and embed good records management into the way that we work.

3. IT incident

3.1. On 3 September a hard drive failed in a server in Spring Gardens. No data was lost, but the failure impacted the majority of the services and applications that are hosted within the on premises hardware at Spring Gardens.

3.2. Services affected included the telephone system, Epicentre and EDI. The services that HFEA hosts in the cloud continued to run, but the failure at Spring Gardens prevented staff based in the office and those working remotely from being able to access these.

3.3. We worked with our IT infrastructure support provider Alscient to isolate services and quickly identified the cause. Services were restored the following day. The Senior Management Team were kept updated on progress and we regularly communicated with the organisation to explain the issue, its impact and expected resolution.

3.4. There was planned downtime during the week after the incident as components were checked and data was synchronised onto the replacement server hard drive.

3.5. While we carry some spares, given the age of the hardware it is not possible to plan for this and keep the variety of spare parts in stock we would need for contingency purposes.

3.6. We have been migrating services to the cloud as part of a long term plan to improve availability and performance.

3.7. We have work planned for the 19/20 financial year to further protect against failure of the aged hardware at Spring Gardens.

4. Telephone / video conferencing

4.1. Our work continues to move our telephone system from on premise to the cloud. This is part of our long term strategy to improve availability and performance of IT services.

4.2. This work has taken slightly longer than we anticipated due to paperwork difficulties leaving our previous telephone carrier service.

4.3. The main technical server upgrades have taken place involving the creation and testing of the new cloud environment.

4.4. The service transition is set to complete on 3 October. The final stage involves:

- Migration of Skype accounts on 2 October, from on-premise hardware to the cloud; and
- The redirection of calls from the on-premise system to the Office 365 Skype service in the cloud. This will take place early in the morning on 3 October 2019

4.5. We have regularly communicated updates to staff and this will continue on 2 and 3 October.

4.6. Once complete, users will continue to access telephone services as they do now, and we expect significant improvements to video conferencing. We will issue guidance to staff and Authority Members about using these facilities in due course.

5. Recommendation

The Committee is asked to note:

- The implementation of our new Electronic Document management system and associated policies / procedures;
- The IT incident on 3 September including action taken and our ongoing work to minimise the risk or a recurrence; and
- The update on work to upgrade our telephone and video-conferencing facilities.

Strategic risk register

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence

Details:	
Meeting	Audit and Governance Committee
Agenda item	13
Paper number	AGC (08/10/2019) 694 HC
Meeting date	8 October 2019
Author	Helen Crutcher, Risk and Business Planning Manager
Output:	
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	Strategic risk register and operational risk monitoring: ongoing. SMT review the strategic risk register monthly. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically (at least twice per year).
Communication(s)	Feedback from AGC will inform the next SMT review in October. Authority is due to receive the register in November.
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes	Annex 1: Strategic risk register

1. Latest reviews

1.1. SMT reviewed the register at its meeting on 23 September. SMT reviewed all risks, controls and scores.

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

1.3. One of the six risks is above tolerance.

2. New risk

2.1. In July, SMT reviewed the strategic risks related to the organisation's office move in 2020 and given the significance of the possible impacts agreed to add a new strategic risk on estates, E1.

3. Recommendation

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

Latest review date – 23/09/2019

Strategic risk register 2019/20

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇔
RE1: Regulatory effectiveness	Improving standards through intelligence	**9– Medium**	Above tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇧⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇔
ME1: Effective communications	Safe, ethical effective treatment Consistent outcomes and support	**6 – Medium**	At tolerance	⇔⇔⇔⇔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	**6 – Medium**	Below tolerance	-⇔ New risk in July

* Strategic objectives 2017-2020:

Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment

Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add-ons and feel prepared

Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics

Consistent outcomes and support: Improve access to treatment

Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients

Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce

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

Recent review points are: SMT 20 May ⇨AGC 18 June ⇨SMT 22 July 2019⇨SMT 23 September 2019

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

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

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

Commentary
While planning our 2019/20 budget, we took a prudent approach, utilising our predictive model, planning based on 2% growth on the current budget rather than against the recent trend, which was higher. This should ensure that should we see a drop in treatment volumes, the HFEA will be able to meet its financial commitments from its annual receipts. Increases of 6% have been confirmed to the civil service pension employer contributions, of which we have funded 2.5% within the HFEA budget with the remainder centrally funded. As this was budgeted for it does not pose a particular risk to financial viability, although there is uncertainty about the arrangement for next year and the possible impact of this. The delays in completing the data migration element of the digital projects has increased costs in 2019/20. In May 2019 the Audit and Governance Committee agreed to secure specialist data migration support to complete this work. This must come out of existing budgets and so will have a knock-on effect on other planned work. To ensure that we do not exceed our control totals with DHSC, at the end of Q1 we have reviewed the emerging situation and reprioritised expenditure in other areas of the organisation. The score of the Regulatory effectiveness risk was adjusted to reflect the possible impact of these risk sources in March.

Causes / sources	**Mitigations**	**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 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.	Quarterly, ongoing, with AGC model review at least annually - next review due in December 2019 - Richard Sydee

Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles.	Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in December 2018. 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.	Ongoing – Richard Sydee In place – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and affect other planned and ad hoc work.	The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact. Ongoing monitoring and reporting against control totals to ensure we do not overspend. Where possible, costs have been covered by the IT budget, reducing the impact on key delivery teams and other strategic deliverables. First quarter budgets were reviewed at CMG, to allow us to consider the impact and reprioritise as appropriate.	Procurement underway – Richard Sydee Ongoing – Richard Sydee July CMG meeting – 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.	Finance staff present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time-critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Olaide Kazeem

Failure to comply with Treasury and DHSC spending controls and finance policies and guidance leads to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. 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.	Quarterly accountability meetings (on-going) – Richard Sydee
	Annual budget has been agreed with DHSC Finance team. GIA funding has been provisionally agreed through to 2020.	December/January annually, – Richard Sydee

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – 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 business as usual capability, rather than capacity, though there are obviously some linkages between capability and capacity. For 18/19 turnover was 26.8%. Evidence suggests that the two main drivers of high turnover are the continuing constraints on public sector pay and the relatively few development opportunities in small organisations like the HFEA. In response, we have revised our recruitment strategy using a wider range of national and social media and recruitment agencies to improve the number and quality of applicants. This approach is having some success and we have in recent months attracted several high-quality candidates. We are also taking active steps to improve retention, focussing on things that we can control like learning and development. AGC receive 6-monthly updates on capability risk to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing further. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations.

Causes / sources	**Mitigations**	**Timescale / owner**
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun

	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise.	In place – Yvonne Akinmodun In place – Peter Thompson
The vacant Director of Compliance and Information is being covered by other staff, this creates a risk that key pieces of work are unable to be delivered due to resource pressures and unforeseen capability gaps.	A new Director has now been appointed and will start in the role in November 2019. In the meantime, other staff are covering elements of this role and work is being re-prioritised as required. There will naturally be a settling in period once the new postholder starts, meaning that there may be a small continuing resource pressure for a time, but given their background in the sector, they will bring valuable capabilities to the role.	Underway – Peter Thompson
Poor morale could lead to decreased effectiveness and performance failures.	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. More regular short 'pulse' staff surveys enable swifter management responses where there are areas of particular concern.	In place, ongoing – Peter Thompson In place – Jo Triggs In Place – Yvonne Akinmodun
	In 2018 new benefit options were implemented, including PerkBox and a buying and selling of annual leave policy (launched July 2018).	In place - Peter Thompson
Increased workload either because work takes longer than expected or reactive diversions arise.	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
	Oversight of projects by both the monthly Programme Board and CMG meetings, to ensure that projects end through due process (or closed, if necessary). Work is underway to review our interdependencies matrix, which supports the early identification of interdependencies in projects and other work, to allow for effective planning of resources.	In place – Paula Robinson Matrix relaunching 2019/20 – Paula Robinson
	Learning from Agile methodology to ensure we always have a clear 'definition of done' in place, and that we record when products/outputs have met the 'done' criteria and are deemed complete.	Partially in place – further work to be done in 2019/20 - 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
	Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends – Dan Howard
We may not be able to find time to implement the People Plan to maximise organisational capability given our small organisational capacity and ongoing delivery of business as usual.	Small focus groups and all staff awaydays have been utilised to make the most of staff time and involve wider staff in developing proposals. The most recent staff awayday was in July 2019 and we engaged external resources to support work on developing HFEA values and culture.	Ongoing – Yvonne Akinmodun
A number of staff are simultaneously new in post. This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	Recognition that a settling in period where staff are inducted and learn, and teams develop new ways of working is necessary. Formal training and development are provided where required. Knowledge management via records management and documentation and the HR team has revised onboarding methods to make them clearer and more effective.	Ongoing – Peter Thompson In place – Yvonne Akinmodun
The future office move, occurring in 2020, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.	See separate E1 risk for full assessment of risk causes and controls.	Early engagement with staff and other organisations underway and ongoing – Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA which divert resource and threaten our ability to deliver our strategic aims.	The department has provided guidance about the impact of a no-deal EU exit on the import of gametes and embryos. We continue to work closely to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. In December 2018, we commenced an EU exit project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU, as a third country in relation to import and export of gametes. This project includes our role in communicating with the sector on the effects of EU exit, to ensure that clinics are adequately prepared	Communications ongoing – Peter Thompson

	in terms of staffing and access to equipment and materials. We continue to engage with the DHSC and clinics to prepare for a no-deal Brexit. As of September 2019, we re-visited our preparedness and core standards for EU exit and reported back to the DHSC. We have developed public and clinic facing webpages on EU exit, SOPs and tools for responding to concerns reported by centres relating to EU exit, updating our processes for ITE import certificate applications and developed all the necessary documents required for EU exit based on the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019. An internal working group attended by the Senior Responsible Officer (SRO) and recently appointed Deputy SRO meet weekly at this point to highlight any current or new issues and concerns and agree actions accordingly. Authority and AGC are also updated at their meetings.	

CS1: There is a risk that the HFEA has unsuspected system vulnerabilities that could be exploited, jeopardising sensitive information and involving significant cost to resolve.

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	Peter Thompson, Chief Executive (pending start of new Director of Compliance and Information)	Whole strategy	⇔⇔⇔⇔

Commentary
We have undertaken cyber security (penetration) testing of the new digital systems such as PRISM and the Register, to ensure that these remain secure. The results have not revealed any significant issues. The third and final test is scheduled ahead of go-live and AGC will consider the results of this at a special meeting in November. Go-live has been delayed owing to issues with data migration. Options were considered by AGC in May and revised deployment plans have been developed with delivery of the new system in winter 2019. The delay poses no increased cyber risk. We continue to assess and review the level of national cyber security risk and take action as necessary to ensure our security controls are robust and are working effectively. A cyber security audit in December 2018 gave us a moderate rating with no significant weaknesses found.

Causes / sources	**Mitigations**	**Timescale / owner**
Insufficient governance or board oversight of cyber security risks (relating to awareness of exposure, capability and resource, independent review and testing, incident preparedness, external linkages to learn from others).	AGC receives reports at each meeting on cyber-security and associated internal audit reports. The Deputy Chair of the Authority is regularly appraised on actual and perceived cyber risks. Internal audit report on data loss (October 2017) gave a 'moderate' rating, recommendations have been actioned, one final recommendation is being reported at each AGC meeting. A further cyber security internal audit report was finalised in December 2018. A final report on cyber security will be signed off by AGC before any decision is made to go live with PRISM.	Ongoing regular reporting – Director of Compliance and Information/ Dan Howard Ongoing – Dan Howard Deployment date of project to be confirmed

		once ongoing data migration issue resolved – Dan Howard
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	The website and Clinic Portal are secure and we have been assured of this. The focus now is on obtaining similar assurance through penetration testing report to the SIRO in relation to the remaining data submission deliverables (PRISM). The second of three rounds of penetration testing has been completed and there have been no significant issues found so far.	Penetration testing underway throughout development and ongoing – Peter Thompson/ Dan Howard
There is a risk that IT demand could outstrip supply meaning IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion. We do not currently have a developer in post.	We continually refine the IT support functional model in line with industry standards (ie, ITIL). We undertook an assessment of our ticketing systems and launched a new system in November 2018. Our vision is to have an internal team working in partnership with a third-party software development provider. In May 2018 we awarded a contract for third-party infrastructure and development support. The service is based on the ITIL framework (IT service standard). Our strategy was to recruit to the in-house software development team following a workload review. The workload review has been completed, however during the delay to PRISM and Data Migration work, the funding for the developer post has been used for this ongoing development. Resourcing for the substantive role will be reviewed in autumn.	Approved per the ongoing business plan – Dan Howard Tender process completed to procure a longer-term support arrangement – Dan Howard Recruitment to internal development team underway from June 2019 – Dan Howard
Confidentiality breach of Register or other sensitive data by HFEA staff.	Staff are made aware on induction of the legal requirements relating to Register data. All staff have annual compulsory security training to guard against breaches of confidentiality, updated information risk training was completed by staff during April / May 2019. Relevant and current policies to support staff in ensuring high standards of information security. There are secure working arrangements for all staff both in the office and when working at home (end to end data encryption via the internet, hardware encryption) Further to these mitigations, any malicious actions would be a criminal act.	In place – Peter Thompson A review of current IT policies is ongoing – Dan Howard

There is a risk that technical or system weaknesses lead to loss of, or inability to access, sensitive data, including the Register.	Back-ups of the data held in the warehouse in place to minimise the risk of data loss. Regular monitoring takes place to ensure our data backup regime and controls are effective. We are ensuring that a thorough investigation takes place prior, during, and after moving the Register to the Cloud. This involves the use of third party experts to design and implement the configuration of new architecture, with security and reliability factors considered. Results of penetration testing have been positive.	In place – Dan Howard The new Register will be deployed once ongoing data migration issue is resolved in winter 2019 – Dan Howard
Business continuity issue (whether caused by cyber-attack, internal malicious damage to infrastructure or an event affecting access to Spring Gardens).	Business continuity plan and staff site in place. The BCP information cascade system was tested in March 2019 and CMG reviewed the plan and agreed revisions in May. Existing controls are through secure off-site back-ups via third party supplier. A cloud backup environment has been set up to provide a further secure point of recovery for data which would be held by the organisation. The cloud backup environment for the new Register has been successfully tested. Once the final penetration tests are complete we will utilise this functionality as we go live with our new Register and submission system.	BCP in place, regularly tested and reviewed – Director of Compliance & Information/ Dan Howard Undertaken monthly – Dan Howard System to be completed Winter 2019 – Dan Howard
Cloud-related risks.	Detailed controls set out in 2017 internal audit report on this area. We have in place remote access for users, appropriate security controls, supply chain security measures, appropriate terms and conditions with Microsoft Azure, Microsoft ISO 27018 certification for cloud privacy, GCloud certification compliance by Azure, a permission matrix and password policy, a web configuration limiting the service to 20 requests at any one time, good physical and logical security in Azure, good back-up options for SQL databases on Azure, and other measures.	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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

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

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

Commentary
We accept that in a contested area of public policy, the HFEA and its decision-making will be legally challenged. 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. Both the likelihood and impact of legal challenge may be reduced, but it cannot be avoided entirely. For these reasons, our tolerance for legal risk is high. We have not had any active legal action since October 2018.

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation. This may result in challenges to the way the HFEA has interpreted and applied the law.	Evidence-based and transparent policy-making and horizon scanning processes. Horizon scanning meetings occur with the Scientific and Clinical Advances Advisory Committee on an annual basis.	In place – Laura Riley with appropriate input from Catherine Drennan
	Through constructive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges or minimise the impact of them. Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to	Ongoing – Catherine Drennan In place – Peter Thompson

	put the HFEA in the best possible position to defend any challenge.	
	Case by case decisions on the strategic handling of contentious issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	In place – Catherine Drennan and Peter Thompson
	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.	In place – Catherine Drennan
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs.	Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes. The Head of Legal has put measures in place to ensure consistency of advice between the legal advisors from different firms. These include: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • A SharePoint site for sharing questions, information and experiences is in development	In place – Peter Thompson Since Spring 2018 and ongoing – Catherine Drennan
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well. Consistent decision making at licence committees supported by effective tools for committees. Standard licensing pack distributed to members/advisers (refreshed in February 2019). Changes made to licensing processes in 2019 to make it more efficient and robust following a 2018 external licensing review.	In place – Paula Robinson
	Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.	In place – Sharon Fensome-Rimmer
High-profile legal challenges have reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime and affecting strategic delivery.	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.	In place – Catherine Drennan, Joanne Triggs In place – Peter Thompson, Catherine Drennan

	The Compliance team stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for effective planning of work. The Compliance management team monitor the number and complexity of management reviews to ensure that the Head of Legal is only involved as appropriate.	In place – Sharon Fensome Rimmer, Director of Compliance & Information
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. Any changes could be perceived as a threat – not necessarily ultimately resulting in legal action, but still entailing diversion of effort.	Risks considered whenever a new approach or policy is being developed. Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics. Stakeholder involvement and communications in place to ensure that clinics 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 – Richard Sydee (BIT) / Clare Ettinghausen
The Courts approach matters on a case by case basis and therefore outcomes can't always be predicted. So, the extent of costs and other resource demands resulting from a case can't necessarily be anticipated.	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.	In place – Peter Thompson
Legal proceedings can be lengthy, and resource draining and divert the in-house legal function (and potentially other colleagues) away from business as usual.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Peter Thompson
HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound	Licensing SOPs were improved and updated in Q1 2018/19, committee decision trees in place. Advice sought through a 2018 Licensing review on specific legal points, and the improvements identified have been implemented where possible.	In place – Paula Robinson In place – Paula Robinson
	Up to date compliance and enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.	In place but a review is planned following the new Director of Compliance and Information starting in post –

		Catherine Drennan
Legal parenthood consent cases are ongoing, and some are the result of more recent failures (the mistakes occurred within the last year). This may give rise to questions about the adequacy of our response when legal parenthood first emerged as a problem in the sector (in 2015).	The Head of Legal continues to keep all new cases under review, highlighting any new or unresolved compliance issues so that the Compliance team can resolve these with the clinic(s).	In progress and ongoing – Catherine Drennan, Sharon Fensome-Rimmer, Director of Compliance & Information
Storage consent failings at clinics may lead to diversion of legal resource and additional costs for external legal advice.	We took advice from a leading barrister on the possible options for a standard approach for similar cases. Significant amendments were made to guidance in the Code of Practice dealing with consent to storage and extension of storage, this was launched in January 2019. This guidance will support clinics to be clearer about their statutory responsibilities and thus prevent issues arising in the future. Session on storage consent provided at the Annual Conference in June 2019. Storage consent will also be covered in the revision of the PR entry Programme (PREP) in the autumn.	Done in Q1 2018/19 – Catherine Drennan Revised guidance will be provided where appropriate to clinics – Laura Riley Underway – Catherine Drennan/ Laura Riley
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place	In place – Peter Thompson

RE1: There is a risk that planned enhancements to our regulatory effectiveness are not realised, in the event that we are unable to make use of our improved data and intelligence to ensure high quality care.

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

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Regulatory effective-ness RE 1: Inability to translate data into quality	Peter Thompson, Chief Executive (pending start of new Director of Compliance & Information)	Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce	⇔⇔⇔⇔

Commentary
Data submission work continues although delivery has been somewhat delayed as described under risks above. We experienced difficulties with migrating Register data and this has delayed the launch of PRISM and the new Register. Fully developed data migration options went to AGC in May and a plan for deployment was agreed which extended delivery timeframes. These issues obviously cause a delay to accessing improved data and we consequently raised this risk in March 2019. Regular updates on this risk are provided to AGC who have oversight over the final stages of this work.

Causes / sources	**Mitigations**	**Timescale / owner**
IfQ has taken longer than planned, and there will be some ongoing development work needed leading to delays in accessing the benefits.	Data Submission development work is now largely complete although deployment has been delayed while remaining data migration issues were resolved. Oversight and prioritisation of remaining development work will be through the IT development programme board with oversight from AGC.	Deployment date of data submission system planned for winter 2019 – Director of Compliance & Information
Risks associated with data migration to new structure, compromises record accuracy and data integrity.	Migration of the Register is highly complex. IfQ programme groundwork focused on current state of Register. There is substantial high-level oversight including an agreed migration strategy	Deployment date winter 2019– Director of Compliance &

	which is being followed. The migration will not go ahead until agreed data quality thresholds are met. AGC will have final sign off on the migration.	Information /Dan Howard
We could later discover a barrier to meeting a new reporting need, or find that an unanticipated level of accuracy is required, involving data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible, through engagement with stakeholders to anticipate future needs and build these into the design. Further scoping work would occur periodically to review whether any additions were needed. The structure of the new Register makes adding additional fields more straightforward than at present. In 2020/21, we plan to establish a review board to manage any ongoing changes.	In place regular reviews to occur once the Register goes live – Director of Compliance & Information
Risk that existing infrastructure systems – (eg, Register, EDI, network, backups) which will be used to access the improved data and intelligence are unreliable.	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery. In March 2018 CMG agreed to a new approach, including some outsourcing of technical second and third line support, this provides greater resilience against unforeseen issues or incidents. A contract was awarded in May for ongoing development and infrastructure support.	In place – Dan Howard
Insufficient capability and capacity in the Compliance team to enable them to act promptly in response to the additional data that will be available.	Largely experienced inspection team. The inspection team is now at complement although there will be a bedding in period for newer staff.	In place – Director of Compliance & Information
Failure to integrate the new data and intelligence systems into Compliance activities due to cultural silos.	Work has been undertaken to bed in systems, such as the patient feedback mechanism, and this is now a part of Compliance business as usual.	Ongoing – Sharon Fensome-Rimmer
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new Register structure until their software has been updated.	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the data submission project. Plan in place to deal with any inability to supply data. The Compliance management team will manage any centres with EPRS systems who are not ready to provide Register data in the required timeframe. Centres will be expected to use the HFEA's PRISM if they are unable to comply. Early engagement with EPRS providers means the risk of non-compliance is slim.	Ongoing - Director of Compliance & Information
Data migration efforts are being privileged over data quality	The Register team uses a triage system to deal with clinic queries systematically, addressing the most critical errors first.	In place – Director of

leading to an increase in outstanding errors		Compliance & Information
	We undertake an audit programme to check information provision and accuracy.	In place – Director of Compliance & Information
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs and FOIs have dedicated expert staff to deal with them although they are very reliant on a small-number of individuals. We have systems for checking consistency of answers.	In place – Clare Ettinghausen
	There is a dedicated team for responding to OTRs and all processes are documented to ensure information is provided consistently	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance from us.

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

Risk area	Risk owner	Links to which strategic objectives?	Trend
Effective communications ME1: Messaging, engagement and information provision	Clare Ettinghausen Director of Strategy and Corporate Affairs	Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add-ons and feel prepared Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics. Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.	⇔⇔⇔⇔

Commentary
Authority discussed our communications strategy in January 2019 and agreed that good progress had been made. Communications should be derived from the strategy and aligned with the key organisational objectives. This included the approach to building relationships with political and other stakeholders and developing a wider public affairs approach. Conversations about messaging and engagement are central to early discussion about the new 2020-2023 strategy to ensure that we take a joined-up approach that takes full advantage of our channels and a public affairs approach.

Causes / sources	Mitigations	Timescale / owner
Some of our strategy relies on persuading clinics to do things better. This is harder to put across effectively, or to achieve firm outcomes from.	When there are messages that need to be conveyed to clinics through the inspection team, staff work with the team so that a co-ordinated approach is achieved and messages that go out to the sector through other channels (eg clinic focus) are reinforced. When there are new or important issues or risks that may impact patient safety, alerts are produced collaboratively by the Inspection, Policy and Communications teams.	In place - Sharon Fensome-Rimmer, Laura Riley, and Jo Triggs

Patients and other stakeholders do not receive the correct guidance or information.	Communications strategy in place, including social media and other channels as well as making full use of our new website. Stakeholder meetings with the sector in place to help us to underline key campaign messages. Our new publications use HFEA data more fully and makes this more accessible. Policy team ensures guidance is created with appropriate stakeholder engagement and is developed and implemented carefully to ensure it is correct. Ongoing user testing and feedback on information on the website allows us to properly understand user needs. We have internal processes in place which meet The Information Standard (although the assessment and certification scheme is being phased out). New providers are in place for the Donor Conceived Register. The executive facilitated a smooth transition of the service to the new supplier to ensure that effective information and support continued to be in place for donor conceived people.	In place and reviewed periodically (last review occurred Jan 2019) – Jo Triggs Ongoing – Nora Cook-O'Dowd In place – Laura Riley, Jo Triggs In place –Jo Triggs Certification in place – Jo Triggs In place – Dan Howard
We are not able to reach the right people with the right message at the right time.	We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Planning for campaigns and projects includes consideration of communications channels. When developing policies, we ensure that we have strong communication plans in place to reach the appropriate stakeholders. Extended use of social media to get to the right audiences. The communications team analyse the effectiveness of our communications channels at Digital Communications Board meetings, to ensure that they continue to meet our user needs.	In place – Jo Triggs In place and ongoing – Jo Triggs In place - Laura Riley, Jo Triggs In place– Jo Triggs Ongoing – Jo Triggs
Risk that incorrect information is provided in PQs, OTRs or FOIs and this may lead to misinformation and misunderstanding by patients, journalists and others.	PQs and FOIs have dedicated expert staff to manage them and additional staff are being trained to ensure there is not over-reliance on individuals. We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission.	In place - Clare Ettinghausen Clare Ettinghausen /SMT - In place

	There is a dedicated OTR team and all responses are checked before they are sent out to applicants to ensure that the information is accurate.	In place - Dan Howard
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
There is a risk that we provide inaccurate information and data on our website or elsewhere. Data in CaFC has not been updated for a number of years, due to the continuation of the digital projects. This means that the data provided about success rates on our website is not current.	All staff ensure that public information reflects the latest knowledge held by the organisation. Small working group looking at any minor CaFC issues and CaFC data will be updated in autumn 2019. The Communications team work quickly to amend any factual inaccuracies identified on the website. The Communications publication schedule includes a review of the website, to update relevant statistics when more current information is available.	In place - Nora Cook-O'Dowd, Laura Riley, and Jo Triggs In place – Jo Triggs In place – Jo Triggs
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NHS.UK: The NHS website and our site contain links to one another which could break	We maintain a relationship with the NHS.UK team to ensure that links are effectively maintained.	In place – Jo Triggs
DHSC: interdependent communication requirements may not be considered	DHSC and HFEA have a framework agreement for public communications to support effective co-operation, co-ordination and collaboration and we adhere to this.	In place – Jo Triggs

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**2**	**3**	**6 - medium**
Tolerance threshold:					**8 - medium**
Status: **Below tolerance**					

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

Commentary
We have taken an active approach to handling this risk. The Director of Finance and Resources has been involved in discussions with the Department about the office relocation since mid-2018. The physical office build and fit-out is being handled by the British Council and the overall project managing the move of the HFEA and four other organisations is being co-ordinated by the Department of Health and Social Care. An internal project to prepare for the office move was started up in May 2019 to handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks.

Causes / sources	Mitigations	Timescale / owner
The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings.	HFEA requirements have been specified up front and feedback given on all proposed designs. We actively engage in all external project meetings. If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected.	Ongoing – Richard Sydee
We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation.	We will advertise the move to Stratford in all job adverts, so that applicants are aware. Monitoring of recruitment data will allow us to assess whether we are seeing any impact early on and provide an early warning indicator to enable us to consider whether other mitigations are possible. We will continue to offer desirable staff benefits and policies, such as flexible working, and will	From July 2019 – Yvonne Akinmodun

	evaluate these to ensure that they support staff recruitment and retention. Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.	
Stratford may be a less desirable location for some current staff due to: • Increased commuting costs • Increased commuting times • Preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention as staff choose to leave before the move.	Excess fares policy to be agreed to compensate those who will be paying more following the move to Stratford. Efforts underway to understand the impact on individual staff and discuss their concerns with them via, staff survey, 1:1s with managers and all staff meetings. 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.	By Winter 2019 – Yvonne Akinmodun, Richard Sydee
The Stratford office may cost more than the current office, once all facilities and shared elements are taken into account, leading to opportunity costs.	Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use. The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary fees, accordingly to ensure that our work and running costs are effectively financed. The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens.	Ongoing - Richard Sydee,
The move to a new office will lead to ways of working changes that we may be unprepared for.	Conversations about ways of working are central to the HFEA project, which started up in May 2019. Policies related to ways of working will be agreed and circulated significantly before the move, to ensure that there is time for these to bed in and be accepted ahead of the physical move. Staff will be involved in their development as appropriate. Conversations have been ongoing with the other organisations who are moving to Stratford with us, to ensure that messaging around ways of working is consistent across organisations, while reflecting the individual cultures and requirements of these.	Ongoing - Richard Sydee, Yvonne Akinmodun

Current staff may not feel involved in the conversations about the move, leading to a feeling of being 'done to' and lower morale.	Conversations about ways of working to occur throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions. An open approach is being taken to ensure that information is cascaded effectively and staff are able to voice their views and participate. Staff will be able to visit the site ahead of time so that they feel prepared.	Ongoing – Richard Sydee
The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.	Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed. Assurance will be provided by regular reporting to AGC and Authority. The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance. A project manager has been allocated from the IT team to ensure there is resource available for day to day management of project tasks. Other key staff such as HR and representatives from other teams involved in the internal HFEA Project Board.	In place – Richard Sydee
Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.	Early discussions with HFEA and other organisations' IT teams underway to determine IT requirements, allowing more time to resolve these. IT upgrades and improvements that were already underway or planned, such as the strategy of moving the IT estate to the cloud where possible, will mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.	Ongoing - Steve Morris, Dan Howard
The physical move may cause short-term disruption to HFEA activities and delivery if necessary resources such as meeting rooms or physical assets are not available to staff.	Careful planning of the move to reduce the likelihood of disruption. Staff would be able to work from home in the short-term if there was disruption to the physical move which would reduce the impact of this.	Ongoing - Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
British Council – lead on physical build – may not understand or take HFEA needs into account.	DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.	In place – Richard Sydee, DHSC

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

Reviews and revisions

SMT review – September 2019 (23/09/2019)

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

- FV1 – SMT noted that more would be understood about the risk of financial pressures on strategic delivery following the next quarterly financial review and that the risk will be re-considered in the round following that discussion in October.
- LC1 –SMT discussed the legal risk and the ongoing lack of legal challenge. SMT considered that at the time of the next Strategic risk register being drafted (in line with the new 2020-2023 strategy), these risk sources should be reviewed in the round to consider the framing of any legal risk, which at present related to resource diversion. The Chief Executive would discuss this with AGC.
- RE1 – SMT noted that although this risk was above tolerance, due to the delays to the digital projects work, it was being very closely monitored, including with direct reporting to AGC. No further controls were proposed.

SMT review – July 2019 (22/07/2019)

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

- LC1 – SMT considered the comments of AGC and the legal risk score. SMT considered the risk and noted that there continued to be no active legal cases to which we were a party. SMT confirmed that it was happy with the assessment of controls and the rating of the risk.
- E1 – SMT considered the new office relocation risk, reviewing each control and mitigation, including interdependencies and agreed that this was a good assessment of the risk as we currently understood it. SMT noted that before the next AGC meeting in October we would have a more complete view of certain areas of this risk, such as the impact on staff, as a survey of all staff would conclude in early September.

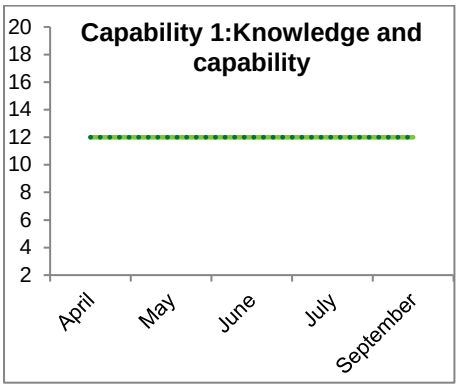
AGC review – June 2019 (18/06/2019)

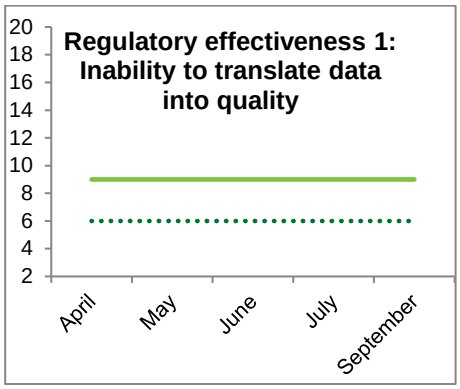
AGC reviewed all risks, controls and scores and made the following point:

- LC1 - The AGC Chair queried whether the score and tolerance level of the legal risk had been considered in the round. The Chief Executive noted that, given the ethical and legal context, the inherent risk relating to HFEA being legally challenged remained high. However, there were mitigations in place to reduce the likelihood. The executive confirmed that it would continue to consider this risk to avoid complacency.

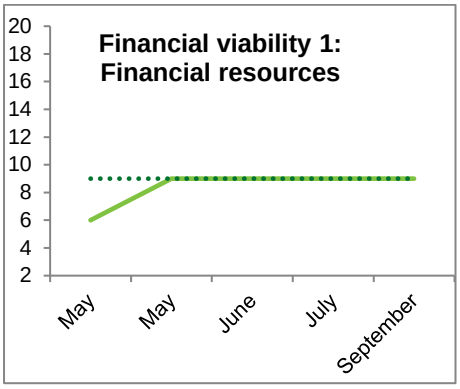
Risk trends

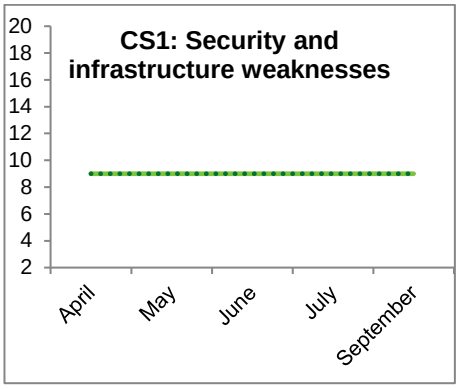
High and above tolerance risks

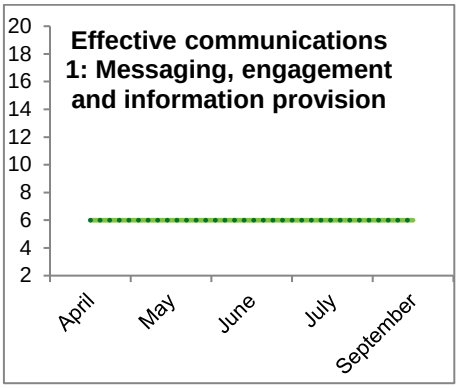


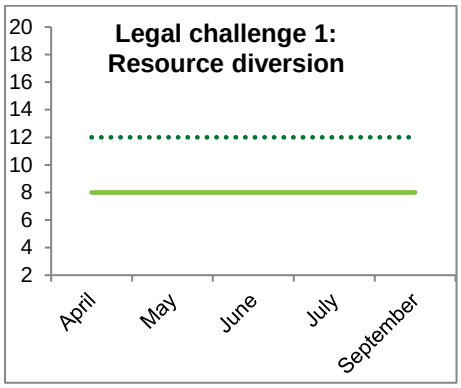


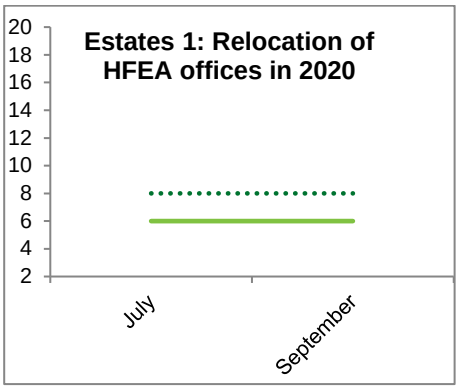
At and below tolerance risks











Criteria for inclusion of risks

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

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

Rank

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

Risk trend

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

Risk scoring system

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

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

Risk scoring matrix

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

Risk Score = Impact x Likelihood

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

System-wide risk interdependencies

As of April 2017, we explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk has been added to the risk register, so as to be sure we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC or auditors as required.

Contingency actions

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

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

Audit and Governance Committee Forward Plan

Strategic delivery:	☐Safe, ethical, effective treatment	☐Consistent outcomes and support	☒Improving standards through intelligence
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	14		
Paper number	AGC (08/10/2019) 695 MA		
Meeting date	08 October 2019		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the Forward Plan		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low	☐ Medium	☐ High
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information		
Annexes	N/A		

Audit & Governance Committee Forward Plan

AGC Items Date:	5 Mar 2019	18 Jun 2019	8 Oct 2019	3 Dec 2019
Following Authority Date:	13 Mar 2019	3 July 2019	13 Nov 2019	29 Jan 2020
Meeting 'Theme/s'	Finance and Resources	Annual Reports, Information Governance, People	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity
Reporting Officers	Director of Finance & Resources	Director of Finance & Resources	Director of Strategy & Corporate Affairs	Director of Compliance and Information
Strategic Risk Register	Yes	Yes	Yes	Yes
Digital Programme Update	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)	Draft Annual Governance Statement	Yes – For approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report	Audit Planning Report	Audit Planning Report
Information Assurance & Security		Yes plus SIRO Report		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Update	Results, annual opinion approve draft plan	Update	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Public Interest Disclosure (Whistleblowing) policy	Reviewed annually thereafter			

AGC Items Date:	5 Mar 2019	18 Jun 2019	8 Oct 2019	3 Dec 2019
Anti-Fraud, Bribery and Corruption policy	Reviewed and presented annually thereafter GovS: 013 Counter Fraud			
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes		Yes Including bi-annual HR report		Bi-annual HR report
Strategy & Corporate Affairs management			Yes	
Regulatory & Register management	Yes			Yes
Cyber Security Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Estates	Yes	Yes	Yes	Yes
General Data Protection Act (GDPR)			Yes	Yes
Review of AGC activities & effectiveness, terms of reference				Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes

Register of Gifts and Hospitality

Strategic delivery:	☐ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	AGC		
Agenda item	15		
Paper number	HFEA (08/10/2019) 696 MA		
Meeting date	8 October 2019		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	Attached is the latest Gifts and Hospitality Register. This has been upgraded from the book previously used to the spreadsheet. The Register is a standing item on the agenda and Members are asked to note the entries.		
Resource implications			
Implementation date	2019/20 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Register of Gifts / Hospitality Received and Provided/Declined

Version: HFEAG0001
Jan-20

DIVISION / DEPARTMENT: HFEA
FINANCIAL YEAR: 2019/20

	Details of the Gift or Hospitality						Provider Details			Recipient Details	
Type	**Brief Description of Item**	**Reason for Gift or Hospitality**	**Date(s) of provision**	**Value of Item(s)**	**Location where Provided**	**Action on Gifts Received**	**Name of Person or Body**	**Contact Name**	**Relationship to Department**	**Name of Person(s) or Body**	**Contact Name**
Either 'Provision' or 'Receipt'	*Give a brief description of the gift or hospitality recorded*	*Summarize the reason or occasion for the gift or hospitality*	*Give the date(s) on which it was provided or offered*	*Give the known or estimated value - if unknown then state 'unknown' and explain further under the 'Reason for Gift' column.*	*Give the name of the venue or location at which the gift or hospitality was provided*	*For Gifts Received only, specify what happened to the item(s) after it was received*	*Give the name of the individual or organization providing or offering the gift / hospitality*	*Give a contact name if an individual is not specified as the provider - otherwise leave blank*	*Specify the relationship of the provider to the Department (e.g. 'supplier', 'sponsor', etc.) - if the Department is the provider then leave blank*	*Give the name of the individual(s) or organisation receiving the gift / hospitality - if there are multiple recipients, specify each on a separate line*	*Give a contact name if an individual is not specified as the recipient - otherwise leave blank*
Receipt	Lunch invitation	To introduce to Legal Trainers	10/08/2017	£ -	Not known	Lunch accepted	Old Square Chambers	Eleena Misra	Legal Consultancy	HFEA	C Drennan
Receipt	Lunch invitation	Introduce Clients to new lawyers	01/11/2017	£ -	Not known	Lunch accepted	Blackstone Chambers	Catherin Callaghan	Legal Consultancy	HFEA	C Drennan
Receipt	Breakfast invitatoin	Breakfast meeting	08/02/2018	£ -	Not known	Breakfast accepted	Fieldfisher	Mathew Lohn	Legal Consultancy	HFEA	P Thompson
Receipt	Invitation to Silk Party	Informing Clients of a change (to QC)	22/03/2018	£ -	Not known	Invitation accpeted	Blackstone Chambers	Catherin Callaghan	Legal Consultancy	HFEA	C Drennan

Counter Fraud Strategy

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	AGC		
Agenda item	16		
Paper number	HFEA (08/10/2019) 697 MA		
Meeting date	8 October 2019		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	Attached is the latest Counter Fraud Strategy setting out what the HFEA will need to do over the period 2019 to 2022. The Committee are asked to note the Strategy.		
Resource implications			
Implementation date	2019/20 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Counter-Fraud Strategy

Purpose of the Counter Fraud Strategy

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

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

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

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

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

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

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

Scope – What is covered by this Strategy

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

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

Basis – What has informed this Strategy

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

11. This standard sets out key principles:

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

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

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

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

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

Key risks and challenges

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

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

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

Objectives – Where the HFEA needs to be

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

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

Implementation

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

Accountability

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

21. Additionally, all other Directors and Heads of Directorates are responsible for ensuring that the Strategy is applied within their areas of accountability and for working with the Head of Finance in its implementation. All employees and

Authority Members have a responsibility to work in line with this strategy and support its effective implementation. Details of responsibilities are set out in the Counter-Fraud Policy.

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

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

Measures of success

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

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

Reporting and review

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

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

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

28. The Audit and Governance Committee will ensure the continuous review and amendment to this Strategy and the Action Plan contained within it, to ensure that

it remains compliant with good practice national public sector standards, primarily Cabinet Office Functional Standards: Counter-fraud.

Annex A: Strategic Action plan 2019-21

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

Inform and Involve					
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**
Risk Assessment	Identify and assess HFEA's fraud risk exposure affecting principle activities in order to fully understand changing patterns in fraud and corruption threats and potential harmful consequences to the authority	Risk Assessment	Complete August 2019 then annually	Controls implemented for fraud risks identified	Head of Finance
Awareness	Raise awareness of fraud and corruption by running awareness campaigns	Culture	Ongoing throughout the duration of the strategy	Improved staff awareness	Head of Finance
Training	Actively seek to increase the HFEA's resilience to fraud and corruption through fraud awareness by ensuring that all existing and new employees in all directorates undertake a fraud and corruption e-learning course	Culture	July annually	All staff have undertaken fraud awareness training via CSL	Head of Finance/Head of HR

Prevent and Deter					
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**
Policies	Refresh and promote the HFEA's suite of anti-fraud related policies and procedures to ensure that they continue to be relevant to current guidance.	Leadership, Management and Strategy	Annually, each April	Updated policies.	Head of Finance
Internal Audit	Use of Internal Audit review to identify further weaknesses	Prevent	TBC	Assurance to AGC	Director of Finance and Resources
Intelligence	Use of information and intelligence from external sources to identify anomalies that may indicate fraud	Prevent	TBC	Increased awareness; additional controls implemented	Head of Finance

Investigate and sanction					
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**
Reporting	Produce fraud investigation outcome reports for management which highlight the action taken to investigate the fraud risks, the outcome of investigations e.g. sanction and recommendations to minimise future risk of fraud	Leadership, Management and Strategy	November, then quarterly as standing item on AGC agenda	Management feel assured and sighted on any actual fraud and resulting investigations	Director of Finance and Resources
Recording	System for recording of and progress of cases of fraud to be utilised where practicable	Leadership, Management and Strategy	On-going, HFEA has access to DHSC AFU	Database of intelligence that feeds into DHSC AFU's benchmarking data	Director of Finance and Resources

Review and held to account					
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**
Embedding the standard (GovS 013)	Maintaining staff awareness through consistent sharing of information.	Culture	On-going	100% of staff complete fraud training	Head of Finance
Sharing	Reporting quarterly to Cabinet Office' Consolidated Data Requests	Leadership, Management and Strategy	September 2019 and quarterly	Basic to maturing standard met	Director of Finance and Resources

Counter Fraud Action Plan Template

Name of Department:	Department of Health and Social Care
Name of ALB:	Human Fertilisation and Embryology Authority
Senior Responsble Owner	Director of Finance and Resources
Completed by:	Head of Finance
Approved by:	

Action Plan June 2019

Ref	Action	Description	Core Discipline	Owner(s)	Date Raised	Due Date	Metric	Outcome	Status	Comments
1	Assign Roles	Assign senior lead for counter fraud activity	Leadership, Management and Strategy	Head of Finance	04/06/2019	01/07/2019		Director of Finance and Resources confirmed	Green	AGC meeting on 18/06/2019 approved
2	Assign Roles	Assign Fraud Champion	Leadership, Management and Strategy	Head of Finance	04/06/2019	01/07/2019		Fraud Champion has been assigned	Green	AGC meeting on 18/06/2019 approved
3	Strategy	Fraud Strategy developed	Leadership, Management and Strategy	Director of Finance and Resources	01/07/2019	15/08/2019	Description of how counter-fraud arrangements will be developed and implemented over 3 years	Strategy approved	Green	Shared with AGC via email due to holiday period.
4	Assessment	Conduct risk assessment across functional areas of the organisation	Prevention/Deterrence	Head of Finance	12/06/2019	16/07/2019 Conduct every 6 months	Risk items have mitigations against them. Actions have owners	Mitigations reviewed and updated	Green	
5	Awareness	Initially ensure staff have undertaken the Anti-fraud training on Civil Service Learning	Culture/Inform and Involve	Head of Finance	04/06/2019	31/07/2019 Conduct annually in	Report extract from CSL	All staff have initial awareness of fraud	Green	
6	Awareness	Provide Counter-fraud workshop/seminar conducted by external supplier	Culture/Inform and Involve	Head of Finance	04/06/2019	By Dec 2019 Conduct at least annually	Number of staff attended	Raising further awareness	Amber	Reached out to RBS to provide 1hr 25min seminar at the staff away-day
7	Training	Review induction processes to ensure fraud awareness is a mandatory element	Culture/Inform and Involve	Head of Finance and Head of HR	01/07/2017	31/03/2020	%ge of new staff who have received fraud awareness training	Staff aware and know where to find information	Amber	Dependent on materials gathered and new staff employed
8	Policies	Review/refresh associated policies and procedures to ensure up to date	Prevention/Deterrence/Review	Head of Finance	04/06/2019	31/07/2019 Annually September	Number of staff who have submitted Declaration of Interest, Gifts and Hospitality	More than 85% of staff submit forms	Amber	HR are yet to confirm number of staff. Deadline is 30/08/2019.
9	Audit	Scope internal audit reviews to identify any gaps in counter-fraud arrangements	Prevention/Deterrence	Director of Finance and Resources	15/08/2019	TBC	No more than X no.of recommendations are 'high'	This is yet to commence	Amber	A discussion is required between GIAA and SMT Lead
10	Data	Reporting quarterly to Cabinet Office as part of the Fraud Landscape Review	Leadership, Management and Strategy	Director of Finance and Resources	04/06/2019	02/09/2019	Number of short-falls or gaps	Assessed as 'basic' per CO	Amber	Our first submission to CO.
11	Intelligence	Use of internal/external sources to help identify the different type of fraud	Prevention	Head of Finance	04/06/2019	On-going	Number of short-falls or gaps	A database of different types of fraud that can be shared with staff	Amber	Network with other ALBs and Fraud specialists
12										
13										
14										
15										