Audit and Governance Committee meeting - agenda

9 October 2018

Derwent Room

HFEA Offices,10 Spring Gardens, London SW1A 2BU

Agenda item			Time
1.	Welcome, apologies and declaration of interests		10:00am
2.	Minutes of 12 June 2018 **[AGC (09/10/2018) 616]**	For Decision	10.05am
3.	Matters Arising **[AGC (09/10/2018) 617 MA]**	For Information	10.10am
4.	Internal Audit a) Progress Report **[AGC (09/10/2018) 618 DH]**	For Information	10.15am
5.	Implementation of Recommendations **[AGC (09/10/2018) 619 MA]**	For information	10.25am
6.	External Audit – Audit Planning Report **[AGC (09/10/2018) 620 NAO]**	Verbal Update	10.35am
7.	General Data Protection Regulation Update **[AGC (09/10/2018) 621 RS]**	Verbal Update	11.45am
8.	Digital Programme Update **[AGC (09/10/2018) 622 DH]**	For Information	10.55am
9.	Resilience, Business Continuity Management Cyber Security **[AGC (09/10/2018) 623 DH]**	For Information	11.40am
10.	Estates Update **[AGC (09/10/2018) 624 RS]**	Verbal Update	12.00pm
11.	Risk Policy **[AGC (09/10/2018) 625 HC]**	For Information	12.05pm
12.	Strategic Risk Register **[AGC (09/10/2018) 626 HC]**	For Information/Comment	12.10pm

13.	Brexit **[AGC (09/10/2018) 627 PT]**	For Information	12.20pm
14.	Legal Risks **[AGC (09/10/2018) 628 RS]**	Verbal Update	12.40pm
15.	AGC Forward Plan **[AGC (09/10/2018) 629 MA]**	For Decision	12.45pm
16.	Whistle Blowing and Fraud **[AGC (09/10/2018) 630 RS]**	Verbal Update	12.50pm
17.	Contracts and Procurement **[AGC (09/10/2018) 631 MA]**	Verbal Update	12.55pm
18.	Any other business		1.00pm
19.	Close (Refreshments & Lunch provided)		1.00pm
20.	Session for members and auditors only		1.00pm
21.	Next Meeting 10am Tuesday, 4 December 2018, HFEA Offices, London		

1.30pm – 2.30pm –Training session for Members - To be conducted by NAO

Audit and Governance

Committee meeting minutes

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value

Details:	
Meeting	Audit and Governance Committee
Agenda item	2
Paper number	AGC (09/10/2018) 616
Meeting date	9 October 2018
Author	Bernice Ash, Committee Secretary
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 meeting held on 12 June 2018

Church House Westminster, Dean's Yard, Westminster, SW1P 3NZ

Members present	Anita Bharucha (Chair) Margaret Gilmore Mark McLaughlin Geoffrey Podger
Apologies	
External advisers	Jeremy Nolan – Head of Internal Audit External Audit - National Audit Office (NAO): George Smiles Sarah Edwards
Observers	Kim Hayes, Department of Health
Staff in attendance	Peter Thompson, Chief Executive Morounke Akingbola, Head of Finance Richard Sydee, Director of Finance and Resources Nick Jones, Director of Compliance and Information Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager Clare Ettinghausen, Director of Strategy and Corporate Affairs Dan Howard, Chief Information Officer Catherine Burwood, Senior Governance Manager Yvonne Akinmodun, Head of Human Resources Bernice Ash, Committee Secretary

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting.

1.2 There were no apologies for the meeting.

1.3 There were no declarations of interest.

2. Minutes of the meeting held on 6 March 2018

2.1 Subject to the amendment of point 7.4 to state that the 'instructions were currently being drawn up for both a deal or no deal scenario for exiting the European Union', the minutes of the meeting held on 6 March 2018 were agreed as a true record and approved for signature by the Deputy Chair.

3. Matters arising

3.1 The Committee noted the progress on actions from previous meetings. Some items were ongoing and others were dependent on availability or were planned for the future.

3.2 15.2 and 12.5: The Director of Finance and Resources reported that legal advice had been taken regarding the alleged fraud, in connection with a contract provider. A fee of £20K had been agreed with the contract provider in full and final settlement of the contract dispute. The retail

value of goods associated with the fraud amounted to around £90K. The DHSC Anti-Fraud unit is still progressing its case for criminal prosecution. However, even if the prosecution is successful, the Authority is unlikely to recover any costs. The Committee noted that a legal pursuit of the individual concerned would have high cost implications.

3.3 6.6, 12.8 and 3.9: The Director of Finance and Resources informed the Committee that a training session would be scheduled after the 9 October 2018 meeting. The content of this training would be discussed with Committee members.

3.4 4.18 and 11.5: The Committee noted that estates and the bi-annual HR report had been added to the Forward Plan; these could be removed from the matters arising log.

3.5 3.7 and 3.8: The Committee agreed that cyber security training should be added to the Forward Plan and could be removed from the matters arising log. The Head of Planning and Governance notified the Committee that verbal checks had been conducted, with all but one Authority member, and that the required cyber training had been completed. Progress from the outstanding individual will be checked and reported at the next meeting.

3.6 5.15 and 5.16: The Director of Finance and Resources confirmed these items, concerning the General Data Protection Regulations (GDPR), had been addressed. Policies and the website had been updated; the internal deadline had been met and outstanding work remains on track. The Committee was informed that the document management aspect of GDPR work remains outstanding. A new document management system is being sought and this will involve migration of data. A verbal update on Q3 commitment work would be provided at the next Committee meeting. The Committee expressed some concern regarding the website process for accepting cookies, expressing the view this should be reduced and simplified; it was agreed this would be rectified.

3.7 5.17 and 5.19: The Head of Internal Audit stated that these items have been addressed; it was agreed these points could be removed from the matters arising log.

3.8 8.15: The Director of Finance and Resources reported that the Authority expects to receive a response from the DHSC in late June, with regards to the capital requested in relation to the digital programme.

3.9 10.5: The strategic risk register had been updated with regards to information concerning mitochondrial applications and the financial risk; this item can be removed from the matters arising log.

Actions

3.10 The Director of Finance and Resources to discuss the content of training, to be scheduled for 9 October 2018, with Committee members.

3.11 The Head of Planning and Governance to check that the required information security training had been undertaken by all members and provide an update at the next Committee meeting.

3.12 The Director of Finance and Resources to provide a verbal update on the progression on Q3 GDPR commitment work at the October Committee meeting. This item to be added to the forward plan for regular updates to the Committee.

3.13 The Chief Information Officer to ensure that the current process for accepting website cookies is simplified.

4. Internal Audit

a) Annual Assurance Statement 2017-18

4.1 The Head of Internal Audit reported on the annual assurance statement for 2017/18, stating that the overall rating for the Authority is 'moderate', meaning there is an overall good standard of assurance, although some improvements are required.

4.2 The Chair particularly noted that the report rating for the financial controls audit had been marked as 'substantial'.

b) 2018/19 Plan

4.3 The Head of Internal Audit confirmed that risk management had been removed from the 2018/19 plan and replaced with anti-fraud controls, as previously agreed by the Committee.

4.4 The Committee noted that the 2018/19 plan does not incorporate two high risk areas, legal and capability. It had been agreed that the inclusion of legal would not make best use of the audits. Capability would be looked at in the following year as this is not currently deemed to be a high priority for audit. The Chair acknowledged that legal continued to be a high residual risk and the capability risk would diminish over time, but not disappear completely.

4.5 The Committee acknowledged that the 2018/19 audit plan consisted of payroll and expenses, cyber security, business continuity, the GDPR and ant-fraud controls.

4.6 The Committee noted there are some broader value for money issues to think about, such as the use of the current ticket and accommodation provider, when considering expenses.

4.7 The Committee approved the 2018/19 internal audit plan.

5. Implementation of Recommendations

5.1 The Head of Finance reported that audit recommendations concerning clinical governance oversight, policy review and staffing/capability remain outstanding.

5.2 The Director of Compliance and Information stated that the clinical governance oversight audit should be completed in the Summer 2018 as an appointment had been made to fill the Senior Inspection (Information Quality) post. Inspection training on the Code of Practice was due over the summer and discussions on clinic leadership and emotional support for patients undergoing treatment, would be incorporated. The Authority desires is to be ambitious in terms of information management. The Chair expressed the need to deal with this issue as swiftly as possible.

5.3 The Committee noted that the policy review audit recommendation was on track, due to be reviewed and ratified by the Corporate Management Group (CMG) on 20 June 2018.

5.4 In regard to the staff training audit, the Chief Executive informed the Committee that a new HR system was due to be launched on 1 June 2018, but would now go live on 1 July 2018. This would greatly assist with the monitoring and recording of mandatory and other training, providing a significant improvement on the capabilities of the current HR system. The slight delay would ensure the system is accurately understood, before implementation, and then consistently monitored.

5.5 The Chief Executive reported that the Authority is improving its HR systems. Staff turnover is becoming more manageable and recruitment and induction processes are becoming swifter. Despite the improvement in staff turnover, the pay issue remains problematic.

6. Annual Report and Accounts

6.1 The Director of Finance and Resources presented the draft annual report and accounts for 2017/18. The Committee agreed that, any further comments on these, following the meeting, should be sent directly to the Director of Finance and Resources.

6.2 The Committee felt the Chief Executive's Foreward was well constructed, setting out timelines, successful challenges, referring to research and distinctly recognising the Authority is a regulatory body. This piece formed a good blueprint for speeches.

6.3 The Director of Finance and Resources reported, with regards to performance, the Authority had met most key performance indicators for 2017/18. The corporate governance report sets out the general processes and a good level of assurance is provided. The Committee raised one issue of concern regarding the wording 'brings unique challenges,' in connection with the shared finance resources with the Human Tissue Authority (HTA) (page 21 of the annual report and accounts 2017/18). It was agreed the tone of this section should be reviewed, making reference to the opportunities this arrangement creates as well.

6.4 The Committee acknowledged that the governance statement does not make reference to the GDPR, Brexit or capital costs. It was agreed, that some reference to the GDPR should be made.

6.5 The Chief Executive reported that, due to the size of the Authority, there was no requirement for the report and accounts to report on the Gender pay gap. However, it had been recognised that more analysis on this area needs undertaking and HR issues need to be bought to the Committee more regularly. Although there are particular reasons, the HFEA's Gender pay gap is material and will be considered by the Remuneration Committee.

6.6 The Director of Finance and Resources noted there had been significant staff costs in 2017/18, related to the Information for Quality Programme and additional exit costs. The increase in income, from 2016/17 was identified. Reference was also made to the costs for provisions.

6.7 The Chief Executive referred to workforce issues. The change in IT systems will result in a smaller in-house team. There had also been a large reduction in the use of agency staff.

6.8 The Committee acknowledged that the level of surplus cash is not reducing. The Director of Finance and Resources recognised that the Authority needs to question how the ongoing increase in cash can be controlled. The DHSC stated that the issue of cash reserves is a constant point of discussion and surplus monies can be used for other business, if deemed appropriate. The Committee questioned why the cash could not be utilised for legal contingency.

6.9 With regards to the increasing cash, the Chief Executive reported that from discussions, it was clear that the sector did not want treatment fees to keep altering as this causes disruption and implementation costs for stakeholders. The Authority does need to develop a plan to reduce the balance in the medium term. There is a requirement to ensure that patients and the wider public understand the position regarding fees and the increasing cash balance of the Authority and this should be included in the annual report.

6.10 The Committee thanked the Head of Finance and the Director of Finance and Resources on a good, easy to read and well-presented set of accounts.

6.11 Subject to the suggested changes, and receipt of the final Audit Completion Report from the NAO, the Committee recommended that the Accounting Officer, the Chief Executive, sign the annual report and accounts.

Actions

6.12 Committee members to directly contact the Director of Finance and Resources with any further comments on the annual report and accounts for 2017/18.

6.13 The governance statement to be reviewed so to include reference to the GDPR.

7. External Audit – Audit Completion Report

7.1 The NAO spoke to the audit completion report, informing the Committee that the draft version circulated had now been updated in some areas.

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 are no adjusted misstatements. One unadjusted misstatement had been identified in relation to VAT, but this would not result in any future issues.

7.3 The Committee noted the NAO's recommendation that audits should be performed cyclically. The Director of Compliance and Information stated that, audit checks of treatments are currently conducted at clinics considered to hold a riskier status. It was acknowledged that more random checks need to be conducted.

7.4 The NAO had identified there is an outstanding invoice for £12K and this is awaiting a credit note.

7.5 The Committee was informed that the draft letter of representation required some further alterations and would then be sent to the Chief Executive. There are no major changes to the accounts.

7.6 The Committee requested to be informed should any changes occur, which impact on the annual report and accounts.

Action

7.7 The Committee to be informed should any changes occur, which impact on the annual report and accounts.

8. HR, People, Planning and Processes

a) HR Strategy

8.1 The Chair welcomed Yvonne Akinmodun, Head of Human Resources to the meeting.

8.2 The Chief Executive and Head of Human Resources gave a presentation to the Committee concerning the HR Strategy.

8.3 The Chief Executive provided some context, informing the Committee that staff have been under pressure for some time owing to a variety of factors, including the wider public sector efficiency programme and the HFEA's organisational change programme.

8.4 The Committee was informed that a staff survey, based on the Civil Service People Survey (CSPS), was undertaken towards the end of 2017. There was a response rate of 71%, compared to 94% in 2016. The survey asked questions across a range of themes and the headline indicators were provided.

8.5 Regarding discrimination, bullying or harassment, two instances were reported. However, it was noted that this percentage was lower than the average number reported in the CSPS survey. The Committee further noted that of the 10 headline indicators, 5 were lower than in 2016 and 5 were higher. The rating for learning and development, alongside pay and benefits, remained low. Leadership and managing change had dropped significantly and there had been a decline in employee engagement, although it still had a good score overall.

8.6 The Head of Human Resources informed the Committee of actions taken as a result of the survey. The key findings were presented to CMG in November 2017, then to all staff in January 2018. Discussions led to the development of the new People Strategy and a clear set of actions to address main themes were identified.

8.7 The People Strategy was launched in February 2018 and is focused on eight elements. On reward and recognition, the survey showed that staff wanted greater recognition, both financial and non-financial. A recognition group was created to review current benefits and make some recommendations to the Senior Management Team (SMT). This has resulted in new policies and processes, which include the ability to buy and sell annual leave and greater flexibility around working.

8.8 Learning and development was another key area of concern as staff felt the range of training available was limited and senior managers were unable to exercise discretion over training provision within their teams. In response to this, some training budgets have been devolved to Heads and an online learning and development calendar has been developed.

8.9 The Head of Human Resources reported that communication was another issue. Some staff felt there was a disconnect with the top of the organisation, principally associated to the ways of working, including the introduction of PRISM. Monthly Q&A sessions with SMT have been introduced and plans are in place for a new intranet which would also help with communication.

8.10 The culture of the organisation has not been discussed formally for some time and there has been higher than average staff turnover in recent years. There is now the opportunity to review this area which should help with staff engagement and improve morale. The Committee was informed that a small focus group has been set up and will review the culture and identify ways to increase employee engagement.

8.11 The Chief Executive stated the survey results reflect the recent changes, noting however, the positive results in connection with team scores, which is a major strength.

8.12 The Committee noted that, being so small, the Authority is at an advantage in relation to its ability to communicate, a fact that could be further exploited. The development of a new intranet was positive and it was suggested this could be the ideal platform for staff questions.

8.13 The issue of pay cannot be altered without changes to the overall approach to public sector pay and the organisation continues to be vulnerable to staff moves. The Committee identified that there might be some scope for fewer staff, in higher paying posts. The Chief Executive stated he was still awaiting receipt of a letter from the DHSC in relation to pay, and that there might be some element of flexibility. The Remuneration Committee was due to meet in the next few weeks.

8.14 The Committee questioned whether staff are still proud of the work they do; the Chief Executive stated that he had no sense that this had changed.

8.15 The Committee suggested some ideas, including an Authority member attending staff meetings, trying to ensure training occurs outside the office and isn't always conducted online, also stating the need for advice to staff on career progression. In relation to career progression, the Head of Human Resources reported that there is a mechanism for this, but it's not overtly stated. It was noted that secondment opportunities are sometimes available. The Chief Executive stated that it wasn't expected that most staff would spend their career at the organisation, but would gain valuable experience over a number of years and move on to other organisations.

8.16 The Committee made reference to the planned office move, due to occur in 2020. If moving into a hub, the Authority needs to ensure it is placed with other similar organisations, requiring comparable administration and inspection skills.

b) Review of Organisation Change Implementation

8.17 The Chief Executive provided a presentation on organisation change, reminding the Committee of the drivers for this process, the Strategy 2017-2020 and opportunities presented by new IT systems. The timetable for the proposed, revised and implementation of organisational change were noted.

8.18 The new Planning and Governance and Intelligence teams had been established. The IT and Information teams had been merged, working under a new Chief Information Officer. Recruitment to the new Senior Inspector role had been postponed until completion of the digital projects.

8.19 The Chief Executive stated that it had been the correct decision to establish an Intelligence team and this was already making a demonstrable difference. More resource might be required to meet the Authority's ambition in this area. The Planning and Governance team was now at full strength and the business planning investment is beginning to show returns. However, the licensing and committee support element of the team are trying to cope with increasing licensing volumes and there is evidence that PGD applications will continue to rise. In light of this, a licensing review was conducted, by external advisers, resulting in a number of suggestions to improve support and streamline administrative processes. Temporary additional support for the team is currently being sought.

8.20 Recruitment to the Information team had been slow, but all posts have now been filled. Difficulties with recruitment had been linked to market pay rates for IT Professionals; it had been difficult to locate the right IT skills for the price the Authority can afford. It is clearly evident that there has been an underinvestment in the IT infrastructure over several years. Due to the delay in the completion of the IT programme, it is difficult to assess the success of the new Information team and more infrastructure is required.

8.21 The Committee stated that, overall, the organisational change had been well done. Some promotions had occurred and talented staff retained. There was recognition of Authority pressures to meet the Key Performance Indicators (KPIs).

8.22 The Committee questioned whether teams have been asked about what had been done well and what could have been improved during the organisational change. The Chief Executive reported this was an exercise yet to be conducted as the IT work remains to be completed.

c) Estates Update

8.23 The Director of Finance and Resources reminded the Committee that Spring Gardens needs to be vacated by Spring 2020.

8.24 The Committee noted that British Council would be relocating to Stratford. Options were being explored for the Authority to move into premises with other ALBs, including the HTA. The Committee supported further work in this area. The Director of Finance and Resources clarified that, at this stage, it is still unknown how much flexibility the Authority will have for its relocation.

8.25 The Committee identified that any decision on the move would have an impact on staff, particularly in terms of commuting. It was suggested that the Authority also needs to consider where other organisations are located, noting where there are empty spaces.

8.26 The Chief Executive confirmed the issue would be discussed with staff once there is more concrete information on the relocation. At the current time, the matter remains uncertain. A further update would be provided in due course.

9. Digital Programme Update

9.1 The Chief Information Officer spoke to the paper and presentation, providing a digital programme update.

9.2 The Committee was provided with a summary of progress, noting the go-live approach was approved at the 6 March meeting. Substantial progress had been made in all areas of the programme and a preview version of PRISM is due to be launched later in June 2018. The approval on the requested additional capital remains outstanding but it is hoped this will be granted shortly.

9.3 The three identified risks and issues concerning data migration, additional development work and loss of key staff were noted. The Register Information Officer would leave her post at the end of August 2018, which could result in the transition potentially being more difficult. However, the impact is reduced due to this occurring only a short time before the planned go-live date. Recruitment for a replacement has started. Reference was made to the remaining programme milestones and the Chief Information Officer confirmed work is going well, with consistent progress.

9.4 The Chief Information Officer stated that the Committee would be provided with regular monthly updates which would highlight any variances or increased risk. The data migration sign off would only occur when there is confidence that the validation, verification and load processes are acceptable. It was suggested that joint approval from the Committee and key staff is obtained for this sign off which would also include full assurance on Register's move from the physical server to the Microsoft Azure 'cloud'.

9.5 In the scenario that any further significant issues occur between the current time and launch date, they would be addressed through a meeting with the Committee Chair and key staff.

9.6 The Committee questioned what risks there might be, should the sign off not occur on time, and what contingencies are in place. The Chief Information Officer reported that the level of risk is reducing as time moves on, but there is some financial contingency should it be needed to work

on any arising issues. The Director of Compliance and Information stated that go-live will not happen if is thought the Register could be placed at risk.

9.7 The Chair stated she was content with the approach being taken, confirming risks cannot be taken with the data migration and Register launch.

9.8 It was noted that the programme milestone set for September 2018, regarding suppliers switching over their clinics to the new systems, was not within the Authority's control. The Chief Executive stated that if there was a lack of a progress of a supplier being able to conduct this exercise, clinics would be expected to use the HFEA system.

9.9 The Chief Information Officer confirmed that, should an issue arise after the migration of data has occurred, it would be possible to roll-back and restore the previous system.

Actions

9.10 The Committee to receive monthly updates highlighting any variances and increased risk.

9.11 There would be joint approval between the Committee and key staff for data migration sign off, with full assurance being provided concerning the move of the Register to the Microsoft Azure 'cloud'.

9.12 Any further significant issues would be addressed through a meeting with the Committee Chair and key staff.

10. Resilience, Business Continuity Management and Cyber Security

10.1 The Chief Information Officer provided an update with regards to resilience, business continuity and cyber security speaking to the paper and providing a presentation.

10.2 The Committee was informed of the three stages of penetration testing, noting that the Phase 1 testing, relating to the PRISM infrastructure had been completed in May 2018, during which no significant risks were identified. Phase 2 testing was scheduled for late June 2018 with Phase 3 testing being conducted ahead of go-live in September 2018.

10.3 A server incident had occurred on 18 April 2018 which initially affected several core systems including TRIM, Outlook, Skype, desk phones, Pulse, EDI and Epicentre (the licensing system). This was due to a hardware failure at Spring Gardens. Most systems were re-established rapidly, with the exception of Epicentre, the QA application and the system clinics use to submit data. Recovery work was started and the issue was resolved with EDI being functional on 8 May 2018 and Epicentre on 14 May 2018. Regular communication updates were circulated to staff and clinics and were well received.

10.4 The Committee were notified that in March 2018, CMG approved an approach for improving the resilience of the infrastructure through a 6 month contract for support and improvement. It was noted that PRISM, the HR system and Intranet are housed within in the Microsoft Azure cloud and Skype, telephones, Sage/WAP, alongside the new document management system will be moved in September 2018. The move of Epicentre will be reviewed in 2019.

10.5 The Director of Compliance and Information reiterated that the server incident was significant, but dealt with well, with good communications. The shift to the cloud model should prevent this type of incident reoccurring.

10.6 Members of the Committee reported on their attendance at a DHSC and National Partners Audit Chairs Conference in May 2018. The event included discussion on cyber security and the GDPR, also providing good networking opportunities.

11. Strategic Risk Register

11.1 The Risk and Business Planning Manager presented the strategic risk register.

11.2 The Committee was informed that the strategic risk register was presented to the May Authority meeting, and due to the organisation entering a period of greater stability, following the organisational change, the capability risk was reduced to 'at tolerance'. An additional capability risk was also added at this meeting regarding Authority appointments.

11.3 The capital cover risk had been explored and was now expressed more clearly within the delivery risk, as agreed at the 6 March 2018 Committee meeting.

11.4 The Risk and Business Planning Manager reported that only one risk is above tolerance, CS1, Cyber Security. This risk had been reassessed, with regards to the impact of any cyber-attack, as this was deemed to have been underestimated. Although not distinctly recognised in the risk register, the risk of staff causing a cyber-attack, either accidently or deliberately, had been identified.

11.5 Legal challenges maintained a high residual risk. The Chief Executive acknowledged that although this area had now calmed down, it will always be an unknown factor, due the nature of the organisation's business. The Committee noted that planning continued for the Choose a Fertility Clinic (CaFC) appeal hearing, scheduled for October 2018. The Chief Executive stated there is now more confidence in dealing with legal challenges and more certainty that any arising would not be due to organisational failures. It was identified that some new types of licensing, particularly mitochondrial donation, were taking the Authority into new territory and could potentially give rise to a legal challenge.

11.6 The Committee questioned whether the legal challenge risk is being formulated correctly and if there is a different way of reflecting this. It was agreed that the executive would discuss the formulation of the legal challenge risk.

11.7 The Committee asked whether any issues were occurring at a corporate level, such as the impact of Brexit. The Chief Executive confirmed Brexit was not considered to be a strategic risk for the HFEA. The DHSC reported that the Authority would be kept informed of any developments. Plans for a no deal Brexit scenario are currently being drawn up and will be shared with the Authority in due course; DHSC agreed that Brexit should not have a dramatic effect on the organisation.

11.8 The Head of Planning and Governance confirmed that the strategic risk register is regularly reviewed by SMT, with input from Heads. The Risk and Business Planning Manager stated that monthly 'deep dive' exercises into particular risks also occur, and this contributes to refreshing risks and risk horizon scanning.

11.9 The Chief Executive noted that a number of research developments were emerging that may have implications for the Authority. He informed the Committee that a paper on new research involving embryo like structures would be presented at the forthcoming Scientific and Clinical Advances Advisory Committee meeting (SCAAC). Depending on the views received this issue would be presented to Authority before the end of 2018.

11.10 The Director of Strategy and Corporate Affairs stated that the consequences of organisational change had its own risks, but can also place the Authority in a stronger position.

Action

11.11 The executive to discuss the formulation of the legal challenge risk.

12. AGC Forward Plan

12.1 The Chair noted that the Forward Plan reflects the items discussed at previous meetings, looking ahead at the schedule for the remainder of 2018.

12.2 The theme for the 9 October 2018 meeting would be based on strategy and corporate affairs. The Committee requested this item should focus on changes in capability as a result of the organisational change, key issues and challenges for the coming year, resource challenges and engagement with other relevant working groups. The Director of Strategy and Corporate Affairs stated that data from PQs and press enquiries might also be of interest to the Committee.

12.3 The Committee noted that an update on GDPR and cash reserves would also be items for the 9 October 2018 agenda and this was added to the forward plan.

Action

12.4 To ensure the strategic and corporate affairs theme, for presentation at the 9 October 2018 meeting, focuses on changes in capability as a result of the organisational change, key issues and challenges for the coming year, resource challenges and engagement with other relevant working groups.

13. Whistle Blowing and Fraud

13.1 The Director of Finance and Resources informed the Committee that, with the exception of the ongoing DHSC fraud investigation, there were no other incidents to report.

14.Contracts and Procurement

14.1 The Head of Finance reported there had been one new contract at the value of just under £90K. The Committee was also notified that the contract for Travel, currently awarded to Redfern via the Crown Commercial Service framework, is due for renewal.

15. Any Other Business

15.1 Members and auditors retired for their confidential session.

15.2 The next meeting will be held on Tuesday, 9 October 2018 at 10am.

16. Chair's signature

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

Signature

Name

Anita Bharucha

Date

9 October 2018

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (09/10/2018) 617 MA]**
Meeting Date:	9 October 2018
Agenda Item:	**3**
Author:	Morounke Akingbola, Head of Finance
For information or decision?	Information
Recommendation to the Committee:	To note and comment on the updates shown for each item.
Evaluation	To be updated and reviewed at each AGC.

Numerically:

- 12 items added from June 2018 meeting, 6 ongoing
- 7 items carried over from earlier meetings, 3 ongoing

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from Audit and Governance Committee – actions from 13 June 2017 meeting			
15.2 The Director of Finance and Resources to ensure the Committee remains updated with regards to the outcome of the investigation	Director of Finance and Resources		**Update -** This relates to item 12.5 from 6 March meeting but should be removed as the investigation is over and we came to agreement with the Contractor.
Matters Arising from Audit and Governance Committee – actions from 3 October 2017 meeting			
6.6 The Director of Finance and Resources to create a training plan for the Committee, ensuring sessions are scheduled to occur on the same dates as planned meetings.	Director of Finance and Resources		**Ongoing –** Training sessions will always succeed the meeting. Members will be asked to suggest areas they wish to gain a better understanding which can be run as a training session or presentation e.g. 'Managing risk of fraud' or 'Governance of risk! Three lines of defence'
Matters Arising from Audit and Governance Committee – actions from 5 December 2017 meeting			
12.8 The Director of Finance and Resources to arrange training for members to follow the 6 March 2018 meeting.	Director of Finance and Resources		**Update** – this has been superseded (see 6.6)
Matters Arising from Audit and Governance Committee – actions from 6 March 2018 meeting			
3.8 The Head of Planning and Governance to reissue the cyber security training link to Authority members.	Head of Planning and Governance		**Update** – Link was not re-issued as most Members had completed training. Head of Planning and Governance spoke to the remaining 2 members who have now completed it.

3.9 The Director of Finance and Resources to liaise with the NAO regarding training to Committee members, providing an overview of the NAO work programme and their perspective on the challenges facing the NHS.	Director of Finance and Resources		**Update** – 01/08 -email sent to GS confirming session for October, awaiting response. This should be combined with 3.10 (12/6 meeting)
8.15 The Committee to be kept informed of developments regarding capital requested from the DHSC and the response obtained.	Chief Information Officer		**Update** – Meeting held with ALB Finance 18/7, capital cover confirmed and letter received.
12.5 The Director of Finance and Resources to update the Committee on the outcome of the DHSC criminal prosecution and agreed settlement with the contractual provider in due course	Director of Finance and Resources		**Ongoing –** Settlement agreed/made with contractual provider. DHSC may pursue. A further update will be provided at the October 2018 meeting.
Matters Arising from the Audit and Governance Committee – actions from 12 June 2018 meeting			
3.10 The Director of Finance and Resources to discuss the content of training, to be scheduled for 9 October 2018, with Committee members.	Director of Finance and Resources		**Update** – See 3.9 above – This can be removed as duplicate entry.
3.11 The Head of Planning and Governance to check that the required information security training had been undertaken by all members and provide an update at the next Committee meeting.	Head of Planning and Governance		**Update** – See 3.8 above. We have since had new Members who will be asked to compete the training. Further question for AGC is should Members, like staff, conduct training annually and an update brought to AGC?

3.12 The Director of Finance to provide a verbal update on the progression on Q3 GDPR commitment work at the October Committee meeting. This item to be added to the forward plan for regular updates to the Committee	Director of Finance and Resources		**Update** – A verbal update will be given at the meeting and has been added to the Forward Plan
3.13 The Chief Information Officer to ensure that the current process for accepting website cookies is simplified.	Chief Information Officer		**Update** – As of 08 Aug cookie banner updated and simplified
6.12 Committee members to directly contact the Director of Finance and Resources with any further comments on the annual report and accounts for 2017/18.	Committee Members		**Update** – Request to remove as AR&A laid 6 July 2018
6.13 The governance statement to be reviewed so to include reference to the GDPR.	Director of Finance and Resources		**Update** – Request to remove as AR&A laid 6 July 2018
7.7 The Committee to be informed should any changes occur, which impact on the annual report and accounts.	Director of Finance and Resources		**Update** – Request to remove as AR&A laid 6 July 2018
9.10 The Committee to receive monthly updates highlighting any variances and increased risk.	Chief Information Officer		**Update** – Paper distributed to AGC 08 August 2018 by the Director of Compliance and Information.
9.11 There would be joint approval between the Committee and key staff for data migration sign off, with full assurance	Chief Information Officer		**Update** – Refer to the above paper.

being provided concerning the move of the Register to the Microsoft Azure 'cloud'.			
9.12 Any further significant issues would be addressed through a meeting with the Committee Chair and key staff.	Chief Information Officer		**Ongoing**
11.11 The executive to discuss the formulation of the legal challenge risk.	Executive		**Update** – SMT have discussed and re-formulated the legal risk.
12.4 To ensure the strategic and corporate affairs theme, for presentation at the 9 October 2018 meeting, focuses on changes in capability as a result of the organisational change, key issues and challenges for the coming year, resource challenges and engagement with other relevant working groups	Director of Strategy and Corporate Affairs		**Ongoing** – This item has now been deferred and will be presented at the 4 December 2018 meeting.

Audit and Governance Committee

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

Details:	
Meeting	Audit & Governance Committee
Agenda item	4
Paper number	AGC (09/10/2018) 618
Meeting date	9 October 2018
Author	Jeremy Nolan

Output:	
For information	To provide an update to the Audit and Governance Committee on the 2018/19 Internal Audit Plan.
Progress Update	**Progress on 18/19 Audit Plan** **Payroll and Expenses Review –** The final report was issued on the 19th July and was given a Moderate assurance rating. 10 recommendations (2 high, 4 medium and 4 low) were made to improve and strengthen the controls in this area. It is presented at Annex A. **Cyber Security –** This review is at the end of fieldwork, with a draft report due early October. **Business Continuity, GDPR and Anti-Fraud Controls** have yet to be started. **Recommendations Follow Up** – Internal Audit have been working closely with HFEA to resolve all outstanding recommendations from previous audit reviews. Progress has been made and we continue to have regular communications to ensure appropriate action has been taken to implement all recommendations. Management present an update paper on recommendations follow up.
Actions from previous meeting	None
Organisational risk	☐ Low ☐ Medium ☐ High
Annexes	Annex A – Payroll and Expenses Review

Government Internal Audit Agency

HFEA

Payroll and Expenses

Final Internal Audit report

Date of issue:	19th July 2018
Audit reference:	1819-HFEA-001

Contents

Executive summary

Opinion	RAG
Moderate Some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.	**Moderate**

The key objectives of this audit were to provide assurances on the adequacy and effectiveness of payroll and expenses controls in place to ensure the correct payments are made to correct employees at the correct time.

Notable positive findings:

- Expenses Policy clearly outlines the key considerations of ensuring fairness, obtaining best value, appropriate use of public funds and the rates are in accordance with HMRC rules.
- A robust process is in place for adding and removing staff to the payroll system to ensure accurate information is recorded, this includes independent checks in place and a clear segregation of duties. No errors were identified within sample of 10 starters and 10 leavers examined.
- From testing a sample of expenses claims: a full audit trail was evidenced of the initial claim, receipts and line management approval.

Notable areas for improvement are as follows:

- Expenses Policy does not include Health and Safety guidelines regarding long distance / journey times incurred by employees driving as part of their role. Within the sample of 30 expenses claims examined, 3 mileage claims were identified in excess of 300 miles in one day (largest 588 miles)
- Single subsistence claims covering multiple employees are made on a regular basis. Related risks include transparency in reporting and difficulty to identify potential repeat claims.
- 9 out of 30 expense claims tested were not independently reviewed by the Finance Team due to a human error. The

compensatory control is the Budget Monitoring process.

- There is no Standard Operating Procedure for overpayment recovery to ensure a fair and consistent process is followed.
- Temporary promotions are appointed by a fair and transparent process, however HR policy does not clearly outline how or when milestone reviews should take place.
- Exception reports are not used for the identification of fraud and error, however compensatory controls are in place within second line of defence checks.

	High	Medium	Low
Recommendations	2	4	4

Summary of findings

1

Policies and procedures

The Expenses Policy clearly outlines the key considerations of ensuring fairness, obtaining best value, appropriate use of public funds and the rates are in accordance with HMRC rules.

We identified the following areas for improvement with HFEA's current policies and procedures:

- There are no Health and Safety guidelines regarding long distance / journey times for employees driving as a part of their role;
- Nothing detailing the consequences of employees providing false information in expenses claims.
- No clarity on the rules for claiming subsistence for more than one person.
- No Standard Operating Procedure for overpayment recovery.
- No formalised process for reviewing Temporary Promotions at milestones.

2

Payments to starters and leavers.

From the fieldwork we have confirmed that controls are adequately designed and operating effectively for adding and removing staff from the payroll. A key control is the Finance and Accounting Manager performing independent checks of the changes processed, including reviewing source documentation, prior to the changes being submitted to the payroll provider. No errors were identified within the sample of 10 starters and 10 leavers tested.

3

Expenses Claimed

- From testing a sample of expenses claims: a full audit trail was evidenced of the initial claim, receipts and line management approval.
- 9 out of 30 were not independently reviewed by the Finance Team due to human error. The compensatory control is the Budget Monitoring process.
- Single subsistence claims are made for multiple employees on a regular basis. Related risks include transparency in reporting and difficulty to identify potential repeat claims.
- Three mileage claims were identified in excess of 300 miles in one day (largest 588 miles). As noted in point 1:

	policy does not adequately address health and safety risks to employees.
4	**Temporary promotions** A formalised process was followed to recruit and approve the salary increment for the one employee on temporary promotion. Whilst extending the initial six month period was valid, there was no formal review of the temporary promotion and there is a lack of a formalised process to review the status at key milestones.
5	**Fraud and Error controls** Whilst exception reports are not available, we have confirmed that second line / independent checks are in place regarding the processing of payroll, expenses and travel / accommodation expenditure. However, there is evidence to suggest that not all Budget Holders are reviewing the invoice from 'Redfern' to confirm accuracy of billing for travel / accommodation.
6	**Overpayments** The most recent overpayment was 'several years ago' and related to a change in leaver date which was low in value and successfully recovered. However, it is noted that there is a lack of a Standard Operating Procedure for overpayment recovery. Exception reports are not used for the identification of fraud and error, however compensatory controls are in place within second line of defence checks.
7	**External providers of payroll services** HFEA do not receive assurance reports from the third-party payroll provider (FPS) regarding the health of the IT systems or strength of internal controls. It is not known whether FPS are contractually obliged to provide this information.

Detailed findings 1

Inadequate policies and procedures	**Opinion on management of risk:** Moderate **Risk categories:** Inadequate policies and procedures

Findings

Payroll and Benefits Policy:

A Standard Operating Procedure is in place for Finance and HR staff with guidelines on production of the monthly payroll, including a summary of procedures for submitting information to process changes. The procedures include a step by step guide for processing starters and leavers, the evidence required and the checks undertaken. All policies are available to employees on the Records Management system (TRIM). At the time of audit fieldwork, a project was ongoing to upgrade the intranet and when concluded all current policy documents will be uploaded and available.

The Expenses Policy

The policy outlines the key considerations of ensuring fairness, obtaining best value, appropriate use of public funds and the rates are in accordance with HMRC rules. However, the following is noted:

- Whilst it is stipulated that prior approval from managers is essential for use of a personal vehicle, there are no Health and Safety guidelines for employees driving as a part of their role. It should be noted that this finding links to expenses testing where exceptional mileage claims were identified including one claim for 588 miles when undertook six hours of driving in one day. The Health and Safety Executive (HS&E) 'Driving at Work' document is an appropriate point of reference. The key issues are health and safety but also value for money: if public transport is not an option, it may be better value to lease a vehicle for the short term.
- There are no messages to highlight the consequences of employees providing false information in claims.
- There is no clarification on the rules for claiming subsistence for more than one person (this links to findings within the review of expenses claims).

Recovery of overpayment

There is no Standing Operating Procedure regarding action to take in the event staff overpayments are identified (please refer to Detailed Findings 6 for more information).

Temporary Promotions

Whilst there is guidance within HR Policy regarding the fair and transparent appointment of temporary promotions, there is no specific reference to formal review periods as a control to ensure temporary promotions are do not exceed what is required operationally (please refer to Detailed Findings 4 for more information).

Other findings to note:

From discussions with the Head of Finance, a wider project is ongoing to revise employee terms and conditions and revisions to HR related policies would be appropriate after the project is concluded.

Implications and recommendations

Expenses Policy:

- Duty of care / Health and Safety regarding employees driving is inadequately addressed within policy.
- Inadequate deterrent message regarding the potential for expenses fraud.
- Insufficient guidance for employees regarding multiple expenses claims.

Recommendation:

The Expenses Policy will be enhanced to include the following:

- Reference to health and safety of employees for driving for prolonged periods and other options to be considered where high mileage claims are to be incurred (for example, Value for Money and options to hire vehicles)
- Include reference to the consequences of providing false information i.e. breach of the employee Code of conduct
- Provide clear guidance on claiming subsistence for more than one person.

Employee overpayments:

Under existing arrangements, the associated risks are that in the event of overpayment: a formalised / documented process is not in place to follow that governs treatment of overpayments fairly and consistently. In event of legal challenge on an overpayment, HFEA would be in the strongest position to defend its position if a fair process / policy is in place to support decisions made.

Recommendation:

HFEA to introduce a Policy Statement regarding the recovery of overpayments that directly links to overarching Debt Recovery policy.

Temporary promotions

Exceed what is required operationally / excess salary costs. The lack of a formalised process and appropriate sign off is not best practice in terms of transparency, accountability and good governance to ensure decision making is fair and consistent.

(Recommendation recorded within the area relating to Temporary Promotion Testing).

Detailed findings 2

Incorrect payments to starters and leavers.	**Opinion on management of risk:** Substantial **Risk categories:** Incorrect payments

Findings

The following is noted from testing of a sample of ten new starters and ten leavers:

- The data recorded within the HFEA HR system and the instructions to the payroll provider (FPS) to process payroll all agree with the contract of employment.
- All contracts were signed by the employee and HR.
- The correct salaries, start dates and job titles were recorded on a changes spreadsheet and emailed to FPS to process the payroll.
- The correct leaver date was instructed to FPS and used in the final payment.
- All leavers within the sample are not shown on the most recent payroll file (May 2018).

From the fieldwork we have confirmed that controls are adequately designed and operating effectively for adding and removing staff. A key control is the Finance and Accounting Manager performing independent checks of the changes processed, including reviewing source documentation, prior to the changes being submitted to the payroll provider.

Use of electronic signatures on employee declarations

One minor recommendation / observation is made in this area regarding acceptability of electronic signatures when employees sign declarations. There were two instances of leaver forms not signed by the employee and one instance of the manager not signing the form. From discussions with the HR Officer and examination of emails, we are satisfied that there is a sufficient audit trail to link the instruction to the relevant person. However, from discussions with the HR Officer, HFEA are increasingly reliant upon electronic signatures but are unsure what is acceptable. HGIAS consider that, in principal, employees typing their name into declaration boxes (as an electronic signature) should be adequate where an email trail is retained as evidence, however clarification should be sought by the HFEAs Legal Professionals to ensure the correct approach is adopted in the event the wording of declarations should be enhanced.

Implications and recommendations

Declarations on contracts or formal notifications from employees not fully signed / legally binding (if necessary).

Recommendation

HR to seek clarification from HFEA Legal Professionals regarding the acceptability of employee electronic signatures in declarations where emails are present as an audit trail.

Detailed findings 3

Inappropriate expense claims paid	**Opinion on management of risk:** Moderate **Risk categories:** Inappropriate expense claims

Findings

Within audit fieldwork, a sample of 30 paid expenses claims were examined from the 2017/18 period (population:1156 in total, value £20,615.53). We can confirm that a full audit trail was evidenced that clearly showed:

- The values, dates and names of employee submitting claims
- An appropriate line manager approving
- Full receipts / invoices (scanned images uploaded into the system)

We consider the expenses we reviewed to be valid expenditure, but the points below need to be noted:

The Finance Team review of expense claims

From discussions with the Finance and Accounting Manager, the approval hierarchy within the WAP system (where expenses are processed) is configured for the Finance Team to undertake a final validity check of all expenses before recording on the ledger. From the sample tested within audit fieldwork it was noted that validity checks were not performed by finance officers in respect of 9 out of 30 expenses. HFEA have investigated the matter and informed us that a human error has occurred and admin rights / accesses to the system have been revised to mitigate the issue.

Independent, secondary checks of expense claims

From Audit fieldwork we have confirmed that Budget Holders review expenditure on a monthly basis and a part of the process includes undertaking validity checks on expenditure incurred. It is noted however that some Budget Holders are reviewing / checking expenses that they have already approved and in this scenario the Budget Holder's secondary check is not independent. In this scenario: if Finance have not performed a check due to the IT issue, the secondary / independent check is not present. A low risk/impact recommendation has been made on the basis that the compensatory controls is the Quarterly review of accounts (chaired by Finance) where transactions are

scrutinised.

Subsistence claims made for multiple employees

Within the sample of expense claims: five food / subsistence claims were examined that Inspectors had submitted for more than one employee. From discussions with the Head of Finance and the Accounts Officer, multiple claims for food is commonplace for Inspectors both in HFEA and HTA. The associated risks are difficulty in extracting full Management Information of expenses claimed per person and the transparency of published information on expenses. There is also an increased risk of multiple / repeated expenses being claimed and greater difficulty detecting at the review / approval stages. Given the risk to reputational damage where expenses claims are erroneous, there is a strong argument in ensuring clear and transparent reporting of expenses.

High value mileage claims

Within the sample of expense claims: three mileage claims were identified in excess of 300 miles in one day (largest 588 miles). We have highlighted the claims to the Head of Finance to investigate whether prior written approval was obtained and clarify circumstances. A related recommendation is made within Detailed Findings relating to Policies regarding the adequacy of current policies to address risks relating to duty of care / health and safety and value for money considerations.

Implications and recommendations

The Finance Team review of expenses claims.

Not all expenses claims are independently checked in the second line of defence stage due to human error.

Recommendation

The Finance Team to review a random sample of expenses on a monthly basis to gain assurances that expenses have been reviewed by members of their team prior to approval (following the revision to the hierarchy) for a minimum period of 3 months, if no concerns are identified.

Independent, secondary checks of expenses claims.

Line managers approving expenses in the system also undertake reviews of Budget Monitoring reports. In this scenario, the secondary check is not independent.

Recommendation

HFEA Finance Team to investigate the extent to which Budget holders are also approving expenses in the system and consider whether any hierarchy adjustments are required to ensure an independent second line defence is in place

Subsistence claims made for multiple employees

The associated risks are:

- Inability to easily extract full Management Information of expenses claimed per person.
- Published expenses data claims may lack clarity / transparency.
- Greater risk of duplicate subsistence claims being made where employees are claiming for each other.
- Reputational damage where expenses claims are erroneous.

Recommendation

Senior Management to review the protocol that enables employees to claim subsistence for more than one person and make an informed decision based on the audit findings of the future approach. The outcome will inform upon the future Expenses Policy review.

Detailed findings 4

Temporary promotions are not initiated / ceased in accordance with policy	**Opinion on management of risk:** Moderate **Risk categories:** Incorrect payments

Findings

At the time of audit fieldwork there was one HFEA employee on a Temporary Promotion that commenced in October 2014. From discussions with the HR Officer and examination of evidence we are satisfied that a formal formalised process was followed to recruit the post and approve the salary increment. It is noted that the Temporary Promotion contract states the role was for an 'Interim 6 months'.

From discussions with the HR Officer and examination of evidence, the role linked directly to an ongoing project within HFEA. It is clear that HR and Director level employees have discussed the Temporary Promotion extending beyond the initial six month period and HR have been informed that the project is continuing beyond the period anticipated.

It is noted however that there is no formalised process in place to review the position at scheduled milestones, including after the initial six month period elapsed. The lack of a formalised process and appropriate sign off is not best practice in terms of transparency, accountability and good governance to ensure decision making is fair and consistent.

Implications and recommendations

The lack of a formalised process / appropriate sign off is not best practice in terms of transparency, accountability and good governance to ensure decision making is fair and consistent.

Recommendation

Policy and procedures regarding appointment of temporary promotions will be enhanced to include the following stages:

- HR booking milestone reviews of the temporary promotion with the relevant Director.
- HR to obtain a decision from the Director / Senior Management regarding whether the appointment will be cease at a specific date or reviewed at a future date.
- The employee will be notified of the decision.
- In the event a future end date or review date cannot be determined, HR to review with the Director / Senior Manager at proportionate intervals (no more than annually).

Detailed findings 5

Failing to identify error and potential fraud	**Opinion on management of risk:** Moderate **Risk categories:** Incorrect payments / failure to identify and recover overpayments.

Findings

Management Information / Exception Reporting

At the time of audit fieldwork, exception reports were not available for HFEA in respect of: expenses data (WAP System and Sage finance system); payroll data or the travel and accommodation booking data (Redfern System) to identify potential error and fraud. The compensatory controls are second line of defence checks as follows:

- Expenses: Budget monitoring checks performed by Budget Holders and the Quarterly review of accounts instigated by Finance.
- Payroll: changes to the payroll file processed by HR are independently checked by the Finance Team, prior to submission to the payroll provider.
- Travel and Accommodation: Finance employees and Budget Holders undertaking a reconciliation of monthly invoices from Redfern with the Budget Holders. Manual analysis undertaken by Finance to identify potential duplicate bookings.

In the event HFEA's IT systems have capability to produce exception reports, the benefits are as follows (acknowledging there are likely to be additional costs for implementation):

- Identifying outliers / potential errors in terms of value and frequency.
- Quicker identification of potential duplicates and coding errors that are less vulnerable to human error.

Other findings: reconciliation of Redfern invoices

From examination of email evidence at the site visit to HFEA, it is clear that the Finance Team engage with appropriate managers to reconcile the Redfern invoice and review the content to confirm accuracy. However, from examination of email trails: no more than three out of six managers replied to Finance within the period from July 2017 to May 2018. On this basis, it is not clear whether a full reconciliation is taking place.

Implications and recommendations

Management Information / Exception Reporting.

Limiting the potential to identify fraud and error and undertake trend analysis regarding expenses.

Recommendation:

HFEA to undertake a cost benefit analysis of introducing expenses reporting / duplicate reporting tools within the systems.

Reconciliation of Redfern invoices

- Failing to reconcile invoice from Redfern
- Incorrect billing not identified

Recommendation:

Senior Managers issue communications to Budget Holders / Managers to highlight the importance of undertaking the reconciliation of the Redfern Invoice data and to notify the Finance Team when the check is undertaken, even if there are no concerns.

Detailed findings 6

Failure to identify and recover overpayments in a timely manner	**Opinion on management of risk:** Moderate **Risk categories:** Incorrect payments / Failure to identify and recover overpayments

Findings

Overpayments

From discussions with the Head of Finance and the HR Officer, the most recent overpayment identified was 'several years ago' and related to a change in leaver date. The overpayment was low in value and reimbursed via a cheque.

Section 14 of the employee contract states that HFEA has the right to make a deduction from salary at appropriate times subject to compliance with the Employment Rights Act. However, there is no formalised process / Standing Operating Procedure regarding action to take in the event staff overpayments are identified (recommendation made within Detailed Findings 1).

Data accuracy checks.

Under existing arrangements, Management Information reports are not produced from the Payroll System to highlight the changes made within the system. The compensatory control is within the second line of defence checks which includes Finance and HR reviewing the changes within the final payroll report provided by FPS before the final ‘sign off’.

Implications and recommendations

(recorded in Detailed Findings 1).

Detailed findings 7

External providers of payroll services operate ineffectively	**Opinion on management of risk:** Unsatisfactory **Risk categories:** Incorrect payments

Findings

Assurance reports from the third party provider for payroll (FPS)

From discussions with the Head of Finance and the HR Officer, HFEA do not receive assurance reports from FPS regarding the quality and strength of their internal controls and it is not known whether FPS are contractually obliged to provide this information.

Implications and recommendations

HFEA have no assurance regarding the strength of controls or stability of systems used by the third party provider of the payroll

Recommendation

HFEA to examine the contract with FPS to establish whether the supplier is obliged to provide assurance reports, then HFEA to request assurance reports accordingly.

Annex 1: Management action plan

Risk 1.	Inadequate policies and procedures
Opinion on Risk:	Moderate

#	Recommendations:	Priority	Actions Agreed	Target date:	Owner:
1.1	The Expenses Policy will be enhanced to include the following: • Reference to health and safety of employees for driving for prolonged periods and other options to be considered where high mileage claims are to be incurred (for example, Value for Money and options to hire vehicles) • Include reference to the consequences of providing false information i.e. breach of the employee Code of conduct • Provide clear guidance on claiming subsistence for more than one person.	**HIGH**	*Agreed: The Expense policy is to be reviewed in line with changes to flexible working. We will look to make refence to the health and safety of employees however the Vfm and options we feel is already represented. We will include reference to providing false information and guidance on claiming for more than one person*	Q2 2018	Head of Finance
1.2	HFEA to introduce a Policy Statement regarding the recovery of overpayments that directly links to overarching Debt Recovery policy.	**MEDIUM**	*Agreed* *HR to draft policy statement on salary overpayments* *General recovery of monies is detailed in overarching Debt recovery policy.*	Oct 2018	Head of HR (HR Officer)

Risk 2.	Incorrect payments to starters and leavers.
Opinion on Risk:	Substantial

#	Recommendations:	Priority	Actions Agreed	Target date:	Owner:
2.1	HR to seek clarification from HFEA Legal Professionals regarding the acceptability of employee electronic signatures in declarations where emails are present as an audit trail.	**LOW**	*Agreed – legal advice to be sought on e-signatures*	Sept 2018	Head of HR

Risk 3.	Inappropriate expense claims paid
Opinion on Risk:	Moderate

#	Recommendations:	Priority	Actions Agreed	Target date:	Owner:
3.1	The Finance Team to review a random sample of expenses on a monthly basis to gain assurances that expenses have been reviewed by members of their team prior to approval (following the revision to the hierarchy) for a minimum period of 3 months, if no concerns are identified.	**MEDIUM**	*Agreed* *(error was not system generated but human error. Admin rights given to AO have been reviewed and agreement reached regards amendments.)*	November 2018	Head of Finance
3.2	HFEA Finance Team to investigate the extent to which line Budget holders are also approving expenses in the system and consider whether any hierarchy adjustments are required to ensure an independent second line defence is in place.	**LOW**	*Agreed:* *We will review the hierarchy of approvals; however, our size and structure will make any changes difficult*	Sept 2018	Head of Finance
3.3	Senior Management to review the protocol that enables employees to claim subsistence for more than one person and make an informed decision based on the audit findings of the future approach. The	**MEDIUM**	*Agreed:* *Incorporated in T&S policy review*	Q3 2018	Director of Finance and Facilities

	outcome will inform upon the future Expenses Policy review.				

Risk 4.	Temporary promotions are not initiated / ceased in accordance with policy				
Opinion on Risk:	Moderate				
#	**Recommendations:**	**Priority**	**Actions Agreed**	**Target date:**	**Owner:**
4.1	Policy and procedures regarding appointment of temporary promotions will be enhanced to include the following stages: • HR booking milestone reviews of the temporary promotion with the relevant Director. • HR to obtain a decision from the Director / Senior Management regarding whether the appointment will cease at a specific date or reviewed at a future date. • The employee will be notified of the decision. • In the event a future end date or review date cannot be determined, HR to review with the Director / Senior Manager at proportionate intervals (no more than annually).	**LOW**	Agreed: We will update our policy on temporary promotions	Oct 2018	Head of HR (HR Officer)

Risk 5.	Failing to identify error and potential fraud				
Opinion on Risk:	Moderate				
#	**Recommendations:**	**Priority**	**Actions Agreed**	**Target date:**	**Owner:**

5.1	HFEA to undertake a cost benefit analysis of introducing expenses reporting / duplicate reporting tools within the finance system.	**LOW**	*Agreed:*	Q3 2018	Director of Finance and Facilities
5.2	Senior Managers issue communications to Budget Holders / Managers to highlight the importance of undertaking the reconciliation of the Redfern Invoice data and to notify the Finance Team when the check is undertaken, even if there are no concerns.	**HIGH**	*Agreed: Communication of importance to be made at CMG and follow-up email to teams*	July 2018	Head of Finance

Risk 6.	Failure to identify and recover overpayments in a timely manner				
Opinion on Risk:	Moderate				
#	**Recommendations:**	**Priority**	**Actions Agreed**	**Target date:**	**Owner:**
	(see Recommendation 1.1)				

Risk 7.	External providers of payroll services operate ineffectively				
Opinion on Risk:	Unsatisfactory				
#	**Recommendations:**	**Priority**	**Actions Agreed**	**Target date:**	**Owner:**
7.1	HFEA to examine the contract with FPS to establish whether the supplier is obliged to provide assurance reports, then HFEA to request assurance reports accordingly.	**MEDIUM**	*Agreed: Contract will be reviewed and reports requested.*	Sept 2018	Head of HR

Annex 2: Objectives, scope and limitations

Objectives:

The key objectives of this review are to provide assurances on the adequacy and effectiveness of payroll and expenses controls in place to ensure the correct payments are made to correct employees at the correct time.

Scope and Limitations:

The scope of the review will include:

- Determining the adequacy of policies in place covering payroll and expenses, ensuring that roles, responsibilities and accountabilities are clearly defined;
- Assessing the adequacy and effectiveness of controls in place to ensure staff are paid accurately and promptly;
- Assessing the adequacy and effectiveness of controls in place to identify and recover overpayments;
- Timetables for processing payroll and expenses transactions have been agreed and circulated;
- HFEA receive appropriate assurances from shared service providers;
- Management information is produced and reviewed on a regular basis covering payroll and expenses.

Distribution:

Customer(s):
Richard Sydee – HFEA Director of Finance
Morounke Akingbola – HFEA Head of Finance

Authors:

Jonathan Smithson – Senior Internal Auditor

Jeremy Nolan - HFEA Head of Internal Audit
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Annex 3: Our classification systems

Opinion

Substantial	The framework of governance, risk management and control is adequate and effective.
Moderate	Some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	There are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Recommendations

Rating	Definition	Action required
High	Significant weakness in governance, risk management and control that if unresolved exposes the organisation to an unacceptable level of residual risk.	Remedial action must be taken urgently and within an agreed timescale.
Medium	Weakness in governance, risk management and control that if unresolved exposes the organisation to a high level of residual risk.	Remedial action should be taken at the earliest opportunity and within an agreed timescale.
Low	Scope for improvement in governance, risk management and control.	Remedial action should be prioritised and undertaken within an agreed timescale.

Progress with Audit Recommendations

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	Progress with Audit Recommendations		
Paper number	AGC (09/10/2018) 619 MA		
Meeting date	9 October 2018		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to Note: there are 11 audit recommendations of which 8 remain open. There has been on new audit – Payroll and Expenses. It is expected that most of the recommendations received will be completed by Q3 2018.		
Resource implications	None		
Implementation date	During 2018–19 business year		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High

SUMMARY OF AUDIT RECOMMENDATIONS

Year of Rec.	Category	Audit	Section	Rec #	Recommendations	Action Manager	Proposed Completion Date	Complete this cycle?
2018/19	Moderate	DH Internal Audit	Payroll and Expenses	1	Inadequate policies and procedures	Morounke Akingbola, Head of Finance and Facilities Yvonne Akinmodun, Head of HR	October 2018	No
				2	Incorrect payments to starters and leavers	Yvonne Akinmodun, Head of HR	October 2018	Yes
				3	Inappropriate expense claims paid	Richard Sydee, Director of Finance (Morounke Akingbola, Head of Finance)	November 2018	No
				4	Temporary promotions are not initiated/ceased in accordance with policy	Yvonne Akinmodun, Head of HR	October 2018	No
				5	Failure to identify error and potential fraud	Richard Sydee, Director of Finance and Facilities	December 2018	No
				6	Failure to identify and recover overpayments in a timely manner	Morounke Akingbola, Head of Finance	September 2018	N0
				7	External providers of payroll services operate ineffectively	Yvonne Akinmodun, Head of HR	September 2018	Yes
2017/18	Moderate		Data Loss	1	Clinic governance oversight	*Chris Hall, Senior Inspector (Information)*	*Post April 2018*	No
				2	Policy Review	*Dan Howard, CIO*	*May 2018*	No
				3	Staff Training	*(Dan Howard, CIO & Head of HR)*	*December 2017*	Yes
			Risk Management	2	Staffing / Capability	*Peter Thompson, CEO (Yvonne Akinmodun, Head of HR)*	*March 2018*	No
TOTAL	11							

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2018/19 – INTERNAL AUDIT CYCLE			
PAYROLL AND EXPENSES			
1. Inadequate policies and procedures			
Expenses Policy: • Duty of care / Health and Safety regarding employees driving is inadequately addressed within policy. • Inadequate deterrent message regarding the potential for expenses fraud. Insufficient guidance for employees regarding multiple expenses claims	The Expenses Policy will be enhanced to include the following: • Reference to health and safety of employees for driving for prolonged periods and other options to be considered where high mileage claims are to be incurred (for example, Value for Money and options to hire vehicles) • Include reference to the consequences of providing false information i.e. breach of the employee Code of conduct • Provide clear guidance on claiming subsistence for more than one person.	Agreed: The Expense policy is to be reviewed in line with changes to flexible working. We will look to make refence to the health and safety of employees however the Vfm and options we feel is already represented. We will include reference to providing false information and guidance on claiming for more than one person **Sep 18 update**: Expense policy has been re-written and inclusions relating to health and safety, single claimants included.	***Morounke Akingbola, Head of Finance*** ***September 2018*** ***COMPLETE***
Temporary Promotions Exceed what is required operationally / excess salary costs. The lack of a formalised process and appropriate sign off is not best practice in terms of transparency, accountability and good governance to ensure decision making is fair and consistent.	Policy and procedures regarding appointment of temporary promotions will be enhanced to include the following stages: • HR booking milestone reviews of the temporary promotion with the relevant Director. • HR to obtain a decision from the Director / Senior Management regarding whether the appointment will be cease at a specific date or reviewed at a future date. • The employee will be notified of the decision. • In the event a future end date or review date cannot be determined, HR to review with the Director / Senior Manager at	Agreed: We will update our policy on temporary promotions. **Sep 18 update:** This work is in progress	***Yvonne Akinmodun, Head of HR*** ***October 2018***

	proportionate intervals (no more than annually).		

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2018/19 – INTERNAL AUDIT CYCLE			
2.	**Incorrect payments to starters and leavers.**		
Use of electronic signatures on employee declarations Declarations on contracts or formal notifications from employees not fully signed / legally binding (if necessary).	HR to seek clarification from HFEA Legal Professionals regarding the acceptability of employee electronic signatures in declarations where emails are present as an audit trail.	Agreed – legal advice to be sought on e-signatures **Sep 18 update:** Based on advice we have been able to obtain - Electronic signatures are considered to be legally binding for employment documents	***Yvonne Akinmodun, Head of HR*** ***Summer 2018*** **COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2018/19 – INTERNAL AUDIT CYCLE			
3. **Inappropriate expense claims paid**			
<u>The Finance Team review of expenses claims.</u> Not all expenses claims are independently checked in the second line of defence stage due to human error.	The Finance Team to review a random sample of expenses on a monthly basis to gain assurances that expenses have been reviewed by members of their team prior to approval (following the revision to the hierarchy) for a minimum period of 3 months, if no concerns are identified.	Agreed (error was not system generated but human error. Admin rights given to AO have been reviewed and agreement reached regards amendments). **<u>Sep 18 update:</u>** Review to commence during Q3	***Morounke Akingbola, Head of Finance*** ***November 2018***
<u>Independent, secondary checks of expense claims</u> Line managers approving expenses in the system also undertake reviews of Budget Monitoring reports. In this scenario, the secondary check is not independent.	HFEA Finance Team to investigate the extent to which Budget holders are also approving expenses in the system and consider whether any hierarchy adjustments are required to ensure an independent second line defence is in place	Agreed: We will review the hierarchy of approvals; however, our size and structure will make any changes difficult. **<u>Sep 18 update:</u>** A review of the hierarchy of approvers was done and we do not feel that any further changes are necessary. Expenses are reviewed by at least 2 separate people	***Morounke Akingbola, Head of Finance*** ***September 2018***
<u>Subsistence claims made for multiple employees</u> The associated risks are: • Inability to easily extract full Management Information of expenses claimed per person. • Published expenses data claims may lack clarity / transparency. • Greater risk of duplicate subsistence claims being made where employees are claiming for each other. • Reputational damage where expenses claims are erroneous.	Senior Management to review the protocol that enables employees to claim subsistence for more than one person and make an informed decision based on the audit findings of the future approach. The outcome will inform upon the future Expenses Policy review.	Agreed: Incorporated in T&S policy review **<u>Sep 18 update:</u>** Refreshed T&S policy stipulates that staff must only claim for the own subsistence.	***N/A*** ***Morounke Akingbola, Head of Finance*** **COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2018/19 – INTERNAL AUDIT CYCLE			
4.	**Temporary promotions are not initiated / ceased in accordance with policy**		
The lack of a formalised process / appropriate sign off is not best practice in terms of transparency, accountability and good governance to ensure decision making is fair and consistent.	Policy and procedures regarding appointment of temporary promotions will be enhanced to include the following stages: • HR booking milestone reviews of the temporary promotion with the relevant Director. • HR to obtain a decision from the Director / Senior Management regarding whether the appointment will be cease at a specific date or reviewed at a future date. • The employee will be notified of the decision. • In the event a future end date or review date cannot be determined, HR to review with the Director / Senior Manager at proportionate intervals (no more than annually).	Agreed: We will update our policy on temporary promotions. **Sep 18 update:** The update will be completed by October.	***Yvonne Akinmodun, Head of HR*** ***October 2018***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2018/19 – INTERNAL AUDIT CYCLE			
5.	**Failing to identify error and potential fraud**		
<u>Management Information / Exception Reporting.</u> Limiting the potential to identify fraud and error and undertake trend analysis regarding expenses. <u>Reconciliation of Redfern invoices</u> • Failing to reconcile invoice from Redfern Incorrect billing not identified	HFEA to undertake a cost benefit analysis of introducing expenses reporting / duplicate reporting tools within the systems. Senior Managers issue communications to Budget Holders / Managers to highlight the importance of undertaking the reconciliation of the Redfern Invoice data and to notify the Finance Team when the check is undertaken, even if there are no concerns	Agreed. **<u>Sept-18 update:</u>** None Agreed: Communication of importance to be made at CMG and follow-up email to teams **<u>Sept 18 update:</u>** Raised at CMG July meeting importance of review/sign-off of Redfern invoice. Follow-up email to be sent post Q2 finance reviews.	***Richard Sydee, Director of Finance and Facilities*** ***December 2018*** ***Morounke Akingbola, Head of Finance*** ~~***July 2018***~~ ***October 2018***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2018/19 – INTERNAL AUDIT CYCLE			
6.	**Failure to identify and recover overpayments in a timely manner**		
Employee overpayments: Under existing arrangements, the associated risks are that in the event of overpayment: a formalised / documented process is not in place to follow that governs treatment of overpayments fairly and consistently. In event of legal challenge on an overpayment, HFEA would be in the strongest position to defend its position if a fair process / policy is in place to support decisions made.	HFEA to introduce a Policy Statement regarding the recovery of overpayments that directly links to overarching Debt Recovery policy.	Agreed HR to draft policy statement on salary overpayments General recovery of monies is detailed in overarching Debt recovery policy. **Sept 18 update:** HR is in the process of drafting an overpayment policy. We are also updating contracts of employment for future employees that make it clearer what is expected in the event of any overpayments	***Yvonne Akinmodun, Head of HR*** ***October 2018***
7.	**External providers of payroll services operate ineffectively**		
HFEA have no assurance regarding the strength of controls or stability of systems used by the third party provider of the payroll	HFEA to examine the contract with FPS to establish whether the supplier is obliged to provide assurance reports, then HFEA to request assurance reports accordingly.	Agreed: Contract will be reviewed, and reports requested. **Sept 18 update:** Our payroll providers have provided us with copies of their GDPR policy. Intermittent reviews of the policy will take place managed by HR to ensure continuing compliance	***Yvonne Akinmodun, Head of HR*** ***September 2018*** **COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
2017/18 – INTERNAL AUDIT CYCLE			
DATA LOSS			
1. **Clinic governance oversight**			
The HFEA regularly inspects UK fertility clinics and research centres. This ensures that every licensed clinic or centre is adhering to standard safety. The purpose of an inspection is to assess a clinic's compliance with the Human Fertilisation and Embryology Act 1990 (as amended), licence conditions; General Directions and the provisions of the Code of Practice. The results of these audits from 2016/17 have not identified any significant weaknesses. The NAO accompany one visit per year.	The new Senior Inspector role should include responsibility over the Clinics' governance arrangements in managing data loss, including: a. Clinics' information governance arrangements to mitigate the risk of data losses; b. Clinics' arrangements for staff training on information management; c. Clinics' BCP arrangements.	The Senior Inspector (Information) role has been reviewed and it includes responsibilities for reviewing Information Governance. This includes staff training and security arrangements which includes reviewing BCP planning. *Inspection regime to be updated to reflect requirements within the new Senior Inspector (Information Quality) post will be filled from – Summer 2018* *Nov 17 update:* no update *Feb 18 update:* no update *May 18 update:* The Senior Inspector (Information Quality) will be filled from August 2018 **Sept 18 update:** The Senior Inspector (Information Quality) will move into his new post later this year (2018).	***Chris Hall, Senior Inspector (Information Quality)*** ~~***Summer 2018***~~ ***Q3/4 2018***
2. **Policy Review**			
Key policies and some of the Standing Operating Procedures were not up to date and were not reviewed on a regular basis - there is a risk that the policy may be out of date and result in incorrect processes being followed.	Key data and information policies should be reviewed periodically to ensure that they are current and aligned.	**Information Access Policy and SOPs to be reviewed, updated and ratified to reflect GDPR requirements. Staff Security Procedures (Acceptable Use Policy) to also be updated** **Sept 18 update:** Acceptable Usage policy presented to CMG in June and was approved subject to minor amendments	***Owner: Dan Howard, CIO*** **COMPLETE**

		To align with GDPR legislation and to be updated as a component of the HFEA GDPR Action Plan - May 2018. Update and approve at CMG – January 2018 ***Nov 17 update:*** *We have established a joint project with the HTA and we are developing an overarching project plan and have started the assessment against the 'Nymity Data Privacy Accountability Scorecard'. The recruitment to the IG Project Officer is ongoing.* ***Feb 18 update:*** no update ***May 18 update***: The new Acceptable Use Policy was reviewed at CMG on 23 May 18. Final comments will be forward to DH before 6 June 18 and the final version of policy will be reviewed and ratified by CMG on 20 June 2018. **Sept 18 update:** *CIO to provide update*	**May 2018**
3.	**Staff Training**		
We identified that the HFEA Business Continuity Plan has not been tested on a regular basis. It was therefore not possible for HFEA to provide assurance that the BCP remains current, fit for purpose and reflects key personnel change to ensure roles and responsibilities are clear.	A process should be put in place to ensure that HFEA are able to capture and monitor all mandatory information management learning and development carried out.	**We will refresh our approach to the completion of the following modules of mandatory training in IG. Our target is that all staff will have completed these in the previous 12 months by the end of the calendar year. The modules are:** • **Responsible for information: general user;** • **Responsible for information: information asset owner (IAOs to complete); and** • **Responsible for information: senior information risk owner (SIRO to complete)**	***Dan Howard, CIO*** *(Yvonne Akinmodun)* **December 2017**

		All staff – December 2017. The framework for mandatory training (in all areas including information training requires refresh). In any event whilst many staff have undertaken training within 12 months we will use Oct-Dec period to ensure all staff have completed, with sign off from Managers. ***Nov 17 update:*** *Information management training has been identified for all staff. Information Asset Owners, SIRO and all remaining staff will be expected to complete this before the end of December 2017.* ***Feb 18 update:*** *All staff were required to complete the online IAO training in December 2017. With HR monitoring to ensure completion.* *HR is also in the process of purchasing a new HRIS which will enable the training, monitoring and recording of mandatory and other training provided by HFEA.* *It is expected the new system will be in place by early spring 2018* ***May 18 update***: The new HR system is in the process of being configured. It is expected that the new system will go live on 1 July 2018 **Sept 18 update**: People HR went live on 17 September 2018	**Complete** **COMPLETE**

RISK MANAGEMENT			
4. **Staffing / Capability**			
There is the potential that HFEA are exposed to continued high staff turnover, loss of experience and expertise, which could lead to knowledge gaps and disruption to key areas of the business, affecting the service provided.	HFEA should put in place mechanisms to ensure that information captured through exit interviews and staff surveys to identify the root causes behind staff turnover, is used effectively to implement practical changes to bring turnover levels in line with agreed tolerances. This should include, but not limited to: •Ensuring that all information gathered from staff during exit interviews and staff surveys is reviewed in detail, with an action plan produced to respond positively to the findings. Any actions agreed should have senior management sponsorship to ensure there is the requisite accountability and a clear mandate for implementing the actions agreed; and	***A management action plan which provides details of planned actions for addressing the root cause of current staff turnover in HFEA, incorporating some or all of the elements detailed in the recommendation.*** ***Agreed. We will look at this suggestion in the near future. Discussion at the next available SMT.*** ***Feb 18 update:*** Review of staff survey results was conducted in Q3 by CMG and shared with staff in January. Plans are currently being put in place to provide quarterly or bi-annual reports to SMT on the general themes that emerge from exit interviews. Action plans to tackle themes identified from exit interviews will also be put in place ***May 18 update:*** In progress – results from the findings from exit interviews will be reported as part of an annual HR report ***Sep 18 update:*** Draft exit interview report has been presented to SMT and is now awaiting final sign off	***Peter Thompson, CEO*** ***Yvonne Akinmodun*** ***Before end of 2017*** ~~***End March 2018***~~ **October 2018**

	•Development of a clear workforce strategy which supports management in the recruitment and retention of staff.	***Agreed – this is in progress. Finalisation discussion planned at leadership and away day on 29 November 2017. Publication shortly thereafter.*** **Feb 18 update:** We have a people plan which identified recruitment and retention processes including the review of our induction process to ensure staff feel able to work effectively in as short a period of time as possible. **May 18 update:** **A new induction policy and checklist was launched in May 2018. Managers are being offered guidance and support in using the new policy** **Sep 18 update:** HR is organising a lunch and learn session in October for managers to ensure understanding of new policy	**October 2018**

Digital Programme Update: October 2018

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	Digital Programme Update		
Paper number	AGC (09/10/2018) 622 DH		
Meeting date	09 October 2018		
Author	Dan Howard, Chief Information Officer		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note: • Progress made on data migration, development of PRISM, release of APIs, and supplier / clinic engagement to date; • The financial update; and that • AGC will provide 'approval to proceed' for the programme during November 2018, once system development, user and performance testing, and all validation checks on data migration have been completed and are satisfactory		
Resource implications	None		
Implementation date	During 2018 - 19		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes:	Annex 1: Summary Programme Plan Annex 2: September AGC Digital Programme Update		

1. Background

1.1. In June 2018, AGC received a progress update on data migration and development of our new data submission system, PRISM.

1.2. Since June, several updates to Members have been provided outside the meeting cycle reporting significant and substantial process across all areas of the programme. The most recent update is provided as Annex 1. Capital approval has been granted (a single approval was made by DHSC for all NHS and DHSC bodies), and good progress has been made in recent days on data migration and we are readying ourselves, clinics and suppliers for a soft launch in November. The June meeting of AGC anticipated a launch during October 2018.

1.3. Final approval to proceed by AGC is anticipated in early November. We will seek this when we are assured as to system development, user and performance testing, and all validation checks on data migration have been completed and have passed a set threshold. The approval to proceed assessment will include a review of the consequences of any data validation discrepancies, however small.

1.4. This paper updates on AGC on progress, the financial forecast and risk/issues.

2. Summary

2.1. Data Migration is progressing well and on track in line with the last AGC report. PRISM development is progressing well although this has taken slightly longer than planned and is the source of the delay. We expect to be ready for launch in November:

- **Data Migration**: Good progress has been made with the reconciliation process underway.
- **PRISM**: Development work for 'Inventory' (to track storage and usage of gametes and embryos) has been completed. Testing has identified some software 'bugs' when this has been incorporated into existing pages.
- **System reporting (RITA)**: Development has been put back to just ahead of testing PRISM, and the initial focus is on being able to support the *go-live* process.
- **Infrastructure**: The Azure cloud server infrastructure is in place ready for PRISM
- **Transition Plan**: The transition plan has been developed to ensure clinics and supplier readiness for go-live ahead of the transition to the new system.
- **Risks and issues**: Remain unchanged since our last update – see Annex 1

3. Data Migration

3.1. The work on data migration is going well and 'reconciliation' is underway to confirm the validity of the migrated data, meaning that data will copy across correctly from the legacy register into the new register and that the data is correct.

3.2. Reconciliation is in two stages:

- **Stage one** involves ensuring the number of records transferred is the same as the number in the legacy Register, or differences can be explained. The process

identifies issues in the migration and allows us to refine the load process through a series of Trial Loads (see table below) – refining the algorithm we use to simulate the transfer of data

- **Stage two** involves analysing the data in the new Register to ensure consistency to the legacy Register in relation to the expected outputs

3.3. Stage one is well advanced and is showing promising results, reflecting the attention to detail and hard work undertaken during the development phase. We are pleased to report we understand the discrepancies and are working through resolving the differences:

- There are very few differences with the data transferred for IVF and DI Cycles and stage one work is complete.
- There are small discrepancies in the data for Registrations, Outcomes and Early Outcomes. We understand the issues and are currently resolving the differences in Registrations before we resolve those in Outcomes and Early Outcomes.
- Gamete Movement requires some remedial work to address the discrepancies, scheduled over the next three weeks.

3.4. Trial load status is as follows, with significant areas of progress highlighted in yellow:

		Differences					
		19-Sep		25-Sep		28-Sep	
	Records	Number	%	Number	%	Number	%
Registrations	1,757,104	-50,836	97.11%	-36,173	97.94%	-36,173	97.94%
Early Outcome	618,797	-59,353	90.41%	-59,353	90.41%	-11,203	98.19%
Outcome	329,372	-29,430	91.06%	-29,430	91.06%	-2,674	99.19%
DI Cycles	171,752	-20	99.99%	-20	99.99%	-20	99.99%
Cycle Count	252,819	599	100.24%	599	100.24%	599	100.24%
IVF1	587,103	-56	99.99%	-56	99.99%	-56	99.99%
IVF2	703,170	-19	100.00%	-19	100.00%	-19	100.00%
Gamete Movement Out	64,246	-21,631	66.33%	-21,631	66.33%	-21,631	66.33%
Gamete Movement In	35,377	-2,863	91.91%	-2,863	91.91%	-2,863	91.91%

3.5. Stage two work is underway. We have developed the base measures (quality metrics) to analyse the data. These show consistency between the new Register and Legacy Register. During October we will use these to build more complex reports (including the base tables used for Choose a Fertility Clinic) to further assess consistency between the Registers and address any discrepancies.

3.6. Given the disproportionate amount of resource required as we near 100%, we do not expect to achieve a perfect level of data quality for data migration. We are continually monitoring any validation errors (number/percentage) and comparing that to the

consequence of any discrepancy. A comprehensive review for each data item will be included within the 'approval to proceed' assessment.

4. PRISM

4.1. Significant progress has been achieved surrounding the development of PRISM. Our preview system was well received by clinics, with positive feedback reported following a user survey we conducted. There are now only a very few remaining components of PRISM to complete, principally the 'view and edit' function.

4.2. Since the update last month, there has again been a small slippage against the plan; from the development work relating to 'inventory' rather than data migration. That work introduced a number of software bugs, being fixed but which take time. This work has largely been completed. Given the small slippage, we now expect PRISM to be available and tested by 29th November. We are planning a soft launch of PRISM and the APIs to help ensure it is well received by the sector.

4.3. Our engagement with EPRS suppliers (just over half of all clinics use electronic third party patient record systems) continues at pace. Suppliers are active and we are regularly responding to queries and to support their development work to make their software compatible with our new register and the requirements of PRISM.

5. Financial

5.1. The programme is delivering on target, and well within the £500k capital cover that has been approved by DHSC.

5.2. A summary of our actual/planned/forecast capital expenditure is below:

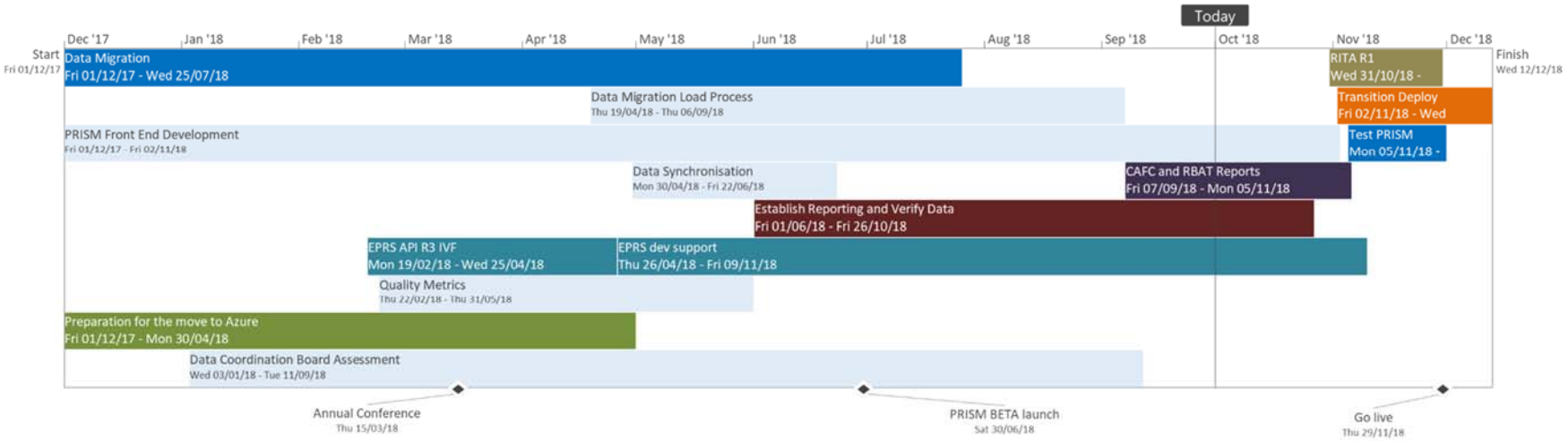
Expenditure to 30 September 18	Planned Expenditure to 30 September 18	Total Planned Expenditure
£290,640	£284,184	£456,070

6. Recommendation

The Committee is asked to note:

- Progress made on data migration, development of PRISM, release of APIs, and supplier / clinic engagement to date;
- The financial update; and that
- AGC will provide 'approval to proceed' for the programme during November 2018, once system development, user and performance testing, and all validation checks on data migration have been completed and are satisfactory

Annexe 1: Summary Programme Plan



Annexe 2: September AGC Digital Programme Update

Digital Programme Update: September 2018

1. Background

1.1. In June 2018, the HFEA Audit and Governance Committee (AGC) received a progress update on data migration and development of our new data submission system, PRISM. It was agreed that for assurance purposes, AGC would receive written monthly updates on progress, highlighting any adverse variances against the programme plan or increased risk. The last update was sent to AGC on 8 August 2018.

1.2. It was agreed that ahead of go-live, AGC would receive a comprehensive update on five areas on 12 September 2018, allowing AGC to provide approval to proceed assuming a launch in early October 2018. That launch date has now been pushed back. It was agreed that the update would include:

- **Data Migration:** Results of detailed data migration testing consisting of 'trial loads' – comparing data within the old register with how it would transfer into the new register, ensuring no change to its integrity, including assurance by third party, Northgate.
- **Cloud data storage:** A comprehensive risk review of our fertility data being transferred from physical servers within Spring Gardens into Microsoft 'cloud' data storage. This component would include the results of scheduled penetration testing of the cloud environment and system and review by a third party CLAS consultant (information assurance expert).
- **PRISM development including APIs:** A review of software development, crucially including detailed user acceptance and performance / volume testing, to ensure the software product meets expectations and provides the necessary functionality. This includes a test that system suppliers have demonstrated they comply by submitting our test data correctly.
- **Transitional planning:** Assurance that all transitional planning is on track to include clinic readiness and EPRS system supplier readiness ahead of go-live. Assurance that clinics are ready to proceed.
- **Internal systems and processes:** Assurance that internal processes for billing and inspection reports are complete and working effectively. Assurance that the Register Information Manager and Donor Information Manager have

access to a view of the new register data (and necessary reports) to ensure their services can operate as expected.

1.3. While significant progress has been made since the last monthly update, we are not yet at the stage where this work is complete. We are perpetually balancing the need for quality; securing a good data transfer within the parameters we set; and achieving this within an acceptable timeframe.

1.4. As a result, we are not yet at the point to ask AGC to provide approval to proceed. Our current expectation is that we will seek approval to proceed at a meeting towards the end of October once data verification and user acceptance testing is complete. The AGC next meets formally on 9 October 2018 and a full update on progress will of course be provided to that meeting.

1.5. This paper therefore provides an update on progress, risk/issues. the financial forecast and communications.

2. Summary

2.1. Data Migration remains on track. PRISM development has however taken slightly longer than planned and will now not be ready for launch until 15 November 2018. The current register will be switched off on that date. Data will be migrated over one week and then clinics will then transition to the new system and register. The transition is scheduled to be completed by 30 November 2018.

2.2. This paper provides a full update on progress to date:

- **Data Migration:** Good progress has been made and data migration remains on track to be ready for the transition process at the end of October
- **PRISM:** While some areas of development have been challenging, progress remains steady. Work on 'Inventory' (to track storage and usage of gametes and embryos) has been complex. Full details of the programme plan is available in Annex 1.
- **RITA:** RITA is the internal system while will provide a view of the new register data allowing the Register Information and Donor Information teams to support and monitor clinics performance and respond to opening the Register requests. Development is due for completion in November alongside the completion and launch of PRISM.
- **Infrastructure:** The Azure cloud server infrastructure is in place ready for PRISM
- **Transition Plan:** The transition plan has been developed to ensure clinics and supplier readiness for go-live ahead of the transition to the new system.

3. Programme Overview

3.1. **Data migration:** The 'Trial Load' has been completed and we are now analysing the results. This will identify any data that is not being migrated; assess the impact and actions required. This will be completed by the 21 September.

In addition, an independent assessment by Northdoor is scheduled for week commencing 1 October, and will confirm the robustness of the migration process.

The basis on which we assess the quality metrics are in place. In short we compare current Choose a Fertility Clinic and HFEA Fertility Trends reports to compare current outputs from the old Register with the data generated from the new Register.

Completed since last update

- Completion of process to extract data from legacy Register
- Completion of Load Process (pending some remedial actions)
- Completion of baseline Quality Metrics
- Completion of Image Storage migration process
- Running Trial Load process to begin verification

In Progress:

- Comparison of counts and exception reports for migrated data against legacy Register - to ensure we are taking all data from the old Register to the new Register
- Follow up actions for issues identified in Gamete Movements
- Development of CaFC and Fertility Trends Reports

Scheduled for September / October

- Comparison of CaFC and Fertility Trends Reports for migrated data against legacy Register
- Sign off Migration Process ready for full migration

3.2. **'PRISM' system development:** Development of PRISM has been tough:

- Development of the 'inventory' (to track storage and usage of gametes and embryos) has been significantly more complex than expected and has overrun by 25 working days
- The new Lead Developer has been fully occupied supporting business as usual and as a result he has not been able to make progress on report development as we wished
- The departure of the Register Information Manager in August has placed burdens on other members of the team, both for PRISM development and support for the Register Team. While the role has been filled (the new starter joins us on 17 September) there has been an unavoidable short-term impact on existing members of the team

Although we have brought in additional support, the overrun of inventory means that under current plans PRISM will be ready and tested on 15 November 2018.

Completed since last update

- Completion of Action Required (highlights where there is an error in the data and a validation rule has been broken)
- Remedial work associated with bugs identified during regular sprints
- Incorporation of completed features into automated testing

In Progress:

- Inventory (to track storage and usage of gametes and embryos)

Scheduled for September/October

- View and Edit (allows you to see and edit data where the data entered appears valid)
- Reporting Dashboard (for clinics to report against their data)
- Full Reporting Suite
- Changing/multiple roles
- Deletions - this is the process that allows a treatment cycle to be flagged as deleted whilst retaining the integrity of the data i.e. ensuring all related / associated activities are flagged as deleted as well
- User Acceptance Testing and Full Preview Release (19 - 25 October)
- Volume and Performance Testing (19 October – 15 November)

3.3. Risk and issues

The main risks faced by the programme are:

- **PRISM Delay:** Delivery of PRISM has slipped by 25 working days. Although we are in the final stages of the programme and naturally the risk of slippage reduces, we now are over-running and any further slippage will directly impact our launch date. We have contingency within the budget for limited further slippage and this will be carefully monitored.
- **Data Migration Verification:** The verification process may identify errors that require significant remedial action. Detailed checks have been carried out throughout development of the migration process and there is confidence about the completeness of data and how it has been migrated. Analysis has also been undertaken to ensure optimal design of the new Register. However, unexpected issues may arise in the way data is structured in the new Register once comparison using the CAFC reports is completed.
- **RITA development (internal data review system for data interrogation) takes longer than expected delaying the roll out**: We are developing using a ‘Waterfall’ rather than ‘Agile’ project management methodology. This will entail detailed up front design, but which give clarity to timeframes. A minimum RITA requirement (Release 1) for the launch date has been specified and will be developed first. Future development requests will be reviewed and prioritised alongside our other identified needs.

3.4. **Financial:** The programme remains within budget and formal confirmation of our capital allowance of £500,000 has been received by DHSC.

Expenditure to 31 July 2018	Planned Expenditure to July 2018	Total Planned Expenditure
£224,189	£223,091	£423,269

3.5. **Communications and Engagement**:

All third-party suppliers have been contacted and briefed about the programme. Ongoing contact is maintained with suppliers to ensure that they are on track to deliver in October.

Regular communication to clinics has been ongoing, providing details of the go-live process and expectations. We will be seeking assurance as to clinics preparedness for go-live through structured 'Are you prepared for PRISM?' briefings and we will continue with our programme of detailed engagement. We will release the go-live schedule during September and we will launch to a pilot group of clinics as part of our testing regime ahead of the main go-live.

Resilience, Business Continuity Management and Cyber Security

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

Details:	
Meeting	Audit and Governance Committee (AGC)
Agenda item	9
Paper number	AGC (09/10/2018) 623 DH
Meeting date	09 October 2018
Author	Dan Howard, Chief Information Officer
Output:	
For information or decision?	For information
Recommendation	The Committee is asked to note: • Summary details on our planned approach of moving our Register from a physical server in Spring Gardens to Microsoft Azure (known as 'the cloud') • An update on an incident during June/July 2018 involving information submitted by a clinic relating to a PGD application • That an encrypted laptop was lost on 23 August 2018, appropriate steps were taken and the resultant risk of a data breach was very low • That our telephone system, network and video-conferencing facilities are due to be upgraded shortly • That a Cyber Security audit took place during July/August and we are awaiting the audit report
Resource implications	None
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. This paper provides summary details on our planned approach of moving our Register from a physical server in Spring Gardens to Microsoft Azure (known as 'the cloud').

1.3. This paper as also provides an update on an incident during June/July 2018 involving information submitted relating to a PGD application, submitted by a clinic through the HFEA Clinic Portal. The application was not received due to a technical fault.

1.4. An encrypted HFEA laptop was lost on 23 August 2018; the risk of a data breach as a result of the loss is very low and all appropriate steps took place immediately afterwards.

1.5. We also plan to make improvements to our telephone system and video-conferencing facilities, an overview is available below.

1.6. An audit was undertaken of our cyber security arrangements during July and August 2018. We have not yet received the draft report for comment. The audit and management response will be presented to a future meeting of AGC.

2. Register move to Microsoft Azure 'the cloud'

2.1. As part of the development of the new Register of treatments we propose moving the Register currently hosted on a local HFEA physical server within Spring Gardens to 'cloud' based hosting through Microsoft Azure.

2.2. We believe there are significant benefits to this new approach. Given the nature of the sensitive personal data we hold within the register, it is appropriate that the proposal is carefully considered by AGC.

2.3. We will seek the final sign-off for our cloud strategy by AGC in November. Ahead of that, an overview is provided below and committee members are invited to seek further clarification and/or ask questions.

2.4. 'Cloud computing' is defined as the move from a traditional server (within our IT network) to a server provided as a service by a third party company and accessed from a large datacentre over the Internet.

2.5. This approach removes the need to invest in and maintain hardware onsite as capital assets, instead using a pay-per-month revenue model.

2.6. Cloud based hosting offers a range of benefits, especially for small organisations such as the HFEA. These include:

- **Better security** with industry leading access controls and protection against cyber threats. Improved boundary security, database security, identify management security, operational security and encryption
- **Cost effectiveness** through shared infrastructure, with data storage always physically separated;
- **Scalability** the opportunity to instantly easily increase or reduce scale (storage or computing power) in line with requirements, without having to invest in new hardware, or have unused redundant hardware;
- **Improved backup, mirroring, and disaster recovery** to industry leading standards

- **Compliance** from the service provider against a vast variety of standards, such as ISO27001 Information security standard, the NHS Data Security and Protection Toolkit, and HMG Cyber Essentials. Data is always stored within the UK.

2.7. Our design within Microsoft Azure has been developed by Alscient (a specialist IT company) to provide access only to authorised individuals. The design has been penetration tested by an independent company and assured by a CLAS consultant (a pre-approved, security-cleared, trusted adviser that HMG departments can use to advise on security requirements).

2.8. The design aligns with the NCSC (National Cyber Security Centre) Cloud Security Guidance, including:

- Encryption of data at rest
- Strongly authenticated access over encrypted links
- Strict Role Based Access Control
- Regular penetration testing
- Auditing of design and build
- Ongoing operations that include auditing of accounts, changes and accesses

3. An incident relating to a PGD application by a clinic

3.1. Clinics submit applications to the HFEA via Clinic Portal, which is a private part of our main website. On receipt of an application Clinic Portal transfers information to an internal licensing system, Epicentre, used by HFEA staff, including inspectors to manage clinic information.

3.2. In May 2018 an application was submitted by a clinic in respect to a PGD application. Epicentre did not provide an alert indicating that the information had been submitted. We were only alerted to the request when the clinic contacted us for an update. The issue was promptly investigated, and the information was manually released for review and processed on 5 July 2018.

3.3. This had several consequential and potentially reputationally damaging impacts. Firstly, it delayed the patient's access to treatment, compounded by the local commissioning group applying a deadline for funding which we were perilously close to breaching. Secondly, and due to this, and with the cooperation of the Chair of the HFEA Statutory Approvals Committee, an extraordinary meeting of the Committee had to be established to consider the application.

3.4. The incident was carefully investigated to

- Identify the cause of the incident;
- Identify whether any other applications were 'stuck' in the system; and,
- Identify the likelihood of a recurrence for any other clinic applications

3.5. The cause of the incident was found to be functionality/software code within Epicentre not functioning correctly. There were no other 'stuck' applications in the system. Should no action be taken, it was found that there is a high likelihood that further applications relating to special direction requests, licence variations and PGD applications could be 'stuck' within the system.

3.6. Rewriting the original software code was carefully considered and it was estimated that this would take a significant amount of resource and so alternatives were explored. A script was developed which would check for any missing applications which has been submitted by clinics through Clinic Portal, but which had not transferred through to Epicentre. The script is now run on a weekly basis.

3.7. Since the incident all applications have filtered through to Epicentre correctly and the script has not discovered any new 'stuck' applications.

4. An incident relating to the loss of an encrypted HFEA laptop

4.1. On 23 August 2018 a member of staff accidentally left an encrypted HFEA laptop on a train in the London area. No further confidential information was with the laptop. This loss was immediately reported to the information area at the station and reported to their line manager on the same day. An incident was logged internally and investigated.

4.2. Our IT team immediately sent a wipe command to the device and confirmed, as with all mobile devices, and in line with public sector guidance, the device was fully encrypted to the appropriate AES-256 standard and on that basis, the risk of a data breach was very low.

4.3. Our Data Protection Officer at the HTA was contacted and reviewed the incident. His advice was that the risk of a possible data breach was very low given the device was fully encrypted.

4.4. The ICO were contacted and confirmed that due to the use of encryption the resultant data breach risk was very low, and no further action should be taken.

4.5. As a result of the incident, and to avoid a recurrence, all staff were reminded about good practice when travelling with HFEA electronic devices, such as laptops and mobile telephones.

4.6. In line with our incident process, the incident was reviewed by SMT, including actions taken following the incident and the incident was closed.

5. Telephone system and video-conferencing system upgrades

5.1. We are due to make improvements to our telephone and video-conferencing system to address concerns raised and to meet our current and future requirements. This upgrade will deliver significant benefits: providing the network capacity we require, supporting improvements to video-conferencing, aligning to our 'cloud first' IT strategy and enabling a smooth transition to new premises in 2020.

5.2. The voice communications system at HFEA is reliant on telephone switch infrastructure that runs on premises at Spring Gardens. 'On premises' means it runs on physical server hardware in the building. This is unchanged since HFEA moved into the building in 2016. Our current data communications link is nearing capacity.

5.3. Following a review of options, our Corporate Management Group (CMG) has approved that we will upgrade our voice and Skype service from Microsoft, move our Skype server into the cloud, and upgrade our network connection.

5.4. We will purchase of a new 'voice service' from Microsoft, upgrading to a new E5 license type in order to use the Microsoft voice service in the cloud, this includes audio and video conferencing.

5.5. The above upgrade requires a faster network 'link'. We will upgrade our current data communications link from 100 Mbs (Megabits per second) to 200 Mbs. A 2 year contract term for the upgraded network has been selected due to the 2020 office move.

5.6. The upgrade was approved by CMG on 19 September and is conditional on the results of testing with a small number of users. This is due to take place during October 2018. Following testing, the network connection will be upgraded during November 2018. The system changes will be completed thereafter with the upgrade due to be fully completed by 31 December 2018.

6. Recommendation

The Committee is asked to note:

- Summary details on our planned approach of moving our Register from a physical server in Spring Gardens to Microsoft Azure (known as 'the cloud')
- An update on an incident during June/July 2018 involving information submitted by a clinic relating to a PGD application
- That an encrypted laptop was lost on 23 August 2018, appropriate steps were taken and the resultant risk of a data breach was very low
- That our telephone system, network and video-conferencing facilities are due to be upgraded shortly
- That a Cyber Security audit took place during July/August and we are awaiting the audit report

Risk policy

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	11		
Paper number	[AGC (09/10/2018) 625 HC]		
Meeting date	9 October 2018		
Author	Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest version of the risk policy, set out in the annex.		
Resource implications	In budget.		
Implementation date	Immediate update to the policy.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: HFEA risk policy		

1. HFEA risk policy

Background

1.1. The HFEA maintains a risk policy ‘Managing risk at the HFEA’ which details the roles, responsibilities and procedures we use to manage risk.

Latest additions

1.2. We have made very minor updates to the policy, including formatting and updating process owners following changes to roles. Further to these we have added:

- A revised statement on risk appetite and tolerance
- Further clarification about the roles of the Authority and AGC

1.3. CMG reviewed the revised risk policy at its meeting on 19 September and agreed that it should be shared with AGC before the updated policy is finalised.

2. Recommendation

2.1. AGC is asked to note the above, and to comment on the risk policy.

Human Fertilisation & Embryology Authority

Managing risk at the HFEA

HFEA risk policy

1. General approach to risk

1.1. Overview

1.1.1. The HFEA's risk management system sits within its wider corporate governance system, which is described in the Annual Governance Statement set out in each year's Annual Report.

1.1.2. The overall system of corporate governance is designed to ensure that responsibility and accountability is clear and, that internal controls support the mitigation of strategic and operational risks. It is also designed to ensure that Authority members and the Chief Executive can be assured that appropriate oversight over operational responsibilities is in place. The HFEA complies with the requirements of the *Corporate governance in central government departments: code of good practice*, in so far as they relate to ALBs.

1.1.3. The HFEA's general approach to the management of risk is based on the principles of good practice set out in HM Treasury's 'Orange Book' on risk management. Accordingly, the HFEA defines risk management as:

> 'The way in which we identify and deal with uncertainties which threaten success.'

1.1.4. The HFEA recognises that good risk management is integral to excellent performance, allowing the organisation to:

- Have increased confidence in achieving desired outcomes
- Effectively constrain threats to acceptable levels
- Take informed decisions about opportunities and changes.

1.1.5. The HFEA therefore actively considers risks and controls in all business and project planning, and in our ongoing management of our staff and our operational delivery.

1.2. Risk and capability

1.2.1. The Authority's attitude to, and management of, the risks it faces in carrying out its functions is robust but proportionate. Risks vary in their likelihood and impact, and the Authority's overall appetite to risk is 'low' (see also later section on risk appetite and tolerance).

1.2.2. The framework the HFEA has established to identify and manage risk is proportional to its small size and allows for reasonable controls to be in place, without adversely impacting on the successful delivery of objectives.

2. Risk management structure in the HFEA

2.1. Levels of risk management

2.1.1. The HFEA's system of internal risk management gives assurance that the risks the organisation faces when exercising its statutory functions are managed appropriately and mitigated against proportionately. Risks are formally managed at several different levels in the HFEA:

- Strategic risk register – capturing risks to delivery of the HFEA strategy and business plan
- Operational risk logs – capturing team level risks to functional delivery

- Project/programme risk logs – capturing risks to successful project delivery
- Business continuity risks – managed through the business continuity plan with regular appraisal of business-critical functions
- Internal incidents system – an adjunct to the risk system, which enables understanding of and corporate learning from internal adverse events.

2.1.2. Alongside its arrangements for managing risk within the organisation, the HFEA also takes a risk-based approach to the way it regulates the fertility sector. In inspecting and regulating clinics, the Authority uses a risk-based assessment tool, ensuring that the HFEA's regulatory resources are targeted proportionately and reasonably. This tool (and all other processes used by the HFEA in carrying out its functions) is subject to a rigorous quality assurance regime. Regulatory risks will not be discussed further in this policy, which focuses on the management of the HFEA's own risks, rather than clinic-based risks. Clearly there is an interaction between the two, and this is recognised where relevant in the strategic risk register and in operational risks, particularly those of the Compliance and Information Directorate.

2.1.3. The Authority takes its responsibilities for information security most seriously. In this regard, the HFEA has a low tolerance for information risks and follows stringent information security good practice. Keeping secure the information the Authority holds, including sensitive personal patient data, is of the highest priority. The HFEA continually works hard to avoid the occurrence of any data losses. Distinct information risks are captured where relevant in the strategic risk register, in operational risk logs maintained by teams, and in project risk logs.

2.2. HFEA in a wider risk context

2.2.1. The HFEA engages with the Department of Health and Social Care ALB Risk Network which meets periodically, convened by the Department. This is a forum for discussing common risk issues and systemic risks and the approach of the Department towards risk management.

2.2.2. The HFEA has committed to consider system-wide and common, interdependent, risks. The strategic risk register includes sections for identifying risk interdependencies between the HFEA, the Department of Health and Social Care and the wider health and social care system.

2.3. Risk appetite and tolerance

2.3.1. 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.

2.3.2. 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.

2.3.3. 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. For example, because we operate in a regulatory environment, we are often involved in legal cases and our decisions are open to legal challenge. This means that we must be willing to accept a higher level of legal risk, as we have limited control over the number of legal cases that we must deal with. On the other hand, we deal with confidential medical data in our Register and we have a statutory duty to maintain this securely. We therefore need to reduce our risk of cyber security threats to a low level and our tolerance for such risk is set as low.

2.3.4. 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. For instance, during a period of organisational restructure, the tolerance for this risk might be raised as the activities that need to be undertaken, such as implementing redundancies, are inherently risky. We may choose to accept a higher risk level because it is necessary to take and tolerate certain risks in order to implement and take advantage of a new structure. On the other hand, risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change, unless the organisation's role or environment changes dramatically.

2.3.5. When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation has to 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.

2.3.6. When a risk exceeds its tolerance threshold, or when a risk becomes 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. For further detail see the section of this policy on risk escalation.

3. Procedures and roles

3.1. Staffing and structure

3.1.1. The Risk and Business Planning Manager leads on risk management organisationally, supported by the Head of Planning and Governance, and is responsible for ensuring:

- The existence and maintenance of a strategic risk register capturing strategic risks
- Regular review by senior staff and members, with regular reporting to the Senior Management Team (SMT), Corporate Management Group (CMG), the Authority, Audit and Governance Committee (AGC) and the DHSC Sponsor team
- That teams apply risk management principles in their own areas, maintaining an operational risk log and including risk management as a key consideration in every project
- That project risks are actively monitored by project teams and by Programme Board, and that lessons learned from projects are recorded, and learning implemented
- The maintenance and monitoring of the system and SOP for internal incident reporting, so as to ensure organisational learning from adverse events
- That business continuity planning remains aligned with overall corporate risk management.

3.1.2. The Corporate Management Group (CMG), which comprises Heads of Department and Directors, is responsible for regular reviews of teams' top three operational risks. These risks are reported from teams' operational risk registers, maintained by Heads.

3.1.3. The Senior Management Team reviews the strategic risk register on a monthly basis to ensure that it accurately reflects all new and emerging risks. This is then circulated to CMG.

3.1.4. Programme Board is responsible for monitoring project risks, referring issues upwards to CMG when necessary. Project managers and sponsors are clear about their obligation to provide

reports to Programme Board, on a monthly basis, which include information about the current risk level and sources of risk within the project. Non-reporting results in automatic escalation.

Authority and AGC

3.1.5. Both AGC and the Authority have critical roles in the HFEA's risk management process, ensuring appropriate reporting and governance are in place to provide effective assurance. This includes reviewing periodic audits of our risk management arrangements and ensuring that appropriate actions are taken to improve processes.

3.1.6. The Authority is accountable for the oversight of the management of risk, part of which it delegates to AGC.

3.1.7. The Authority and AGC both receive the strategic risk register for comment on a regular basis. The report goes to every quarterly AGC meeting and comes to Authority at least twice a year.

3.1.8. When reviewing the strategic risk register, AGC ensure that the organisation is properly identifying and controlling strategic risks and effectively escalating risk developments to the Authority.

3.1.9. The Authority receives the strategic risk register for oversight and information, at which point members are invited to discuss the executive's approach to addressing risks, particularly those which are high or above tolerance.

Internal audit

3.1.10. AGC commissions an ongoing internal audit programme which includes audits of risk management, relating to both specific topics of risk, such as cyber security and the general risk management system.

3.1.11. Actions following on from internal audits are tracked by AGC and progress is reported by the executive at each meeting. Internal audit provides ongoing assurance that the risk system is working, controls are appropriate and effective, and any issues identified have been effectively addressed.

3.1.12. Internal Audit provides AGC with an annual assurance report, which includes a formal opinion, based on their assessment of whether the controls in place support the achievement of our objectives.

3.1.13. Periodically, Internal Audit supports the executive to undertake risk assurance mapping exercises focused on a particular risk area, which allow the executive to further understand the make-up of the control environment. This process can help establish whether controls are appropriately split between 'preventative' and 'detective' controls and gain assurance on the operation of controls identified.

3.2. Strategic risk register

3.2.1. The HFEA strategic risk register is reviewed on a monthly basis by SMT, with reporting to AGC and Authority.

3.2.2. In addition, a grass roots review, starting from a blank sheet of paper, is undertaken periodically, and at least once every three years.

3.2.3. The most recent such review was undertaken in 2017, following the publication of the HFEA's three-year Strategy (in April 2017). The purpose of this grass-roots review is to capture afresh the

risks to delivering our current strategic aims and business plan. As part of this exercise, we consider the HFEA's current operating context, environment and resources.

3.2.4. Ongoing areas of strategic risk include the management of people and resources, legal and cyber security. Other risks relate to specific areas of the current strategy, and the particular challenges involved in delivering them.

3.3. Operational risk logs

3.3.1. The operational risk logs that feed into the Authority's strategic risks are reviewed regularly, within teams, and the top risks are reported on a quarterly basis to CMG, which in turn assesses and reports on the key risks to AGC.

3.3.2. In addition to noting individual operational risks, and discussing their sources and controls, CMG also takes a managerial overview of current operational risks, identifying prevalent themes and considering whether these are adequately reflected in the strategic risk register, and whether any issues or trends require further discussion and decision-making.

3.3.3. This allows for a proactive and proportionate approach to risk management throughout the work of the Authority and its executive. The system facilitates continual identification and monitoring of operational risks, and the regular reviews by CMG act as a prompt for any needed decision as to whether to escalate an operational risk or to recognise a new or emerging issue.

4. Project and programme risks

4.1. Projects are scrutinised by the HFEA's Programme Board. Risk assessment and management are a substantial aspect of this oversight arrangement and both the Project Manager and the Project Sponsor (usually a Director) must report to the Programme Board at monthly intervals. In turn, the Programme Board reports to CMG every month, with a highlight report outlining progress, risks and issues for each live project.

4.2. The Senior Management team is also briefed on current project risks and issues following each monthly Programme Board meeting, enabling prompt management of any new or increasing project risks.

4.3. The Risk and Business Planning Manager is responsible for the HFEA's Programme Management Office (the PMO), which runs the Programme Board. The PMO consists of the Risk and Business Planning Manager and one Programme Support Officer (PSO). The PMO/PSO gives frequent guidance and support to Project Managers on all aspects of project management, including the identification, reporting and management of project risks, and the identification of lessons learned at the end of projects, for future risk prevention purposes. The PMO provides a toolkit, including a risk log and other templates, and both corporate and personalised training for staff in project management methodology as needed.

4.4. One of the main sources of project risk within the HFEA is the amount and complexity of the interrelations between the HFEA's various systems and our legal and regulatory framework. The PMO therefore offers an interdependencies matrix tool to assist with good risk management at the early planning stage of a project. This is regularly reviewed and kept up to date to reflect any changes in our systems, information assets or structure.

5. Internal incidents

5.1. The HFEA's executive maintains an internal incident procedure, which ensures that any process failures are quickly and thoroughly investigated. This allows CMG to learn lessons and correct procedural vulnerabilities. All reported incidents are recorded, regardless of whether there was a need to investigate in order to understand what went wrong. This is to encourage a learning culture and transparent recording of perceived adverse events.

5.2. The process is relaunched periodically (the last such occasion being in June 2016) to remind new and old staff alike of the importance of identifying and learning from incidents, and to provide clarity to staff about reporting and investigating incidents.

6. Risk escalation

6.1. Where a risk changes or a new one arises where the impact is beyond the capability or capacity of the relevant team to control or mitigate it, or when it becomes a higher-level risk (for instance when a project risk threatens HFEA strategic delivery) it should be escalated. The escalation process depends upon the type of risk, the severity and urgency of it, and where in the organisation it has been recognised as an escalation issue.

6.2. Project risks recognised by the Sponsor can be escalated to the HFEA Programme Board. Programme Board can then report to CMG and highlight any action that is needed that is beyond the project team or programme board's power to implement.

6.3. Operational risks are escalated through monthly CMG meetings. There is a standing item on the agenda and Heads are responsible for raising new operational risks that have arisen and any that are becoming more severe. CMG are then able to note this or offer assistance in planning mitigations.

6.4. If either a project risk or an operational risk needs to be escalated quickly, or between meetings of the Programme Board or CMG, this can also be achieved through weekly SMT meetings, for expediency.

6.5. Severe or increasing strategic risk with high residual risk level and impact on delivery should be added to the strategic risk register. If the risk proximity, likelihood or impact are such that the risk requires immediate counter measures to be put in place, the Risk and Business Planning Manager, Head of Planning and Governance, and the individual raising the risk should consider whether a paper to CMG or a more immediate discussion with the Senior Management Team may be necessary.

6.6. Once the risk has been escalated, CMG or SMT will guide the risk owner to plan an appropriate approach to dealing with the risk. If necessary, additional reporting to AGC or the Authority can also be put in place.

7. Risk management methodology

7.1. The HFEA considers the following as the key stages of risk management:

- Identification

- Clear description
- Likelihood/probability of risk occurring
- Consequences and impact of the risk if it does occur
- What controls or actions can be put in place?
- What is the 'residual risk'?
- Is this tolerable or is a further action plan needed?
- Who is responsible?

7.2. When articulating risks, the HFEA follows the following principles:

- Risks should relate to objectives, and should also include generic risks which affect all objectives
- State risks, NOT impacts
- Avoid defining risks with statements which are simply the converse of an objective

7.3. In considering what controls can be put in place, the HFEA considers the following options, based on a common model:

- Tolerate the risk (ie, do nothing, but be aware)
- Treat the risk (ie, do something to actively reduce the risk)
- Transfer the risk (eg, to an insurer or contractor)
- Terminate (ie, stop doing the activity that causes the risk).

7.4. In setting out controls, the HFEA:

- Assigns internal controls to named individuals with authority to undertake or delegate the relevant actions
- Identifies specific actions
- Keeps on monitoring and reviewing residual risks and internal controls

7.5. In any grass roots review of risks, the HFEA considers the following factors:

External:

- PESTLE model:
  - Political
  - Economic
  - Social
  - Technological
  - Legal
  - Environmental

Operational:

- Delivery:
  - Service/product failure; project (delivery failure)

- Capacity and capability:
  - Resources (money, people, information and evidence, physical assets); planning; relationships (partners, clients, accountability); quality management; operational delivery (overall capacity and capability); reputation (confidence and trust in the organisation)
- Risk management performance and capability:
  - Governance (oversight and scrutiny, propriety, compliance, ethics, due diligence); scanning (failure to identify threats); resilience (capacity to withstand adverse impacts, business continuity); security (of assets and information)

Change

- Environmental changes and challenges
- New targets and performance indicators
- Change programmes
- New projects
- New policies
- Changes in resource availability

8. Assessing and estimating risk:

8.1. The HFEA defines 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.'

8.2. HFEA defines residual risk (also known as 'exposure') as:

> 'The exposure arising from a specific risk after action has been taken to manage it, and making the assumption that the action is effective.'

8.3. Any given risk score is a combination of:

- The likelihood of something happening
- The impact which arises if it actually does happen

8.4. Risk scoring system

We use a 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

The risk matrix can be seen below:

Risk scoring matrix

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

Risk Score = Impact x Likelihood

Likelihood

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	12
Paper number	[AGC (09/10/2018) 626 HC]
Meeting date	9 October 2018
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 strategic risk register at its meeting on 3 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, CS1, Cyber Security.

2. Recommendation

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

Latest review date – 13/09/2018

Strategic risk register 2018/19

Risk summary: high to low residual risks

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

* 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,⇧⇔⇩⇔).
Note: as of April 2018, SMT review the strategic risk register rather than CMG. It is circulated to CMG afterwards.

Recent review points are: AGC 12 June ⇨ SMT 2 July⇨ SMT 8 August ⇨ SMT 3 September

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

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

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
Below tolerance. As at the beginning of September, indications are that income is in line with the predictive income model and there has been a small increase in treatment cycles from last year; this risk is therefore stable. In September, SMT reflected that the inherent risk score did not feel as high as indicated, and so they reduced the inherent likelihood to 3, reducing the overall inherent risk score from 16 to 12. They did not change the residual risk score. Developments in the digital projects require an increase in capital spending in the 2018/19 budget and this was formally approved in August, meaning that development could continue as planned. All risks pertaining to this uncertainty have now been removed. We are confident we are able to work within this revised budget estimate.

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 established a model for forecasting treatment fee income and this reduces the risk of significant variance, by utilising historic data and future population projections. As at September 2018, the current receipts are within 1% of the model's forecast. 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 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. 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 – reserves policy to be reviewed by AGC in December 2018 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
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. Finance training was provided to all project managers to improve project budgeting following some very minor (less than £5,000) overspends. There has been a renewed focus on project budgeting at Programme Board from Q2.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Morounke Akingbola Ongoing – Wilhelmina Crown
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance leads to serious reputational risk and a loss of	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing and this includes engaging and networking with the wider government finance community.	Continuous - Richard Sydee

financial autonomy or goodwill for securing future funding.	All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation. As at September 2018 there is one litigation matter on the horizon (scheduled to be held in the high court in Autumn 2018).	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.	Accountability quarterly meetings (on-going) – Richard Sydee
	Annual budget agreed with DHSC Finance team alongside draft business plan submission. 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	**3**	**3**	**9 - Medium**
Tolerance threshold:					**12 - High**

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

Commentary

Below tolerance

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. Since we are a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level.

As at September, there are two main challenges relating to capability. Turnover remains uncomfortably high, even though the organisational change programme is complete. 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. Consequently, we are carrying a handful of vacancies, such as two vacant posts in the inspection team and in some areas, there is a tend towards over-reliance on key individuals. These causes and the mitigations we are employing are addressed below.

Work continues to improve the offer to staff, with the aim of increasing the likelihood of staff staying in post and developing at the HFEA, rather than leaving, although we are limited by wider government pay constraints. Elements of this include the PerkBox incentive scheme for staff buying and selling of annual leave policy and ongoing cultural change work.

Looking further ahead, we need to find ways to tackle the issues of pay and development opportunities, to prevent this risk increasing. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations.

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 has been written and this will be circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist written and 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
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. New intranet to be launched in Autumn 2018 should also improve communications.	In place, ongoing – Peter Thompson Autumn – Jo Triggs
	Staff survey results for 2017/18 informed the development of the people strategy. The all staff awayday in January 2018 gave staff a chance to feed back in further detail. The strategy was launched in April 2018. New benefit options have been implemented, including PerkBox and the development of a buying and selling of annual leave policy (launched July 2018).	Annual survey and staff conferences – Yvonne Akinmodun/ 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). We are re-launching our interdependencies matrix in autumn 2018, which supports the early identification of interdependencies in projects and other work, to allow for effective planning of resources.	In place – Paula Robinson Review underway autumn 2018 – 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 2018/19 -

	Agile approach to be brought into project processes under new project governance framework.	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 in Autumn 2018 – Dan Howard
Future increase in capacity and capability needed to process and assess licensing activity including mitochondrial donation applications. Since Summer 2017, we have experienced resource pressures relating to the Statutory Approvals Committee, caused in part by mitochondrial donation applications and also the increasing complexity and volume of PGD conditions.	Licensing processes for mitochondrial donation are in place (decision trees etc). An external review of the HFEA licensing processes has been carried out to assess current capabilities and processes and make changes for the future. A business case for a project to implement relevant proposals was approved by CMG in August and we are in the process of implementing the relevant proposals. To mitigate the present capacity and capability issues, the executive has signed up more experienced mitochondria peer reviewers, have received feedback on the process and have made administrative changes to improve it. This includes improvements to the application form, to prevent additional administration and/or unnecessary adjournments.	Licensing review implementation underway from September 2018 – Paula Robinson / Clare Ettinghausen
Implementing the People Strategy to maximise organisational capability will necessarily involve some team building time, developing new processes, staff away days to discuss new ways of working, etc. This will be challenging given small organisational capacity and ongoing delivery of business as usual.	A leadership awayday in November 2017 and an all staff awayday in January 2018 focused on building an HFEA culture following organisational changes. Small focus groups have since been utilised to make the most of staff time and involve wider staff in developing proposals. The next staff away day is planned for December 2018.	Ongoing – Yvonne Akinmodun
Following organisational change implementation and a period of churn, 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.	In progress – Peter Thompson In place – Yvonne Akinmodun

The new organisational model may not achieve the desired benefits for organisational capability Delay in completing our digital projects means that elements of the new model have not been fully implemented. It will therefore take more time for us to validate whether the changes have been effective.	The model will be kept under review following implementation to ensure it yields the intended benefits. The forthcoming staff survey will provide an opportunity for staff to reflect on whether change has been well managed. The results will help to inform any further actions related to the model.	A review of the new model was presented to AGC in June 2018. Staff survey in October 2018 – Peter Thompson
Failure to appoint new Authority members before existing members' terms of office expire, leads to loss of knowledge and impacts on formal decision making.	Confirmation for three new Authority appointments was received in July and a fourth new member was confirmed in September for appointment in January 2019. Training has been made available at the earliest opportunity to boost the capability of new appointees once in post.	In place – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC: The government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	We were proactive in reducing headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively in the past eg, the Triennial Review in 2016.	In place – Peter Thompson

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:					**6 - Medium**

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

Commentary
Above tolerance. Our IT policy review and our work on data migration is ongoing. The first trial load is being undertaken at present and the results will be known shortly. Penetration testing is scheduled ahead of system go-live in October / November 2018. There has been no evidence to suggest the national cyber risk has been further heightened. We continue to assess and review the risk and take action as necessary to ensure our security controls are robust and are working effectively. A cyber security audit was recently undertaken, the results of which are expected shortly. An internal incident in August, where a staff member's surface pro was lost was handled swiftly and professionally and there was no risk to sensitive data – the machine was encrypted and has been wiped of all data. We contacted the ICO to confirm our actions were suitable and they were very impressed with the controls we have in place.

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 Vice 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, and recommendations are being actioned and reported at each CMG Risk and AGC meeting. Fieldwork for a further cyber security internal audit report was undertaken in August. This will be reporting in Autumn 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 - Nick Jones/Dan Howard Ongoing – Dan Howard To occur Autumn 2018

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 first of three rounds of penetration testing has been completed. Two further rounds are planned before the service goes live.	Penetration testing underway throughout development and ongoing - Nick Jones/Dan Howard
There is a risk that IT demand could outstrip supply and so IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion.	We continually refine the IT support functional model in line with industry standards (ie, ITIL). As at September, an assessment of ticketing systems has taken place. Final checks are being undertaken on the preferred system. Alongside implementation we will introduce ways to capture user feedback. We have an agreement in place for additional support delivered by a third party. However, this is due to come to a close in autumn 2018. It is expected that for financial, continuity and stability reasons we will extend the contract for a further 6 months, at which point we will engage the market to seek a long-term provider. We will also continue to assess other options such as partnering with other organisations.	Approved per the ongoing business plan – Dan Howard Short term arrangement was finalised in May ongoing options are in the process of being reviewed.– 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. 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 As at September 2018, our 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.	In place – Dan Howard Results of penetration testing in May were positive. The new Register will be in use from Autumn 2018 – 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. Improved testing of the BCP information cascade to all staff was undertaken in September 2017 as well as a tabletop test and testing with Authority members. The next Business Continuity test is planned for September 2018. 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 annually – Nick Jones Undertaken monthly – Dan Howard The new Register cloud backup environment will come into use in Autumn 2018 - Dan Howard
The corporate records management system (TRIM) is unsupported and unstable and we are carrying an increased risk of it failing. The organisation may be at risk of poor records management until the new system is functioning and records successfully transferred.	A comprehensive review of our records management practices and document management system (TRIM) has started including the formation of a working group. A formal project will be initiated in October 2018 once initial scoping has been completed. We are continuing to manage the existing risk with the TRIM system by minimising changes and monitoring performance regularly. All staff have been reminded to continue to use TRIM to ensure records are complete.	Project to be delivered within 2018/19 business year – Peter Thompson
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 Q2, we are considering the Microsoft NHS information governance toolkit assessment, to consider whether the risk has changed and the controls remain effective.	In place – Dan Howard Being considered in Q2 – 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**
5	5	25 – Very high	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**

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
At tolerance. 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. Planning continues for the CaFC appeal hearing in October 2018. The Chief Executive has reached an in-principle agreement with the appellant to settle the case, although the question of the apportionment of costs remains unresolved. This may mean that the court case still goes ahead.

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	Ongoing – Catherine Drennan

	experience across other sectors can be applied to put the HFEA in the best possible position to defend any challenge.	In place – Peter Thompson
	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
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs. **Note**: Inspection rating on CaFC may mean that more clinics make representations against licensing decisions.	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 (next due March 2019) • 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 April 2018). As at September 2018 a project is being scoped to review and implement changes in the light of the findings of the final report of the licensing review, to make the licensing process more efficient and robust.	In place, licensing SOPs were refreshed in Q4 2017/18 and this will be further informed by the licensing review, implemented from September 2018 – 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

Involvement of the Head of Legal in an increased number of complex Compliance management reviews and related advice impacts other legal work.	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 will 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, Nick Jones
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 – 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 the Licensing review on specific legal points, so that improvements can be identified and implemented.	In place – Paula Robinson Being discussed and implemented Summer 2018 – 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 in the process of being reviewed Q3 2018/19 – 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, Nick Jones
Storage consent failings at clinics are leading to a significant diversion of legal resource and additional costs for external legal advice.	We have taken advice from a leading barrister on the possible options for a standard approach for similar cases. The Head of Legal made significant amendments to guidance in the Code of Practice dealing with consent to storage and extension of storage. This guidance should mean that clinics are clearer about their statutory responsibilities.	Done in Q1 2018/19 – Catherine Drennan Revised version of the Code comes into force Autumn 2018 – Laura Riley
GDPR requirements require a large number of changes to practice. If we fail to comply with the requirements, this could open the HFEA up to legal challenge and possible fines from the Information commissioner's office.	The GDPR project introduced a number of new and updated policies and processes, to ensure that the HFEA complies with the requirements. These will now be bedded into BAU to ensure that they are effective. The project has been handled proactively, with a joint HFEA and HTA project team and sponsored directly by the Director of Finance and Resources to ensure senior oversight. AGC have regular updates on progress.	Project ongoing until October 2018 - Richard Sydee
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.	In place – Peter Thompson

	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.	

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	**2**	**3**	**6 – Medium**
Tolerance threshold:					**6 - Medium**

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Regulatory effective-ness RE 1: Inability to translate data into quality	Nick Jones, Director of Compliance and 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
At tolerance. Data submission work continues at a good pace. Clinics are on course to be using the new system (PRISM) by Autumn.

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, with clinic implementation and access to it following by Autumn 2018. Oversight and prioritisation of any remaining development work will be through the IT development programme board.	Completion of data submission project Autumn 2018 – Nick Jones
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 which is being followed. The migration will not go ahead until agreed data quality thresholds are met. Work on the migration is broadly going to plan as at September 2018.	Autumn 2018 with regular reporting on progress prior to this – Nick Jones/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	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,	In place regular reviews to occur once the Register

fields which we do not currently focus on or deem critical for accuracy.	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.	goes live – Nick Jones
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 will provide greater resilience against unforeseen issues or incidents. As noted above, this short term solution is about to come to a close in autumn 2018. It is expected that for financial, continuity and stability reasons we will extend the contract for a further 6 months, at which point we will engage the market to seek a long-term provider. We will also continue to assess other options such as partnering with other organisations.	In place with work underway to improve arrangements in Autumn 2018 – 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. There are currently two vacancies in the inspection team which are being proactively addressed. The Business Support, team is now complete. In both cases there will be a period of bedding in.	In place – Nick Jones
Failure to integrate the new data and intelligence systems into Compliance activities due to cultural silos.	Work is underway in 2018 to further define and bed in HFEA culture in the light of organisational changes. The people strategy was agreed in spring 2018.	Ongoing, Q1 and 2 2018/19 - Yvonne Akinmodun
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. The Compliance management team are considering how to manage any centres with EPRS systems who are not ready to provide Register data in the required timeframe. This may include regulatory sanctions. Early engagement with EPRS providers means the risk of non-compliance is slim.	Plan in place to deal with any inability to supply data - Nick Jones
Data migration efforts are being privileged over data quality leading to an increase in outstanding errors	The Register team uses a triage system to deal with clinic queries systematically, addressing the most critical errors first.	In place – Nick Jones
	We undertake an audit programme to check information provision and accuracy.	In place – Nick Jones

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/teams 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 / Caylin Joski-Jethi
	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 that we do not get enough patient feedback to be useful / usable as soft intelligence for use in regulatory and other processes, or to give feedback of value to clinics.	The intelligence strategy focuses in part on making the best use of the information gleaned from patients, and converting our mix of soft and hard data into real outcomes and improvements. This includes a new patient survey being piloted in 2018 to give us qualitative and quantitative data on patient's experience of fertility treatment in the UK.	Plan to be developed following the pilot patient survey 2018 – Clare Ettinghausen /Caylin Joski-Jethi/Jo Triggs
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**

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
At tolerance. The last few months have seen us undertake several high-profile pieces of work to present more and better information to stakeholders, examples include the new egg freezing report, which will be published later in September, the Code of Practice consultation and various messaging around the 40th anniversary of IVF. The national patient survey pilot project has been developed with input and clear direction from the Intelligence Advisory Board which includes both Authority member representatives and external experts. This survey should provide data which will better inform HFEA information provision and other interventions. The results of this are due Autumn 2018. We are in the process of revisiting our stakeholder approach to ensure that this remains fit for purpose. This will be presented to the Authority in November 2018. A review of FOI processes and training has been undertaken. An action plan is being devised and implemented in Autumn 2018. We do not therefore believe that this risk has risen at this point in time. In Autumn 2018 we plan to review our external communications to ensure that these are effective.

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.	In place - Sharon Fensome-Rimmer, Laura Riley, and Jo Triggs

	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.	
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. The new publication schedule use HFEA data more fully and make 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. We are actively reviewing options for delivery of the Donor Conceived Register (DCR) to ensure the new service meets the needs of donor conceived people and is an improvement on the existing service. We have agreed a four-month rolling contract with The National Gamete Donation Trust (current service providers) until a decision is made on the new service to ensure a smooth transition. Due to the withdrawal of one of the potential providers for the new Donor Conceived Register (DCR) we have taken the decision to pause the current consultation. We had hoped to implement a range of proposed improvements to the DCR but this will temporarily be put on hold to ensure that any future options are viable. We will regularly measure the quality of service and effectiveness after go-live.	In place and reviewed periodically (next review due Winter 2018/19) – Jo Triggs Ongoing - Caylin In place – Laura Riley, Jo Triggs In place –Jo Triggs In place, although this standard is being phased out – Jo Triggs Interim arrangement in place and ongoing plans being considered Autumn 2018 - Nick Jones
We are not able to reach the right people with the right message at the right time.	We have an ongoing partnership with NHS Choices 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.	In place – Jo Triggs In place and ongoing – Jo Triggs In place - Laura Riley, Jo Triggs

	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 in order to ensure that they continue to meet our user needs.	In place– Jo Triggs Ongoing through Digital Communications Board meetings – 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/teams to deal with them. However, as at August 2018, organisational training is required in relation to FOIs. We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission. A future review of the FOI processes and procedures in the organisation is planned. This will include a review of general staff understanding of FOIs.	Ongoing training to be planned - Clare Ettinghausen Clare Ettinghausen /SMT - In place Clare Ettinghausen – to occur summer 2018
	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.	All staff ensure that public information reflects the latest knowledge held by the organisation. 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 - Caylin Joski-Jethi, Laura Riley, and Jo Triggs In place – Jo Triggs In place – Jo Triggs
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NHS Choices: Choices site and our site contain links to one another which could break	We maintain a relationship with the NHS Choices 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

Reviews and revisions

SMT review – September 2018 (03/09/18)

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

- LC1 – A full deep dive had been done with the CE and Head of Legal to reframe the risk in the light of comments from AGC. More would be known about the upcoming legal case by the end of September.
- C1 – A deep dive review of this risk would happen prior to AGC (13/09/18).

SMT review – August 2018 (06/08/18)

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

- FV1 – Departmental capital cover had been verbally confirmed by DHSC and the organisation was proceeding with the digital projects on this basis. Following earlier discussion about the process for flagging data submission issues to allow estimating of treatment volumes, the Director of Compliance and information confirmed the Compliance process had been reviewed and confirmed to be effective.
- CS1 – A full deep dive had been conducted prior to SMT, with the CIO and Director of Compliance. Particular updates were provided around controls, including penetration testing for the digital projects. The score was not changed.

SMT review – July 2018 (02/07/2018)

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

- Under FV1, SMT discussed the mitigation of estimating treatment volumes based on historic treatment data when no data was received from clinics. Some clinics had recently experienced this issue. Although the Director of Compliance and Information noted that this problem had been resolved for the affected clinics, further work was needed to ensure there was a truly effective process for flagging up such difficulties to relevant Compliance and Finance colleagues.
- SMT reconsidered the Capability risk and took the view that the inherent likelihood of this risk had reduced to 4, bringing the overall inherent risk to high (16) and the residual risk reduced to medium (9) as a result. SMT agreed that the pending confirmation of Authority appointments was a risk since the term of office of one Member finished on 23 July. If an appointment was not made in a timely manner then this could become a real capability issue, however, mitigations included temporarily appointing an existing Member to the LC and ensuring that relevant training was available as soon as the appointments were made would help mitigate the risk. This risk was being managed closely and the impact would be considered if appointments were not made by mid-August. The key meetings potentially impacted would be Licence Committee and Authority and neither would meet again until September (following the 12 July LC).
- Cyber-security. SMT noted the next BCP test would be in September 2018. The CIO team were discussing ways to ensure the effective management of IT expertise to maintain operational support for the systems which were awaiting improvements and which may be less reliable. A full deep-dive review of this risk would take place later in July.
- Legal risk – SMT discussed the comments raised at AGC about the formation of the risk and the need to reflect the possible negative impact of legal cases upon the organisation's reputation which could severely impact the organisation's ability to function effectively. SMT agreed that the risk could do with a full review and the Risk and Business Planning Manager and Chief Executive would do this at a separate meeting and circulate to SMT for further discussion.
- RE1 – SMT noted that discussions are underway in July 2018 to consider how best to manage the audit programme while experienced audit resource is allocated to the digital projects work and another experienced member of the Register team leaves the organisation in August.
- ME1 – SMT noted that several changes had been made to this risk during a deep dive, though this did not affect the score.

Criteria for inclusion of risks

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

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

Rank

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

Risk trend

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

Risk scoring system

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

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

Risk scoring matrix

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

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

System-wide risk interdependencies

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.

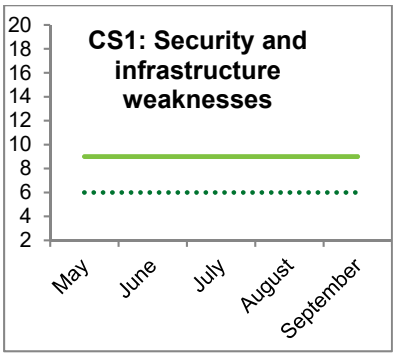
Contingency actions

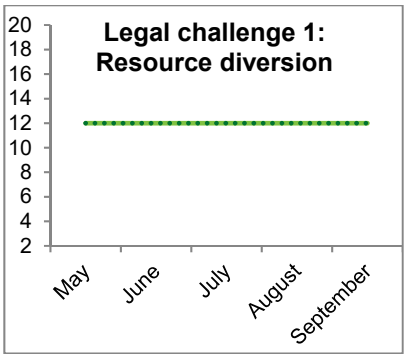
When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be 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.

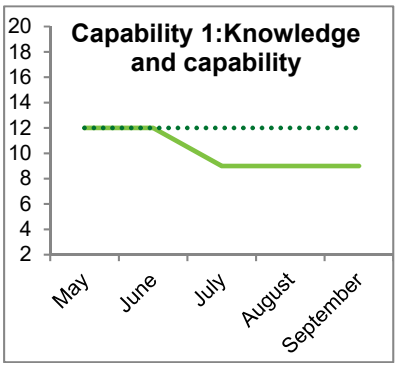
Risk trends

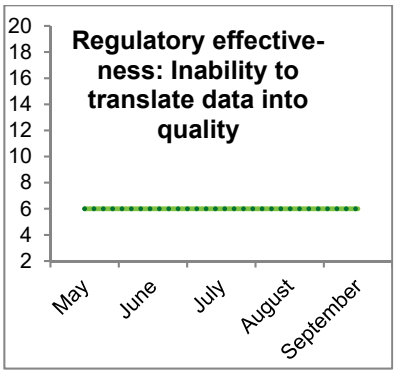
High and above tolerance risks

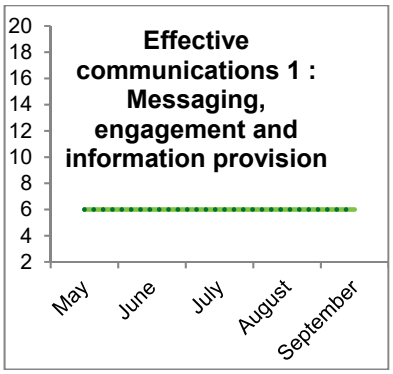


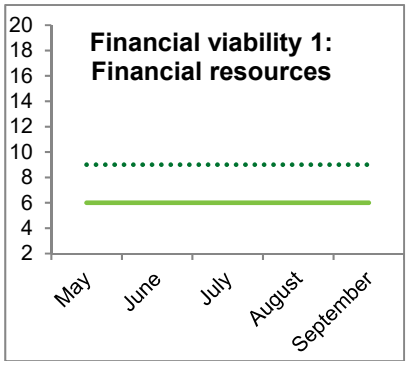


Low and below tolerance risks









Technical guidance - Tissues and Cells in a no Brexit deal scenario

Strategic delivery:	**X** Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	13		
Paper number	HFEA (09/10/2018) 627		
Meeting date	9 October 2018		
Author	Peter Thompson, Chief Executive		
Output:			
For information or decision?	For information		
Recommendation			
Resource implications			
Implementation date	DD Month YYYY		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High
Annexes	Annex 1: DHSC Technical Guidance - Quality and safety of organs, tissues and cells if there's no Brexit deal		

1. Background

1.1. On the 22 August 2018 the Government released 25 technical notices relating to planning for a scenario in which the United Kingdom leaves the European Union without agreement.

1.2. The notice attached at annex A highlights the possible implications of a no deal scenario on the ability of UK establishments to access and use organs, tissues and cells (including reproductive cells).

2. Analysis

2.1. The documents sets out two key points

- That in a no deal scenario on 29 March 2019 tissues and cells from the UK would meet the current EU safety and quality standards.
- After exit day, the UK and EU countries would consider each other as third countries, and that written agreements would need to be made to import and export tissues and cells for human use between EU countries and the UK.

2.2. We believe that this worst case scenario does not represent a significant short term risk to the sector. Third party agreements are already in place with non EU countries and licensed establishments could quickly establish third party agreements with any relevant EU establishments in order to continue their access to imported gametes.

2.3. The Government plans to publish further information in November 2018, when the likely outcome of negotiations may be clearer. We will bring further guidance to the Audit and Governance Committee at the December meeting.

GOV.UK

Quality and safety of organs, tissues and cells if there's no Brexit deal

Updated 14 September 2018

Contents

A scenario in which the UK leaves the EU without agreement (a 'no deal' scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential 'no deal' outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a no deal scenario would have to be accelerated. Such an acceleration does not reflect an increased likelihood of a 'no deal' outcome. Rather it is about ensuring our plans are in place in the unlikely scenario that they need to be relied upon.

This series of technical notices sets out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario, so they can make informed plans and preparations.

This guidance is part of that series.

Also included is an overarching framing notice explaining the government's overarching approach to preparing the UK for this outcome in order to minimise disruption and ensure a smooth and orderly exit in all scenarios.

We are working with the devolved administrations on technical notices and we will continue to do so as plans develop.

Purpose

The purpose of this notice is to set out to organisations, businesses and members of the public the actions they should consider taking, to ensure continued access to and use of organs, tissues and cells, including reproductive cells, in the unlikely event that the UK leaves the EU in March 2019 with no agreement in place.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

Organisations may also wish to consider other relevant notices, including Ensuring blood and blood products are safe if there's no Brexit deal, Batch testing medicines if there's no Brexit deal, How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal, Submitting regulatory information on medical products if there's no Brexit deal.

Before March 2019

The EU has a common set of standards to ensure the quality and safety of:

- organs for transplantation, and
- tissues and cells for human use, including reproductive cells

The UK regulatory frameworks set high standards and are taken from a number of EU directives. These regulations cover issues such as obtaining, testing, processing, storing and tracing organs, tissues and cells.

UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics that undertake licensable activities working in this area are regulated by:

- the Human Tissue Authority (HTA) for organs, tissues and cells other than reproductive tissues and cells
- the Human Fertilisation and Embryology Authority (HFEA) for reproductive tissues and cells

At present some organs, tissues and cells move between the UK and EU countries, but also between the UK and non-EU countries (third countries).

Only a small number of organs are shared with EU and non-EU countries:

- 22 organs from deceased donors came into the UK from the EU in 2017/18
- 26 organs left the UK in 2017/18, with 19 going to the EU and 7 to non-EU countries

Tissues and cells (for example bone, heart valves and corneas) are imported from and exported to EEA countries less often than they're imported and exported from and to countries outside the EEA.

The UK imports donated sperm, primarily from commercial sperm banks in the USA and Denmark. Approximately 4,000 samples were imported from the USA and 3,000 samples from Denmark in 2017, as well as a small number from other EU countries. Imports of eggs and embryos are far less common (usually fewer than 500 a year) and come mostly from EU countries.

After March 2019 if there's no deal

If there's no deal, the EU Organ Directives and EU Tissues and Cells Directives would no longer apply to the UK. UK law already implements the EU directives, so the safety standards would not change. The UK would, however, become a 'third country' and the law would be amended under the EU (Withdrawal) Act to reflect this change.

UK licensed establishments working in this area, such as hospitals, stem cell laboratories, tissue banks and fertility clinics would continue to work to the same quality and safety standards as they did before exit but some would need new written agreements with relevant EU establishments. UK licensed establishments that import or export tissues or cells from EEA establishments would need to make written agreements with those EEA establishments to continue importing or exporting these products post-exit. However, this will for the most part be a minimum burden on industry.

For example, UK licensed establishments that already hold an import licence to import tissues and cells from third countries will be able to use their existing written agreements with third country organisations as a template.

What you would need to do

Members of the public

These changes will not affect the availability of organs or the safety or quality of organs, tissues and cells in the UK as the current standards will be maintained.

Organs for transplantation

NHS Blood and Transplant (NHSBT), which is the organisation responsible for organ donation and transplantation in the UK, is currently working with the UK regulator for organs, the HTA, to ensure that appropriate written agreements are in place with EU

organisations to allow organ exchange to continue post-exit. Transplant centres do not need to take any further action.

If there's no deal, on 29 March 2019 the UK would meet the current EU safety and quality standards for organs, and these would be traceable from donor to recipient and from recipient to donor.

After exit day, the UK and EU countries would consider each other as third countries. The EU directive 2010/53/EU allows for organ exchange between EU countries and third countries. Organisations that currently exchange organs can make written arrangements to ensure organs can still move between the UK and EU countries.

Tissues and cells for human use, including reproductive cells

If there's no deal, on 29 March 2019 tissues and cells from the UK would meet the current EU safety and quality standards.

After exit day, the UK and EU countries would consider each other as third countries. The EU directives 2004/23/EC and 2015/566 allow for written agreements to be made to import and export tissues and cells for human use between EU countries and third countries. The details of what these written agreements cover are set out in EU directive 2015/566. Licensed establishments that import or export tissues or cells would need written agreements with the relevant EU licensed establishments to continue importing and exporting. UK licensed establishments that already hold an import licence to import tissues and cells from third countries can use their existing written agreements with third country organisations as a template. Licensed establishments are recommended to consult the HTA and HFEA for more information. Further information on the agreement process will be published in November.

The government continues to plan for all negotiation outcomes, and will make the necessary changes to national regulations to maintain day one operability for the import and export of organs, tissues and cells in the unlikely event there is no agreement between the UK and the EU.

More information

We'll be publishing more information and instructions on putting written agreements in place in November 2018. The aim is to give organisations, businesses and individuals as much certainty as possible, as soon as possible, and to ensure that any new requirements are not unduly burdensome.

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North-South cooperation between Northern Ireland and Ireland, which we're committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government have indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU Member States. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK-EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we'll take full account of the unique circumstances of Northern Ireland.

Norway, Iceland and Liechtenstein are party to the Agreement on the European Economic Area and participate in other EU arrangements. As such, in many areas, these countries adopt EU rules. Where this is the case, these technical notices may also apply to them, and EEA businesses and citizens should consider whether they need to take any steps to prepare for a ‘no deal’ scenario.

Audit and Governance Committee Forward Plan

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	15		
Paper number	AGC (09/10/2018) 629		
Meeting date	9 October 2018		
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 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:	6 Mar 2018	12 Jun 2018	9 Oct 2018	4 Dec 2018
Following Authority Date:	9 May 2018	27 Jun 2018	14 Nov 2018	Jan 2019
Meeting 'Theme/s'	**Finance and Resources**	**Annual Reports, Information Governance, People**		**Register and Compliance, Business Continuity** **Strategy & Corporate Affairs, AGC review (deferred from 9 October meeting)**
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
Information for Quality (IfQ) Prog	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc 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		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Update	Results, annual opinion approve draft plan	Update	Update

AGC Items Date:	6 Mar 2018	12 Jun 2018	9 Oct 2018	4 Dec 2018
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
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
Cyber Security Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Estates		June	Yes	Yes
General Data Protection Act (GDPR)			Yes	Yes
Review of AGC activities & effectiveness, terms of reference	Yes			Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				HFEA Risk Policy