Audit and Governance Committee meeting - agenda

4 December 2018

Abbey Room

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

	Agenda item		Time
1.	Welcome, apologies and declaration of interests		10:00am
2.	Minutes of 9 October 2018 **[AGC (04/12/2018) 632]**	For Decision	10.05am
3.	Matters Arising **[AGC (04/12/2018) 633 MA]**	For Information	10.10am
4.	Strategy and Corporate Affairs **[AGC (04/12/2018) 634 CE]**	Presentation	10.15am
5.	Internal Audit a) Audit Recommendations Follow-Up **[AGC (04/12/2018) 635 DH]** b) Progress Report **[AGC (04/12/2018) 636 DH]**	 For Information For Information	10.40am
6.	Implementation of Audit Recommendations **[AGC (04/12/2018) 637 MA]**	For information	10.50am
7.	External Audit – Audit Planning Report **[AGC 04/12/2018) 638 NAO]**	For Information	11.00am
8.	General Data Protection Regulation Update **[AGC 04/12/2018) 639 RS]**	Verbal	11.10am
9.	Digital Programme Update **[AGC ((04/12/2018) 640 DH]**	For Information	11.20am
10.	Resilience, Business Continuity Management and Cyber Security **[AGC (04/12/2018) 641 DH]**	For Information	11.35am

11.	HR Issues Organisational Capability and HR Report **[AGC (04/12/2018) 642 PT]**	For Information	11.50am
12.	Brexit **[AGC 04/12/2018) 643 PT]**	Verbal Update	12.10pm
13.	Estates **[AGC (04/12/2018) 644 RS]**	Verbal Update	12.15pm
14.	Strategic Risk Register **[AGC (04/12/2018) 645 HC]**	For Discussion	12.20pm
15.	Reserves Policy **[AGC (04/12/2018) 646 RS]**	For Information	12.30pm
16.	AGC Forward Plan **[AGC (04/12/2018) 647 MA]**	For Decision	12.35pm
17.	Whistle Blowing and Fraud **[AGC (04/12/2018) 648 RS]**	Verbal update	12.40pm
18.	Contracts and Procurement **[AGC (04/12/2018) 649 MA]**	Verbal update	12.45pm
19.	Review of AGC activities and effectiveness Terms of reference **[AGC (04/12/2018) 650 PR]**	For discussion (Members Only)	12.50pm
20.	Any other business		12.50pm
21.	Close (Refreshments & Lunch provided)		1.00pm
22.	Session for members and auditors only		1.00pm
23.	Next Meeting 10am Tuesday, 5 March 2019, London		

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 (04/12/2018) 632		
Meeting date	4 December 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 9 October 2018

HFEA Offices, 10 Spring Gardens, London SW1A 2BU

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 Jill Hearne
Observers	Kim Hayes, Department of Health and Social Care Samantha Hayhurst, Department of Health and Social Care
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 Caylin Joski-Jethi, Head of Intelligence 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 12 June 2018

2.1 The minutes of the meeting held on 12 June 2018 were agreed as a true record of the meeting and approved for signature by the 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 the investigation had now concluded and an agreement with the contractor had been reached; this item could be removed from the matters arising log.

3.3 6.6,12.8 and 3.9) The Committee noted that a training session, providing an overview of NAO work, was scheduled to occur after the meeting. The Chair stated that training on managing risk and fraud, alongside the three lines of defence would be beneficial. It was agreed that a training session, concerning the three lines of defence would be timetabled to occur after the 4 December 2018 or 5 March 2019 meeting, depending on the Committee's availability. The Committee Secretary would contact members regarding a date for this training. These items could be removed from the matters arising.

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 3.8 and 3.11) The Head of Planning and Governance confirmed that all Authority members had completed their cyber security and information security training, with the exception of new members. It was suggested that an annual reminder is sent to members, coinciding with the yearly review of Committee activities and effectiveness. The Chair agreed this would be a useful mechanism for checking members are undertaking the necessary training. It was agreed these items can be removed from the matters arising.

3.6 9.10, 9.11 and 9.12) The Committee agreed that these points, relating to the Digital Programme and PRISM, should be retained as the issues remain ongoing.

3.7 The Committee agreed that items 8.15, 12.5, 3.10, 3.12, 3.13, 6.12, 6.13, 7.7 and 11.11 can be removed from the matters arising log as the issues raised had been addressed.

Action

3.8 The Committee Secretary to contact members regarding availability for training after the meeting on 4 December 2018 or 5 March 2019.

4. Internal Audit

a) Progress report

4.1 The Head of Internal Audit stated that the draft report on cyber security would be finalised in October 2018. Work on the remaining audits regarding business continuity, the GDPR and anti-fraud controls were yet to commence, but these would be completed within the year.

4.2 The Head of Internal Audit commented on the payroll and expenses review, noting this had resulted in a moderate rating, with areas for improvement identified, although broadly a good picture had been acknowledged. All the recommendations made in the report had been accepted by the Authority.

4.3 The Committee particularly noted the recommendation made in the report concerning the health and safety of employees driving for prolonged periods and high mileage particularly when they may be under personal or family pressures to return home on the same day. The Director of Finance and Resources reported that a driving at work policy had been presented, and approved, by the Corporate Management Group (CMG); this deals with issues including excessive mileage, ensuring drivers take the appropriate breaks. The policy also removed the ability for staff to make expenses claims for colleagues.

4.4 The Director of Compliance reported that a majority of inspectors travel by train, but some did drive. The Committee suggested it might be beneficial to speak to individuals about the best

mode of travel being by train, if this was feasible for the journey; the Director of Finance confirmed this was clearly stated in the policy.

4.5 The Director of Finance and Resources informed the Committee that the recommendations pertaining to payroll were relatively straight forward. All the recommendations made in the report would be dealt with, and implemented, by the end of the year.

4.6 The Chair stated the payroll and expenses audit has been extremely helpful, giving this area beneficial external scrutiny and recommendations to act upon.

5. Implementation of recommendations

5.1 The Head of Finance reported on the progress with audit recommendations, stating that with regard to data loss, the Senior Inspector (Information Quality) would move into his new post later in 2018. The Chief Information Officer reported that a formal proposal, to establish an Information Governance post within the CIO team, will be considered by the Senior Management Team (SMT) in October 2018, and that the data loss level of risk for the Authority is not high. The acceptable usage policy had been presented to CMG in June 2018 and approved, subject to some minor amendments.

5.2 The Committee acknowledged that all mandatory staff training was completed last year and the new People HR system went live on 17 September 2018.

5.3 The Chief Executive suggested that issues surrounding staffing and capability should be discussed at the next Audit and Governance Committee meeting. The new HR system would enable a series of reports to be extracted i.e., training undertaken and movement of staff. The annual staff survey would be circulated imminently, and information gained from exit interviews would be amalgamated. A discussion with the Authority on HR issues, including staff turnover, was also scheduled.

5.4 The Chair stated it would be interesting to explore the causes for the high staff turnover, comparing this with similar healthcare organisations and considering the risks to the Authority. It was important to acknowledge the extent to which the new organisational structure had been embedded, looking at the risks removed and those which are current. The Chief Executive stated that, typically staff remain with the Authority for four to five years, following the same pattern as many other organisations. However, the ongoing turnover of staff does leave a meaningful hole in small organisations. The Chair stated the need to understand the drivers for staff leaving the Authority and the availability of career pathways.

Action

5.5 The Committee to receive a paper on staffing and capability at the 4 December 2018 meeting.

6. External Audit – audit planning report

6.1 The NAO reported that Jill Hearne had taken over Sarah Edward's position, dealing with external audit for the Authority.

6.2 The Committee noted that a meeting between the NAO, the Head of Finance and the Director of Finance and Resources would be scheduled to discuss the formal planning.

7. General Data Protection Regulation update

7.1 The Director of Finance and Resources reported that two large pieces of GDPR work remained outstanding, but these did not pose any risks to the Authority.

7.2 The Director of Finance and Resources informed the Committee that, due to the current document management system being outdated, it was a complex exercise to work through documentation for destroying and retaining. CMG had agreed a new document management system would be required, and once implemented, consideration of exactly which information needs to be migrated can be conducted. Due to this, the Authority is not totally compliant with the GDPR at present, but SMT is comfortable with this, as an interim position, whilst a new document management system is implemented. Policies, regarding the holding of data, also need to be aligned. Finance for a new document management system, which would cost £160K over a five-year period, is still to be agreed. it is anticipated that the Authority will be compliant with the GDPR in April/May 2019.

7.3 The Department of Health and Social Care (DHSC) stated that the new Secretary of State has an interest in the GDPR across the health sector, particularly regarding the Arm's-Length Bodies (ALBs), noting that compared to other similar organisations, the Authority is well placed with regards to implementing these regulations. The Chair stated the importance of the Authority being fully compliant with the GDPR; there needs to be a plan to ensure this happens.

7.4 The Committee noted that the Authority and the Human Tissue Authority (HTA) discuss GDPR issues at their formal joint project group meetings.

7.5 The Director of Finance and Resources reported that a further update would be provided at the next Committee meeting. The NAO stated that the GDPR would need to be considered in the Governance Statement, which was likely to be presented to the Committee at the 5 March 2019 meeting.

8. Digital Programme update

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

8.2 The Committee was informed that significant and substantial progress has been made over the summer, noting the update, circulated to members, in September 2018. There had been positive feedback after the launch of the preview system, capital approval for £500k had been granted by the DHSC, PRISM development was progressing well, the infrastructure was ready to accept the new register and system, and the communications strategy remained ongoing. Approval to proceed, from the Committee, would only be sought once development, user/performance testing and data migration checks had all been satisfactory completed. The Chief Information Officer reported there had been some slippage on the PRISM 'inventory' work but a soft launch should occur on 29 November 2018.

8.3 There were two stages of data migration; transfer and analysis of data (quality metrics, Choose a Fertility Clinic). Stage one is advancing well and there have been some small discrepancies in the data for registrations, outcomes and early outcomes, which are being worked through for resolution. There are very few differences with the data transferred for IVF and DI Cycles. It was not expected that 100% accuracy would be reached for all data sets. The Committee expressed some concern regarding risks to patients, in light of the data issues. The Chief Information Officer provided assurance that the risk was minimal and where necessary for a period after go-live,

additional manual checks would take place, for example relating to Opening the Register requests.

8.4 Regarding PRISM/EPRS development, 'bug' resolution was ongoing, the 'view and edit' module should be completed within four weeks and there had been good engagement with the sector.

8.5 The Committee noted that the programme is delivering on target with the financial forecast being £456,070 against the capital budget of £500k. However, it was acknowledged that this capital budget also needed to cover other IT related work, apart from PRISM.

8.6 The Chief Information Officer stated that the soft launch would incorporate a small group of clinics, including some that use third party systems. Feedback would be analysed prior to the hard launch of PRISM.

8.7 The Committee was notified that a new Lead Developer had unfortunately needed to leave the Authority for personal reasons. An interim service is being sought to help cover the medium term work.

8.8 Reassurance was provided that there had been no significant issues with system bugs and any issues arising were being fixed on an ongoing basis. The Director of Compliance and Information stated that the investment on bug testing, early in the project, had been extremely valuable.

8.9 The Chair spoke of the quality and risk issues associated to data migration, questioning the business impact of inaccurate statistics. The Chief Information Officer stated that, although it should be sought, data migration correctness would never reach 100%, noting that data quality inaccuracies are always present for example occurring through typing errors.

8.10 The Chief Executive stated that the current system held over twenty-five years of data, noting the importance of this aggregated information. However, the information, collected by the clinics, during the last three years, is of greater significance. Noticing that the gamete movement out statistics, attained from the data migration, is low, the Chief Executive recognised that complete accuracy for all information gathered, does not matter enormously.

8.11 The Director of Compliance and Information stated the need to be clear on the consequences of the discrepancies identified and these need to be considered at the point of decision for the launch of PRISM. The Committee would receive a full matrix, regarding the data migration, before the launch date.

8.12 The Committee would receive a further paper, providing updated detail on the digital programme, which would be followed up with a teleconference with members, prior to the launch of PRISM, to attain approval to proceed.

Action

8.13 The Committee to receive a further paper on the digital programme, which would be followed-up by a teleconference, prior to the launch of PRISM, to attain approval to proceed.

9. Resilience, business continuity management and cyber security

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

9.2 The Committee noted that it was proposed that the Register would be moved from the Authority's server to Microsoft Azure. This would provide a range of benefits including security, cost

effectiveness, scalability, backup and disaster recovery, alongside compliance. A design had been approved in conjunction with third parties and the final approval should occur as part of the approval to proceed in November 2018.

9.3 The Chief Information Officer spoke of a recent incident whereby a PGD application, submitted by a clinic on the Clinic Portal, did not give rise to an alert through Epicentre, which is the usual process to trigger the processing of applications. This resulted in several potential consequences including a delay to patient treatment, with a risk of breaching the deadline for the patient's funding. In order to address this risk, an extraordinary meeting of the Statutory Approvals Committee was held, with the agreement of the Chair and members. The incident was fully investigated and was found to be due to faulty software code and system functionality on Epicentre. The Committee was informed that although no other applications had been caught up in the same issue, a script had been developed to check that there are no other incidents of this nature and this is run on a weekly basis. The Chair of the Statutory Approvals Committee felt the Executive had initially been slow in responding to this incident, but that she and the Committee were fully supportive of the additional meeting, which had then been arranged and run well. She reported the Committee commended staff for the extra work involved.

9.4 On 23 August 2018, an encrypted laptop was left on a train by a staff member. This was immediately reported to the station, to the relevant line-manager and the IT team. A wipe command was immediately sent to the laptop. It was acknowledged that the device was fully encrypted so the risk of data breach was subsequently very low. The Data Protection Officer at the HTA was informed, in accordance with protocol, and the ICO contacted. Following this incident, a reminder on good practice, when travelling with an Authority device, was issued.

9.5 The Chief Information Officer reported on upgrades being made to the telephone and video-conference system at the Authority's Spring Gardens offices. The old infrastructure and network connection are nearing capacity and there have been persistent call quality issues. CMG had approved an upgrade to the voice/Skype service from Microsoft alongside a significant upgrade to the network link, from 100Mbs to 200Mbs. This system should be fully functional by 31 December 2018.

9.6 The Chair spoke of unreliability of the current system, particularly evident at Licence and Statutory Approvals Committee meetings, questioning whether the extent of the causes is entirely known, whether the planned changes will be sufficient and cost effective, particularly in light of the office move in 2020, and what contingency will be in place. The Chief Information Officer stated that the planned changes are fundamental, a whole selection of causative issues had been considered and third-party consultation had occurred. However, categorical assurance that the upgrade will address all problems and that there will be no further issues, cannot be given at this stage.

9.7 The Committee felt that some of the issues may lie with participants joining the conference calls from outside the office. They need advice and support in the use of equipment, minimum system requirements, and reminders not to use mobile phones for important meetings where quoracy needs to be maintained. The Director of Compliance and Information agreed that meeting participants need to be aware of the minimum system requirements required to attend meetings externally, acknowledging that different people, using different devices, from different locations, can be difficult to handle under any system.

9.8 The Chief Executive stated that the investment in these upgrades was not significant and particularly needed, as it is unrealistic for individuals to travel to meetings in person on a regular basis. The new systems would only be used for formal meetings once there was substantial

confidence in them. The Chief Information Officer reassured the Committee that the upgraded network would only be paid for whilst the Authority remains in occupancy at Spring Gardens.

9.9 In conclusion, the Chair stated the importance of managing expectations with regards to telephone and video conferencing. Training or advice, and contingency plans, are crucial.

10. Estates update

10.1 The Director of Finance and Resources reiterated that the contract at Spring Gardens concludes in November 2020. The Authority sublets space from The National Institute for Health and Care Excellence (NICE), within the British Council building.

10.2 An offer had been made for the Authority to join NICE in Stratford. The DHSC had initialised a programme for the move of ALBs, and both hubs at Stratford and Canary Wharf were for consideration, although Stratford was preferred. Moving to Croydon had been discounted. It was noted that 75% of hubs had already moved out of the South-East.

10.3 A formal business case must be submitted in November 2018 to the DHSC, setting out the space required by the Authority. Several factors would be considered, including the cultural way of working and need for sufficient meeting facilities to conduct core statutory business. Discussions were occurring with other ALBs including NICE and the HTA, all of which are public facing bodies. The move would need to be signed off by the DHSC.

10.4 The Chair stated that the principal moving choice would be a decision for the main Authority, but scrutiny of the detailed planning is for the Committee's agenda. The consultation of staff was considered to be a crucial aspect, particularly as there is already a high level of turnover. Investigation needs to be made as to where staff live to ascertain whether Stratford is more accessible then Canary Wharf.

10.5 The Committee considered the risks associated with attracting staff with the required skills, particularly in relation to inspections, following the move, and whether the DHSC hubs would possibly facilitate future recruitment opportunities between co-located bodies. It is important to consider the Authority's business model and how any chosen relocation would support this. The Chief Executive stated that common techniques are used by inspectors across a variety of bodies.

10.6 Committee members also raised points regarding the Authority's commonalities with other ALBs, whether there would be scope for staff development opportunities as a result of working in this new environment, the possibility of sharing services, and whether Stratford is a suitable location for the organisation's Headquarters.

10.7 The Director of Finance and Resources stated there would be a 60% desk ratio at the proposed hub and this raised questions pertaining to staffs' capability to work at home. There is a significant risk that many staff will leave their positions before the move occurs, or within in year afterwards. There was no particular desire to share services like Human Resources, but the integration of some areas might be beneficial and provide some resilience.

10.8 On the basis that the business case would be presented to the DHSC in November, an update would be provided at the 3 December 2018 meeting, with more substantial information shared at the 5 March 2019 meeting. The Authority would receive an update at their meeting in January 2019.

11. Risk policy

11.1 The Risk and Business Planning Manager spoke to the paper and presentation, giving the Committee an update on the revised risk policy.

11.2 The policy was first drafted and then reviewed by the Committee in June 2014. Since this time, some changes have been made including revised roles and responsibilities and responses to internal audit recommendations, such as including more information on risk tolerance. Although assessments of risk tolerance were done for individual risks at each risk review, the statement of overall risk appetite had not been formally reviewed in a long time. As this should be confirmed periodically, it was intended this would be presented for consideration at the 14 November Authority meeting.

11.3 The Committee noted the risk system plan for 2018, which included the relaunch of the internal incident process, collaborative working with the HTA to plan risk training for both organisations and advanced training for key risk staff. Ongoing work included support for operational risk management and engagement with risk networks.

11.4 The Committee had some discussion about point 2.3.3. of the risk policy, regarding risk appetite and tolerance, particularly how much control the Authority actually has over its risk environment. Overall, it was felt the risk policy takes a sensible approach and the emphasis on management is well placed. It was identified that there are some areas of strong appetite, with particular reference made to the risks of regulating new techniques, such as mitochondrial donation. However, it was also pointed out these are areas which still bring the potential for legal challenge.

11.5 Risk tolerance in relation to Authority policy was discussed. It was noted that we are averse to risks which threaten our ability to perform our statutory regulatory functions, but as processes and scientific developments become more innovative, the Authority must also be willing to take more innovative approaches in some areas, and we must consequently tolerate greater risk, as the potential benefits outweigh the threats.

11.6 Following the presentation of a slightly updated version of the risk policy to the Authority, the Risk and Business Planning Manager would circulate a final copy to the Committee.

Action

11.7 The Risk and Business Planning Manager to circulate a final version of the risk policy to the Committee, following the 14 November Authority meeting.

12. Strategic Risk Register

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

12.2 The Committee noted that SMT reviewed the strategic risk register on 3 September 2018. At present, only one of the six risks, cyber security, is above tolerance.

12.3 Confirmation was provided, that since the last Committee meeting, the formulation of the legal challenge risk had been discussed and updated. Acknowledging that this risk is not only about resources, but also reputation, the new formulation provides a wider perspective. The Risk and

Business Planning Manager stated that with regard to the capability risk, further data and commentary would be presented in due course.

12.4 As stated at the last Committee meeting, Brexit was not considered to be a strategic risk for the Authority. However, as this event becomes closer, it may require more active management. The Committee felt that Brexit and estates should both be reflected in the strategic risk register, noting they have the capacity to impact on the organisation and staffing respectively.

Action

12.5 The Risk and Business Planning Manager to ensure Brexit and estates are reflected in the strategic risk register.

13. Brexit

13.1 The Chief Executive informed the Committee that technical notices were being issued by the government relating to planning for a scenario whereby the United Kingdom leaves the European Union without an agreement. Should this occur, the UK would be considered a third country.

13.2 The Government notice entitled 'Quality and safety of organs, tissues and cells if there's no Brexit deal' discusses systems that would need to be in position, for the import of gametes, if there is no Brexit agreement. The Chief Executive stated that safety of transfer for gametes would not be affected, but the process will become more bureaucratic. This guidance had been communicated to centres through Clinic Focus; communication with centres is crucial and will be ongoing. With regard to EU ITE certificates for imports, many centres had not yet complied with the guidance for applications, resulting in numerous applications initially giving insufficient information, often regarding third-party agreements, and having to be returned for further work.

13.3 The DHSC stated that work is still continuing on a 'no deal' scenario and the necessary regulations will be sent to the Authority imminently for discussion; there should be no areas of concern. These regulations will be laid before Parliament in November 2018. Some concern was raised, that should the 'no Brexit deal' text be unclear, any essential agreements would not be signed until after the United Kingdom's Departure from the European Union. Clinics need to be aware that draft agreements must be drawn up, in preparation, should this situation arise.

13.4 The Chair stated the importance of communicating information to centres concerning Brexit, but also ensuring this is conducted in a timely manner, and not at too early a date. As patients are at the centre of the Authority's business, reputational damage could occur if an application was unable to be processed due to Brexit. There is a need to be equipped to respond to several different Brexit scenarios, therefore requiring internal contingency planning.

13.5 Members agreed that it would be beneficial to receive an update on Brexit at each Committee meeting. This would be added to the forward planner.

13.6 Action: Brexit to be added to the forward planner as a standing item.

14. Legal risks

14.1 The Chief Executive provided an update on legal risks and this was noted by the Committee.

14.2 Further information will be given at the 4 December 2018 meeting.

15. AGC forward plan

15.1 The Chair noted that the reserves policy and Strategy and Corporate Affairs items had been deferred to the 4 December 2018 meeting. Owing to the risk policy being discussed at the present meeting, this could be removed from the forward plan. As previously discussed, Brexit would be added to the forward plan as a regular agenda item.

16. Whistle blowing and fraud

16.1 The Director of Finance and Resources informed the Committee there were no cases of whistle blowing or fraud to report since the last meeting.

17. Contracts and procurement

17.1 The Head of Finance reported there were no issues, new contracts let or procurement to report since the last meeting.

18.Any other business

18.1 Members and auditors retired for their confidential session.

18.2 The next meeting will be held on Tuesday, 4 December 2018 at 10am.

19.Chair's signature

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

Signature

Name

Anita Bharucha

Date

4 December 2018

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (04/12/2018) 633 MA]**
Meeting Date:	4 December 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:

- 7 items added from October 2018 meeting, 3 ongoing
- 4 items carried over from earlier meetings, 3 ongoing

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 12 June 2018 meeting			
9.10 The Committee to receive monthly updates highlighting any variances and increased risk.	Chief Information Officer		**Ongoing**
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'.	Chief Information Officer		**Ongoing**
9.12 Any further significant issues would be addressed through a meeting with the Committee Chair and key staff.	Chief Information Officer		**Ongoing**
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		**Complete –** This item is on the agenda for the meeting.
Matters Arising from the Audit and Governance Committee – actions from 9 October 2018 meeting			
3.8 The Committee Secretary to contact members regarding availability for training after the meeting on 4 December 2018 or	Committee Secretary		**Ongoing –** Training will occur after the 5 March 2019 meeting.

5 March 2019			
5.5 The Committee to receive a paper on staffing and capability at the 4 December 2018 meeting.	Chief Executive		**Complete –** This item is on the agenda for the meeting.
8.13 The Committee to receive a further paper on the digital programme, which would be followed-up by a teleconference, prior to the launch of PRISM, to attain approval to proceed.	Chief Information Officer		**Ongoing**
11.7 The Risk and Business Planning Manager to circulate a final version of the risk policy to the Committee, following the 14 November Authority meeting.	Risk and Business Planning Manager		**Ongoing –** The risk policy is awaiting rebranding and will be circulated once this has been actioned.
12.5 The Risk and Business Planning Manager to ensure Brexit and estates are reflected in the strategic risk register.	Risk and Business Planning Manager		**Complete**
13.6 Brexit to be added to Forward Planner			**Complete**

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	4		
Paper number	AGC (04/12/2018) 638 MA		
Meeting date	4 December 2018		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to Note: there are 14 outstanding audit recommendations of which 7 remain open. Since the last meeting there has been one new audit. There were 6 findings of which 3 were subject to recommendations and 3 will not be actioned. Committee to note a new target dates.		
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	Yes
				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	Yes
				4	Temporary promotions are not initiated/ceased in accordance with policy	Yvonne Akinmodun, Head of HR	~~October 2018~~ January 2019	No
				5	Failure to identify error and potential fraud	Richard Sydee, Director of Finance and Facilities	~~December 2018~~ Q2 2019/20	No
				6	Failure to identify and recover overpayments in a timely manner	Morounke Akingbola, Head of Finance	September 2018	No
				7	External providers of payroll services operate ineffectively	Yvonne Akinmodun, Head of HR	September 2018	Yes
			Review of Cyber Security	1	The absence of a defined information security management framework and governance approach, supported by an appropriate high-level risk assessment could lead to the inconsistent treatment of cyber-security and potential security compromises that could have been avoided	Authority Chair/Chair of AGC	March 2019	No
				4	Ongoing use of ports, protocols and services on networked devices are not managed, increasing the windows of vulnerability available to attackers	Dan Howard, Chief Information Officer	March 2019	No
				6	The life cycle of system and application accounts is not actively managed, including their creation, use, dormancy and deletion, potentially	Dan Howard, Chief Information Officer	March 2019 (first review)	No

					increasing the number of deliberate and accidental attacks.			
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*	Yes
				3	Staff Training	*(Dan Howard, CIO & Head of HR)*	*December 2017*	Yes
			Risk Management	4	Staffing / Capability	*Peter Thompson, CEO (Yvonne Akinmodun, Head of HR)*	*March 2018*	Yes

TOTAL	14

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
PAYROLL AND EXPENSES			
2018/19 – INTERNAL AUDIT CYCLE			
1.	**Inadequate policies and procedures**		
<u>Expenses Policy:</u> • 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 reference 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 **<u>Sep 18 update</u>**: Expense policy has been re-written and inclusions relating to health and safety, single claimants included.	***Morounke Akingbola, Head of Finance*** ***September 2018*** ***COMPLETE***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
PAYROLL AND EXPENSES			
2018/19 – INTERNAL AUDIT CYCLE			
2.	**Incorrect payments to starters and leavers.**		
<u>Use of electronic signatures on employee declarations</u> 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 **<u>Sep 18 update:</u>** 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
PAYROLL AND EXPENSES			
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 **<u>Dec-18 update</u>** **Expense claims reviewed prior to pay-runs by Director of Finance or Head of Finance. Minor issues detected and rectified before payment. This is an on-going process.**	***Morounke Akingbola, Head of Finance*** ***November 2018*** ***COMPLETE***
<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	***September 2018*** **COMPLETE**
<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.	**COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
PAYROLL AND EXPENSES			
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 ceased 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: This work is in progress **Dec 18 update:** We expect to have a draft policy for SMT review by mid-December with dissemination to CMG early January 2019	***Yvonne Akinmodun, Head of HR*** ~~***October 2018***~~ ***January 2019***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
PAYROLL AND EXPENSES			
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 **<u>Dec-18 update:</u>** A review of systems is underway however; indications are that a wider view needs to be taken with regards the finance, expense and P2P systems. We aim to look into this further in 19/20 business year. 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 sent post Q2 finance reviews.	***Richard Sydee, Director of Finance and Facilities*** ~~*December 2018*~~ ***Q2 2019/20*** ***Morounke Akingbola, Head of Finance*** ***July 2018*** **COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
PAYROLL AND EXPENSES			
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. **Dec 18 update:** New contract of employment templates has been updated to reflect recovery of overpayments. A policy statement will be drafted and shared.	***Yvonne Akinmodun, Head of HR*** ~~***October 2018***~~ ***January 2019***
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
CYBER SECURITY			
2018/19 – INTERNAL AUDIT CYCLE			
1.	**The absence of a defined information security management framework and governance approach, supported by an appropriate high-level ris assessment could lead to the inconsistent treatment of cyber-security and potential security compromises that could have been avoided**		
HFEA has a defined information security management framework and appropriate structures to support the oversight of the cyber risk. Scrutiny and challenge could be improved further by appointing to the AGC a non-executive member with a background in technology. The management of the cyber security risk should be improved so there is a clear articulation of the controls 'gap' for each element of the cyber risk and necessary steps required to reduce the risk exposure (current score 9) to the desired level (residual risk score 6).	Management should consider appointing a non-executive member to the Audit & Governance Committee who has a background in technology. Management should ensure that the Strategic Risk Register update is improved to clearly articulate details of individual cyber risk element control gaps, the necessary specific mitigating actions, including timelines, to bring cyber risk exposure within tolerance and report these to the next AGC and Authority meetings.	To be considered by AGC **Dec 18 update:** We have undertaken further cyber security (penetration) testing of the new digital systems such as PRISM and the Register, to ensure that these remain secure. The results have not revealed any significant issues. SMT raised the tolerance level of this risk to 9 in November, reflecting that though we believe our cyber controls are fit for purpose, the context in which we operate, with a high level of national cyber risk, means we are tolerating a higher level of risk. 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. This strategic risk register has been updated to reflect the above and it will continue to be regularly reviewed as part of our risk monitoring cycle.	***AGC Chair?*** ***March 2019*** ***Dan Howard, Chief Information Office*** ***N/a***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
CYBER SECURITY			
2018/19 – INTERNAL AUDIT CYCLE			
4.	**The absence of an established security configuration of laptops, servers and workstations using a rigorous configuration management and c controls process increase the risk of unauthorised changes to systems, exploitation of unpatched vulnerabilities and insecure system config and increases the number of security incidents**		
Aligning more closely with NCSC guidance will help support more robust cyber risk management as will improving discovery and monitoring capability. This is especially important given the confidential nature of information resident in HFEA systems and their acknowledgement that strategic level cyber risk is considered to be outside tolerance.	Management should formally document baselined security configuration standards and develop a process to maintain these on an ongoing basis. Management should develop a software and hardware inventory and integrate this with the protective monitoring capability to help prevent the downloading of unauthorised software by staff and detect instances of unauthorised hardware connecting to the HFEA networks and unauthorised software put onto the HFEA network by external attackers.	Agreed – these will be documented and reviewed on a quarterly basis Agreed: We will create a software inventory of approved software and annually review the results of the software audit to ensure only authorised software is present on the network. No user has administrative permissions by default on HFEA devices which in turn prevents users installing unauthorised software. We use Microsoft Insight to ensure essential security patches are applied as required.	***Dan Howard, Chief Information Officer*** ***1 March 2019*** ***1 January 2019***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
CYBER SECURITY			
2018/19 – INTERNAL AUDIT CYCLE			
5.	**Ongoing use of ports, protocols and services on networked devices are not managed, increasing the windows of vulnerability available to attackers.**		
HFEA has the appropriate directive controls in the form of a comprehensive suite of policies to describe the process and limitations in staff being granted access to systems and services and the associated Role-Based Access Controls. However, we are unclear as to how this is managed in the supply chain.	Management should consider seeking periodic assurances from Azure and Alscient over the management of elevated users, the number with access to HFEA infrastructure, confirmation that the privilege account actions are appropriate and that they cannot see HFEA data or access the systems.	Agreed: This will happen on a quarterly basis.	***Dan Howard, Chief Information Officer*** ***First review*** ***March 2019***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
DATA LOSS			
2018/19 – INTERNAL AUDIT CYCLE			
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). **Dec 18 update:** The expectation is that the above time frame is still achievable.	***Chris Hall, Senior Inspector (Information Quality)*** ~~***Summer 2018***~~ ***Q3/4 2018/19*** ***Q4 2018***

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
CYBER SECURITY			
2018/19 – INTERNAL AUDIT CYCLE			
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** ***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:** Acceptable Usage policy presented to CMG in June and was approved subject to minor amendments.	***Owner: Dan Howard, CIO*** **May 2018** **COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
CYBER SECURITY			
2018/19 – INTERNAL AUDIT CYCLE			
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) *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.* ***Feb 18 update plus*** *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	***Dan Howard, CIO*** *(Yvonne Akinmodun)* **December 2017** **COMPLETE** **COMPLETE**

FINDING/*RISK*	Recommendation	Management Response and agreed actions / Progress update	Owner/Completion date
CYBER SECURITY			
2018/19 – INTERNAL AUDIT CYCLE			
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 •Development of a clear workforce strategy that supports management in the recruitment and retention of staff.	*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 ***Dec 18 update:*** Summary Exit interview data shared with CMG in November and AGC to receive as part of bi-annual HR report. 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	***Peter Thompson, CEO*** ***Yvonne Akinmodun*** ***Before end of 2017*** ~~***End March 2018***~~ ~~**October 2018**~~ **November 2018** **COMPLETE**

		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 **Dec 18 update:** Lunch and Learn session conducted 12 November.	**October 2018** **COMPLETE**

National Audit Office

Human Fertilisation and Embryology Authority

Audit planning report on the 2018-19

FINANCIAL STATEMENT AUDIT

Report to those charged with governance
December 2018

This report presents details of our proposed approach for the audit of 2018-19 financial statements

We plan our audit of the financial statements to respond to the risks of material misstatement and material irregularity. This reports sets out how we have built our assessment of risk, what we base materiality on, those risks we expect to be significant and how we will respond to those risks. We also set out in this report details of the team carrying out the audit, the expected timing of the audit and our fees.

Actions for the Audit Committee

Members of the Audit Committee are invited to discuss:

- Whether our assessment of the risks of material misstatement to the financial statements is complete;
- Whether management's response to these risks are adequate;
- Our proposed audit plan to address these risks;
- Whether the financial statements could be materially misstated due to fraud, and communicate any areas of concern to management and the audit team

We would also like to take this opportunity to enquire of those charged with governance about the following areas:

- Other matters those charged with governance consider may influence the audit of the financial statements
- The entity's objectives and strategies, and the related business risks that may result in material misstatements
- Possibility, knowledge of and process for identifying and responding to the risks of fraud
- Oversight of the effectiveness of internal control
- Whether any non-compliance with any laws or regulations (including regularity) have been reported to those charged with governance (e.g. from staff, service organisations or other sources)
- Policies, procedures and systems for recording non-compliance with laws, regulations and internal policies.

George Smiles
Engagement Director

Contents

Audit Risks (pages 6 to 8)

We plan our audit of the financial statements to respond to the risks of material misstatement to transactions and balances and irregular transactions.

We have identified the following two risks, both of which are risk presumed by Auditing Standard, which have the most significant impact on our audit:

Management Override of Controls

Revenue Recognition

We have identified the following areas of audit focus:

Assets under construction (PRISM)

Exiting the European Union

Materiality (page 9)

- When setting materiality, we consider both qualitative and quantitative aspects that would reasonably influence the decisions of users of the financial statements. Quantitative materiality is:

Audit team, fee and timetable

- George Smiles will be responsible for the overall audit. The full engagement team is presented on page 12.
- Our proposed audit fee for this year is £28,000. This remains in line with that charged in 2017-18.
- We are planning to complete the audit in advance of the summer 2019 Parliamentary recess.

Building our assessment of risk

We are well placed to develop an understanding of the risks to the HFEA drawing on your own assessment, the historic assessment of risk and the broader context.

Human Fertilisation & Embryology Authority

HFEA assessment of risk

The HFEA strategic risk register sets out a number of risks. We have engaged with management to understand the background to these risks, movement in impact and likelihood and have considered how these inform our assessment of audit risks.

- LC1: Legal challenge
- RE1: Regulatory effectiveness
- CS1: Cyber security
- ME1: Effective communications
- C1: Capability
- FV1: Financial viability

Past assessment of audit risk

The 2017-18 audit highlighted a number of areas of audit risk and focus, we have built on this historical assessment to consider whether these remain risks for the year.

Significant audit risks

- Management Override of Controls
- Revenue Recognition

Areas of audit focus

- Assets under construction (PRISM)
- Exiting the European Union

Broader context

Our risk assessment draws on the understanding of the broader environment in which the HFEA operates.

- Legal environment
- Financial sustainability in the NHS
- Data and information security
- EU Exit

Our response to the significant risks*

Presumed risk of management override of controls

Detail

Management is in a unique position to perpetrate fraud because of its ability to manipulate accounting records and prepare fraudulent financial statements by using its position to override controls that otherwise appear to be operating effectively.

Under International Standards on Auditing, there is a ***presumed*** risk of material misstatement due to fraud arising from management override of controls.

The standard requires that auditors perform audit procedures to address this risk, focusing on three key areas: journal entries, bias in management estimates and significant or unusual transactions.

Audit Impact

Potential impact across all audit areas

Audit response

Controls

We will review the design and implementation of controls over journal entries, accounting estimates and significant or unusual transactions.

This will be supplemented by the substantive testing of these areas described adjacently.

We will also review the production of the management accounts and the scrutiny of these accounts by senior management with a view to placing reliance on this high level control.

Substantive

Our interim and final audit work will consider:

- the appropriateness of journal entries and other adjustments processed in preparing the financial statements;
- a sample test of journals based on a risk criteria;
- Any accounting estimates present in the financial statements, for evidence of management bias; and
- any significant transactions outside of HFEA's normal course of business, or that otherwise appear to be unusual.

Our response to the significant risks*

Presumed risk of fraud in revenue recognition

Detail

Under International Standards on Auditing, the Auditor's responsibilities relating to fraud in audit of financial statements there is a ***presumed*** risk of fraud in revenue recognition, albeit rebuttable.

HFEA's income is material and the main income stream relates to treatment fees from clinics; there is a risk that treatment is not reported accurately to HFEA which would impact on the income reported in the accounts. Therefore the risk has not been rebutted.

This significant risk relates only to the fraud element of revenue recognition – other elements of revenue recognition are not considered a significant risk.

Audit Impact

Potential impact on income balances

Audit response

Controls

We will review the production of the management accounts and the scrutiny of these accounts by senior management with a view to placing reliance on this high level control.

We will also review controls in place over HFEA's income streams.

This will be supplemented by the substantive testing of these areas.

Substantive

- We will perform a substantive analytical review using the invoices sent to clinics.
- We will consider any new income streams for 2018/19.
- We will be assessing the work that the Compliance Audit team carry out on their visits to clinics. This is the control we will seek to rely for income, in order to provide us with assurance that the data provided by the clinics to HFEA is complete and accurate.

Areas of audit focus and other matters

The following are matters which we consider have a direct impact on the financial statements but do not represent significant risks of material misstatement as defined by ISA (UK) 315.

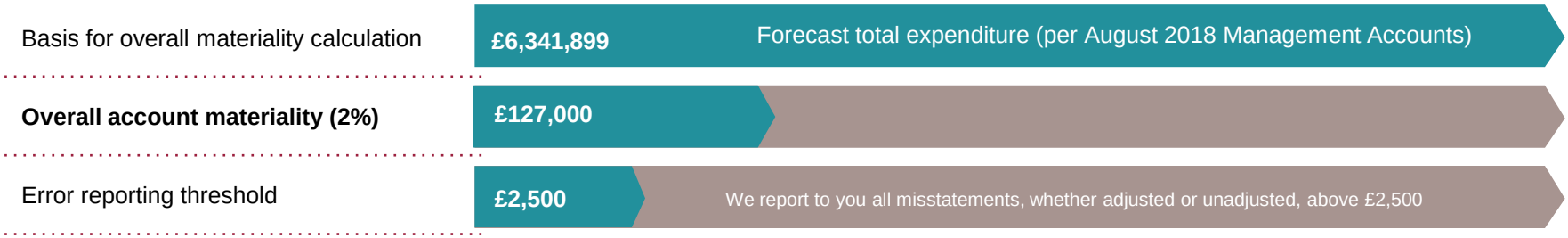
If during the audit these areas of focus have a significant effect on the overall audit strategy, the allocation of resources in the audit and directing the efforts of the engagement team, we may include these in our extended auditor report as key audit matters, as defined by ISA (UK) 701.

Title	Audit Area Affected	Audit Response
Completion of PRISM project	PPE and Expenditure	HFEA are working towards the implementation of their new customer interface system (PRISM), with the system due to go live by the end of 2018. HFEA will need to ensure that any capital expenditure relating to this upgrade is treated correctly, in particular related to assets categorised as 'under construction' in the prior year. We will discuss this with HFEA as our audit work progresses, and carry out testing of intangible asset additions.
Exiting the European Union	Disclosure impact (and potentially other areas)	The process of exiting the EU is continuing. As part of our audit enquires we will review management's consideration of the impact of Brexit and any disclosures that may be required in the accounts, for example, the impact on HFEA's role in respect of EU regulations.

Financial Reporting: Changes in accounting standards for 2019-20

Title	Audit Area Affected	Audit Response
Future accounting treatment of leases held by HFEA	Disclosure	HFEA hold material operating leases, therefore, when the new Leases standard, IFRS 16, comes into force it is expected that there will be an impact on the HFEA accounts. However, the expected impact of IFRS 16 will not be known until HM Treasury decides on how and when to implement the standard in the FReM. If it is to be implemented on 1st April 2019, a disclosure relating to the impact will be required in the 2018-19 accounts. We will discuss this with HFEA during the course of the audit to ensure they are prepared for the implications of the new accounting standard. Further information on IFRS 16 is provided in Appendix 5 on page 16.

Materiality



In line with generally accepted practice and NAO methodology, we have set our quantitative materiality threshold for HFEA as approximately 2% of forecast 2018-19 gross expenditure, which equates to £127,000.

These levels remain comparable to those used in the prior year.

Our overall account materiality is based on gross expenditure, since expenditure is the main driver of HFEA's accounts and is the area of focus for users of the accounts.

A matter is material if its omission or misstatement would reasonably influence the decisions of users of the financial statements. The assessment of what is material is a matter of the auditor's professional judgement and includes consideration of both the amount and the nature of the misstatement.

The concept of materiality recognises that absolute accuracy in financial statements is rarely possible. An audit is therefore designed to provide reasonable, rather than absolute, assurance that the financial statements are free from material misstatement or irregularity. We apply this concept in planning and performing our audit, and in evaluating the effect of identified misstatements on our audit and of uncorrected misstatements, if any, on the financial statements and in forming the audit opinion. This includes the statistical evaluation of errors found in samples which are individually below the materiality threshold but, when extrapolated, suggest material error in an overall population. As the audit progresses our assessment of both quantitative and qualitative materiality may change.

We also consider materiality qualitatively. In areas where users are particularly sensitive to inaccuracy or omission, we may treat misstatements as material even below the principal threshold(s).

These areas include:

- the remuneration report;
- disclosures about losses and special payments;
- our audit fee; and
- irregular income and expenditure.

Other Matters

Independence	We are independent of HFEA in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities/public interest entities. We have fulfilled our ethical responsibilities in accordance with these requirements and have developed important safeguards and procedures in order to ensure our independence and objectivity. Information on NAO quality standards and independence can be found on the NAO website: https://www.nao.org.uk/about-us/our-work/governance-of-the-nao/transparency/. We will reconfirm our independence and objectivity to the Audit & Governance Committee following the completion of the audit.
Management of personal data	During the course of our audit we have access to personal data to support our audit testing. We have established processes to hold this data securely within encrypted files and to destroy it where relevant at the conclusion of our audit. We confirm that we have discharged those responsibilities communicated to you in the NAO's Statement on Management of Personal Data at the NAO. The statement on the Management of Personal Data is available on the NAO website: http://www.nao.org.uk/freedom-of-information/publication-scheme/how-we-make-decisions/our-policies-and-procedures/policies-and-procedures-for-conducting-our-business/
Using the work of internal audit	We liaise closely with internal audit through the audit process and seek to take assurance from their work where their objectives cover areas of joint interest.
Communication with the NAO	Organisations we audit tell us they find it helpful to know about our new publications, cross-government insight and good practice. We share this through our e:newsletter, Round-up for Audit Committees and email notifications about to our work on particular sectors or topics. If you would like to receive any of these, please sign up at: http://bit.ly/NAOoptin. You will always have the option to amend your preferences or unsubscribe from these emails at any time.

Appendix 1: Timing of the audit and audit fee

The proposed timetable comprises an interim visit commencing 11th February 2019 for 1 week; a further second interim visit week commencing 11th March 2019 for 1 week; and a final visit commencing 27th May 2019 for 2 weeks, with certification planned for late June 2019.

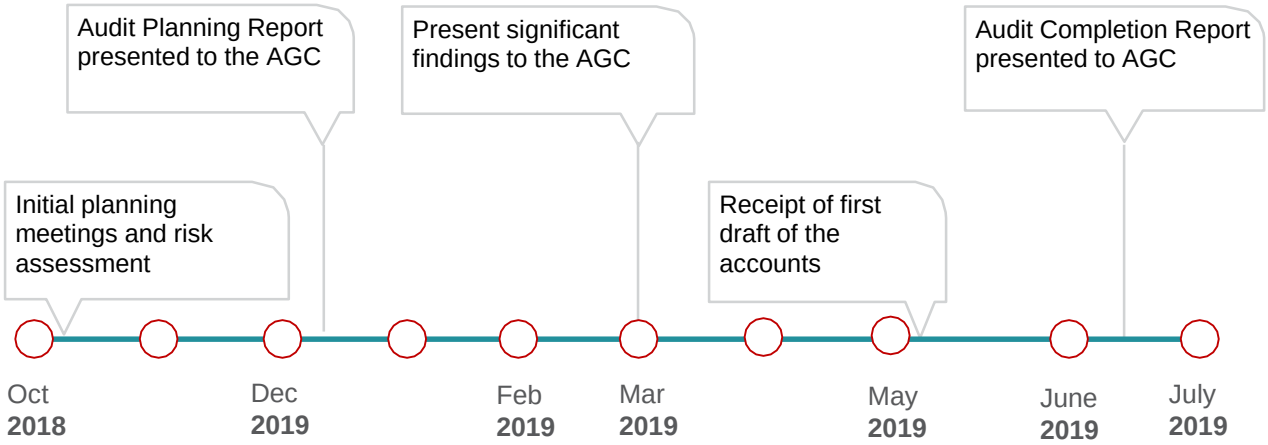
Fees

The fee for the audit is £28,000.

Completion of our audit in line with the timetable and fee is dependent upon HFEA:

- delivering a complete Annual Report and Accounts of sufficient quality, subject to appropriate internal review, on the date agreed;
- delivering good quality supporting evidence and explanations within the agreed timetable;
- and making staff available during the audit.

If significant issues arise and we are required to perform additional work this may result in a change in our fee. We will discuss this with you before carrying out additional work.



Planning

Consultation with:
- Management,
- Audit & Governance Committee; and
- Others eg IA

Review HFEA's operations.

Assess risk for our audit and evaluate the control framework.

Determine audit strategy.

Interim fieldwork

Test expenditure and income.

Attendance at a Compliance Audit clinic inspection visit.

Final fieldwork

Test expenditure and income and significant balances and disclosures

Completion

ACR:

present our findings/ recommendations.

Seek management representations.

C&AG issues opinion.

Appendix 2: The NAO audit team

Catherine Hepburn
Portfolio Director

George Smiles
Engagement Director

T: **020 7798 7395**
E: **George.Smiles@nao.org.uk**

Experience:
- Fourth year on engagement acting as Engagement Director
- 20+ years experience of financial audit in the public sector

Jill Hearne
Engagement Manager

T: **020 7798 5382**
E: **Jill.Hearne@nao.org.uk**

Experience:
- First year on engagement
- 10+ years experience leading and managing financial audits in the public sector

Finnian Bamber
Audit Lead

T: **020 7798 5362**
E: **Finnian.Bamber@nao.org.uk**

Experience:
- Second year on engagement, first year taking the lead role
- 2 years experience of financial audit in the public sector specifically in Health

Appendix 3: Scope and responsibilities

In line with ISAs (UK) we are required to agree the respective responsibilities of the C&AG/NAO and the Accounting Officer/Client, making clear that the audit of the financial statements does not relieve management or those charged with governance of their responsibilities.
These responsibilities are set out in the Letter of Understanding, which will be reissued by early 2019, and are summarised here.

Area	Accounting Officer/management responsibilities	Our responsibilities as auditor
Scope of the audit	• Prepare financial statements in accordance Human Fertilisation and Embryology Act 1990 and that give a true and fair view. • Process all relevant general ledger transactions and make these, and the trial balance, available for audit. • Support any amendments made to the trial balance after the close of books (discussing with us). • Agree adjustments required as a result of our audit. • Provide access to documentation supporting the figures and disclosures within the financial statements. • Subject the draft account to appropriate management review prior to presentation for audit	• Conduct our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)). • Report if the financial statements do not, in any material respect, give a true and fair view. • Review the information published with the financial statements (e.g. annual report) to confirm it is consistent with the accounts and information obtained during the course of our audit. • During the course of the audit of the financial statements, matters may be identified where the C&AG deems that it is in the public interest to report to the relevant authority in accordance with ISA (UK) 250A – Consideration of laws and regulations in an audit of financial statements. Any such reports which are made in good faith without malice shall not constitute a breach of any contractual or legal restriction on disclosure of information in accordance with Article 7 of Regulation (EU) No 537/2014.

Appendix 3: Scope and responsibilities (cont'd)

Area	Accounting Officer/management responsibilities	Our responsibilities as auditor
Regularity	• Ensure the regularity of financial transactions. • Obtain assurance that transactions are in accordance with appropriate authorities, including the organisation's statutory framework and other requirements of Parliament and HM Treasury.	• Conduct our audit of regularity in accordance with Practice Note 10, 'Audit of financial statements of public sector bodies in the United Kingdom (2016)', issued by the Financial Reporting Council. • Confirm the assurances obtained by the HFEA that transactions are in accordance with authorities. • Have regard to the concept of propriety, i.e. Parliament's intentions as to how public business should be conducted.
Fraud	• Primary responsibility for the prevention and detection of fraud. • Establish a sound system of internal control designed to manage the risks facing the organisation; including the risk of fraud.	• Provide reasonable assurance that the financial statements (as a whole) are free from material misstatement, whether caused by fraud or error. • Make inquiries of those charged with governance in respect of your oversight responsibility.
Governance statement	• Review the approach to the organisation's governance reporting. • Assemble the governance statement from assurances about the organisation's performance and risk profile, its responses to risks and its success in tackling them. • Board members, with the support of the Audit & Governance Committee, evaluate the quality of internal control and governance, and advise on any significant omissions from the statement.	• Confirm whether the governance statement is consistent with our knowledge of the organisation, including its internal control. • Consider whether the statement has been prepared in accordance with HM Treasury guidance, including Managing Public Money.
Accounting estimates and related parties	• Identify when an accounting estimate, e.g. provisions, should be made. • Appropriately value and account for estimates using the best available information and without bias. • Identify related parties. • Appropriately account for and disclose related party transactions.	• Consider the risk of material misstatement in respect of accounting estimates made by management. • Perform audit procedures to identify, assess and respond to the material risks of not accounting for or disclosing related party relationships appropriately.

Appendix 4: Follow up to recommendations we made in the previous year

In 2017-18 we made the below recommendations to the Human Fertilisation and Embryology Authority. Below is an update on the status of these recommendations.

Clinic Inspections		Low risk
Finding HFEA currently undertake data register site inspections of clinics on the basis of a riskbased criteria. Whilst risk is an appropriate basis the Authority should also consider an element of cyclicality, otherwise the lower risk clinic may not be visited during their licence tenure.	**Our recommendation** We recommend that management review the criteria for clinic visits and consider including an element of cyclicality.	**Management response:** Agreed -HFEA will consider the cyclicality of the audits. **Status: open (to be reviewed during the audit)**
Outstanding Accrual		Low risk
Finding During our testing we identified that the Authority was disputing an invoice for £12,000, dated April 2017, for work performed which they considered had not been completed to the expected standards. HFEA are awaiting a credit note to reduce this balance prior to paying, however this item has not been actively pursued and remains outstanding.	**Our recommendation** We recommend that management be more proactive and resolve this matter so that the transaction can be cleared.	**Management response:** Agreed - HFEA will endeavour to resolve this issue. **Status: open (to be reviewed during the audit)**
myCSP incorrect billing of redundancy costs		Medium risk
Finding During our testing we identified that myCSP had overbilled HFEA £25k for redundancy costs. We had requested a confirmation of cost from MyCSP (these had been recalculated as a result of the court case) and found that the confirmation did not agree to the payment made to CSP by HFEA.	**Our recommendation** We recommend that management review invoices from myCSP and agree them to calculations/myCSP documentation to ensure that costs charged are accurate.	**Management response:** Agreed - HFEA will endeavour to resolve this issue. **Status: open (any further such payments to be reviewed during the audit)**

High risk: major issues for the attention of senior management which may have the potential to result in a significant deficiency in internal control

Medium risk: important issues to be addressed by management in their areas of responsibility.

Low risk: problems of a more minor nature which provide scope for improvement

Appendix 5: Future accounting standards

IFRS 16: Leases

Effective from 2019-20

HM Treasury have consulted on the public sector interpretation of this Standard for FReM bodies. We expect to be notified on the implementation date in due course.

The following slide summarises some of the changes made and provides information regarding disclosures in line with IAS 8.

We advise all bodies affected, whether lessors or lessees, to read IFRS 16 in full to understand the implications to the accounting treatment of leases.

IFRS 16 eliminates the operating/finance lease distinction and imposes a single model geared towards the recognition of all but low-value or short term (<12m) leases. The proposals arise partly from the IASB's view that:

- disclosures around operating lease commitments have lacked prominence and tended towards understatement; and
- even in leases where the underlying asset is not acquired for its whole useful life, the lessee nevertheless acquires an economic right to its use, along with obligations to make good on minimum lease payments.

These will now be recognised on the Statement of Financial Position as a 'right of use' asset and lease liability. The lease liability will be measured at initial recognition as the value of future lease payments, with the asset additionally including any initial direct costs incurred by the lessee, plus an estimate of any dismantling/restoration costs. Subsequent measurement of both asset and liability will need to respond to any changes in lease terms, and the accounting for the asset can be on a cost less depreciation and impairment model or a revaluation (fair value) model.

Successful transition will depend on organisations pro-actively capturing additional information about leases – new and existing – which they expect to remain in place at 1 April 2019, especially regarding future minimum lease payments. Organisations should also ensure systems for capturing cost information are fit for purpose, can respond to changes in lease terms and the presence of any variable (e.g. RPI-based) lease terms where forecasts will need to be updated annually based on prevailing indices.

Changes affecting a lessor are limited, such as the revised guidance on the definition of a lease and the definition of the lease term.

Disclosures in line with IAS 8 will be required in 2018-19 by bodies following IFRS or the FReM in line with IAS 8:

IAS 8, paragraph 30

When an entity has not applied a new IFRS that has been issued but is not yet effective, the entity shall disclose:

- this fact; and
- known or reasonably estimable information relevant to assessing the possible impact that application of the new IFRS will have on the entity's financial statements in the period of initial application.

Paragraph 31 of IAS 8 goes on to provide more detail of what disclosures should contain.

Appendix 6: Guidance for governance

Guidance for governance

Support to Audit Committees

We have developed a range of guidance and tools to help public sector Audit Committees achieve good corporate governance.

http://www.nao.org.uk/search/pi_area/support-to-audit-committees/type/report/

Cyber security and information risk guidance for Audit Committees

Audit committees should be scrutinising cyber security arrangements. To aid them, this guidance complements government advice by setting out high-level questions and issues for audit committees to consider.

https://www.nao.org.uk/report/cyber-security-and-information-risk-guidance/

Corporate Governance Code for central government departments

The document was released in April 2017 and lays out the model for departmental boards, chaired by Secretaries of State and involving ministers, civil servants and non-executive board members. The principles outlined in the code will also prove useful for other parts of central government and they are encouraged to apply arrangements suitably adapted for their organisation.

https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments-2017

Sustainability reporting

This guidance is to assist with the completion of sustainability reports in the public sector. It sets out the minimum requirements, some best practice guidance and the underlying principles to be adopted in preparing the information.

https://www.gov.uk/government/publications/public-sector-annual-reports-sustainability-reporting-guidance-2016-to-2017

Developments in government internal audit and assurance

The handbook released in March 2016 reflects developing best practice in governance and the increasing significance of risk management, and associated assurance needs, in the governance of government organisations.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/512760/PU1934_Audit_committee_handbook.pdf

Disclosure Guides

Our disclosure guides for clients help audited bodies prepare an account in the appropriate form and that has complied with all relevant disclosure requirements.

http://www.nao.org.uk/report/nao-disclosure-guides-for- entities-who-prepare-financial-statements-in-accordance-with-the-government-financial-reporting-manual-frem/

Appendix 7: Fraud matters

ISA 240 (UK&I) 'The auditor's responsibility to consider fraud in an audit of financial statements' requires us, as your auditors, to make inquiries and obtain an understanding of the oversight exercised by those charged with governance.

What can constitute fraud?

Fraudulent Financial Reporting: Intentional misstatements including omissions of amounts or disclosures in financial statements to deceive financial statement users.

Internal misappropriation of assets: Theft of an entity's assets perpetrated by management or other employees.

External misappropriation of assets: Theft of an entity's assets perpetrated by individuals or groups outside of the entity, for example grant or benefit recipients.

Fraud risk factors

Rationalisation/attitude: Culture of environment enables management to rationalise committing fraud – attitude or values of those involved, or pressure that enables them to rationalise committing a dishonest act.

Incentive/Pressure: Management or other employees have an incentive or are under pressure.

Opportunity: Circumstances exist – ineffective or absent control, or management ability to override controls – that provide opportunity

ISA inquiries

Our inquiries relate to your oversight responsibility for

- Management's assessment of the risk that the financial statements may be materially misstated owing to fraud, including the nature, extent and frequency of such assessments;
- Management's process for identifying and responding to the risks of fraud, including any specific risks of fraud that management has identified or that has been brought to its attention;
- Management's communication to the Audit Committee (and others charged with governance) on its processes for identifying and responding to the risks of fraud; and
- Management's communication, if any, to its employees on its views about business practices and ethical behavior.

We are also required to ask whether you have any knowledge of any actual, suspected or alleged fraud.

Audit approach

We have planned our audit of the financial statements so that we have a reasonable expectation of identifying material misstatements and irregularity (including those resulting from fraud). Our audit, however, should not be relied upon to identify all misstatements or irregularities. The primary responsibility for preventing and detecting fraud rests with management.

We will incorporate an element of unpredictability as part of our approach to address fraud risk. This could include, for example, completing procedures at locations which have not previously been subject to audit or adjusting the timing of some procedures.

We will report to the Audit & Governance Committee where we have identified fraud, obtained any information that indicates a fraud may exist or where we consider there to be any other matters related to fraud that should be discussed with those charged with governance.

Appendix 8: Recent health-related NAO publications

Publication	Report	Outline
January 2018	Sustainability and Transformation in the NHS	This study provided a summary of the financial position of local NHS bodies as well as NHS England in 2016-17. It examined the support that the Department of Health and its arm's-length bodies give to local bodies and the incentives and mechanisms they are putting in place to make local sustainability and transformation plans a success.
February 2018	Investigation: Clinical correspondence handling in the NHS	This investigation looked into an additional backlog identified of misdirected clinical correspondence following the first PAC session. It examined: how and when the clinical correspondence was first identified; action taken by NHS England to address the backlog; work to establish whether there has been any harm to patients as a result of delays in forwarding the correspondence; and what NHS England has done to gain assurance that the system for handling misdirected correspondence is working.
February 2018	The Adult Social Care Workforce in England	This study looked at how central government and other national bodies work with local authorities and providers to ensure there are enough paid care workers, with the right skills and qualities, to meet adults' statutory entitlements to publicly funded care.
March 2018	Reducing Emergency Admissions	The study examined the progress the Department of Health and its partners are making in reducing emergency admissions into hospital. This included: their knowledge of what is increasing emergency admissions; their plans to reduce emergency admissions; and whether they are implementing plans and initiatives to reduce emergency admissions effectively.
May 2018	Investigation: NHS England's management of the primary care support services contract with Capita	The investigation looked at the contract commissioning and subsequent performance of the primary care support services. We examined: the business objectives of the Primary Care Support Services contract and the award of the contract to Capita; the root causes and extent of service failures; and the action taken by NHS England and Capita to improve services.

Appendix 8: Recent health-related NAO publications (cont'd)

Publication	Report	Outline
June 2018	Investigation: NHS spending on generic medicines in primary care	Published on 8 June, this investigation looked at the price rises in 2017 of generic medicines and the impact on primary care prescribing budgets (noting the costs of concessions at £315m). It covers the generic market and the impact, what action was taken during the period of turbulence and the new powers granted to the DH&SC regarding access to price and information.
June 2018	Developing new care models through NHS vanguards	In 2015, 50 vanguard sites were selected to lead the development of new care models. The study looked at the programme's set-up, the support provided by national partners, progress in implementing the programme and future plans for new care models.
July 2018	Adult social care at a glance	This overview updates our report 'Adult social care in England: an overview (2014)', highlighting key trends, developments and system pressures.
July 2018	The health and social care interface	This 'think piece' drew on our past work highlighting the barriers that prevent health and social care services working together effectively, examples of joint working and the move towards services centred on the needs of the individual, to inform the ongoing debate about the future of health and social care in England.

Digital Programme Update: December 2018

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	9		
Paper number	AGC (04/12/2018) 640 DH		
Meeting date	04 December 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; • We will continue to provide regular updates to AGC as the programme concludes, and during CaFC improvements in 2019; • As before, we will escalate any issues to the Chair of AGC in conjunction with the HFEA Executive; and • That AGC will provide 'approval to proceed' for the programme during January 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:	None		

1. Background

1.1. This paper provides an update on progress relating to data migration, system development, the implementation of the new register and the associated transitional activities.

1.2. During November, we experienced a data migration issue relating to the use of historical migrated data within the new Register. This issue led us to reconsider our readiness for launch and further details are available below, including our revised launch date.

1.3. As a result of the data migration issue, we were unable to provide the detailed assessment to allow AGC to review progress and authorise go-live by providing approval to proceed, as planned. The AGC decision to go live is now expected to take place in January 2019 and the assessment to support this meeting will be predicated on a detailed review of risk, to include reputational, business and financial.

1.4. Given we cannot go live before the data migration issue is fully resolved; we are now planning a launch at the end of January 2019.

1.5. PRISM development is progressing well, and we are in regular contact with system suppliers to ensure they will have updated their systems in readiness for launch.

1.6. We will continue to provide regular updates to AGC on progress surrounding the implementation as the programme concludes. We will provide a full lessons learned review following its conclusion.

2. Summary

2.1. We are in the final stages of the programme. The major elements of PRISM have been developed or are approaching completion and we are undertaking the verification of the migrated data.

2.2. While steady progress has been made since the last update in October, issues relating to data migration have recently been identified.

Data Migration

2.3. Data migration contains two stages of work. Stage 1 is a reconciliation phase that includes simulating the movement of data from the old register to the new register to ensure it can be transferred correctly into the new structure and format. Stage 2 ensures interrogation of the data provides expected results once transferred. This includes uses such as the Choose a Fertility Clinic (CaFC) results on our website, ensuring correct information is provided in response to Opening the Register (OTR) requests and ensuring with the information previously provided for PQs can be replicated.

2.4. Good progress has been made with the reconciliation process (stage 1). Excluding gamete movements, it has been confirmed that over 99% of records have been migrated into the new register. The process of rectifying any gaps is working well

2.5. Stage 2 is proving more challenging, and will need more time before we can recommend proceeding. Initial testing of the data shows between 94-100% correct matches, however the algorithm needed for CaFC and Gamete Movement (EggBatchID) is taking significantly longer than expected to develop.

2.6. EggBatchID is a data item that is used within the Register to link data and treatment cycles over time. It is crucial that it is correct given it allows traceability of gamete movements and is used to generate CaFC reports providing performance data on clinics.

2.7. Whilst it has recently come to light, we estimate the EggBatchID algorithm will be complete by 18 December. Once this is complete, we will complete the full CaFC verification and address any issues.

PRISM

2.8. Development is close to completion, however we have experienced a small amount of slippage. We are approaching the end of 'view and edit' and we will soon be moving onto developing the reporting module. We will then work on deletions, extended validation, revalidation and changing roles.

2.9. The substantive HFEA employed Lead Developer is not in post meaning we have had to allocate those development tasks to the existing temporary development team.

2.10. PRISM development will now be complete on 20 December. We now plan to start User Acceptance Testing at beginning of January, with system release scheduled for around 28 January.

Stakeholder engagement

2.11. We continue to provide updates to, and respond to clinic queries during PRISM and API development. Our dialogue with system suppliers continue and no significant issues have been raised to date.

3. Data Migration impact and progress

3.1. We have carefully considered the impact of data migration progress on direct and indirect use of the register including any impact on stakeholders.

3.2. **Opening the Register requests**

At present, the state of the data indicates that there is good match between the live Register and the migrated data. We have very specialist and bespoke systems and will introduce a system of double-checking to address the very small risk that there are no errors in the OTR response we provide to applicants. We plan to introduce additional manual processes to provide further assurance that the OTR responses we provide are correct. This will involve checking against the old and new register and checking with clinics. We will also have checked historic sample OTRs in the new register against results from the old register to ensure consistency ahead of go live.

3.3. **New register structural improvements and CaFC**

It is important to note that the new Register has fundamental structural improvements. Firstly, it allows us to introduce greater data integrity due to the inbuilt validation rules and the use of a relational database. It also provides a more logical structure which will allow greater ease of data interrogation in the future.

Given this, the data fields in the current Register (used to populate CaFC) cannot simply be mapped to the new Register. Instead, a calculation is made which is based on a new algorithm.

Further analysis is required to understand the full impact on CaFC and this relies on the completion of EggBatchID to confirm that longitudinal linkages are correct. As detailed above, it is necessary that this is correct to ensure that individuals can be correctly associated to previous treatment cycles. This issue affects around 180,000 linkages between data and without that work, we would not have assurance that data reported or future queries are correct. The indicators suggest that the counts are largely accurate and indicate they are likely to be consistent, pending the full analysis and reconciliation of inconsistencies.

3.4. PQs and other reports

As with OTRs there is a good match between the live Register and the migrated data, however current differences exist which suggest a risk that responses using the migrated data from the new Register will be inconsistent pending reconciliation, which needs further analysis.

3.5. Summary

While this analysis suggests the migrated data is largely being migrated correctly and the level of inconsistency is small, further work is necessary to provide conclusive and absolute assurance. The process is continuing to address the inconsistencies and a complete a full impact assessment of any missing data. We anticipate having the reconciliation (excluding EggBatchID) complete by 18th Dec.

3.6. The process for reconciling EggBatchID is in development. The simple cases have been tested and show good levels of matching. It is estimated that the process of generating EggBatchID – specifically the algorithm which generates linkages over time (e.g. thaw, freeze, refreeze, and mix) is being carefully managed and we anticipate it will be complete before launch. We are actively working on contingencies should this not be possible given the complexity of the data and linkages. The verification (excluding CaFC) will be complete by mid-January.

3.7. To allow sufficient time to resolve the EggBatchID data migration issue while allowing good engagement by clinics and EPRS providers, we will now undertake a full launch around 28 January 2019.

3.8. This allows time to ensure PRISM is working fully. Full CaFC validation will be undertaken to ensure data are accurate and it will allow us to put into place full support for the Register Team to respond to data quality or system user queries as we go live.

4. Choose a Fertility Clinic

4.1. The Choose a Fertility Clinic part of our website (CaFC) provides a view of clinics performance which allows comparison of many clinic specific metrics by the public, one of which is success rates.

4.2. The published results would typically be updated and refreshed once every 6 months. Given our work on IfQ/PRISM, the current published results are around 2 years out of date.

4.3. We recognise the need to publish new CaFC data which is likely to include any overlap between old and new registers. Following go-live, we plan to work closely with clinics to support them to check previously entered data. This will ensure greater accuracy of any future CaFC results published. This is likely to include 2 years' worth of data and will

require targeted effort by clinics. Our launch communications will include specific communications relating to the refresh of CaFC and the support we will provide at the time.

4.4. It is likely that this data quality work will be complete in autumn 2019 and at that point, we will revert to our cycle of refreshing CaFC data once every six months. At that time, we may seek to make wider improvements to the provision of clinic performance data, such as refreshing performance data more frequently.

4.5. The launch of PRISM and the built-in validation rules means that reduced effort will be required in the future to check data once submitted – data will be captured 'correctly at source' and minimal rework will be required by clinics afterwards.

5. Progress update - additional programme elements

5.1. RITA

RITA is the internal system which will be used to interrogate the system providing HFEA performance reports and supporting internal business processes. The new Register Information Manager has reviewed the scope of RITA and development will commence just ahead of testing PRISM in early January. The initial focus will be on being able to support the go-live process. It is not required that the work on RITA is completed before we go live.

5.2. Infrastructure

The Azure cloud server infrastructure is in place ready for PRISM. Penetration Testing ahead of full PRISM testing is scheduled for December 2018.

5.3. 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. This includes providing user accounts, testing access, telephone and email support, and training.

6. Financial

6.1. There will be additional capital and revenue costs to support a final data migration and launch in January. We have contingency within the capital budget to accommodate a January launch.

6.2. There are other capital commitments during 2018/19, such as the new electronic document management system and IT hardware. We will not exceed our capital allocation, as approved by DHSC.

7. 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;
- We will continue to provide regular updates to AGC as the programme concludes, and during CaFC improvements in 2019;

- As before, we will escalate any issues to the Chair of AGC in conjunction with the HFEA Executive; and
- That AGC will provide ‘approval to proceed’ for the programme during January 2018, once system development, user and performance testing, and all validation checks on data migration have been completed and are satisfactory.

Resilience, Business Continuity Management and Cyber Security

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

Details:	
Meeting	Audit and Governance Committee (AGC)
Agenda item	10
Paper number	AGC (04/12/2018) 641 DH
Meeting date	04 December 2018
Author	Dan Howard, Chief Information Officer
Output:	
For information or decision?	For information
Recommendation	The Committee is asked to note: • The arrangement to extend the current IT infrastructure support contract with Alscient and the inclusion of essential software development support; • The longer term arrangement to go to market for IT infrastructure support with an expected contract start date in spring 2019; • The update on work to upgrade our telephone system, network and video-conferencing facilities
Resource implications	None
Implementation date	Ongoing
Communication(s)	Regular, range of mechanisms
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes:	Annex 1: IT infrastructure and software development support

1. Introduction and background

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

1.2. Our IT infrastructure support arrangements are under continual review to ensure our systems are supported effectively and our controls are robust. We have benefitted from an arrangement for IT infrastructure support from specialist providers, Alscient. SMT recently approved a short-term extension to our contract. This paper provides an overview of the scope of service, our procurement route and our forward plan for securing a longer-term arrangement in 2019.

1.3. In October, AGC received details on our plan to make improvements to our telephone system and video-conferencing facilities. An update is available below.

1.4. An audit was undertaken of our cyber security arrangements during July and August 2018. We have now received the draft report for comment, provided management comments and we await the final report in due course.

2. IT infrastructure support

Background

2.1. Given the nature of our systems and data, our IT infrastructure is complex, detailed and our small internal IT team do not possess the detailed technical knowledge to support the breadth of in-depth technologies we utilise.

2.2. We have decided that the inhouse team is best placed to concentrate on supporting HFEA-specific systems and the configuration of enterprise systems. We agreed that we will source infrastructure support for enterprise systems – such as our Office 365 infrastructure, certain hardware such as generic network components and some healthcare monitoring – to a third party.

2.3. Since April 2018, we have been using Alscient who are a medium sized IT services provider, procured using Framework day rates, on a call off basis. A joint programme of work has provided infrastructure stability, appropriate monitoring and we have progressed a programme of work to move services from in-house server hardware to Microsoft centrally hosted enterprise grade datacentres based in the UK.

Approval route

2.4. This arrangement was reviewed in November 2018 by SMT who assessed the circumstances and risk and approved a tender waiver for a contract extension. This was approved on the basis of using the same Framework day rates as before. The new contract extension will conclude in March / April 2019. This agreement also included essential short-term software development support, to compensate for the vacant Lead Developer post.

2.5. The paper presented to SMT, including risk assessment, is available as Annex 1.

Longer term arrangement

2.6. The tender waiver and contract extension was approved on the basis of a procurement exercise-taking place in early 2019 to engage the market to secure a longer-term arrangement. It is likely that this will involve procuring via Crown Commercial Services

Framework RM1043. This provides access to around 45 suppliers. We anticipate some additional handover between the current provider and any new service provider.

2.7. The planned timeline is as follows:

Detail	Date
Specification written and agreed	By 30 December 2018
Specification agreed by CMG / SMT	By 11 January 2019
Go to market using agreed Framework route	W/c 14 January 2019
Closing date for responses	01 March 2019
Bids scored, any clarification meetings held and communication of winning bidder	29 March 2019
Proposed contract start date	01 May 2019

3. Telephone system and video conferencing upgrades

3.1. In October 2018, AGC received confirmation that we were 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.

3.2. The work to upgrade our voice and Skype service from Microsoft, move our Skype server into the cloud, and upgrade our network connection is going well.

3.3. The network upgrade has been ordered and an expected completion date of 31 December 2018. We have also requested the porting of one of our telephone number ranges into the new service.

3.4. The upgraded E5 license types have been ordered for 6 accounts for testing purposes. These will allow the use of the Microsoft voice service in the cloud, and this includes audio and video conferencing.

3.5. Subject to the upgrade taking place as expected, and the sample licenses providing the functionality we are seeking, this work is on track for completion during January 2019.

4. Recommendation

The Committee is asked to note:

- The arrangement to extend the current IT infrastructure support contract with Alscient and the inclusion of essential software development support;
- The longer term arrangement to go to market for IT infrastructure support with an expected contract start date in spring 2019;
- The update on work to upgrade our telephone system, network and video-conferencing facilities

Annex 1: IT infrastructure and software development support

1. IT infrastructure support

1.1. Given the small size of the HFEA (and supporting IT team), we do not possess the breadth of specialist IT skills needed to support our digital ambition. During the past 6 months, we have chosen to access the necessary skills through a dedicated IT service provider.

1.2. On 20 April 2018 we agreed a contract for IT infrastructure support services with Alscient which included around 6 months' of infrastructure support and a programme of activity to migrate some services from on-premise server architecture to the Microsoft Azure cloud.

1.3. Procurement was reviewed and SMT agreed that costs and risks would increase should we wish to engage the market in a full tender exercise and there would be no financial advantage in doing so given the Alscient quote was based on framework prices.

1.4. On that basis, a tender waiver was approved and the order was placed. The total value including contingency, travel and VAT was £80,784 against a budget estimate of £89,856. As of 5 Nov 2018, all days within this contract have been used up and there is no cover in place.

1.5. At that time, we also agreed we would look to engage the market for a longer-term agreement which would start in autumn 2018. It has been suggested since, that this longer-term agreement should be put into place from 2019 and costs should form part of our longer time financial model for the Information / IT service. This will be explored in more depth later in 2018.

1.6. Since April 2018, significant progress has been made to improve our IT infrastructure through this contract – developments include:

- Build of infrastructure for PRISM production
- Build of infrastructure for PRISM pre-production
- Resolving problems with clinic portal and website instability issues
- Resolving problems with Epicentre failure
- Daily checks on the old on premises servers to fix any incidents and ensure continued availability
- Reviewing technical firewall policies to ensure security of IT at HFEA
- Assisting in config of single sign on for cloud hosted HR and intranet
- Configuration of PRISM and other infrastructure to enable penetration test
- Reconfiguration of database backups - to backup, restore and replace on our virtualised server infrastructure

1.7. Continued cover is needed to provide essential support cover, and also for the following work items:

- Support for the migration of the SAGE on-premise server into the Microsoft Azure cloud
- Limited support to migrate Skype for Business server into the Microsoft Azure cloud
- Limited support to implement the new Electronic Document Management system

- Limited support to implement an upgrade to the data communications network
- Moving Active Directory to Azure in order to improve availability for all services

1.8. The attached proposal CC001 is for the continuation of this service, albeit at a reduced resource rate (45 days in total). The cost of this is £45,792 (inc VAT and expenses).

1.9. We do not currently have essential cover in place and the risk of not approving this contract is that we would not be able to respond quickly should an IT incident occur. We would not have access to skills from a service provider who is already familiar with our IT infrastructure resulting in a longer break in service until the issue is resolved. Using another provider at short notice also is likely to lead to longer lead-time to schedule in resource.

2. Software Development support

2.1. On 17 September 2018, SMT discussed the vacant Lead Developer post and it was agreed to engage Alscient to provide short-term cover, for a period of 4/5 month. This has since been explored in depth and the attached proposal covers the scope, remit and costs.

2.2. The scope of this work is as follows:

- Full stack development using ASP.NET C#, Azure, Umbraco 7, TFS (Visual Studio Online), and Octopus Deploy.
- Maintenance, support and development of new data submission system PRISM, RITA, APIs and any necessary decommissioning of existing system EDI
- Maintenance of existing systems e.g. Epicentre
- Maintenance, support and (limited) development of website – Umbraco 7 –address ongoing cookie issue relating to cookie preferences, content not being displayed correctly etc.
- Maintenance, support and (limited) development of Clinic Portal
- Maintenance, support and (limited) development of Online Apps
- Maintenance, support and (limited) development of Code of Practice displayed as rich content via the website including search facility
- Maintenance, support and (limited) development of CaFC (Choose a Fertility Clinic) – e.g. resolution of issues such as treatments not displaying properly
- Add clinic users to Clinic Portal, and resolve access issues

2.3. The attached proposal CC002 is **£51,228** (inc VAT and expenses) for the four-month engagement.

2.4. This equates to £12,807 per month which is a reduction compared against day rate agency cover which would be around £13,248 per month inc VAT.

2.5. The substantive vacant post is £6,041.67 per month including on-costs.

2.6. The Alscient engagement represents a cost pressure of £6,765.33 per month against the vacant substantive post.

3. Procurement

3.1. In April 2018, we agreed a tender waiver for the IT infrastructure support contract with Alscient based on the following clauses:

7.	When the task is essential to complete the project, and arises as a consequence of a recently completed assignment and engaging different consultants for the new task would be inappropriate (35.g)	X
8.	There is a clear benefit to be gained from maintaining continuity with an earlier project. However in such cases the benefits of such continuity must outweigh any potential financial advantage to be gained by competitive tendering (35.h)	X

3.2. **The risk of not proceeding on the infrastructure support contract** is that we do not have sufficient cover in place resulting in an incident occurring, or the inability to respond to an incident should it occur. We would also not be able to move as swiftly as we would like with respect to our development projects.

3.3. **The risk of not proceeding on the development support contract** is we do not have development cover in place and we would not an agreed strategy to handover PRISM code on the conclusion of this project.

3.4. **The risk of proceeding** is that we are exposed to procurement challenge. This was mitigated in April 2018 by agreeing a tender waiver, based on a workload transition from IfQ/PRISM and the support required at the time. To date, we have not been challenged.

3.5. There is a good rationale to extend the existing contract:

a) we will undertake a full market review shortly on our IT infrastructure support requirements and we will seek a long term agreement;
b) day rates within this contract are framework market rates and so it is unlikely we could agree a similar contract elsewhere for a reduced rate;
c) we need an extension for a short period only, and;
d) we require immediate software development cover (including PRISM transition)

3.6. In summary, we do not currently have essential software development cover in place and the risk of not approving this contract extension is that we are not able to resolve software issues as they occur. We are not able to work through the backlog of issues raised. We are also not able to hand over the PRISM code enabling a smooth transition to an in-house team when recruited.

4. Recommendation

Infrastructure support

4.1. It is recommended that the order be placed for CC001, the extension to the IT infrastructure support, providing continuation of essential cover. Alscient have a detailed and comprehensive understanding of our business, systems and requirements and the quality of their work has been excellent. We will engage the market shortly to seek a longer-term support model.

Software development support

4.2. It is recommended that the order be placed for CC002, for essential software development cover. Once this cover has commenced, and in line with previous discussions, we will look to recruit to an in-house software development team (limited external support is likely to be needed for the in-house team on a permanent ongoing basis and this will be explored in due course).

Dan Howard, 5 November 2018

Organisational capability

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Audit and Governance Committee		
Agenda item	11		
Paper number	AGC (04/12/2018) 642		
Meeting date	04 December 2018		
Author	Peter Thompson, Chief Executive Yvonne Akinmodun, Head of Human Resources		
Output:			
For information or decision?	For information		
Recommendation	To consider the proposed actions set out at paragraph 4.3		
Resource implications			
Implementation date	During 2019		
Communication(s)	Dependant on discussion. Largely internal with staff over the coming months.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	None		

1. Introduction

1.1. Organisational capability has been a strategic risk for the HFEA for some time. The risk is expressed as: 'There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy'. The risk currently has an inherent risk level of 16 (or High) and a residual risk rating of 12 (or Medium). An essential component of this risk is staff turnover, which has been above our target range (of 10-15%) for many months – in October this year it stood at 22% measured over the previous 12 months. Both the wider Authority and AGC have been aware of this issue for many months and we have discussed the factors driving this risk on more than one occasion.

1.2. This paper aims to bring together the relevant evidence to support a more considered look at the issue. It begins with a brief summary of the essential organisational characteristics of the HFEA. Though largely familiar, these bear repeating as they limit and shape potential actions. The paper then goes on to look at turnover in more detail, drawing on evidence from exit interviews. The final section then sets out the actions taken to address the issue so far and raises some questions for discussion (in particular paragraph 4.3).

1.3. People issues are obviously essential to the health and productivity of any organisation and this paper draws on recent investment in a new HR system that will provide more easy access to our HR data. Over time, we plan to use such data to have a more regular and informed conversation with AGC about the key HR risks and opportunities we face.

2. Background

2.1. The HFEA is a small, specialist regulatory body sponsored by the Department of Health and Social Care. As such it is subject to wider HMT controls on expenditure and salaries, which is relevant to the question of turnover (see below). The key organisational characteristics (as at November 2018) can be summarised as follows:

- Headcount 68 (currently carrying 7 vacancies); of the 61 in post 98% are on permanent contracts
- Staff costs represent 63% of total expenditure
- A predominantly female workforce (79% of staff are female)
- A young age profile (the average age of employees is 42; similar public sector organisations have an average age of 52)
- A relatively healthy workforce: sickness absence is consistently below the public sector average of 2.9% (in October it stood at 2.5% the highest rate for some months, or 35.5 days lost, of which 26 days were due to a very small number of long term sickness cases which are being actively managed).

2.2. The HFEA is led by a Senior Management Team (SMT) of four (3.5 FTE – the Director of Finance and Resources is shared with the Human Tissue Authority). There are three Directorates:

- Compliance and Information (34.8 FTE – comprising Inspection and clinical governance, Business support, Information and the Register, IT development and network support)

- Strategy and Corporate Affairs (20.8 FTE – comprising Planning and governance, Intelligence, Regulatory policy, Engagement and communications)
- Finance and Resources (2.5 FTE – comprising Budgeting, Accounting, Financial control, Audit and risk assurance, Facilities)
- HR and Legal report direct to the Chief Executive.

2.3. The HFEA has a relatively 'flat' organisational structure, with just four bands: the SMT, Band 4 (Head of function roles), Band 3 (Manager level roles, including inspectors) and Band 2 (Administrative roles). 52% of staff are in just one band (Band 3) which reflects the specialist work that the HFEA does. This also has implications for promotion and development opportunities, which are discussed later (although there are a small number of roles within Bands 4 and 3 that have additional seniority – the Chief Inspector and Chief Information Officer roles in Band 4 and the three Senior Inspector roles in Band 3).

3. Turnover

3.1. All organisations experience staff turnover; indeed it is vital to the health of any organisation. Turnover can bring in new ideas and enthusiasm and be generally beneficial to the continuing growth of the organisation. That said, the loss of staff does inevitably create problems, in terms of a loss of expertise, corporate memory and additional burdens on remaining staff while replacements are found. In the last 12 months 13 staff have resigned from the HFEA. Of these, 76% had been with the organisation for over 3 years. Although the loss of such experienced staff is problematic, given the limited promotional opportunities in a small organisation like the HFEA, it is not surprising in itself. Moreover, high turnover should not be read as an indication that the HFEA is somehow an organisation that is in poor health. An individual deciding to leave after 3 or more years is making a rational decision about managing their career.

3.2. The HR team conduct exit interviews with each member of staff when they resign to gain a better understanding of why the individual decided to leave and to help identify any themes or areas of concern that need to be addressed. The interviews are voluntary, but the vast majority of staff do participate. Eighteen exit interviews have been conducted since June 2017. The top three reasons given for leaving were:

- Lack of opportunities for progression – of those that gave this as the main reason for leaving, all recognised that the small size of the HFEA limited the opportunities for progression.
- Pay – while all staff would ideally like to be paid more, the impact of the constraints on public sector pay is felt differently by staff depending on their role and the market rate for roles elsewhere. Unsurprisingly, perhaps, the belief that they could earn more elsewhere is articulated most often by colleagues working in IT.
- Relationship with line manager – four members of staff said that they did not feel that they had been offered appropriate support from their line manager, though there was no clear pattern to these reasons.

4. Discussion

4.1. As noted above, staff turnover has been a concern for some time. Our approach to date, has been to identify a range of concrete measures that might improve the position – for example, on

recruitment processes, learning and development, reward and recognition – while also working on a broader piece of work designed to reinvigorate the 'culture' of the organisation. Those wider ambitions were set out in our People Strategy which was approved in late 2017. And while it would be a mistake to view all this activity through the lens of reducing staff turnover, we had hoped that a reduction would have been one of the beneficial side-effects of this wider work on organisational health.

4.2. We conduct an annual staff survey each Autumn (we are currently analysing the latest survey results) which usually forms the backdrop to an all staff awayday each December. At last year's awayday we identified a range of actions, which have been delivered over the past few months, notably:

- Learning and development – we have increased the total amount of resource spent on L&D and devolved a proportion of the budget to teams to provide staff with greater control over an aspect of their development. Unfortunately to date the take up of L&D has not increased significantly;
- Rewards – like other parts of the public sector we have joined a benefits scheme (in our case 'Perkbox') which provides staff with access to a range of discounts at supermarkets, cinemas and the like – anecdotal feedback to date has been positive but we will need to do a review in time to assess whether it is worth the investment;
- New intranet – introduced in late summer this has the potential to significantly improve internal communications, something which has been a focus of criticism among many staff for some time.
- Culture – we have been a series of initiatives to reinvigorate our working culture, ranging from small scale exercises to bring colleagues together to consultant led workshops to identify areas for improvement.

4.3. However successful, such initiatives have clearly not reduced the rate of turnover. How then might we approach this issue in future?

- **We need to recognise that the key drivers of turnover are unlikely to change in the short to medium term** – public sector pay constraint is likely to continue and even if we do see increases above the 1-1.5% level of the last few years, staff are unlikely to feel better-off for some time to come regardless of what happens to the cost of living. And since the size of the HFEA is broadly fixed, promotion opportunities will remain limited.
- **We need to further improve measures to mitigate the impact of turnover** – our recruitment processes are quicker than they were, but we are not always attracting the right candidates first time. In part that is a reflection of near full employment, but we should, for example, develop a more targeted method of advertising roles – NHS and Civil Service jobs (our default methods of recruitment) work well for some roles but not for others, and we have barely begun to exploit the potential of social media as a recruiting platform.
- **We may be able to improve internal promotion by looking at the breadth of our Bands (particularly Band 3)** – our Bands are wide and allow few opportunities for advancement, without creating new hierarchies we may be able to identify more senior roles within Bands (as we have with the Senior Inspector roles) which will give more staff a sense of greater progress in role.
- **We need to articulate better the wider benefits of working in the public sector** – we are members of the civil service pension which is still one of the best schemes around and our

flexible working package is improving, particularly with better IT to support more home working. The office move in 2020 will provide an opportunity to agree new ways of working with the aim of helping staff with work/life balance issues.

- **We need to articulate better the 'employment bargain' that we can offer staff** – we deal with some of the most interesting public policy issues around. Our staff survey tells us that staff find the work interesting and understand their role in helping the public we serve. The HFEA also has a good reputation with other parts of the public sector. For most staff 2-5 years at the HFEA will allow them to develop and gain valuable experience which will serve their career well. We have begun to set out this career development model, but we could do more.
- **Work with other bodies to facilitate career development across the public sector** – if staff are unlikely to be able to make a varied career within the HFEA we can try to work with other public bodies to facilitate staff movement between bodies. Fair employment rules will stand in the way of simply slotting individuals into roles but increasing interchange must be possible. In part this is about raising awareness among staff of the possibilities elsewhere, but it is also about helping other organisations think outside of their typical employment pool. The various ALBs in the health and care sector already undertake some joint talent management of more senior roles and there is an initiative among non-economic regulatory bodies to see whether something similar might be developed. We are involved in both these networks. Some of this will be about formal development schemes, but it will also be about developing informal networks too. Making this work without devoting significant resource to such initiatives will always be a challenge.

4.4. We would welcome discussion of the proposals raised at paragraph 4.3 above.

Strategic risk register 2018/19

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**12 – High**	At tolerance	⇔⇧⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – 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,⇧⇔⇩⇔).

Recent review points are: AGC 9 October ⇨ SMT 29 October⇨ Authority 14 November ⇨ SMT 19 November

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. Indications to date 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. We have forecast an underspend on our legal budget, following the resolution of a pending appeal in October. CMG are in the process of considering options for the effective reallocation of this money, to achieve the maximum strategic benefit.

Causes / sources	Mitigations	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We have a model for forecasting treatment fee income and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC.	Quarterly, ongoing, with AGC model review at least annually - next review due in 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 financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are	Continuous - Richard Sydee Annually and as required –

	reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model.	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	**4**	**3**	**12- High**
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
At 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. Turnover remains high. 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, and in some areas, there is a trend towards over-reliance on key individuals. 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 a small organisation with little room to offer opportunities for promotion and wider government pay constraints. Elements of this include the PerkBox benefits scheme for staff, buying and selling of annual leave policy and ongoing cultural change work. We have run the 2018 staff survey and are considering the results. These have been discussed by CMG in November and will be shared with staff at the all staff awayday in December and will be used to identify further improvements. AGC will receive a paper on HR data in December, to consider the situation in the round, including ongoing strategies for the handling of these risks. Looking further ahead, we need to find ways to tackle the issues of pay and development opportunities, to prevent this risk increasing further. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations.

Causes / sources	Mitigations	Timescale / owner

High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise.	In place – Yvonne Akinmodun In place – Peter Thompson
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 (launched in October 2018) should also improve internal communications.	In place, ongoing – Peter Thompson In place – Jo Triggs
	Staff survey results for 2017/18 informed the development of the people plan. 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 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 - 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 Winter 2018/19 – 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 was carried out to assess current capabilities and processes and make changes for the future. We are in the process of implementing the relevant proposals. As part of this, recruitment is underway in Q3 2018, for two new posts within the governance team, to support the licensing function and ensure our committees are supported effectively. 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 Plan 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 in 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 future office move,	We will consult with staff, to ensure that their	Early

occurring in 2020, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.	needs are taken into account, where possible, when planning for the move. We plan to explore possible knowledge and capability benefits arising from the office move, such as the potential to open up closer working and career progression with other health regulators.	engagement with staff and other organisations underway and ongoing – Peter Thompson
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 staff survey provided 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 is made available at the earliest opportunity to boost the capability of new appointees once in post.	In place and further Authority recruitment underway from October 2018 – 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
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA which divert resource and threaten our ability to deliver our strategic aims.	The department has provided early guidance about the impact of a no-deal Brexit on the import of gametes and embryos. Further guidance is due to follow in November 2018. We continue to work closely to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. Once more is known, and at the earliest feasible opportunity, we will commence a project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of Brexit, as a third country in relation to import and export of gametes.	Communications ongoing – Peter Thompson Implementation project to be initiated when more is known-meanwhile a watching brief and close

		communications are ongoing– Laura Riley

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

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

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
At tolerance. We have undertaken further cyber security (penetration) testing of the new digital systems such as PRISM and the Register, to ensure that these remain secure. The results have not revealed any significant issues. SMT raised the tolerance level of this risk to 9 in November, reflecting that though we believe our cyber controls are fit for purpose, the context in which we operate, with a high level of national cyber risk, means we are tolerating a higher level of risk. 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 and we are reviewing the draft report.

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 AGC meeting. Fieldwork for a further cyber security internal audit report was undertaken in August and we received the draft report in November. 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 Winter 2018/19

Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	The website and Clinic Portal are secure and we have been assured of this. The focus now is on obtaining similar assurance through penetration testing report to the SIRO in relation to the remaining data submission deliverables (PRISM). The second of three rounds of penetration testing has been completed and there have been no significant issues found so far.	Penetration testing underway throughout development and ongoing - Nick Jones/ Dan Howard
There is a risk that IT demand could outstrip supply meaning IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion. We do not currently have a developer in post.	We continually refine the IT support functional model in line with industry standards (ie, ITIL). We undertook an assessment of our ticketing systems and have now purchased a new system. This will be launching in November. Following implementation we will introduce ways to capture user feedback. Following the completion of an earlier short-term cover arrangement, we have agreed to engage the third-party supplier again to provide further short-term cover, from November 2018 for a period of 4/5 months. We will now look to recruit to an in-house software development team following a workload review to take place jointly with the external supplier. Limited external support is likely to be needed for the in-house team on a permanent ongoing basis and this will be explored in due course	Approved per the ongoing business plan – Dan Howard New short-term arrangement in place from November 2018 for 4/5 months. Longer-term discussions underway – 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 Our review of current IT policies has yet to commence – 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 have been positive. The new Register will be in use from Winter

		2018/19 – 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. A plan is in place for the next Business Continuity test. 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 – Nick Jones Undertaken monthly – Dan Howard The new Register cloud backup environment will come into use in Winter 2018/19 - 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 formal project to replace our electronic document management system has been initiated, for delivery of a new system in 2019. 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 in 2019 – 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 place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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

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

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
Below 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. The Chief Executive reached an agreement with the appellant to settle the CaFC appeal. Actions agreed in the process of settlement, including some minor changes to the presentation of data on the website, have been implemented.

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

	put the HFEA in the best possible position to defend any challenge.	
	Case by case decisions on the strategic handling of contentious issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	In place – Catherine Drennan and Peter Thompson
	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law.	In place – Catherine Drennan
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs. **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). Project underway to implement changes in the light of the findings of an external licensing review, to make the licensing process more efficient and robust.	In place, further development underway as part of the licensing review implementation project – 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 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. A project to implement these is underway.	In place – Paula Robinson From October 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 to launch shortly (we are awaiting ministerial sign off, see interdependencies below) – 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 was handled proactively, with a joint HFEA and HTA project team and sponsored directly by the Director of Finance and Resources to ensure senior oversight. Although the project was closed in October, ongoing actions are being closely monitored to ensure effective compliance. AGC have regular updates on progress.	Ongoing- 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	Our regular communications channels with the Department would ensure we were aware of any	In place – Peter

interdependency. We are experiencing a delay in the final ministerial sign-off of the 2018 Code. We expected sign-off ready for launch in October and this has not occurred. Further delays have various impacts, for instance for clinics, who may become unsure about which guidance to follow, and this may result in increased queries for the inspection and legal teams. More significantly, the ongoing delay may lead to a loss of legitimacy and momentum when speaking about changing behaviour through changes to our Code of Practice because of delayed implementation. Our reputation may also suffer.	planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place – though we are dealing with unexpected delays at present, we are in ongoing communication with DHSC about the delays and we have provided clear messaging to clinics and inspectors, with updates about the likely publication date. We plan to indicate that the changes in the Code are now our expectations from clinics, although we will not retrospectively inspect against them.	Thompson

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**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 although delivery has been somewhat delayed owing to complexities. Delivery should be during winter 2018/19.

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 Winter 2018/19. Oversight and prioritisation of any remaining development work will be through the IT development programme board.	Completion of data submission project Winter 2018/19 – 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. AGC will have final sign off on the migration.	Winter 2018/19, 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, through engagement with stakeholders to	In place regular reviews to occur once the Register

fields which we do not currently focus on or deem critical for accuracy.	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 under CS1, we have a further temporary arrangement in place for ongoing external support for 4/5 months from November 2018 and are considering ongoing requirements.	In place with work underway to improve arrangements in Q3/4 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. Two vacancies in the inspection team have been filled. There will be a period of bedding in now that they have joined (in November 2018).	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 plan was agreed in spring 2018.	Ongoing - 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. Plan in place to deal with any inability to supply data. 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.	Ongoing - 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. The minimum National Audit Office required audits have been delivered, however, we have deferred several further audits to be completed before the years' end.	In place with conversations about the remaining audit programme in Q3 – 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 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 we piloted in 2018 to give us qualitative and quantitative data on patient's experience of fertility treatment in the UK. We are currently in the process of reviewing the findings of this survey.	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.	⇔⇔⇔⇔

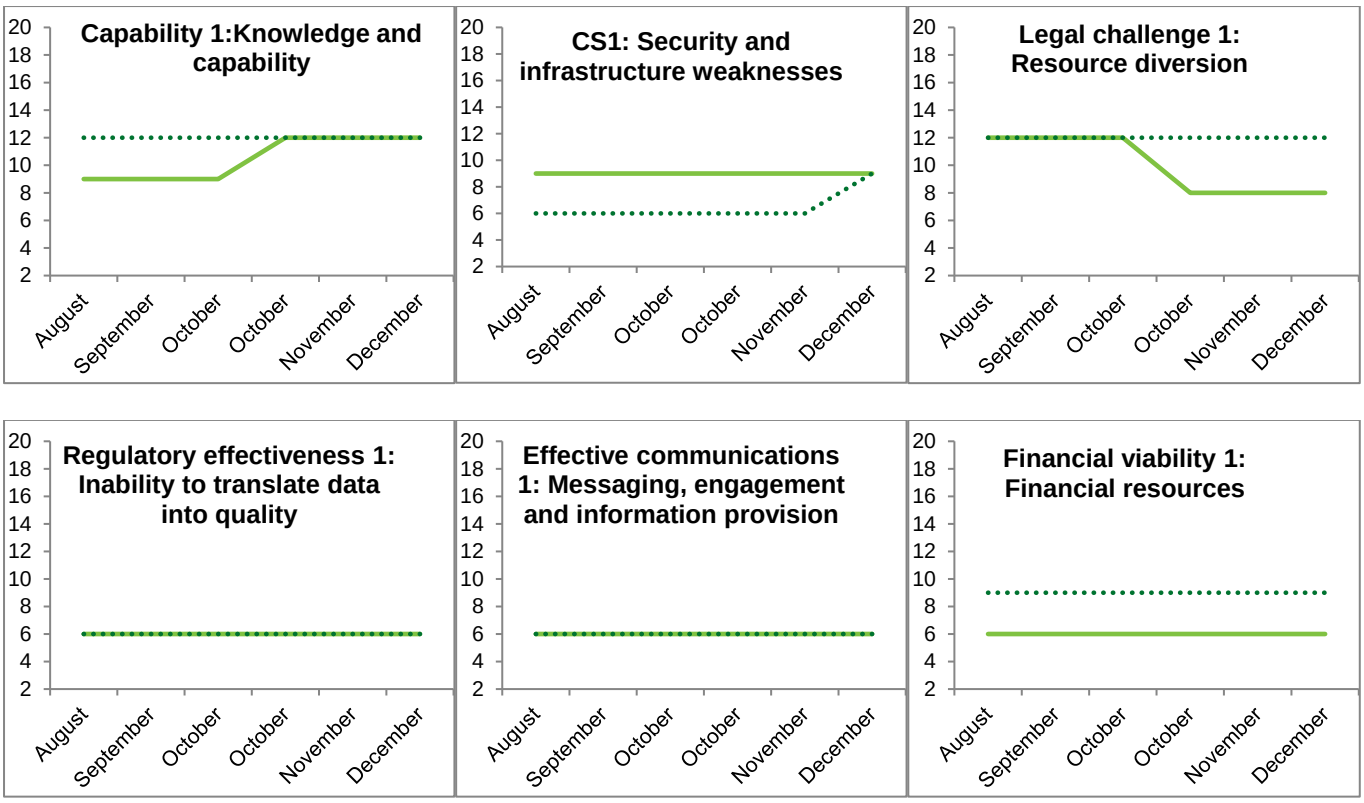
Commentary
At tolerance. The last few months have seen us undertake several high-profile pieces of work to present more and better information to stakeholders, examples include the new egg freezing report, which was published in September, the Code of Practice consultation and various messaging around the 40th anniversary of IVF and Fertility Week. The national patient survey pilot project was developed with input and clear direction from the Intelligence Advisory Board which includes both Authority member representatives and external experts. This survey data will better inform HFEA information provision and other interventions. The results of this are currently being reviewed. We are in the process of revisiting our wider communications strategy to ensure that it remains fit for purpose. This will be presented to the Authority in January 2019.

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

Patients and other stakeholders do not receive the correct guidance or information.	Communications strategy in place, including social media and other channels as well as making full use of our new website. Stakeholder meetings with the sector in place to help us to underline key campaign messages. The new publication schedule uses HFEA data more fully and makes this more accessible. Policy team ensures guidance is created with appropriate stakeholder engagement and is developed and implemented carefully to ensure it is correct. Ongoing user testing and feedback on information on the website allows us to properly understand user needs. We have internal processes in place which meet the Information Standard. 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. The Authority considered options in November 2018 and tasked the executive with exploring these further. 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 - 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.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Planning for campaigns and projects includes consideration of communications channels. When developing policies, we ensure that we have strong communication plans in place to reach the appropriate stakeholders. Extended use of social media to get to the right audiences. The communications team analyse the effectiveness of our communications channels at Digital Communications Board meetings, to ensure that they continue to meet our user needs.	In place – Jo Triggs In place and ongoing – Jo Triggs In place - Laura Riley, Jo Triggs In place– Jo Triggs Ongoing – Jo Triggs
Risk that incorrect information is provided in PQs, OTRs or FOIs and this may lead to misinformation and misunderstanding by patients, journalists and others.	PQs and FOIs have dedicated expert staff to manage them. We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission.	In place - Clare Ettinghausen Clare Ettinghausen /SMT - In

		place
	There is a dedicated OTR team and all responses are checked before they are sent out to applicants to ensure that the information is accurate.	In place - Dan Howard
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
There is a risk that we provide inaccurate information and data on our website or elsewhere.	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.UK: The NHS website and our site contain links to one another which could break	We maintain a relationship with the NHS.UK team to ensure that links are effectively maintained.	In place – Jo Triggs
DHSC: interdependent communication requirements may not be considered	DHSC and HFEA have a framework agreement for public communications to support effective co-operation, co-ordination and collaboration and we adhere to this.	In place – Jo Triggs

Risk trends



Reviews and revisions

SMT review – November 2018 (19/11/18)

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

- C1 – SMT noted that the upcoming discussions about capability risk at CMG and AGC would help to shape future controls, meanwhile the detailed commentary of this risk was helpful for transparency.
- CS1 – SMT discussed business continuity arrangements and plans. SMT noted that a plan was not yet in place for the next business continuity test, a test had not occurred since September 2017. SMT agreed that a check of staff contact details should occur and the business continuity plan should be circulated to ensure all staff were clear about roles and responsibilities. This was particularly important given the number of new starters. A test should follow. The timing was expedient as a business continuity audit was underway.
- SMT had a full discussion about the tolerance level for the cyber risk, noting that we had reported this as above tolerance since July. Every care was continuing to be taken around data security and SMT were satisfied the controls were effective. However, as had been acknowledged when SMT raised the residual risk level in July, the context in which the organisation was operating was inherently riskier. SMT therefore agreed that we were not 'above tolerance' for this risk, but our tolerance level had increased somewhat. SMT agreed that the risk should have a tolerance of 9.
- RE1- SMT discussed the effect of current resource pressures on the delivery of the audit programme. The minimum number of audits required by the National Audit Office had already been delivered, however further audits that were due to be scheduled at the outset of the year had not been undertaken due to lack of resource in the Register team. The Director of Compliance noted that he was discussing this with the new Register Team Leader to ensure that further audits were planned and enable a greater level of control and assurance.
- Updates had been done throughout to reflect the delayed delivery of the data submission and migration projects.

Authority review – November 2018 (14/11/18)

Authority received the risk register during its November meeting. Comments were also made on risk throughout the meeting

- FV1 –. Authority noted that the executive were reviewing options for reallocating the legal contingency
- CS1 – Authority noted that AGC had had an in-depth report on cyber risk and received frequent updates from the Chief Information Officer. The Deputy Chair commented that the Authority was in a good position in relation to cyber risk. Authority noted that the results of an audit on cyber risk would follow imminently and further controls considered in the light of this.
- Authority also considered the statement on risk appetite and discussed the position on risk. Authority agreed the risk appetite statement which had been revised following AGC's comments.

SMT review – October 2018 (29/10/18)

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

- SMT reflected on the inclusion of Brexit and the future office move on the register and agreed to wording in relation to these risks. It was clear that the nature of these risks and the mitigations needed would become clearer over time.
- FV1 – SMT discussed the financial position in relation to the legal budget. Underspending against budget could impact on wider organisational funding, so SMT took the view that any underspend should be effectively re-allocated towards achieving our strategic aims. The Director of Finance was currently collating proposals, which would be considered in the coming weeks.
- C1 – SMT discussed capability challenges. An ongoing dialogue with CMG and AGC about capability risks was helpful for considering these in the round and would inform ongoing planning of mitigations. The recruitment to two new posts in the licensing team would ultimately provide more capability and resilience and address resource pressures. SMT decided that given the wider context, much of which is outside of its direct control, to raise the residual likelihood of this risk at this time.
- LC1 – SMT discussed legal risk and the recent settlement of an appeal against Choose a Fertility Clinic. SMT agreed that this left the organisation in an improved position in relation to legal risk and reduced the inherent likelihood somewhat to a score of 4 (likely) rather than 5 (almost certain). The residual likelihood had reduced, which brought the overall risk score down to a medium score of 8, which was below tolerance. Interdependent risk in relation to the ministerial sign off of the Code of Practice was being managed proactively, although we were reliant upon the department and, ultimately, the minister.

AGC review – October 2018 (08/10/18).

AGC reviewed the risk register and scores and did not raise any of these. The committee requested two additions to the register:

- AGC had discussed estates earlier in the meeting and felt that the risks around the office move that would happen in 2020 should be captured in the strategic risk register, owing to the possibility of this impacting turnover and therefore capability.
- AGC requested that Brexit, though not considered a significant strategic risk to the Authority, should also be reflected in the register, given the uncertainty around this and possibility that there may be implications as yet unknown or not fully understood.

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.

Reserves policy

Strategic delivery:	X Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	15		
Paper number	HFEA (04/12/2018) 646		
Meeting date	4 December 2018		
Author	Richard Sydee, Director of Finance and Facilities		
Output:			
For information or decision?	For information		
Recommendation	In deliberation for the approval of the latest iteration of the HFEA Reserves Policy, the Members of the AGC are required to note the HFEA's historic cash flows set out in this paper. The AGC is requested to approve the latest iteration of the HFEA's Reserves Policy.		
Resource implications			
Implementation date	April 2019		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

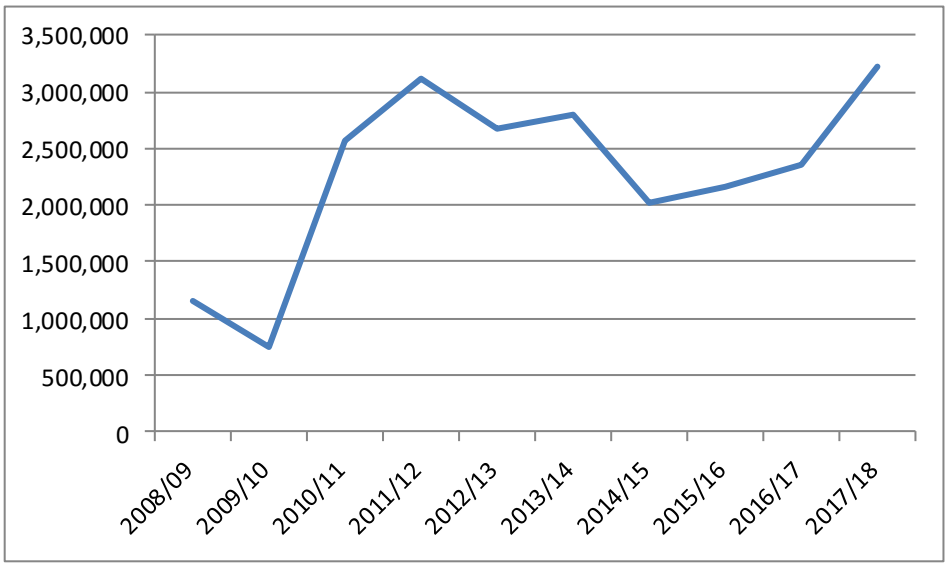
1. Background

1.1. The purpose of this paper is to provide the Audit and Governance Committee (AGC) with additional information to inform its consideration of the latest iteration of the HFEA Reserves Policy.

1.2. A copy of the HFEA Reserves Policy was presented to the AGC at its meeting on 3 October 2017. On that occasion, the Committee agreed the current level of reserves being proposed.

1.3. The HFEA has historically operated with a significant cash reserve. At inception, the HFEA was in receipt of cash grants from the Department of Health & Social Care (DHSC) and its initial fees were levied at levels that covered a proportion of its expenditure. The bulk of its cash from DHSC came in years 2003 and 2004. From 2005 onwards, Grant in Aid (GIA) was received with the most significant amount being £6.2m in 2005/06. The graph bellows sets out the historic year-end cash balances for the HFEA over the past 10 years.

HFEA historic cash balances 2008/09 - 2017/18



1.4. As can be seen from the graph, except for 2009/10 financial year where the cash balance was at its lowest due to a reduction in creditors relating to the completion of Programme 2010, we have seen an increase in HFEA holdings at the end of each financial year. There are a few reasons for this continued position.

- The HFEA is by default required to make a surplus each financial year. Our agreement with our sponsor department is that our finances will never exceed the total of annual income plus GIA. As we will always make a surplus our cash holding will always increase dependent on the size of the annual surplus – a 1% surplus equates to £60k increase in cash;
- All HFEA income is cash but some costs (Depreciation and amortisation) are non-cash. Cash holdings therefore increase by our non-cash expenditure each year. We have now rectified this by ensuring that our non-cash costs are covered by the department by ring fencing.
- We have no simple mechanism to return cash either to stakeholders or the General Fund (HM Treasury). The sums involved would be immaterial to most and therefore we have been reluctant to enter in to a bureaucratic exercise that would yield little benefit to stakeholders.

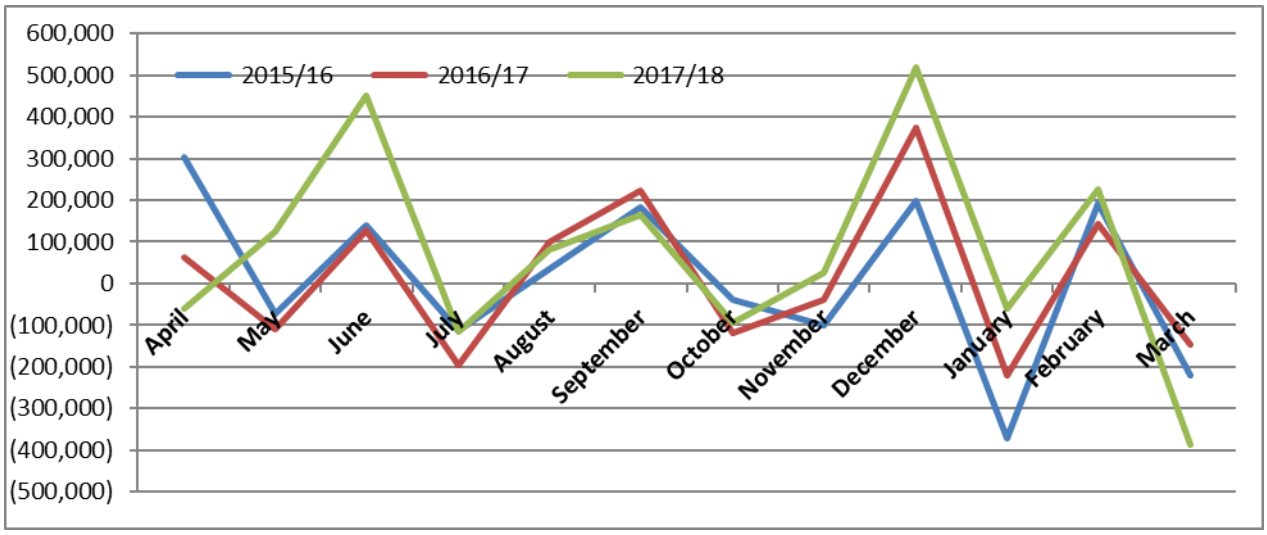
1.5. In terms of possible approaches to reducing our cash balance there are a number of options, none without issue:

- Returning cash to the General Fund is of course an option; however, our cash surplus has been built up primarily through an excess of licence fees compared to the cost of regulation. There would need to be consideration of whether it was appropriate to hand over income generated for the benefit of the regulated sector to HM Treasury.
- Returning an element of fees back to stakeholders would require some consideration of the methodology for returning historic fees – over what period generated, would it be a cash return or a reduction on 2019/20 fees. This would require considerable effort and would, depending on the total amount to be returned, likely to return only a small percentage of a treatment fee.
- Investment in the HFEA infrastructure and funding the wider programmes could help reduce surpluses.

1.6. None of these options are straightforward and would need to be considered and approved by the Authority and DHSC.

1.7. In terms of the amount that could be returned/recycled, that would be dependent on the minimum cash reserve deemed necessary for the HFEA to operate. Below we have analysed cash flows over the past three financial years to illustrate the likely requirement

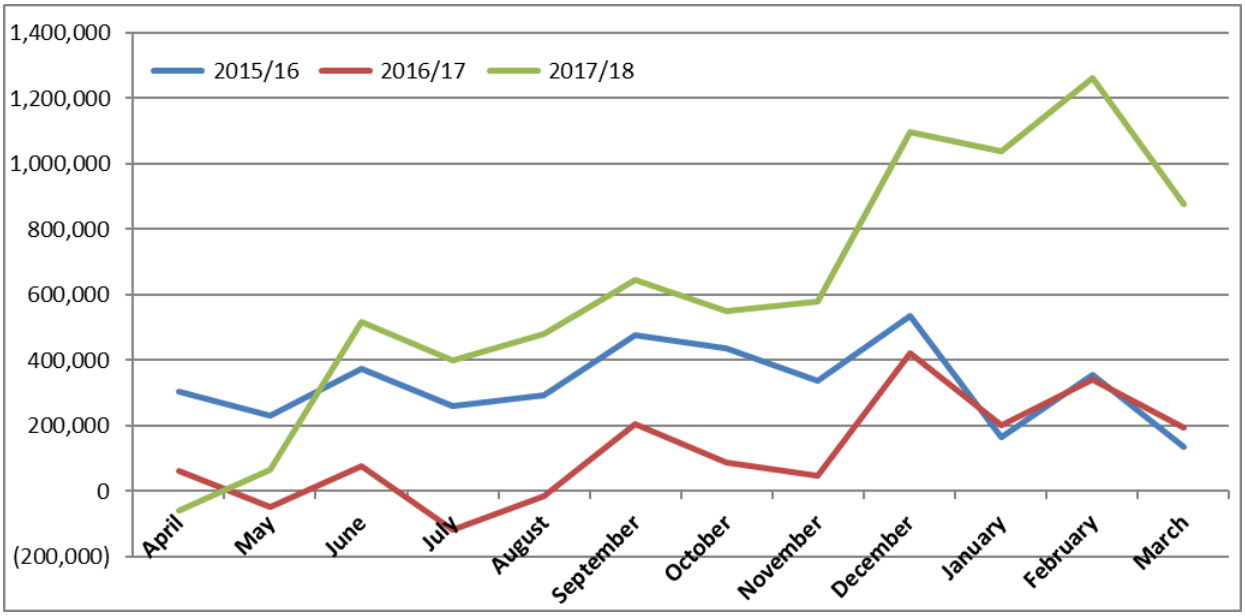
HFEA annual cash flows 2015/16 – 2017/18



1.8. As the above graph demonstrates, the HFEA received the bulk of its income in four tranches, where there is a push on credit control activities. This slightly uneven cash inflow compares unfavourably to very stable cash outflows where close to 80% (where approximately £4m in staff salaries and staff expenses are paid monthly with accommodation costs paid quarterly) of expenditure is evenly apportioned across the financial year. As a result, HFEA needs a cash buffer to meet outflows during the periods where outflows are high.

1.9. The current reserves policy suggests a minimum cash holding of £1.4m to ensure that the HFEA always has sufficient cash reserves to meet regular and unforeseen cash requirements. The graph below sets out the net cash position for the last three financial years.

HFEA net cash flows 2015/16 – 2017/18



1.10. The graph shows that the HFEA has a relatively steady flow of cash. In 2017/18 there was a period of three months where net cash flow is in excess of £1m

1.11. Historically the HFEA has experienced cash balances in excess of £2.5m against the Reserve Policy level of £1.4m agreed by the Committee.

1.12. The Committee are requested to think about the how best the HFEA can utilise its reserves in order that the levels can be reduced over time.

Reserves Policy

Introduction

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

Principles

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

Reserves Policy

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

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

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

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

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

Cashflow

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

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

Contingency

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

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

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

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

    a. salaries (including employer on-costs);

    b. the cost of accommodation.; and,

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

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

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

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

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

Minimum reserves

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

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

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

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

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

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

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

Version/revision control

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

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	16		
Paper number	AGC (04/12/2018) 647		
Meeting date	4 December 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:	5 Mar 2019	18 Jun 2019	8 Oct 2019	3 Dec 2019
Following Authority Date:	13 Mar 2019	3 July 2019	13 Nov 2019	Jan 2020
Meeting 'Theme/s'	**Finance and Resources**	**Annual Reports, Information Governance, People**	**Strategy & Corporate Affairs, AGC review**	**Register and Compliance, Business Continuity**
Reporting Officers	**Director of Finance & Resources**	**Director of Finance & Resources**	**Director of Strategy & Corporate Affairs**	**Director of Compliance and Information**
Strategic Risk Register	Yes	Yes	Yes	Yes
Digital Programme Update	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)		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
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

AGC Items Date:	5 Mar 2019	18 Jun 2019	8 Oct 2019	3 Dec 2019
HR, People Planning & Processes		Yes Including bi-annual HR report		Bi-annual HR report
Strategy & Corporate Affairs management			Yes	
Regulatory & Register management	Yes			Yes
Cyber Security Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Estates	Yes	Yes	Yes	Yes
General Data Protection Act (GDPR)			Yes	Yes
Review of AGC activities & effectiveness, terms of reference				Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				