Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

6 March 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 5 December 2017 **[AGC (06/03/2018) 585]**	For Decision	10.05am
3.	Matters Arising **[AGC (06/03/2018) 586 MA]**	For Information	10.10am
4.	Finance and Resources Update **[AGC (06/03/2018) 587 RS]**	Presentation	10.15am
5.	Internal Audit a) Internal Audit Progress Report **[AGC (06/03/2018) 588 DH]** b) Progress with Audit Recommendations **[AGC (06/03/2018) 589 MA]**	 For Information For Information	10.45am
6.	External Audit – Interim Feedback **[AGC (06/03/2018) 590 NAO]**	Verbal Update	11.00am
7.	Impact of Brexit **[AGC (06/03/2018) 591 PT]**	For information	11.10am
8.	Digital Programme Update **[AGC (06/03/2018) 592 DH]**	For Information	11.20am
9.	Resilience, Business Continuity Management Cyber Security **[AGC (06/03/2018) 593 DH]**	For Information	11.35am
10.	Strategic Risk Register **[AGC (06/03/2018) 594HC]**	For Information/Comment	11.45am
11.	AGC Forward Plan **[AGC (06/03/2018) 595 MA]**	For Decision	12.00pm
12.	GDPR (General Data Protection Regulation) **[AGC (06/03/2018) 596 RS]**	Presentation	12.05pm

13.	Whistle Blowing and Fraud **[AGC (06/03/2018) 597 RS]**	Verbal update	12.10pm
14.	Contracts and Procurement **[AGC (06/03/2018) 598 MA]**	Verbal update	12.15pm
15.	Review of AGC activities & effectiveness, terms of reference **[AGC (06/03/2018) 599 PR]**	For discussion (Members Only)	12:20pm
16.	Any other business		12.35pm
17.	Close (Refreshments & Lunch provided)		12.40pm
18.	Session for members and auditors only		12.40pm
19.	Next Meeting 10am Tuesday, 12 June 2018, Church House, 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 (06/03/2018) 585
Meeting date	6 March 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 5 December 2017

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

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

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting.

1.2 Apologies were received from George Smiles, National Audit Office.

1.3 There were no declarations of interest.

2. Minutes of the meeting held on 3 October 2017

2.1 The minutes of the meeting held on 3 October 2017 were agreed as a true record 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 8.11) The Director of Finance and Resources had explored the potential to use surplus funds to commission research on data held by the Authority. The Committee agreed this item could be removed from the matters arising log.

3.3 4.7) The Director of Compliance and Information and the Head of Planning and Governance were ensuring that all new, and established, Authority and Committee members receive the mandatory e-learning 'responsible for information training' regularly. The Committee had received an email from the Head of Planning and Governance regarding access to this training. It was agreed this item could be removed from the matters arising log.

3.4 6.5) The NAO had updated the audit planning report, regarding the wording concerning fraud. The Committee agreed this item could be removed from the log.

3.5 Items 15.2, 6.6, 7.12, 8.5 and 9.13 relating to the fraud investigation, training plan for the Committee, the data submission project, member access to O365 and the strategic risk register have been addressed in the items on the agenda below.

3.6 11.3) The Head of Planning and Governance had confirmed that the item on reviewing activities, effectiveness and terms of reference for the Committee can be deferred to the 6 March 2018 meeting. If the review results in any proposals to amend Standing Orders, this could be relayed verbally at the March Authority meeting, when the annual review of Standing Orders will be considered.

4. Regulatory and Register Management

4.1 The Director of Compliance and Information spoke to the presentation, providing an overview of regulatory and Register management.

4.2 The Committee was informed of the current strategic risks, concerning cyber security, regulatory effectiveness (data migration and creating new cultures in clinics) and associated capability, capacity and change.

4.3 The Authority is aware of its exposure concerning cyber security, and it is vital that staff receive security training, and that the Register retains a usable format and processes well. Business Continuity and good records management must also be maintained. The need to comply with the new General Data Protection Regulation (GDPR), which takes effect in April 2018, was also identified.

4.4 To maintain regulatory effectiveness, the Authority needs to explore new ways of obtaining and analysing intelligence from data, including that available from clinics. The new intelligence team would be looking at the best ways to use data, noting that there is a great deal of information that can be exploited to the benefit of the Authority. The Director of Compliance and Information acknowledged the effective work conducted by the inspectors, giving the Authority credibility and robustness. The need to be equipped to answer Freedom of Information requests and Parliamentary Questions was noted.

4.5 The Committee was provided with a structural overview of the newly formed Compliance and Information Directorate. Particular reference was made to the four new teams operating under the Chief Information Officer, dealing with operating the Register, Register management, IT development and contracts, and IT system management. The Chief Inspector's team incorporates three senior inspectors, 12 inspectors and two business support officers. There are

some scientific inspectors, who specifically deal with inspections of research centres and assist with treatment and storage inspections, focusing on laboratory aspects.

4.6 A new senior inspector, focusing on information quality, will start in Spring 2018. This role will deal with the implications of the new GDPR and help embed the necessary processes into clinics, taking into account the requirements stated within the new information policy, which would be presented to the Authority in January 2018.

4.7 The Director of Compliance and Information identified that the Register management team is currently consumed with data migration work. The development and contract work is, at present, being dealt with by temporary staff, which requires careful handling. A new manager for the system management team will commence work in December 2017. The Compliance and Information Directorate restructure should then be complete.

4.8 The Committee acknowledged the regulatory and Register management achievements, which included 81 inspections. The number of inspections has been more than anticipated, but reports had generally been completed to timescales. Increasingly, the more difficult cases are being referred to the Licence Committee. 74% of clinics attain a five star rating (four year licence) and 299 non-compliances had been identified at inspections, with relatively few being critical or major. Since reports are published on the website, there is transparency in the Authority's work.

4.9 The Committee noted there had been 540 incidents in clinics, with only one identified as the most serious, Grade A. The new state of the sector report enabled a good selection of data to be held in one place.

4.10 Work on the Multiple Birth Reduction Strategy was noted. In 2009, this rate stood at 24% in clinics, but had now decreased to 11%. The Committee recognised the huge reduction in multiple births, agreeing that there should be some publicity, celebrating this achievement, once the 10% target of the strategy has been reached.

4.11 The Director of Compliance and Information spoke of the need to acquire more patient feedback. At present, some information is being gained through inspectors and use of the website, but work to encourage more patients to rate clinics is ongoing.

4.12 Reference was made to the investigation into the Daily Mail media report, which had identified issues at a number of clinics. These clinics had been inspected and some areas for improvement had been identified. The Committee noted that as a result of this work, one clinic had been given a reduced licence length.

4.13 The Director of Compliance and Information referred to the possible opportunities for the Authority, including a new deal on information quality with clinics (due in Spring 2018), adding value and improvement at inspections and a resilient, versatile Register. Low cost infrastructure could be achieved through working in partnership with other organisations, such as the Human Tissue Authority (HTA). The necessity to prepare for GDPR, review records management arrangements and release the potential of O365 was also stated.

4.14 The Committee acknowledged the operational risks, including issues resulting from the data submission work, IT resilience, recruitment and the pace and breadth of work which incorporated GDPR, leadership assessments and changes to the Code of Practice.

4.15 The planned assessment of leadership in clinics was discussed. In general the Committee thought this is an important and potentially impactful development, but in undertaking this work it is important for the Authority not to cross the line from a regulatory to a managerial role at centres. The Committee felt that good compliance would result in centres operating as good

businesses, and that this then links into the provision of high patient care. The Chief Executive stated the need to be explicit about what good leadership actually means in this context.

4.16 Resilience, with regard to inspectors, was discussed and the Director of Compliance and Information assured the Committee that despite losing a number of inspectors over the past year, recruiting replacements had not proved difficult. This may be due to inspectors being able to work from home and have autonomy with their work. New inspectors had been recruited from Northern Ireland and the North West. Candidates applying for these positions often sought a break from working in clinics.

4.17 The Chair thanked the Director of Compliance and Information for the valuable update, identifying that it would be beneficial to revisit this area, on the completion of further work.

Action

4.18 The Director of Compliance and Information to provide the Committee with an update on regulatory and Register management in due course.

5. Internal Audit

a) Progress Report

5.1 The Head of Internal Audit provided an update on progress against the current Internal Audit Plan. The audits on data loss and risk management and governance had been completed. Fieldwork was underway regarding audits on financial control and the General Data Protection Regulation. The Committee was informed that following up on agreed recommendations of previous audits, will commence in December.

b) Risk Management Final Report

5.2 The Head of Internal Audit spoke to the risk management final report which had been positive overall. There were two recommendations in relation to the risk register and exit interviews.

5.3 The risk register required some changes to mitigating actions, contingency actions, risk appetite/tolerance and details of actions conducted. The Head of Planning and Governance reported there has been a productive deep dive audit regarding the risk register which had enhanced ideas. The Committee was informed there is a formal system for reporting risk and a Risk Champion exists in each team.

5.4 The importance of exit interviews was acknowledged, particularly at a time of high staff turnover. The Chief Executive confirmed exit interviews are always conducted, but the Authority could be better at reflecting on the issues raised.

5.5 The Chair asked why the Authority was only awarded a moderate rating, considering the content of the final report. The Head of Internal Audit confirmed this was due to there being two recommendations, which required changes; these would be followed-up in due course.

5.6 It was identified that the report did not comment on risks associated with the role of the Authority and of the Audit and Governance Committee. The Head of Internal Audit confirmed this had not been identified as a focus for the report.

5.7 The Committee noted that risks cannot always be anticipated and it is important to be aware that risks can be associated to any daily tasks.

6. Implementation of Audit Recommendations

6.1 The Head of Finance reiterated that there has been six audit recommendations, surrounding data loss and risk management. The recommendation concerning business continuity testing had been completed.

6.2 Regarding staffing and capability, the Committee was informed that a new Information Project Officer will take up post in January 2018. The staff training work should be completed in December 2017. Authority and Audit and Governance members had been sent the necessary training information. Completion dates for risk register and staffing and capacity work are yet to be confirmed. DH internal audit confirmed that, from now on, completed audit recommendations would be looked at within their follow-up work.

7. External Audit – Audit Planning Report

7.1 The NAO notified the Committee there is no update on the audit planning report at present. The interim visit would occur in February 2018.

8. Handling Brexit

8.1 The Chief Executive spoke to the presentation, providing some context to Brexit and information currently known. Britain is expected to leave the EU by April 2019, but discussions on a potential transition period is still ongoing.

8.2 The Committee was informed that Brexit would impact on the fertility sector in two ways, internally and externally. With regards to the internal impact, the Chief Executive referred to five pieces of relevant EU legislation. The EU Tissues and Cells Directive (2004/23/EC), the First Technical Directive (2006/17/EC) and Second Technical Directive (2006/86/EC) are already incorporated into UK law so will continue to apply regardless of Brexit.

8.3 The Coding Directive (EC/2015/565) and Import Directive (EC/2015/566) are in the process of being transposed to UK law and this should be completed before Brexit. Therefore, Brexit is unlikely to have any direct or immediate impact on the Authority's legal framework. It was noted that the absence of these two Directives would not be particularly problematic for the Authority, but the future impact of any Court of Justice of the European Union (CJEU) or European Convention on Human Rights (ECHR) rulings is uncertain.

8.4 The Department of Health reported they were undertaking work on EU legislation and its association with Brexit. It was hoped that further information on the regulations would be known before January 2018 and that The Coding Directive (EC/2015/565) and Import Directive (EC/2015/566) would be transposed to UK law by April 2018. However, these Directives give patients no significant material gain as their aims are already met by existing requirements in the Human Fertilisation & Embryology Act 1990. It was noted that these particular Directives are expected to have a greater impact on tissue establishments licenced by the Human Tissue Authority.

8.5 The Chief Executive explained that the Authority had contacted the 20 largest fertility clinics in the UK to gain insight into the potential external impact of Brexit. Clinics answered questions regarding EU nationals in their workforce, the type of work they undertake, any evidence that EU nationals are returning to their home country to work and any concerns on the potential impact of Brexit on the workforce. Responses indicated there is currently little evidence of Brexit having an 'unsettling effect' on the workforce but recruitment of trained embryologists had become more problematic, worsened by the recent cutback in the number of UK training places.

8.6 The Committee felt reassured by the information provided, noting there is good motivation for specialists in the fertility field to work in the UK. The importance of establishing the type of relationship the Authority wants with the EU, at the point of Brexit, was identified. The Committee noted the particular impact on the labour market Brexit might cause, alongside the impact on science and technology and access to high quality researchers. It was also questioned whether the UK would remain in the EU research programme.

8.7 The Committee and Chief Executive agreed that it would be useful to gain further insight into the bio-science research field and access to staff in the UK market, with regard to the impact of Brexit. This information could be acquired by use of an interactive tool or trend data. It would be beneficial to establish the percentage of current research deriving from the EU. The Chief Executive would conduct further investigation into the impact of Brexit for revisiting at the 6 March 2018 Committee meeting, then consider what information to present to the Authority.

Action

8.8 The Chief Executive would conduct further investigation into the impact of Brexit, for revisiting at the 6 March 2018 Committee meeting.

9. Digital Programme Update: Including Data Submission

9.1 The Chief Information Officer spoke to the paper, providing a digital programme update, confirming there had been huge progress on work, with more clarity on the project plan and timescales. There had also been an increase in staffing levels.

9.2 The Committee was alerted to the risks within the project mainly concerning critical local knowledge of the data and database which resides in a few key individuals, the duration of any unpredicted remedial work and the availability of specialist skills. However, the Chief Information Officer stated that work is progressing well.

9.3 Good progress on the data submission system work had been made and the process of exposing the Electronic Patient Record System (EPRS) to APIs for modules completed to date had continued, with positive feedback received thus far.

9.4 Technical work relating to the launch of the new Register is ongoing and centres are being kept up to date with that work. Guidance for clinics and suppliers of third party systems will be issued and new Information Standards will be launched in 2018.

9.5 The Committee commended the Chief Information Officer on the progress made on this work, but expressed some concern regarding the reliability of the current infrastructure and systems. The Chief Information Officer confirmed work addressing these issues is being undertaken and it is crucial these are rectified.

9.6 The Chair noted that the programme of work had moved forward since the last Committee meeting. The timetable for completion is tight, but assurance points had been inserted throughout. The Chair requested that the Committee be alerted should any of the assurance points be missed. The Chief Information Officer notified the Committee that the next major trigger point would fall in mid-January 2018, and it currently looked as if this would be completed to the timetable.

9.7 The Director of Compliance and Information stated that should the project fall behind the timetable, it would not pose a risk to the integrity of the register.

9.8 Noting that the next Committee meeting would not occur until 6 March 2018, it was agreed that an update on progress would be circulated to members at the end of January 2018.

Actions

9.9 The Chief Information Officer to alert the Committee, should any of the assurance points be missed.

9.10 The Chief Information Officer to circulate an update on progress to members at the end of January 2018.

10. Resilience, Business Continuity Management and Cyber Security

10.1 The Committee was provided with an update regarding resilience, business continuity and cyber security.

10.2 Since the 3 October 2017 meeting, business continuity testing has progressed well and Authority members could now access the Business Continuity Plan Sharepoint page, using O365. The Chief Information Officer acknowledged the relevant page is difficult to locate and this would be rectified.

10.3 Cyber security risks remain and are being continually monitored and escalated where necessary. All staff will be required to complete the refreshed mandatory training 'Responsible for Information: general user' course before the end of December 2017.

11. Strategic Risk Register

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

11.2 The Committee was informed that the Authority received the risk register at its meeting on 15 November 2017 and the Corporate Management Group (CMG) gave its views on 22 November 2017. All risks, controls and scores were reviewed. As requested at the last Committee meeting, statements have been added on risk tolerance and appetite in the background information of the report. A review of the risk policy will be conducted, for agreement at CMG in February 2018.

11.3 The Risk and Business Planning Manager notified the Committee that with the agreement of the Authority, the organisational change risk had been adjusted back to tolerance given that almost all of the voluntary redundancies had occurred and most of the recruitment is complete. It was agreed this strategic risk could be removed at the end of the business year. Any risks pertaining to organisational change could then be incorporated into the relevant areas of the risk register as required.

11.4 The Committee was notified that the capability risk remained above tolerance due to the internal staff changes and resulting knowledge gaps, alongside ongoing data submission and data work. The Chief Executive stated that although this risk remains above tolerance, it now feels more manageable, paying tribute to staff working on recruitment needs. A difficulty in attracting the right candidates for some positions was identified and the loss of knowledgeable staff remained a real issue.

11.5 The Chief Executive informed the Committee that a new Head of HR had been appointed which would assist with recruitment and staff issues. A leadership awayday for senior management and Heads had occurred and an all staff awayday is scheduled for January 2018. A replacement for the current Director of Strategy and Corporate Affairs had been appointed and would commence work in January 2018.

11.6 The Chief Executive spoke of the underlying factors concerning the difficulties in retaining staff, acknowledging the fact that public sector rules meant there had not been a pay increase of more than 1% in the last seven years. The staff survey had just been conducted and the outcomes of this will be viewed by the Committee in due course.

11.7 The Committee stated the importance of ensuring there is a career structure for staff, which should help in the retention of knowledge.

11.8 Issues in assigning Specialist Advisers and Legal Advisors, for Statutory Approvals Committee meetings in particular, due to conflicts of interest, were noted. This is becoming an increasing problem, particularly with the increase in PGD applications and the introduction of Mitochondrial Transfer applications.

11.9 The risk concerning legal challenge was acknowledged, noting the consent to legal parenthood judgments and the reduction in the number of new and upcoming cases. A judicial review hearing of one of the discrete elements of the IfQ Choose a Fertility Clinic project had been won by the Authority in January 2017, but a decision by the Court of Appeal on whether permission to appeal will be granted is still awaited.

11.10 The Committee noted that a licensing matter was considered by the Appeals Committee in October 2017, but was settled by way of a consent order, resulting in the judicial review claim becoming redundant and withdrawn.

11.11 Regarding cyber security, the Committee referred to the risk of becoming more dependent on external advice and support, stating that the current wording used for mitigation within the risk register, may not be phrased correctly, and needs some attention.

11.12 The Head of Finance and Resources stated that discussion had occurred concerning reducing the residual risk of the financial viability area. A deep-dive examination of this risk would be done following the Authority's review of the proposed forecasting model in January. This would be reflected in the risk register that would go to the Committee for consideration at their next meeting.

11.13 The Chief Information Officer spoke of the Skype issues present at the Spring Gardens office, stating work is ongoing to resolve the problems. An explanation on the exact cause of the difficulties is being acquired, so a permanent fix can be found. The possible cost associated with this was acknowledged.

12. AGC Forward Plan

12.1 The Head of Finance, with regard to the forward plan for 2018, noted that due to timings in the reporting cycle, a draft annual report and accounts would be presented to the 12 June 2018 meeting.

12.2 The Committee noted that the theme for the 6 March 2018 meeting would be finance and resources. The Committee agreed that the Director of Finance and Resources should focus on budget forecasting, risks and assumptions, likely income and budget spends.

12.3 The Committee discussed their training needs for 2018. Members felt that feedback on audit reviews and outcomes, from other regulatory bodies, would be useful, but agreed this could be incorporated into meeting agendas. Cyber security and emerging trends were also seen to be valuable information.

12.4 The Committee felt that it would be useful to receive training providing a reminder as to the areas they are responsible for and where they could provide improved scrutiny.

12.5 The NAO would investigate which areas of training similar committees have been receiving.

12.6 The Committee agreed that the Director of Finance and Resources should arrange training for members, to follow the 6 March 2018 meeting.

Action

12.7 The NAO to investigate which areas of training similar committees have been receiving.

12.8 The Director of Finance and Resources to arrange training for members to follow the 6 March 2018 meeting.

13. Whistle Blowing and Fraud

13.1 The Director of Finance and Resources informed the Committee that the investigation into the case of alleged fraud in connection with a contract provider remains ongoing. The DH Anti-Fraud team require further information from the Authority before discussion with the Crown Prosecution Service. It is hoped that the matter will be concluded early in 2018.

13.2 The Committee raised a point for clarification regarding access to their HFEA email accounts. The Director of Compliance and Information confirmed that, as these email accounts are owned by the Authority, these could be accessed and viewed by others within the organisation.

14. Contracts and Procurement

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

15. Any Other Business

15.1 Members and auditors retired for their confidential session.

15.2 The next meeting will be held on Tuesday, 6 March 2018 at 10am.

16. Chair's signature

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

Signature

Name

Anita Bharucha

Date

6 March 2018

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (06/03/2018) 586 MA]**
Meeting Date:	6 March 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:

- 6 items added from December 2017 meeting, 6 ongoing
- 6 items carried over from earlier meetings, 6 ongoing

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from Audit and Governance Committee – actions from 7 December 2016 meeting			
11.6 Head of IT to provide the Audit and Governance Committee with regular updates on Cyber Security.	Head of IT		**Ongoing**
Matters Arising from Audit and Governance Committee – actions from 13 June 2017 meeting			
15.2 The Director of Finance and Resources to ensure the Committee remains updated with regards to the outcome of the investigation	Director of Finance and Resources		**Ongoing** - An update will be provided at the March 2018 meeting
Matters Arising from Audit and Governance Committee – actions from 3 October 2017 meeting			
6.6 The Director of Finance and Resources to create a training plan for the Committee, ensuring sessions are scheduled to occur on the same dates as planned meetings.	Director of Finance and Resources		**Ongoing -** An update will be provided at the March 2018 meeting
8.5 The Chief Information Officer to ensure all new and existing Committee members have access to O365 set up quickly, with the correct permissions, including the ability to view the business continuity SharePoint site in O365.	Chief Information Officer		**Ongoing**
9.11 To ensure that the Authority member responsible for cyber security is informed of any issues.	Chief Information Officer		**Ongoing**

9.12 To ensure all staff receive cyber security training.	Chief Information Officer		**Ongoing**.
Matters Arising from Audit and Governance Committee – actions from 5 December 2017 meeting			
4.18 The Director of Compliance and Information to provide the Committee with an update on regulatory and Register management in due course.	Director of Compliance and Information		**Ongoing**
8.8 The Chief Executive would conduct further investigation into the impact of Brexit, for revisiting at the 6 March 2018 Committee meeting.	Chief Executive		**Ongoing** - An update will be provided at the March 2018 meeting
9.9 The Chief Information Officer to alert the Committee, should any of the assurance points be missed.	Chief Information Officer		**Ongoing** - An update will be provided at the March 2018 meeting
9.10 The Chief Information Officer to circulate an update on progress to members at the end of January 2018.	Chief Information Officer		**Ongoing -** An update will be provided at the March 2018 meeting
12.7 The NAO to investigate which areas of training similar committees have been receiving.	NAO		**Ongoing** - An update will be provided at the March 2018 meeting
12.8 The Director of Finance and Resources to arrange training for members to follow the 6 March 2018 meeting.	Director of Finance and Resources		**Deferred** – Possibly to June meeting.

Audit and Governance Committee

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

Details:	
Meeting	Audit & Governance Committee
Agenda item	5a
Paper number	AGC (06/03/2018) 588 DH
Meeting date	6 March 2018
Author	Jeremy Nolan

Output:	
For information	To provide an update to the Audit and Governance Committee on progress against the current Internal Audit plan.
Progress Update	The agreed plan for 17/18 has now been completed in full (see Annex A). The final report for the Financial Controls review was issued on the 17th January (see Annex B). In addition, the final report for the GDPR (an advisory review) was issued on the 27th February (see Annex C). Work on recommendations follow up has commenced and is expected to be completed by mid-March. Please find at Annex D the draft Internal Audit plan for 18/19 for your consideration and approval.
Actions from previous meeting	None
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes	Annex A - Progress against the latest iteration of the HFEA Internal Audit plan 2017/18 Annex B - The final report for the Financial Controls review, which was given a 'Substantial' rating. Annex C – Final Advisory report for GDPR Annex D – Draft Internal Audit Plan – 2018/19

Annex A

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY INTERNAL AUDIT PLAN 2017/18

Audit Ref No	Audit Title	Audit Review Detail	Directorate/Grouping	Current Status (27/2/18)	Quarter Review Due to Start	Days Indic' and Agreed	Notes
1	Data Loss	This audit will review the controls around the key risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Compliance & Information	Final Report	Q1	13	As agreed at the June Audit and Governance Committee meeting, extra days were moved to this review, from the Risk Management audit. Final report issued on 25th September.
2	Risk Management and Governance	Overview of general governance, risk management and assurance arrangements. Review will focus on ensuring there is a formal governance structure in place, that key risks are identified, that they are reflected accurately within the assurance framework and are a key focus for the HFEA Board.	Strategy and Corporate Affairs	Final Report	Q2	7	Final report issued on the 29th November.
3	Financial Controls	This is a standard key financial controls review. We will identify and review key financial processes and controls operated by HFEA as well as consider any potential overlaps with HTA.	Finance & Resources	Final Report	Q3	10	Final report issued on 17th January.

4	General Data Protection Regulation	This will consider the state of preparations for the introduction of this regulation in May 2018. An audit at this stage will be useful to give assurance to the Audit and Governance Committee and to give time for any recommendations to be implemented.	Compliance and Information	Final Report	Q4	10	Final advisory report issued on 27th February.
5	Follow up recommendations	Follow up of agreed recommendations of previous Audits. A summary of findings and results to be presented at each ARC	Various	Fieldwork	Q4	5	Work on this has commenced and is expected to be completed by mid-March.

Health Group Internal Audit

Reference number: 217 008 004
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
JANUARY 2018

Report Name: Financial Controls

Overall report rating: SUBSTANTIAL

Health Group Internal Audit, part of the Government Internal Audit Agency (GIAA) provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

The focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- **Review and evaluation** of internal controls and processes;
- **Advice to support management** in making improvements in risk management, control and governance; and
- **Analysis of policies, procedures and operations** against good practice.

Our findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:
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Leeds, LS2 7UE

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Date fieldwork completed:	8th December 2017
1st draft report issued:	3rd January 2018
Management responses received:	16th January 2018
2nd draft report issued:	
Management responses received:	
Final report issued	17th January 2018

Report Author: Sahir Hussain
Version №: FINAL

Distribution List – Draft Report

Main recipient(s)

Richard Sydee	Director of Finance and Resources
Morounke Akingbola	Head of Finance

cc:

Tony Stanley	HFEA Deputy Head of Internal Audit
Jeremy Nolan	HFEA Head of Internal Audit
Cameron Robson	Group Chief Internal Auditor

Distribution List – Final Report

As for draft report.

EXECUTIVE SUMMARY

1. Introduction

1.1 Effective financial control plays an important role in achieving an organisation's financial goals and meeting obligations of corporate governance, fiduciary duty and due diligence. It is also key in ensuring the accuracy of reporting, eliminating fraud and protecting the organisation's resources. Internal control processes in relation to key financial controls also help reduce process variation, leading to more predictable outcomes whilst minimising the risk faced by the organisation.

1.2 This audit considered the processes, policies and procedures that are implemented to manage finances within Human Fertilisation & Embryology Authority (HFEA). Our fieldwork involved interviews with the finance team. In addition to this, we reviewed the Standing Operational Procedures in place within the Finance function at HFEA, and carried out sample testing on expenditure, income streams and journal entries to verify their accuracy, as well as reviewing segregation of duties and authorisation processes in place.

2. Review Conclusion

2.1 The overall rating for the report is SUBSTANTIAL – in our opinion, the framework of financial controls in place at HFEA is adequate and effective. Our summary of findings is presented directly below.

3. Summary of Findings

3.1 Our overarching finding is that HFEA have robust controls in place to support the accurate and appropriate recording of financial information. All expenditure is subject to a two stage authorisation process, which is line with good practice. A suite of Policies and Standing Operating Procedures (SOP's) are maintained by the organisation to provide staff with guidance in relation to various aspects of the finance function. Some of the key Policies and SOP's include:

- Payroll and Benefits Standing Operating Procedure;
- Debt Collection Standing Operating Procedure;
- Expenses Policy; and
- Procurement and Tendering Policy (including a list of delegated authority for the approval of expenditure).

3.2 Through review of the Policies and SOP's, HFEA have demonstrated that sufficient documentation is in place to inform and guide staff for functions relating to finance. However, we did note that no SOP's were in place to aid staff with posting journal entries or using Sage, and we suggest that HFEA should consider implementing such SOP's to aid in strengthening their current processes and controls.

Accuracy and completeness of financial data:

3.3 HFEA have two main sources of income, the first being treatment fees and the second being income from annual renewal and license fees. HFEA have a record of all clinics maintained on the Epicentre platform whilst individual clinics manage their relationship with HFEA through their respective Clinic Portal.

3.4 Treatment income is generated via an automated system. Each clinic has a mandatory requirement to disclose all treatments performed on a monthly basis via the Clinic Portal which feeds into HFEA's Automatic Billing System (ABS). At the end of each month, the HFEA Finance team trigger the ABS to generate an invoice for each clinic that completed treatments, which is required to be paid within 28 days. To verify the accuracy of invoices, we carried out testing on a random sample of 10 invoices. Testing found that all invoices were accurate with process followed correctly. Additionally, we can confirm that our sample of ten invoices had been accurately recorded on Sage. However, we did note that in two cases, the clinic had not paid HFEA within 28 working days. In both of these cases evidence was on file to confirm that debt chasing letters were sent to the clinic in line with the Debt Collection Procedure.

3.5 The invoicing of clinics in relation to annual renewal and license fees occurs approximately six months prior to the clinics current license expiring. Invoices are uploaded via Epicentre to the clinic's Clinic Portal as well as the clinic being notified that an invoice has been generated. We selected a random sample of ten invoices to verify accuracy. In all cases we were able to confirm that the information was accurate and processes had been followed correctly. We identified one case where the clinic had not paid HFEA within 28 working days; however evidence was on file to confirm that debt chasing letters were sent to the clinic in line with the Debt Collection Procedure.

3.6 Purchase requisitions are raised by staff via the Web Authorisation Processor (WAP).Once the invoice has been received by HFEA, this is uploaded to WAP which then triggers the second stage of authorisation. Once this has been completed, a remittance advice is sent to the supplier and the HFEA Finance

team to trigger the payment for release. We tested a random sample of 10 purchase orders to verify accuracy. These were checked against the relevant invoices and remittance advice. Testing identified no issues with accuracy or the process of raising and approval of purchase orders. Furthermore, we can confirm that the expenditure as part of our sample was accurately recorded on Sage.

3.7 We were informed by the head of finance that no overpayments had been made to staff since April 2017. Therefore, we did not complete sample testing on this area.

3.8 From our review and testing around the risk related to financial information being incomplete or inaccurate, we can confirm that HFEA has robust controls in place to provide assurance that financial data is being accurately recorded.

Staff Capability

3.9 Completion of a finance training module via the Civil Service Learning (CSL) Portal is a mandatory requirement for all staff employed by HFEA, including members of the finance team.

3.10 As the Finance team is relatively small, on the job training is provided (when required). In addition we found that there was sufficient guidance in place in the form of the SOP's, which provide a good level of support for the team. Members of the Finance team are responsible for managing their own Continuous Professional Development (CPD). CPD modules are accessible via the CSL Portal as well as privately offered modules being available from providers such as the Chartered Institute of Management Accountants.

3.11 Job descriptions for the Finance and Accounting Manager and the Accounts Officer are maintained on file and were up to date. We confirmed that the four members of the Finance team have the following qualifications:

- Director of Finance and Resources: CIMA qualified;
- Head of Finance: CIMA qualified;
- Finance and Accounting Manager: CIMA part-qualified; and
- Accounts Officer: ACCA qualified.

3.12 We did not identify any issues with staff effectiveness. We were additionally informed that staff effectiveness is reviewed with each individual member of staff during their mid and end of year appraisal.

Fixed Assets

3.13 We can confirm that a Fixed Asset Register is in place recording all fixed assets owned by HFEA. A Fixed Asset (Capitalisation and Depreciation) Procedure is maintained to assist HFEA staff in relation to the valuation and treatment of fixed assets. We confirmed that any asset purchased by HFEA is capitalised if it costs in excess of £5,000. The Fixed Asset (Capitalisation and Depreciation) Procedure outlines the process to be followed when depreciating assets as well as providing sufficient information regarding the useful life of assets, dependant on the category in which they fall.

Compliance with month-end procedures, Standing Orders and financial instructions

3.14 Monthly and quarterly reconciliations are undertaken by HFEA's Finance team to ensure that the information is accurate and reflective of the supporting documentation maintained on file. From review of HFEA's quarter two balance sheet reconciliation, as well as discussions with the Finance and Accounting Manager and

the Accounts Officer, we can confirm sufficient controls are in place to ensure financial information recorded is as accurate as possible.

3.15 We identified that no formal timetable is in place for the reporting of financial information. We were informed by the Head of Finance that detailed meetings relating to finance are held on a quarterly basis with various Directorates. A Finance Activities spreadsheet is maintained by the Finance team highlighting key monthly tasks, expected completion date and responsible owners.

Journal Entries

3.16 The Finance and Accounting Manager maintains a spreadsheet which manually records all journals posted to Sage. We were provided with this spreadsheet from which we selected a sample of 10 journal entries since April 2017. Testing identified:

- In 10/10 cases, the journal entry was recorded on Sage. The entry included sufficient narrative detailing the reason for the journal. Additionally, we can confirm that the value as per the journal entry on Sage reconciled with the value included within the spreadsheet;
- In 10/10 cases, we can confirm that Sage included the name of the individual who posted the journal as well as the date on which it was posted;
- In 10/10 cases, we were provided with the supporting documentation in relation to the journal entry. We can confirm that in all 10 cases, the supporting documentation had been prepared and entered by two separate individuals therefore demonstrating segregation of duties.

3.17 In 2/10 of these cases, we identified a delay in excess of five working days in between the date on which the journal was prepared and checked. We were informed by the Finance and Accounting Manager that this is due to a combination of the Head of Finance working remotely as well as being responsible for both HFEA and HTA and therefore being unable to check all HFEA journal entries within five working days. However, all the journals sampled were checked.

Audit trail

3.18 From all of our testing undertaken on income streams, expenditure and journal entries, we can confirm that sufficient supporting documentation was on file for all cases included within our samples.

3.19 Performance Reports are produced collating the information as per HFEA's finance system and presented to both the Centre Management Group (CMG) and the Authority. Some of the information covered in these Performance Reports includes:

- 2017/18 Income from IVF and DI;
- HFEA Income and Expenditure 2017/18; and
- Key Performance Indicators (KPI's).

3.20 Through review of meeting minutes for both the CMG and the Authority, we can confirm that these Performance Reports are regularly being presented and discussed. In addition to this, we reviewed the Terms of Reference and previous three sets of meeting minutes for the Audit and Governance Committee (AGC). From review of these documents we can confirm that finance related activities are being actively presented and discussed.

Areas for improvement

3.21 At 3.2 above, we suggested that HFEA should develop a SOP covering the use of journals and Sage. In addition, we note that there is no reporting timetable in place at HFEA to outline the governance arrangements for the presentation and

discussion of financial information. We therefore suggest that HFEA consider implementing such a timetable to clearly outline the groups/committees at which financial information is to be presented and discussed. By doing so, HFEA will provide assurance that financial information is not being overlooked as well as preventing any silo's between the Finance team and the rest of the organisation.

4. Next Steps

4.1 Although we have observed areas where existing procedures and controls could be developed, we have not needed to make any formal recommendations in this report. Thus, no responses are requested from management, and no follow up action will be undertaken by Internal Audit.

4.6 We would like to thank management for their help and assistance during this review.

Suggested Risk Ratings:

Priority	Description
HIGH	Fundamental weaknesses in control which expose the Accounting Officer / Director to high risk or significant loss or exposure in terms of failure to achieve key objectives, impropriety or fraud. Senior managers are expected to oversee the prompt implementation of agreed actions, or to confirm in writing that they accept the risks of not implementing a high priority internal audit recommendation.
MEDIUM	Significant weaknesses in control, which, although not fundamental, expose the Accounting Officer / Director to a risk of loss, exposure or poor value for money. Managers are expected to oversee the prompt implementation of agreed actions, or to confirm in writing that they accept the risks of not implementing a medium priority internal audit recommendation. Failure to implement recommendations to mitigate these risks could result in the risk moving to the High category.
LOW	Minor weakness in control which expose the Accounting Officer / Director to relatively low risk of loss or exposure. However, there is the opportunity to improve the control environment by complying with best practice. Suggestions made if adopted would mitigate the low level risks identified.

Report Rating – Definitions

Substantial	In Internal Audit's opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In Internal Audit's opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In Internal Audit's opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In Internal Audit's opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Health Group Internal Audit

Reference number: DHX 217 008 001
Final Report
Human Fertilisation and Embryology Authority
February 2018

Report Name:

General Data Protection Regulation (GDPR) Preparedness Review

Overall report rating:

ADVISORY REVIEW

Health Group Internal Audit, part of the Government Internal Audit Agency (GIAA) provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

The GIAA focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- **Review and evaluation** of internal controls and processes;
- **Advice to support management** in making improvements in risk management, control and governance; and
- **Analysis of policies, procedures and operations** against good practice.

Our findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and Social Care and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

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Health Group
Internal Audit

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Cameron Robson	Group Chief Internal Auditor Health Group Internal Audit Services

1. Introduction

1.1. The General Data Protection Regulation (GDPR), which is coming into force in May 2018, will apply to the collection, storage, processing, transfer, and destruction of personal data. The GDPR will reform existing data protection rules and introduce several new concepts and restrictions on data processing. The new rules will significantly increase sanctions for data breaches, expand the audit and investigatory power of the regulator and the rights of data subjects, and force both data controllers and data processors to be much more transparent and accountable for their data processing operations.

1.2. The Government has introduced a Data Protection Bill which is intended to set new standards for protecting general data, in accordance with the GDPR. The Bill is intended to implement the GDPR standards across all general data processing and to exercise a number of agreed modifications to the GDPR to make it work for the benefit of the UK in areas such as academic research, financial services and child protection. Once enacted it will address areas including:

- Providing clarity on the definitions used in the GDPR in the UK context;
- Ensuring that sensitive health, social care and education data can continue to be processed to ensure continued confidentiality in health and safeguarding situations can be maintained;
- Providing appropriate restrictions to rights to access and delete data to allow certain processing currently undertaken to continue where there is a strong public policy justification, including for national security purposes;
- Setting the age from which parental consent is not needed to process data;
- Enacting additional powers for the Information Commissioner, including allowing the Commissioner to levy higher administrative fines on data controllers and processors for the most serious data breaches; and
- Empowering the Commissioner to bring criminal proceedings against offences where a data controller or processor alters records with intent to prevent disclosure following a subject access request.

1.3. The objective of this review was to assess the preparedness of HFEA for GDPR, including recognising where good controls are already in place, and highlighting areas of potential weakness and/or non-compliance with the new regulations, to ensure that these areas receive the necessary attention by HFEA prior to May 2018.

2. Summary of Findings

2.1. Following completion of our fieldwork, it is our opinion that HFEA's preparations for GDPR are in ongoing, with further work needed to ensure full compliance prior to the May 18 implementation date.

2.2. It should be noted that the findings in this report are based solely upon the findings and evidence available to us at the time our fieldwork was concluded. It is therefore likely that activities to implement GDPR will have moved on in the intervening period.

2.1 Positive action already taken by HFEA:

- HFEA has recruited a dedicated Information Governance Manager with responsibility for ensuring HFEA's compliance with GDPR;
- A Data Protection Office (DPO) has been appointed;
- A Senior Information Risk Owner and Caldicott Guardian are both in place;
- A GDPR steering committee has been appointed, working to a formally agreed and documented terms of reference and is meeting on a fortnightly basis to address the imminent implementation of the GDPR;
- An information flow and risk exercise has been undertaken to identify all information assets in use by HFEA for review and compliance with GDPR;
- A number of documented GDPR implementation plans have been developed including a GDPR Project Plan, a Detailed Action Plan and a documented project timeframe. If effectively implemented, these plans should address the known requirements for GDPR;

- Legal advice and guidance is being sought on the relationships with third parties to ensure third party contracts are made GDPR compliant; and
- Plans are in place for communicating GDPR requirements to all staff and stakeholders and for provision of required training.

2.2 During our fieldowork we identified the following areas where there are gaps in compliance with GDPR rules, or where processes and controls should be strengthened:

- A formal DPO has been appointed. However, the precise role and responsibilities have not yet been agreed and documented. Furthermore, there are currently no defined reporting lines in place and it is not currently clear how the DPO role will be discharged. .
- GDPR impact assessments have not yet been completed for all HFEA information assets, though formal templates and guidance for assessments have been devised;
- The GDPR implementation plans in place did not identify any formal milestones, and whilst the detailed plan recorded responsibility and timescales for the delivery of most activities, it did not allocate a task owner for all;
- While actions to communicate GDPR requirements and deliver training are recorded in the GDPR plans, there is currently no defined and documented approach to how this will be achieved or when this will be communicated to all staff and stakeholders;
- While activities are ongoing to seek advice and guidance on third party responsibilities, third party contracts are yet to be reviewed and amended;
- Activities have also begun to address the need for GDPR to be formally considered when IT systems and operational processes are either designed or updated. However policies and standard operating procedures to ensure HFEA meets this requirement are still to be devised;
- Risks arising from the implementation of GDPR have been identified and documented in a formal data mapping exercise. However a formal documented risk register recording risk owners, risk mitigations, residual risks and risk appetites etc. has not been produced;
- An accurate and up to date Information Asset Register (IAR) is still to be fully completed;
- The GDPR's changes to the use of consent as a condition for data processing (including the requirement for informed and explicit consent) are still to be considered and addressed by HFEA as part of their preparations;
- The current policies and procedures for addressing Subject Access Requests (SARs) have yet to be amended to address GDPR timescale changes; and
- A defined policy and procedure to ensure that reporting of incidents are carried out within the 72 hours timescale are yet to be devised.

3. Next Steps

3.1 As an advisory review, no formal recommendations have been made. However, we strongly suggest that HFEA expedite its GDPR activities to ensure timely progress is made to address all of the issues highlighted in this report, and ensure that the resources required to do this are in place. Our intention is to carry out a further GDPR review as part of the 18/19 audit plan, to assess the progress made, and look in further detail about implementation of GDPR requirements.

3.2 Finally, we would like to thank management for their help and assistance during this review.

Human Fertilisation & Embryology Authority

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY DRAFT INTERNAL AUDIT PLAN 2018/19

Government Internal Audit Agency

CONTENTS

1. INTRODUCTION

This document sets out the proposed Human Fertilisation & Embryology Authority (HFEA) annual Internal Audit plan for 2018/19.

2. HFEA CONTEXT

The HFEA is the regulator of fertility treatment and human embryo research in the UK. The role of the organisation includes licencing of clinics, setting standards and checking compliance with them through inspections. HFEA also plays a public education role by providing information about treatments and services for the public, people seeking treatment, donor-conceived people and donors. HFEA's role is defined in law by the Human Fertilisation and Embryology Act 1990 and the Human Fertilisation and Embryology Act 2008.

HFEA has identified its overall strategic goals as follows:

- **Objective 1:** Ensure that all clinics provide consistently high quality and safe treatment;
- **Objective 2:** Publish clear information so that patients understand treatments and treatment add ons and feel prepared;
- **Objective 3:** Engender high quality research and responsible innovation in clinics;
- Objective 4: Improve access to treatment;
- **Objective 5:** Increase consistency in treatment standards, outcomes, value for money and support for donors and patients; and
- **Objective 6:** Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.

3. INTERNAL AUDIT POLICY, PURPOSE AND RESPONSIBILITIES

Our professional responsibilities as Internal Auditors are set out in the UK Public Sector Internal Audit Standards. In line with these requirements, we perform our Internal Audit work with a view to reviewing and evaluating the risk management, control and governance arrangements that HFEA has in place to ensure the achievement of its objectives and adds value to the organisation. This Plan also takes account of our Audit Charter and is compliant with the guidance provided in this document.

The internal audit work that we are planning to undertake during 2018/19 will be focused on governance, internal control, risk management, as well as key strategic and tactical risks faced by the HFEA.

4. INTERNAL AUDIT PLANNING 2018/19

The planning process

To ensure that internal audit resources are used efficiently, we plan on a risk basis. Therefore, internal audit work will be closely aligned to the key risks and uncertainties pertaining to HFEA's objectives.

Audits were therefore selected using the approach outlined below:

- Review of HFEA's corporate risk register to identify corporate risks, their assurance sources and mitigating actions with a view to providing added assurance where required.
- Consulting with the Senior Management Team;
- Consulting with the Audit and Governance Committee; and
- Our knowledge of other emerging issues and intelligence gathered via audit work undertaken in the last financial year.

Planning outcomes

Our planning work has identified a number of risks and challenges facing HFEA.

Table A: Shows a summary of the draft audit reviews drawn from sources (cited above) and a proposed prioritisation of audit work.

Table B: Outlines our proposed allocation of audit days against the Audit Plan for the period April 2018 to March 2019.

The Audit and Governance Committee are invited to approve:

- The Internal Audit Plan for 2018/19
- The associated allocation of resources in terms of days and budget.

5. PROPOSED AUDIT COVERAGE & AUDIT PLAN 2018/19

5.1 Summary of Audit Coverage

Set out below is a summary of the total coverage of the audit work proposed to be carried out within HFEA in 2018/19.

Table A: Summary of Audit Topics

No	Audit topic	Overview of rational and scope	Business Area	Suggested Quarter for commencement
1.	**Business Continuity**	This audit will be undertaken to review the Business Continuity arrangements currently operating within HFEA.	Compliance & Information	• **Q1**
2.	**Cyber Security**	A review of the Cyber Security arrangements within HFEA, with a focus on how HFEA are compliant with the 10 steps to Cyber Security (as defined by the National Cyber Security Centre)	Compliance & Information	• **Q2**
3.	**General Data Protection Regulation**	This will consider the extent to which HFEA are complying with the General Data Protection Regulations that will be introduced in May 2018, and will also include follow up on the 17/18 GDPR Advisory review.	Compliance and Information	• **Q3**
4.	**Risk Management and Governance**	Review of the current risk management arrangements, following up on the recommendations made in 17/18 audit. This review will also include a deep dive look at the legal challenge arrangements within HFEA. This is currently the highest rated risk on the strategic risk register (and one of 3 red risks). Capability (one of the other red rated risks) was reviewed last year.	Strategy and Corporate Affairs	• **Q3**
5.	**Payroll and expenses**	A review of how payroll and expenses are managed within HFEA, including the controls in place to ensure the accuracy	Finance	• **Q4**

No	Audit topic	Overview of rational and scope	Business Area	Suggested Quarter for commencement
		and validity of payments made.		

Table B: Resource allocation

Audit Area	Total Inputs (indicative days)
Audit engagements:	
Business Continuity	10
Cyber Security	10
General Data Protection Regulation	7
Risk Management and Governance	10
Payroll and Expenses	8
	45
Other resource allocation	
Head of Internal Audit and General Management	15
Contingency	5
TOTAL	**65**

SUMMARY OF AUDIT RECOMMENDATIONS

Year of Rec.	Category	Audit	Section	Rec #	Recommendations	Action Manager	Proposed Completion Date	Complete this cycle?
2017/18	M	DH Internal Audit	Data Loss	1	**Clinic governance oversight**	***Chris Hall, Senior Inspector (Information)***	***Post April 2018***	No
	M			2	**Policy Review**	***Dan Howard, CIO***	***May 2018***	No
	M			3	**Staff Training**	***(Dan Howard, CIO & Yvonne Akinmodun, Head of HR)***	***December 2017***	No
	M			4	**Business Continuity Testing**	***Dan Howard, CIO***	***November 2017***	Yes
	M		Risk Management	1	**Risk Register**	***Paula Robinson, Head of Planning & Governance***	***February 2018***	No
	M			2	**Staffing / Capability**	***Peter Thompson,CEO (Yvonne Akinmodun, Head of HR)***		No
	S		Financial Controls		**None**	***None***	***N/A***	N/A
TOTAL	**7**							

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

3.	**Staff Training**			
We identified that the HFEA Business Continuity Plan has not been tested on a regular basis. It was therefore not possible for HFEA to provide assurance that the BCP remains current, fit for purpose and reflects key personnel change to ensure roles and responsibilities are clear.	A process should be put in place to ensure that HFEA are able to capture and monitor all mandatory information management learning and development carried out.	**We will refresh our approach to the completion of the following modules of mandatory training in IG. Our target is that all staff will have completed these in the previous 12 months by the end of the calendar year. The modules are:** • **Responsible for information: general user;** • **Responsible for information: information asset owner (IAOs to complete); and** • **Responsible for information: senior information risk owner (SIRO to complete)** ***All staff – December 2017. The framework for mandatory training (in all areas including information training requires refresh). In any event whilst many staff have undertaken training within 12 months we will use Oct-Dec period to ensure all staff have completed, with sign off from Managers.*** ***Nov 17 update:*** *Information management training has been identified for all staff. Information Asset Owners, SIRO and all remaining staff will be expected to complete this before the end of December 2017.* ***Feb 18 update:*** All staff were required to complete the online IAO training in December 2017. With HR monitoring to ensure completion. HR is also in the process of purchasing a new HRIS which will enable the training, monitoring and recording of mandatory and other training provided by HFEA. It is expected the new system will be in place by early spring 2018	***Dan Howard, CIO*** *(Yvonne Akinmodun)* **December 2017**
4.	**Business Continuity Testing.**			
There was no management assurance documented to demonstrate that all HFEA staff have complete the mandatory e-learning 'responsible for information' training. Therefore, there is a risk that this training has not been carried out by some or all staff	The BCP should be updated on a regular basis to ensure that it reflects all key changes and is appropriately tested to ensure that it is fit for purpose.	**BCP test and table top test to take place in September 2017. BCP to be updated to reflect lessons learnt from the above tests and to reflect new CIO role responsible.**	***Dan Howard, CIO*** **November**

resulting in staff handling data incorrectly potentially leading to loss of data.		***BCP summary test findings report submitted to AGC in October 17. BCP approved by CMG in November 17.*** ***Nov 17 update:*** *BCP summary findings presented to AGC in October - action complete. The revised BCP has been circulated and will be reviewed at CMG on 23 November 2017.* ***Recommendation completed.***	**2017** **COMPLETE**
RISK MANAGEMENT			
5. C1 Risk Register			
dating of strategic risk register That HFEA are not effectively managing the capability risk within agreed tolerances, and that any mitigations and contingencies are not effective in managing or reducing the risk.	The current strategic risk register (for the C1 Capability risk) should be reviewed and updated to ensure it provides more comprehensive data to help inform management decisions on risk, including: • Review all current mitigating actions to ensure they include effective controls which address the root cause of the risk identified and are sufficient to reduce the severity; • Contingency actions in instances where identified mitigating actions have not been effective should be detailed, or a clear rationale for these not being in place should be included;	***A revised strategic risk register which has addressed all of the recommendations and has been reviewed and signed off by management.*** ***Agreed. We already do such a review at every risk CMG but we could usefully focus more on ensuring the controls are really controls and are controlling root causes. Next available CMG Risk meeting*** ***Feb 18 update:*** Being reviewed at Feb CMG Risk. In addition to this we are setting up a rolling programme of deep dives to review the controls in detail more regularly. ***This links to a useful point made at AGC in October – which was about considering the adequacy of controls for any over-tolerance risks. This is done but we could be clearer in the risk commentary if we have chosen to tolerate the position for a period of time, or if no further controls are available. Next available CMG Risk meeting*** ***Feb 18 update:*** We now have a clear statement about handling over-tolerance risks and contingency actions in both the risk register and the policy. When CMG are reviewing each risk, we will prompt them if the resulting score is over tolerance to consider whether this means that further actions are needed, or whether the summary section for the risk should provide some context if there are no further actions the HFEA can take.	***Owner: Paula Robinson, Head of Planning and Governance*** ***Helen Crutcher*** ***February 2018*** ***Completed*** ***February 2018*** ***Completed***

	• The register should include a risk appetite/tolerance which clearly reflects the amount of risk HFEA is willing to undertake to meet their strategic objectives; and • An additional column should be added which details the latest actions carried out by management and confirms that the risk and mitigation has been reviewed and agreed.	***Agreed and implemented. We have updated this section of the risk policy now, to clarify what we mean by risk appetite and risk tolerance, and to state that our risk appetite is low. We have also reflected this in the risk register.*** ***Agree that we should find a way of making it clearer what the most recent actions/controls have been. Dates of recent risk reviews appear on the summary page at the start of the risk register. We will look at this and see if we can achieve the same thing without adding a column (since that would be hard to fit in elegantly).*** ***Feb 18 update:*** We are going further to make sure that dates are attached to actions and controls, see above. ***Recommendation completed.***	***Completed*** ***February 2018*** ***Completed*** ***COMPLETE***
6.	**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 which 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* ***Agreed – this is in progress. Finalisation discussion planned at leadership and away day on 29 November 2017. Publication shortly thereafter.***	~~***Juliet Tizzard, Director of Strategy & Corporate Affairs***~~ ~~***Paula Robinson***~~ ***Before end of 2017*** ***Peter Thompson, CEO*** ~~***Yvonne Akinmodun***~~ ***End of financial year***

		Feb 18 update: *We have a people plan which identified recruitment and retention processes including the review of our induction process to ensure staff feel able to work effectively in as short a period of time as possible.*	

Written evidence submitted by the Human Fertilisation and Embryology Authority (HFEA) to the House of Commons Health Committee inquiry into Brexit – medicines, medical devices and substances of human origin inquiry

1. Summary

- Brexit, in any form, will not impact on the legal scope of the work of the HFEA
- The HFEA has the capacity to cope with Brexit and does not envisage that transitional arrangements are necessary.
- The movement of gametes (eggs and sperm) and embryos across European borders will continue post Brexit, but it is not yet clear whether the type of Brexit will impact on the ease with which such imports and exports can take place.
- As one of the 28 Competent Authorities the HFEA currently shares information about the quality and safety of gametes and embryos across the EU. It is not yet clear whether such information sharing will continue post Brexit and the HFEA is actively considering how best it can maintain its productive working relations.
- The licensed fertility sector in the UK appears to be coping with the impact of Brexit so far, although some clinics are concerned about workforce issues.

2. About the HFEA

2.1. The HFEA was established in 1991 following the passing of the Human Fertilisation and Embryology Act 1990 (the HFE Act). The HFE Act was revised in 2008. The HFEA is a statutory NDPB responsible for the regulation of assisted reproduction services, like IVF, and research involving human embryos. The HFE Act sets the broad framework within which the HFEA has to operate, and requires the HFEA to publish a Code of Practice setting out detailed guidance on how licensed clinics should operate. The Code is updated periodically. The HFEA's responsibilities are UK wide. The HFEA is also one of 28 national Competent Authorities for gametes and embryos across the EU (see paragraph 3.4 below).

2.2. However, the HFEA's responsibilities in respect of the focus of the Committee's inquiry – medicines, medical devices and substances of human origin - is limited. Medicines and medical devices are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) and our interest in substances of human origin is restricted to gametes (eggs and sperm) and embryos. As a result, we have close working relationships with the MHRA and other relevant regulatory bodies like the Human Tissue Authority (HTA).

3. EU law in the field of assisted reproduction and research involving human embryos

3.1. There are five pieces of EU law that are relevant to the responsibilities of the HFEA:

- The EU Tissues and Cells Directive (2004/23/EC)
- The First Technical Directive (2006/17/EC)

- The Second Technical directive (2006/86/EC)
- The Coding Directive (EC/2015/565)
- The Import directive (EC/2015/566)

3.2. The first three Directives came into effect in 2006 and were transposed into domestic law in 2007. They are now fully incorporated into the HFE Act with the effect that regardless of what happens with Brexit, including a 'No Deal' scenario, none of the legal requirements which arise from the EU Tissue and Cells Directive or the other two Technical Directives will be affected in anyway. Or to put it another way, this means that all licensed fertility clinics in the UK will therefore continue to meet EU standards of quality and safety regardless of the Brexit outcome.

3.3. The remaining two Directives on Coding and on Imports build on the robust systems currently in place in the UK to ensure that gametes and human embryos imported into the UK are traceable and meet certain quality and safety standards. The two Directives set out an EU wide set of rules to the same broad effect; though they should have the added benefit of levelling up traceability requirements across the EU and make it a little easier for UK clinics to export to other EU Member States. The Directives have recently been transposed and draft Regulations were laid in Parliament on 18 December 2017. If approved by both Houses of Parliament, the changes to the HFE Act will come into force on 1 April 2018. As before, this will mean that they are fully incorporated into the HFE Act. It is, however, not yet clear whether the nature of the final Brexit deal will impact on the ease with which UK licensed clinics can import from, or export to, other EU Member States.[1]

3.4. This legal framework is reinforced by the existence of Competent Authorities across the EU. As noted above, the HFEA is the Competent Authority for gametes and human embryos in the UK. Our main obligations are: to communicate with other competent authorities across Europe, including investigations and reporting of serious incidents involving the use of gametes or embryos; to collaborate on inspections (if relevant); and to collaborate and share information when it comes to matters of quality and safety that might require the withdraw gametes or embryos from use in human application. As these obligations are set out in the HFE Act they will remain post-Brexit, though it is not yet clear whether day-to-day working relationships will remain as before.

4. Responses to the Committee's questions

The remainder of this written evidence addresses the six questions that the Committee has asked the HFEA.

4.1. What the effects of Brexit could be on the scope of the work of the HFEA?

As noted above (section 3) Brexit will not change the legal scope of the work of the HFEA. It will be for the Government of the day to decide whether it wishes to revisit the HFE Act.

4.2. What considerations arise over the capacity of the HFEA to successfully transition to a post-Brexit operating environment, and any risks and opportunities this brings?

[1] A recent note from the European Commission simply noted that once the UK had left the EU it will be viewed as a third country for the purposes of the Directives; as a consequence exporting or importing establishments would need to assure themselves that tissues and cells met the quality and safety standards required across the EU (which they will by virtue of the HFE Act) - see: https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2017_btc_brexit_en.pdf

The vast majority of the HFEA's resources are devoted to the regulation of its responsibilities in the UK. We do not envisage any significant capacity issues which arise because of Brexit.

However, as noted above at paragraph 3.4, it is not yet clear how our obligations as a Competent Authority will be affected post Brexit. Gametes and embryos will continue to move across borders and we will need to maintain relationships with other competent authorities in Europe. The concern will be that post Brexit, the sharing of information between Competent Authorities and the UK is in some way reduced by virtue of our status under the Directives as a 'third country'. We are currently considering how best to maintain our positive working relationships across Europe in the future.

The position of the UK as a world leader in fertility services and human embryo research can assist in post Brexit positioning. It has meant that we have played an active role on European Commission working groups tasked with developing new legislation, updates to safety and quality standards, sharing information, learning exchange programmes and other related matters. Such work has had benefit in raising standards across the EU which have had, in turn, direct benefits for UK patients.

4.3. Any contingency planning from the HFEA in relation to the various Brexit modalities that could occur ('No Deal', Norway model, Canada model etc)?

None of the various Brexit outcomes would impact on the broad legal framework within which the HFEA has to operate, for the reasons stated at section 3 above. However, looking ahead, the future impact of any European Union Court of Justice (CJEU) or European Court of Human Rights (ECHR) rulings pertaining to the sector regulated by the HFEA is uncertain, though it is recognised that those cases are rare. It may be that the future model will impact on how any relevant European jurisprudence is interpreted and applied by UK courts.

The HFEA has contacted the 20 largest fertility clinics in the UK to better understand the potential impact of Brexit on the viability of clinics, particularly in relation to staffing issues. Though the HFEA is not responsible for clinic workforce, we are concerned about the quality of services offered to patients, and whether fertility clinics can attract and retain skilled staff is clearly relevant to the quality of services they are able to provide. The responses we have received to date suggest that there is currently little evidence of Brexit having an 'unsettling effect' on the workforce, but recruitment of trained embryologists has become more problematic and is worsened by the recent cutbacks in the number of UK training places.

The results of this survey has been discussed at our Audit and Governance Committee (AGC) and we are committed to rerunning the survey periodically and reporting the results to AGC.

Work is also underway to understand the impact of Brexit on the bio-science research field and access to staff in the UK market. Again, this work will be considered by our AGC.

4.4. Following the UK's withdrawal from the EU, what alternative arrangements for the regulation of medicines, medical devices, medical products and substances of human origin could be introduced?

Medicines and medical devices will primarily be a matter from the MHRA and the Government of the day. As far as gametes and embryos are concerned, the existing arrangements work well and we see little need to put in place alternative arrangements. Indeed, to the contrary, the UK regulatory scheme is viewed as a World leader combining high standards of quality and safety with innovative treatment and research - like mitochondrial donation in treatment, following Parliamentary approval of regulations in 2015, and genome editing in human embryos in research in the same year.

It will be for the Government of the day to decide whether it wished to reopen the HFE Act.

4.5. What are the respective opportunities, risks and trade-offs involved?

The existing regulatory regime represents a 'bargain' between science and society. There is, as noted above, no real evidence to suggest that that bargain is broken or that there would be significant benefit in reopening it at this time.

4.6. How much time is needed to facilitate a smooth transition to new arrangements post-29 March 2019, or are transitional arrangements needed?

Given the stable UK framework for the regulation of assisted reproduction and research involving human embryos we do not envisage any need for transitional arrangements.

HFEA

11 January 2018

Digital Programme Update: March 2018

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	Patient treatment submission system		
Paper number	AGC (06/03/2018) 592 DH		
Meeting date	06 March 2018		
Author	Dan Howard, Chief Information Officer		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to Note: • Summary information on the launch of the new system and new register during 2018 • Progress on data migration and cleansing, and the development of the 'PRISM' Submission System • Our transitional arrangements, notably the key elements of our communications and engagement Plan • Financial outturn for 2017/18 and forecast for 2018/19 • The key risks, mitigations and contingency		
Resource implications	None		
Implementation date	During 2017–18 and 2018 - 19 business year		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes:	Annexe 1: Programme Project Plan		

1. Background

1.1. In December 2017, AGC received an update on data migration and progress made on the development of our new data submission system. This paper updates progress, and outlines the approach for completing the development work and the launch of the new HFEA register and system later this year.

1.2. The work remains intrinsically aligned to the benefits we are seeking - an improved structure of the Register enabling better reporting; the introduction of 'validation rules' leading to better quality data – putting the onus on clinics rather than us; a reduction in effort for clinics to submit data and a better experience for clinic users in using the system; higher quality information for individuals, clinics and researchers, and for the HFEA in driving intelligence-led regulation; and a reduction in overheads to support and manage the new register and system with our resources switched to maximising value from the data we hold.

2. Introduction

2.1. **System and new register launch:** Our initial plan signalled the launch of the system during 2018. We planned a soft launch in April 2018 and implementation within clinics along with integration by third party system suppliers staged later in 2018. Detailed planning has now taken place and a beta (initial) release of the submission system will take place in April with familiarisation taking place thereafter with the full launch taking place at the end of September 2018.

2.2. **Data cleansing and migration:** Substantial progress has been made on the detailed work associated with data migration and data cleansing. In December 2017 we signalled that this would conclude with the technical data migration taking place at the end of March 2018. Although we have realised some slippage due to risks previously identified, this work remains broadly on track with the migration scheduled for 26 April 2018. Thereafter necessary ongoing data verification will take place alongside the launch of the new register.

2.3. **'PRISM' Data Submission System:** Work associated with the creation of our new data submission system (now branded as PRISM) is progressing well. We have completed all Application Program Interfaces (APIs) for third party system suppliers to use. APIs are the technical interface to allow third party system suppliers to communicate with our register.

2.4. **Transitional Arrangements:** Significant work in preparing the move from the current system to the new register and system later in 2018 is complete. Dialogue with system providers has started and a stepping up of dialogue with clinics is soon to be underway. We have engaged a specialist technical consultancy company building the server 'cloud' environment to house the new register. To ensure security, penetration testing of the environment is scheduled.

2.5. **Risk Management:** Given the specialist nature of the work, a significant degree of risk is being monitored and managed. Our scrutiny has stepped up given the impending conclusion, That said, our appetite for risk remains unchanged and risk remains within accepted tolerance levels.

2.6. **Financial:** In 17/18 the programme is forecast to spend £342k of the £350k capital budget agreed. Due to the nature of the programme, modest additional (programme) costs will be realised in 18/19.

3. System and new register launch

3.1. Since the previous update in December 2017, our plans for system and register launch have matured. The IfQ programme has been running for several years and offers significant benefits to the HFEA and the sector. Internal and external stakeholders have a shared expectation that the wider programme of work will conclude shortly. While a large amount of work has been completed, there is still a body of disparate work remaining to undertake transition to the new register.

3.2. We are keen to bring the programme to a controlled close and wish to minimise potential issues during implementation. The programme team have spent some time scrutinising the elements of work required for transition, the required resources and timelines. As ever challenging, it presents a mature and realistic plan for delivery of the new register.

3.3. Over December and January, we carefully reviewed our approach for implementation. Our original implementation plan assumed clinics (linked directly to the HFEA system) going live after April 18 with the majority of clinics (using third party patient record systems - EPRS) joining in Summer 2018. We recognised that this would lead to dual running of two registers - involving the introduction of unnecessary complexity for example to support, maintain and report on data we hold in both the old and the new register.

3.4. Following our careful evaluation we have adopted a single implementation in Sept/Oct 2018 - to allow time for clinics to review the beta system and for providers of the EPRS systems to clinics to implement the necessary upgrades required to their systems.

3.5. The programme plan sees all pre-transition work to be complete by the end of August, switch off the legacy system and cut-over to the new register during September, with the new register fully live by 1st October.

Several milestone events are scheduled for transition:

- The final elements of the EPRS API specification is released to system suppliers by end March 2018 (on target)
- PRISM will be demonstrated at the HFEA annual conference on 16th March
- Testing the new register works in Azure with the migrated data, scheduled for April/May 2018. Azure is the Microsoft cloud and so this work involves a move from physical servers in Spring Gardens to an external Microsoft hosted data-centre (in the UK).
- The PRISM system will be made available to clinics for for familiarisation (in Beta form) during April 2018.
- Creating the interfaces from the register to EPICENTRE, the website and portal - April/May 2018
- Work to enable our Register Information team to have a holistic view of clinics' performance in submitting their data in place by August

- Suppliers to have switched over their clinics to the new system by end August 2018
- The legacy register will be switched off during September 2018, final data migration will take place and cut over to the new system will take place thereafter
- Data submissions via PRISM and the EPRS API enabled by end September 2018.

3.6. Communications and engagement is a core part of our work before, during and after the launch of the new register and system. Our communications and engagement plan includes elements relating to engagement with clinics, third party system providers, and other stakeholders such as NHS Digital.

3.7. A branding exercise has taken place and the new system / register is now known as PRISM – representing our brand themes of openness, quality, simplicity, and intelligence. Our new logo aligned to the HFEA colour and 'brand palette' rich with meaning will be demonstrated at the meeting.

4. Data Migration and Cleansing

4.1. Work continues at pace to migrate data from the current register into the new register. Given the significant structural changes this work is complex and detailed – and will not take place until we are all satisfied that it is safe and secure to do so.

4.2. The plan expects a full (and final) 'trial load' will take place in April 2018. This is a significant milestone. Thereafter and during the summer a programme of verification and validation will continue as planned. Although slightly behind schedule, it is expected that there will be no impact to the overall delivery schedule for this programme and clinics will go live as expected once the system and register have been launched in September 2018 (that is all the data that is submitted by clinics from April-September must be 'moved over.'

4.3. Significant progress has been made. At the time of the meeting the following is expected to have been completed. De-duplication of records, data verification and data quality improvements relating to HFEAID will be ongoing post data migration as originally planned.

Completed	Remaining work
• Registration • Outcomes • Gamete Movement pre-migration rules • Donor Insemination pre-migration rules • Gamete Movement • Link between patient and partner registration forms • Schema changes • Mapping data from ART extract to ART register • Link between IVF and registration	• Remaining 40% of IVF • Quality metrics • Thawed Embryo/ Egg Cycles • Hybrid Cycles • EggBatchID

5. PRISM Data Submission System

5.1. The software coding development work to produce the PRISM system is proceeding at pace and we are now approaching completion.

5.2. Two tranches of APIs have been launched to the EPRS (Electronic Patient Record System) suppliers and the third and final release is scheduled for the end of March 2018.

5.3. As previously signalled, testing on developed modules is underway using specialist contractors and internal staff.

5.4. The summary project plan for PRISM development is available as Annexe 1

6. Transitional Arrangements

6.1. Our Communications and Engagement Plan remains central to our work over the coming months. Dialogue with clinics, suppliers and stakeholders has been stepped up.

6.2. We will be taking a balanced, fair, but firm line with EPRS providers in that suppliers will be given a reasonable timeline by which to update and deploy their systems to align to our new dataset. For any who are unable to do this, the default position for clinics is that they will need to use the PRISM system to submit data to us. We have had early dialogue with EPRS suppliers and clinics to ensure this is understood and we will listen to any feedback and concerns they may have.

6.3. Work to create the server infrastructure to house the new register within the Microsoft Azure cloud is progressing well. Work to build the server architecture has started along with configuration relating to account management, auditing, network design, security and failover (contingency) planning to ensure the register is replicated across UK South (London) and UK West (Cardiff). This work is scheduled for completion by mid-March 2018.

6.4. Once complete, the infrastructure will be penetration tested by a specialist and following this any remedial work will be undertaken. The Azure environment will then be ready for PRISM / migrated data testing.

7. Risk Management

7.1. Several significant risks remain to delivery of this programme; these include:

- **The complexity of data migration** means that unforeseen issues emerge during sprints, risking slippage to the project and overall programme. Our mitigation is continued review and analysis of the project to ensure it keeps on track and contingency is to complete the pre-trail load process with partially verified data to allow testing of RISS in Azure and continue verification beyond March. This risk carries a post mitigation score of 15.
- **Loss of key staff:** The programme is heavily dependent upon a few key staff. The loss of any one will have a severe impact on the plan and quality of deliverables. There is no real mitigation for this. One of the outcomes of the project is that the data and processes are less opaque and skills and knowledge can be shared. Loss of key

staff will necessarily mean the project will take longer as new staff will need to learn and understand processes. This risk carries a post mitigation score of 10.

- **Pace of Delivery:** The programme delivers at pace for 9 months. Key staff have been working on the project for 3 years already and risk burnout. Our mitigation is careful management of time and demands on key staff members. Loss of key staff will necessarily mean the project will take longer as new staff will need to learn and understand processes. This risk carries a post mitigation score of 10.
- **EPRS API rollout takes longer** than planned delaying the roll out. Our mitigation is early engage with suppliers to ensure development is complete and roll-out plans are realistic and deliverable. Our contingency is the PRISM will be available to sites who cannot go live. This risk carries a post mitigation score of 10.

7.2. The full risk register is available on request.

8. Financial

8.1. The programme is delivering on target, and within our agreed capital allocation. Our expected financial outturn for 2017/18 is £342k against our agreed capital budget of £350k.

8.2. There will be modest additional costs incurred during the completion of this programme in 2018/19.

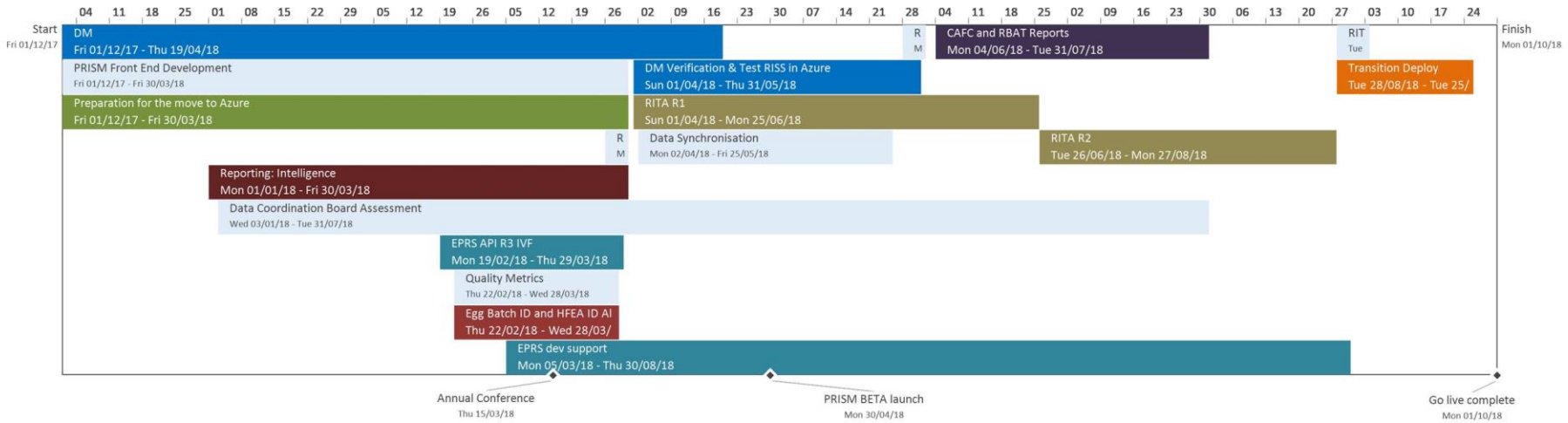
8.3. Our 2018/19 IT and Information budget is being finalised at present. Completion of this programme will be one of several capital and revenue items within that budget. With regards to capital approval cover, given the nugatory level of our 'bid' in relation to the Department of Health and Social Care overall amount, we will continue as previously.

9. Recommendation

The Committee is asked to note:

- Summary information on how we will launch our new system and new register during 2018
- The progress update relating to Data Migration and Cleansing and the development of the PRISM Submission System
- Information relating to our transitional arrangements, notably key elements of our Communications and Engagement Plan
- The financial update, and
- Details of key risks, mitigations and contingency

10. Annexe 1: Summary Programme Plan



Resilience, Business Continuity Management and Cyber Security

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	9		
Paper number	AGC (06/03/2018) 593 DH		
Meeting date	06 March 2018		
Author	Dan Howard, Chief Information Officer		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note: • Progress made relating to the completion of Information Risk training • The new server environment created for the new register • Our work to align policies and procedures to principles to accredited standards • An incident affecting the HFEA CaFC website		
Resource implications	None		
Implementation date	Ongoing		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes:	None		

1. Background

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

1.2. We experienced an incident relating to unusual activity detected on our website on 09 February 2018. Automated feedback relating to 46 clinics was submitted through the Choose a Fertility Clinic pages of the HFEA website. This update summarises the incident, and sets out action we have taken to date.

2. Progress update

2.1. **Information Risk training:** We require staff to complete mandatory management of information and cyber security training 'Responsible for information: general user' delivering through Civil Service Learning. At the time of writing 97% of staff have completed successfully with the remainder being encouraged to complete it. It is expected that, by the time of the meeting, 100% compliance will be achieved.

2.2. **Microsoft Azure (cloud) server environment for our new Register:** Our new Register will be housed within the Microsoft Azure cloud rather than on a physical server within Spring Gardens. As detailed in the primary programme update; work continues to ensure the new environment is robust and security controls are commensurate with the type of data held.

This configuration work involves building the environment and the following security configuration items are highlighted:

- Enabling auditing and threat detection for the register database within Azure
- Creating security groups for account management
- Restrict outbound traffic to know endpoints
- Separate public facing applications form internal applications
- Implement endpoint security controls along with application gateway and firewall controls
- Load balance servers
- Secure admin through remote access gateway
- Full Azure backup using 'Geo' replication of all servers, scripting the build of the second environment in UK West (Cardiff) for disaster recovery purposes
- Create security architecture document for appropriate key stakeholders such as fertility clinics and Department of Health and Social Care
- Document and test the disaster recovery fail-over to UK West

Once complete this work will be subject to a third party technical penetration test and in addition to this, a third party review of overall security controls and architecture will take place.

2.3. **ISO27001:** We have started to work towards closer alignment to the principles of this information security standard. This will involve, in due course and where necessary, updating and a review of our policies and procedures in line with the standard. Given the size of the organisation, we do not intend to gain accreditation against the standard however we do see benefits to closer alignment to the areas of policies, asset

management, information classification, access control, media handling and physical/environmental security.

3. Patient feedback incident

3.1. **Background:** On Friday 9th February at 10pm around 50 patient feedback ratings per clinic were submitted for 46 clinics (of 90 or so) through the Choose a Fertility Clinic part of our website – totalling around 2300 individual submissions of feedback. This resulted in the overall patient feedback rating reducing to around '2 out of 5' for many of the affected clinics. The patient feedback rating is one of a number of indictors used by individuals to measure clinic performance.

3.2. **Alerting and action taken:** We were alerted to this on Monday 12 February and immediately investigated the incident and the additional feedback was removed within 48 hours. We immediately contacted the affected clinics to inform them of the incident and the action we were taking to rectify the situation.

3.3. **Initial investigation:** Our initial review suggested that it was likely that the additional feedback was added by an automated script by a third party unconnected to the HFEA. This affected one section of the public facing part of our website and did not affect our underlying IT infrastructure or introduce any malicious code. No clinical information was present or accessed and no data breach occurred.

3.4. **Risk management:** At the time of the Choose a Fertility Clinic launch**,** we considered the risks relating to its use. To encourage engagement and feedback, the patient feedback section was purposely designed to be open to support ease of use. In response to the incident and following a review of the risk, we have since introduced a CAPTCHA validation check to help prevent a recurrence. CAPTCHA is the 'are you human?' check commonly found on similar websites. Since our website launch this technology has advanced and it now far less intrusive to the user experience.

3.5. **Reporting:** At the time of the incident we notified the digital team at the Department of Health and Social Care. They were grateful that we had alerted them and they confirmed that they were satisfied with actions we had taken are there was no reason to investigate further.

4. Recommendation

The Committee is asked to note:

- Progress made relating to the completion of Information Risk training
- The new server environment created for the new register
- Our work to align policies and procedures to principles to accredited standards
- An incident affecting the HFEA CaFC website

Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	10		
Paper number	[AGC (06/03/2018) 594 HC]		
Meeting date	6 March 2018		
Author	Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the annex.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest reviews

1.1. CMG reviewed the risk register at its meeting on 21 February. CMG reviewed all risks, controls and scores but deferred further risk updates in relation to the RE1 regulatory effectiveness risk, ME1 messaging and engagement and the C1 capability risk to the risk owners. At these meetings the mitigations were reviewed in detail and additional commentary added where relevant.

1.2. CMG felt that it was too soon to lower the residual risk level of the capability risk, as it was unclear whether mitigations had materially reduced the risk but agreed that the risk could be reviewed in detail by the Head of HR and Chief Executive.

1.3. On reviewing the mitigations and actions underway the Chief Executive and Head of HR, were minded to lower the risk score to an at tolerance score of 12. This reflected the view that the actions that we put in place to reduce this risk have been partially effective and given this, and the overall organisational context, reduced the residual likelihood of this risk, but retained a high tolerance as this bedding in process will take time. However, on balance they decided to leave the risk score unchanged for now. This is the only above tolerance of the seven risks.

1.4. CMG's comments are summarised at the end of the risk register, which is attached at Annex A. The annex also includes a graphical overview of residual risk scores plotted against risk tolerances.

1.5. Following the CMG meeting, and further risk reviews, one risk is above tolerance, and the remaining six risks are at or below tolerance.

2. Recommendation

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

Latest review date – 20/02/2018

Human Fertilisation & Embryology Authority

Strategic risk register 2017/18

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**16 – High**	Above tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇔
OC1: Organisational change	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇩⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**6 – Medium**	At 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, CMG, or the Authority (eg,⇧⇔⇩⇔). Recent review points are: Authority 15 November ⇨ CMG 22 November ⇨ AGC 5 December ⇨ CMG 7 February

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

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

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

Commentary
Below tolerance. As of Q4, the Authority have approved the new forecasting model and initial indications are that it is accurate. We are forecasting a surplus against budget which is due to the steady increase in our treatment fee income and slower than planned expenditure, of which unfilled vacancies were a major part. Owing to the near certainty of a surplus as at February, CMG have reduced the residual risk, which brings the overall risk score to a below tolerance score of 6. The whole of this risk has been reviewed and updated in the light of developments, including all causes and mitigations. Our contingency has been more explicitly articulated.

Causes / sources	Mitigations	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	CMG see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We have established a model for forecasting treatment fee income and this reduces the risk of significant variance, by utilising historic data and future population projections. As at February 2018, the current receipts are within 1% of the model's forecast. We will refresh this quarterly internally and review at least annually with AGC.	Quarterly, ongoing, with AGC model review at least annually - 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 – 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 flags 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.	Senior 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.	Ongoing – Richard Sydee or Morounke Akingbola
	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.	Monthly (on-going) – Morounke Akingbola
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance leads to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**

DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola As at February 2018 there is one litigation matter on the horizon (scheduled to be held in the high court in Autumn 2018).
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
	We will be undertaking a review of budgets for 2018/19 as part of our business planning process.	Planned for Q4 2017/18 – Morounke Akingbola

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**4**	**4**	**16 - 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
Above 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. After a period of high turnover and internal churn, in part caused by the organisational change programme, the organisation is entering a period of greater stability. Vacancy levels as at February 2018 are at an historic norm. The central task now is ensuring that new staff are given the support and time to acquire the necessary expertise and build relationships, both internal and external. The people strategy has been completed. Internal appointments have helped to ensure a degree of knowledge retention. The work on a formal knowledge capture and handover process is underway. The actions that we put in place to reduce this risk have been partially effective, however as the bedding in process will take time we have decided not to reduce the risk rating prematurely.

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.	In place – Yvonne Akinmodun
	We plan to put in place corporate guidance for all staff for handovers. This checklist will reduce the risk of variable handover provision.	To be reviewed as part of handover work Q4 2017/18 – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Yvonne Akinmodun

	CMG and managers prioritise work appropriately when workload peaks arise.	In place – Peter Thompson
Poor morale leading to decreased effectiveness and performance failures.	Engagement by managers through team and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Staff survey results for 2017/18 have informed the development of the people strategy. The all staff awayday in January 2018 gave staff a chance to feedback in further detail. Follow-up plan and communications now in place.	Annual survey and staff conferences – Yvonne Akinmodun/ 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).	In place – 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. Agile approach to be brought into project processes under new project governance framework.	Partially in place – further work to be done by early 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 Autumn 2018 – Dan Howard
Possible future increase in capacity and capability needed to process mitochondrial donation applications.	Starting to be considered now, but will not be known for sure until later, so no controls can yet be put in place. Only one clinic licensed to provide these treatments, applications unlikely to be many at first. New licensing processes for mitochondrial donation are in place (decision trees etc).	Issue for further consideration – Clare Ettinghausen

Loss of knowledge in the Policy team as at February 2018 particularly acute given high-turnover of key individuals, including the Head. This may have a knock on impact on other teams.	As above, knowledge transfer has been prioritised. New starters have been thoroughly inducted. Policy work has been reprioritised with a focus on the Code of Practice October 2018 revision.	In place - Clare Ettinghausen
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 (including the McCracken review and Triennial Review).	In place – Peter Thompson

OC1: There is a risk that the implementation of organisational changes results in instability, loss of capability and capacity, and delays in the delivery of the strategy.

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

Risk area	Risk owner	Links to which strategic objectives?	Trend
Organisational change OC1: Change-related instability	Peter Thompson, Chief Executive	Whole strategy	⇩⇔⇔⇔

Commentary
At tolerance. As at February 2018, all of the agreed voluntary redundancies have taken place and most of the recruitment is complete. There is only one organisational change role still to be filled, the developer role, which has been revised in the light of a previous failed attempt to recruit and this should reduce any risk of further recruitment delays. As agreed by the Authority in November, this strategic risk will be removed at the end of the business year. This still feels appropriate given the current organisational circumstances. Any outstanding risk sources will be considered at that time, to ensure that they are captured in the relevant operational risk logs or under the Capability strategic risk, as relevant.

Causes / sources	Mitigations	Timescale / owner
The change period may lead to dips in morale, commitment, discretionary effort and goodwill. There are likely to be differential impacts as different changes affect different groups of staff at different times. Risks are to the delivery of current work, including IfQ, and possibly technical or business continuity risks.	Clear published process, with documentation.	In place – Peter Thompson
	Consultation, discussion and communication, with opportunity to comment, and being responsive and empathetic about staff concerns. Staff informed of likely developments and next steps and, when applicable, of personal role impacts and choices.	Completed – Peter Thompson
	Relatively short timeline for decision making, so that uncertainty does not linger.	In place – Peter Thompson
	HR policies and processes are in place to enable us to manage any individual situations that arise.	In place – Yvonne Akinmodun

	Employee assistance programme (EAP) support accessible by all.	In place – Peter Thompson
Organisational change combined with other pressures for particular teams could lead to specific areas of knowledge loss lasting some months (pending recruitment to fill any gaps).	Policies and processes to ensure we treat staff fairly and consistently, particularly those 'at risk'. We will seek to slot staff who are at risk into other roles (suitable alternative employment).	In place – Peter Thompson
	Well established recruitment processes, which can be followed quickly in the event of unplanned establishment leavers.	In place – Yvonne Akinmodun
	Good decision-making and risk management mechanisms in place. Knowledge retention via good records management practice, SOPs and documentation.	In place – Peter Thompson
Potential impact on our ability to complete IfQ on time.	Ability to use more contract staff if need be.	In place – Peter Thompson
Implementing the new structure involves significant additional work across several teams to embed it so that the benefits are realised. There will also be result in some internal churn.	Business plan discussions acknowledging that work in teams doing IfQ or organisational change should not be overloaded.	In place – Paula Robinson
	CMG able to change priorities or timescales if necessary, to ensure that change is managed well.	In place – Paula Robinson
	Organisational development activity has continued, including summer awayday (10 July 2017), to support new ways of working development. A leadership awayday (November 2017) and another all staff awayday happened in January 2018 with a focus on building an HFEA culture following the organisational changes.	In place – Yvonne Akinmodun
Additional pressure on SMT, HR and Heads, arising from the need to manage different impacts and responses in a sensitive way, while also implementing formal processes and continuing to ensure that work is delivered throughout the change period.	Recognition that change management requires extra attention and work, which can have knock-on effects on other planned work and on capacity overall. Ability to reprioritise other work if necessary.	In place – Peter Thompson
	Time was set aside by managers to discuss the changes with staff as needed, with messaging about change repeated via different channels to ensure that communications were received and understood.	In place – Peter Thompson
	SMT/CMG additional informal meetings arranged to enable mutual support of managers, to help people retain personal resilience and be better able to support their teams.	In place – Paula Robinson

Level of service to Authority members may suffer while the changes are implemented, negatively impacting on the relationship between staff and members.	Communicate the changes clearly to Authority members so that they understand when staff are particularly under pressure, and that they will have reduced capacity. Inform Members when staff are new in post, to understand that those staff need the opportunity to learn and to get up to speed.	In place – Peter Thompson
Once the changes have been implemented, a number of staff will simultaneously be 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 provided where required. Knowledge management via records management and documentation.	In progress, Yvonne Akinmodun is reviewing onboarding methods – Peter Thompson
Bedding down the new structure 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.	Change management will be prioritised, where possible, so that bedding down occurs and is effective, and does not take an unduly long time.	Done – Peter Thompson
	Continuing programme of leadership development for Heads and SMT.	Ongoing – Yvonne Akinmodun Most recent development day November 2017.
The new model may not achieve the desired benefits, or transition to the new model could take too long, with staff losing faith in the model.	The model will be kept under review following implementation to ensure it yields the intended benefits.	A review of the new model will be presented to the Authority in Summer 2018 – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
-		

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

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

Commentary
At tolerance. As at February 2018, a review of all IT policies is underway, to ensure that these remain fit for purpose. All new development has been done with cyber security in mind and this is especially true of the Register migration which will not be completed until we receive adequate external assurance of data security. This external assurance has been ongoing throughout the migration planning process. We are scoping and will soon launch a records management project to replace our outdated TRIM system, this project will be completed by the end of 2018/19. Although TRIM is a source of risk, the IT team are assured that data is backed up and the system can be sustained until a replacement is in place. The cyber-security event earlier in 2017, affecting the NHS and other organisations demonstrates that there is no room for complacency. However regular audits and our own assessments indicate that the HFEA is well protected. We were not affected by the 2017 incident.

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. Internal audit report on data loss (October 2017) gave a 'moderate' rating, and recommendations are being actioned and reported at each CMG Risk and AGC meeting. Detailed information on our security arrangements is available in other documents. A business continuity plan is in place.	Ongoing regular reporting - Nick Jones/Dan Howard

Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	The Website and Clinic Portal are secure and we have been assured of this. The focus now is on obtaining similar assurance through penetration testing report to the SRO in relation to the remaining data submission deliverables.	Further assurance expected April-May 2018 - Nick Jones/Dan Howard
There is a risk that IT demand could outstrip supply and so IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion.	We continually refine the IT support functional model in line with industry standards (ie, ITIL). As at February 2018, we are actively improving our controls by investigating additional support delivered by a third party. This includes partnering with similar organisations such as the HTA, or entering into a separate agreement with an infrastructure support provider (it is likely that desktop support would remain unaffected by such an arrangement).	Approved per the ongoing business plan and budget agreement process – 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 the Register team and other relevant staff both in the office and when working at home (end to end data encryption via the internet [VPN], hardware encryption) Further to these mitigations, any malicious actions would be a criminal act.	In place – Peter Thompson As at Feb 2018, we are undertaking an update of key existing policies. To be completed by end Q1 2018/19 – 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 As part of the R2 project development, by end April 2018 – Dan Howard
Business continuity issue (whether caused by cyber-attack, internal malicious damage to infrastructure or an event affecting access to Spring Gardens).	Business continuity plan and staff site in place. Improved testing of the BCP information cascade to all staff was undertaken in September 2017 as well as a tabletop test and testing with Authority members. Existing controls are through secure off-site back-ups via third party supplier.	BCP in place, regularly tested and reviewed annually – Nick Jones

	Work is underway to implement a cloud backup environment to provide a further secure point of recovery for data which would be held by the organisation.	Undertaken monthly – Dan Howard March 2018 - Dan Howard
The corporate records management system (TRIM) is unsupported and unstable and we are carrying an increased risk of it failing. Alongside this, there is the risk of poor records management by staff.	A comprehensive review of our records management practices and document management system (TRIM) has started including the formation of a working group. A formal project will be initiated shortly.	Project to be delivered within 2018/19 business year – Peter Thompson
Cloud-related risks.	Detailed controls set out in 2017 internal audit report on this area. We have in place remote access for users, appropriate security controls, supply chain security measures, appropriate terms and conditions with Microsoft Azure, Microsoft ISO 27018 certification for cloud privacy, GCloud certification compliance by Azure, a permission matrix and password policy, a web configuration limiting the service to 20 requests at any one time, good physical and logical security in Azure, good back-up options for SQL databases on Azure, and other measures.	In 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 in such a way that resources are significantly diverted from strategic delivery.

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

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

Commentary
At tolerance. A judicial review hearing of one discrete element of the IfQ CaFC project was held in December 2016 and January 2017. The HFEA won this case. The Court of Appeal has granted permission to appeal against this decision and a hearing date has been set in the Autumn. The judgment on consent to legal parenthood in 2015 and subsequent cases, which include cases where errors have been made as recently as 2016/17, have administrative and policy consequences for the HFEA, and potentially reputational consequences too if we are criticised in judgments. The number of new and upcoming cases has reduced; however, recent cases suggest that learning has not been embedded in every clinic. This raises the question of whether further guidance or training is required in clinics.

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.	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 put the HFEA in the best possible position to defend any challenge.	Ongoing – Catherine Drennan In place – Peter Thompson

	Case by case decisions on the strategic handling of contentious issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	In place – Catherine Drennan and Peter Thompson
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs. **Note**: Inspection rating on CaFC may mean that more clinics make representations against licensing decisions.	Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision making processes.	In place – Peter Thompson
	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 2017). As of January 2018, a licensing review is underway to assess whether changes are indicated, to make the licensing process more efficient and robust.	In place, SOPs are being refreshed in Q4 2017/18 and this will be further informed by the licensing review to be completed by March 2018– Paula Robinson
	Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.	In place – Sharon Fensome-Rimmer
Risk that involvement of the Head of Legal in an increased number of complex compliance management reviews causes disruption to other important legal work.	The Compliance team stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for effective planning of work. The Compliance management team will monitor the number and complexity of management reviews to ensure that the Head of Legal is only involved as appropriate.	In place – Sharon Fensome Rimmer, Nick Jones
Moving to a bolder strategic stance, eg, on add ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Any changes could be perceived as a threat – not necessarily ultimately resulting in legal action, but still entailing diversion of effort.	Risks considered whenever a new approach or policy is being developed. Business impact target assessments carried out whenever a regulatory change is likely to have a 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	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	In place – Peter Thompson

resource demands resulting from a case can't necessarily be anticipated.	different potential outcomes and plan resources accordingly.	
Legal proceedings can be lengthy and resource draining, and divert the in-house legal function 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
Adverse judgments require us to alter or intensify our processes, sometimes more than once.	Licensing SOPs being improved and updated, committee decision trees in place.	In progress (to complete in Q4 2017/18) and in place – Paula Robinson
HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound,	Licensing SOPs being improved and updated, committee decision trees in place.	In progress (to be completed in Q4 2017/18) and in place – Paula Robinson
	Up to date compliance and enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.	In place – Nick Jones / Sharon Fensome-Rimmer
Additional regulatory sanctions activity around legal parenthood consent diverts resources.	Robust assurance was sought from the sector regarding parenthood consent issues, and detailed plans were provided to address identified cases and anomalies.	In progress and ongoing – Nick Jones
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If	In place – Peter Thompson

	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.	

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

Risk area	Risk owner	Links to which strategic objectives?	Trend
Regulatory effective-ness RE 1: Inability to translate data into quality	Nick Jones, Director of Compliance and Information	Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce	⇔⇔⇔⇔

Commentary
At tolerance. Data submission work continues at a good pace. The plan for implementation was revised at the end of 2017, so that both clinics using EPRS systems and those using the HFEA's standalone submission system, PRISM, will be brought onboard at the same time – this will remove the risk of double running systems. The background development work is on course to be completed in Spring 2018 and clinics will be using the new system by Autumn. Register migration work is continuing carefully, with due consideration of risks. External assurance has been sought throughout the planning and testing process, and the migration will not go ahead until we have expert assurance that the quality of the data migrated is at the required level. The work of the Intelligence team has been set out in the intelligence strategy (launched January 2018). This will focus on improving the use of our existing data and making the most of the new Register post-migration.

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.	The data submission project is well planned and under way after initial delays. Data Submission development work will largely complete by end 2017/18 financial year with clinic implementation and access to it following by Autumn 2018. Oversight and prioritisation of any remaining development work will be through the IT development programme board.	Completion of data submission project Autumn 2018 – Nick Jones
Risks associated with data migration to new structure,	Migration of the Register is highly complex. IfQ programme groundwork focused on current state	Autumn 2018 with regular

compromises record accuracy and data integrity.	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.	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 fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible, through engagement with stakeholders to anticipate future needs and build these into the design. Further scoping work would occur periodically to review whether any additions were needed. The structure of the new Register makes adding additional fields more straightforward than at present.	In place regular reviews to occur once the Register 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 and as at March 2018 the new IT systems manager is reviewing support arrangements to ensure that skills and service gaps are managed.	In place with work underway to improve arrangements in Spring 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. Business support and the inspection teams are at full complement. Although not all systems are in place in relation to providing data to inspectors eg, patient feedback, workarounds are in place which are working.	In place – Nick Jones
Organisational change could take too much time to embed, the necessary culture shift may not be achieved, or new structure not accepted, with an accompanying risk to our ability to make full use of our data and intelligence as intended by the new organisational model.	During IfQ delivery, product owners were in place, and a communications plan. The changes were developed involving the right staff expertise (as well as contractors) and part of the purpose of this was to ensure that the changes are culturally embraced and embedded into new ways of working. Organisational re-shaping was done in 2017 to ensure the right staffing structure and capabilities in place to realise IfQ's benefits. This included the establishment of the Intelligence team and reshaping of the Register team. Work is underway in 2018 to further define and bed in HFEA culture in the light of these organisational changes. The people strategy will be signed off in February 2018.	In place – Peter Thompson Done – Peter Thompson Ongoing, Q4 2017/18 - Yvonne Akinmodun
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new register	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the data submission project.	Revised timeline in place, as at Feb 2018 planning

structure until their software has been updated.	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.	underway to manage submission gaps - Nick Jones
Data migration efforts are being privileged over data quality leading to an increase in outstanding errors	The Register team has introduced a triage system to deal with clinic queries systematically, addressing the most critical errors first.	In place – Nick Jones
	We undertake an audit programme to check information provision and accuracy.	In place – Nick Jones
	Data verification work (February 2017) in preparation for Register migration improved overall data accuracy, and the exercise included tailored support for individual clinics that were struggling.	Completed – Nick Jones
Risk that subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error)	We will explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. We have systems for checking consistency of answers. FOI requests are refused when there are grounds for this.	In place – Clare Ettinghausen / Caylin Joski-Jethi
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.	During the patient feedback trial a communications strategy has been in place, including considering ways to encourage more patient feedback. The intelligence strategy focuses in part on making best use of the information gleaned from patients, and converting our mix of soft and hard data into real outcomes and improvements.	In place for the trial however, a plan needs to be developed post March 2018 with input from the Authority – Clare Ettinghausen /Caylin Joski-Jethi
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.

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. As at February 2018, the Fertility Trends report is being completed and will be published in mid-March. These new statistics will provide a significant update on the data available to patients and other stakeholders and will replace figures from the report published in 2016 which included pregnancy data from 2014 and birth data from 2013. Birth data from 2016 will be available in the new report. This update will require a review of all statistics on the website to ensure that these are current. This is particularly important as patients may mainly access the statistics through other patient information on the website. The overall risk description for this risk has been updated, and the phrase 'so we miss opportunities to bring about positive change' has been removed. This is not because we are more concerned about the engagement and strategic risks associated with providing incorrect information to the public and other stakeholders, rather than the potential for lost opportunities. We have identified a potential risk source in the handling of FOIs, relating to lack of organisational awareness and understanding. This is mitigated by the existing sign off process, which ensures that a Head or Director must sign off any FOI response. A review of FOI processes and training will occur in Spring 2018 to ensure that any further mitigations are identified and we strengthen our expertise. We do not therefore believe that this risk has risen at this point in time.

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.	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.	In place – Jo Triggs

	The Communications team cannot do this in isolation and a good deal of communication with clinics occurs through the inspectorate. When there are messages that need to be conveyed to clinics through the inspection team, Policy or Communications work with the team so that a co-ordinated approach is achieved. Equally, the inspection team keep abreast of all communications with the sector through Clinic Focus, Chairs letters etc. 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 to quickly ensure that.	Sharon Fensome-Rimmer, Laura Riley, and Jo Triggs
Patients and other stakeholders do not receive the correct guidance or information.	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 about the information on the website allows us to properly understand user needs. We have internal processes in place which meet the Information Standard.	In place – Laura Riley, Jo Triggs
We are not able to reach the right people with the right message at the right time.	We have an ongoing partnership with NHS Choices to get information to patients early in their fertility journey. 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 in order to ensure that they continue to meet our user needs.	In place and developing – Jo Triggs In place and ongoing – Jo Triggs In place - Laura Riley, Jo Triggs In place– Jo Triggs Ongoing through Digital Communications Board meetings – Jo Triggs
Risk that incorrect information is provided in PQs or FOIs and this may lead to misinformation and misunderstanding by patients, journalists and others. As at February 2018, a number of people who are involved in FOIs are not trained in FOI practices and procedures, which means this risk is increased.	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. However, as at February 2018, organisational training is required in relation to FOIs. We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission. A future review of the FOI processes and procedures in the organisations will be planned.	Clare Ettinghausen Clare Ettinghausen /SMT - In place Clare Ettinghausen – being planned, to

	This will include a review of general staff understanding of FOIs.	occur Spring 2018
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 data on our website. This is a particular risk at the moment due to some of the data currently being from 2014 (this is particularly relevant in relation to egg freezing data).	The Communications team ensure that public information reflects the latest knowledge from intelligence and Policy. Intelligence and Policy teams take all steps to ensure that accurate information is provided to Communications. The Communications team work quickly to amend any factual inaccuracies identified. The Communications publication schedule includes a review of the website, to update relevant statistics when more current information is available.	In place - Caylin Joski-Jethi, Laura Riley, and Jo Triggs In place – Jo Triggs In place – Jo Triggs
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NHS Choices site and our site contain links to one another.	We maintain a relationship with the NHS Choices team.	

Reviews and revisions

CMG review – February 2018 meeting (20/02/2018)

CMG reviewed the strategic risk register and made the following points in discussion:

- CMG discussed the capability risk at length and considered whether the additional mitigations put in place to bring this risk back to within tolerance had been effective. CMG discussed the fact that the organisational changes were nearly complete and this would have some effect on this risk, however, it was clear that the outstanding position, the developer role, was of some concern to members. Changes in the Policy team would also lead to a loss of capability while new staff came up to speed. This would impact the Compliance and Legal teams. In the light of discussion, CMG considered that the additional mitigations had not yet materially improved the position and the risk was still above tolerance, however it agreed that the Chief Executive and Head of HR would meet to review the mitigations in detail and consider other actions available.
- On reviewing the mitigations and actions underway at a further meeting between the Chief Executive and Head of HR were minded to lower the risk to an at tolerance score of 12, to reflect the view that the actions that we put in place to reduce this risk have been partially effective and this, and the overall organisational context, reduced the residual likelihood of this risk. However, on balance they decided to retain the higher score for now as this bedding in process will take time.
- When discussing the Cyber security risk, CMG discussed whether the business continuity side of this risk belonged alongside the cyber risks or whether these should be split out. CMG agreed to consider whether there was a place for a more general information risk to be included on the register, but were mindful not to proliferate risk areas where this was not necessary.
- In relation to legal risks, CMG noted that there are no upcoming cases on the near horizon, however, this risk encompasses all legal activity and resources were stretched owing to increased demands from Policy (from project work) and Compliance (management reviews). CMG discussed the score and considered whether it was appropriate to lower the risk likelihood. Given the new sources of this risk relating to skills gaps, CMG felt that it was more appropriate to leave the risk score the same, in spite of the reduced likelihood of litigation in the near future.
- CMG discussed whether there were any other strategic risk missing from the register. One member queried whether some of the risks listed in the operational report may in fact have strategic consequences and so should be reflected in the strategic register. No new risks were added, but CMG agreed to continue to consider this in future.

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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.

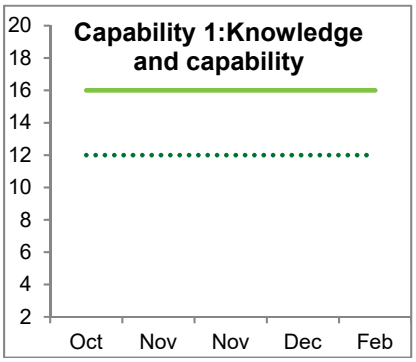
Contingency actions

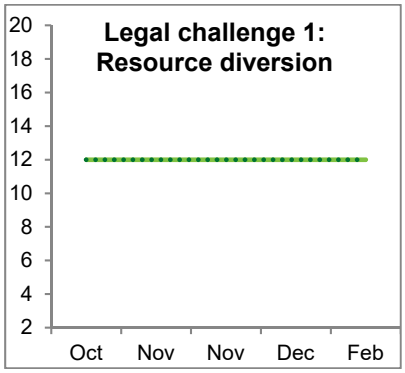
When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be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

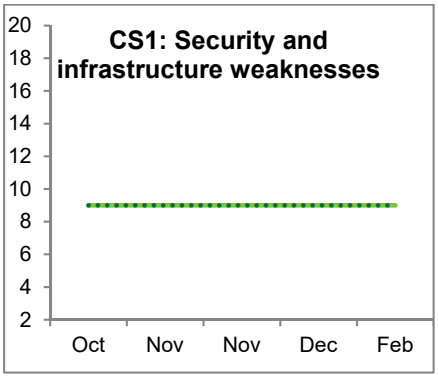
Tolerance vs Residual Risk:

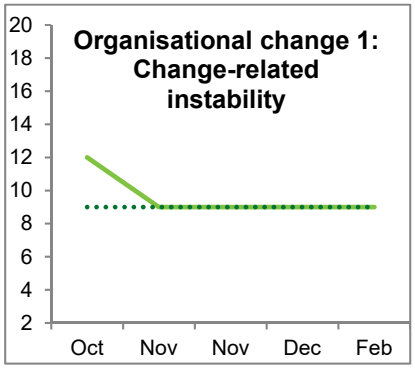
High and above tolerance risks

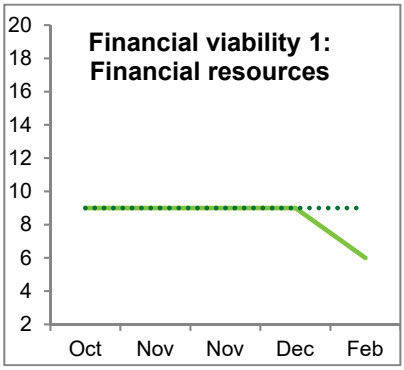


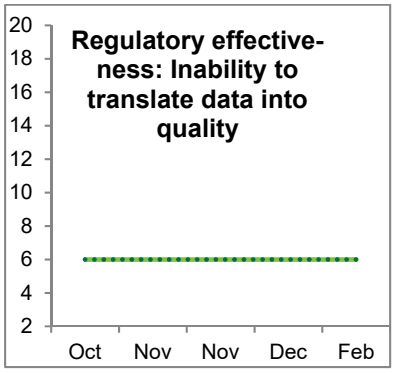


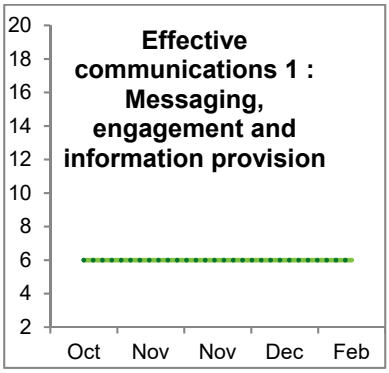
Lower level / in tolerance risks











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	11		
Paper number	AGC (06/03/2018) 595		
Meeting date	6 March 2018		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the plan.		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low	☐ Medium	☐ High
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information		
Annexes	N/A		

Audit & Governance Committee Forward Plan

AGC Items Date:	6 Mar 2018	12 Jun 2018	9 Oct 2018	4 Dec 2018
Following Authority Date:	9 May 2018	27 Jun 2018	14 Nov 2018	Jan 2019
Meeting 'Theme/s'	**Finance and Resources**	**Annual Reports, Information Governance, People**	**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
Information for Quality (IfQ) Prog	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)		Yes – For approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report	Audit Planning Report	Audit Planning Report
Information Assurance & Security		Yes		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Update	Results, annual opinion approve draft plan	Update	Update
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:	6 Mar 2018	12 Jun 2018	9 Oct 2018	4 Dec 2018
HR, People Planning & Processes		Yes		
Strategy & Corporate Affairs management			Yes	
Regulatory & Register management				Yes
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Review of AGC activities & effectiveness, terms of reference	Yes			Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				