Audit and Governance Committee meeting - agenda

3 October 2017

Derwent Room

HFEA Offices,10 Spring Gardens, London SW1A 2BU

	Agenda item		Time
1.	Welcome, apologies and declaration of interests		10:05am
2.	Minutes of 13 June 2017 **[AGC (03/10/2017) 558]**	For Decision	10.15am
3.	Matters Arising **[AGC (03/10/2017) 559 MA]**	For Information	10.20am
4.	Strategy and Corporate Affairs Management **[AGC (03/10/2017) 560 JT]**	Presentation	10.30am
5.	Internal Audit a) Progress Report **[AGC (03/10/2017) 561 DH]**	For Information	10.50am
6.	External Audit – Audit Planning Report **[AGC 03/10/2017) 562 NAO]**	To follow	11.00am
7.	Data Submission Project (formerly IfQ) **[AGC ((03/10/2017) 563 NJ]**	For Information	11.15am
8.	Business Continuity, Resilience and Cyber Security **[AGC (03/10/2017) 564 DH]**	For Information	11.30am
9.	Strategic Risk Register **[AGC (03/10/2017) 565 HC]**	For Discussion	12.00pm
10.	Reserves Policy **[AGC (03/10/2017) 566 MA]**	For Information	12.10pm
11.	Legal Risks **[AGC (03/10/2017) 567 RS]**	Verbal Update	12.20pm
12.	AGC Forward Plan **[AGC (03/102017) 568 MA]**	For Decision	12.30pm

13.	Whistle Blowing and Fraud **[AGC (03/10/2017) 569 RS]**	Verbal Update	12.35pm
14.	Contracts and Procurement **[AGC (03/10/2017) 570 MA]**	Verbal update	12.45pm
15.	Any other business		12.55pm
16.	Close (Refreshments & Lunch provided)		1.00pm
17.	Session for members and auditors only		1.00pm
18.	Next Meeting 10am Tuesday, 5 December 2017, 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 (03/10/2017) 558		
Meeting date	3 October 2017		
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 13 June 2017

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

Members present	Anita Bharucha (Chair) Margaret Gilmore Gill Laver Jerry Page
Apologies	
External advisers	Internal Audit - PricewaterhouseCoopers (PwC): Jeremy Nolan External Audit - National Audit Office (NAO): Sarah Edwards George Smiles Northdoor Plc (Item 9) Padraic O'Connor
Observers	Kim Hayes, Department of Health Kevin Wellard, Human Tissue Authority
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 Ian Peacock, Systems Manager Bernice Ash, Committee Secretary

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting, in particular:

- Kevin Wellard, Human Tissue Authority, observing the meeting.

1.2 Apologies were received from Siobhain Kelly, Senior Governance Manager and David Moysen, Head of IT.

1.3 There were no declarations of interest.

2. Minutes of the meeting held on 21 March 2017

2.1 The minutes of the meeting held on 21 March 2017 were agreed as a true record and approved for signature by the Chair.

2.2 The Chair requested that, for future meetings, the first draft of the minutes be circulated to internal staff for comment, prior to requesting comments from Committee members.

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 Items 11.6, 13.5, 4.24 and 8.6 relating to updates on cyber security and business continuity have been addressed in the items on the agenda below.

3.3 9.5) The forward plan had been amended to reflect the changes made by the Committee at the 21 March 2017 meeting.

3.4 10.9) The Head of Planning and Governance confirmed that, on next year's calendar of meetings, AGC would precede Authority. This would enable the Committee to consider the strategic risk register prior to its presentation to Authority.

3.5 Some Committee members raised concern regarding receipt of information distributed to their HFEA email accounts, as they generally only access these in periods leading up to a main meeting. It was identified that it would be useful for a message to be sent to individuals' private email addresses, informing them of any new information sent to their HFEA accounts. This suggestion was noted by the Chief Executive.

Action

3.6 Staff members to alert Committee members, by means of their private email addresses, when information is sent to their HFEA email accounts, between meetings.

4. Internal Audit

a) Annual Assurance Statement 2016-17

4.1 The new Head of Internal Audit reported on the annual assurance statement for 2016/17, stating that the overall rating for the Authority is 'moderate', meaning that there was room for improvements. The committee noted that a rating higher than moderate could be deemed as being perfect.

4.2 The Committee noted the audits in the three key areas of management, governance and control had been marked as 'moderate' and there were no high priority recommendations.

b) 2017-18 Plan

4.3 The Head of Internal Audit reported that the 2017/18 plan focused on data loss, financial controls, the General Data Protection Regulation, risk management and governance. The plan does fit in with the budget.

4.4 The Committee felt that, given the strengths of the organisation's risk management and control system, too many indicative days had been allocated to this, suggesting there should be some reallocation of these to the data loss audit.

4.5 The Committee was informed that a scoping exercise around the key risk that Authority data could be lost, become inaccessible, or be inadvertently released or accessed, will need to be conducted to deal with any crossover issues with the General Data Protection Regulations.

4.6 The Head of Internal Audit confirmed that a three year plan would be developed in due course and some thoughts for 2018-19 plan had already been considered. The Committee was informed that the 2017-18 plan had been produced with the benefit of looking retrospectively at previous three year plans.

Action

4.7 The Head of Internal Audit to look at reallocating some of the indicative days from the area of risk management and control to the data loss audit area.

5. Implementation of Audit Recommendations

5.1. The Head of Finance reported there had been two additional items added to the tracker since the last meeting, both concerning board effectiveness. These had both been completed.

5.2. The Committee noted that all the audit recommendations had been completed and could be removed from the tracker.

6. Annual Report and Accounts

6.1 The Director of Finance and Resources presented the annual report and accounts 2016/17, making specific references to the increase in income, notably in fees for IVF cycles shown on page 42. The Committee was informed that there were 100,000 more cycles than expected in the 2016/17 financial year. The importance of attaining improved information from the sector within this area was identified and this would be explored in more depth over the latter half of 2017.

6.2 The Committee were taken through the balance sheet and noted that there was an issue with intangible assets that were showing a zero. The Director of Finance and Resources confirmed there were in fact intangible assets and the balance sheet does balance, so it appears there was a formatting error. The increase to intangible assets during the financial year related to the investment in the IfQ programme.

6.3 The Director of Finance and Resources drew the Committee's attention to note 3 on page 49 the professional and administrative fees, relating to legal costs incurred which had increased, in addition the effects of the organisational changes were reflected in the provision.

6.4 The Committee noted that at the date of finalising the accounts, there were two matters in litigation that may have financial consequences for the Authority. The Chief Executive provided an update on these issues.

6.5 The Committee identified that the cash is not reducing, and that 80% of income is derived from centres, and therefore patients. The Chief Executive stated that constantly changing the fee amounts causes issues for the centres and therefore the preference was for a medium term

stability in fee rates. The Committee agreed that the forthcoming work to improve forecasting and fee setting is necessary.

6.6 The Committee discussed the Chief Executive's foreword, and generally felt the Authority needed to highlight its achievements through this piece. The Committee advised this should make clearer reference to helping patients, technology and mitochondrial work, also making suggested wording changes.

6.7 The Committee suggested several other changes to the report including stronger references to the roles of the committees and the core work of the Authority. It was felt that risks, particularly in connection to resources, needed to be more explicit.

6.8 Subject to the suggested changes, the Committee recommended that the Accounting Officer, the Chief Executive, signs the annual report and accounts.

6.9 The Committee noted the Executive's plan to sign off the annual report and accounts by 3 July 2017.

Action

6.10 The Director of Finance and Resources to liaise with Committee members and senior management to finalise the accounts.

7. External Audit - Audit Completion Report

7.1 The NAO spoke to the audit completion report, noting the outstanding actions, which still required review by the Authority.

7.2 The NAO referred the Committee to the key audit findings, stating there were no particular items to report. Only one recommendation had been made regarding the internal control over contracts and this had been corrected. It was confirmed that the identified adjusted misstatements would be changed in the accounts.

7.3 The Chair thanked the Head of Finance, the Director of Finance and Resources, and the team for all their hard work.

8. HR – Update on Reorganisation and Post Staff Survey

8.1 The Chief Executive gave the Committee an update on the current structural reorganisation and actions resulting from the staff survey conducted in December 2016.

8.2 The Chief Executive stated the key drivers for the organisational change were the new three year strategy and the Information for Quality (IfQ) Programme. To deliver the new strategy and IfQ, it was necessary to look at the roles required to fulfil the Authority's strategic ambitions and assist clinics in attaining better performance.

8.3 The Committee was provided with progress updates regarding recruitment for the newly formed Planning and Governance team (which is now complete), the Intelligence team, Chief Information Officer and new Senior Inspector role. It was noted that 3 staff had accepted voluntary redundancy and temporary additional staff are covering the current skill gaps. The Chief Executive acknowledged the desire to move quickly with the reorganisation process, but noting the importance of completing IfQ first.

8.4 The results of the 2016 Staff Survey had revealed a mixed picture, in comparison to previous surveys. As a result of the staff survey, Task and Finish Groups were established, covering leadership and managing change, engagement and taking action, resources and workload, line management and managing performance, learning and development, recruitment and careers and pay and benefits.

8.5 The Chief Executive reported that the outcomes of the Task and Finish Groups would be discussed at an all staff awayday in July. Work on a new People Strategy was also in progress.

8.6 The Committee noted the risks associated with the organisation change regarding corporate memory and knowledge within the Authority. The necessity to produce updated SOPs had been identified.

8.7 The Chief Executive reported there had been no evidence of lack of engagement from staff so far, although understandably, morale in the IT team had been low.

8.8 The Chair thanked the Chief Executive for his leadership during this time of organisational change, acknowledging the good level of staff engagement.

8.9 The Committee discussed how often data collected by the Authority is used for research projects. The Director of Compliance and Information spoke to the Committee about the Register Research Panel, to which applications to use data can be made. The latest research application would study the connection between individuals born through IVF and their educational outcomes.

8.10 The Chief Executive stated that the Authority has high level powers to collect data but only general powers to make this available to others. Permission is required from the Department of Health to commission certain research, and use any surplus monies for this purpose.

Action

8.11 The Director of Finance and Resources to explore the potential to surplus funds to commission research on the data held by the Authority.

9. Information for Quality (IfQ) Programme

9.1 The Director of Compliance and Information spoke to the paper, providing an update on progress, the programme budget and risks.

9.2 The required work to satisfy the GDS standards, following the feedback received in early May 2017, was duly completed, and a further assessment then occurred on 7 June 2017; results were currently awaited. Necessary work for the new website and Choose a Fertility Clinic had been complex and time consuming for the clinics, but should be completed shortly.

9.3 The Committee noted that the IfQ Programme budget had now closed. Final expenditure (subject to final accounts) was £1.276m compared to the planned budget of £1.227m. The Committee also noted that the necessary funding for completing the outstanding aspects of the programme would be in addition to the original Programme budget; and that the funding was budgeted within the 2017-18 budget.

9.4 The Committee was informed about the current data migration work, noting that the third ‘trial load’ would be due for completion in July 2017. The Committee was reminded that Northdoor Plc. had been commissioned to ensure the Authority remained compliant with the data migration strategy, and a second migration audit had just been completed.

9.5 Northdoor Plc. gave the Committee a presentation on the data migration exercise, covering the background to their work, recommendations status, project status and next steps to be taken prior to migration going live.

9.6 The Systems Manager reported that the IfQ work continued to be time consuming. There had been some slippage with the migration trial loads, and as with all projects of this nature, more issues were likely to arise.

9.7 The Committee noted the top five risks for the project included loss of knowledge within the team, increasing workload and lack of resources and key IT knowledge being transferred to contractors. The mitigations in place were noted.

Action

9.8 The Director of Compliance and Information to distribute information concerning the outcome of the recent GDS assessment to the Committee. A further update on IfQ will be provided at the next meeting.

10. Information Assurance and Security

10.1 The Director of Compliance and Information spoke of the importance of ensuring the organisation had a robust records management policy. This would be a main work stream for the Head of Intelligence, once recruited.

10.2 The Committee was informed that an internal audit on data loss was about to commence, and would provide the Executive and Committee with assurance.

11. Cyber Security and Resilience and Business Continuity Management

11.1 The Director of Compliance and Information spoke to the cyber security paper, referring to the recent 'WannaCry' cyber-attack which affected more than 300,000 organisations in 200 countries. It was confirmed that the Authority was not a victim of this cyber-attack.

11.2 The Committee was informed that further attacks were possible and since these would become more sophisticated in nature, the Authority could be vulnerable. Risk indicators had been identified. The importance of a robust IT strategy and being open to the possibility of attack was stated. Although it had been assessed that the Authority did not currently show any risk indicators, it was important for the organisation not to become complacent.

11.3 The Director of Compliance and Information referred to the move to Office 365 (0365) and the development of a document management system within this. The necessity to make this product more bespoke to the Authority had been identified, noting that certain processes, including ensuring track changes in on-lne documentation could be shared, needed to be in place.

11.4 The Committee was reassured there was no increased security risk to their HFEA email accounts. However, encryptions on personal devices should be the same as those on HFEA devices. The risk associated with downloading Authority documents to personal devices was discussed.

11.5 The Committee referred to the Resilience and Business Continuity paper, indicating that it felt that given O365 is highlighted as a mitigation for business continuity risks, its partially tested status represented a risk in itself.

11.6 The Committee noted the actions being taken with regard to business continuity and resilience, and work due for completion by the end of June 2017, following which another emergency alert test would occur. The Director of Compliance and Information confirmed there had been a training exercise with all the inspectors. Training for Authority members, regarding the emergency alert system, needed to be conducted.

11.7 The current limitations of O365 were recognised and the Authority needed to be more proactive dealing with members' issues. The Business Continuity Plan would be reviewed.

Action

11.8 The Director of Compliance and Information to report back to the Committee with the results of the next emergency alert test.

11.9 The Director of Compliance and Information to consider the use of personal devices by members and provide guidance at necessary.

12. ALB Risk Interdependencies

12.1 The Head of Planning and Governance spoke to the paper, providing some background on the 2016 internal audit report for the Department of Health (DH) which had identified interdependencies between DH and its ALBs, or between the ALBs themselves, as a potential area of weakness in the system-wide risk management system.

12.2 The Head of Planning and Governance reported on the risk interdependencies workshop, held on 28 February 2017 and attended by various Department of Health staff and risk leads from all other health ALBs. Several common themes become evident from this meeting, including workforce, money and cyber security.

12.3 The Authority's main risk interdependencies are with the Department of Health on items like our legislation, funding, and sometimes policy or media matters.

12.4 The Committee was informed that identified interdependencies had been added to the new risk register for 2017/18.

13. Strategic Risks 2017/18

13.1 The Head of Planning and Governance presented the strategic risks for 2017/18

13.2 The strategic risk register had been refreshed to reflect the new strategy for 2017-2020, and now incorporated a number of core high level risks to the overall delivery of the strategy. These included financial risks, legal challenge and cyber security. A summary of the risks was provided at the top of the document. Risk interdependencies with other ALBs and the Department of Health had also been incorporated. CMG had reviewed the new risk register and made some suggestions for changes.

13.3 The Committee was informed that two risks were currently above tolerance - these were the risks regarding legal challenge and organisational change. It had been identified that cyber security had several potential aspects and had therefore been given its own dedicated entry in the risk register.

13.4 The Committee raised some concern that the risk regarding technical issues with communication systems was evident, believing this issue had already been resolved. This would be investigated after the meeting.

13.5 The Chief Executive provided the Committee with an update concerning the legal cases relating to legal parenthood. A Judicial Review hearing of one of the discrete elements of the IfQ CaFC project was held in December 2016 and January 2017; the Authority won this case. A decision on whether to grant permission to appeal is expected to be heard by the court soon.

13.6 The Committee was also informed of a recent licensing matter, which would go to the independent Appeal Committee shortly. If the earlier decision was endorsed by the Appeal Committee, a Judicial Review could be expected to follow.

13.7 The Committee noted that legal challenges were always time consuming and expensive, therefore constituting a high risk.

14. AGC Forward Plan

14.1 The Head of Finance reported the item on Legal Risks has been moved forward to the 3 October 2017 meeting.

14.2 The Committee noted that the theme for the 3 October 2017 meeting would be strategic and corporate affairs. The Chair requested this meeting to provides a particular focus on risks associated with the new business structure.

14.3 The NAO reported that the Audit Planning Report would be presented at the 3 October 2017 meeting.

Action

14.4 To ensure the theme for the 3 October 2017 meeting provides a focus on risks associated with the new business structure.

15. Whistle Blowing and Fraud

15.1 The Director of Finance and Resources informed the Committee there had been one case of alleged fraud reported by a contract provider. This had been reported to the Department of Health and was currently under investigation by the Anti-Fraud team. It was confirmed that, at present, the HFEA had not suffered any financial losses in relation to this case. The Committee would be updated in due course.

Action

15.2 The Director of Finance and Resources to ensure the Committee remains updated with regards to the outcome of the investigation.

16. Contracts and Procurement

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

17. Any Other Business

17.1 Members and auditors retired for their confidential session.

17.2 The next meeting will be held on Tuesday, 3 October 2017 at 10am

Chair's signature

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

Signature

Name

Anita Bharucha

Date

3 October 2017

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (03/10/2017) 559 MA]**
Meeting Date:	3 October 2017
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:

- 9 items added from June 2017 meeting, 3 ongoing
- 2 items carried over from earlier meetings,1 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 21 March 2017 meeting			
10.9 Head of Business Planning to ensure when the next year's calendar of meetings was planned, that wherever possible AGC consideration precedes the Authority receiving the strategic risk register.	Head of Business Planning	September 2017	**Completed**
Matters Arising from Audit and Governance Committee – actions from 13 June 2017 meeting			
3.6 Staff members to alert Committee members, by means of their private email addresses, when information is sent to their HFEA email accounts, between meetings.	All		**Ongoing**
4.7 The Head of Internal Audit to look at reallocating some of the indicative days from the area of risk management and control to the data loss audit area.	Head of Internal Audit		**Completed -** Agenda item for October 2017 meeting
6.10 The Director of Finance and Resources to liaise with Committee members and senior management to finalise the accounts.	Director of Finance and Resource		**Completed**

8.11 The Director of Finance and Resources to explore the potential to surplus funds to commission research on the data held by the Authority.	Director of Finance and Resources		**Ongoing** - An update will be provided at the October 2017 meeting
9.8 The Director of Compliance and Information to distribute information concerning the outcome of the recent GDS assessment to the Committee. A further update on IfQ will be provided at the next meeting.	Director of Compliance and Information		**Completed -** Agenda item for October 2017 meeting
11.8 The Director of Compliance and Information to report back to the Committee with the results of the next emergency alert test.	Director of Compliance and Information		**Completed -** Agenda item for October 2017 meeting
11.9 The Director of Compliance and Information to consider the use of personal devices by members and provide guidance at necessary.	Director of Compliance and Information		**Completed -** Agenda item for October 2017 meeting
14.4 To ensure the theme for the 3 October 2017 meeting provides a focus on risks associated with the new business structure.	Head of Finance		**Completed** - Agenda item for October 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 October 2017 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	5		
Paper number	AGC (03/10/2017) 561		
Meeting date	3 October 2017		
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	Good progress is been made against the agreed plan. The Final Report for the Data Loss review was issued on the 25th October, with the review awarded a Moderate rating. Fieldwork has also commenced on the Risk Management review, with a draft report expected early October. A meeting to discuss the scope of all remaining audits on the plan will take place on 28th September, with Terms of Reference to be issued shortly afterwards.		
Actions from previous meeting	1) The number of days allocated to the Risk Management audit have been reduced to 7, with 3 days added to the Data Loss audit; 2) We will be looking to develop a three year Internal Audit plan for HFEA for 2018/19 onwards.		
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 Data Loss review, which has been given a MODERATE assurance rating.		

Annex A

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY INTERNAL AUDIT PLAN 2017/18

Audit Ref No	Audit Title	Audit Review Detail	Directorate/Grouping	Current Status (25/9/17)	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	Fieldwork	Q2	7	Fieldwork is nearing completion with a draft report expected in early October.
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	Not started	Q3	10	Audit to be aligned with HTA audit – early October start Scoping meeting with Richard Sydee on 28th September

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	Not started	Q3/Q4	10	Audit to be aligned with HTA audit – early October start Scoping meeting with Richard Sydee on 28th September
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	Not started	Q3/Q4	5	Scope of this work to be discussed with Richard Sydee on 28th September

Annex B

Health Group Internal Audit

Reference number: DHX 217 008 002
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
SEPTEMBER 2017

Report Name:
Data Loss

Overall report rating: MODERATE

Health Group Internal Audit part of 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:
Cameron Robson - 01132 54 6083
1N16 Quarry House, Quarry Hill,
Leeds, LS2 7UE

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Date fieldwork completed:	10/08/2017
1st draft report issued:	15/09/2017
Management responses received:	25/09/2017
2nd draft report issued:	N/A
Management responses received:	N/A
Final report issued	25/09/2017

Report Author: Kashem Ali
Version №: Final

Distribution List – Draft Report

Main recipient(s)

Nick Jones	Director of Compliance and Information

cc:

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

Distribution List – Final Report

As for draft report and:

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

EXECUTIVE SUMMARY

1. Introduction

1.1. The Human Fertilisation & Embryology Authority (HFEA) is the regulator of fertility treatment and human embryo research in the UK. The role of the organisation includes licensing 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.

1.2. Due to the sensitive and confidential nature of the data, it is critical that HFEA operates a robust data recording process, ensuring that for each activity, accurate and timely data is recorded and submitted. The HFEA Register is a large database which holds all the data in one place. Like all large data bases, there are risks associated with maintaining and updating the database.

1.3. HFEA have also established The Information for Quality (IfQ) programme to transform the way data is collected, stored and published.

1.4. During the audit fieldwork we were informed that the programme has closed following:

- The redevelopment of the HFEA website and the Choose a Fertility Clinic search tool;
- The redevelopment of Clinic Portal.

1.5. A new project has been started to deliver the development of an improved system for collecting and reviewing data.

1.6. This review forms part of the HFEA annual audit plan for 2017/2018. In line with the agreed scope, we considered whether:

- A robust approach has been taken to ensure that the high level governance arrangements for the IfQ project are in place, and that all products developed have been subject to expert advice and security testing;
- HFEA have detailed data protection policies, effective guidance, clear reporting processes and robust management checks in place;
- Staff have undergone compulsory annual security training, and that home working arrangements for register team members have been appropriately risk assessed;
- Business Continuity Plans are in place, comprehensive and tested regularly;
- HFEA resource management policies, staff training and contingency arrangements are embedded and reviewed regularly; and
- The controls and processes in place for the data transfer from clinics to HFEA, and how the data register is updated, accessed and reported.

2. Review Conclusion

2.1. The rating for the report is **MODERATE** – some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control. Section Three below provides an overview of the positive assurances we identified as well as areas where we believe improvements can be made.

3. Summary of Findings

3.1. A Chief Information Office role has been created. This will provide HFEA with enhanced strategic stewardship in developing effective strategies and strengthening existing management controls.

3.2. There is a nominated Senior Manager in place with responsibility for day to day information and data management, this provides accountability and facilitates focus on data loss risks and management assurance.

EXECUTIVE SUMMARY

3.3. The newly formed Senior Inspector role should again strengthen oversight of the clinics. We believe that this role should explicitly include oversight over the clinics' information governance and data loss arrangements. This is crucial as it will help clarify HFEA management expectations on the controls registered clinics need to establish over data loss risks and help HFEA discharge its regulatory role. Currently there is limited HFEA management assurance on the governance arrangements clinics have in place to mitigate data loss risks.

3.4. In discussion with HFEA management, we were informed that the IfQ Programme is now closed and this encompassed the delivery of the new website and clinic portal. We have not reviewed the detailed security testing aspects of the new website and clinic portal as a review of the Digital Projects Programme Board minutes demonstrates that the testing had already identified a number of issues. Furthermore, actions and owners had been identified to address these issues and periodic updates were being provided to the programme board on the progress prior to handover as business as usual.

3.5. One of the IfQ programme products was to replace the Register and implement an improved system for collecting and reviewing clinics' data. A separate programme is now underway to complete this requirement - we understand that the details of the programme are yet to be confirmed but in discussion with HFEA management we understand that testing of the security of the system will be built in the process

3.6. There are key detailed polices and processes for both internal staff and registered clinics on how data should be captured and transferred. However, we identified that some of these documents were not up to date or reviewed on a regular basis.

3.7. 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 accopmany one visti per year.

3.8. However, 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.

3.9. 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.

3.10. 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 resulting in staff handling data incorrectly potentially leading to loss of data;

3.11. The table below summaries the number of recommendations by rating and review area:

	Total Recs	High	Medium	Low
Clinic governance oversight	1	-	1	-
Policy Review	1	-	1	-
Staff Training	1	-	1	-
Business Continuity Testing	1	-	1	-
Overall	4	-	4	-

1.1

4. Next Steps

EXECUTIVE SUMMARY

4.1. To support the provision of a meaningful report to the Audit and Governance Committee you are now required to:

- consider the recommendations made in Section 2; and
- complete section 5 (Recommendations Table: Agreed Action Plan) detailing what action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date.

4.2. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendation have been implemented effectively. Management should implement the agreed recommendations before or by the agreed due dates and:

- advise HGIAS that the actions have been completed; and
- provide relevant evidence to demonstrate how the recommendations have been implemented effectively.

4.3. If HGIAS does not receive a response from management by or before the agreed due dates, HGIAS will then follow up all high and medium rated recommendations with the action owner on the relevant due date (as specified in the agreed action plan). This is to verify that the recommendation have been implemented effectively.

4.4. In the absence of a response to our follow up, the outstanding recommendations will be escalated to the relevant Director General and routinely reported to the Audit Committee.

4.5. If management do not accept any of the recommendations made then a clear reason should be provided in the action plan.

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

5.Recommendations Table

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place

№	RATING	RECOMMENDATIONS	MANAGEMENT RESPONSE	AGREED ACTION PLAN: OWNER & PLANNED IMPLEMENTATION DATE	*EXPECTED EVIDENCE TO DEMONSTRATE RECOMMENDATION IMPLEMENTATION
1.	M	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.	Owner: Chris Hall, Senior Inspector (Information) Inspection regime to be updated to reflect requirements within the new Senior Inspector (Information) post – April 2018	Updated Senior Inspector role document.
2.	M	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	Owner: Dan Howard, CIO 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	Updated information policies as outlined in Detailed Finding 2
3.	M	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	All staff – December 2017. The framework for mandatory training (in all areas including information training requires refresh). In any event whilst many staff	An audit trail demonstrating management oversight of mandatory information management learning and development,

RECOMMENDATIONS TABLE

№	RATING	RECOMMENDATIONS	MANAGEMENT RESPONSE	AGREED ACTION PLAN: OWNER & PLANNED IMPLEMENTATION DATE	*EXPECTED EVIDENCE TO DEMONSTRATE RECOMMENDATION IMPLEMENTATION
			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)	have undertaken training within 12 months we will use Oct-Dec period to ensure all staff have completed, with sign off from Managers.	
4.	M	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 tabletop 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.	Owner: Dan Howard, CIO BCP summary test findings report submitted to AGC in October 17. BCP approved by CMG in November 17	Evidence that the BCP is updated and tested regulaly

RECOMMENDATIONS TABLE

1. FINDING/OBSERVATION:

High Level Governance Arrangements: The IfQ Programme has now ceased with the remaining deliverables taken on as a separate project. HFEA have limited management assurance on the clinics governance controls on mitigating data loss.

RISK RATING: MEDIUM

The Information for Quality Programme (IfQ)

To help strengthen and improve data quality and management within HFEA, the IfQ was set up achieve the following:

- The redesign of the website and Choose a Fertility Clinic (CaFC) function;
- The redesign of the 'Clinic portal' (used for interacting with clinics) and combining it with data submission functionality;
- A revised dataset and data dictionary which will be submitted for approval by the Standardisation Committee for Care Information (SCCI);
- A revised Register of treatments, which will include the migration of historical data contained within the existing Register;
- The redesign of HFEA's main internal systems that comprise the Authority's Register and supporting IT processes.

We reviewed the key stakeholders and expert groups consulted on the IfQ programme to ensure that representation was adequate and appropriate. The IfQ Advisory Group comprised of senior stakeholders including expert groups that provided the oversight on subject matter expertise.

We have not reviewed the detailed security testing aspects of the website and clinic portal as a review of the Digital Projects Programme Board minutes demonstrates that the testing had already identified a number of issues. Furthermore, actions and owners had been identified to address these issues and periodic updates were being provided to the programme board on the progress prior to handover as business as usual.

In discussion with HFEA management towards the end of the audit, we were informed that the IfQ Programme is now closed and this encompassed the delivery of the new website and clinic portal. The timeframe for the programme and funding has elapsed for the rest of the deliverables. The Electronic Data Interchange (EDI) replacement system is being taken forward as a separate project and we understand from discussion with HFEA management that new funding has been agreed with the Department of Health (DoH) for this.

Data Governance

The overarching responsibility for HFEA data governance lies with the Director of Compliance and Information. In discussion with HFEA management, we understand that a new Chief Information Officer (CIO) is being recruited. This is a key role ensuring that there is senior leadership and stewardship of information management from a strategic perspective. The findings below are

interrelated and the role of the CIO will be crucial in bringing a strengthened approach to data management.

In addition, during the audit we were informed that a new Senior Inspector (Information) post is being created to strengthen information governance and provide assurance and a challenge function to the clinics regarding information management responsibilities. The purpose of this role is to focus on licensed centres' performance relating to their information responsibilities. The Senior Inspector is yet to be confirmed, but the position will be in place for autumn. This will provide a much needed oversight for the clinics. To further strengthen information governance, we believe that HFEA should ensure that Senior Inspector role explicitly covers the clinics' governance arrangements on how data loss risks are managed.

RISK/IMPLICATION:

Without appropriate management assurances over clinics governance arrangements, there is a risk that clinics may implement ineffective governance arrangements which may result in the materialisation of data loss risk and consequent reputational damage to HFEA.

RECOMMENDATIONS:

1. 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.

2. FINDING/OBSERVATION:
The key policies are in place but they need to be periodically reviewed to ensure that are aligned with processes.

RISK RATING: MEDIUM

There are a number of data/information policies within HFEA. This includes:

- The HFEA's Information Access Policy, with a number of Standing Operation Procedures (SOPs). The policy sets out the general principles that will be adopted by the HFEA in response to any requests for information under any statutory access regimes, with particular reference to recording and monitoring requests for information. The policy is easily accessible via the intranet system (last reviewed 2011).

- Staff Security Procedures - this policy sets out guidelines on acceptable use of IT resources and information security within the HFEA (last reviewed 2015).

- Information Access SOPs - these documents set out how HFEA will ensure effective processing of requests for information, openness and transparency of the HFEA as a public body; consistency of response and process; proper delegation of responsibility to subject

experts; and cultural change in the HFEA's management of enquiries and its fulfilment of its statutory role as an information provider (last reviewed 2012).

These are key Policies and therefore the HFEA management team should ensure that they are reviewed periodically to ensure that the policies and processes are aligned. The issue of updating policies has previously been raised twice in the 16/17 HFEA audit on Request for Information IT and the 14/15 report on FOIs and PQs.

A draft version of updated Information Access policy was provided. Although the policy is currently under review, there is no reference to the new the General Data Protection Regulation (GDPR) which comes into effect in May 2018. The government has confirmed that the UK's decision to leave the EU will not affect the commencement of the GDPR and therefore it is crucial that HFEA are compliant with the updated regulations. There is a 2017/18 internal audit planned on GDPR, and so we will not be raising a recommendation on this issue in this report.

There are a number of general guidance documents available for clinics to adhere to when collecting and recording information. These are easily accessible via the clinics new portal.

RISK/IMPLICATION:
Without periodic review of key polices there is a risk that staff may follow incorrect processes leading to data loss and reputational damage.
RECOMMENDATIONS:
2. Key data and information policies should be reviewed periodically to ensure that they are current and aligned.

3. FINDING/OBSERVATION: **Management do not have assurances in place to confirm that all staff members have completed the mandatory annual information management e-learning module.**
RISK RATING: MEDIUM

Staff Training

HFEA have a Learning and Development policy in place. The aim of this policy is to ensure that all HFEA employees are aware of the procedures for applying for a learning opportunity, to ensure that all CPD requirements are met and that all employees have equal access to learning and development opportunities. This policy places responsibility on the line manager to ensure that their staff members complete the mandatory training. There a number of training requirements that the policy classifies as mandatory, the most significant for this audit is the 'responsible for information' training. In discussion with HFEA management, it is not clear how management have obtained assurance that all HFEA staff completed this important training.

Homeworking

HFEA facilitates homeworking for its staff. Previously a risk assessment form was required to be carried out to ensure that appropriate security protocols were in place for those staff members that handle personal information at home. However, this requirement was superseded by a working at

home policy that was issued in 2011 but not reviewed since. Whilst the details in the policy are adequate, the policy should be reviewed to ensure that it is current and aligns to best practice and that the line manager and staff agree working at home protocols. A recommendation covering review of key polices has been covered in the above section.

Clinics' Training

In addition, it is not clear on what training clinic staff have available to them in respect of information management. From discussions with management, we understand that each clinic will have autonomy to set standards that comply with the general requirements stipulated by the Information Commissioners Office (ICO). However, given that the HFEA is UK Government's independent regulator overseeing fertility treatment and research, we think that it is important that HFEA has a level of oversight/assurance on clinics' training programmes regarding information handling. A recommendation covering assurance over clinics' information management training has been covered in the above section.

RISK/IMPLICATION:

Without assurance that staff members have undertaken the appropriate information training, there is a risk that staff may handle data incorrectly leading to the loss of data and resulting in reputational damage.

RECOMMENDATIONS:

3. 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.

4. FINDING/OBSERVATION:
The Business Continuity Plan needs to be updated to reflect the changes in the organisation and tested to ensure that it is fit for purpose.

RISK RATING: MEDIUM

Business Continuity Planning (BCP)

The Director of Finance & Resources is responsible for ensuring business continuity arrangements are in place. The BCP states HFEA has made a business impact assessment and that no areas of operation would be critical for at least seven days. After that time, it may be critical to issue licences or special directions, or suspend a licence. In addition, at certain times, some activities would be judged critical, such as confirming payroll or attending to legal issues.

This document is owned by the Head of IT, who is responsible for reviewing this plan on a regular basis, ensuring that the document is kept up to date, that up to date copies of the document are held by key staff and that the plan is tested. However, we noted that the Head of IT has left the organisation and this has not been updated on the plan.

A review of management minutes demonstrates that the BCP was tested as regards staff communication protocols. This was carried out in 2016. A BCP test has not been conducted to gauge the effectiveness of the actual BCP. HFEA should undertake, at minimum, a desktop

exercise periodically to identify any issues with the current BCP arrangements and implement any lessons learnt. In discussion with management regarding the BCP arrangement that clinics have in place, it was established that currently there is no BCP oversight from HFEA over the clinics. The new Senior Inspector role provides an opportunity for HFEA to build in some management assurance over clinic BCP arrangements.
RISK/IMPLICATION:
Without appropriate BCP testing there is a risk that the BCP may not be fit for purpose and delay the recovery of key processes resulting in reputational damage.
RECOMMENDATIONS:
4. 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.

5. FINDING/OBSERVATION: **There is no specific resource management policy, but it is a standing discussion topic in the senior management team meeting.**
RISK RATING: LOW
There is no specific resource management policy, as a small organisation the Corporate Management Group (comprising SMT and Heads) is responsible for oversight of the workforce and resourcing. There is a standing item 'resources and prioritisation' which ensures that every area of the organisation can be involved in that discussion and/or raise issues. The resources and prioritisation' minutes demonstrate discussion regarding ongoing vacancies, HR frameworks, PDPs, capacity of teams. A learning and development policy has been developed and is available on the intranet - the aim of the policy is to ensure that all HFEA employees are aware of the procedures for applying for a learning opportunity, to ensure that all CPD requirements are met and that all employees have equal access to learning and development opportunities. No concerns were raised in the Corporate Management Group minutes we reviewed relating to the resourcing of information governance.

6. FINDING/OBSERVATION: **Data is submitted via a portal that is only accessible by licensed clinics through standard templates; a new project is underway to replace the register that holds clinical data.**
RISK RATING: LOW
Licensed fertility clinics submit information about each cycle of treatment they carry out, such as patient and donor details, the treatment provided and its outcome. This information is held on a database called the Register. The requirement to keep a Register of Treatments stems from the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). The Register is an extremely valuable asset to HFEA and its stakeholders. It is used to: • Securely hold information about donors and their donations;

- ensure traceability of gametes and embryos;
- provide patient information on success rates;
- monitor clinic performance; and
- facilitate research into the safety of treatments.

The Register is held on a spreadsheet on an internal server and is known as the EDI. One of the IfQ programme products was to replace the EDI and implement an improved system for collecting and reviewing data, as discussed earlier in the report. A separate programme is now underway to complete this requirement, we understand that the details of the programme are yet to be confirmed but in discussion with HFEA management we understand that testing of the security of the system will be built in the process. The Register Information Manager, she has confirmed that access to the register is restricted. It is limited to her team, one IT lead, Director Of Compliance & Information and the Interim Head of Information.

The HFEA website contains a clinic portal to which clinics submit their information. Clinics are expected to manage their own access control and data management from their side. Data is sent by clinics via the portal into the EDI system. There are number of set forms available on the HFEA intranet with associate guidance on what forms to use for specific actions.

Annual audits are undertaken at clinics by the inspectorate team as part of the licence renewal inspection with the NAO accompanying one audit per year. 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. Inspection reports are prepared by the inspection team and are publicly available on the HFEA website. In discussion with HFEA management we understand that informal feedback is directly provided to the person responsible at the centre. We were unable to obtain the NAO report for 2016/17, however in the published HFEA Audit and Governance Committee meeting, the NAO reported that the interim audit at the HFEA had just been completed and that there were no significant issues identified. The NAO would be visiting a clinic based in Cambridge in April 17 as this is part of the external audit process.

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.

RECOMMENDATIONS TABLE

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.

Data submission project: (formerly IfQ)

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and		
Agenda item	7		
Paper number	AGC (03/10/2017) 563 NJ		
Meeting date	03 October 2017		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note: • Good progress on the new data submission system • Slower than expected progress with data migration • The budget update and spending to date which is in line with plans • Key risks and issues		
Resource implications	The budget for data submission work has been established at £350,000		
Implementation date	During 2017–18 business year		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes:	None		

1. Background

1.1. The Information for Quality Programme has now closed, following the launch of the new HFEA website in June 2017 – having successfully met all Government Digital Standards. With the Clinic Portal (launched in February 2017), our digital communications channels are now established and working well (always a few teething issues) and we are now evolving the way we work – the next step to realising the benefits of the investment – to maximise their impact.

1.2. We will bring forward 'an end of programme lessons learned' report at the December 2017 meeting of the Audit and Governance Committee. Many of the lessons are being incorporated in real time in this, final, leg.

1.3. The remaining work to complete is on the data submission project. This work towards completion of the data submission system and associated infrastructure will continue as a defined project, with progress reported to Authority and scrutiny at AGC.

1.4. By way of background, the project encompasses:

- A revised dataset and data dictionary which will be submitted for approval by the Data Coordination Board (DCB) - part of NHS Digital. This is to ensure data collection arrangements that affect NHS organisations are applied consistently and are not burdensome.
- A revised Register of treatments, which will include the migration of historical data contained within the existing Register

  The redesign of the system that many clinics use to record and submit treatment data to the HFEA enhancing the experience and speeding it up; and enabling clinics using their own (or third party) patient record systems to plug-in, or link, to the HFEA Register.

1.5. This paper updates Members on:

- Work in progress
- Programme budget
- Risks and issues

2. Work in progress

2.1. The Authority meeting in September 2017 referenced forthcoming user testing. This was to test the experience, navigation between screens, design, and fit with clinic business processes.

2.2. Testing took place on 21/22 September 2017 with representatives from six clinics. The response was overwhelmingly positive – more so than for any user-testing carried out to date. Clinic staff were very excited by the developments and enthusiastic for us to move to implementation without delay. This is very encouraging and work to complete the

system for the next round of using testing is likely to be completed within two fortnight sprints.

2.3. Work has also now been completed on the technical environment by which third party suppliers (this includes clinic groups that have designed their own patient record system – most clinics) can interact with the new system. In short, those systems need to be able to send to us the data, and in the format we specify, and we need those systems to be able to receive information back from us as to the accuracy or otherwise of those transmissions.

2.4. We have been greatly aided in this aspect of the work by support and advice provided by colleagues in HMRC, used to dealing with many hundreds of such suppliers. This has been invaluable in providing pointers and lessons learned from their experiences and also confirming the approach adopted by our team is a robust one. This is important given that most treatments are now reported to us via third party systems.

2.5. These are important milestones, as clinics will see the very real improvements to the system and they will be reassured that the (promised) benefits to them are now in sight – rather than a slightly theoretical promise that things will be better.

2.6. With the completion of the majority of development effort and the task then becomes one of implementation, and roll-out.

Data migration

2.7. As we have reported previously, that implementation and roll out is dependent on a key factor. Until the migration of existing Register data to the new Register design is completed we are unable to move to launch. Moreover, until we have greater certainty as to the completion of this important work we are wary of committing to a schedule for the launch of the new data submission system.

2.8. We have adopted a consistently cautious and careful approach to the migration task. We had expected to have concluded by now. The work has been slow over the Summer because of organisation change, holiday period, and capacity constraints. That said, we have now completed ‘trial load three’ of five – which will provide us with an important benchmark as to likely completion period. At the time of writing this analysis had not been completed.

2.9. Given the risks to the project – a further oral presentation will be given at the meeting setting out the main issues and considerations for us – including the extent to which applying additional, or bringing forward, resources may have utility.

3. Data submission/Data migration budget

3.1. The budget for completion of the data submission project has been established at £350,000 for the 17/18 financial year.

3.2. The budget is in line with capital expenditure expectations - such expenditure is on investment, or development, of the IT system estate provided by contractors on short-term contracts, and some programme management resource (delivered by internal secondment).

3.3. Overall, the current spend is in line with forecasts.

Budget this F/Y	Planned spend	Actual to date	Variance
350,000	£116,800	£135,800 (Aug 17)	£19,000 Invoices awaited

Forecast

Sept 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Feb 2018	Mar 2018
£166,906	£197,746	£226,38	£269,722	£289,900	-*	-*

*contingency

4. Risks and issues

4.1. Risks are reviewed regularly, with several new risks to the project identified since the last reporting period. The main area of risk relates to staffing, particularly given the departure of colleagues from the organisation further to the organisational change programme.

4.2. The top five risks to the project have been identified as:

- Workload and lack of resources
- Loss of knowledge within the IT team, with knowledge transferred to contractors on a transitional basis
- Data migration supported by only a few people, often diverted to other work
- Reliance on external contractors, which means there is a risk of contractors leaving at short notice

4.3. The principal mitigation activities relate to:

- Retaining our existing external contractors by appropriate scrutiny, support and documenting procedures and processes
- The recruiting of additional (short-term) expertise to provide extra capacity during the period of organisational change
- Institute new ways of working, better balancing business as usual and project priorities
- The new posts of Chief Information Officer and Head of Intelligence have now started providing capacity and capability

5. Recommendation

Audit and Governance Committee is asked to note:

- Good progress on the new data submission system
- Slower than expected progress with data migration; and that a presentation will be made at the meeting to bring members up to date
- The budget update and spending to date which is in line with plans
- Key risks and issues

Business Continuity, Resilience and Cyber Security

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	8		
Paper number	AGC (03/10/2017) 564 DH		
Meeting date	03 October 2017		
Author	Dan Howard, Chief Information Officer		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to Note: • Progress and headline results relating to the Business Continuity Test undertaken in September 2017 • Details of the BCP 'tabletop' test due to take place shortly • The 'Impact on Members section' regarding BCP awareness • Details of the Office 365 security safeguards which are in place • Headline information from the Cyber Security component of the IT work programme		
Resource implications	None		
Implementation date	During 2017–18 business year		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes:	None		

1. Background

1.1. This paper provides an update on our arrangements for business continuity, for preparing and managing our activity in the event of loss of staff, information technology support, or office accommodation. This paper provides details of improvements that have recently been made along with the results of associated testing.

1.2. This paper also provides an update on resilience and cyber security and contains an update on key aspects of the associated work programme. This will be continually developed and reviewed to address actual and perceived threats associated to our data, infrastructure and technology landscape.

2. Introduction

2.1. In June 2017, AGC received an update on Business Continuity Planning. The update included details of future arrangements including a communications exercise, configuration of our BCP 'landing page' within O365 Sharepoint, a refresh of contact information and the integration of Members within our BCP arrangements. This work is now nearing completion and this paper provides a further update on progress.

2.2. We are developing our work programme. This programme will include elements relating to cyber security. Further details will be available as the programme is confirmed.

3. Business Continuity Testing

3.1. Following the BCP update reported to AGC in June 2017, several improvements have been made. These include:

- **Communication:** User guidance for accessing our BCP site within Sharepoint was revised and forwarded to all staff. Staff were given instructions for accessing via different device types. Staff were encouraged to test out access and feedback was invited. Support was made available to anyone who did not feel confident accessing the site;
- **BCP 'landing page':** Minor amendments were made to the structure and content of the page. To encourage all activity to remain on the BCP page, the link to Yammer (Collaboration social network tool) was also removed;
- **Contact information:** As part of the BCP awareness campaign, staff were encouraged to update their contact details – namely the mobile telephone number to be used in the event of the BCP being invoked; and,
- **Integration of Members in Business Continuity Planning:** Rather than require an immediate response from Authority Members as part of the main BCP test, it was agreed that the focus would be on awareness and testing access to the BCP site by Members. This work is ongoing and is expected to be concluded ahead of the meeting.

3.2. During the week commencing 18th September 2017, we tested our Business Continuity Plan. Staff were informed that a BCP test was likely to take place but not given details of timescales.

- The test involved sending a text message to the mobile telephone number on record and requesting they a) access our BCP site and b) to follow further instructions on arrival.
- A test message was sent out at 7.07pm on Wednesday 20 September. The first message notified staff that the test was taking place and contained details of the BCP site weblink. A second message contained further information on the format of username to use.
- The test was largely successful. Around 60% of staff accessed the site within the first four hours and added a comment to the comments section. This rose to around 90% of staff accessing the page during the following working day. Staff on leave or otherwise absent from work are excluded from these totals. It should be recognised that this was a test and evidence suggests access rates in a real BCP situation are typically higher. Staff who did not access within the timeframe above were contacted to provide support to ensure they are able to access the site if required in the future.

3.3. The BCP test above can only test one scenario and so to further strengthen our controls, we will be undertaking a 'tabletop' BCP test on 27 September 2017. This will involve simulating several scenarios. Participants will have no knowledge of details ahead of the session. An oral update on results and lessons learned will be provided to the Committee.

4. Cyber Security

4.1. Our cyber security controls (such as technology, processes and practices – for example firewalls, access controls and user access) remain under review and improvements will be made as necessary to address actual or perceived risk.

4.2. Our work programme includes associated awareness training for staff and our target is all staff will have completed necessary training within the previous 12 months by the end of the 2017 calendar year. Our work programme includes a strand to move our remaining data and infrastructure into the Microsoft cloud.

5. Impact on Members

5.1. We recognise that our BCP testing must include Members' readiness. Following the all-staff test we now plan to invite feedback from Authority Members. Guidance will be forwarded during the week commencing 25 September requesting the BCP site is accessed and an oral update will be provided to the Committee.

5.2. Assurance has been sought on the security safeguards in place within Office 365. As standard, these include built in anti-virus and anti-spam. They also include protection from incoming threats e.g. viruses from machines used to connect to the Office 365 environment when it is accessed through the Office 365 website.

5.3. There are significant additional controls in place which include physical (access to datacentres such as personnel), logical (processes used to minimise risks to data, such as anticipating malicious access) and security (such as the technical encryption of all data while in use). For further assurance Microsoft comply with the ISO 27018 Code of Practice for Protecting for Protecting Personal Data in the Cloud. They were the first Cloud provider to do so.

5.4. To follow good practice, Authority Members are reminded that they should install anti-virus software on personal devices and ensure it remains up to date.

6. Risks and issues

6.1. While the access rate following the BCP site was encouraging, feedback suggested that access from a smartphone was difficult as the page was not easy to navigate. To address these concerns, we have updated the page layout to make it easier to use.

7. Recommendation

The Committee is asked to note:

- Progress and headline results relating to the Business Continuity Test undertaken in September 2017
- Details of the BCP 'tabletop' test due to take place shortly
- BCP awareness within the Impact on Members section within this paper
- Details of the Office 365 security safeguards which are in place
- Headline information from the Cyber Security component of the IT work programme

Strategic risks

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 (03/10/2017) 565 HC]		
Meeting date	3 October 2017		
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. The Authority will receive the risk register at its meeting on 15 November.

1.2. CMG reviewed the risk register at its meeting on 6 September. CMG reviewed all risks, controls and scores.

1.3. 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.

1.4. Two of the seven risks are currently above tolerance.

2. Recommendation

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

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	**12 – High**	Above tolerance	-⇧⇔⇔
FV1: Financial viability	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	-⇔⇔

* 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:

- Old risk register 2014-2017: CMG 8 February
- New risk register 2017-2020: CMG 17 May 2017⇨ AGC 7 June ⇨ CMG 6 September
- (Some risks are new or recent, as at May 2017, and therefore do not yet show four trend points.)

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

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

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
At tolerance. Post Q1's detailed finance review, we are forecasting a surplus in our income over expenditure. Monitoring of our treatment fee income has seen an increase in receipts when compared to the same period in 17/18. Work on 'drivers' of treatment fee income will commence at the end of Q2.

Causes / sources	Mitigations	Timescale / owner
Our annual income can vary significantly as: - Our income is linked directly to level of treatment activity in licensed establishments - Forecasting treatment numbers is complex - We rely on our data submission system to notify us of billable cycles.	Activity levels are tracked and significant changes are discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Richard Sydee
	Fees Group enables dialogue with sector about appropriate fee levels.	Ongoing – Richard Sydee
	We have sufficient reserves to function normally for a period if there was a steep drop-off in activity, or clinics were not able to submit data and could not be invoiced. If this happened, resolving it would be high priority, and the roll-out of the new data submission system will be planned carefully.	In place – Richard Sydee/Nick Jones
	Worked planned in 2017/18 to better understand the likely future trends in treatment cycle activity.	Planned, will begin in Q2 – 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.	Quarterly meetings (on-going) – Morounke Akingbola

Project scope creep.	Senior Finance staff present at Programme Board. Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
DH: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Morounke Akingbola
DH: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Accountability quarterly meetings (on-going) – Richard Sydee
	Annual budget agreed with DH Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December annually – Richard Sydee
	Detailed budgets for 2017/18 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – 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. We are currently in a period of turnover and internal churn, with some knowledge gaps, and IfQ related work ongoing until September. Turnover is also variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.

Causes / sources	Mitigations	Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Staff have access to Civil Service Learning (CSL); expectation is five working days per year of learning and development for each member of staff. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Rachel Hopkins/Peter Thompson
	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Peter Thompson
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers through team and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Implementation of staff survey outcomes, followed up after December 2016 staff conference (follow-up staff conference held on 10 July 2017). Task and	Survey and staff conferences

	Finish Groups submitted ideas for improvements, which are being included in the people strategy for 2017-2020.	done – Rachel Hopkins Follow-up plan and communications in place – Peter Thompson
Particular staff changes could lead to specific knowledge loss and low performance.	CMG and managers prioritise work appropriately when workload peaks arise.	In place – Peter Thompson
	Policies and processes to treat staff fairly and consistently, particularly in scenarios where people are or could be 'at risk'.	In place – Peter Thompson
Insufficient Register team resource to deal properly with OTR enquiries.	The team is now at full capacity (headcount) and this risk is reducing over time as the new member of staff gets up to speed.	In place – Nick Jones
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.	In place – Paula Robinson
	Oversight of projects by both Programme Board and CMG, 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.	Partially in place – agile approach to be brought into project processes under new project governance framework – Paula Robinson
	Early emphasis on team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends (Autumn 2017) – Paula Robinson
Possible future increase in capacity and capability needed	Starting to be considered now, but will not be known for sure until later, so no controls can yet be put in	Issue for further

to process mitochondrial donation applications.	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). One Licence Committee variation agreed, with first Statutory Approvals Committee decision at August 2017 meeting.	consideration – Juliet Tizzard
Technical issues with our communications systems since our office move in 2016. This leads to poor service (missed calls, poor quality Skype meetings), reputational impacts, additional costs (meetings having to be held externally), and potentially to complaints.	IT team working to identify and resolve the issues, with staff encouraged to continue to send support tickets. External expert commissioned to assist and the system has subsequently displayed improvements. Continued use of external venues with appropriate facilities. A project is underway to implement a new switchboard, this will be in place from September 2017 and may prevent some of the Skype issues. The Director cannot be assured that the mitigations in place have been comprehensively effective. The newly appointed CIO will give this day to day attention and will therefore be proactively managing this risk ongoing, from September 2017.	In progress – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
Government/DH: 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	**4**	**3**	**12 - High**
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	-⇧⇔⇔ (Added in February 2017)

Commentary
Above tolerance. Organisational change programme nearing conclusion. With new staff arriving, we can expect this risk to diminish as they become more familiar with the organisation.

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 – Rachel Hopkins
	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 – Rachel Hopkins
	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 will continue, including summer awayday (took place 10 July), to support new ways of working development	In place for 2017 – Rachel Hopkins
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 being set aside by managers to discuss the changes with staff as needed, with messaging about change repeated via different channels to ensure that communications are 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, with some implementation ongoing – 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.	To be implemented – 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.	To be implemented – Peter Thompson
	Continuing programme of leadership development for Heads and SMT.	Being planned – Rachel Hopkins
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.	Being planned – to occur beginning of 2018/19 business year – Peter Thompson
Risk interdependencies (ALBs / DH)	**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	-⇔⇔ (added in April 2017)

Commentary
At tolerance. The cyber-security event earlier in 2017, affecting the NHS and other organisations demonstrates that there is no room for complacency. However recent 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 regular information on cyber-security and associated internal audit reports. Internal audit report (2017) gave a 'moderate' rating, and recommendations are being actioned. Detailed information on our security arrangements is available in other documents. A business continuity plan is in place.	In place - Nick Jones/Dan Howard
Recent system infrastructure changes open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is now more digital than ever before, and patient data or clinic information could therefore be exposed to attack.	All key IfQ products were subject to external expert advice and penetration testing, with recommendations implemented.	In place - Nick Jones/Dan Howard
	A security consultant provided advice throughout IfQ. At the end of the programme, we have received documented assurance of security and the steps necessary to maintain that security at a high level. Penetration testing for the portal and website (completed and passed). Ongoing security advice is in place for the development of the new data submission systems.	In place – Dan Howard

We could become more dependent on external advice and support, with the risk that we cannot identify or fix problems quickly.	Budget available to commission external support when needed.	In place – Nick Jones
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. We know we need to refresh this obligation. Secure working arrangements for Register team, including when working at home.	In place, but corporate oversight of completion of security training is needed, this is being reviewed – Peter Thompson
Loss of Register or other data by staff or through lack of encryption.	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards. CIO will review these arrangements and can do so alongside a review of the arrangements for implementing the new GDPR requirements.	In place – Dan Howard
Register or other data (electronic or paper) becomes corrupted or lost.	Back-ups and warehouse in place to ensure data cannot be lost. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. As above, this needs refreshing.	In place but needs review – Nick Jones/ Dan Howard
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation prior to the move to the Cloud, with security and reliability factors considered.	In place – Dan Howard
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place – Nick Jones
Business continuity issue (whether caused by cyber-attack 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 needs to be prioritised (September 2017). Thereafter, we need to test the full plan. New technology options need to be further explored, to enable us to restore critical on premise systems into a cloud environment if our premises become unavailable for a period. Records management systems to be reviewed in 2017/18. During an outage, staff cannot access TRIM, our current records management system.	In place and ongoing – Nick Jones Update done Dave Moysen (former Head of IT) – September 2016

	As above, we need to consider this in relation to GDPR project.	
Poor records management or failure of the document management system.	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2018/19, following planned organisational changes and the conclusion of IfQ.	To follow in 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 – Nick Jones
Risk interdependencies (ALBs / DH)	**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. The judgment on consent to legal parenthood in 2015 and subsequent cases have administrative and policy consequences for the HFEA, and potentially reputational consequences too if we are criticised in judgments. Further cases were heard in May and July 2017 one judgment has been handed down but others are outstanding. The stream of cases is slowing down and the number of upcoming cases has reduced. We were in court on 18 July 2017 and faced further criticism in relation to guidance on one discrete issue. We await the written judgment but this may be somewhat critical of how the HFEA chose to address this discrete issue as far as clinics are concerned. 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. A decision by the Court of Appeal on whether permission to appeal will be granted is still awaited. This is entirely in the hands of the Court as far as timescales go. A licensing matter is currently being challenged and will be considered by the Appeal Committee in October. This matter is also subject to a judicial review in tandem with the appeal. Once a decision is made, it's possible that the judicial review which is currently stayed will be revived (depending on the outcome of the Appeal).

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation, leading to a need for court decisions.	Panel of legal advisors at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson
	Evidence-based and transparent policy-making and horizon scanning processes.	In place – Hannah Verdin
	Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson

Decisions or our decision-making processes may be contested. Policy changes may also be used as a basis for challenge (Licensing appeals and/or JRs). Note: New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against licensing decisions.	Panel of legal advisors in place, as above.	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 2015).	In place, further work underway on licensing SOPs – Paula Robinson
	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer
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 – Juliet Tizzard
Subjectivity of judgments means we often cannot know which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining.	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 work should this become necessary.	In place – Peter Thompson
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs being improved and updated, committee decision trees in place.	In progress and in place – Paula Robinson
HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound, or generate additional regulatory	Licensing SOPs being improved and updated, committee decision trees in place.	In progress and in place – Paula Robinson
	Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones /

sanctions activity (eg, legal parenthood consent).		Sharon Fensome-Rimmer
	Seeking robust assurance from the sector regarding parenthood consent issues, and detailed plan to address identified cases and anomalies.	In progress and ongoing – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
DH: 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 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 DH would be involved in resolving it.	In place – Peter Thompson
DH: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**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	-⇔⇔ (added in May 2017)

Commentary
At tolerance. Resource strains, reflected elsewhere in this risk register, have at times affected our ability to progress the data submission project and migration activities.

Causes / sources	Mitigations	Timescale / owner
IfQ has taken longer than planned, and there will be some ongoing development work needed.	The data submission project is well planned and under way after initial delays. Data cleansing is being done to improve the quality of the data in the Register. The new Register has been designed to be easier to extract data from for analytical purposes.	Completion of data submission project anticipated by end 2017 – Nick Jones
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – 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.	In place – Nick Jones

Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery. Though there has been a reduction in desktop support, there are mitigations in place to ensure day to day support, however, we are running a risk due to lack of resilience.	In place – Dan Howard
The new Intelligence team is critical to the new model, and needs to draft an information strategy before it will be possible to use the data for regulatory and other purposes.	Head recruited and due to start in September. The development of the team, and the information strategy, will follow. An Information Strategy will be produced by the new Intelligence team, to ensure that data analysis and associated internal mechanisms are in place.	In place – Juliet Tizzard To be developed – Caylin Joski-Jethi
Benefits of IfQ not maximised and internalised into ways of working.	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. The data submission project has been delayed but is now making good progress. Inevitably, this will impact the timeframe of benefit realisation delivery on a range of fronts.	In place (from June 2015) – Nick Jones
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. Gaps in business support, however, soon at full complement. Recruitment process underway for final additions to inspection team. 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.	Organisational re-shaping in progress, to set the right staffing structure and capabilities in place to ensure we can realise IfQ's benefits. This includes the establishment of an Intelligence team.	New organisational model in place – Peter Thompson
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new register structure until their software has been updated.	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the EDI replacement (Data submission project). Mitigation plans for this risk have been agreed as part of planning.	Mitigation in place - Nick Jones

Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer
Data accuracy in Register submissions.	Data migration efforts are being privileged over data quality currently (Aug 2017) this is an accepted risk. The Register team has introduced a triage system to deal with clinic queries systematically. Completion of verification processes, steps in the OTR process, regular audit alongside inspections.	In place – Nick Jones
	Audit programme to check information provision and accuracy.	In place – Nick Jones
	There are data accuracy requirements for different fields as part of migration planning, and will put in place more efficient processes.	In place – Nick Jones
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we 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
	Data verification work (February 2017) in preparation for Register migration has improved overall data accuracy, and the exercise included tailored support for individual clinics that were struggling.	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 and the flexibility to push PQ deadlines if necessary. FOI requests are refused when there are grounds for this. PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place – Juliet Tizzard / Caylin Joski-Jethi
Insufficient understanding of our data and/or of the topic or question, leading to misinterpretation or error.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / 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.	Communications strategy in place, including more patient feedback. Part of the information strategy will focus 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 and to be developed – Juliet Tizzard

Risk interdependencies (ALBs / DH)	Control arrangements	Owner
None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance, so we miss opportunities to bring about positive change.

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	Juliet Tizzard 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.	-⇔⇔ (added May 2017)

Commentary
At tolerance.

Causes / sources	Mitigations	Timescale / owner
Our ability to provide patient information via the website or CaFC could be compromised by a website failure.	We have good cyber-security measures to prevent website attacks, and the new content management system is more reliable than the old one.	In place – Juliet Tizzard
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 – Juliet Tizzard
Our information does not meet the needs or expectations of our audience.	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 – Juliet Tizzard
We are not able to reach the right people with the right message at the right time.	Partnering with NHS Choices to get information to patients early in their fertility journey. Planning for campaigns and projects includes consideration of communications channels.	In place and developing – Jo Triggs

	Extended use of social media to get to the right audiences.	
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
Risk interdependencies (ALBs / DH)	**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

AGC – June 2017 meeting

AGC welcomed the new presentation of the risk register, and noted the contents.

The Committee raised some concern that the risk regarding technical issues with communication systems was still listed, believing this issue had been resolved. We agreed this would be investigated after the meeting.

CMG – September 2017 meeting

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

- CMG discussed the Capability risk (C1) in detail and acknowledged that the main source of risk relating to knowledge and capability is the current period of turnover. The organisational change programme has had an impact on the Compliance and Information directorate in particular and on top of this, non-organisational change related turnover is affecting teams across the organisation. CMG acknowledged that knowledge and capacity gaps because of turnover were not straightforward to deal with. If internal promotion and maternity leave are included, one third of staff have spent less than 12 months in their current posts. CMG acknowledged the need to manage the bedding in of new staff effectively and agreed to look at how to manage this to mitigate the risk, including staff development and induction. CMG agreed that in the light of the changes to this risk and the period of organisational change and bedding in, the inherent rating for C1 had risen. The residual risk was also raised to a high score of 16 which is above tolerance.
- CMG discussed the organisational change risk and acknowledged that though it relates to the capability risk, the organisational change was planned for so it was integrally less risky. Members discussed when the review of the new organisational model would be done and agreed that this should be towards the beginning of the 2018/19 business year, when the effectiveness of the model could be properly assessed. An Authority paper will be required, probably to the May Authority.
- CMG discussed the cyber security risk and acknowledged the need to provide further assurance about the effectiveness of the business continuity plan. A further test is needed and this will be done in September. CMG also acknowledged that following the departure of the Head of IT, the responsibility for ensuring staff have undertaken mandatory information security training will lie with line managers, to ensure through the PDP process that all staff complete this training annually on Civil Service Learning.
- CMG agreed to amend the wording of the regulatory effectiveness (RE1) and effective communications (ME1) risks so that they better capture that they are opportunity risks.
- CMG acknowledged the concerns of AGC at its last meeting in relation to ongoing technical issues affecting communications. CMG noted that this was continuing to be investigated and external committee meetings will not be returned in house until all technical issues have been satisfactorily resolved. CMG acknowledged that issues relating to Skype will be managed day to day by the newly appointed Chief Information Officer. A review of the switchboard system (in progress) should also have a positive effect on telephone issues.

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:

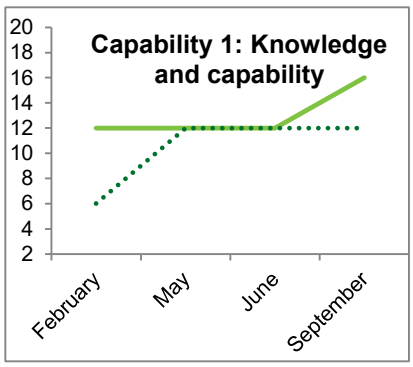
Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

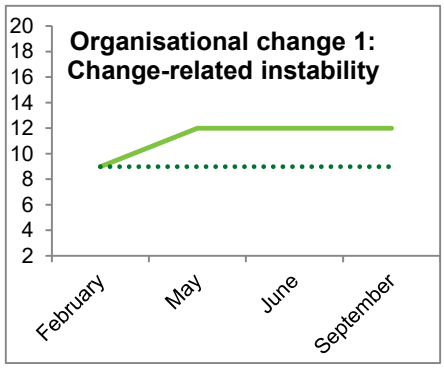
Risk scoring matrix

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				

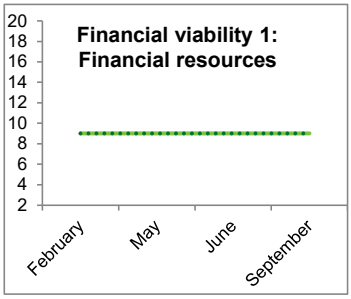
Tolerance vs Residual Risk:

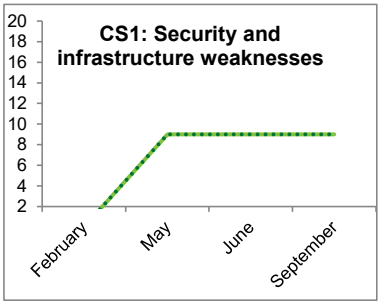
High and above tolerance risks

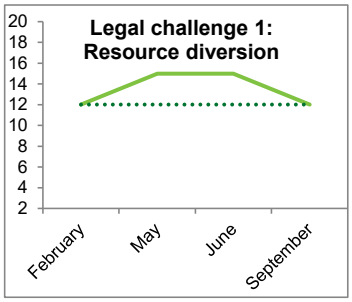


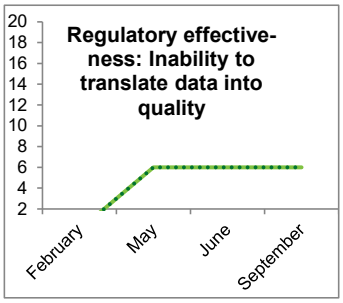


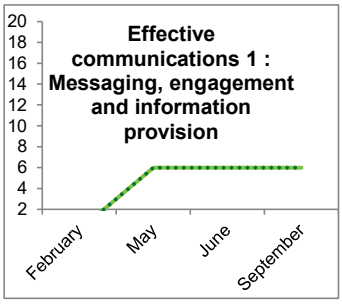
Lower level / in tolerance risks











Reserves Policy

Introduction

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

Principles

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

Reserves Policy

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

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

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

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

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

Cashflow

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

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

Contingency

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

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

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

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

    a. salaries (including employer on-costs);

    b. the cost of accommodation.; and,

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

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

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

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

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

Minimum reserves

13. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£520k), provides £860k for contingency. The minimum level of cash reserves required is therefore £1.4m. These reserves will be in a readily realisable form at all times.

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

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

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

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

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

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

Version/revision control

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

Audit and Governance Committee Forward Plan

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	15		
Paper number	AGC (03/10/2017) 568		
Meeting date	3 October 2017		
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:	21 Mar 2017	13 Jun 2017	3 Oct 2017	5 Dec 2017
Following Authority Date:	10 May 2017	28 Jun 2017	15 Nov 2017	Jan 2018
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:	21 Mar 2017	13 Jun 2017	3 Oct 2017	5 Dec 2017
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
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				