Audit & Governance Committee meeting - agenda

16 March 2016

etc.venues, Tenter House, 45 Moorfields, London EC2Y 9AE

Agenda item		Time
1.	Welcome, apologies and declaration of interests	10:00am
2.	Minutes of 9 December 2015 **[AGC (16/03/2016) 486]**	
3.	Matters Arising **[AGC (16/03/2016) 487 SG]**	
4.	Finance and Resources – Risks (Presentation)	
5.	Information for Quality (IfQ) Programme – Managing Risks **[AGC (16/03/2016) 488 NJ]**	
6.	Strategic Risks **[AGC (16/03/2016) 489 PR]**	
7.	Legal risks (Oral)	
8.	Internal Audit a) 2015/16 Plan and progress report **[AGC (16/03/2016) 490 DH Internal Audit]** b) Assurance mapping report – capacity and resilience **[AGC (16/03/2016) 491 DH Internal Audit]**	
9.	External Audit - Interim feedback (Oral)	
10.	Implementation of Recommendations – Progress Report **[AGC (16/03/2016) 492 WEC]**	

11.	AGC training programme (Oral)	
12.	AGC Forward Plan **[AGC (16/03/2016) 493 SG]**	
13.	Any other business	
14.	Close (Refreshments & Lunch provided)	1:00pm
15.	Session for members and auditors only	1:00pm
16.	Next Meeting 10am Wednesday, 15 June 2016, London	

Minutes of Audit and Governance Committee meeting 9 December 2015

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 (16/03/2016) 486		
Meeting date	9 December 2015		
Author	Dee Knoyle, 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 on 9 December 2015 held at etc.venues, Tenter House, 45 Moorfields, London EC2Y 9AE

Members present	Rebekah Dundas (Chair) Anita Bharucha Gill Laver Jerry Page
Apologies	Margaret Gilmore
External advisers	Internal Audit James Hennessey, Price Waterhouse Coopers (PWC) (item 7 only) National Audit Office (NAO) Sarah Edwards
Observers	Kim Hayes (Department of Health) Ted Webb (Department of Health)
Staff in attendance	Peter Thompson, Chief Executive Sue Gallone, Director of Finance & Resources Morounke Akingbola, Head of Finance Wilhelmina Crown, Finance & Accounting Manager Nick Jones, Director of Compliance & Information Paula Robinson, Head of Business Planning Siobhain Kelly, Authority & Committee Business Manager Catherine Drennan, Head of Legal Dee Knoyle, Committee Secretary

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting. The Chair announced that this was Anita Bharucha's first meeting as an Audit and Governance Committee member and that Anita brings a wealth of experience to the committee. The Chair also welcomed Ted Webb from the Department of Health who attends the HFEA Authority meetings regularly.

1.2 There were apologies from Margaret Gilmore.

1.3 There were no declarations of interest.

2. Minutes of the meeting held on 10 June 2015

2.1 The minutes of the meeting held on 7 October 2015 were agreed as a true record of the meeting and approved for signature by the Chair.

3. Matters arising

3.1 The committee noted the good progress on actions from previous meetings.

3.2 Action 9.6 - The Information Governance Group has made little progress due to other work priorities. Policies have been updated but need refining, communicating and embedding into the organisation better. Although progress is slow, the risks are low and staff are aware of how to handle and protect sensitive data. Management controls are also in place.

4. Register & Compliance Risks

4.1 The committee received a presentation from the Director of Compliance & Information.

4.2 There are three areas of the directorate: Compliance, Information and IT. The committee were reminded of the directorate's risks and opportunities at this point last year.

4.3 Over the last year, resilience has improved and staff are balancing requests for information and work on the Information for Quality (IfQ) programme. There have been some difficult compliance cases and overall the risks are at tolerance although the last quarter has been challenging.

4.4 In the coming year, there will be a focus in inspections on patient experience and the inspection process will be adapted to take account of the increase in groups of clinics. Inspections of one clinic should be able to bring about improvements in the group. Data will be used better to develop the inspectorate's risk based assessment tool. The quality of Register data is being improved before migration into new systems. IfQ will provide better information for centres to improve their performance.

4.5 IfQ delivery provides some challenges, with staff also retaining responsibility for delivering business as usual. There are additional staff on IfQ, including IT experts, working alongside HFEA staff. The directorate is realistic about what can be achieved and prepared to make adjustments where possible and necessary.

4.6 The IT team are also working on the office move and providing staff with new software and hardware by March 2016.

4.7 The committee acknowledged the programme of work ahead and the challenges facing the directorate, working with limited resources to meet the demands and trying to retain the same level of quality. The committee was satisfied that the directorate recognises its pinch points and needs to continue to be prepared to pause or delay work where possible.

4.8 The committee noted the reputational risks of adjusting work and highlighted the importance of managing centres' expectations, guiding them to the new products and the level of support that will be offered.

4.9 The committee encouraged the Executive to make a cultural shift to match delivery on, for example, Freedom of Information requests to the resource available.

5. Information for Quality (IfQ)

5.1 The committee received a progress report and presentation from the Director of Compliance & Information.

5.2 The Alpha stage of the programme was successfully completed which is a significant milestone. Formal Department of Health (DH) approval has been achieved and further approval is required from Government Digital Service (GDS), which may take some time. The IfQ Programme Board has agreed to proceed at risk into the Beta stage to avoid delaying the delivery any further. Due to the time and effort it takes to go through the approvals process more time will be built into future plans.

5.3 A near final version of the website and portal will be available in March 2016 in time for the HFEA conference. Go live to the external audience is likely to take place slightly later. Subject to prompt approval, the planned complete implementation of IfQ by October 2016 is still achievable.

5.4 There is a data migration strategy in place for the HFEA Register data. (The committee heard that the organisation who developed the data migration strategy is no longer in business.) Register data migration is a complex and a well monitored area of risk. The data cleansing exercise is very important and there will be appropriate time to complete this before data is migrated.

5.5 There is a risk with the resilience of the current HFEA website that is being borne until the replacement is in operation.

5.6 The committee noted that the IfQ Programme budget remains consistent with the original business case and expenditure will extend to the next financial year. Approximately £200k of the 2015 funding is likely to be carried forward. Arrangements for the capitalisation of the development will be discussed with NAO.

5.7 The committee acknowledged the risks in a programme of this nature and was of the view that what is being developed will enhance future resilience of the organisation. They urged the Executive to be careful that they do not lose focus on the organisation's role as a regulator when faced with competing demands.

5.8 The committee noted the recommendations from the DH assessment, and that the Executive are considering carefully working with other healthcare professionals such as NHS Choices.

6. Strategic risks

6.1 The committee was provided with a paper and explanation from the Head of Business Planning.

6.2 The committee noted the changes to risk levels and plans for assurance mapping.

6.3 A new risk in relation to the office move has been added. The contract for the new premises has recently been signed and the risks have now reduced.

6.4 The committee was concerned about the organisation losing three senior members of staff within a short space of time, one of whom starts maternity leave. The committee was reassured that the Executive are taking appropriate action to bridge the gap between staff leaving and new people being recruited.

7. Internal Audit

a) 2015/16 Plan and progress report, b) Final Report – Incident handling

c) Final Report – Requests for information

7.1 The Internal Auditor reported progress against the internal audit plan with no high risk findings identified to date. This is a good position so far for the 2015/2016 Head of Internal Audit opinion and the Annual Governance Statement.

7.2 Both high risk findings from the 2014/15 Internal Policies report have now been completed.

7.3 More detailed testing for data migration data is planned at the appropriate time.

7.4 Assurance mapping of capacity and resilience is planned for February and the outcome will be reported to the next committee meeting. The committee was pleased to hear that a proportionate approach is planned and will be interested in the outcome.

7.5 The committee advised that the HFEA should keep up to date and follow the complaints policy – there may have been a tendency to go further. If complainants are not satisfied, they can follow the recourse action set out to them.

7.6 The Incident handling audit included a survey of clinics, through Clinic Focus. The committee noted centres' poor response to the survey which was disappointing. Two respondents indicated that more needs to be done to encourage reporting and the new clinic portal will help.

8. External audit

8.1 The committee was provided with an oral update by the NAO.

8.2 The plan for year end audit was presented at the last meeting. NAO will bear in mind the possible impact of the office move around this time.

8.3 The committee noted that the Audit & Governance Committee meeting scheduled in June 2016 has been moved to 15 June 2016.

9. Implementations of recommendations progress report

9.1 The Finance Manager provided the committee with an update.

9.2 Two recommendations have been absorbed by the IfQ programme. There are currently no recommendations outstanding. The recommendations from the latest internal audit report (Incident handling) will be added next time.

10. Resilience & Business Continuity Management

10.1 The Director of Finance & Resources gave a presentation to the committee.

10.2 There is a Business Continuity Plan and a Pandemic Response Plan in place and named staff have responsibilities. Tests have been carried out on communications channels and evaluated, with some adjustments having been made. Further tests will be carried out before the office move.

10.3 The emergency site has been visited, however this will change in April 2016.

10.4 The office move and changes to IT arrangements will impact on business continuity and the plan will be updated in 2016. The new IT arrangements involve using Office 365 and cloud storage facilities. The risks around the office move are being managed.

10.5 The committee was reassured that the organisation's business continuity arrangements are suitable, including resilience of financial arrangements to make payments in an emergency and offsite servers.

11. Review of Audit & Governance Committee activities and effectiveness

11.1 The Authority and Committee Business Manager provided the committee with the NAO checklist and received views.

11.2 The committee and Executive discussed how information is presented to the committee. While there is candid reporting, it was agreed that the Executive tends to take a positive view and the committee could challenge more.

11.3 The comments and suggestions from the NAO checklist questions will be collated and sent to the committee for comment. Actions will be added to the action log and any suggested changes to the role of the committee will be fed into the annual review of standing orders reported to the Authority in March 2016.

12. Licensing Appeals – an evaluation

12.1 The committee received a paper and briefing from the Chief Executive.

12.2 The process of representations and appeals was described. The statutory scheme is such that no decision can be put into effect until the full two-stage process has been completed, or the clinic has acknowledged and accepted the proposed decision. A judicial review judgment against the HFEA in 2013 reinforced this point. However, in cases that put patient safety at risk, a licence can be suspended. The legislation has a limited range of sanctions and no civil enforcement powers. This means that if the HFEA has serious concerns about the performance of a clinic its only action is the proposed removal or suspension of the licence.

12.3 Representations and appeals review whether the decision was correct. The route for examining any deficiencies in the process used to make a decision would be judicial review. A suggestion to use a DH tribunal instead of the appeal hearing, which would have streamlined the process, was not accepted when the legislation was drawn up.

12.4 Evaluating the operation of representations and appeals has shown that the representations process can be as burdensome as an appeal, with high legal expenses and administrative resources. In view of the similarity of these two procedures, there may be a more proportionate

first step than the current representations process. It was clarified that each side meets their own costs at representations and appeal hearings, unlike court hearings where costs may be awarded.

12.5 The committee agreed that ideally the process should not be the same for representations and appeals, while noting that the primary legislation requires two stages. The committee agreed that the Executive should review the process later in 2016/17 with a view to making it more proportionate. This would include considering how other regulators administer these processes and the external implications of new processes.

Action

12.6 The Executive to add a review of the procedures for representations to the Business Plan for 2016/17 and report back to the Authority with recommendations, in due course.

13. Forward plan

13.1 The committee reviewed the Forward Plan of agenda items for meetings.

13.2 The committee requested more feedback on cultural change and legal risks, to gain assurance that these areas are properly controlled.

Action

13.3 The Director of Finance and Resources to ensure cultural change and legal risks are reported to the committee.

14. Any other business

14.1 The Director of Finance & Resources confirmed the following:

- There were no whistleblowing or suspected fraud incidents reported since the last meeting.
- There were no contracts awarded since the last meeting.

14.2 The Chief Executive announced that the Triennial Review Programme Board will discuss the draft of the report in January 2016. The indications at this stage are that there are no significant changes recommended. The report will be shared with the committee.

14.3 Members and auditors retired for their confidential session.

14.4 The next meeting will be held on Wednesday, 16 March 2016 at 10am.

Action

14.5 The Triennial review report is to be sent to committee members.

15. Chair's signature

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

Signature

Name

Rebekah Dundas

Date

16 March 2016

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (16/03/2016) 487]**
Meeting Date:	16 March 2016
Agenda Item:	**3**
Author:	Sue Gallone
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:

- 3 items added from December 2015 meeting, 1 completed.
- 3 items carried over from earlier meetings, 1 completed.
- 3 items carried over from AGC self–assessment of performance, 0 completed.

Matters Arising from Audit and Governance Committee – actions from 11 June 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
3.2 HFEA to monitor Authority members' completion of online information governance training	Executive Assistant to Chair and Chief Executive	20 September 2014	**Ongoing** – two new members to be asked to complete

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
e) Arrange for external members to attend Authority meeting as observers	Head of Governance & Licensing	September 2015	**Ongoing** – members invited to meetings, suitable dates to be agreed.
f) Arrange for external members to observe an inspection	Head of Governance & Licensing	September 2015	**Ongoing** – Inspectorate's business support team in contact with external members and attempting to find suitable dates.
i) Institute formal annual report to Authority board	Head of Governance & Licensing	July 2015	**Ongoing** – To be introduced for July 2016.

Matters Arising from Audit and Governance Committee – actions from 10 June 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
9.6 Report progress on actions from the information governance group to AGC	Director of Finance and Resources	December 2015 March 2016	**Ongoing**
12.7 Discuss number of AGC meetings at March 2016 meeting	AGC members	March 2016	**Completed** – item 12 of agenda

Matters Arising from Audit and Governance Committee – actions from 9 December 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
12.6 The Executive to add a review of the procedures for representations to the Business Plan for 2016/17 and report back to the Authority with recommendations, in due course.	Head of Business Planning	April 2016	**Ongoing** – added to business plan, work to start in October 2016
13.3 The Director of Finance and Resources to ensure cultural change and legal risks are reported to the committee.	Director of Finance	March 2016	**Completed** – items 4 and 7 of agenda
14.5 The Triennial review report is to be sent to committee members.	Director of Finance	When published	**Ongoing** – Review report not yet published

Information for Quality (IfQ) Programme – Managing Risks

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	5		
Paper number	HFEA (16/03/2016) 488		
Meeting date	16 March 2016		
Author	Nick Jones, Director of Compliance & Information		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note this report		
Resource implications	As outlined		
Implementation date	Ongoing		
Communication(s)	Ongoing		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes	Annex A - Beta plan and IFQ high level delivery plan		

1. Introduction and summary

1.1. The purpose of this report is to provide the Committee with progress on the IfQ programme. The Programme is now currently around the half way point of the Beta phase of release and is building tangible components of the Website and Clinic Portal. In early May, both will be subject to assessment by the Department of Health (DH), and Government Digital Service (GDS), to ensure it meets requisite standards, and before the release of 'Public Beta' stage.

1.2. The programme is on track to showcase the website and clinic portal at the HFEA annual conference on 24 March 2016.

1.3. Annex A sets out the overall timeline for IfQ, together with the more detailed plan for Beta – to July 2016.

2. IfQ projects update

2.1. IfQ website

- Work has continued on the CaFC Search tool. This work has included design work, front end development, API work by the internal systems team and back end development. This has led to the delivery of fully working CaFC search tool albeit with some minor bugs to resolve and some small design enhancements taking place.
- The website content template has also been produced. The design has then been developed enabling the HFEA team to begin inputting new website content to Umbraco – the content management system we have selected.
- The stakeholder group met recently where the CaFC search design and CaFC prototype were shared with the group, which were received positively - and with further feedback being included in the upcoming design work.
- Work has continued on the drafting of new website content this has involved working with internal HFEA teams, sharing with Authority members and with external stakeholders.

2.2. IfQ clinic portal

- Decisions have taken on the content of the inspection, risk & performance pages; security and incentivising good behaviours by clinics by our not being able to access a clinic's pages – to 'help' them out. This enhances overall security;
- Design of front-end, and back-end development has been has been undertaken on the user-management and access control; and on front-end development of Knowledge Base and Licensing & Authorisation pages;

2.3. IfQ internal system

- The 'Internal Systems' team is making good progress through the 'back end' work to support the Website and Clinic Portal Release 1 Beta stage.
- The team has also continued work on cross programme technical dependencies for release 1, with the team on track. Key work completed included data validation work and synchronisation

mechanisms between different components of the internal systems architecture – it integrates well.

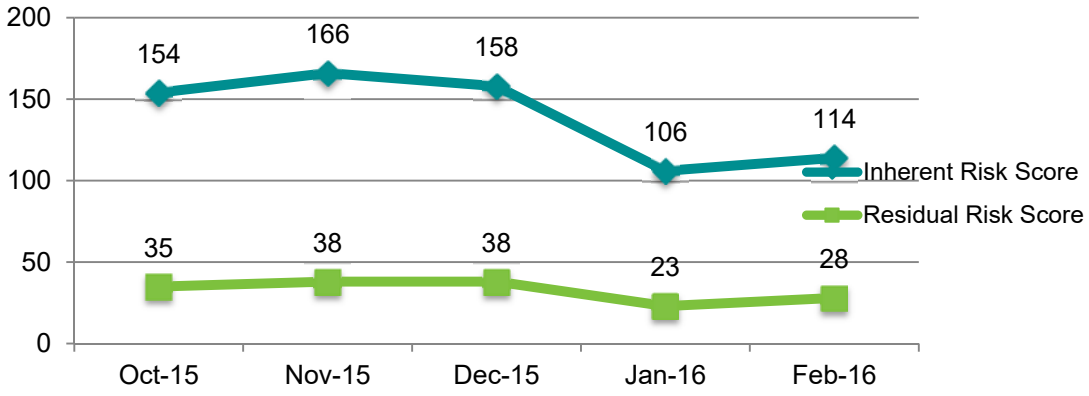
- The team is now turning their attention to understanding the upcoming work to support Release 2 of IfQ (how clinics' submit treatment data to us - and therefore a key component) and gathering the associated requirements for key pieces of the work. Initial conversations are now taking place regarding the way we will keep data secure, and facilitate our new Register and EDI system – and to do so alongside the work completed to date in Release 1.

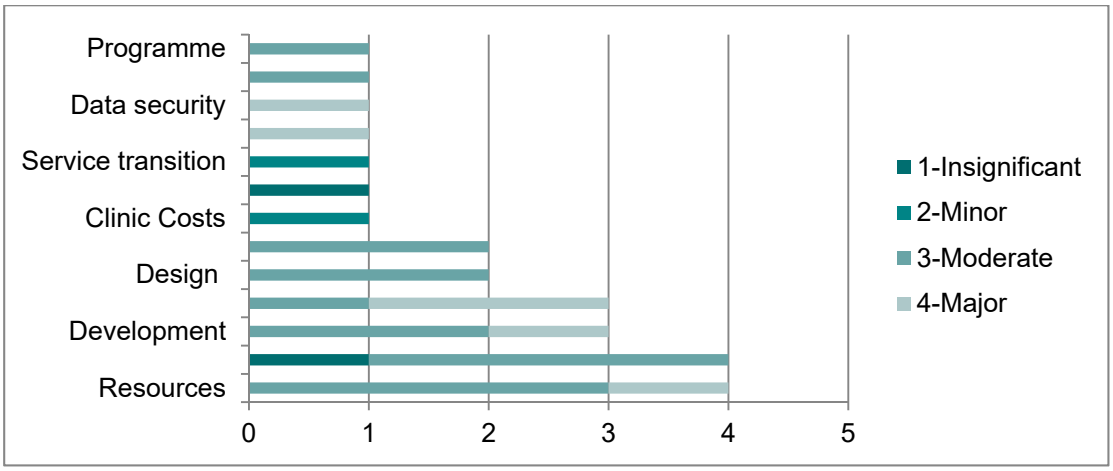
2.4. Data migration

- The team's time has been divided between data migration efforts and cleansing work to support the forthcoming Fertility Trends report – publishing on 24 March 2016 – particularly data regarding egg freezing.
- To meet our commitments to centres we need to review errors before they are returned so that any which we can resolve will not be sent to centres. Our focus is on 'severity one' errors – that is those that unless resolved will prevent data migration.
- We will be using the HFEA conference to highlight clinics' responsibilities here in what is likely to be a burdensome (albeit necessary) task. That said the volume of errors for each clinic to resolve is likely to be manageable.
- We are currently seeking a third party supplier to be in place to provide assurance as regards our data migration strategy commitments, that is to ensure that we have carried out all the necessary 'health check' assessments prior to the migration of existing Register data to the new Register database.

3. IfQ risks and issues

- The below line graph represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month. The overall risk score for the IfQ programme has increased.
- The major risks score are associated with resources, development, timescale, resilience and data security.





- The upcoming DH/GDS approval has also been identified as a major risk for the project. The impact on the timeline could be significant due to the length of the process and the external interdependencies.

4. IfQ budget

4.1. Our forecast at year end has been reviewed. We expect that £945k of our original total budget (£1,135k) will now be spent. There will be some carry-over to 2016/17 which may be in the region of £200k.

4.2. Beta expenditure (only) has been approved as follows:

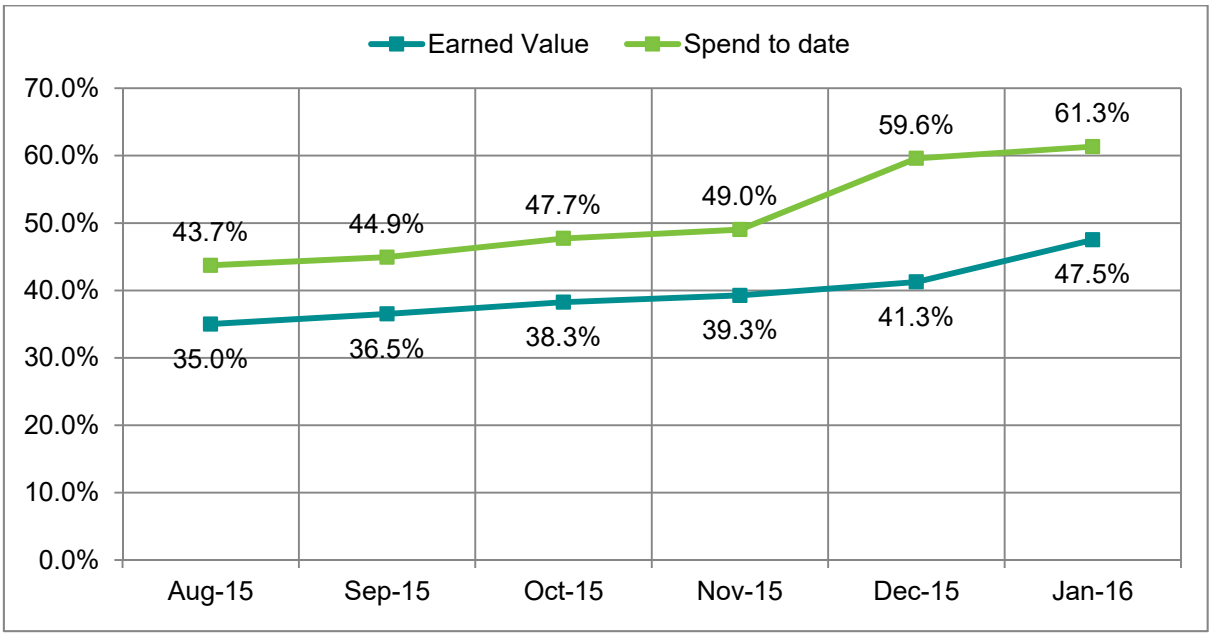
Category of expenditure	Planned at Nov 2015	Recommended for approval	Variance
Reading Room costs	£196,878	£196,878	£0
Internal Systems	£217,627	£321,546	+£103,919
Programme support	£41,376	£42,029	+£653
IfQw Project manager backfill	£3,206	£3,239	+£33
Other	£0	£355	+£355
Total	**£459,087**	**£564,047**	**+£104,960**

- The cost of Beta phase is £104,960 higher than the amount approved by IfQ Programme Board in November 2015, as it accounts for the extension of Beta's end date from end March 2016 to end June 2016. This increase is contained within the overall IfQ budget of £1.134m and does not increase the costs associated with Reading Room's services.
- The Committee is also reminded that one of the consequences of such an extensive programme on a small overall staff group is that a material amount of internal HFEA resources are absorbed within the IfQ programme and not reflected in the overall programme budget – which predominantly relate to suppliers, contractors, programme management (now substantially reduced) and 'backfill' costs.

5. Earned value

- The programme has been in building tangible products and the jump in the earned value reflects this statement. We expect the earn value to continue increasing toward March as we progress through Beta.

Period	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15	Jan-16
Earned Value	35.0%	36.5%	38.3%	39.3%	41.3%	47.5%
Spend to date	43.7%	44.9%	47.7%	49.0%	59.6%	61.3%



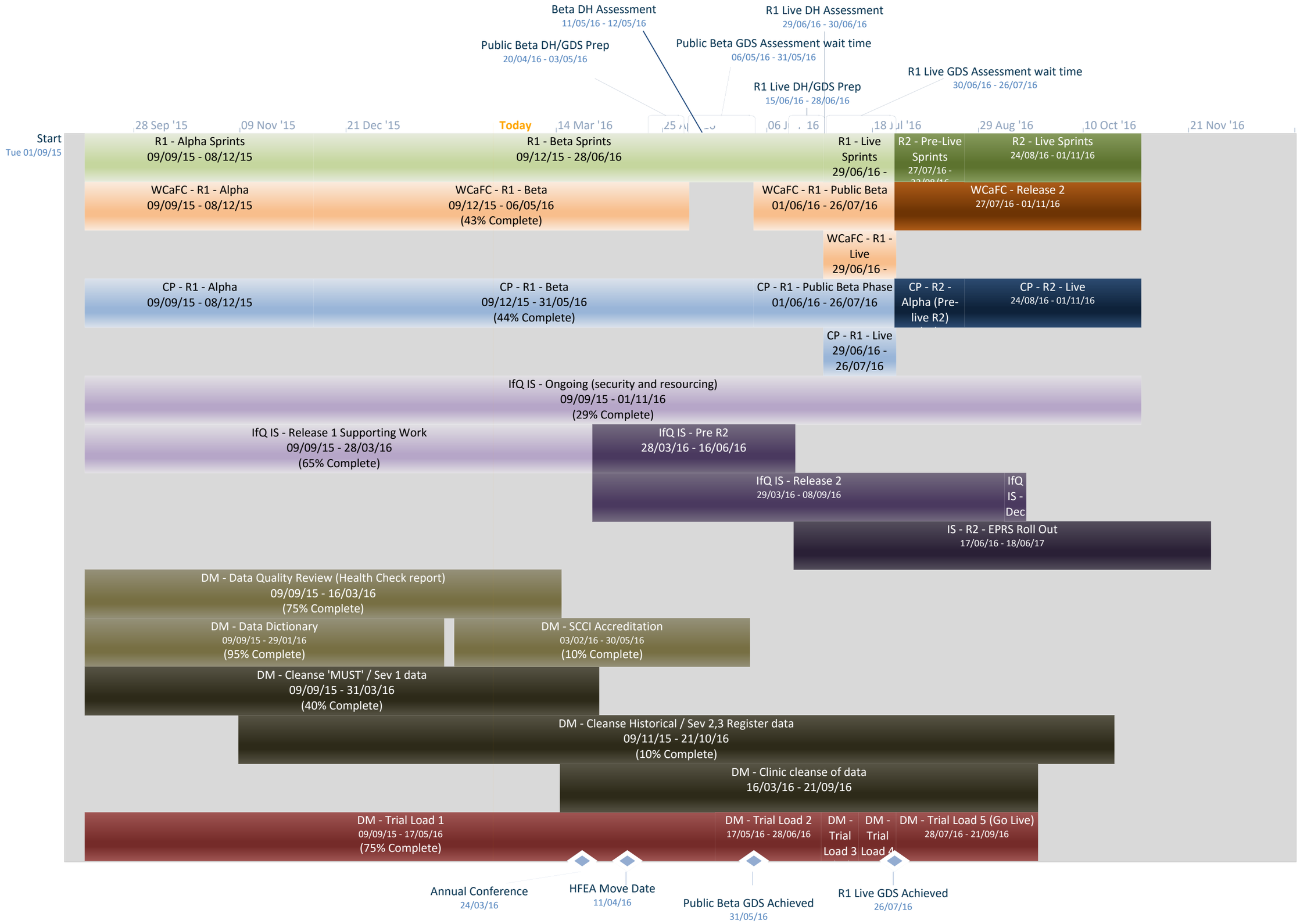
6. Recommendation: The Audit and Governance Committee is asked to:

6.1. Note progress, risks and the budget position on IfQ.

Annex A - **IfQ Beta Schedule at** end Beta Sprint 4 (17/2/16)

	Proposed key dates / deadlines							Ann Conf (24 Mar) **EASTER (25 - 28 Mar)**	**HFEA MOVE (8 April)** CP Private Beta (19 April)	User testing 1st week GDS prep 2nd week	GDS prep in 1st week GDS held (11-12 May)	GDS achieved (31 May)	Website Public Beta (1 June)	GDS Prep	GDS held (29 June)	GDS achieved (26 June)
	Sprint Commence date	09-Dec-15	06-Jan-16	20-Jan-16	03-Feb-16	17-Feb-16	02-Mar-16	16-Mar-16	30-Mar-16	20-Apr-16	04-May-16	18-May-16	01-Jun-16	15-Jun-16	29-Jun-16	13-Jul-16
	Sprint Complete date	22-Dec-15	19-Jan-16	02-Feb-16	16-Feb-16	01-Mar-16	15-Mar-16	29-Mar-16	19-Apr-16	03-May-16	17-May-16	31-May-16	14-Jun-16	28-Jun-16	12-Jul-16	26-Jul-16
	Proposed Sprints by phase	**Beta Sprint 1**	**Beta Sprint 2**	**Beta Sprint 3**	**Beta Sprint 4**	**Beta Sprint 5**	**Beta Sprint 6**	**Beta Sprint 7**	**Beta S8 - Move Sprint**	**Beta S9 - Contingency**	**Beta - S10 DH Approval**	**Beta - S11 - GDS Approval**	**Public beta 1**	**Public beta 2**	**R1 Live S3 - DH Approval**	**R1 Live S4 - GDS Approval**
Clinic Portal Features	CP 1 - Access Control				90%						GDS ASSESSMENT - Pre Private Beta NOTE: up to 4x weeks waiting period for approval	GDS Assessment wait time			GDS ASSESSMENT - Pre Live Review NOTE: up to 4x weeks waiting period for approval	GDS Assessment wait time
	CP 2 - Licensing				40%											
	CP 3a - Reg and Guidance Info				80%											
	CP 3b - Search				5%											
	CP 4 - Clinic Profile				55%											
	CP 5 - Clinical Governance				40%											
	CP 6 - Risk, Performance and Compliance				30%											
	CP 7 - Communcation Exchange				30%											
	CP 8 - Billing				40%											
	CP 9 - Dashboard				40%											
	CP 10 - Annual Returns				25%											
	CP 11 - Help				0%											
	CP 12 - CMS				90%											
	CP XX - User Testing				0%			pre-private beta					post-public beta			
Website Features	W 1 - Content (including video content)				60%						GDS ASSESSMENT - Pre Public Beta NOTE: **up to 4x weeks** waiting period for approval	GDS Assessment wait time			GDS ASSESSMENT - Pre Live Review NOTE: **up to 4x weeks** waiting period for approval	GDS Assessment wait time
	W 2 - Website Templates				40%											
	W 3 - CMS				45%											
	W 4 - CaFC Search				90%											
	W 5 - CaFC Clinic Profile				70%											
	W 6 - CaFC Patient Feeback				50%											
	W 7 - Website Search				0%											
	W 8 - Emotional Content				20%											
	W 9 - Internal Systems Integration				0%											
	W 10 - Website Feeback				0%											
	W 11 - Code of Practice				50%											
	W 12 - Web Forms				0%											
	W 13 - Anom Data				0%											
	W 14 - Register Forms and Info				0%											
	W XX - User Testing				0%			pre-public beta					post-public beta			

Annex A - IfQ Delivery Plan - At end Beta Sprint 4 (17/2/16)



Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	6		
Paper number	AGC (16/03/2016) 489		
Meeting date	16 March 2016		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the annex.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest reviews

1.1. CMG reviewed the risk register on 4 February 2016. CMG discussed all risks, their controls, and scores. Six of the thirteen risks are currently above tolerance.

1.2. The strategic risk register is attached at Annex A, and includes an overview of CMG's general discussions about the risk register. The annex includes the graphical overview of residual risks plotted against risk tolerances.

1.3. The Authority will receive the risk register at its meeting on 9 March 2016, the same day that the papers for this Committee are due to be circulated. Any feedback from the Authority will therefore be reported verbally at the meeting.

2. Risk assurance mapping

2.1. A risk assurance workshop (our first) took place on 10 February 2016. The workshop was run by DH Internal Audit.

2.2. As agreed previously, based on recent analyses of our highest operational risks, the workshop focused on people management and resourcing (capacity, capability, resilience, succession planning, resource prioritisation, etc.). Relevant operational risks carried by teams include turnover and recruitment, the forthcoming office move, general resource and timescale pressures (especially due to the IfQ programme), team interdependencies and particular role-related bottlenecks.

2.3. The workshop approach was well received by staff, and we now have a report for consideration internally, making a number of suggestions for possible additional risk mitigations in this area.

3. Recommendation

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

Annex A

HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage[1]	Residual risk	Current status	Trend*
Office move	OM1: Office move	Efficiency, economy and value	**16 – High**	Above tolerance	⊙⇔⇔
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	**15 – High**	Above tolerance	⇔⇔⇔⇔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	**12 – High**	Above tolerance	⇔⇔⇔⇔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	**12 – High**	Above tolerance	⇔⇔⇔⇧
Data	D2: Incorrect data released	Efficiency, economy and value	**12 – High**	Above tolerance	⇔⇩⇔⇧
Data	D1: Data loss or breach	Efficiency, economy and value	**10 – Medium**	At tolerance	⇔⇔⇔⇔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	**9 – Medium**	At tolerance	⇔⇔⇔⇩
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Capability	C1: Knowledge and capability	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇧⇔⇔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	**4 – Low**	At tolerance	⇔⇔⇔⇔

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

Recent review points are: AGC 7 October ⇨ CMG 18 November ⇨ AGC 9 December ⇨ CMG 4 February.

[1] Strategic objectives 2014-2017:
Setting standards: improving the quality and safety of care through our regulatory activities. (Setting standards – quality and safety)
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)
Increasing and informing choice: using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)
Increasing and informing choice: ensuring that patients have access to high quality meaningful information. (Increasing and informing choice – information)
Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government. (Efficiency, economy and value)

CMG overview – summary from February risk meeting

CMG reviewed the risk register and discussed each risk in detail at its meeting on 4 February.

CMG confirmed that the departure of three Heads (two for new jobs, one on maternity leave) was being managed by Directors covering the roles in the interim while recruitment was completed. Recruitment to the Head of Policy post had successfully taken place internally, so there was no gap between post holders. Recruitment for the other two posts, Head of Corporate Governance and Chief Inspector, was also successful, but there has been an unavoidable gap of several months before the successful candidates could take up their posts, leading to some additional pressures across affected teams.

CMG reviewed the three strategic risks relating to IfQ, in particular to see if their relative scores seemed correct. The discussion identified that IfQ3 (the risk of not achieving planned efficiency savings) was partly subject to the same GDS gateway review requirements as IfQ1 (engagement channels), and that the risk levels of the two risks should therefore be the same. Therefore, CMG raised the risk level of IfQ3 to 12.

CMG updated the legal challenge risk (LC1) to reflect the latest position on active legal cases, but made no change to the score for this risk.

CMG raised the risk level for D2 (release of incorrect data) to 12, to reflect a resurgence in the volume of PQs received after a quieter period. This was potentially compounded by the recent loss of some corporate knowledge, owing to turnover.

CMG also discussed risks relating to the office move, and agreed that further assurance was needed to ensure that all managers had a good grasp of the tasks and timelines. Cultural risks were also recognised, given that the HFEA would be moving into the same space as another organisation. It was agreed that further corporate discussion was needed after the meeting, to ensure that surrounding themes, some of which may be outside the scope of the move project, were picked up effectively (ie, the right channel could be the ways of working group, SMT or CMG, rather than the move project).

CMG also considered operational risks (under a separate report), and noted the need to add floor security to our operational risks. The building was now largely empty, and on a number of recent occasions, workmen had been found in the HFEA's offices before and after normal working hours. It was not always the case that there was a good explanation for this, although at least some of the occurrences had proved to be legitimate. The landlord had already been reminded of their obligation to inform us every time workmen needed to visit the floor. HFEA staff had challenged the individuals each time this had happened, which may itself reduce the incidence. The possibility is also being explored of isolating the floor from external visitors via the door security system.

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
Risks are arranged above 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 arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system
See last page.

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇧ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Nick Jones	At tolerance. The Head of Governance and Licensing and the Chief Inspector have both left the HFEA (in late November and mid January, respectively). Recruitment has taken place, but neither of the new members of staff have started yet. Meanwhile ownership of controls has moved upwards to the relevant Director. The need to manage this gap, together with the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to June 2016.
	Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Juliet Tizzard	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Nick Jones	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Nick Jones	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones	
	Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Nick Jones	
Insufficient inspectors or licensing staff	Inspection team up to complement. The new Chief Inspector is expected to join the HFEA in early May 2016.	In progress – Nick Jones	
	Licensing team up to complement following earlier	In progress – Juliet Tizzard	

	recruitment. The new Head of Corporate Governance is expected to join the HFEA in March 2016.	
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Nick Jones
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Nick Jones
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Nick Jones
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Nick Jones
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Nick Jones
	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 – Nick Jones

	A detailed action plan in response to the legal parenthood judgement is in place. There has been correspondence with clinics, who have completed full audits. PRs are responsible for the robustness of the audit. The HFEA has required that clinics support affected patients – using Barts as a good example. In working with clinics, the HFEA has experienced good cooperation. All clinics engaged and have provided assurances about current practice. Through a detailed review of every clinic's responses, a summary list of all concerns is being produced. Management review meetings are taking place for all clinics at which there are handling concerns or anomalies. Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent. Range of lessons learned identified.	In progress – Nick Jones	On legal parenthood, a strong set of actions is in place and continues to be implemented. As at 20 January 2016, 28 of our 92 clinics had one or more anomaly. < 5 clinics are now subject to ongoing inquiry. Seven cases have been determined in court to date. Nine cases are currently under consideration. There is no certainty about future cases.

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Juliet Tizzard	At tolerance. Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.
	Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Juliet Tizzard	
	Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Juliet Tizzard	
	Staffing structure for sufficient committee support.	In place – Juliet Tizzard	
	Decision trees; legal advisers familiar.	In place – Juliet Tizzard	
	Proactive management of quoracy for meetings.	In place – Juliet Tizzard	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Juliet Tizzard Licensing Officer role – postponed pending recruitment of Head of Corporate Governance Delegations in SOs – April 2016 (tbc)	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones	
	Inspector training, competency-based recruitment, induction process, SOPs, quality management	In place – Nick Jones	

	system (QMS) and quality assurance all robust.	
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Nick Jones
	SOPs and protocols with Communications team.	In place – Nick Jones
	Fairness and transparency in licensing committee information.	In place – Nick Jones
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Nick Jones
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Juliet Tizzard
	Further work planned on records management in parallel with IT strategy.	Linked to IT strategy work – in progress – Jamie Munro/David Moysen
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Nick Jones
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using Red-Dot). This risk is informing our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard
Negative media or criticism from the	HFEA approach is only to go into cases on the basis	In place - Peter Thompson

sector in connection with legally disputed issues or major adverse events at clinics.	of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.		
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Juliet Tizzard	
	Update of compliance and enforcement policy (and application of existing policy meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones	
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones	
	QMS and quality assurance in place in inspection team.	In place – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level: Likelihood: 4 / Impact: 4 / Inherent risk: 16 High **Residual risk level:** Likelihood: **3** / Impact: **4** / Residual risk: **12 High** Tolerance threshold: 8 Medium	⇔ ⇔ ⇔ ⇔	Juliet Tizzard

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme received only partial approval; full delivery still requires additional gateway approvals at this stage (ie, prior to beta). The Department of Health gateway review took place in November and awarded a high score to the HFEA, but we still
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and extensive user research completed as intrinsic part of programme approach. This is being elaborated further during subsequent sprints.	In place and ongoing – Juliet Tizzard	
Stakeholders not on board with the changes.	In-depth stakeholder engagement done, to inform the programme's intended outcomes, products and benefits – including user research consultation, expert groups and Advisory Board.	In place and ongoing – Juliet Tizzard/ Nick Jones	
Cost of delivering better information becomes too prohibitive, either because the work needed is larger than	Costs were taken into account as an important factor in consideration of contract tenders and	In place – Nick Jones	

anticipated, or as a result of the protracted approval periods associated with required DH/GDS gateway reviews.	negotiations. Attempts have been made to discuss the GDS review process and long timelines with those responsible at DH, although so far our approaches have unfortunately not met with success.	Being pursued – Nick Jones	did not receive a formal decision on this by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (now resolved). However, obtaining this approval also meant committing to a number of requirements and conditions which need to be added to the delivery; and a further two approval gateways are still to come. If there are further blockages at those stages (public beta and go-live), this will have more of an impact, since this will mean pausing the work (ie, it will not be possible to proceed at risk at those stages). Therefore, there remains an ongoing risk of negative impact from the lengthy GDS gateway review processes. Owing to the previous delays, it has been necessary to extend the timeline for the beta phase from March to June 2016.
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end June 2016 – Juliet Tizzard	
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. Both GDS approvals sought so far have been granted, albeit with some delays. Additional sprints of work have been incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline has been extended by 3 months to compensate for previous and anticipated future delays.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery.	In place – Juliet Tizzard	

staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Agile project approach includes a 'one team' ethos and required close joint working and communication among all involved contractors during the Sprint Zero start-up phase and beyond. Sound project management practices in place to monitor. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary.		
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS now chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, June 2016 – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place – Nick Jones	
Potential risks associated with the HFEA's office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning. A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.	The HFEA is considering other sources of assurance, and will agree a new plan shortly.	To be resolved by end March – Nick Jones	
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporates consideration of fields and reporting needs are 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.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping being done between IfQ and business as usual.	Done – Nick Jones	
Benefits not maximised and internalised	During IfQ delivery, product owners are in place, as	In place – Nick Jones	

into ways of working.	is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.		
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning. A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇧	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**4**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects.	In place – Nick Jones/Juliet Tizzard	Above tolerance.
Clinics not consulted/involved enough.	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops are planned with the sector regarding how information will be collected through the clinic portal.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones	
Cost of improvements becomes too prohibitive.	Contracts only awarded to bidders who made an affordable proposal.	In place (July 2015) – Nick Jones	

Required GDS gateway approvals are delayed or approval is not given.	Both GDS approvals sought so far have been granted, albeit with some delays. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha phase approval. Additional sprints of work have been incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline has been extended by 3 months to compensate for previous and anticipated future delays.	In place – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place (June 2015) – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning. A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**5**	**15 High**		
			Tolerance threshold:		12 High		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. **Current cases:** One case decided in the HFEA's favour at summary judgment, but has now been appealed (8 February 2016 – outcome not yet known). The 'M' case regarding the export of gametes for treatment abroad has been given permission to go to trial (in April 2016). The judgment in 2015 on consents for parenthood has had administrative and policy consequences for the HFEA. Further court cases are coming to light now, and more are also likely, although the HFEA is unlikely to participate in legal proceedings directly.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Juliet Tizzard	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court. (eg, one current case challenging the long-held policy position on storage regulations may need to be decided by a court).	Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Juliet Tizzard	
Subjectivity of judgments means the	Scenario planning is undertaken at the initiation of	In place – Peter Thompson	

HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	any likely action.		
HFEA could face unexpected high legal costs or damages which it could not fund.	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.	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, committee decision trees in place.	In place – Juliet Tizzard.	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 4 / Impact: 5 / Inherent risk: 20 Very high Residual risk level: Likelihood: **2** / Impact: **5** / Residual risk: **10 Medium** Tolerance threshold: 10 Medium	⇔ ⇔ ⇔ ⇔	Nick Jones

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	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.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	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 (March 2015) – Nick Jones	
Business continuity issue.	BCP in place and staff communication procedure	In place – Sue Gallone	

	tested. A period of embedding the policies is in progress. Awareness of the importance of maintaining business continuity will be built into our office move planning.		
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **4** / Impact: **3** / Residual risk: **12 High** Tolerance threshold: 8 Medium	⇔ ⇩ ⇔ ⇧	Juliet Tizzard

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT Head post in place - SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 (for example) were among the highest we have ever experienced. Volumes decreased in the second half of 2015, but have now increased again.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Juliet Tizzard	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Juliet Tizzard	
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. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones	
	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific	In place - Juliet Tizzard	

	Policy Manager.	
Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Juliet Tizzard / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed – under discussion in February 2016 – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	**4**	**4 Low**		
			Tolerance threshold:		4 Low		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish 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	
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones	
Process error or human error.	As above.	In place – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service pilot established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries. However, there is currently also one member of staff on long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with current team capacity issue under discussion – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the Pilot by Rosetta Wotton.	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇩	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	At tolerance. Previous 2014/15 overspend was able to be met from reserves. 2015/16 on course for small under-spend but risk of legal costs remains. In November 2015, the Authority approved a proposal to increase per-cycle fees by £5 (to £80) and to end the small 'eSET discount' for elective single embryo transfer, which has been in place for a few years to assist with the introduction of the Authority's multiple births policy (now firmly established and in place). This should help secure sufficient funds going forward. Treasury approval for the fee change has since been received.
	Fees Group created enabling dialogue with sector about fee levels. Fee increase agreed (November 2015), approved by Treasury (February 2016), and eSET discount to end.	In place. Fees Group meetings in April and October, ongoing – Sue Gallone	
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.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Detailed budgets for 2016/17 are being prepared for Directorate Review DH has previously agreed our resource envelope.	In place – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	
Upwards scope creep during projects, or emerging during early development of	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with	Ongoing – Wilhelmina Crown	

projects eg, IfQ.	finance.		
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		6 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk. At present we are carrying two Head vacancies pending new starters.
	Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK 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.	The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	

	Staff survey and implementation of outcomes, following up at December 2015 all staff conference.	Survey and staff conference done – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	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
	Early emphasis given to team-level service delivery planning, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning for 2016/17 prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning (2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson
Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	Issue for consideration when applications commence – Juliet Tizzard

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Office move OM 1: Office move	There is a risk that the office move could compromise our capability and capacity to deliver our strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **4** / Impact: **4** / Residual risk: **16 High** Tolerance threshold: 6 Medium	New ⊙⇔⇔	Sue Gallone

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Contractual risks.	Contract signed.	In place (December 2015) - Sue Gallone	Above tolerance.
Preparation and space planning risks, including establishing clarity about the facilities available in the building (eg, lockers).	Project manager in place. Staff engagement group established. Detailed information available about the new office space. Visits started, building relationship with NICE facilities team.	From now until the move – Jamie Munro	
Storage availability will be limited. The HFEA has some unavoidable paper records in Register team, Legal, Finance.	Planning work being done to identify unavoidable paper records, and to determine whether any of these can be scanned to reduce storage needs. Contractor to be hired to take on all the scanning.	Plan agreed in February 2016 – to be implemented in February/March – Jamie Munro	
Potential for culture clash with other organisations that share the same space but have a different culture and their own staff rules.	Project team giving consideration to NICE's staff rules and whether the HFEA wishes to adopt them. Communication with staff about any non-negotiable considerations that may impact on culture. There may need to be some senior level negotiation with NICE about messaging and the HFEA retaining its own culture and rules. We will allow some time after the move for people to adapt to the changed environment, and will then consider whether any changes or further negotiations with NICE (or the British Council) are needed.	Consideration of actions before the move – Jamie Munro Consideration of actions after the move - SMT	

The office will be shared with another organisation, and there will be generally less space, and limited meeting room availability.	The meeting room risk partly applies to smaller meetings such as one to ones. Larger meeting room availability in the building is limited and will be a challenge. Some meeting rooms are being secured in advance from April/May onwards (on a like-for-like basis). Further thought will need to be given to how to secure the rest of the needed meeting space. Staff engagement group to consider cultural and ways of working impact of having less 'free space' in which to have impromptu or small meetings. Trips to the new office will be planned so that staff can see the space. Our IT kit will be replaced with laptops/tablets before the move, so that smaller desks will not be an issue. There will be preparation planned in before the move, to deal with the reality of reduced storage (eg, 'Tidy Fridays' etc. - but staff capacity for this will be very limited owing to IfQ and other high workloads).	From now until the move and slightly beyond – Jamie Munro
The actual move – practical risks.	We will be moving minimal kit and no desks, reducing both risk and cost. Detailed planning and communications will take place with all involved, including contractors, NICE and HFEA staff. Following procurement framework to select contractors, and selecting carefully.	From now until the move – Jamie Munro
Cabling risks – ensuring communications lines are available to HFEA in new office	Establish needs and place orders as necessary.	From now until the move – David Moysen

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IT risks (information security, business continuity, introduction of new equipment and Office 365 upgrade in advance of move).	Office 365 upgrade project in place to include issuing of new laptops. Register safeguards will be put in place; security of new Comms Room will be considered with NICE. Business continuity plan already in place, and arrangements will continue for now – to be reviewed after move. Planned timing of surrounding tasks (eg, IfQ milestone delivery) will need to allow for some down-time. Back-ups will continue and will be stored off site as now.	From now until the move and slightly beyond – David Moysen
People risks: resources to participate in planning, packing etc., turnover and/or extra management work resulting from change of location, engagement on ways of working, willingness to adapt etc.	Staff engagement, communications and HR contractual considerations built into project plan. Staff engagement group being established and first meeting being planned. Staff being issued with new, smarter IT kit, including tablets/laptops replacing PCs, a better access method for secure HFEA login, and Office 365 available.	In place and ongoing – Jo Triggs
Diversion from business. Coincides with the delivery period for some IfQ milestones, which are key to delivering our strategy to publicly announced timescales. Some other work will also coincide because of year-end considerations.	Early awareness of the potential for disruption means that this can be managed through careful planning and prioritisation.	Detailed planning and awareness raising from November 2015 onwards – Paula Robinson (and all managers)
Cost increase compared to current rent	Unavoidable, but in keeping with DH requirements	In place – Sue Gallone

(potentially including additional costs for both internal and external meeting rooms).	which will reduce costs overall for the health ALBs as a whole group. Costs factored into to funding required from 2016/17. Business case includes ensuring the HFEA is in line with Government Estates Strategy.		
Project failure - The move could fail to take place if unforeseen issues arise, or the timetable could be jeopardised by factors outside the HFEA's control.	Contract secured and planning is in place. Should the new building become unavailable for some reason, at any point, (eg, fire, flood), business continuity arrangements would apply while a new plan was put in place. (There is no option to stay on in Finsbury Tower beyond April.)	Detailed risk-based planning in place – Jamie Munro	

Scoring system

The HFEA uses the five-point rating system when assigning a rating to both 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

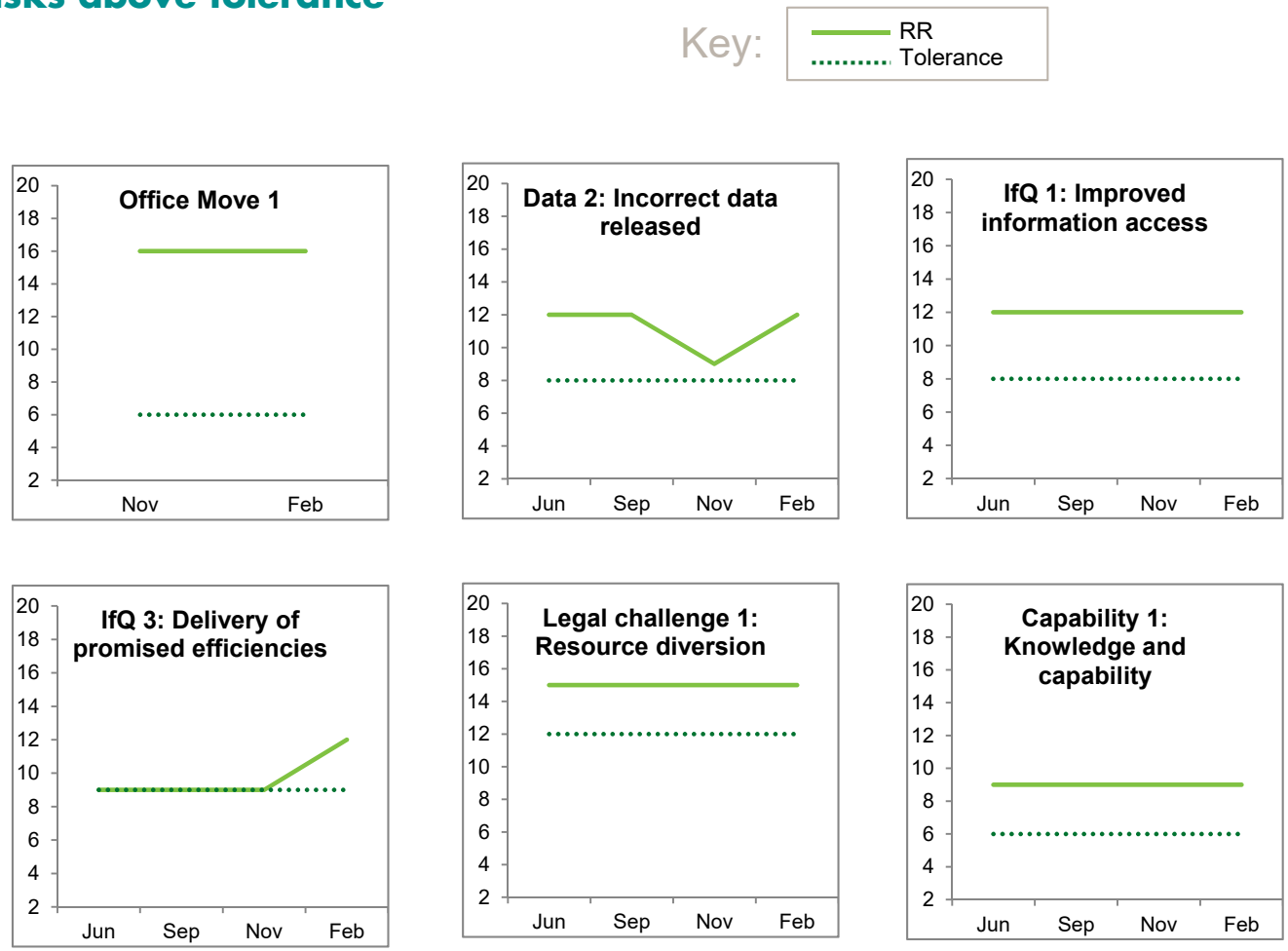
Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low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

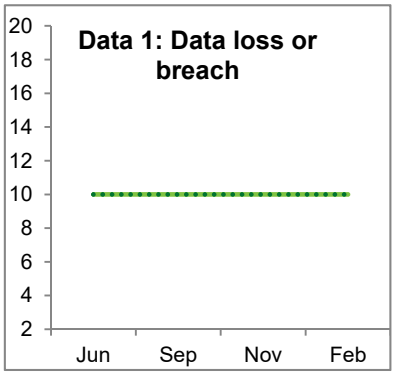
Likelihood

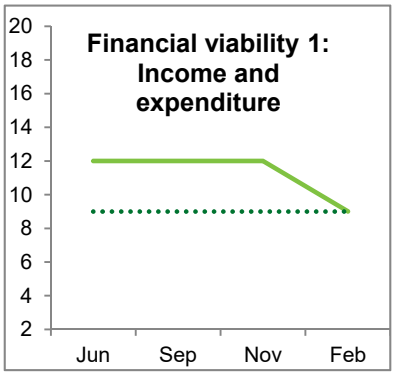
Tolerance vs Residual Risk:

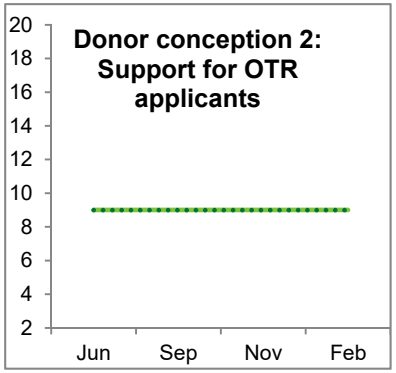
Risks above tolerance

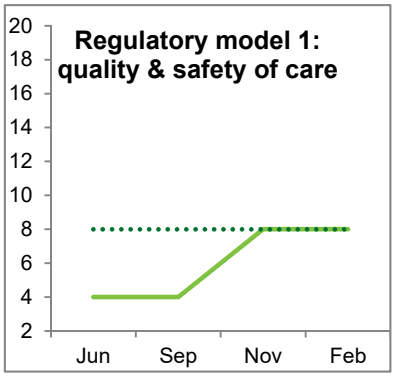


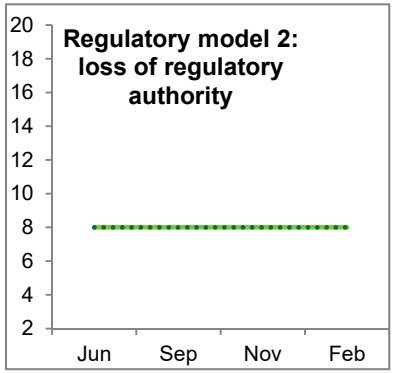
Risks at or below tolerance

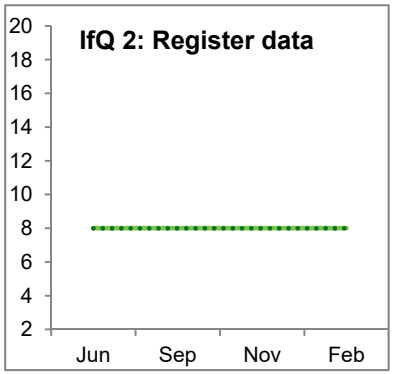


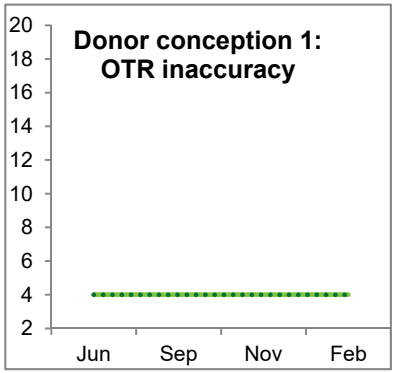












HFEA Internal Audit Progress Report March 2016

1) Purpose of paper

This paper sets out the progress in completing the 2015/16 Internal Audit Plan since the last meeting of the Audit and Governance Committee in December 2015.

2) Progress against 2015/16 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2015/16 Audit Plan:

Reviews per 2015/16 IA plan	Audit scope	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
Requests for Information	The HFEA may be required to release information as a result of: • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. We examined current policies and procedures for the release of information under these circumstances and considered whether: • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and • Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating	Final report issued 26/10/15	0	2	2	**Moderate**	15	10.5	10.5

Reviews per 2015/16 IA plan	Audit scope	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
	controls.								
Incident Handling	It is a requirement of licensed centres to report adverse incidents to the HFEA. Adverse incidents are described as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.' There are circa 500 incidents raised in each year in relation to circa 50,000 activities undertaken by clinics. These incidents must be notified to the HFEA within 24 hours of them taking place. Once these reports are received, the HFEA must investigate the incident and respond in line with its Compliance and Enforcement Policy. In addition, HFEA has a responsibility to review and respond to complaints made about clinics. Circa 10 complaints are received each year. We reviewed current policies and procedures relating to incident and complaints reporting and responses and considered whether: • The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to incident and complaint reports; • Clear and sufficient information is available to all licensed centres to encourage the timely and appropriate reporting of adverse incidents and complaints;	Final report issued 24/11/15	0	0	6	**Moderate**	12	10	10

Reviews per 2015/16 IA plan	Audit scope	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
	• HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.								
Data Migration – Register of Treatments	Building on the 2014/15 'Register of Treatments' review, we are: • Providing 'critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database; and • Testing a sample of data between the old and new Registers to verify the accuracy and completeness of data.	First update memo issued September 2015. Awaiting request for further input.	N/A – No ratings provided			N/A	12	10.5	3
Assurance mapping	The focus of assurance mapping of 'capacity and resilience' was agreed with the Director of Finance and Resources and the Head of Business Planning. The workshop was held on 10 February 2016.	Draft report issued 15 February 2016 for management review and comment.	N/A – No ratings provided			N/A	0	3	3
Audit Management	All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit and Governance committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	Ongoing	N/A – No ratings provided			N/A	8.4 (inc. 2.4 days c/f from 14/15)	8.9	10
		Total Findings:	**0**	**2**	**8**				
						Total days	**47.4**	**42.9**	**36.5**

2.2 Summary of reports issued since the last Audit and Governance Committee:

Since the last Audit and Governance Committee in December 2015 we have issued the draft report on Capacity and Resilience following the assurance mapping workshop. The assurance map will be shared with the Committee once it has been reviewed by, and agreed with, management.

2.3 Follow-up work:

The HFEA performs its own follow-up work, reviewing the status of agreed audit actions prior to each Audit and Governance Committee.

As such, Internal Audit has been asked to provide independent assurance of the completion of agreed actions only over those actions which relate to high priority recommendations. This approach was agreed with the Director of Finance and Resources.

No high priority actions have been agreed as a result of us undertaking the 2015/16 audit plan. The two high priority actions that arose from the 2014/15 Internal Policies review were confirmed as completed in our report to the Committee in December 2015. Accordingly, there are currently no outstanding high priority recommendations requiring internal audit tracking.

2.4 Impact on Annual Governance Statement:

All reports issued with an overall Limited or Unsatisfactory rating or with report findings that are individually rated high importance should be considered for their possible impact on the Authority's Annual Governance Statement (AGS). To date, no Limited reports and no high priority issues have been raised as a result of us completing the work forming part of the 2015/16 audit plan and all actions relating to previous high priority issues have been completed. Accordingly, there are no matters arising from our work that we believe require reference in the AGS.

Internal Audit coverage 2013/14 - 15/16

Review area	High-level scope	2013/14	2014/15	2015/16
Strategy/Compliance				
Francis and McCracken	Robust arrangements are in place to respond to the recommendations of the Francis and McCracken reports.	✓		
Corporate Governance	An assessment of the efficacy of key HFEA committees.	✓		
Risk Management	Review and testing of the arrangements in place for managing risk at all levels across HFEA, including monitoring, filtering and escalation processes.	✓		
Internal Policies	Review of the HFEA's arrangements to monitor, review and refresh key policies, procedures and terms of reference.		✓	
Operational				
Requests for information	Review of policies and procedures in relation to Parliamentary Questions (PQs), Freedom of Information (FOI) requests and Data Protection (DP) requests.			✓
Incident Handling	Review of current policies and procedures relating to incident and complaints reporting and responses.			✓
Financial				
Payroll and expenses	Accuracy and completeness of payroll and expense payments. Compliance with HMRC rules of payments for expenses and emoluments made to committee members.	✓		
Standing Financial Instructions	Assurance over current standing financial instructions, including a comparison of HFEA's existing arrangements versus good/best practice.		✓	
Information Technology				
Information for Quality	Assurance over the IfQ programme using PwC's 'Twelve Elements Top Down Project Assurance Model'.		✓	
Register of Treatments	'Critical friend' input into key project meetings in relation to the migration of data to the new Register of Treatments.		✓	
Data migration – Register of treatments	'Critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database. Testing a sample of data between the old and new registers to verify the accuracy and completeness of data.			✓

Appendix A – Report Rating Definitions

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

Appendix B - Limitations and responsibilities

Internal control

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Future periods

Historic evaluation of effectiveness is not relevant to future periods due to the risk that:

- the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or
- the degree of compliance with policies and procedures may deteriorate.

Responsibilities of management and internal auditors

It is management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management's responsibilities for the design and operation of these systems. We endeavour to plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we shall carry out additional work directed towards identification of consequent fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, do not guarantee that fraud will be detected. Accordingly, our examinations as internal auditors should not be relied upon solely to disclose fraud, defalcations or other irregularities which may exist.

Our work is conducted and our report prepared solely for the benefit of the Department of Health and its arms length bodies and in accordance with defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, our work and reports may not consider issues relevant to such third parties, any use they may choose to make of our reports is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties requiring access to our reports may be required to sign 'hold harmless' letters.

Health Group Internal Audit

External File Note to the Human Fertilisation and Embryology Authority

This document has been prepared solely for the Human Fertilisation and Embryology Authority (HFEA) in accordance with the terms and conditions set out in our engagement letter for internal audit services. We do not accept or assume any liability or duty of care for any other purpose or to any other party. This document should not be disclosed to any third party, quoted or referred to without our prior written consent.

To:	From:
Paula Robinson (Head of Business Planning)	**Karen Finlayson (Head of Internal Audit)**

Date: 12th February 2016

Subject: Assurance Mapping – Capacity and Resilience

Background:

This review was undertaken as part of the 2015/16 Internal Audit Plan which was approved by the HFEA's Audit Committee.

The HFEA management and Audit Committee have requested that we perform an assurance mapping exercise focused on Capacity and Resilience. The terms of reference for this review are set out in **Appendix A**.

We took a workshop-based approach to this review. The key benefit of assurance mapping in the area of 'Capacity and Resilience' is to understand the make-up of the control environment in line with the "Three Lines of Defence" (**see Appendix A**). This allows us to establish if controls in this area are appropriately split between "preventative" and "detective" controls and being able to provide those charged with scrutiny and governance with assurance on the operation of controls identified.

The work was undertaken on 10th February 2016. Detailed in this file note are key observations from our workshop with staff. Contributors to the workshop were as follows:

Peter Thompson (Chief Exec)
Paula Robinson (Head of Business Planning)
Chris Hall (Head of Information team)
David Moysen (Head of IT)
Hannah Verdin (Head of Policy)
Joanne Anton (Head of Policy-in-waiting)
Jo Triggs (Head of Stakeholder Engagement)
Juliet Tizzard (Director of Strategy & Corporate Affairs)
Morounke Akingbola (Finance)

Nick Jones (Director of Compliance & Information)
Rachel Hopkins (Head of HR)
Sue Gallone (Director of Resources, HTA with a shared role with HFEA)

The workshop was facilitated by Stuart Rimmer and Poppy Jones from Internal Audit.

Summary and recommendations

As management consider their responses to our findings and recommendations below it is important that any new controls to be implemented are proportional to the risks they address. As can be seen from the detailed points below there are a number of strong controls within the business to address risks relating to capacity and resilience. However it is also apparent that monitoring and assurance over controls is not formalised in all cases which would enable management to more easily quantitatively assess the capacity and performance of the business and its employees.

Based on the workshop discussions, the assurance mapping process has risk rated 3 out of the 5 general controls/activities as green. The first line of defence – which corresponds to controls and processes undertaken directly by the business – is also robust, as demonstrated by the fact that 56% of controls identified were located in this first line versus 44% and 0% in the second and third lines of defence respectively. We have noted a positive ratio of preventative controls (88%) versus detective (12%) controls currently in place.

Please refer **to Appendix B** for full results.

We have however suggested a number of recommendations, as listed below, to enhance the current control environment in relation to Capacity and Resilience.

Key aspects of the review:

1. Governance

- **Specific measures of staff capacity:** A number of qualitative measures of business activity are reported on a regular basis to senior management. These include progression against the agreed business plan and specific projects, along with the volume of freedom of information and parliamentary questions received (these are particularly time intensive). Management use this information to make judgments on staff resourcing and current capacity within the business.
  Recommendation: Management could develop quantitative metrics of staff performance and capacity in order to have a precise view of business performance. This information could then be used to make more informed management decisions. Indicators could include the amount of overtime worked in a week or the proportion of staff time spent on internal projects compared to normal business delivery.

- **Investigating general and specific performance issues:** Reporting to management is accompanied by explanatory narrative (when required) to articulate the reasons for failing metrics or delayed progress in delivering the plan.
  Recommendation: A specific process for analysing and documenting the root cause of issues could be implemented to provide specific details and greater information on these areas.

- **Quality of reported information:** Reports are collated and shared to senior management on a regular basis, however there has not been a review (in last couple of years) to confirm the accuracy and completeness of underlying data and information.
  Recommendation: Review underlying data used for reporting to consider completeness.
- **Effectiveness of the support of staff:** A suite of supporting processes and groups are in place to assist staff when required. At present there isn't a monitoring process to confirm that support is sufficient and is appropriately managing staff pressures.
  Recommendation: Introduce monitoring to assess whether staff support adequately and promptly provides assistance for employees.

2. Succession and resilience planning

- **Identification of key business roles:** Whilst it is noted that the business is small in size (67 employees), there has not been a recent review to identify business critical roles.
  Recommendation: Undertake a review to identify key roles and business critical activities.

- **Developing staff:** Each team already have an awareness of their colleagues' roles within the business however there has not been a specific focus to develop team capability and manage roles during periods of employee absence.
  Recommendation: Consider holding team events to upskill junior members of staff (may only be appropriate in specific teams in non-specialist areas).

3. Demand management and prioritisation

- **Post-event analysis:** A structure is in place to facilitate assessment of priorities for the business, however at present there is no process to review decisions after an event to learn for future scenarios. There is a lessons learned process in place for both projects and internal incidents.
  Recommendation: Consider introducing a post-event analysis to learn lessons from decisions made.

4. Contingency planning

- **Handover process to new staff:** Informal processes are in place to transition roles and responsibilities to new staff when someone leaves.
  Recommendation: Formalise and document the handover process (where possible) during long recruitment timeframes. It is recognised that there is not always the opportunity to fully transfer business and systems knowledge due to tight timeframes and government mandated recruitment processes (going to the ALB pool first).

Health Group Internal Audit

Further details of our findings can be found in **Appendix B**.

I do hope the above comments are useful and give sufficient information for you to take forward the proposed recommendations but in the interim any queries please do not hesitate to contact me.

Yours sincerely

Karen Finlayson - Head of Internal Audit
Date 12th February 20

Health Group Internal Audit

REFERENCE NUMBER: HFEA215008XX
FINAL TERMS OF REFERENCE
HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY
NOVEMBER 2015

Health Group Internal Audit 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.

Health Group Internal Audit 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.

Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees 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:

Bronwyn Baker

01132 54 5515 – 2W12 Quarry House, Quarry Hill, Leeds, LS2 7UE

ASSURANCE MAPPING –

- **Capacity and resilience**

CONTENTS **PAGE**

Distribution List – Draft Terms of Reference

Paula Robinson

Sue Gallone

Cc:

Lynn Yallop

Distribution List – Final Terms of Reference

Paula Robinson

Sue Gallone

Cc:

Lynn Yallop

1. INTRODUCTION

1.1 This review is being undertaken as part of the 2015/16 Internal Audit Plan which has been approved by the Human Fertilisation and Embryology Authority's (HFEA) Audit and Governance Committee (AGC).

1.2 HFEA management and AGC have requested that we perform an assurance mapping focused on Capacity and Resilience. This will consist of an assurance mapping workshop only, which will be undertaken in February 2016.

1.3 The key benefit to assurance mapping is being able to understand the make-up of the control environment in line with the "three lines of defence*", establishing if the controls are appropriately split between "preventative" and "detective" controls and being able to provide those charged with scrutiny and governance, assurance on the operation of assurance controls identified.

*

- The First line of defence relates to the 'front-line' or business operational areas. This comes direct from those responsible for delivering specific objectives or operation (i.e. direct management); it provides assurance that performance is monitored, risks identified are addressed and objectives are being achieved.
- The Second line of defence is associated with oversight of management activity. It is separate from those responsible for delivery, but not independent of the organisation's management chain.
- The third line of defence relates to independent and more objective assurance, for example the provision of assurance by Internal Audit.

1.4 As part of developing the Terms of Reference, we have consulted with the Head of Business Planning at the HFEA.

2. KEY RISKS, OBJECTIVES AND SCOPE

2.1 Key Risks

Through discussion with management, the following general risks relating to the current lack of assurance mapping were identified:

- Lack of information around the make-up of the control environment in order to make informed risk management/operational decisions, i.e. not identifying that the organisation is over reliant on “detective” controls and controls within the third line of defence.
- Those charged with governance and scrutiny do not have a full understanding of the control environment in order to discharge their responsibilities, effectively and efficiently.
- Divisional managers may not have full oversight of the controls operating/controls gaps within their remit.
- Duplicate, redundant or ineffective controls may not be identified and streamlined.

2.2 Objectives

Internal Audit will support the management responsible for Capacity and Resilience in undertaking the assurance mapping process in February 2016.

2.3 Scope

The mapping exercise will be carried out using a workshop based approached with the management team of the chosen activities.

2.4 Exclusions from scope

Our work will not provide an assurance opinion on the operating effectiveness of controls identified as part of this mapping exercise.

3. RELEVANT CONSIDERATIONS FOR THE REVIEW

None noted.

4. GOVERNANCE OF THE REVIEW

The review fieldwork will be overseen by the Audit Team Leader, James Hennessey, and reviewed by the Head of Internal Audit, Lynn Yallop.

5. AUDIT APPROACH

Our approach in undertaking this mapping exercise will include the following:

- A workshop style meeting with key stakeholders to facilitate the assurance mapping process.
- Production of a draft assurance map for management to sign off.

6. DELIVERABLES

The deliverable from this review will be an assurance map for HFEA management. The assurance map will identify controls for each related process, and categorise the controls identified within their line of defence and whether they are preventative or detective. The assurance map will also detail the frequency of controls and whether the control is manual or systematic. We will also comment on the monitoring controls in place for each control identified.

7. FEEDBACK

On completion of the mapping exercise, we will seek feedback on our performance from the customer in the form of a Client Satisfaction Questionnaire.

8. TIMING & RESPONSIBILITY

Objective	Responsibility	Completed by
Terms of Reference agreed	Paula Robinson / Sue Gallone	18 November 2015
Workshop	Lynn Yallop	10th February 2016
1st Draft Report issued	James Hennessey /Lynn Yallop	15th February 2016
Management Responses received	Paula Robinson / Sue Gallone	25th February 2016
Final Report issued	Lynn Yallop	3rd March 2016

9. KEY CONTACTS

Audit Team		
Name	Title	Telephone no.
Lynn Yallop	Head of Internal Audit	07715 705063
James Hennessey	Team Leader/ Auditor	07833 680859

Terms of Reference have been agreed by:

……..Date…….

……..Date…….

HFEA Assurance Mapping – Capacity and Resilience– February 2016 – Summary:

	Adequate controls/ Monitoring controls operating as intended
	Some activities not fully supported by controls/Monitoring controls not always operating
	Controls missing/No monitoring controls in place

Activity	**Control RAG**	**Line of Defence (No)**			**Type of Control (No)**		**Monitoring/ Assurance RAG**	**Comments**
		1	2	3	P	D		
Governance		0	6	0	4	2		Business may benefit from formal recording of support provided to individuals and quantitative measures of employee capacity and performance.
Succession and resilience planning		5	2	0	7	0		Formal assessment of key roles required, which could be achieved through a documented resourcing strategy.
Demand management and prioritisation		0	1	0	1	0		Formal monitoring not currently in place to manage demand and prioritisation of tasks.
Contingency planning		5	2	0	7	0		HFEA may benefit from considering contingency planning for extended recruitment periods, and formalised knowledge sharing. This would reduce reliance on key staff members.
Culture of support for staff		5	1	0	5	1		
Total		**15 (56%)**	**12 (44%)**	**0 (0%)**	**24 (88%)**	**3 (12%)**		

This assessment is based upon requirements of the NHS Information Governance Toolkit Acute Trust Version 13 (2015-2016). It specifically excludes matters concerning IT security such as system access controls and website vulnerability as those are covered within the area of IT Assurance. It also excludes back-up and business continuity as there has been a separate review of Business Continuity undertaken as part of the 2015/16 audit programme.

Note

It is important to note that within the organisation the teams are of varying sizes and some teams consist of just two individuals. Some services are particularly reactive or subject to external influences and so use a high level plan for their annual activities while others have detailed delivery service plans, e.g. inspection programmes. As such this has inevitably resulted in a variety of activities occurring within teams with regards to Capacity and Resilience.

The Senior Management Team (SMT) consists of the Chief Executive, Director of Strategy and Corporate Affairs, Director of Finance and Resources, Director of Compliance and Information and Head of HR.

The Corporate Management Group (CMG) consists of the heads of each division as well as all members of SMT and deals with more operationally focused aspects of the HFEA.

HFEA Assurance Mapping – Capacity and Resilience – February 2016 – The Detail:

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
Governance									
The Corporate Management Group has oversight of capacity, demand, current and future pressure points and informs prioritisation of workload. There is an understanding of the "available" capacity within business team establishments to accommodate projects and extra activity in addition to "business as usual". The Corporate Management Group has visibility of non-business as usual activity and the resource requirements. There is an identification of those teams or roles under most pressure / demand. Where teams face pressures there is open discussion to	CMG may not be aware of the pressures within individual teams, which may means that a small increase in workload or an unexpected event could suddenly lead to major difficulties that need to be resolved. Without an understanding	"Business as usual" is work which HFEA sets itself through its annual business plan. Additional projects may presented to HFEA throughout the year by the Department of Health. The CMG have oversight of capacity and resilience through various aspects of		X X		X X		Business plan is approved by the Board in public annually. HFEA are held to account by the Board to deliver the projects. Each level in the reporting structure holds the level below to account to ensure that discussions are happening throughout the	

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
seek solutions on a corporate rather than a silo basis. Whilst individual teams should seek to manage pressures themselves where possible, the fact that this is being done is shared to inform a corporate view of the pressures on the organisation and level of risk being carried.	of capacity and pressures, contingency planning may be inadequate.	the upward reporting structure (captured as 1 control here): i) One to ones take place between individuals and line managers on a weekly to monthly basis to discuss individual's workloads and capacity; ii) Teams hold workload meetings to discuss capacity. Heads of department attend. Multi-team meetings take place to discuss joint projects and ensure workload is shared effectively. Oversight by Programme Board. iii) Programme Boards meet						organisation. This culminates with the Board as the ultimate Authority in the business and with accountability to the DoH and public.	

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
		quarterly to discuss performance against the business plan. The Boards feed up to the Corporate Management Group (CMG). iv) Meetings between directors and heads of departments take place fortnightly and project delivery is discussed; v) Corporate Management Group (CMG) meetings are held monthly. There are standing agenda items on capacity and performance. A "third hour" is held in these meetings to discuss staff wellbeing, capacity and resilience matters arising;							

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
		vi) Senior Management Team meetings are held weekly and will include relevant points relating to delivery of projects, performance, and capacity; vii) The Board meets six times a year in public. This includes a discussion on performance against the business plan. We are aware that an internal audit on governance has been held in the last two years.							
Corporate Management Group receives sufficient, timely information on organisational performance and project progress to be able to identify and issues requiring action. Appropriate KPIs have been defined for business as usual and milestones are set for additional activities to provide a baseline against which to monitor. The Corporate Management Group receives comprehensive reporting on business as usual activity	CMG may be unaware of pressures building within the organisation and therefore scope to take early action to share tasks or adjust deadlines may not be taken. This	Head of Business Planning produces strategic performance report, aligned to the HFEA strategy. Report is delivered to CMG monthly and a		X			X	The CMG, the Board and the DH hold the Head of Business Planning to account to deliver this report.	HFEA could consider using appropriate quantitative metrics to indicate how hard staff are working. Management comments:

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
performance (KPIs) and the progress of other projects / work against milestones. Where there is slippage in performance or meeting timescales, the causes are fully understood and the implications for resourcing and workload management considered.	could lead to more significant problems from overloaded teams or individuals, which then require more radical actions to solve them.	summary is provided to the Board six times a year and to the DH quarterly. KPIs reported include establishment, staff turnover and staff sickness. Capacity is additionally assessed through reporting of progress against the business plan and inspection programmes. Turnaround times for freedom of information requests and parliamentary questions are also reported as these are time consuming items. The report shows trends over the preceding quarter and comparisons to the prior year. Figures are informally checked for		X		X			Agreed for future consideration – PR to consider how this could be done as an improvement on our existing regular consideration of resources (which lacks metrics), and take proposals to CMG. Where appropriate, root cause analysis could be formalised through further investigation and more detailed reporting. Management comments: CMG to consider this idea, when it would be

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
		reasonableness by the Head of Business Planning. Reasons for failing metrics or delayed progress on the delivery of a plan are noted.							applicable, and how we could use it. Undertake a review of underlying data to confirm it is accurate and complete for reporting purposes. Management comments: Agreed this would be useful. Best timing would be when new strategy is set (July 2017), when the scorecard is also reviewed.
Managers / management teams engage with staff to understand the pressures they as individuals and the team are under. Through regular 1-2-1, liaison meetings and ad hoc discussions managers are aware of pressures facing individuals within their teams, including any personal matters that may have a bearing on individual performance. Where individuals face personal challenges, support is	Individuals may face pressures that cause their individual performance to be limited, or may try to solve issues without sharing the problem.	Support is available for staff facing personal challenges through one to one meetings with line managers, direct contact with HR, and an online Employee		X		X		No formal monitoring of these controls.	HFEA could consider formally monitoring support provided to individuals to understand pressures and how they are being

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
available / provided to help and reduce the risk of that becoming an absence or the individual leaving.	If then issues become too big, this can cause greater stress for individuals compared to being able to share and seek support at an earlier stage.	Assistance Portal. HFEA may refer staff to a third party occupational health provider where required. Individuals performing below expectations are identified through formal appraisal meetings. These are moderated and documented every 6 months.		X			X		responded to. Management comments: PR to discuss the potential for this with the HR team.
Succession / resilience planning									
Key roles within the HFEA have been identified and steps taken to provide for succession / capability to maintain those roles during any periods of absence or to manage across staff turnover. HFEA has formally assessed the risks relating to key roles and knowledge that are important to continuity of operations. As assessment has been made of the alignment of notice periods to the risks of individual roles / individual's knowledge. To the extent possible, notice periods provide for sufficient time to secure replacements / transfer knowledge and where there is any non-alignment contingency arrangements have been considered. For all roles, but particularly those assessed as higher	In the absence of succession planning and attempts to upskill others to cover key roles, interruption to business activity in the event of staff leaving or absences (e.g. due to illness) may be significant. Misalignment of notice periods to role can lead to senior staff	Team members have a six week notice period, senior management three month notice period. We are aware that in 2010 HFEA completed an exercise to recognise the core and support functions of the organisation. Job descriptions are in place	X	X		X X		No formal monitoring of these controls.	Consider formalising the identification of key roles. Management comments: CMG to consider a proposal to refresh the earlier work done in 2010 on business critical functions and resilience.

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
risk, formal assessment of the scope to share knowledge and experience with others in the organisation has been performed. Where appropriate, such knowledge and training / experience has been shared so that others can deliver key elements of the role to keep operations in progress for a suitable time.	leaving rapidly, before alternative interim or permanent arrangements can be established. If individuals have never performed a role, even though they may be capable there is greater risk should they need to step up to fill a role or cover a task during a period of absence.	outlining key responsibilities for each role. Reports to SMT and storage of working papers on shared systems means that these are accessible to new joiners. Finance team have Standard Operating Procedures available to new joiners. Policy team share knowledge and methodology at team meetings.	X X X			X X X			Consider holding team events to upskill junior members of staff (this may only be appropriate in specific teams in non-specialist areas). Management comments: PR to raise at CMG to agree whether there are certain teams where this would be a good approach.
Management and staff capacity has been aligned to workload. The resource requirements of organisation for business as usual has been identified and actual establishment aligned. In this alignment, there is an understanding of the degree of pressure that exists just to deliver business as usual and what capacity might therefore be available for other activities.	If workload exceeds capacity then performance is likely to slip, either in not meeting timescales or producing lower quality outputs. Business plans	A business plan, estimating the timetables for projects and the resources required to deliver them, is formally signed off by the Board in public and submitted to the DH in January	X			X		There is reporting on progress against the business plan through the oversight of the CMG, Board and DH. See section 1.	HFEA could consider more formally identifying the level of capacity available for additional activities (point has been raised

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
	may be undermined from the start if there is not the capacity to deliver the planned actions.	each year. HFEA discuss the prioritisation order of projects with the Board / DH where there are capacity issues. HFEA's workload is determined by the annual business plan and any additional tasks assigned by the DH. We are aware that HFEA's establishment is set by the DH and the Treasury.		X		X			in "governance" section). Management comments: As above - Agreed for future consideration – PR to consider how this could be done as an improvement on our existing regular consideration of resources (which lacks metrics), and take proposals to CMG.
Demand management and prioritisation									
The resource requirements for additional work and projects is considered in relation to capacity and this is reflected in the allocation of work and timescales set. Where work requires input from certain roles, or projects in one area require support from another, this is identified and it is ensured that needs are considered within each team or for each role. Resourcing within individual teams is monitored in relation to the business plan and activity, .including for example the impact of absences.	Additional work may be initiated when there is no capacity to deliver it.	Where capacity issues are identified, reassessments of priorities are made through discussion with key stakeholders (Board, DH) in order to minimise the risk to HFEA.		X		X		There is no formal monitoring of these controls.	Consider introducing after-event analysis to review whether correct decisions were made for HFEA and its

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
Where additional workload arises and exceeds capacity, there is a corporate re-assessment or priorities and re-setting of deadlines as necessary.		Decisions are ultimately made at CMG and SMT meetings. Resourcing within teams is monitored through the reporting structure. See point 1.							people. Management comments: Agreed, and I see this as linking with the recommendation made under governance above, about resource metrics. PR to consider how to include the concept of after-event analysis of decisions in thinking about this.
Contingency planning									
Consideration has been given to those roles essential to business operations and to how those can or might be procured to fill any absences. HFEA has identified those roles essential to the running of the organisation. Where possible, succession planning is in place to allow those roles to be met during any periods of absence or in the event of a staff member leaving. Where there is no internal solution to meeting a key	Where the size of the organisation or nature of roles means that there may be difficulties maintaining roles, the absence of contingency planning can mean	If an employee resigns or leaves the business quickly, discussions are held with the relevant director or the Chief Executive to discuss the resourcing approach to fill their role.	X				X	Explicit DH approval is required for recruitment to the most senior roles. There are no regular checks from the DH that the pool is being used, but the requirements are very clear. There are no HFEA monitoring controls in this area.	Consider formalising the handover process during long recruitment timeframes. Management comments: PR to discuss with CMG (several

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
role, arrangements are established to allow support to be obtained at short notice if required in the event of a short term absence. This might, for example, involve being able to call on support from another ALB. Where there may be no internal solution to cover a longer term absence or departure, consideration is given to what can be done to manage in the short term and to expedite recruitment of a replacement.	immediate difficulties and time pressures over finding solutions.	Government restrictions mean that HFEA must initially seek to recruit from within a pool of staff working for the DH, Civil Service and NHS. This can lead to difficulties with long recruitment processes which reduce the possibility of formal handovers between the former and future post holder. If unsuccessful, HFEA can recruit external or agency staff on fixed term contracts. This can however extend the recruitment time which reduces the likelihood of full handovers between outgoing and incoming staff. HFEA are very							teams already have formal handover materials in place, so we would need to consider if anything more is needed). HFEA may benefit from succession planning for key roles which could be temporarily vacant (raised in succession and resilience section above). Management comments: Agreed, and this links with the point about business continuity and business critical

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
		tightly resourced so there are minimal opportunities for existing staff to fill roles left vacant by others.							functions above. PR to raise for consideration at CMG.
Culture of support for staff									
The organisation has an open and supporting culture such that those under, or foreseeing, excessive pressures or difficulties share that information so that they can be supported if required and management can consider any actions required to mitigate risk. There is a culture of open discussion or workloads, pressures and sharing such information is not seen as a sign of weakness.	If there is a culture where staff have to absorb pressures and deliver regardless of workload, the degree of pressure on them and level of risk that they may not deliver or could suffer under the pressure is increased. In this situation the HFEA is less able to plan to mitigate the risk.	Annual staff survey (March each year) assesses wellbeing and capacity of staff. Survey is based on civil service competency framework. One to one conversations are held with line managers (see point 1). Leadership team have an open door policy, sit with their teams and lead by example – recognising staff who have gone the extra mile and supporting flexible working. A full staff	 X X X	X		 X X X	X	The staff survey results are fed back to CMG and the wider business through the all staff away day. SMT meetings discuss culture and feeling within the business (67 staff) and act when necessary.	

Activity	Risks	Control in place/ Frequency/ RAG	Line of Defence			Type of Control		Monitoring/Assurance/ RAG	Comments
			1	2	3	P	D		
		meeting takes place once a month in the office. These facilitate team discussion and the dissemination of key information. This is also an opportunity for staff to ask questions of management. Organisation wide communications ensure staff receive consistent messages. These are through various mediums, including team meetings and bulletins. There is a small leadership team and staff feel comfortable approaching these individuals.	X X			X X			

Implementation of Audit Recommendations – Progress Report

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency economy and value**	☒	
Meeting	Audit and Governance Committee						
Agenda item	10						
Paper number	[AGC (16/03/2016) 492 WEC]						
Meeting date	Wednesday, 16 March 2016						
Author	Wilhelmina Crown						
For information or decision?	Decision						
Recommendation	AGC is requested to review the enclosed progress updates and to comment as appropriate.						
Resource implications	As noted in the enclosed summary of outstanding audit recommendations						
Implementation	As noted in the enclosed summary of outstanding audit recommendations						
Communication	CMG						
Organisational risk	As noted in the enclosed summary						
Annexes	Annex 1: Summary of Recommendations						

1. Report

1.1. This report presents an update to the audit recommendations paper presented to this committee in December 2015.

1.2. New recommendations agreed by this committee in December 2015 have been added whilst those agreed as completed removed.

1.3. Recommendations are classified as high (H - red), medium (M - amber) and low (L - green) priority.

1.4. Six new recommendations were received with one requiring no further action and the remaining identified as low risk.

1.5. Recent updates received from Action Managers are recorded under a December 2015 heading in this document.

1.6. All recommendations are noted as completed with none outstanding.

1.7. Progress with the implementation of all audit recommendations will be provided to future AGC and CMG Risk meetings on a quarterly basis

2. Recommendation

AGC is requested to review the enclosed summary of recommendations and updated management responses.

Annex 1: Summary of Recommendations

Recommendation Source	**Status / Actions**	2015/16	Total
Internal – *DH Internal Audit*	*Complete*	*5*	***5***
COUNT		***5***	***5***

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Owner/Completion date
2015/16 – INTERNAL AUDIT CYCLE			
HFEA INCIDENT HANDLING			
1. Risk Management	**The Risk Matrix in the policy is not entirely reflective of the incident grading in practice**		
Incidents reported to HFEA are graded A (red), B (yellow) and C (green) according to their severity and likelihood of recurrence. This is depicted in the policy by way of the following Risk Matrix:  Likelihood → / Severity ↓ Almost certain 5 | Likely 4 | Possible 3 | Unlikely 2 | Rare 1 Severe 5: 25 | 20 | 15 | 10 | 5 Major 4: 20 | 16 | 12 | 8 | 4 Moderate 3: 15 | 12 | 9 | 6 | 3 Minor 2: 10 | 8 | 6 | 4 | 2 Insignificant 1: 5 | 4 | 3 | 2 | 1 When we reviewed the grading of our sample of 25 incidents, the gradings applied appeared reasonable to us under the framework but in some cases did not fully align with the matrix. For instance, a severe incident is usually rare and might rightly be graded A, but per the matrix rare incidents are all coloured green regardless of their severity. Similarly, mild to moderate OHSS (Ovarian Hyper stimulation Syndrome) is a known and fairly common side effect of fertility treatment and is graded C in practice, but per the matrix it might be argued to be Grade B as whilst the severity is minor the likelihood is likely or possible. *There may be uncertainty as to the grading of incidents, which could lead to an inconsistent response and potential for challenge.* *In practice, the limited number of staff involved in the process means coding is likely to be consistent, but could be open to question by someone referring to the matrix.*	The risk matrix should be reviewed to see whether it can be updated to better reflect the balance between severity and likelihood of recurrence.	***Review risk matrix. It has been revised to reflect the balance between severity and likelihood of recurrence. Waiting for sign off by the Chief Inspector to be completed by 31 December 2015***. **December 2015 update**: Signed off by Chief Inspector - December 2015 **Recommendation Complete**	**Chief Inspector** **31 December 2015** **COMPLETE**
2. Policies and Procedures	**Key Policies and Procedures are overdue for review**		
We noted that a number of key policies and procedures are under review having not been updated for some time: • The SOP for Managing Patient Complaints and that for Managing A grade Adverse Incidents have not been updated since August 2012; • The SOP for Managing B and C grade Incidents has not been updated since November 2011; and • The Compliance and Enforcement Policy has not been updated since October 2011. The version published on the HFEA website states that it is due for review in April 2013. We noted that within the existing policies there are some references to certain systems and processes that are no longer applicable or relevant. However, we recognise that this has been identified by management and that these policies and procedures are already undergoing review.	Management should ensure that the ongoing review of policies and procedures is completed and revised versions formalised and issued. The updates should take account of the findings from this review. The wording around when	***SOP review. In process for completion 31 December 2015*** **December 2015 update**: SOP review and revision completed. **Recommendation Complete**	**Clinical Governance Lead** **31 December 2015** **COMPLETE**

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Owner/Complet -ion date
We also noted that the narrative for the Grade A category states that an inspection is required for these incidents but we understand that HFEA does not always need to undertake an investigation itself, for instance if it can obtain assurance from external investigations. *Staff may not be fully aware of the required process for managing incidents and complaints. This could lead to HFEA's response being inappropriate or ineffective.* *Lapses in process may be more likely to arise if there is staff turnover or if roles have to be reassigned during a period of absence of a key individual.* *There could be uncertainty as to whether investigation by the HFEA is required in circumstances where there is a severe incident but other bodies are undertaking their own investigations.*	an investigation should be undertaken should be reviewed to better describe when HFEA would undertake its own investigation and when it might rely on the results of investigations by others.		
3. Closure of formal complaints	**Rationale for closure of one complaint in our sample was not formally documented.**		
We reviewed a sample of five formal complaints and in one instance there was evidence that the complainant was not wholly satisfied with the final correspondence. The SOP indicates that where the complainant is not satisfied, HFEA should advise them that they may request a review by the Head of Clinical Governance within 10 working days of notification of the outcome of the initial consideration. However, in this instance the complaint was closed on the system without any further follow up. The final correspondence from the complainant noted that they did understand that there was nothing further the HFEA could do, but that they remained dissatisfied with their treatment and the service at the particular clinic. The Clinical Governance Lead/Inspector stated that HFEA could have written another letter re-iterating that there is nothing further they could do, but in this case it was felt that it would have only induced further unnecessary correspondence. This rationale for closing the complaint, however, was not documented. *There is a risk of inconsistency, which could lead to challenge and reputational harm if complaints are not fully dealt with in line with the SOP.* *HFEA may find it harder to demonstrate full compliance with the SOP if the rationale for decisions is not formally recorded on the system.*	As best practice, when closing complaints on the system, a rationale should to be documented for closure if it is noted that the complainant is fully satisfied with the response.	***Further information on how to handle an unhappy complainant now added to the complaint handling SOP. Rolled into the SOP update to be completed by the end of December 2015.*** **December 2015 update**: Completed as part of SOP review and revision **Recommendation Complete**	**Clinical Governance Lead** **31 December 2015** **COMPLETE**
4. Performance reporting	**Performance reporting of incidents and complaints to management is not documented.**		
It was confirmed by the Clinical Governance Lead/Inspector that the number of incidents and complaints are reported to, and discussed within, management. This is usually done within her monthly one to one meetings with the Chief Inspector. The numbers and trends are also discussed with Director of Compliance from time to time. However, these meetings are not documented and there are no formal reports so there is limited evidence that management has considered the number and type of incidents and complaints and assessed whether any particular response may be required.	Some formalisation of brief reporting of the number of incidents and complaints and of any relevant trends or other matters should be	***Quarterly meetings now in calendar. The Clinical Governance Lead and the Chief Inspector will meet in December to set the standing agenda and use this first meeting as a "look back" over 2014.***	**Clinical Governance Lead & Chief** **31 December 2015**

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Owner/Complet -ion date
In due course, the numbers are summarised within the Annual Report, which states the number and trends of the reported incidents and details any Grade A incidents along with the key learning outcomes are published on the HFEA website. *If the numbers and the resulting trends of incidents and complaints are not appropriately analysed and monitored on a timely basis management may fail to identify potential issues that may have warranted action. If action is not taken where required, then there is increased risk of issues recurring or of policies and procedures not being developed to improve services.*	considered formalised. This could perhaps be done on a quarterly basis.	**December 2015 update:** Completed – first meeting held in December 2015 **Recommendation Complete**	**COMPLETE**
5. Survey Results	**Performance reporting of incidents and complaints to management is not documented.**		
While the response rate to the survey was low there are some comments that HFEA management may wish to reflect on in terms of enhancements to incident reporting. Please refer to Section 5 of this report for the full survey results. As mentioned in section 1.7 above, the survey was issued with the Clinic Focus paper in September 2015 which is sent to all clinics (approximately 130) and has a total of around 500 subscribers. Unfortunately there were only eight responses which means the results must be treated with caution *Where stakeholders do not see any change a as a result of comments made from such surveys, engagement levels may fall.* *Not acknowledging appreciation to those who responded to the wider population of subscribers might miss an opportunity to encourage more people to respond to any future surveys.*	Send out a thank you communication regarding the survey to the full population and a brief summary of any changes that are planned to be taken as a result of the comments made.	***A brief thank you will be sent out in the December edition of Clinic Focus. Clinic Focus is sent to over 120 clinics and 500 individual subscribers. Due to the very low volume of responses (8) – no meaningful information was gleaned to make any changes to the current system. Therefore a brief thank you to those that participated will be mentioned in Clinic Focus.*** **December 2015 update**: Brief thank you held over until February's edition – urgent contents took priority for December and January. **Recommendation Complete**	**Clinical Governance Lead** **31 December 2015** **COMPLETE**

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	12		
Paper number	AGC (16/03/2016) 493		
Meeting date	16 March 2016		
Author	Sue Gallone, Director of Finance & Resources		
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:	15 June 2016	21 Sept 2016	7 December 2016	Mar 2017
Following Authority Date:	6 July 2016	16 November 2016	January 2017	May 2017
Meeting 'Theme/s'	Annual Reports, Information Governance, People	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity	Finance and Resources
Reporting Officers	Peter Thompson	Juliet Tizzard	Nick Jones	Sue Gallone
High Level Risk Register	Yes	Yes	Yes	Yes
Information for Quality (IfQ) Programme	Yes	Yes		
Annual Report & Accounts (inc Annual Governance Statement)	Approval			
External audit (NAO) strategy & work	Audit Completion Report	Audit Planning Report	Update	Interim Feedback
Information Assurance & Security	Yes			
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Plan, Results, annual opinion	Update	Update	Early Results, approve draft plan
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes	Yes			

AGC Items Date:	15 June 2016	21 Sept 2016	7 December 2016	Mar 2017
Strategy & Corporate Affairs management		Yes		
Regulatory & Register management			Yes	
Resilience & Business Continuity Management			Yes	
Finance and Resources management				Yes
Reserves policy		Yes		
Review of AGC activities & effectiveness, terms of reference			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				