

Audit and Governance Committee meeting - agenda

7 December 2016

River Meeting Room

King's College London, Strand Campus, Strand, London WC2R 2LS

Agend	a item	Time
1.	Welcome, apologies and declaration of interests	10:00am
2.	Minutes of 21 September 2016 [AGC (07/12/2016) 512]	
3.	Matters Arising [AGC (07/12/2016) 513 MA]	
4.	Rating [Oral - Jon Whitfield, Government Internal Audit Agency (GIAA)]	
5.	Register & Compliance Risks [Presentation NJ]	
6.	Information for Quality (IfQ) Programme – Managing Risks [AGC (07/12/2016) 514 NJ]	
7.	Strategic Risks [AGC (07/12/2016) 515 PR]	
8.	Internal Audit	
	a) Progress report 2016/17 [AGC (07/12/2016) 516 DH Internal Audit]	
9.	External Audit	
	a) Audit Planning Report [AGC (07/12/2016) 517 NAO]	
10.	Implementation of Recommendations – Progress Report [AGC (07/12/2016) 518 WEC]	

11.	Cyber Security - Information Security & Testing [AGC (07/12/2016) 519 DM]	
12.	Disclosure and Barring Service (DBS) checks [Oral RH]	
13.	Resilience & Business Continuity Management [Oral DM]	
14.	Whistle Blowing Policy [AGC (07/12/2016) 520 MA]	
15.	Contracts & Procurement [Oral MA]	
16.	Review of AGC activities & effectiveness [AGC (07/12/2016) 521 SK]	
17.	AGC Forward Plan [AGC (07/12/2016) 522 MA]	
18.	Any other business	
19.	Close (Refreshments & Lunch provided)	1.15pm
20.	Session for members and auditors only	1.15pm
21.	Next Meeting 10am Tuesday, 21 March 2017, London	



Audit and Governance

Committee meeting minutes

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance	Committee	
Agenda item	2		
Paper number	AGC (07/12/2016) 512		
Meeting date	7 December 2016		
Author	Dee Knoyle, Committe	e Secretary	
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to the meeting	confirm the minutes as	a true and accurate record of
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	Low	☐ Medium	🗆 High
Annexes			

Minutes of Audit and Governance Committee meeting held on 21 September 2016 at HFEA, 10 Spring Gardens, London SW1A 2BU

Members present	Rebekah Dundas (Chair) Gill Laver Jerry Page Anita Bharucha
Apologies	Margaret Gilmore
External advisers	Internal Audit: Paul Foreman, Price Waterhouse Coopers (PWC) National Audit Office (NAO): Sarah Edwards
Observers	Kim Hayes (Department of Health)
Staff in attendance	Peter Thompson, Chief Executive Morounke Akingbola, Head of Finance Adam Ashiwaju, Accounts Officer Juliet Tizzard, Director of Strategy and Corporate Affairs Nick Jones, Director of Compliance and Information David Moysen, Head of IT Paula Robinson, Head of Business Planning Ian Brown, Head of Corporate Governance Dee Knoyle, Committee Secretary

1. Welcome, apologies and declarations of interests

- **1.1** The Chair welcomed attendees to the meeting.
- **1.2** There was one apology from Margaret Gilmore.
- **1.3** The Chair made the following announcements:
 - Sally Cheshire, Chair of the Authority will continue the role for a further three years.
 - Margaret Gilmore will become Deputy Chair of the Authority from November 2016.

Margaret will remain a member of the Audit and Governance Committee until the end of December 2016 and will continue her role on the Licence Committee. Margaret will also take on the role of Chair of the Statutory Approvals Committee from October 2016.

- Rebekah Dundas will be leaving the Authority in December 2016 as her term has come to an end.
- Anita Bharucha will become Chair of the Audit and Governance Committee from January 2017.
- Sue Gallone will be retiring from the HFEA in September 2016. Members acknowledged her hard work and expressed sincere and grateful thanks for her support.

- Richard Sydee has been appointed Director of Finance and Resources and will start this role on 1 November 2016.
- Ian Brown, Head of Corporate Governance will be leaving the HFEA on 30 September 2016 and interim arrangements will be in place e until recruitment begins for this role.
- **1.4** There were no declarations of interest.

2. Minutes of the meeting held on 16 March 2016

2.1 The minutes of the meeting held on 15 June 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 progress on actions from previous meetings. Some items were ongoing and others were dependent on availability or were planned for the future.
- **3.2** e) The two external members of the committee, Gill Laver and Jerry Page are awaiting suitable dates to attend an Authority meeting as an observer.
- **3.3** 9.6) The Information Governance Group are establishing a meeting date.
- **3.4** 12.6) The Executive will review the Appeals process and consider what a proportionate first step, the representations would look like. Work will start in October 2016 and recommendations will be presented to the Authority by the end of the business year.
- **3.5** 14.5) The Triennial review report is expected to be circulated to Arm's Length Bodies (ALBs) shortly after political party conferences which take place in October.
- **3.6** 5.7) The Information for Quality (IfQ) Internal Systems Project Manager will circulate a list of recommendations and planned actions (relating to 'Public Beta') to the committee after review by Programme Board.
- **3.7** 8.5) The Executive is consulting with other healthcare professionals on Disclosure and Barring Service (DBS) checks and will take a light touch approach. The Executive will aim to feed back to the Audit and Governance committee at the meeting in December 2016.

4. Strategy and Corporate Affairs Management

- **4.1** The Director of Strategy and Corporate Affairs provided the committee with a presentation and briefing on managing the Directorate's risks tied to the corporate strategy, the current risks over the next 6 months.
- **4.2** The committee was reminded of the content of the update on the Directorate presented last year.
- **4.3** The committee noted the Directorate's contributions to the HFEA Strategy which focuses on setting standards, increasing and informing choice and efficiency, economy and value. The focus of the Strategy has shifted from regulatory in previous years to patients' needs.
- **4.4** Understanding patients' needs at all stages of treatment has shaped the design of services such as Choose a Fertility Clinic on the new HFEA website, where the brand has been refreshed and the tone of voice has changed. New features on the website include a donor egg and sperm availability service and a new patient rating service, allowing patients to review a clinic's performance before treatment.

- **4.5** A new counselling and support service for people seeking donor information or re-registering has also been launched.
- **4.6** The HFEA has continued to inform patient choice by publishing reports such as fertility trends and sharing information on new or tested treatments.
- **4.7** The Executive has established a working relationship with NHS (National Health Service) Choices and plan to apply for Information Standards, awarded by NHS (National Health Service) England for good quality patient information.

Key Risks:

- **4.8** Patient: The committee noted that further work is required to market the services provided by the HFEA as a regulator, to ensure that information is accessed at the appropriate time, especially at the early stages when a patient is first seeking treatment.
- **4.9** Stakeholder engagement: The committee noted that there has been a legal challenge to the presentation of clinic information on Choose a Fertility Clinic on the new HFEA website. The Executive is engaging with the sector and seeking acceptance from all clinics to ensure that the planned services are fully delivered.
- **4.10** Communication: The new website is due to become live in January/February 2017. However, the content management system on the existing website is dated and no longer supported by the original supplier which has led to instability from time to time. The committee was informed that should the HFEA website fail to operate completely for a period of time, other forms of communication would be used to communicate with stakeholders and the public via the HFEA Portal and social media. Due to recent delays to the programme, the committee advised the Executive to consider seeking support for the content management system of the existing website in the interim, until the new website is available, as the risk of the existing website failing will increase with time. There committee noted that there are financial costs involved and agreed that this should be an option.

Action

4.11 Head of Communications to seek support for the content management system for the existing website in the interim until the new website is available.

5. Information for Quality (IfQ)

5.1 The Director of Compliance and Information provided the committee with a paper, presentation and briefing on the delivery of the 'Public Beta' phase of the new Website and Clinic Portal and the plans for data mitigation to the new Register.

5.2 The Programme

The Plan

- **5.3** The committee was informed that following an unexpected legal injunction, relating to the display of clinic information, brought by a clinic in July 2016, which has since been lifted, a judicial review has been scheduled in December 2016 and therefore the delivery plan has been revised, including the next Government Digital Service (GDS) assessment.
- **5.4** The consequences of the updated timeline as well as the judicial review have been assessed and the risks are currently being mitigated.

5.5 There has been no formal revision to the budget. However, the Executive is currently working through the consequences of the revised timeline.

Release One - HFEA Website and Clinic Portal

- **5.6** The Programme is now running through its 'Public Beta' phase for both the new Website and Clinic Portal. During this stage, all feedback from the public and stakeholders will be analysed and reviewed for further developments and this process will continue when the system goes live, to ensure that the users' needs are met.
- **5.7** The Government Digital Service (GDS) assessment of the Clinic Portal to enable progression to 'live' is scheduled for October 2016.
- **5.8** The GDS assessment to enable the website to 'go live' has been pushed back to January 2017 due to the pending judicial review.

Release Two – Electronic Data Interchange (EDI) and Electronic Patient Record System (EPRS)

- **5.9** The next phase 'Release two' has completed its planning stage and partially started its development. EDI is now scheduled for February 2017 and EPRS is still on schedule for March 2017.
- **5.10** The Executive is engaging with EPRS providers (suppliers of patient reporting systems to approximately half of all clinics). The providers have been notified of the development path to March 2017 and are well informed, however some providers are not keen to develop systems and there is a risk that some clinics may want to continue using a system which is not aligned to submit data to the HFEA. The Executive plan to maintain a close level of engagement with providers to enable gradual adoption of ways to 'connect' to the HFEA and maintain the necessary security.
- **5.11** The Standardisation Committee for Care Information (part of NHS (National Health Service) Digital) accreditation process for the 'UK ART (Assisted Reproductive Technology) dataset' and its implementation is on schedule.
- **5.12** The overall risk score for the IfQ Programme has increased. The main risk added relates to EPRS providers and the impact on treatment fees linked to the submission of data should there be any delays.
- **5.13** There were three new inter-related strategic risk sources arising from the IfQ programme which would only apply following IfQ Release Two in 2017. These risks included the various impacts if EPRS providers did not make the necessary changes to their systems to submit clinic treatment data to the new Register structure. There would be a risk of loss of regulatory authority as any gaps in data could impact effective regulatory monitoring; a risk to improved information access since any data that had not been provided would not be available to provide to patients through Choose a Fertility Clinic; and also a risk to financial viability negative impact on cash flow, if the HFEA were not able to bill clinics for treatments provided but not reported. The Executive is currently working to develop further mitigation plans for these risks, alongside the HFEA finance and compliance departments.

Register - Data Migration

- **5.14** The committee was informed that data cleansing and migration work is slightly behind schedule.
- **5.15** Clinics are encouraged to deal swiftly with HFEA requests to fix errors and this process will be monitored closely.

- **5.16** An expert in data migration has been commissioned to provide assurances for all steps leading up to the transfer of data.
- **5.17** The committee noted the legal situation and the impact on the timeline and that this may have financial consequences affecting the budget for the programme. The committee agreed that a report should be provided on the financial consequences as soon as possible.
- **5.18** The committee noted that stakeholder engagement is key to the success of the programme and encouraged the Executive to maintain the momentum.
- **5.19** The committee also asked the Executive to give more consideration to 'plan B' for the website, in the event of an adverse JR judgment, or in the event of Red Dot (the current, outgoing content management system, which was old and unsupported) failing completely.

Action

- **5.20** Director of Compliance and Information to provide a report on the financial consequences as a result of movement to the timeline due to the judicial review as soon as possible.
- **5.21** The Executive to consider mitigations for the website in the event of an adverse JR decision or a complete failure of the current content management system.

6. Strategic Risks

- **6.1** The Head of Business Planning presented the strategic risk register.
- **6.2** The committee discussed the strategic risks, in particular the three risks above tolerance which include improved information access (currently under development in the Information for Quality (IfQ) programme), the risk of incorrect data being released and knowledge and capacity.
- **6.3** The committee was informed that work was underway to develop further mitigation plans for the three new inter-related strategic risk sources arising from the IfQ programme (as discussed at item 5) which would only apply following IfQ Release Two in 2017.
- **6.4** Parliamentary questions fluctuate and there are times when the volumes are challenging to process with a quick turnaround. The committee noted that the Executive is working to capacity and currently doing all that is possible to mitigate the risks of incorrect data released and the standard operating procedures have been revised. The committee noted that the Executive is granted the maximum time to provide answers to Parliamentary questions and this must be adhered to. However, the Department of Health will continue to give early warning to ALBs when there is a rise in the number of Parliamentary questions to be answered.
- **6.5** The committee discussed the new finance risk of non-payment to suppliers, caused by technical issues with migration to internet banking. This has been escalated with the bank and the HFEA finance team are currently working around the situation until the issues have been resolved.
- **6.6** The committee noted the risk relating to knowledge and capacity and was reassured that the risk would not increase as a result of having one vacancy for a member of staff at Head's level.
- **6.7** The Executive has encouraged junior members of staff to learn more about risks to improve awareness and reporting within the organisation.
- 6.8 The committee noted that the Department of Health's risk audit recommendation that Arm's Length Bodies (ALBs) and the Department consider risk interdependencies across the health and care system and the HFEA will seek to embed this approach into future management of risk.

6.9 The committee was satisfied with the current controls and mitigation plans in place to manage the organisation's strategic risks.

7. Internal Audit a) Progress Report

- 7.1 The committee was provided with a progress report on the annual programme.
- 7.2 The audit on income generation has been completed.
- **7.3** The Board effectiveness review is in progress.
- 7.4 The field work on Cyber Risks will begin in November 2016
- 7.5 All field work is to be completed by the end of March 2017.

b) Income Generation

- **7.6** The committee was provided with an Income Generation Report.
- **7.7** The business process was mapped from data submitted by the clinic to the production of invoices and controls were reviewed and tested.
- **7.8** The auditors reported that a few areas in the process could be enhanced including closer monitoring of clinics not submitting data.
- **7.9** The committee questioned why the Executive had resisted some of the recommendations which were low priority. The Executive reassured the committee that the organisation had other means of covering the recommendations which were aligned to the function and capacity of the organisation. The committee acknowledged that the Executive's way of working did not undermine the organisation's control systems, however encouraged the Executive to implement the recommendation relating to data extracted from Sage, accounting software if at all possible.
- 7.10 Risk management controls are to be in place for the new portal before it becomes live. The Management team are confident that they know how to manage the risks using the new software.
- 7.11 The overall rating for income generation was moderate.
- **7.12** The committee discussed the rating system and agreed that Jon Whitfield from the Government Internal Audit Agency (GIAA) will be invited to attend the Audit and Governance Committee meeting in December 2016 to engage in a further discussion on rating.

Action

7.13 Jerry Page to invite Jon Whitfield from the Government Internal Audit Agency (GIAA) to attend the Audit and Governance Committee meeting in December 2016 to engage in a further discussion on rating.

8. External audit

8.1 The National Audit Office (NAO) provided the committee with an oral update.

- **8.2** The committee noted that an audit planning meeting took place with the HFEA and the NAO on 14 September 2016 and a report will be presented to the Audit and Governance Committee at the meeting in December 2016.
- 8.3 The committee was informed that Sarah Edwards and George Smiles will remain NAO representatives for the HFEA, however the lead auditor has changed from Melini to Payal who has good experience working with smaller Arm's Length Bodies (ALBs).

9. Implementations of recommendations progress report

- 9.1 The Head of Finance provided the committee with an update.
- **9.2** The committee noted that there are currently no outstanding recommendations.

10. Cyber Security

- **10.1** The Head of IT provided the committee with an oral update on the security and testing of the organisation's IT systems.
- **10.2** The new HFEA Portal and website have been tested. There were seven low risk issues which have been resolved.
- 10.3 The design for the architecture for Release Two of the IfQ programme, Electronic Patient Record System (EPRS) has just been completed with the assistance of external experts. Class consultants will complete a review of the infrastructure before moving onto the next steps, creating and testing the system. The committee agreed that the Executive should ask all external expert consultants to provide documented evidence of advice given.
- **10.4** The committee was informed that the review of Release Two by Class consultants would take 4-6 weeks.
- **10.5** Wider testing for the whole organisation will be completed after the testing period for Release Two is complete.
- **10.6** The organisation will be moving to a secure system using the Cloud in future and this will increase security.
- **10.7** A detailed Risk Management and Accreditation Document Set (RMADS), which explains the threats and mitigation will be created and signed off by the SIRO (Senior Information Risk Officer).
- **10.8** The committee highlighted that the legislation requires HFEA data to be fully protected and requested evidence from external providers that they are doing what was agreed and that we have written assurances. The committee agreed that the Head of IT should provide a further update paper on information security and testing at the next meeting in December 2016 including evidence of assurance received.

Action

10.9 Head of IT to provide the Audit and Governance Committee with a further update paper on information security and testing and documented evidence of assurances obtained at the next meeting in December 2016.

11. Reserves Policy

- **11.1** The Head of Finance presented the revised Reserves Policy and briefed the committee on the recent changes.
- **11.2** There were revisions to the figures included in the policy but no changes to the actual policy. Key changes included:
 - an increase in rent charges due to relocating to the office of NICE (The National Institute for Health and Care Excellence)
 - salary costs increased slightly
 - The Head of Finance advised the committee that further work on forecasting our income which would impact on reserves will be carried out at a later date.
- **11.3** The committee acknowledged that HFEA income and expenditure may fluctuate in some areas and this is unpredictable for example treatment income and legal costs.
- **11.4** The committee noted that the sum allocated for reserves remains largely the same.
- **11.5** The committee noted the changes and approved the Reserves Policy.

12. Forward plan

12.1 The committee was satisfied with the content of the Forward Plan of agenda items for the forthcoming meetings, with the addition of Cyber Security and Internal Audit Ratings to the next agenda in December 2016. The committee also noted that all internal audit work needs to be complete by March 2017 as there is likely to be new suppliers of internal audit.

13. Any other business

- **13.1** There was nothing to report on whistleblowing or suspected fraud incidents and no contracts were awarded since the last meeting.
- **13.2** The Chair thanked attendees for their contributions to the meeting.
- **13.3** Members and auditors retired for their confidential session.
- **13.4** The next meeting will be held on Wednesday, 7 December 2016 at 10am.

Chair's signature

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

Name

Rebekah Dundas

Date

7 December 2016

Audit and Governance Committee Paper

Paper Title:	Matters arising from previous AGC meetings
Paper Number:	[AGC (07/12/2016) 513 MA]
Meeting Date:	7 December 2016
Agenda Item:	3
Author:	Morounke Akingbola, Head of Finance
For information or decision?	Information
Recommendation to the Committee:	To note and comment on the updates shown for each item.
Evaluation	To be updated and reviewed at each AGC.

Numerically:

- 5 items added from September 2016 meeting, 3 ongoing
- 8 items carried over from earlier meetings, 5 ongoing
- 1 items carried over from AGC self-assessment of performance 2014, 1 ongoing

Matters Arising from Audit and Gover	nance Committee re	view of perform	mance 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.		
Matters Arising from Audit and Gover	nance Committee –	actions from 1	0 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 2016	Ongoing – Group to establish first meeting.		
Matters Arising from Audit and Gover	nance 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 and recommendations will be presented to the Authority by the end of the business year.		
14.5 The Triennial review report is to be sent to committee members.	Director of Finance	When published	Ongoing – an update is on its way.		
Matters Arising from Audit and Governance Committee – actions from 15 June 2016 meeting					
5.7 Circulate a list of recommendations and planned actions (relating to public beta) to the committee after review by Programme Board	Information for Quality (IfQ) Internal Systems Project Manager	January 2017	Ongoing		

8.5 Consider the need for possible Security checks for new staff, such as DBS	CEO/Head of HR	October 2016	Completed – Agenda item for December 2016
Matters Arising from Audit and Gover	nance Committee –	actions from 2	1 September 2016 meeting
4.11 Head of Communications to seek support for the content management system for the existing website in the interim until the new website is available.	Head of Communications	asap	Ongoing
5.20 Director of Compliance and Information to provide a report on the financial consequences as a result of movement to the timeline due to the judicial review as soon as possible.	Director of Compliance & Information	asap	Ongoing
5.21 The Executive to consider mitigations for the website in the event of an adverse JR decision or a complete failure of the current content management system.	Head of Communications	asap	Ongoing
7.13 Jerry Page to invite Jon Whitfield from the Government Internal Audit Agency (GIAA) to attend the Audit and Governance Committee meeting in December 2016 to engage in a further discussion on rating.	Jerry Page, AGC Member	December 2016	Completed – Agenda item for December 2016
10.9 Head of IT to provide the Audit and Governance Committee with a further update paper on information security and testing and documented evidence of assurances obtained at the next meeting in December 2016.	Head of IT	December 2016	Completed – Agenda item for December 2016



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	AGC (07/12/2016) 514	1 NJ	
Meeting date	07 December 2016		
Author	Nick Jones, Director o	f Compliance & Informati	on
Output:			
For information or decision?	For information		
Recommendation	The Committee is ask	ed to note this report.	
Resource implications	As outlined		
Implementation date	Ongoing		
Communication(s)	Ongoing		
Organisational risk	□ Low	□ Medium	🗷 High
Annexes			
Annex A –			

1

1. Introduction and summary

1.1. The purpose of this report is to provide the Committee with a progress report on the IfQ Programme. The Programme is currently in the closing stages of its 'public beta' phase for both the new Website and Clinic Portal. Slow but steady progress is being made against Release 2 of the Clinic Portal, which centres on the data submission facility for clinics and the new Register.

2. If Q projects update

2.1. IfQ Release 1

- The HFEA website work is currently focused on closing the Beta phase, having delivered the key outputs for the project, with some lower priority work remaining before Beta concludes. Valuable user feedback has been collected; there has been substantial stakeholder engagement; and further user research sessions have been completed.
- Further to the outcomes of the November 2016 Authority meeting and pending the judicial review hearing scheduled in December, some further adjustments will be made between now and January 2016 essentially to the way data is presented on the Website. After this point, the service will undergo a GDS assessment for its readiness to be transitioned to full 'live' service.
- We are now formally verifying with clinics, the data that will be made available on the new Choose a Fertility Clinic facility. Clinics have 12 weeks to verify their data, which is slightly longer than is usual accounting for a slight increase in complexity of the data. This work is expected to conclude in February 2017.
- Release 1 of the Clinic Portal has now also delivered all key outputs of the project, spent considerable time in 'public beta', received its DH/GDS assessment on the 21 November 2016, and on 28 November 2016 a full pass assessment was received. The team is now preparing to go live, and preparing to de-commission the existing Clinic Portal. There is a few weeks' work to do this. This is obviously extremely gratifying for the team.

2.2. IfQ release 2

• This relates to the treatment data submission system, much awaited by clinics. It is 'Release 2' because it forms part of the Clinic Portal (Release 1). Release 2 of the Clinic Portal has been making slow but steady progress. This builds on the substantial amount of foundational work that the HFEA has completed over the last year to prepare for the development of Release 2, including the finalisation of the new Register structure, data cleansing, and internal systems infrastructure completed during Release 1.

- Despite good progress, the work has slowed due to a continued focus on finalising Release 1 at a time when the teams were anticipated to be working solely on Release 2. As a result, the risk of not delivering the required outputs in line with the current budget constraints and within this financial year have grown sharply. In response, the Programme team has conducted an exercise to re-examine programme scope and the management and support structure in order to reduce this risk. It is evident that without a further addition of resources, Release 2 of the Clinic Portal will not be substantially complete until end of Q1 2017. (See annex A)
- Having explored the scope, and rescheduled, a further option is to explore securing additional
 resources to bring the completion date forward. The Programme has been run very tightly in terms
 of resources and has absorbed several unexpected events over its course (albeit these are
 inevitable in almost any programme). Further, the team is aware that the fate of many IT-based
 transformation programmes is cost and time overruns.
- The team has focused on the costs of continued involvement of key programme resource at an estimated cost of an additional up to £90k. We continue to review the merits of this approach, and the scope for permitting this within the rules, with DH. This additional budget is expected to enhance the likelihood that all key deliverables of Release 2 are complete by April 2017.
- The Standardisation Committee for Care Information (part of NHS Digital) accreditation process for the 'UK ART dataset' and its implementation has been delayed to March 2017 accommodate dependencies with development activity that is now anticipated to take place in early 2017.

2.3. If Q data cleansing/Migration

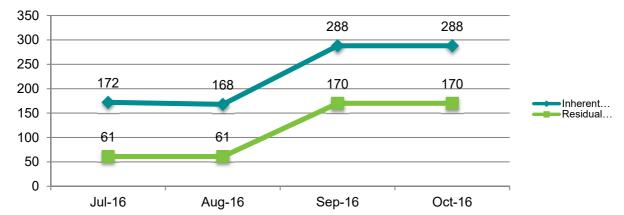
- Data cleansing work has now dealt with all 'severity 1' items that are possible to address. This is an important milestone for the IfQ Programme, as these issues would have prevented the 'data migration' process from progressing.
- Due to the continued diversion of key resource to Release 1, the data migration of the existing (cleansed) database to a new structure is behind schedule. Trial Load 1 has been run, with the team working towards running Trial Load 2 in December 2016. Assurance services for the data migration are now anticipated to provide their first assurance audit in January 2017. Data Migration is now anticipated to be finally completed in April 2017.

3. IfQ risks and issues

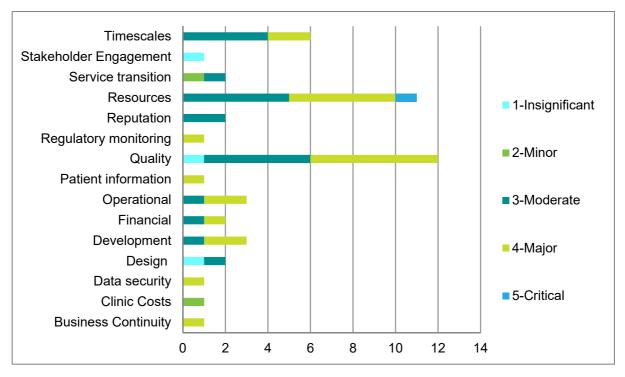
3.1. Overall update

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- The line graph below 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 significantly increased in the last month, all risks have been reviewed mitigated and escalated to SMT as per the governance processes in place and are currently being monitored.



• The major risks are associated with resources, timescales, regulatory monitoring, quality, financial, development, patient information, data security and business continuity.



4. IfQ budget

4.1. The current budget position (excluding VAT) for 2016/17 is as follows:

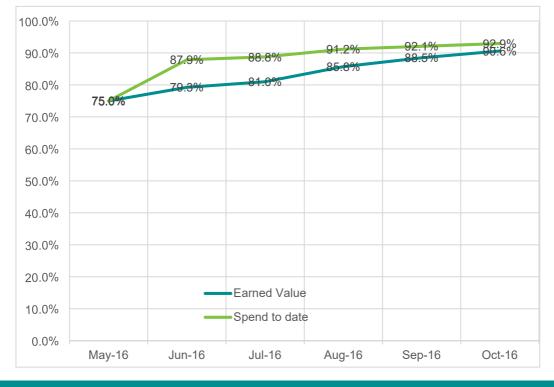
Total IfQ budget May 2016	Budget this F/Y	Planned spend	Actual to date	Monthly Variance
1,227,402	£619,025	£1,171,626	£1,158.700	£12,926
	(16/17)	(Oct 2016)	(Oct 2016)	

4.2. The delay to the programme had some financial consequences, the detailed of the proposed plan is explained above.

5. Earned value

• The spend to date has raised slightly comparing to last month and is now again joining the earned value. As we reach the end of beta and complete the live phase we expect the earned value to reach its peak reflecting the work completed.

Period	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16
Earned Value	75%	79%	81%	85.8%	88.5%	90.6%
Spend to date	75%	87%	88%	91.2%	92.1%	92.9%



6. Recommendation:

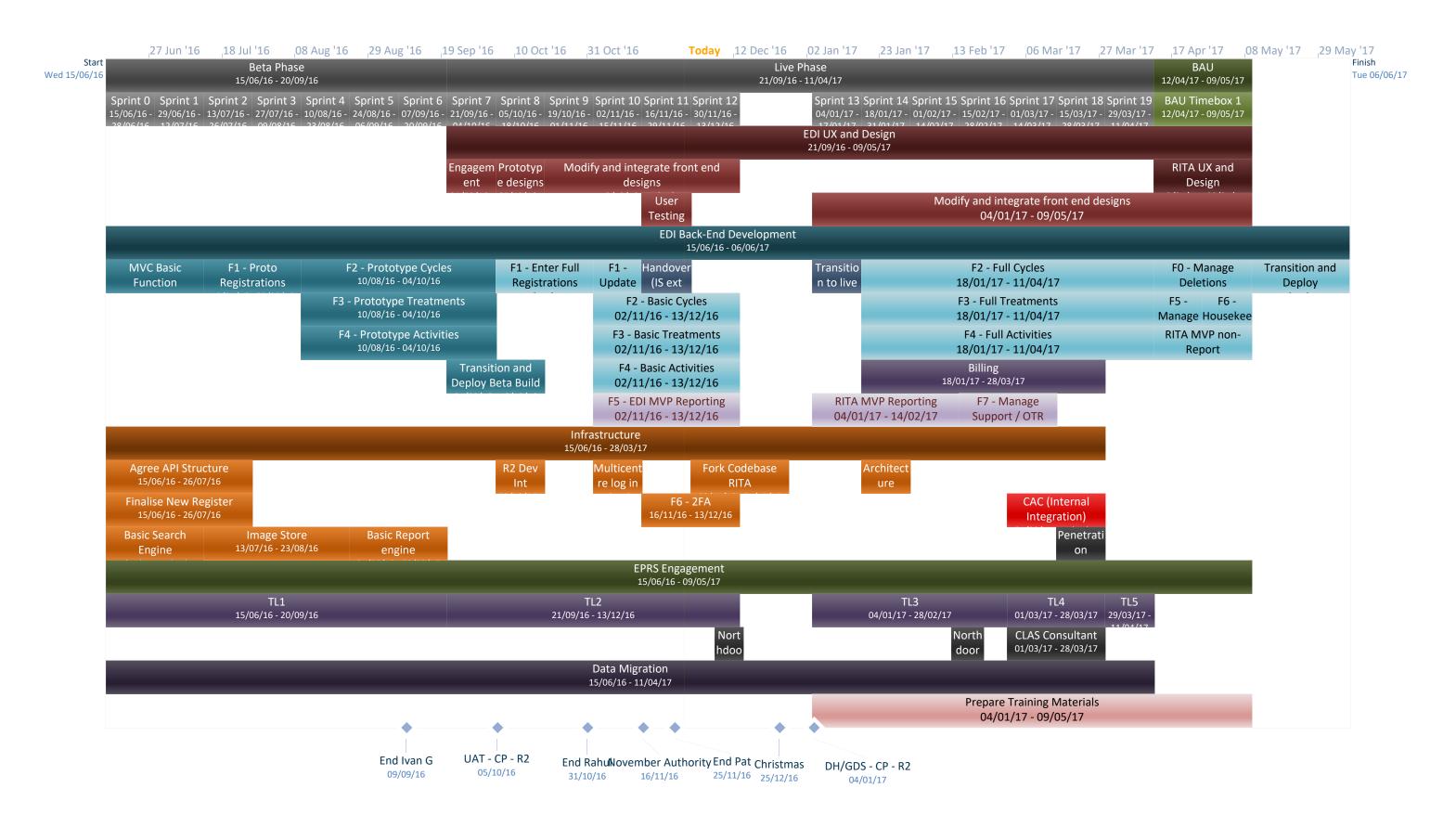
- **6.1.** The Audit and Governance Committee is asked to:
 - Note progress, risks and the budget position on IfQ.
 - Note in particular the update on the new risks.

7. Annexes:

• Annex A: Timeline for the remaining IfQ Beta phase



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Attachment - Proposed Release Plan for IfQ Release 2 Sprints



Strategic delivery:	Setting standards	☑ Increasing and informing choice	Demonstrating efficiency economy and value				
Details:							
Meeting	Audit and Governance	Audit and Governance Committee					
Agenda item	7						
Paper number	[AGC (07/12/2016) 51	5 PR]					
Meeting date	7 December 2016						
Author	Paula Robinson, Head	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 a	and operational risk mo	nitoring: 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					

2

1. Strategic risk register

Latest reviews

- **1.1.** The Authority noted the risk register at its meeting on 16 November. CMG reviewed the risk register on 23 November 2016. CMG discussed all risks, their controls, and scores. Three of the twelve risks are currently above tolerance.
- **1.2.** The current strategic risk register is attached at Annex A, and includes an overview of CMG's recent discussions about the risk register. The annex includes the graphical overview of residual risks plotted against risk tolerances.

2. Recommendation

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

HFEA strategic risk register 2016/17

Annex A

Risk summary: high to low residual risks

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

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg, $\hat{u} \Leftrightarrow \mathbb{Q} \Leftrightarrow$).

Recent review points are: Authority 6 July ⇒ CMG 7 September/AGC 21 September ⇒ Authority 16 November (noted) ⇒ CMG 23 November

- 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)

2016-12-07 Audit and Governance Committee Meeting Page 25 of 167

¹ Strategic objectives 2014-2017:

Setting standards: improving the quality and safety of care through our regulatory activities. (Setting standards - quality and safety)

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 November risk meeting

CMG reviewed the risk register and risk scores at its meeting on 23 November.

CMG updated various risks and scores, and especially discussed IfQ risks – both in the context of strategic risks and related operational risks within teams. The ongoing IfQ work alongside business as usual is undoubtedly causing pressures on resources across the organisation. This was reflected in teams' operational risk logs as well as the strategic risk register. CMG lowered the residual risk for IfQ1, improved information access, since much of the improvement in our engagement channels and information has been completed, and is available in beta. CMG raised the risk level for IfQ3, delivery of promised efficiencies. This risk relates to release two of the clinic portal, incorporating the new electronic data interchange, which is being delayed by competing resource demands from the tail end of release one (website, choose a fertility clinic, and the portal).

Coupled with IfQ delivery, we are going through a period of turnover and internal churn, as a combined result of IfQ contracted resources coming to an end (meaning that staff need to take over their roles), and other incidental turnover. Some internal interim recruitment to bridge gaps has resulted in other recruitment activity to replace or backfill the staff who are moving into different roles. Some of the turnover involves staff with good knowledge of dealing with Parliamentary Questions. Therefore, CMG raised the risk level for Data 2, incorrect data released, and Capability 1, knowledge and capability.

AGC feedback from September meeting

The committee asked the executive to give more consideration to 'plan B' for the website, in the event of an adverse JR judgment, or in the event of Red Dot (the current, outgoing content management system, which was old and unsupported) failing completely.

CMG discussed this issue at its monthly meeting in September, and confirmed that the new website was capable of being used in place of the current website, and that if we needed to deploy it before the JR was resolved, the information under dispute could be removed as a short term measure. The new website made use of a different content management system, Umbraco, which was up to date and supported, as well as more stable and reliable than RedDot. This option meant that our communications channels would remain open, and this seemed sufficient mitigation. In addition, the HFEA had a range of other channels for communicating important information to clinics and other stakeholders, including the clinic portal, social media, Clinic Focus, and email. This was felt to provide a sufficient range of options for important communications should the worst happen and access to the current website be lost.

Authority – November meeting

In the event, the Authority did not actively consider the item, but agreed to note it and submit any comments after the meeting. To date, no comments have been received.

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 the arrow indicates whether the risk is: Stable \Leftrightarrow , Rising $\hat{\Upsilon}$ or Reducing ϑ .

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.'

System-wide risk interdependencies

We also consider whether any HFEA strategic risks or controls have a potential impact for the Department or any other ALBs.

6

Risk area	Description and impact	Strategic objective linkage	Risk scores		Recent trend	Risk owner	
Regulatory	There is a risk of adverse effects on the quality and	and of care through our regulatory activities.	Inherent risk level:			$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Peter
safety of ca			Likelihood	Impact	Inherent risk		Thompson
	safety of care if the HFEA were to fail to deliver its		3	5	15 High		
RM 1: Quality and	duties under the HFE Act	F	Residual	risk level:			
safety of	(1990) as amended.		Likelihood	Impact	Residual risk		
care			2	4	8 Medium		
			Tolerance	threshold:	8 Medium		
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
Inspection/re	porting 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 – Sharon Fensome-Rimmer		At tolerance. The Head of Corporate		
		Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details. The correction of errors found is in progress and should be complete shortly.	Siobhain Ke Corrective	work in progr in November	ess for	Governance and Chief Inspector started in their pos (in March and May 2016 respectively). The Head of Corporate Governance subsequently left the HFEA September 2016, leaving a head vacancy again (now fil internally on an interim basis The need to manage recent Heads vacancies, the continuing training period ar also the action plan being implemented in connection legal parenthood consent issues, has raised the residu	
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – S	Sharon Fenso	ome-Rimmer		
Regulatory monitoring processes may be disrupted as a result of the temporary inability of Electronic Patient Record System (EPRS) providers to submit data to the new register structure until their software has been updated. This could impact performance information used in inspection notebooks and RBAT alerts		Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk by extending the release date for the EDI replacement by 3 months (IfQ release 2). Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	• •	lanning in pr - Nick Jones	•		
Monitoring fa	ilure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – S	Sharon Fenso	ome-Rimmer	risk likelihood fro unlikely) to 2 (ur	om 1 (very
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Update of compliance and enforcement policy.			through to at lea	• /	

Strate	aic	risks	
Juale	yıc	11343	

Insufficient inspectors, administrative or licensing staff	Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc. Inspection team up to complement. The new Chief	In place – Sharon Fensome-Rimmer In place – Nick Jones	On legal parenthood, a strong set of actions is in place and continues to be implemented. The issue will also be picked up
	Inspector joined the HFEA in early May 2016. Business support is operating below complement, and this will be addressed shortly, as part of addressing gaps resulting from internal recruitment and churn.	To be addressed shortly – Sharon Fensome-Rimmer	during the next review of the Code of Practice.The inspection team continue to work with colleagues in licensed
	Licensing team up to complement following earlier recruitment.	In place – Siobhain Kelly	centres where there are anomalies. The focus is on
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts	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 – Sharon Fensome-Rimmer	anomalies. The focus is on ensuring all affected patients are informed and appropriately supported.
felt across all teams.	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Sharon Fensome-Rimmer	
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	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 – Sharon Fensome-Rimmer	
particular issue).	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing rate since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer	

Some unanticipated event occurs	that Resilient staffing model in place.	In place – Sharon Fensome-Rimmer
has a big diversionary impact on resources, eg, legal parenthood of issues, or several major Grade A incidents occur at once.		In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer
	 A detailed action plan in response to the legal parenthood judgment 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 took 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. The policy team will develop a range of tools to support licensed clinics in ensuring patients provide effective consent. Range of lessons learned identified. 	In progress – Nick Jones/Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores		Recent trend	Risk owner	
Regulatory	There is a risk that the	Setting standards: improving the quality and safety	Inherent risk level:		⇔⇔⇔⇔⇔ Peter	Peter	
model	HFEA could lose authority	of care through our regulatory activities.	Likelihood	Impact	Inherent risk		Thompson
	as a regulator, jeopardising		3	5	15 High		
2.	its regulatory effectiveness, owing to a loss of public /	F	Residual I	Residual risk level:			
Loss of	sector confidence.		Likelihood	Impact	Residual risk		
regulatory authority		-	2	4	8 Medium		
autionty			Tolerance	threshold:	8 Medium		
Causes / sou	lices	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness – commentar	
Failures or we making proces	eaknesses in decision sses.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations	In place – Siobhain Kelly		At tolerance.		
		and appeals.				Although two additional ris	
		Learning from past representations and Appeal			•		
		Committee hearings incorporated into processes.			(website outages until the new beta website is live and the plar of work to address legal parenthood consent issues),		
		Appeals Committee membership maintained.	In place – Siobhain Kelly				
		Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.					
		Staffing structure for sufficient committee support.	In place S	Siobhain Kelly	1	these are being well mana	
		Decision trees; legal advisers familiar.	In place – Siobhain Kelly In place – Siobhain Kelly		and/or tolerated		
		Proactive management of quoracy for meetings.	· ·	Siobhain Kelly		risk score has not increase	
		New (ie, first application) T&S licences delegated to	· ·	Siobhain Kell		-	
		ELP. Delegations were revisited during 2016 review	· ·				
		of Standing Orders. Licensing Officer role to take	implementation September 2016 –				
		certain decisions from ELP –the documentation for					
		recording Licensing Officer decisions is complete as	Delegations	s in SOs were	e put in place -		
		at September 2016 and this process is ready for implementation.	Spring 2016	3			
-	nonstrate competence as a	Update of compliance and enforcement policy and		evised policy	-		
regulator		implementation of new policy and related		6 – Nick Jone	es / Sharon		
		procedures.	Fensome-R	limmer			

Strate	gic	risks

	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer
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 – Sharon Fensome-Rimmer
	SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer
	Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk	Staff have annual information security training (and on induction).	In place – Dave Moysen
and incident management, data security.	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below).	New work in development as at September 2016
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped.	Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen
	Guidance/induction in handling FOI requests, available to all staff.	In place – Siobhain Kelly
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
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	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 – Sharon Fensome-Rimmer
pages.	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 RedDot). This risk has informed 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 sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis 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.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Siobhain Kelly
weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer
consent).	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 – Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
lfQ	If the information for	Increasing and informing choice: ensuring that	•			⇔⇔⇔↓ Juliet Tizzard	Juliet Tizzard
	Quality (IfQ) programme	patients have access to high quality meaningful	Likelihood	Impact	Inherent risk		
	does not enable us to	information.	4	4	16 High		
Improved	provide better information and data, and improved		Residual	risk level:			
access engagement of patients will no access the im information the assist them in	engagement channels,		Likelihood	Impact	Residual risk		
	patients will not be able to		2 4	8 Medium			
	access the improved information they need to assist them in making important choices.		Tolerance	threshold:	8 Medium		
Causes / so	ources	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 requires correction before migration. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		At tolerance. The approval process has had to be tightly managed; a summary is set out below. The first Department of Health gateway review took place in November 2015 and awarded a high score to the HFEA, but the formal decision on this was still		
Reduced ability to provide for patient choice based on CaFC information as a result of EPRS inability to submit/correct data in the new register structure if they do not update their systems in time to comply. This could impact the publication of CaFC data.		Proposals on an updated IfQ delivery plan were agreed at August IfQ Programme Board, these should help address this risk. A mitigation and communication plan for this risk is in place, including ongoing dialogue with EPRS centres and providers.	s In place - Nick Jones not made by the C Digital Service bo January (a month expected). This meant that th stage initially had risk (subsequently		board until mid- th later than the beta (build) d to proceed at		

Human Fertilisation and Embryology Authority 13

Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.	In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones	Approval also carried a number of requirements and conditions which need to be added to the delivery. Owing to these delays, it was
Cost of delivering better information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the approval periods associated with required DH/GDS gateway reviews.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.	In place – Nick Jones In place – Nick Jones	necessary to extend the timeline for the private beta phase from March to June 2016. The live beta gateway approval in May was much more efficient, with approvals received within days of the assessment taking
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. GDS Beta assessment was passed on all 18 points.	In place – user research delivered end Oct 2016 – Juliet Tizzard	place. However, there were a number of requirements to address before implementing live beta. The move to public beta was delayed by an injunction brought by a licensed clinic. We successfully managed to have the injunction lifted, but it meant that we could not issue the new website to public beta testing
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. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	until August 2016. Due partly to this, the timeline was extended further, with additional work impacting on the planned start- up of release two work, and on the timelines for go live GDS assessments for both the portal and the website. The GDS go live assessment for the portal subsequently took

2016-12-07 Audit and Governance Committee Meeting Page 35 of 167

	compensate for previous and anticipated future delays.		yet been set for the go live gateway assessment for the
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	website.
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor delivery. 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. Regular contract meetings in place. This remains a challenge.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, July 2016 – Juliet Tizzard	
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. Knowledge handover with the contractors will take place.	In place – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
lfQ	HFEA Register data	Increasing and informing choice: using the data in	Inherent risk level:			$\Leftrightarrow \Leftrightarrow $	Nick Jones
	becomes lost, corrupted, or	S .	Likelihood	Impact	Inherent risk		
IfQ 2:	is otherwise adversely affected during IfQ	and research.	2	5	10 Medium		
Register data	programme delivery.		Residual I	Residual risk level:			
uala			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
			Tolerance		8 Medium		
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
	ated with data migration to e, together with records	IfQ programme groundwork focused on current state of Register. Extensive planning in place, including	In place – N	lick Jones/Da	ave Moysen	At tolerance.	
	data integrity issues.	detailed research and migration strategy.				This risk is being intensively	
•	oca) which was scheduled to	The HFEA has considered other sources of	•	successful ap	•	managed – a major focus of IfQ detailed planning work,	
•	ance on data migration has	assurance and have now sourced a supplier and is		would expe			
gone out of b	usiness.	currently going through procurement processes to appoint them.	company to begin providing assurance in September/October– Nick Jones		e particularly around data migration.		
	cleansing is needed prior to	A detailed migration strategy is in place, and data cleansing is in progress.	In place – N	lick Jones/Da	ave Moysen		
migration.	porting needs mean we later	IfQ planning work incorporated consideration of	In place – N	lick lones		-	
	rrier to achieving this, or that						
	ted level of accuracy is	Decisions about the required data quality for each					
•	data or fields which we do	field were 'future proofed' as much as possible					
not currently faccuracy.	focus on or deem critical for	through engagement with stakeholders to anticipate future needs and build these into the design.					
Reliability of e	existing infrastructure	Maintenance of desktop, network, backups, etc.	In place – D	ave Moysen			
systems – (eg backups).	g, Register, EDI, network,	core part of IT business as usual delivery.					
System interc	dependencies change / are	Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones				
notrecognise							
Benefits not r	naximised and internalised	During IfQ delivery, product owners are in place, as	as In place – Nick Jones]		

Strategic risks		Human Fertilisation and Embryology Author	rity 16
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. Knowledge handover with the contractors will take place.		

Risk area	Description and impact	Strategic objective linkage	Risk scores		Recent trend	Risk owner	
lfQ	There is a risk that the	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:		⇔₽⇔ĵ	Nick Jones	
IfQ 3: Delivery ofefficiency improvements Register data collection	HFEA's promises of	remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk		
		sector and Government.	4	4	16 High		
	and submission are not		Residual	risk level:			
promised efficiencies	ultimately delivered.		Likelihood	Impact	Residual risk		
			3	4	12 High		
			Tolerance	threshold:	9 Medium		
Causes / so	ources	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
	ceptance of changes, or not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – N	lick Jones/Ju	uliet Tizzard	Above tolerance. In September 2016, since we	
development of IfQ, and will cont Advisory Group and expert group a stakeholder group for the imple in place. Workshops were delivered with t how information will be collected portal. From beta live onwards w		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 were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.				believed that the mitigations that are in place are working effectively and mean that we are on track to achieve the promised efficiencies, we reduced the level of likelihood for this risk. This in turn brough the risk to below the tolerance threshold of 9.	
for realistic resourcing and on-time stakeholde 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				
•	ovements becomes too r resources are insufficient to Programme.	Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the	In place (July 2015) – Nick Jones In progress (September 2016) – Nick Jones		 electronic data interchange system for data submission b clinics), we increased this risl again. The delays stem from 		

	 introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs. A contingency amount was built into the budget, although this has now been used. The support function is being re-shaped and streamlined to deal with the departure in November of the release two project manager. 	In progress (November 2016) – Nick Jones	ongoing work still needed on release one, which requires the attention of the same staff who are needed for release two. In addition, some key IfQ contracted staff are coming to the end of their contracts with work still ongoing.
Delivery is delayed, causing reputational damage to the HFEA.	Ongoing communication with clinics via Clinic Focus and direct correspondence, to keep them up to date and make them aware of delays.	In place – Nick Jones	
Required GDS gateway approvals are delayed or approval is not given.	All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval. Additional sprints of work were incorporated into 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 was 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. Knowledge handover with the contractors will take place.	In place (June 2015) – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal	There is a risk that the	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:		$\uparrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Peter	
challenge HFEA is legally challenged		remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk		Thompson
	in such a way that resources are significantly	sector and Government.	5	4	20 Very high		
LC 1:	diverted from strategic		Residual r	isk level:			
Resource diversion	delivery.		Likelihood	Impact	Residual risk		
			4	3	12 High		
		-	Tolerance	threshold:	12 High		
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
Complex and	controversial area.	Panel of legal advisors from various firms at our	In place – F	Peter Thomps	son	At tolerance.	
		disposal for advice, as well as in-house Head of				Current cases: The judgment in 2015 and	
		Legal.					
		Evidence-based policy decision-making and horizon				consequences for the HFEA. Further cases are going throug court, although there have bee no cases arising from new	
		scanning for new techniques.					
		Robust and transparent processes in place for seeking expert opinion – eg, external expert	In place – Joanne Anton/Juliet Tizzard				
		advisers, transparent process for gathering					
		evidence, meetings minuted, papers available					
		online.					
HFE Act and	regulations lead to the	Panel in place, as above, to get the best possible	In place – F	Peter Thomps	son	incidents post th	
• •	there being differing legal	advice.				judgment. The H to participate in	
•	different legal advisers, that	, , , , , , , , , , , , , , , , , , , ,				legal proceeding	
	be decided by a court.	court cases, so as to clarify the position.				though the court	•
	d actions of the HFEA and	Panel in place, as above.		Peter Thomps		us to provide inf	
its committee	s may be contested.	Maintaining, keeping up to date and publishing	In place – S	Siobhain Kell	у	clarification in re	
New quide to	licensing and inspection	licensing SOPs, committee decision trees etc.				legal parenthood	d cases.
New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against		consistent decision making at licence committees supported by effective tools for committees				A judicial review hearing of one	
		Standard licensing pack completely refreshed and				discrete element of the IfQ	
		distributed to members/advisers (April 2015).				CaFC project ha	
licensing deci	isions.	Well-evidenced recommendations in inspection	In place – S	Sharon Fenso	ome-Rimmer	December. Auth	•
		reports.				in November may impact on the scope of the JR. We are	
Subjectivity of judgments means the		Scenario planning is undertaken at the initiation of	In place – Peter Thompson		advised that our case is strong;		

2016-12-07 Audit and Governance Committee Meeting Page 42 of 167

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.		however, if it were lost then it may impact on aspects of the presentation of data.
HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also interdependent risk because DH would be involved in resolving it.	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 – Siobhain Kelly	

Risk area	Description and impact	Strategic objective linkage	Risk score	S		Recent trend		
Data	There is a risk that HFEA	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$		
	data is lost, becomes	remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk			
D 1:	inaccessible, is	sector and Government.	4	5	20 Very high			
Data loss or	inadvertently released or is		Residual risk level:		, , ,			
breach	inappropriately accessed.		Likelihood	Impact	Residual risk			
			2	5	10 Medium			
			Tolerance	threshold:	10 Medium			
Causes / sou	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness – commentary		
Confidentiality	y breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen		e Moysen At tolerance.			
		Secure working arrangements for Register team, including when working at home.						
Loss of Regis	ster 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, In place (Marc is controlled through off-site back-ups and the fact that any malicious tampering would be a criminal act.		arch 2015) –	Nick Jones			
Business continuity issue.		BCP in place and staff communication procedure	In place – F	Richard Syde	9]		

	tested. A new BCP is being produced by the Head of IT to reflect the changes to this following changes to infrastructure and the office move.	Update done Dave Moysen – September 2016	
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	
Poor records management	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below). New work in development as at September 2016	New work in development as at September 2016	
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped. Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen	Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner	
Data	There is a risk that	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			$\Leftrightarrow \Leftrightarrow \Leftrightarrow \uparrow$	Juliet Tizzard	
in resp	incorrect data is released	remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk			
	in response to a	sector and Government.	5	4	20 Very high			
D 2:	Parliamentary question (PQ), or a Freedom of		Residual r	isk level:				
Incorrect data	Information (FOI) or data		Likelihood	Impact	Residual risk			
released	protection request.		3	4	12 High			
Toroadoa			Tolerance	threshold:	8 Medium			
Causes / so	burces	Mitigations	Timescale mitigations	and owner	ship of	Effectiveness -	- commentary	
Poor record	keeping	Refresher training and reminders about good records management practice.	In place – S	SMT		Above tolerance) .	
		TRIM review and retention policy implementation work – part of records management project	-	umn 2016 –	egy. RM project Dave Moysen/	controls in place for dealing with PQs and other externally		
		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 – Siobhain Kelly Implementation of actions following Epicentre audit planned and to be completed by November 2016– Siobhain Kelly In September 2016 we h			annot control es, complexity 016 we have not		
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, it is occasionally necessary 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		yet registered an unusual spik in volumes following on from recess (during which time the were no PQs). However, with the current work on the mitochondria scientific review due to be published in December, this situation is like to change in future months. W continue to closely monitor volumes.			

	PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place - Siobhain Kelly
Staff turnover resulting in the loss of corporate knowledge regarding the history and handling of PQs, in particular, resulting in slower handling and therefore potential reputational effect with the Department of Health.	Staff have access to past records to inform new responses. Recruitment in progress. Additional legal advice will be sought when beneficial. Good lines of communication with the Department so that any difficulties can be highlighted at the earliest possible point.	In place – Siobhain Kelly Recruitment in progress – Siobhain Kelly
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 – Siobhain Kelly / 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 is ongoing to address consent reporting issues	Inspections now routinely sample check a clinic's performance comparing original consent form with the detail held on the Register, to ensure it has been transcribed effectively. Where the error rate is above tolerance the clinic must undertake a full audit and carry out corrections to the Register as necessary – Nick Jones

Human Fertilisation and Embryology Authority **26**

Risk area	Description and impact	Dact Strategic objective linkage Risk scores				Recent trend	Risk owner	
Donor	There is a risk that an OTR		Inherent ris	sk level:		$\Leftrightarrow \Leftrightarrow $	Nick Jones	
conception	applicant is given incorrect	for donors, donor-conceived people, patients using	Likelihood	Impact	Inherent risk			
	data.	donor conception, and their wider families.	3	5	15 High			
DC 1:			Residual ri	sk level:				
OTR inaccuracy			Likelihood	Impact	Residual risk]		
maccuracy			1	4	4 Low			
			Tolerance	threshold:	4 Low			
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	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 lov for this risk).		
		Audit programme to check information provision and accuracy.	In place – Nick Jones 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.						
Issuing of wrong person's data.		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 is In place – Nick Jones					
		OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.						
			1			7		

Human Fertilisation and Embryology Authority 2

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner	
Donor There is a risk that		Setting standards: improving the lifelong experience Inf		Inherent risk level:			Nick Jones	
conception	inadequate support is	for donors, donor-conceived people, patients using	Likelihood	Impact	Inherent risk			
	provided for donor-	donor conception, and their wider families.	4	4	16 High			
DC 2:	conceived people or donors at the point of		Residual ri	isk level:				
Support for OTR	making an OTR request.		Likelihood	Impact	Residual risk			
applicants			3	3	9 Medium			
approarte			Tolerance	threshold:	9 Medium			
Causes / so	urces	Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary		
Lack of coun applicants.	selling availability for	Counselling service established with external contractor in place.	In place (June 2015) – Nick Jones			At tolerance.		
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 returning to work from 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).				The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on uptake and the delivery experience. Reporting to the		
Risk of inade	quate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones			Authority will oc	•	
		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			during the pilot period, and the first such report was provided to the July Authority meeting.		

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner	
Financial	There is a risk that the	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			$\Leftrightarrow \Leftrightarrow $	Richard	
viability HFEA could significantly	remains demonstrably good value for the public, the sector	Likelihood	Impact	Inherent risk		Sydee		
	overspend (where significantly = 5% of	and Government.	4	4	16 High			
FV 1: significantly = 5% of budget, £250k)		Residual	risk level:	1				
expenditure			Likelihood	Impact	Residual risk			
			3	3	9 Medium			
				e threshold:				
Causes / so	purces	Mitigations	Timescal mitigation	e and owne າຣ	rship of	Effectiveness -	 commentary 	
Fee regime n	nakes us dependent on	Activity levels are tracked and change is discussed	Monthly (o	on-going) – N	lorounke	At tolerance.		
sector activity levels.		at CMG, who would consider what work to deprioritise and reduce expenditure.	Akingbola			2015/16 achieved a small under-spend but risk of additional legal costs remains.		
		Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Morounke Akingbola			The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for		
EPRS suppliers may not make required changes to their systems in line with IfQ data submission mechanism (EDI, Register) changes. Clinics using these suppliers would be unable to provide treatment data leading to deferral of fee payment since we could not bill centres for treatments. GIA funding could be reduced due to changes in Government/policy		Proposals were made to August IfQ Programme Board for adjustments to the IfQ schedule which would impact when this risk is likely to be felt. Further discussions are needed with Finance to understand the scale of the potential impact of this risk and to plan for an effective mitigation to secure cash flow. These discussions will be ongoing while IfQ release 2 develops further.	Ongoing -Nick Jones has now bee following Tre February 20 help secure s going forward e It is too early whether this			has now been ir following Treasu February 2016. help secure suff going forward. It is too early for whether this red	asury approval in 6. This should ufficient funds for us to tell educes this risk	
		A good relationship with DH Sponsors, who are well informed about our work and our funding model.	-	meetings (or Akingbola	n-going) —	further. The situation will be clearer following IfQ implementation.		
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December Akingbola	r annually – N	Morounke	The potential impact of the IfQ		
		Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.			kingbola	risk here, related to EPRS suppliers and the impact on treatment fees, is not yet fully		

Human Fertilisation and Embryology Authority **29**

Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	understood. It is also clear that this would not potentially impact	
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 – Morounke Akingbola Monthly – IfQ Programme Board	the organisation until 2017, so the risk level is not affected at this time. Meanwhile, the IfQ team will work together closely with the finance team and the	
Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Wilhelmina Crown	 mitigation for this risk will be updated once more information is gathered and a plan agreed. We will keep this under review. 	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola		

30

Risk area Description and impact				Risk scores			Risk owner		
Capability There is a risk that the HFEA experiences				Inherent risk level:			Peter		
		remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk		Thompson		
C 1:	unforeseen knowledge and	sector and Government.	4	4	16 High				
Knowledge capability gaps, and threatening delivery of	threatening delivery of the		Residual r	isk level:					
capability	strategy.		Likelihood	Impact	Residual risk				
oapability			4	3	12 High				
			Tolerance	threshold:	6 Medium				
Causes / so	urces	Mitigations	Timescale mitigations	and owner	rship of	Effectiveness -	- commentary		
-	r, sick leave etc. leading to	People strategy will partially mitigate.	Done – Ma	y 2015 – Ra	chel Hopkins	Above tolerance			
temporary knowledge loss and capability gaps. 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. Poor morale leading to decreased		Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.				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			
		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 Hopkinsobviously managing also mean fluctuation ensuring k are succes handed ov Since the organisation resilience, retain a low this risk.In place – Peter Thompsonorganisation resilience, retain a low this risk.In place – Peter ThompsonOur Head 2016, in L Compliance (in March respective Head of C subsequel 2016, and						
		Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.				are successfully handed over.	knowledge and skills ssfully nurtured and/or ver. HFEA is a small		
		Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.				organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level for			
		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.							
		Engagement with the issue by managers. Ensuring							

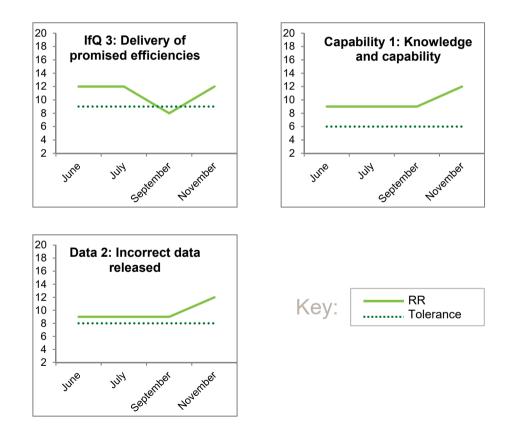
Strategic risks		Human Fertilisation and Embryolog	y Authority 31	
effectiveness and performance failures.	managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.		internally on an interim basis, with associated recruitment activity needed in the team.	
	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	Several staff (including end of contract IfQ staff) have left the organisation recently, with two more establishment staff	
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge	for particular teams steps, and when applicable of personal role impacts and choices. year.		leaving before the end of the year. This means we are currently in a period of turnove and internal churn, with some	
loss and low performance.	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	/ if people are 'at risk'.		
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	ongoing for both release one and release two.	
	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	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but	Issue for consideration when applications commence – Juliet Tizzard		

Strate	aic	risks

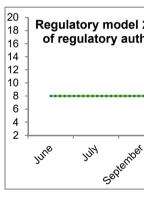
need to increase both capability and	will not be known for sure until later. No controls can	
capacity in this area, depending on	yet be put in place, but the potential issue is on our	
uptake (this is not yet certain).	radar.	

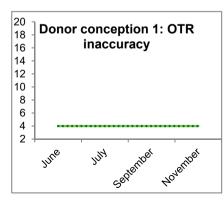
Tolerance vs Residual Risk:

Risks above tolerance



RR **Risks at tolerance** Key: Tolerance 20 20 20 20 Legal challenge 1: Data 1: Data loss or Donor conception 2: Financial viability 1: 18 18 18 18 Resource diversion Support for OTR breach Income and expenditure 16 16 16 16 applicants 14 14 14 14 12 12 12 12 10 10 10 10 8 8 8 8 6 6 6 6 4 4 4 4 2 2 2 2 September November November September November September September JUN June June November JUN June June MUL JUN 20 20 Regulatory model 1: IfQ 1: Improved 18 18 quality & safety of care information access 16 16 14 14 12 12 10 10 8 8 6 6 4 4 2 2 September November September November JUN June JUN June







Risk below tolerance

None.

Human Fertilisation and Embryology Authority **35**

Scoring system

The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

Likelihood: Impact:	1=Very 1=Insig	•	-	•	3=Possible 3=Moderate	4=Likel 4=Majo	-		
					Ris	k scori	ing matrix		
			5.Very high	5	10		15	20	25
			5.Vel	Medium	Mediu	m	High	Very High	Very High
			4. High	4	8		12	16	20
			4.	Low	Mediu	im	High	High	Very High
		Inpact	3. Medium	3	6		9	12	15
		<u>u</u>	3. ≤	Low	Mediu	m	Medium	High	High
			Low	2	4		6	8	10
			N'	Very Low	Low	'	Medium	Medium	Medium
			1. Very Low	1	2		3	4	5
			1. <6	Very Low	Very L	ow	Low	Low	Medium
			x Score	1. Rare (≤10%)	2. Unlik (11%-33		3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
			elihood				Likelihood		

Health Group Internal Audit

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arm's length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

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

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

Our findings and recommendations:

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

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

INTERNAL AUDIT PROGRESS REPORT DECEMBER 2016

For further information please contact: Cameron Robson - 01132 54 6083 1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

Health Group Internal Audit

CONTENTS

PAGE

1.	Introduction	1
2.	Progress against 2016/17 Internal Audit Plan	1
	2.1 Status of agreed plan	1
	2.2 Summary of reports issued since the last Audit and Governance Committee	4
	2.3 Follow up work	4
	2.4 Impact on Annual Governance Statement	4
	Appendix 1: Report Rating Definitions	5
	Appendix 2: Limitations and responsibilities	6

Health Group Internal Audit

HFEA Internal Audit Progress Report December 2016

1) Introduction

This paper sets out the progress in completing the 2016/17 Internal Audit Plan since the last meeting of the Audit and Governance Committee in September 2016.

2) Progress against 2016/17 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2016/17 Audit Plan:

Reviews per	Audit scope	Status	Findings	Findings			Audit	Actual
201/17 IA plan			High	Medium	Low	report rating	days per plan	audit days
Income generation process Quality and efficiency of revenue data	These reviews were merged into one as they both focused on the revenue process. We mapped the income generation and invoicing process from receipt of the electronic treatment forms from clinics to the raising of an invoice. In addition, we evaluated the design and operating effectiveness of controls over the data being used within the income process, considering the mechanisms to ensure that the original source data is of appropriate quality to support invoicing and the checks in place to ensure that integrity of data is maintained during the income and invoicing process. Management also requested that we review the risk management process in place in	Final report issued September 2016	0	1	4	Moderate	4	9

Reviews per	Audit scope	Status	Findings			Overall	Audit	Actual
201/17 IA plan			High	Medium	Low	report rating	days per plan	audit days
	relation to the transition of income processing to the Integrated Clinic Portal.							
Information standards	Initially this review was to be aimed at providing assurance over the application of a new policy on the publication of patient oriented information on the HFEA's website. However, NHS England are assessing the information governance arrangements of the patient oriented information to ensure published information is up to date and accurate. Following a scoping meeting with the Audit Sponsor and to avoid duplication, it has therefore been agreed that our work should focus on the application of the policy to corporate information and information provided to clinics.	Scoping meeting held and date for review in January agreed.					5	0.25
Board effectiveness	This review has been a high level review to assess the Board effectiveness via a self- assessment survey and follow-up interviews.	Draft report issued	0	0	2	Not rated	6	6
Management of Cyber Penetration threat	Following scoping discussions with the Head of IT, it has been agreed that this work will be focussed on identifying security risks relating to a cloud environment and identifying any gaps in HFEA's security control framework.	Draft terms of reference issued. Fieldwork to be undertaken in December 2016.					5	0.75
Assurance	We will deliver an assurance mapping	Scope to be				Not	3	0

Health Group Internal Audit

Reviews per			Findings			Overall	Audit	Actual
201/17 IA plan			High	Medium	Low	report rating	days per plan	audit days
mapping	workshop, having prepared a controls assessment framework for the area under review and agreed that with management. The area to be mapped will be agreed in consultation with management and the Audit and Governance Committee. There is the potential for this to be directed towards further considerations on Cyber Security, depending on the outcome of the initial work in that area as outlined above.	determined.				applicable – no rating will be provided as it is workshop		
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; Resourcing and risk management; and Contingency. 	Ongoing	Not applical	ble		Not applicable	7	5
Contingency							5	-
	То	tal Findings:	0	1	4	-	40	
						Total days	40	21

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

Since the last Audit and Governance Committee in September 2016 we have issued the report on Board Effectiveness.

2.3 Follow-up work:

The HFEA performs its own follow-up work, reviewing the status of agreed audit actions and reporting progress to the 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 former Director of Finance and Resources.

No high priority actions have resulted from us undertaking the 2016/17 audit reviews to date and none were outstanding at the start of the year from previous audit work. Accordingly, there have been no outstanding high priority recommendations requiring internal audit follow-up work in the year to date.

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 priority, 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 2016/17 audit plan and all actions relating to previous high priority issues have been completed. Accordingly, there are no matters arising from our work to date that we believe may require reference in the AGS.

Appendix 1 – Report Rating Definitions

Risk Ratings of individual findings:

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

Ratings of audit reports

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

Appendix 2 - 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 guarante e 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.



Human Fertilisation and Embryology Authority

Audit planning report on the 2016-17 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE December 2016

http://www.nao.org.uk/



Contents

We have pleasure in setting out details of our proposed financial statement audit approach for the Human Fertilisation and Embryology Authority (HFEA) for the year ending 31 March 2017.

Financial statement audit plan	3
How are we going to conduct the audit – approach and team	4
When do we plan to complete this work – timetable and fee	5
Our audit approach	6
Significant financial statement risks	8
Risk factors and matters to keep in view	10
Follow up to recommendations we made in the previous year	11
Appendix 1: Fraud matters	12
Appendix 2: Future accounting standards	13
Appendix 3: Guidance on Governance	14
Appendix 4: Key messages from our wider work	15
Appendix 5: Quality assurance in NAO audits	17

We have prepared this report for HFEA's sole use although you may also share it with the Department of Health. You must not disclose it to any other third party, quote or refer to it, without our written consent and we assume no responsibility to any other person.



Financial statement audit plan

What work will we complete?

Our audit, which will be conducted in accordance with International Standards on Auditing (UK and Ireland) (ISAs (UK and Ireland)), will enable the C&AG to give an opinion on the financial statements.

Further details of the scope of the audit, as well as our respective responsibilities in relation to this engagement, have been set out in our Letter of Understanding issued on 23 October 2013 which has previously been separately provided to the audit committee.

Member of the Audit Committee are invited to consider and discuss:

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





How are we going to conduct the audit?

Risk based approach

We plan our audit of the financial statements to respond to the risks of material⁽¹⁾:

- misstatement to transactions and balances; and
- irregular transactions.

The auditing standards ISA 240 state that there is a significant risk in all entities for:

- Management override of controls to perpetrate fraud; and
- Presumed risk of fraud arising from revenue recognition.

Further details of these risks and our response are set out on pages 8-9.

In addition to these significant risks we have also identified one 'risk factor' i.e. a risk that is not expected to represent a material misstatement in the year but we would like to keep in view in our audit work (details on page 10):

• HFEA's judicial review case

Our team

The details of the key audit staff who will complete this audit are:

- George Smiles, Engagement Director
- Sarah Edwards, Engagement Manager
- Payal Patel, Engagement Lead for audit and will complete the on-site work.

^[1] A matter is material if its omission or misstatement would reasonably influence the decisions of users of the financial statements. The assessment of what is material is a matter of the auditor's professional judgement and includes consideration of both the amount and the nature of the misstatement. Further information on materiality is included on page 6. 2016-12-07 Audit and Governance Committee Meeting Page 70 of 167

When do we plan to complete this work?

Timetable

The timetable comprises an interim visit week commencing 23 January 2017 for 1 week and a further second interim visit week commencing 13 March 2017 for 1 week and a final visit commencing 30 May 2015 for 2 weeks with certification planned for start of July 2017. Further details are provided in the table below.

Date	Activity	delivering good
September/ October 2016	Planning: review HFEA's operations, assess risk for our audit and evaluate the control framework.	and explanationmaking staff av
January 2017	Interim audit work: test expenditure and income.	If significant issues
February 2017	Update to audit committee on interim work.	perform additional v in our fee. We will d
30 May 2017	Receipt of 1 st draft account	carrying out addition
May 2017	Final audit work: test expenditure and income and significant balances and disclosures.	
June 2017	ISA 240 report including management letter: compromising audit completion report and management letter to be presented to the audit committee.	
July 2017 5	Certification: seek representations and C&AG issues 2016-12-07 Audit and Governa	ance Committee Meeting Page 71 of 167 OFFICIAL

Fees

The fee for the audit is £28,000 (PY £27,500).

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

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

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



Our audit approach

Our assessment of materiality

For the purposes of determining whether the financial statements are free from material misstatement or irregularity we consider whether: 1. the magnitude of misstatement; or
1. the magnitude of misstatement; or
2. the nature and cause of misstatements (e.g. because of the sensitivity of specific disclosure or regularity requirements)
would influence the users of the accounts.
In line with generally accepted practice, we have set our quantitative materiality threshold based on our judgement of a range of factors including historic error and level of expenditure.
Other elements of the financial statements that we consider to be more sensitive to users of the accounts will be assessed using a lower qualitative materiality threshold. These elements include the remuneration report disclosures; the losses and special payments note; our audit fee.
We apply the concept of materiality in planning and performing our audit and in evaluating the effect of misstatements on our audit and on the financial statements. As the audit progresses our assessment of both quantitative and qualitative materiality may change.
For reporting purposes, we will treat any misstatements below £2,500 as "trivial" and therefore not requiring consideration by the Audit Committee.
Please note that this is a separate threshold to our consideration of materiality as described above. It is materiality, not the error reporting threshold, which is used in forming our audit opinion.



Our audit approach

Other matters

Independence	We comply with relevant ethical requirements regarding independence and have developed important safeguards and procedures in order to ensure our independence and objectivity.
	Information on NAO quality standards and independence can be found on the NAO website: <u>http://www.nao.org.uk/about-us/role-2/what-we-do/audit-quality/audit-quality/</u>
	We will reconfirm our independence and objectivity to the Audit Committee following the completion of the audit.
Management of personal	During the course of our audit we have access to personal data to support our audit testing.
data	We have established processes to hold this data securely within encrypted files and to destroy it where relevant at the conclusion of our audit. We confirm that we have discharged those responsibilities communicated to you in the NAO's Statement on Management of Personal Data at the NAO.
	The statement on the Management of Personal Data is available on the NAO website: http://www.nao.org.uk/freedom-of-information/publication-scheme/how-we-make-decisions/our-policies-and- procedures/policies-and-procedures-for-conducting-our-business/
Using the work of	We liaise closely with internal audit through the audit process and seek to take assurance from their work where their objectives cover areas of joint interest.
internal audit	Following our review of internal audit's plans we will consider the outcome of the planned report for the Information for Quality capital expenditure project.



Significant financial statement risks (1)

Management override of controls (ISA 240)

Key features

Under International Standards on Auditing (UK and Ireland) 240 The Auditor's
responsibilities relating to fraud in audit of financial statements there is a presumed risk
of management override of controls in all organisations, We are required to assess the
risk of material misstatements arising from management override, in particular in relation
to significant or unusual transactions, bias in accounting estimates and journals.

Change from prior year

Audit response

Same approach to meet ISA 240 requirements

Substantive

- · Review of significant transactions;
- Journal sample testing
- Consider the assumptions underpinning each of the key estimates in the accounts (i.e. provisions and impairments).



Significant financial statement risks (2)

Revenue Recognition	 Key features Under International Standards on Auditing (UK and Ireland) 240 The Auditor's responsibilities relating to fraud in audit of financial statements there is a presumed risk of fraud in revenue recognition, albeit rebuttable in all entities. As HFEA's main income stream is treatment fees from clinics; there is a risk that not all treatment income is reported to HFEA.
Change from prior year	Audit response
Same approach to meet ISA 240 requirements	 Substantive and controls testing A substantive analytical procedure will be performed by using the invoices sent to clinics. We will be assessing the work that the Compliance Audit team carry out on their visits to clinics. This is the control we will seek to rely for income, in order to provide us with assurance that the data provided by the clinics to HFEA is complete and accurate.



Risk factors

Risk factors represent developments or ongoing issues in HFEA that are potential risks to the financial statements or the C&AG's audit opinion. They differ from significant risks as they do not currently require a specific audit response other than already covered by our standard audit approach.

HFEA's judicial review case

HFEA is subject to a judicial review relating to the IfQ project. A risk exists, depending on the outcome of the JR that the IfQ project may be delayed which could increase costs relating to this project and , more widely, may damage HFEA's reputation. We await the outcome of the JR.

Other Matters

These are issues that we do not anticipate giving rise to a risk to the financial statements or the C&AG's opinion but may have an impact on HFEA.

Information for Quality expenditure

HFEA need to ensure that any expenditure relating to IfQ that is capitalised in year meets the recognition criteria as set out on IAS 38 intangible assets.

New Finance Director

The new FD has recently taken up post and, as with any change of personnel at a senior level, there is a loss of corporate knowledge particularly when a long-standing member of staff leaves. We will consider the actions that HFEA takes to ensure that there is no consequential adverse impact on the operation of the overall controls environment following this change in personnel.

Brexit

All EU laws to be transposed into UK law, and so we do not expect this to affect our audit. However due to the recent announcement on timing that Article 50 is to be triggered in March 2017, management will need to consider any impacts on the Financial Statements and disclosures after March 2017.



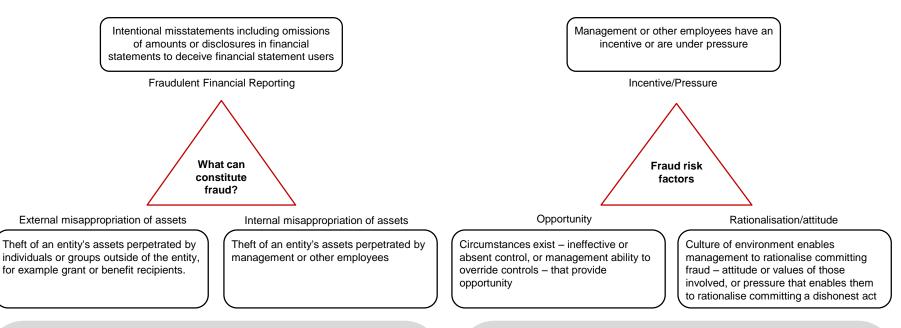
Follow up to recommendations we made in the previous year

Title	Area	What was the recommendation?	Response/Progress	Status
Capitalisation of expenditure	Intangible Assets	Management need to ensure they only capitalise what is permitted under Accounting Standards IAS 38. This consideration should be ongoing, for instance the treatment of maintenance/ enhancement of systems,	HFEA are in the process of conducting a piece of work on the IfQ expenditure and hope that this will be completed by the time the NAO attend for their interim visit.	Ongoing



Appendix 1 - Fraud matters

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



ISA inquiries

Our inquiries relate to your oversight responsibility for:

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

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

Audit approach

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

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

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

2016-12-07 Audit and Governance Committee Meeting Page 78 of 167

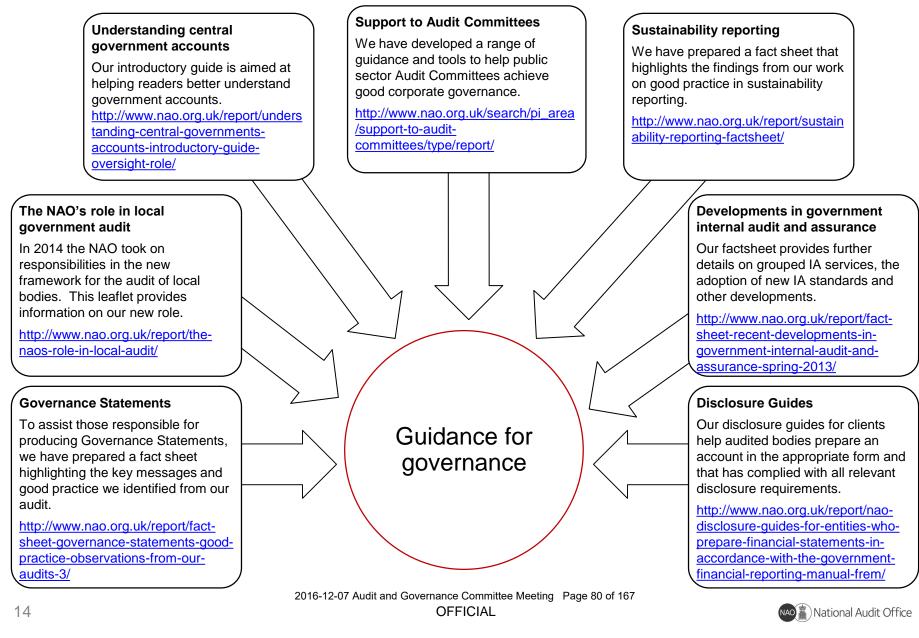


Appendix 2: Future accounting standards (not specifically relevant to HFEA, for information only)

IFRS 9: Financial instruments	Replacing IAS 39, IFRS 9 aims to simplify financial instrument accounting and more closely align accounting and practices with how instruments are used in the business. Specifically:			
Effective from 2018-19	classification and measurement rules have been adapted to incorporate a more principles-based model with fewer categories – with measurement at fair value except for some debt instruments depending on			
IASB project summary	 characteristics; impairments due to changes in credit quality will result in earlier remeasurement, on an 'expected loss' basis; and hedge accounting will become more principles-based, with the elimination of the 80-125% effectiveness test 			
	and a greater reliance on assessing the purpose of transactions within businesses' risk management strategies.			
IFRS 15: <i>Revenue from</i> <i>Contracts with</i> <i>Customers</i>	IFRS 15 aims to replace a significant amount of existing guidance and reduce inconsistencies by setting a new principles-based Standard. The step by step process in IFRS 15 involves identifying contractual performance obligations, allocating the transaction			
	price to those obligations, and recognising revenue only when those obligations are satisfied. Impact for most central			
Effective from 2018-19	government clients will be limited.			
IASB project summary				
IFRS 16: Leases	IFRS 16 eliminates the operating/finance lease distinction and imposes a single model geared towards the recognition			
Effective from 2019-20	of all but low-value or short term (<12m) leases. The proposals arise partly from the IASB's view that:			
IASB project summary	 disclosures around operating lease commitments have lacked prominence and tended towards understatement; and 			
2013 exposure draft (now superseded by issued Standard)	 even in leases where the underlying asset is not acquired for its whole useful life, the lessee nevertheless acquires an economic right to its use, along with obligations to make good on minimum lease payments. 			
Decisions remain for HM Treasury on if or how to interpret/adapt this Standard for FReM bodies, and what allowances to make for transitional relief.	These will now be recognised on the Balance Sheet as a 'right of use' asset and lease liability . The lease liability will be measured at initial recognition as the value of future lease payments, with the asset additionally including any initial direct costs incurred by the lessee, plus an estimate of any dismantling/restoration costs. Subsequent measurement of both asset and liability will need to respond to any changes in lease terms, and the accounting for the asset can be on a <i>cost less depreciation and impairment</i> model or a <i>revaluation (</i> fair value) model. Successful transition will depend on organisations pro-actively capturing additional information about leases – new and existing – which they expect to remain in place at 1 April 2019, especially regarding future minimum lease payments. Organisations should also ensure systems for capturing cost information are fit for purpose, can respond to be updated annually based on prevailing indices.			



Appendix 3: Guidance for Governance (not all relevant for HFEA)



Appendix 4 - Key messages from our wider work

	The UK government detected fraud figure of 0.02% of expenditure is significantly lower than some estimates
	of 3-5% in the EU and US. While comparisons should be treated with caution, this suggests there could be
	significant fraud and error which is unreported or undetected and losses which are not being adequately
	addressed.
Cross Government	
Fraud Landscape	Concludes that, overall, the Government lacks a clear understanding of the scale of the fraud problem and
Review	departments vary in their ability to identify and address fraud risks. The data that does exist is patchy,
	inconsistent and of variable quality. The most comprehensive data relates to areas of known risk - tax credit
(February 2016)	and benefit fraud - but information across the rest of government is clearly incomplete. It is difficult to
	formulate solutions if the scale and nature of the problem is unknown.
	www.nao.org.uk/report/fraud-landscape-review

	NHS England's spending on the 146 specialised services it offers has increased at a much greater rate than
	other parts of the NHS. There is no overarching service strategy and increasing demand for effective but
The	expensive new drugs is adding to existing financial pressures. Governance arrangements for specialised
Commissioning of	commissioning are ineffective and there are concerns over the transparency of decision making.
Commissioning of	
Specialised	Concludes that if NHS England is unable to control spending on specialised services this will affect its ability
Services in the NHS	to resource other services, such as primary care. Without consistent information from all providers on costs,
	access to services and outcomes, it cannot manage the ongoing pressure on its budget for specialised
(April 2016)	services, make effective strategic decisions or gain assurance that its objectives are being met.
	www.nao.org.uk/report/the-commissioning-of-specialised-services-in-the-nhs

2016-12-07 Audit and Governance Committee Meeting Page 81 of 167

National Audit Office

Appendix 4 - Key messages from our wider work

Department-'	We looked at and compared how four departments oversee and manage the relationships with their arm's- length bodies (ALBs). These departments are BIS (now BEIS), MoJ, Defra and DCMS. There is no single list of ALBs across government nor a common understanding of when ALBs should be
Departments'	used or what type of ALB is most appropriate for particular circumstances. Although the Cabinet Office is
oversight of arm's- building on its Public Bodies Reform Programme and taking further steps to address the	
length bodies: a	prevailing inconsistency hampers a coherent approach to overseeing ALBs that is consistent with their purpose.
comparative study	
(July 2016)	To get the best from ALBs we recommend the Cabinet Office works with departments to improve understanding of the costs and benefits of different approaches, and develop and implement a guiding framework for effective oversight. We propose a principles-based approach. We do not argue for a one size fits all approach, but it's clear that the broad range of approaches cannot all be equally good at getting value from ALBs.
	www.nao.org.uk/report/departments-oversight-of-arms-length-bodies-a-comparative-study
Protecting	Protecting information while re-designing public services and introducing new technology to support them is complex challenge for government. The responsibility for protecting information held by government from unauthorised access or loss must increasingly be balanced with the need to make information available to other organisations, users and citizens via new digital services.
information across government	We considered the effectiveness of government in managing the risk of information loss, including cost, breach reporting and deployment of the right skills. We found that some departments have made significant improvements in information governance, but most have not given it the same attention as other forms of
(September 2016)	governance. We also found that few departments have the skills and expertise to risk manage their information by themselves and will continue to depend on effective support from the centre of government. But at present too many bodies, with overlapping responsibilities, operate in the centre of government, confusing departments about where to go for advice. Although the new National Cyber Security Centre (NCSC) will bring together much of government's cyber expertise, wider reforms will be necessary to further enhance the protection of information.
	www.nao.org.uk/report/protecting-information-across-government/

www.nao.org.uk/report/protecting-information-across-government/



Appendix 5: Quality assurance in NAO audits

Uncompromising on professionalism

- Applying professional auditing standards
- Committed to recruitment and development of professionally qualified and experienced auditors
- Two stage review of all audit work
- Internal post-audit quality assurance reviews

Risk-based and proportionate

- Range of internal review and consultation processes available for higher risk issues
- Training and knowledge-sharing initiatives to promote consistency of approach across audits

Audit quality at the NAO

Responsive

- Committed to positive client relationships
- Client feedback survey on all financial audits
- Moderated feedback on a selection of clients annually

Independent

- Applying the highest ethical standards and approach in our work
- External review of compliance with professional standards by the Audit Quality Review team of the FRC
- Annual survey of MPs as our key stakeholders and users of financial statements





Implementation of Audit Recommendations – Progress Report

Strategic delivery:	☐ Setting standards	Increasing and informing choice	Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance C	committee	
Agenda item	10		
Paper number	[AGC (07/12/2016) 518	WEC]	
Meeting date	7 December 2016		
Author	Wilhelmina Crown - Finance & Accounting Manager		
Output:			
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 date	As noted in the enclosed summary of outstanding audit recommendations		
Organisational risk	□ Low	Medium	🗆 High

Report

- **1.1.** This report presents an update to the verbal briefing given to this committee at its meeting in September 2016.
- **1.2.** These recommendations were received and agreed for follow up action by this committee in September.
- **1.3.** Recommendations are classified as high (red), medium (amber) or low (green).
- **1.4.** Three new recommendations were received with one noted as medium and two as low.
- **1.5.** Recent updates received from Action Managers are recorded under a November 2016 heading in this document.
- **1.6.** Two recommendations are noted as completed with one due to be completed by end December 2016.

Recommendation

AGC is requested to review the enclosed summary of recommendations and updated management responses and to advise whether they have any comments or queries in respect of them.

Annex 1: Summary of Recommendations

Recommendation Source	Status / Actions	2015/16	Total
Internal – DH Internal Audit	Complete	2	2
	To complete	1	1
COUNT		3	3

FINDING/RISK

Recommendation

Human

Agreed actions / Progress Made

Owner/Completion date

2015/16 – INTERNAL AUDIT CYCLE

INCOME GENERATION

Follow-up procedures with those clinics that do not submit activity data could be more robust.				
Clinics that have not submitted data to the HFEA for a period longer than one month are identified by the Head of Information and the Senior Network Analyst on a monthly basis. However, this is primarily to allow accurate accruals and deferrals of income to be made rather than to enable HFEA to identify clinics that may be having issues in submitting data. Some follow up is performed if a particular issue is noted, but this is on an ad hoc basis and there is no formalised process to follow- up all clinics to identify whether data should have been received.	The monthly report of clinics which have not submitted data for one month should be used as a basis to ensure that clinics have been, or are, contacted or otherwise checked to identify the reasons and any action that HFEA may need to take to resolve any issues. The reasons for any problems that clinics are experiencing should be documented and progress monitored. The record could be cross referenced to the IT support system ticket number(s) where the cause is an IT matter	Using the monthly report of clinics which have not submitted data for a month, a document will be created listing the clinics and the problems they are experiencing, the person responsible for resolving the issue and the status of the problem. This will be discussed in a monthly meeting with actions designated to appropriate individuals to resolve them and to contact the clinic as necessary. <u>November 2016 update:</u> Check has already been done for November. The appropriate Register SOP will be updated prior to December's, to enable monthly checking.	Head of Information Date: September 2016 billing run End December 16	
2. Review of the error report which identified It is our understanding that the Finance Manager generates an error report ("uspReport_ABSMissingInvoiceImages) on a quarterly basis to identify any missing invoices. However, this process is not evidenced. In addition, we suggest consideration be given to whether this control might more effectively be performed on a monthly basis so any omissions can be identified on a more timely basis.	s missing invoices is only performed quarter Whilst we recognise that the last issue to be identified from the report was in February 2014, we suggest that consideration be given to generating and reviewing the report on a monthly basis to ensure that any missing invoices are identified in a timely manner. Evidence of the review should also be retained.	The exception report will be run on a monthly basis and the evidence retained. November 2016 update The action has been implemented and the exception report now forms part of the monthly billing process. Recommendation Complete	rd. <i>Finance & Accounting Manager</i> Date: August 2016 billing run COMPLETE	

ა.	Action plans in response to the risks associated with transition of the billing process to the new Integrated Clinic Portal have yet to be
	identified.

Risks relating to the Information for Quality (IfQ) programme are being identified and captured in a Risk Log, with specific owners, action plans and timelines, and the risks are discussed monthly during the IfQ programme board meetings. At the time we started our review, no risks specifically relating to the transition of the income process had been included within the log, but the Head of Information did add them during the course of our review. As with other risks, they were then due to be discussed at the next monthly board meeting where relevant action plans should be identified. Consequently, at the time of our review there were no plans in place to respond to these specific risks and while there is a formal process to ensure that this is addressed it is important that this is completed promptly to ensure actions are in place in good time to mitigate the risks that HFEA faces.	Whilst we recognise that there is a formal process in operation to ensure that risks are responded to and that the new Integrated Clinic Portal is not due to be implemented until the end of October, management should ensure that appropriate action plans are identified and implemented on a timely basis.	the transition of the income process will be identified during the next board meeting.	Head of Information Date: September 16 board meeting COMPLETE
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Cyber Security - Information Security & Testing

Strategic delivery:	☐ Setting standards	Increasing and informing choice	X	Demonstrating efficience economy and value			
Details:							
Meeting	AGC						
Agenda item	11						
Paper number	[AGC (07/12/2016) 51	9 DM]					
Meeting date	07 December 2016						
Author	David Moysen, Head o	of IT					
Output:							
For information or decision?	For information						
Recommendation	The Committee is ask	ed to note this report.					
Resource implications	As outlined						
Implementation date	Ongoing						
Communication(s)	Ongoing						
Organisational risk	□ Low	□ Medium		🗷 High			
Annexes							
Annex A - Application Security assessment							

Annex B – IfQ security model

1. Introduction and summary

1.1. The purpose of this report is to provide the Committee with our approach to cyber security, further to its request following an oral presentation at its last meeting.

2. Background

- 2.1. The National Cyber Security Strategy 2016-2021 was published in November 2016 and noted the UK is critically dependent on the Internet. 'However, it is inherently insecure and there will always be attempts to exploit weaknesses to launch cyber attacks. This threat cannot be eliminated completely, but the risk can be greatly reduced to a level that allows society to continue to prosper, and benefit from the huge opportunities that digital technology brings.
- **2.2.** Our systems have grown and developed over the years alongside the growth of cyber threat. We have put in place a range of mechanisms, and ways of providing assurance, that those mechanisms are effective, to guard against threat.
- **2.3.** At the last meeting of the Audit and Governance Committee an oral presentation set out the steps the HFEA is taking, as the IFQ programme moves from development to implementation, to ensure cyber security. This paper builds on that presentation and provides documentation supporting our assessment that, in developing our new systems within the Information for Quality Programme, our arrangements are as secure as possible.

3. Standards

- **3.1.** There is a plethora of standards, assurance frameworks and expectations in place. The '10 Steps to Cyber Security' are widely known and are recognised as an effective means of raising awareness of cyber threats within the leadership of organisations, and to enable a greater capability to safeguard their most important information assets, such as personal data, online services and intellectual property. The 10 Steps to Cyber Security features controls to reduce risks in the following areas:
 - Information Risk Management Regime;
 - Secure Configuration;
 - Network Security;
 - Managing User Privileges;
 - User Education and Awareness;
 - Incident Management;
 - Malware Prevention;
 - Monitoring;
 - Removable Media Controls;
 - Home and Mobile Working.
- **3.2.** The HFEA has a successful track record in ensuring its systems, over time, meet these important expectations. We have policies in place relating to information governance and security. Periodically, we have sought assurance by a range of means including review by internal audit and penetration testing (carried out by independent third party experts) and by the application of regular vulnerability assessments.

- **3.3.** Equally the HFEA has devoted two years to a fundamental redesign of its information architecture. Principles relating to security considerations have been built in from inception.
- **3.4.** The IFQ team has adopted the principle of "Secure by Design". This is an approach, developed in conjunction with our retained security consultant working alongside us since the inception of the Programme, which has as its paradigm that software and systems are designed and implemented with security in mind from the ground up.
- **3.5.** The HFEA is developing an Assurance Plan leading to a full Risk Management and Accreditation Document Set for approval prior to the EDI replacement going live. This RMADS is being developed by an independent security consultant. In effect, this document provides details about the system being developed and a full risk assessment. The document will then go on to provide details of how risks are to be mitigated by the application of a Baseline Control Set and will need to be signed off by the Siro prior to the application going live. Current CESG guidance suggests that the RMADS approach is often disproportionate in terms of the effort that is required and that the business should decide what level of risk management is suitable to its needs. However, given the sensitive nature of the data the HFEA feels that the creation of an RMADS is proportionate.

4. Security progress to date

- **4.1.** The high level aims of the security objectives are set out here, and ensure the:
 - i. Confidentiality, integrity and availability of the sensitive data held in the solution
 - ii. Confidentiality, integrity and availability of all data and systems in all environments hosting the systems. (This includes stages of development, testing, pre-production and production).
 - iii. Solution adheres to relevant legislation and regulatory standards
 - iv. Solution (and any infrastructure changes required for it) do not have any effect on the operations of the core corporate systems.
 - v. Reputation of the organisation is not damaged by any activities surrounding the implementation and operation of the new systems.
- **4.2.** A set of technical security model documents have been produced as part of the Programme principally for use by the various internal and external development teams to ensure integrity with the model and to provide background briefing information to independent assessors, contracted to provide external assurance.
- **4.3.** Appendix A contains the IfQ security model and high level security and architecture solutions for the HFEA Clinic Portal and the Release 2 data submission (EDI) replacement systems. Whilst these are dense and technical in nature given the audience they are intended for they are a demonstration that the architecture is being developed with security at its core, and are annexed as information.
- **4.4.** Nevertheless, what is more important is that there is a programme of independent assessment for vulnerabilities in place, providing assurance to the SIRO, Authority and the Audit and Governance Committee.

- **4.5.** Members are aware there are three main components of the Programme the HFEA website; the HFEA Clinic Portal; and 'Release 2' of the Clinic Portal the ability for clinics to submit treatment information to the HFEA. (A separate agenda item updates the Committee on progress with the IfQ Programme more generally). In terms of security, the website is lowest risk; increasing with the Portal (as there is more two-way interaction) and reaches its peak with Release 2. Currently, the system threat is limited as there is a direct link between clinics and the HFEA. The new system is browser based and therefore the 'attack surface' is greatly increased.
- **4.6.** Our testing programme is established in two phases firstly at Beta (broadly) and then prior to live release. The HFEA website and Clinic Portal have been independently assessed for vulnerabilities at the Beta stage, with the recommendations made in the report addressed. It reported:
- **4.7.** "In general, the security of the application components reviewed was high, as the applications are employing some of the latest technologies from Microsoft they are following good security practices in the main when it comes to the application code with no apparent weaknesses that are covered by the OWASP Top 10, such as Cross Site-Scripting and Injection attacks being handled by the .NET platform security features. The application is employing security features of the platform to provide protection as a
- **4.8.** result when testing many types of attack are being defended by these features as a result it is not possible to fully assess the underlying code for weaknesses should the platform protect fail or be removed."
- **4.9.** The full report produced by Reaper Technologies is at annex B.
- 4.10. We have now engaged a CESG Check approved consultancy who will be performing end to end vulnerability assessment of the HFEA website, Clinic Portal and Release 2 in addition to penetration testing of the HFEA's perimeter network as each aspect of the Programme goes live. The IfQ Programme Board receives these reports, and further updates will be provided to the Audit and Governance Committee as part of the update reports by the Director of Compliance and Information.

5. Recommendation:

- **5.1.** The Audit and Governance Committee is asked to:
 - Note this report

6. Annexes:

- Annex A Application Security assessment
- Annex B IfQ security model

Commercial in Confidence

Annex B Audit and Governance Committee 7 December 2016 Agenda item 11 - Cyber Security



APPLICATION SECURITY ASSESSMENT

FOR

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

Security Assessment Summary 28 May 2016





Client Information	
Company Name:	Human Fertilisation and Embryology Authority
City:	10 Spring Gardens
	London
	SW1A 2BU
URL:	http://www.hfea.gov.uk

Client Contact Information				
Contact Name:	David Moysen			
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Company Name:	Reaper Technologies Limited			
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1.0 Business Risk Summary

Overview

A security review was conducted of the new HFEA website, portal and supporting API. The review looked at assessing the services against the OWASP Top 10 to determine if any security issues were present. The following is a summary of the findings and conclusions and recommendations based on these findings.

The security review was conducted between the 10th and 24th May (5 days) and looked at the following services:

- ifq-website.azurenetworks.net
- ifq-portal.azurenetworks.net
- ifqclouddevwebapi.azurewebsites.net

General

In general, the security of the reviewed applications was good, the website and portal leverage the Umbraco CMS platform to provide the frontend elements, with extensions implemented to provide specific features for the HFEA. The Umbraco CMS platform is a web supported .NET based CMS and HFEA appear to be running the latest release. The entire frontend is hosted on Microsoft Azure and uses various elements of the Azure platform to provide services for the application, for example authentication is provided through integration with the authentication services provided by the Azure platform.

During the course of the assessment each of the areas was tested for common security vulnerabilities including those outlined in the OWASP Top 10 the review did not identify any significant issues, however there are some areas of concern as detailed as follows.

Communications Security

The first area of concern was the security of the communications with the HFEA systems, neither the website or the portal required the use of TLS to provide transport security to the application. As a result authentication information for the portal and authentication information for the management of the Umbraco CMS is not protected as it is transmitted over the Internet.

As a result, the lack of transport security means that features such as Strict Transport Security and protection mechanisms for preventing eavesdropping of session cookies are not present.

The backend API however was protected by HTTPS; this was using the default SSL termination for the azurewebsites.net domain.

It is recommended that all externally visible components of the application are secured by using HTTPS to ensure that all information is protected while in transit, with requests to the HTTP version of the applications redirected to the secured versions. Additionally, once this has been implemented implement Strict Transport Security and options on session cookies to further secure the information transmitted.

Information Leakage through Error Messages

During the course of the security assessment a number of error messages where recorded that leaked potentially useful information regarding the environment the application runs within. The error messages in themselves did not leak anything sensitive in terms of the data handled by the applications, however they did leak system information for example one error message leaked the path information for the application on the server and detailed call stack information. This type of information is useful for an attacker, it can provide them useful insight into the application, providing the attacker with a location for files on the system as well as being able to deduce the version of the Umbraco CMS in use.

Information like this can be used to improve the success of other attacks or provide enticement information for areas to exploit. As a result it is highly recommended that custom error handling is implemented to capture errors, log the specifics of the errors to a log file for investigation and return a basic minimal error response to the application user.

Umbraco CMS Configuration

There is an concern within the Umbraco CMS environment, some default content appeared exist without having been removed or default configuration changed. This doesn't follow best practice as recommended by the Umbraco maintainers. It could be



indicative of other elements of the Umbraco code that may not have been properly configured to remove default settings or features.

It is recommended that the Umbraco installation 'hardening' be completed. Ensure that default configurations have been customised and unused features are disabled or removed from the environment.

Conclusions and Recommendations

In general, the security of the application components reviewed was high, as the applications are employing some of the latest technologies from Microsoft they are following good security practices in the main when it comes to the application code with no apparent weaknesses that are covered by the OWASP Top 10, such as Cross Site-Scripting and Injection attacks being handled by the .NET platform security features. The application is employing security features of the platform to provide protection as a result when testing many types of attack are being defended by these features as a result it is not possible to fully assess the underlying code for weaknesses should the platform protect fail or be removed.

It is recommended that the application code undergo a security review to provide insight into the security of the application code at a deeper level. This would be in the form of a source code review and it is also recommended that as part of the build and deployment process a static code analysis step be introduced to provide insight into code issues as the application is being developed with any identified problems being fed back into the development teams to be addressed earlier in the development process.

As the application development progresses with the next phases where patient data being handled it is more important that the security of the application code is reviewed in more depth. Any source code review would look for the common security weaknesses, static analysis tools will help identify these, however another area that would be reviewed by a manual review would be the logic behind the scenes to assess if there are any issues being introduced.

Additionally, to help going forward with the identification of potential areas of concern and to guide remediation and development of security controls and features I would recommend that the next phase of development have a Threat Modelling exercise performed. This threat model would then be used to guide the future design and implementation to ensure that later phases of development address security risks.



2.0 Technical Summary

2.1 Test Area Summary

The following is a summary of the posture of the applications reviewed as part of this assessment.

Vulnerability Area Brief Description		N/A	Good	Fair	Weak	Poor
Configuration	How secure the configuration of the application is.					
Authentication	Are there any specific issues regarding the authentication of users.					
Session Management and Authorisation	How well the application handles the authorisation and keeps the session secure.					
Encryption	Is there any encryption in place in the application and how well it is configured.					
Data Validation	How well the application handles sensitive user input.					
Error Handling	How the application reacts when an error occurs					

2.2 Test Findings

The assessment findings are included in the accompanying spreadsheet.



3.0 Risk Rating

This report harnesses the power of CVSS v3, the latest industry standard for vulnerability scoring, it combines this with the simplicity of colour coding. This enables access to this report by all levels of management.

CVSS v3 Explanation

CVSS (currently version 3) is the Common Vulnerability Scoring System. This is a vendor independent way of scoring vulnerabilities in a more granular way than just being assigned as a critical, high, medium, low or no (informational) risk.

This system takes a variety of factors (known as metrics) into account such as the level of complexity required to reach the affected system, whether or not exploit code exists, the impact successful exploitation of the issue would have on the business and the type of area of concern (availability, confidentiality and integrity).

By applying these factors to each unique vulnerability, a score from 0 to 10 calculated and assigned.

Reaper Technologies assigns high, medium or low to each vulnerability based on the following criteria as defined by the CVSS v3 standard:

Critical:	Any issue with a CVSS score of 9.0 or higher
High:	Any issue with a CVSS score of 7.0 or higher but lower than 9.0
Medium:	Any issue with a CVSS score of 4.0 or higher but lower than 7.0
Low:	Any issue with a CVSS score of 0.01 or higher but lower than 4.0
Informational:	Any issue with a CVSS score of 0.0

This assures that each vulnerability has been tailored to the client, as each vulnerability affects each client in different ways.

For example, an SQL injection issue affecting a public facing website would be an high risk. That same issue on an internal host with adequate firewall configurations could be classed as a medium risk. A high risk issue on a low impact server may carry a lower CVSS score than a medium risk issue on a critical server.

For more information on CVSS please refer to the First.org website link below: http://www.first.org/cvss/

IFQ Security Model

Identity Solution

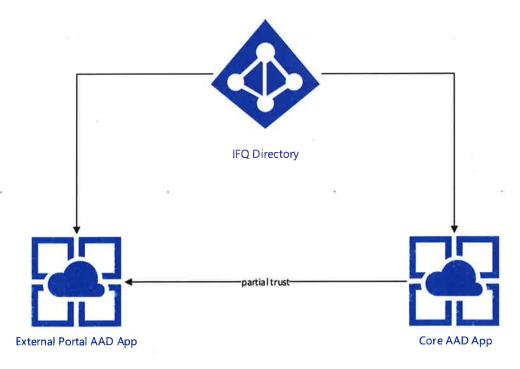
We have chosen Azure Active Directory (AAD) to store user identities. AAD replicates well both with Microsoft Active Directory and third party providers. In addition to that AAD supports modern identity standards such as OpenID Connect and OAuth 2.0, as well as multi factor authentication when required in future.

Azure Active Directory Partitioning

IFQ Application owns a separate directory in HFEA Azure Tenant. That means it's totally separate from any other directories in the Azure Tenant, has its own users, groups and roles. In addition to that a designated people can be assigned to manage this directory with very granular permissions depending on what they need to do.

In general, any system that needs to access AAD has to be registered as an AAD application. Applications is another abstraction which allows to set up more granular access to the directory data. A single AAD can have many applications registered, each with it's own permissions, access keys, roles, and permissions.

IFQ registers at least two applications.



Core App

The first "Core AAD App" is intended for backend use. It has been granted enough permissions to both authenticate users and fully manage AAD. Core App can:

Create/Update/Delete Users

- Create/Update/Delete Groups
- Create/Update/Delete Application Roles
- Authenticate users
- Change user membership in Roles and Groups

IFQ internal services such as API and Orchestration Layer are a part of the Core AAD app so they can perform these operations on request.

External App

External application is created on demand for any application outside of IFQ network, typically this is an API user, including Website or Clinic Portal. They can be two extra applications or the same one.

External application is registered by HFEA in IFQ directory with minimum permission set possible, it can:

- Sign in a user and read profile
- Access Core App (be able to communicate with it)

This gives HFEA flexibility in terms of outsourcing the development of external apps and services as AAD app has its own access keys and not enough permission to do anything dangerous.

Trust

HFEA administrator needs to configure minimum trust so that external application can sign-in users and call core application in Azure Portal on the external application configuration page:

Sign-in

One permission in Microsoft's "Windows Azure Active Directory" application for users to be able to sign-in at all:

REPLY URL	https://localhost:44300/		Read and write all groups				
5.	(ENTER A REPLY URL)			Read all groups Read and write directory data Access the directory as the signed-in user Read directory data			
permissions to other appl	ications		Read all users' full profiles				
IFQ Backend	Application Permissions: 0		Read all users' basic profiles Sign in and read user profile				
Windows Azure Active Directory	Application Permissions: 0	~	Delegated Permissions: 1	~	×		

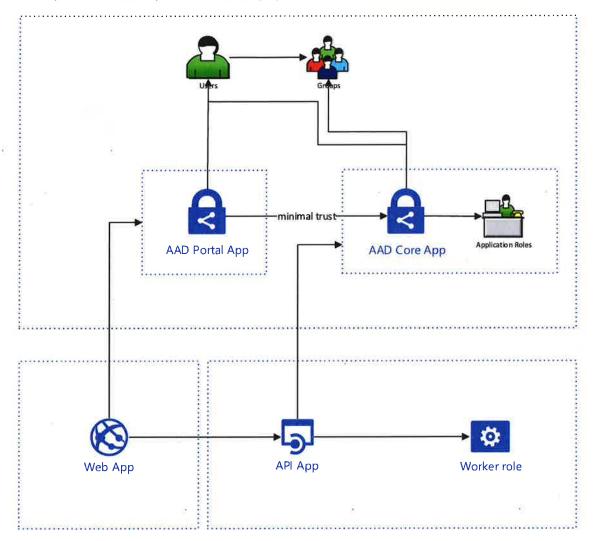
Access IFQ Core App

One permission to our own Core App which is named "IFQ Backend" in this screenshot:

permissions to other applica	tions				0
IFQ Backend	Application Permissions: 0	~	Delegated Permissions: 1	~	×
Windows Azure Active Directory	Application Permissions: 0		Access IFQ Grid		

Authentication Sequence

In the diagram below dotted rectangles represent authentication boundaries. In order to cross them a component needs to perform a security operation to have a specific permission.

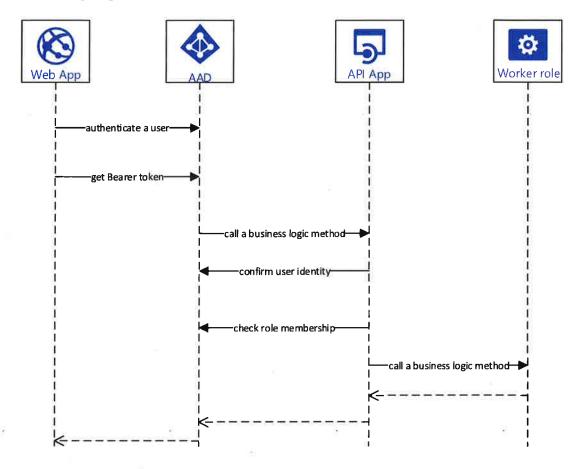


In order for a web site to make a generic call the following authentication parts will be involved:

- Web App (Website or Clinic Portal) which already has application details for the "AAD Portal App" authenticates a user across IFQ directory. Technically this is done by an OWIN component for ASP.NET MVC supplied by a Microsoft and there is a minimal developer effort.
- 2. Web App obtains an authentication token and stores session data in browser cookies.
- 3. Before making the call to API App, Web App calls Azure Active Directory Graph API to obtain a JWT authentication token. Due to the fact HFEA administrator has set up the trust permission AAD returns such a token.
- 4. Web App uses a simple **Bearer Authentication** to call the Web API. Bearer authentication only requires you to include one extra HTTP header in the call and is supported by most of the web frameworks such as RestSharp.

- 5. API App validates the JWT bearer token to make sure the user is genuine and authenticates as a user in the Core App.
- 6. AAD Core App also contains a list of application roles registered for this application. API App performs a check against AAD that the user belongs to an appropriate role and either allows to denies the call. Note that application roles are private to the AAD Core App and external applications don't have access to read them even if they had full permissions in their own app space.

The following diagram illustrates the flow:



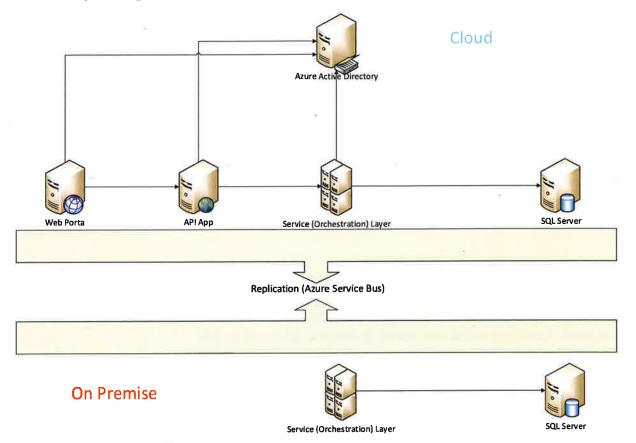
We will provide a full blown easy-to-use authentication library both for internal use and for external developers building applications with ASP.NET MVC.

We will also provide a .NET SDK for calling IFQ REST API, including Bearer authentication support.

Design proposal

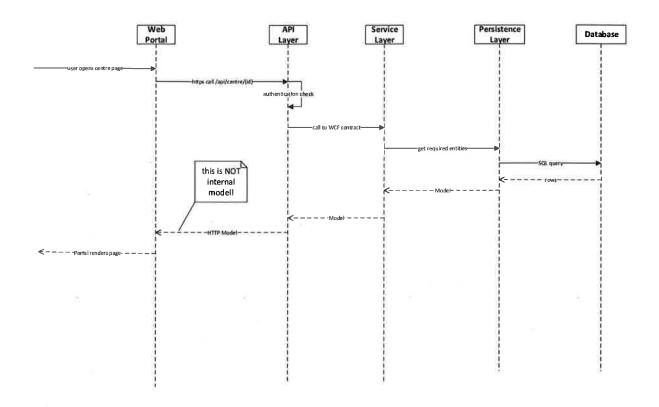
Overview

See the simplified logical structure here:



- Web Portal. Developed outside of the scope of this project, is an external caller (such as Umbraco CMS) calling our API App.
- **API App.** The only public facing service accessible outside of the network. This is an ASP.NET Web API project defining and standardising the public and private API functions available. Potentially this app can be wrapped behind the API Management portal which should be discussed separately.
- Service (Orchestration) Layer. Contains all the business logic of the IFQ application. Any API apps or any additional public services must call this layer to perform any business operation. This layer exposes some high level functionality via it's WCF contracts.
- SQL Server. Existing sql database with existing tables.

To display a typical web page, the system will involve all the parts in this order:



Due to the fact that parts of the system stays on premise we do replicate some data between the two sides. Azure Service Bus was chosen as the best options to do that.

Solution / Project structure

All the code is written in C#, with the exception of occasional T-SQL stored procedures or queries depending on the application needs. Some code may be written in PowerShell or any other scripting language required for Microsoft Azure deployment scripts.

The solution should have the following projects (approximately):

- HFEA.Model contains all the model classes following the DDD strategy (see below).
- HFEA.WebApi the API app (ASP.NET MVC WebApi with Swagger support). This application uses its own model specific to the REST/SOAP calls it exposes to the public.
- HFEA.DataLayer the data access layer project. Interfaces for accessing the data must be defined in the HFEA.Model project and use the Model in method parameters and return results exclusively. Internally we will use the latest version of the Entity Framework (v6 at the time of this writing). We will utilize code first approach as much as possible here.
- **HFEA.SDK** contains all the business logic.
- HFEA.WebPortal a test portal which demonstates some of the functionality of the application, and contains some administration functionality (for example adding users, assigning roles etc.)
- **HFEA.Tests.Unit** unit tests only.
- **HFEA.Tests.Integration** integration tests only.

 In addition to this there will be an extra project or two which hosts business logic. Depending on where we host the logic (on premise or in Azure) these can be either Azure Worker Role or a Windows Service application. To test this locally we can use Compute Emulator coming with Azure SDK.

Code Structure

HFEA.Model

Collection of model classes describing IFQ domain and according to DDD:

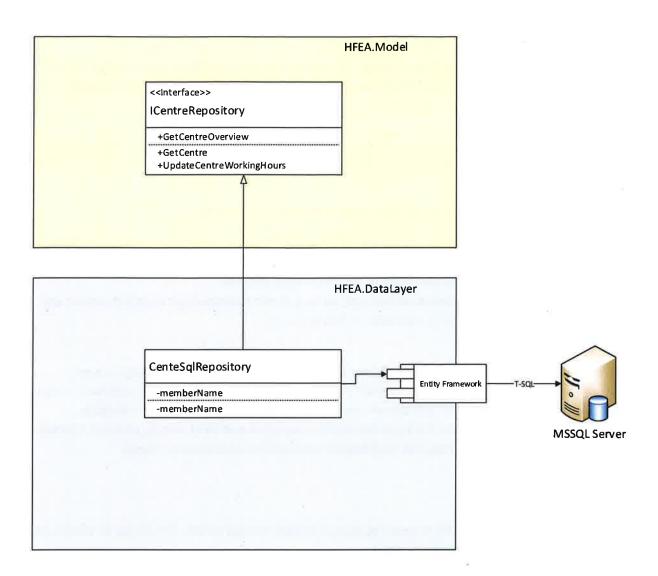
- Not used or exposed in any sense outside of the IFQ solution to external world, including Portal and public website.
- Not compromised by serialisation or database requirements.
- They can and should have business logic, as long as this business logic does not require any
 external dependencies i.e. database or network calls.

HFEA.WebApi

ASP.NET WebApi application i.e. it *doesn't have a frontend* other than Swagger. Swagger is an industry standard for API discovery, cross platform and widely adopted. This application has it's own model exposed via REST or SOAP and doesn't expose HFEA.Model in any way. This is because external model can't change and has to be backward compatible and dead simple, whereas internal model is rich and is subject to frequent modification as business requirements change.

HFEA.DataLayer

This is a C# library responsible for translating repository calls into sql server. The library is referenced later by a process running the business logic.

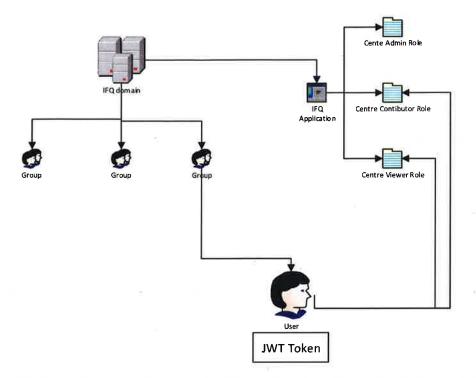


Actual repository interfaces are declared in HFEA.Model and DataLayer only implements them following these practices:

- A repository is a DDD repository with all the attributes implied:
 - Repository does not have any business logic and is only designed to store/retrieve data
 - Repository always operates with Model classes, i.e. repository methods accept model classes as parameters and return model classes as result – it's the DataLayer's responsibility to translate Model into underlying database technology.
- We will use EF6 and code-first to map database to model.

Identity Model

We have chosen Azure Active Directory (AAD) to store user identities. AAD replicates well both with Microsoft Active Directory and third party providers. In addition to that AAD supports modern identity standards such as OpenID Connect and OAuth 2.0, as well as multi factor authentication when required in future.



IFQ Application (see diagram below) is registered in IFQ domain. In terms of AAD application is a separate entity which can hold application specific roles and control user access separate to the primary domain. Application also allow to control directory access in a finer grained way comparing to using the global directory.

IFQ application holds application specific roles which can be added or removed dynamically. Once a user is authenticated against AAD his identity token (JWT – JSON Web Token) carries his identity and roles/groups he belongs to which allows us to do proper authorisation on API calls and other resources.

Authentication scenarios

- Web Portal application developed externally authenticates to AAD itself, then passes the auth token to our API App call which performs authorization checks.
- An external developer authenticates to AAD and passes the token.

Data Replication

It's worth mentioning that data must be replicated only due to the fact that system can't be hosted 100% in Azure Cloud. When this is not the issue we don't need two separate databases on each side and the whole system can use just one single primary replica.

Not all of the data will be replicated, but only a subset required for the API calls. For comparison, there is around 20Gb of SQL table data on premise and only around 300Mb in the cloud.

Database schema (at least for the subset of replicated tables) is identical both on premise and in the cloud, however we don't have to keep SQL server in the cloud and free to choose any technology.

Design decision

Due to the fact that cloud database may disappear in future as the whole solution
potentially can be hosted in Azure Cloud we've decided to keep SQL server and not to use
anything more modern. When the physical boundary is removed queries for Azure side
should just work with the big on premise database meaning no code changes.

- Due to the fact that the database on premise can be changed by anyone directly avoiding service layer, we don't have a reliable way to intercept the events to send the replication event to the cloud. There are a few options here:
 - Add trigger functions to SQL server which will notify SL on changes so we can push it further.
 - Intoduce a call in SL which external callers have to call in order to notify they have changed particular data.
- We still need to see the database in action to make the best architectural decision here.

Logging

All the layers must log as much as possible. Any sort of problem or failure must be able to be replicated in the dev environment by analysing logs.

When there is no preference on any particular logging frameworks I would recommend choosing one of two: log4net or NLog.

Scope for Release 1

- Build a deployable solution which can be pushed to Windows Azure with Continuous Integration.
- Data Replication between cloud and on premise systems. Depending on the complexity and amount of work we may not finish all of it but will build a good framework with best practices.
- Some or all the API calls implemented in all layers. Due to the fact we have no idea how many calls we need to implement or how complex they may be we will do the most.

Methodologies

DDD (Domain Driven Design). DDD is one of the most successful design approaches to tackle easy to most complex problems in building software. The most important principle is that our business domain is described in terms of model classes. DDD is getting even more popular in the Micro services world.

TDD (Test Driven Design). Each new functionality should have a minimal test written before it's implemented. Most suitable frameworks of choice:

- NUnit general unit/integration test framework
- Moq mocking framework

HFEA

Release 2 Solution Architecture

Version 1

Ivan Gavryliuk 9-15-2016

2016-12-07 Audit and Governance Committee Meeting Page 108 of 167

Contents

Problem2
Security
Authentication
Network Security
Core Subnet6
SQL Server
Image Storage6
Orchestration Layer8
EPRS Subnet
Key Authentication9
Generating HMAC-SHA1 key9
Calling EPRS API with security key9
Validating EPRS API call on the server10
IP Address Restrictions
Internal Subnet
EDI Web Application12
Scaling Options
Virtual Machines13
Scaling Up13
Scaling Out13
EDI Web Application14

Problem

R2 requires a certain security guarantees which would impact the architecture for the next part of the system. Some of them are:

- Data cannot leave UK premises
- All the systems need to be closed down, except for those which need to be accessed by the public
- All the public system must have a fine grained security rules implemented

Most of the public cloud providers such as Microsoft Azure or AWS do not have physical data centres in the UK which prevents us from hosting data there. However, Microsoft Azure is building one at the moment where we have a private preview access. If that happens the overall architecture and costs are considerably lower than creating a hybrid system.

Generally, HFEA system consists of several basic layers:

- Persistence. Microsoft SQL server (relational data) and large files (binary data).
- Business Logic (Orchestration Layer).
- Public API for EPRS access.
- Clinic Portal Website.
- QA Website.

We use both IaaS and PaaS Azure offerings, balancing between security, support costs, ease of use, and developer productivity.

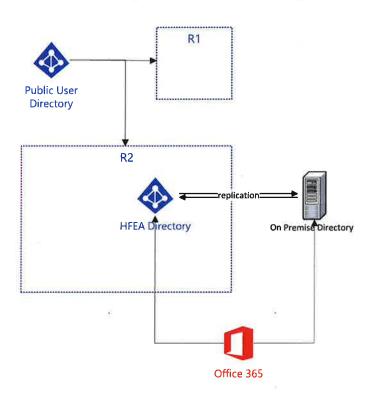
Also we assume that all of the services are built with .NET Framework and T-SQL.

Security

Authentication

Release 1 (R1) is already using Azure Active directory B2C for authentication (see R1 architecture document for choice decisions). Due to the fact that same users will be able to access R1 and R2 systems it is a natural choice to reuse the same directory. This allows to reuse technology, experience and frameworks built around B2C.

However, QA Website app requires authentication with HFEA Active Directory by internal staff, this is the same directory used to login to Windows or access Office 365 accounts. It is also replicated to Microsoft Azure Active Directory, making it simple to use the Cloud version for authentication from Azure data centre. We assume replication is already configured and is outside of the scope of this document.





Network Security

Considering we are using Azure UK data centre the whole system is hosted physically in the UK. To achieve low latency, high performance and restrict the network from the outside attacks R2 will utilise Azure Virtual Networking technology. It allows customers to replicate physical network in Azure data centres as they would on premise.

Azure Virtual Network is a dedicated workspace for services which is never visible from outside world, unless specifically told by configuring integration with outside world, just like on premise network.

R2 virtual network never talks to HFEA on premise network, and the only piece of information they share is the Active Directory information replicated.

A subnet in a virtual network is a range of IP addresses, with its own security rules and routing tables.

The Virtual Network is divided into 4 subnets (see Figure 2 - Network Diagram):

- **Core.** Contains all the internal (core) services of HFEA application. This subnet does not have outside access from anywhere except for *Orchestration Layer* from other subnets. None of the services in this network have outside internet access. Contained services:
 - Microsoft SQL Server Machine.
 - Orchestration Layer Service.
 - o Image Storage.
- **EPRS.** Hosts Public REST API used by EPRS providers.
- Internal. Contains QA Web Application used exclusively by internal HFEA staff. Theoretically it could live in the Core subnet, however for easier access management it is recommended to create a separate subnet.
- Gateway Subnet. This subnet is used only for administrative access to the parts of the system and can be accessed by individuals using Azure VPN Gateway. Required mostly for troubleshooting and access by software developers. Note that this subnet doesn't have NSG attached which is a requirement for VPN connection to work properly in Azure.

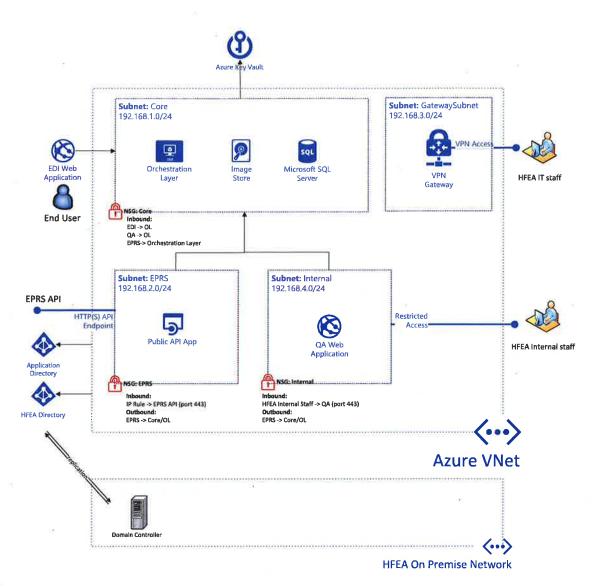


Figure 2 - Network Diagram

Core Subnet

Due to the geographical limitations that data must not leave the UK and be encrypted at rest we cannot use traditional Azure Storage or Azure SQL Server.

SQL Server

We will rent a Virtual Machine with SQL Server 2014 SP1 from Azure Marketplace on PAYG license which is a usual VM with all capabilities a normal VM has. This can be joined to our Virtual Network in Storage subnet with restricted access only by Orchestration Service from the Business Logic subnet. SQL Server database is encrypted¹ using Transparent Data Encryption² (TDE) for laaS instances. Encryption has to be configured manually after installing SQL Server instance³.

Image Storage

Image Storage is a set of files falling under the same security restrictions. There are two major options in Azure to protect file data:

- 1. **Azure Storage Service Encryption for Data at Rest** enables encryption on blob storage on the Azure Cloud side. Encryption is handled
- Azure Disk Encryption. Encrypts OS and data disks on a VM level using BitLocker on Windows or DM-Crypt on Linux. Raw data never leaves VM boundaries and customer secrets are stored in Azure Key Vault service. It is the safest choice for maximum security.
- 3. **Custom Encryption.** Involves writing a software component in the Orchestration Layer for handling encryption from the software.

	Azure Storage	Azure Disk Encryption	Custom Encryption
Encryption at Rest	Yes	Yes	Implementation
Transport Encryption	HTTPS only	Not applicable	Implementation
Implementation Effort	Trivial	Hard (infrastructure configuration)	Hard (developer resources)
Deployment Effort	Trivial	Hard	Trivial
Encryption Method	AES 256	AES 256 (BitLocker)	Implementation
Overall Security	Medium	High	Medium-High
Scalability	Up and Out	Up Only	Up and Out

Table below outlines the pros and cons of every approach.

Based on the comparison and requirements I would strongly recommend implementing storage with Azure Disk Encryption. Read more: <u>https://azure.microsoft.com/en-gb/documentation/articles/azure-security-disk-encryption/</u>.

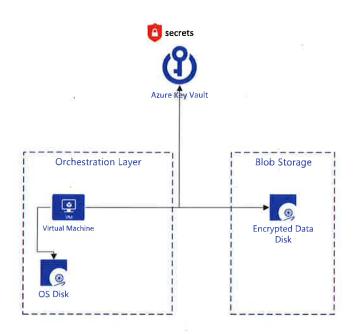
This is not a scripted process and has to be configured manually.

¹ SQL Server Encryption, https://msdn.microsoft.com/en-us/library/bb510663.aspx

² Transparent Data Encryption, https://msdn.microsoft.com/en-us/library/bb934049.aspx

³ Configuring SQL Server Encryption, https://blogs.technet.microsoft.com/kv/2015/01/12/using-the-key-vault-for-sql-server-encryption/

In essence when configuring a disk encryption a new data disk is attached to Orchestration Layer machine with a new drive letter. Software running on this machine can access the drive as it would normally do and configured Windows OS takes care encrypting and decrypting data on the go.



One of the limitations of this approach is it's not scalable for the reason that a disk cannot be shared between two or more instances of virtual machines. For that reason, Orchestration Layer machine can only be scaled up.

When workload will reach a certain limit in future OL can be moved to a separate VM instance and existing instance can act as a file server freeing up resources for the actual business logic processes.

In order to scale even more you can implement custom encryption in the Orchestration Layer endpoint which will allow to scale out infinitely, but none of the scaling options are included in this release implementation.

Orchestration Layer

Unlike R1 where Business Logic was hosted in an Azure Cloud Service we can't do this anymore, because Cloud Services have a public access and require creating a public IP address for communication purposes. There are many options available to solve this problem, however considering a low load and security restrictions the most appropriate one is using Azure Virtual Machines. There are a few pros and cons to using VMs.

Pros:

- Cloud provider agnostic, every single cloud provider supports Virtual Machines and running executables which is what a windows service is.
- Flexibility when configuring security and installing custom software.
- Lower cost comparing to other alternatives.

Cons:

- Management overhead comparing to Cloud Services or Service Fabric.
- No auto deployment built-in (but you can utilise existing Octopus Deploy⁴ instance)

In the first release we will use one virtual machine, however you must consider scaling options (see the section) before going to production or when performance is going bad.

Orchestration Layer is a Microsoft Windows Service application running in a background and hosting all the business logic and model. Other layers provide only integration or user interface services.

Orchestration Layer both hosts services for API or internal applications via Windows Communication Foundation (WCF) and performs long-running background tasks when needed.

There are no special security requirements for OL VM, it doesn't have outbound Internet access and only needs to access SQL server database.

⁴ Octopus Deploy, https://octopus.com/

Figure 3 - EPRS API EPRS API HTTP(S) API Endpoint NSG: EPRS Inbound: IP Rule -> EPRS API (port 443) Outbound: EPRS -> Core/OL

EPRS API lives in a separate subnet only for security reasons. EPRS provide API access for external clients to their dedicated centres and have a key-based authentication. In addition to that EPRS service has only port 443 (HTTPS) open for internal calls.

HFEA is responsible for giving out keys to the EPRS customers. Every key has access to only one single centre. For increased simplicity and cross platform support (we suppose that EPRS clients can use a multitude of different client platforms) we recommend using Hash-Based Message Authentication Code (HMAC) with SHA-1 algorithm which is still considered to be secure and performing well.

Key Authentication

EPRS Subnet

Generating HMAC-SHA1 key

In Windows Server the key can be generated by calling to Cryptography API, see <u>MSDN</u> <u>Documentation</u>. The key then must be assigned to the client by putting in SQL Server database on HFEA side and transferring to EPRS user.

Calling EPRS API with security key

In order to call EPRS client have to sign their request before issuing. The signature is generated in a few steps:

- 1. Get the current clock time in UTC T.
- 2. Get your centre ID C.
- 3. Format a signature string as "C:T".
- 4. Compute HMACSHA1 hash of the signature string using your key and represent as a BASE64 encoded string.
- Add HTTP header "x-hfea-date" to request. Note that you have to agree on time format on both client and server side, the most common is (C# example):

T.ToUniversalTime().ToString("ddd, dd MMM yyyy HH:mm:ss UTC");

6. Add HTTP header "x-hfea-signature" to request by setting the value of the string computed in step 4.

Validating EPRS API call on the server

The validation can be performed in a few simple steps too:

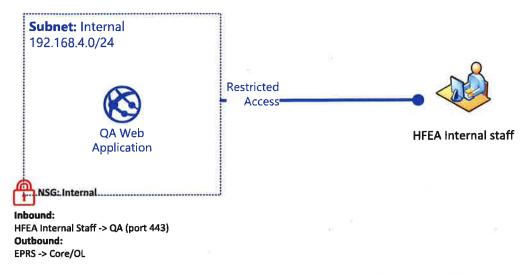
- 1. Check that both *"x-hfea-date"* and *"x-hfea-signature"* is present, otherwise reply with 401 (Unauthorized) code.
- 2. Take the current clock time and compare to *"x-hfea-date"* to check if they differ a lot. If the difference is more than 1-minute reply with 401.
- 3. Compute HMACSHA1 hash of the request following steps 1, 2, 3, 4 in "Calling EPRS API with secure key" section. Remember to take "x-hfea-date" for date value as current clock will be different from client's clock.
- 4. Validate if your hash is matching client's hash. Deny authentication if they aren't and allow otherwise.

IP Address Restrictions

In order to restrict access from certain IP addresses or ranges a built-in functionality of Network Security Group EPRS can be used to create Inbound Access Rules⁵.

⁵ Managing Network Security Groups in Azure, https://azure.microsoft.com/engb/documentation/articles/virtual-networks-create-nsg-arm-pportal/

Internal Subnet



This subnet hosts internal QA Application accessed exclusively by HFEA Staff.

For authentication it uses Azure Active Directory replicated from the on-premises directory. It is not to be confused with Application Directory used to access the system from the Internet.



QA Web Application is also an IIS hosted solution on Windows Azure VM.

It has a direct access to Orchestration Layer from the *Core* subnet to interact with data. The access is controlled by Network Security Groups.

EDI Web Application



Is another part of IFQ visible from outside (the other one is EPRS API). It's hosted as a PaaS solution on Azure Platform⁶. PaaS is possible in this case because the target audience is internet facing and there are no special security requirement except for a strong authentication.

Due to the fact we are using Azure B2C to offshore authentication process it's satisfied too.

Having this hosted as PaaS also gives us better flexibility in terms of scaling, deployment and monitoring.

EDI connects directly to the Orchestration Layer by connecting to our Virtual Network⁷.

 ⁶ Azure Web Apps, https://azure.microsoft.com/en-gb/documentation/articles/app-service-web-overview/
 ⁷ Integrate your app with Azure Virtual Network, https://azure.microsoft.com/en-gb/documentation/articles/web-sites-integrate-with-vnet/

Scaling Options

Virtual Machines

Most of the services are hosted inside virtual machines, which have two major scaling approaches.

Scaling Up

Scaling up involves adding more virtual resources depending on where the bottleneck is in current performance scenario (CPU, Disk, Memory etc.). You can rescale the machine instance in Azure Portal.

Scaling Out

Scaling up is not a perfect option and always comes with it's drawbacks:

- During scaling up virtual machine goes offline for a short period of time, and needs warming up again to start your hosted application
- Scaled up instances are expensive, as they always billed for provisioned resources regardless whether they are in use
- Scaled up instances can't provide enough continuity when the service fails a manual intervention is required.

Scaling out comes to the rescue and covers all the bad points. Essentially scaling out means cloning a virtual machine to run two or more instances. Every instance has its own virtual internal IP address, regardless whether it's public or private facing.

Client of scaled out instances are not aware of the change; they are calling a virtual endpoint called a Load Balancer. Load Balancers can be internal or external, which only indicates which sort of IP address they are assigned to (public or private). For instance, Orchestration Layer will use internal load balancer as it's not publicly visible from the Internet, whereas all of the remaining services are using External Load Balancer.

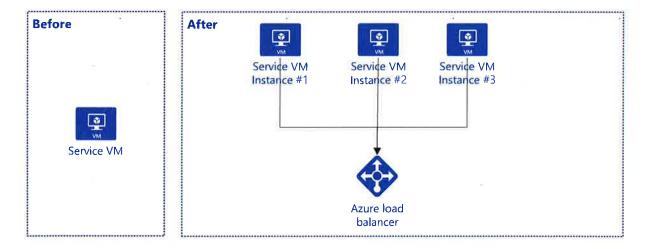


Figure 4 - Without and With Scaling out

EDI Web Application

This application is hosted inside Azure App Service container, therefore scaling is trivial as it's baked into App Service package and works out of the box⁸.

⁸ Scaling Out Application Plans, https://azure.microsoft.com/en-us/documentation/articles/insights-how-to-scale/

2016-12-07 Audit and Governance Committee Meeting Page 123 of 167



Public Interest Disclosure ("Whistleblowing") Policy

Strategic delivery:	Setting standards	Increasing and informing choice	Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	14		
Paper number	AGC (07/12/2016) 520	HR	
Meeting date	7 December 2016		
Author	Rachel Hopkins, Head	of Human Resources	
Output:			
For information or decision?	For decision		
Recommendation	The Committee is aske	ed to agree the amended	policy.
Resource implications	None		
Implementation date	Ongoing		
Communication(s)	Ongoing		
Organisational risk	X Low	□ Medium	□ High
Annexes			
Annex A –	Whistleblowing Policy		

1. Purpose

- **1.1.** The Public Interest Disclosure Policy generally referred to as the "Whistleblowing" Policy was implemented to ensure people working for the HFEA were aware of the channels available t report inappropriate behaviour.
- **1.2.** This paper also confirms that a review of the HFEA Whistleblowing Policy has been undertaken and to set out the updated policy which includes a few minor amendments for the committees agreement.

2. Policy

- **2.1.** The policy was shared with the Staff Forum and tabled at CMG who approved the draft policy. In December 2014, the Committee approved it. r of minor amendments that have been proposed.
- **2.2.** A review was not undertaken in 2015 due to staff and work commitments and therefore was not presented to AGC for approval.
- **2.3.** We have now reviewed the policy and have updated names where appropriate and re-branding.
- **2.4.** Any comments or changes the Committee deems necessary are requested.



Public Interest Disclosure ("Whistleblowing") Policy

1. Introduction

1.1 In accordance with the Public Interest Disclosure Act 1998, and the corporate values of integrity, impartiality, fairness and best practice, this policy intends to give employees a clear and fair procedure to make disclosures which they feel are in the public interest ("whistleblowing") and will enable the HFEA to investigate these disclosures promptly and correctly.

2. Aim

2.1 To outline what constitutes a Public Interest disclosure, and to provide a procedure within the HFEA to deal with such disclosures

3. Scope

3.1 This policy applies to all employees, both permanent and fixed term and also Authority members

4. Responsibility

4.1 The HR department is responsible for ensuring that all staff have access to this policy. Managers and Senior Executives are responsible for ensuring that any public interest disclosure is dealt with immediately, and sensitively, and confidentially.

5. Principles

- **5.1** Employees who raise their concerns within the HFEA, or in certain circumstances, to prescribed external individuals or bodies will not suffer detriment as a result of their disclosure, this includes protection from subsequent unfair dismissal, victimisation or any other discriminatory action.
- **5.2** The Public Interest Disclosure Act 1998, (more widely known as the 'Whistleblowers' Act) protects 'workers' from suffering any detriment where they make a disclosure of information while holding a reasonable belief that the disclosure tends to show that:
 - (a) a criminal offence has been committed, is being committed or is likely to be committed,
 - (b) a person has failed, is failing or is likely to fail to comply with any legal obligation to which he is subject,
 - (c) A miscarriage of justice has occurred, is occurring or is likely to occur,
 - (d) The health and safety of any individual has been, is being or is likely to be endangered,
 - (e) The environment has been, is being or is likely to be damaged, or
 - (f) Information tending to show any matter falling within any one of the preceding paragraphs has been, is being or is likely to be deliberately concealed.
- 5.4 It should be noted that disclosures, which in themselves constitute an offence, are <u>not</u> protected.

- 5.4 HFEA's policy is intended to ensure that where a member of staff, including temporary or contractual staff, have concerns about criminal activity and/or serious malpractice e.g. fraud, theft, or breaches of policy on Health and Safety, they can be properly raised and resolved in the workplace. Such matters <u>must be raised internally</u> in the first instance. Please refer to the paragraph on gross misconduct in the Authority's Disciplinary Policy, and also the Authority's Fraud and Anti-Theft Policy.
- 5.5 HFEA seeks to foster a culture that enables staff who witness such malpractice to feel confident to raise the matter in the first instance in the knowledge that, once raised, it will be dealt with effectively and efficiently. The HFEA will not tolerate the victimisation of individuals who seek to bring attention to matters of potentially serious public concern, and will seek to reassure any individual raising a concern that he or she will not suffer any detriment for doing so. If an individual is subject to a detriment for raising a concern the HFEA will seek to pursue an appropriate sanction.
- **5.6** Frivolous or vexatious claims which fall outside the protection of the Act or such other provisions as may be held to protect them (e.g. HFEA's codes of conduct, confidentiality clause etc.) may be considered acts of misconduct and subject to disciplinary action.

6. Procedure

Internal Disclosure

- 6.1 HFEA staff who become concerned about the legitimacy or public interest aspect of any HFEA activity or management of it should raise the matter initially with their line manager. If a member of staff feels unable to raise the matter through their line manager, they may do so through the HR Department.
- 6.2 It will be the responsibility of the line manager to record and pursue the concerns expressed; consulting such other parts of the Authority; (e.g. HR, SMT) as may be necessary, including where appropriate consideration as to whether external expert assistance is required.
- 6.3 The identity of the individual making the disclosure will be kept confidential if the staff member so requests unless disclosure is required by law.
- 6.4 In other than serious cases, the line manager will normally be responsible for responding to the individual's concern. They must maintain appropriate records and ensure that they provide the individual raising the concern with:
 - An explanation of how and by whom the concern will be handled
 - An estimate of how long the investigation will take
 - Where appropriate, the outcome of the investigation
 - Details of who he/she should report to if the individual believes that he/she is suffering a
 detriment for having raised the concern
 - Confirmation that the individual is entitled to independent advice.

- 6.5 Should a member of staff feel that they are not satisfied that their concern has been adequately resolved, they may raise the matter more formally with the Chief Executive.
- 6.6 Any member of staff wishing to make a disclosure of significant importance may approach the Chief Executive in the first instance. Matters of significant importance include, but are not restricted to, criminal activity e.g. fraud or theft, or other breaches of the law; miscarriage of justice; danger to health and safety; damage to the environment; behaviour or conduct likely to undermine the Authority's functions or reputation; breaches of the *Seven Principles of Public Life* (Annex A) and attempts to cover up such malpractice.
- 6.7 The matter of significant importance may have taken place in the past, the present, or be likely to take place in the future.
- 6.8 Concerns may be raised either in writing or at a meeting convened for the purpose. A written record of meetings must be made and agreed by those present. In serious cases or in any case where a formal investigation may be required, line managers concerned should consult the Head of HR and SMT, unless they are implicated, when they should speak to the Chair. Line managers must not take any action which might prejudice any formal investigation or which might alert any individual to the need to conceal or destroy any material evidence.
- 6.9 Where an individual has reason to believe that the concerns about which he / she intends to make a disclosure are condoned or are being concealed by the line manager to whom they would ordinarily be reported, the matter may be referred directly to the Head of HR r who will determine in conjunction with the Chief Executive the need for, and the means of, investigation. In exceptional circumstances, the Head of HR may take the disclosure directly to the HFEA Chair. Any such approach should be made in writing, clearly stating the nature of the allegations.
- **6.10** Unless inappropriate in all the circumstances, investigations will normally be undertaken by the following posts:

Allegation against	Investigated by
Directors	Chief Executive
Chief Executive	Chair
Member	Chair
Audit Committee Member	Audit Committee Chair
Chair	Department of Health*
Deputy Chair	Chair

*Via Senior Sponsor at the DH (currently Mark Davies, Director, Health Science and Bioethics (tel. 0207 210 6304[MA1] / mark.davies@dh.gsi.gov.uk)

6.11 Individuals under contract to the HFEA for the delivery of services should raise any issues of concern in the same way, via the appropriate line manager.

6.12 Once investigations and follow up actions as appropriate have been concluded, a written summary of the matter(s) reported and concluding actions taken should be forwarded to the Chair of the Authority (the Chair) for inclusion in the central record of issues reported under this policy. The anonymity of the individual who made the disclosure should be preserved as far as possible.

External Disclosure

- 6.13 The HFEA recognises that there are circumstances where the matters raised cannot be dealt with internally and in which an individual may make the disclosure externally and retain the employment protection of the Act. Ordinarily such disclosure will have to be to a person or regulatory body prescribed by an order made to the Secretary of State for these purposes.
- 6.14 Prescribed bodies under the Act include the Comptroller and Auditor General of the National Audit Office (NAO), who are the external auditors to the Authority. The Act states that disclosure to the NAO should relate to "the proper conduct of public business, fraud, value for money and corruption in relation to the provision of centrally-funded public services."
- 6.15 The NAO have a designated whistle blowing hotline which can be used in confidence on 020 7798 7999. Further information about this service and other bodies prescribed under the Act is available via the NAO's website: http://www.nao.org.uk/contact-us/whistleblowing-disclosures/
- 6.16 In these circumstances the worker will be obliged to show that the disclosure is made in good faith and not for personal gain, that he or she believed that the information provided and allegation made were substantially true, and that they reasonably believed that the matter fell within the description of matters for which the person or regulatory body was prescribed.
- 6.17 Unless the relevant failure of the employer is of an exceptionally serious nature, the worker will **not** be entitled to raise it publicly unless he/she has already raised it internally, and/or with a prescribed regulatory body and, in all the circumstances, it is reasonable for him / her to make the disclosure in public.
- 6.18 If a member of staff is unsure of their rights or obligations and wishes to seek alternative independent advice, Public Concern at Work is an independent organisation that provides confidential advice, free of charge, to people concerned about wrongdoing at work but who are not sure whether or how to raise the concern (telephone 020 7404 6609 or 020 3117 2520, email: whistle@pcaw.org.uk), or visit their website at http://www.pcaw.org.uk/. HFEA staff may also use the Whistleblowing Helpine, which offers free, confidential and anonymous advice to the health sector: http://wbhelpline.org.uk/
- 6.19 Where matters raised from external disclosure procedures are (as appropriate) subsequently investigated and resolved internally, a written record of the matters raised and actions taken should be forwarded to the Chair for inclusion in the central record of issues referred under this policy. The anonymity of the individual who made the disclosure should be preserved as far as possible.

Information held on the HFEA Register

Under Section 31 of the Human Fertilisation and Embryology Act 1990 ("the Act"), the HFEA is required to keep a register containing certain categories of information. The Act prohibits disclosure of data held on the HFEA register, subject to a number of specified exceptions. Disclosure of information which is not permitted by an exception may constitute a criminal offence.

7. Notes

- 7.1 This policy will be reviewed by the Audit and Governance Committee annually.
- 7.2 An anonymised summary of issues raised under this whistleblowing policy and remedial actions taken will be forwarded annually to the Authority for information.
- 7.3 The role of the HFEA as a regulatory body:

Under the provisions of the Public Interest Disclosure Act 1998 employees of an organisation are able to disclose publicly (under certain circumstances) their concerns about legitimacy or public interest aspects of the organisation within which they work. Although the Act requires that concerns be raised internally in the first instance, there are provisions for disclosure to be made to a regulatory body. The HFEA is itself one such regulatory body.

The procedure for dealing with a public interest disclosure from a member of staff of one of the licensed centres for which the HFEA is the regulatory body is <u>not covered by this policy</u> and prior to any separate procedure being issued, guidance must be sought from the Director of Compliance and Information.

Procedure Diagram

ISSUES OF CONCERN IDENTIFIED

OBTAIN INFORMATION FROM PUBLIC CONCERN AT WORK or NAO IF REQUIRED

RAISE ISSUE(S) WITH LINE MANAGER / CEO / HR MANAGER AS APPROPRIATE (Para. 6.1)

ISSUE(S) DOCUMENTED

INVESTIGATION OF MATTERS RAISED BY APPROPRIATE INDIVIDUALS

FEEDBACK PROVIDED TO WHISTLEBLOWER

FOLLOW UP ACTION TAKEN IN RESPECT OF ALLEGATION AS APPROPRIATE

SUMMARY NOTE FORWARDED TO CHAIR FOR INCLUSION IN CENTRAL RECORD

Procedures for **external disclosures** will depend upon the procedures of the body to whom disclosures are made. **Public Concern at Work** or the **NAO** will be able to provide information in this respect. Where matters raised from external disclosure procedures are (as appropriate) subsequently investigated and resolved internally, a written record of the matters raised and actions taken should be forwarded to the Chair for inclusion in the central record of issues referred under this policy.

The identity of the individual making the disclosure will be kept confidential if the staff member so requests unless disclosure is required by law.

Seven Principles of Public Life (The as recommended by the Nolan Committee)

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations which might influence them in the performance of their official duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards or benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

Leadership

Holders of public office should promote and support these principles by leadership and example.

These principles apply to all aspects of public life.

Document name	Public Interests Disclosure
Doc Ref No.	2014/021228
Release date	10 December 2014
Author	Head of HR
Approved by	CMG/AGC/Staff Forum
Next review date	December 2015
Total pages	9

Version/revision control

Version	Changes	Updated by	Approved by	Release date
0.1	Created	Head of Finance	Head of HR	July 2010
0.2	Revisions and updates	Head of Finance	CMG/AGC/ Staff Forum	May 2012
0.3	Revisions and updated	Head of HR	Staff Forum/CMG/ AGC	December 2014
0.4	Minor clarification in 6.8 omitted at time of (0.3 above)	Head of HR	As above	February 2015
0.5	Reviewed/updated prior to AGC	Head of Finance and Head of HR		December 2016



Annual review of committee effectiveness

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	Demonstrating efficiency economy and value	
Details:				
Meeting	Audit and Governance	Committee		
Agenda item	16			
Paper number	[AGC (07/12/2016) 52	1 SK]		
Meeting date	7 December 2016			
Author	Siobhain Kelly			
Output:				
For information or decision?	Information and comm	ent.		
Recommendation	AGC is invited to consider and comment on the Committee's effectiveness, using the supplied NAO checklist as a basis for discussions			
Resource implications	In budget.			
Implementation date	Any suggested changes to be fed into annual review of standing orders, reported to Authority in March 2017			
Organisational risk	🛛 Low	☐ Medium	🗆 High	
Annexes	Annex 1: NAO checklis	st for Audit Committees		

1. Introduction

- **1.1.** It is now an established process for the HFEA's committees to conduct a review of their effectiveness annually. Such reviews are conducted in the autumn, with the results feeding in to the Authority, along with any changes to Standing Orders, in the following spring. While other HFEA committees have standard internal proformas as a guide to their annual review, the Audit and Governance Committee uses the NAO's Audit Committee checklist (at annex A) as a guide for its review.
- **1.2.** This NAO checklist has not been updated since the committee used it for its annual review in 2015.
- **1.3.** This paper provides some prompts on the matters committee members may wish to reflect upon regarding the activities and performance of the committee in the past year.

2. Committee meetings, functions and agendas

- 2.1. Since the last annual review in 2015, the Committee has met four times, as planned. The Committee has been quorate at all meetings, and had a full complement of four members at two meetings. In addition, observers or representatives from DH have been present. Both internal and external auditors were represented at all meetings. The committee had recognised the challenge of achieving quoracy and has recently increased its membership to five, to reduce the burden on the existing members.
- 2.2. After a year of change (2014, with a new Chair and Director of Finance and Resources) this year has been one of stability and building capacity. Apart from the usual items taken to AGC, focus has been put on providing assurance for the IfQ project. Further work has been undertaken on a move to risk assurance mapping, which will continue in the future. Delegated powers and functions appear to be appropriate and lines of communication with the Authority will have improved with a formal report each year. There are two ongoing actions from last year's review external member attendance at inspections and Authority meetings which are dependent on members' availability.

3. Recommendation

- **3.1.** The NAO checklist is seen as a guide for all public sector organisations, from the largest to the smallest, and therefore and must be applied in a proportionate way. It is not intended as having to be fully completed by every committee regardless of the organisations size; rather, it acts as a prompt for committees to follow in conducting their reviews.
- **3.2.** AGC is invited to consider the NAO checklist in advance of the 7 December meeting, and feed back views at that meeting. The Head of Corporate Governance (interim) will capture views during the meeting, before circulating a final report for agreement remotely after the meeting.



GOOD PRACTICE

The Audit Committee self-assessment checklist

2nd edition January 2012

Financial Management and Reporting

Our vision is to help the nation spend wisely.

We apply the unique perspective of public audit to help Parliament and government drive lasting improvement in public services.

The National Audit Office scrutinises public spending for Parliament and is independent of government. The Comptroller and Auditor General (C&AG), Amyas Morse, is an Officer of the House of Commons and leads the NAO, which employs some 860 staff. The C&AG certifies the accounts of all government departments and many other public sector bodies. He has statutory authority to examine and report to Parliament on whether departments and the bodies they fund have used their resources efficiently, effectively, and with economy. Our studies evaluate the value for money of public spending, nationally and locally. Our recommendations and reports on good practice help government improve public services, and our work led to audited savings of more than £1 billion in 2011.

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Contents

Introduction 4

Section I

Good practice principles for Audit Committees **6**

Section II

The role of the Chair: good practice 21

Section III

Committee support: good practice 24

Introduction

1 This Checklist1 has been designed to help Audit Committees in central government assess how well they apply good practice. The criteria we have used are derived largely from the Audit Committee Handbook (March 2007)2 published by HM Treasury.

2 The Handbook highlights five good practice principles which aim to answer the following key questions:

- **Principle 1: The Role of the Audit Committee** Does the Audit Committee effectively support the Board and the Accounting Officer by reviewing the completeness of assurances to satisfy their needs, and by reviewing the reliability and integrity of these assurances?
- Principle 2: Membership, Independence, Objectivity and Understanding Is the Audit Committee suitably independent and objective, and does each member have a good understanding of the objectives, priorities and risks of the organisation, and of their role on the Audit Committee?
- **Principle 3: Skills** Does the Audit Committee contain or have at its disposal an appropriate mix of skills to perform its functions well?
- **Principle 4: Scope of Work** Is the scope of the Audit Committee suitably defined, and does it encompass all the assurance needs of the Board and Accounting Officer?
- **Principle 5: Communication** Does the Committee engage effectively with Financial and Performance Reporting issues, and with the work of internal and external audit? And does the Audit Committee communicate effectively with the Accounting Officer, the Board, and other stakeholders?

3 For each principle, we have developed a series of Good Practice Questions to help Audit Committees conclude whether they are meeting these principles. These are set out in **Section I** of this checklist.

4 In addition, the role of the Chair and the provision of appropriate secretariat support are key for an effective Audit Committee. The Handbook details Good Practice Questions on these two roles. **Sections II** and **III** of this checklist include questions that will enable the Audit Committee to determine if they currently meet this guidance.

¹ This Checklist was originally published in November 2009 and has been updated (January 2012) to reflect the requirement for departments, their executive agencies and arm's-length bodies to produce a Governance Statement in place of the Statement on Internal Control in their annual report and accounts for 2011-12 onwards. Guidance on the Governance Statement is set out in the revised Chapter 3 of Managing Public Money (HM Treasury, 2011)

² Corporate governance in central government departments: Code of good practice (HM Treasury, July 2011) provides that Audit Committees should be established and function in accordance with the Audit Committee Handbook (HM Treasury, March 2007).

5

How to use this Checklist

5 To help Audit Committees conclude as to whether they are meeting the Principles highlighted above, we have developed Good Practice Questions to inform the thinking process. These Questions are phrased to identify 'yes', 'no' or 'not applicable' responses.

6 We recognise, though, that organisations and their Audit Committees vary considerably in their size and in the complexity of issues that they deal with. In some circumstances, it may therefore be more appropriate to only use the more important Questions to help inform debate – and we have highlighted these in **bold**.

7 Also, the checklist is not exhaustive, and should the Audit Committee or their organisation feel that they have experience of other good working practice that will make the Committee work more effectively, they should not be deterred from implementing these practices, after consulting with the Board, if appropriate.

NAO Facilitated Workshops

8 To help Audit Committees use this checklist, the National Audit Office, as part of its performance improvement work, offers **Facilitated Workshops** for Audit Committees to help them use a tailored version of this checklist and draw conclusions as to their effectiveness. In this way, the workshop provides an opportunity for individual Audit Committees to work together, away from their normal business, to assess how well they work and establish areas to develop further. The workshop is followed up with an Action Plan that draws from the decisions and actions raised. This Action Plan will be owned by the Audit Committee, and act as the means by which decisions are implemented and reviewed.

9 If you would like the NAO to facilitate a workshop for your Audit Committee, please ask your usual NAO contact or Client Lead.

10 This checklist is also available as a Word document to enable Audit Committees to record their responses electronically.

National Audit Office November 2009

Section I Good practice principles for Audit Committees

Principle 1: The role of the Audit Committee

The Audit Committee should support the Board and the Accounting Officer by reviewing the comprehensiveness of assurances in meeting the Board and Accounting Officer's assurance needs, and reviewing the reliability and integrity of these assurances.

Good Practice Questions

Те	rms of Reference	Yes	No	N/A
1	Have all executive responsibilities, and making or endorsing of decisions been excluded from the roles and responsibilities of the Audit Committee members?			
2	Does the Audit Committee follow up recommendations regarding its effectiveness?			
3	Does the Audit Committee's role include monitoring and reviewing the executive's processes for assessing, reporting and owning business risks and their financial implications?			
4	Has the role and responsibilities of the Audit Committee been clearly defined and communicated to all Audit Committee members, along with details of how the Committee supports the Board?			
5	Are the Terms of Reference reviewed at least annually by the Board and the Audit Committee, to ensure that the work of the Audit Committee is aligned with good practice and business needs?			
6	Do the Terms of Reference include rules for a quorum?			
7	Does the Audit Committee meet regularly (at least four times a year), and do meetings coincide with key dates in the financial reporting and audit cycle?			

Additional Comments:

Conclusions

Do we achieve **Principle 1: The Role of the Audit Committee** – Does the Audit Committee support effectively the Board and the Accounting Officer by reviewing the comprehensiveness of assurances to satisfy their needs, and by reviewing the reliability and integrity of these assurances?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

Principle 2: Membership, Independence, Objectivity and Understanding

The Audit Committee should be independent and objective; in addition, each member should have a good understanding of the objectives and priorities of the organisation and of their role as an Audit Committee member.

Good Practice Questions

Ind	Independence		No	N/A
8	Is the Chair of the Audit Committee different from the Chair of the Board?			
9	Are the Audit Committee members either independent non- executive Board members or independent external members, and have they been appointed for an appropriate period of time (e.g. three years)?			
Re	ationship with the Executive			
10	Are the Executive members of the organisation invited to attend Audit Committee meetings, participate in discussions, and provide information to the Audit Committee as and when the Audit Committee deems it necessary?			
Oth	ner Participants			
11	Where appropriate, does a representative from the sponsoring body attend the Audit Committee meetings (e.g. if an Executive Agency, does a member of the Sponsoring Department attend the meeting)?			
12	Does the Accounting Officer, Finance Director, Head of Internal Audit and the External Auditor routinely attend the Audit Committee, or attend at the request of the Audit Committee members?			
13	Are the numbers attending the Audit Committee meetings sufficient to deal adequately with the agenda, but not too many to blur issues?			
Co	nflict of Interest			
14	Is the first agenda item of every meeting a request for the Audit Committee members to declare any potential conflict of interest with any of the business items on the Audit Committee's agenda?			

Con	flict of	Interest (continued)	Yes	No	N/A
15	agen meml	tances where there is a declaration of interest in any of the da business items, are appropriate actions taken, e.g. is the ber asked to leave the meeting while the business item is discussed?			
16	time,	tances where the conflict of interest is likely to last for a long has the Audit Committee member been asked to relinquish her membership?			
17		ne Audit Committee members required to declare their est in a register of interests?			
Tern	ns of A	Appointment			
18	of wh	I Audit Committee members have a clear understanding nat is expected of them in their role, set out in a letter of intment, including:			
	a.	their appointment and purpose;			
	b.	the support and training that they will receive;			
	c.	the commitment required;			
	d.	their remuneration;			
	e.	conflict of interest procedures;			
	f.	expected conduct;			
	g.	duration of appointment and how often it may be renewed;			
	h.	how their individual performance will be appraised, including a clear understanding of what would be regarded as unsatisfactory performance; and			
	i.	termination conditions?			

Conclusions

Do we achieve **Principle 2: Membership, Independence, Objectivity and Understanding** – Is the Audit Committee suitably independent and objective, and does each member have a good understanding of the objectives, priorities and risks of the organisation, and of their role on the Audit Committee?

What do we need to do to enhance the Audit Committee?

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

Principle 3: Skills

The Audit Committee should collectively possess an appropriate skills mix to perform its functions well.

Ran	ge of S	Yes	No	N/A	
19	Are there formal assessment criteria for the appointment of the Audit Chair, including attitudes to non-executives, strength of personality, experience of chairing, and time commitment?				
20	or ex	e assessment criteria of Committee members include, pect Audit Committee members to acquire as soon as ible after appointment:			
	a.	understanding of the objectives of the organisation and current significant issues for the organisation;			
	b.	understanding of the organisation's structure, including key relationships such as that with a sponsoring department or major partner;			
	c.	understanding of the organisation's culture;			
	d.	understanding of any relevant legislation or other rules governing the organisation; and			
	e.	broad understanding of the government environment, particularly accountability structures and current major initiatives?			
21		the Audit Committee ensure that there are areas of ctive understanding, including:			
	a.	accountancy – with at least one member having recent and relevant financial experience;			
	b.	governance, assurance and risk management;			
	c.	audit;			
	d.	technical or specialist issues pertinent to the organisation's business;			
	e.	experience of managing similar sized organisations;			
	f.	understanding of the wider environments in which the organisation operates; and			
	g.	detailed understanding of the government environment and accountability structures?			

Add	litional Skills			No	N/A
22	Do th	e Audit Committee members feel empowered to:			
	a.	co-opt members for a period of less than one year to provide specialist skills that the members do not have to be an effective Committee;			
	b.	procure specialist advice at reasonable approved expense to the organisation, on an ad-hoc basis to support them in relation to particular pieces of Committee business.			
Trai	ning a	nd Development			
23	mem to im	ere an induction checklist for new Audit Committee bers that details key things that they must do e.g. visits portant business locations, meetings with Board, Risk iger, Internal Audit and External Auditors?			
24	trainir	l new members of the Audit Committee attend an induction ng course for Audit Committee members run by the National ol of Government, or other sector-related organisation?			
25	suffic and to	the Audit Committee ensure that new members have ient knowledge of the business to identify the key risk areas o challenge both line management and internal and external ors on critical and sensitive issues?			
26		the Audit Committee and the Chair make recommendations Board on the Committee's and individual members training s?			
27	devel	the Audit Committee keep abreast of best practice and opments in corporate governance in central government and widely?			

Conclusions

Do we achieve Principle 3: Skills - Does the Audit Committee contain or have at its disposal an appropriate mix of skills

to perform its functions well?

What do we need to do to enhance the Audit Committee?

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

Principle 4: Scope of Work

The scope of the Audit Committee's work should be defined in its Terms of Reference, and encompass all the assurance needs of the Board and Accounting Officer. Within this, the Audit Committee should have particular engagement with the work of Internal Audit, the work of External Auditor, and Financial Reporting issues.

Rela	tionship with Internal Audit	Yes	No	N/A
28	Does the Audit Committee consider the independence and effectiveness of Internal Audit?			
29	Does the Audit Committee consider that the experience, expertise and professional standard of the Internal Audit team are appropriate for the size, complexity, and inherent risk of the organisation?			
30	Does the Audit Committee consider that the scope of Internal Audit work, the available resources at its disposal, and their access to information and people allow it to address significant risks within the organisation?			
31	Does the Audit Committee review and approve the Internal Audit plan before they commence any work and make suggestions regarding risk and problem areas that the audit could address in the short and long term?			
32	Does the Audit Committee receive regular progress reports on studies/work undertaken by Internal Audit?			
33	Does the Audit Committee review internal audit reports and management responses to issues raised, and monitor the progress made on Internal Audit's recommendations?			
Rela	tionship with External Audit			
34	Where relevant, does the Audit Committee consider the independence, objectivity, and effectiveness of the External Auditors?			
35	Does the Audit Committee periodically obtain the views of the External Auditor on the work and effectiveness of the Audit Committee?			

Rela	tionship with External Audit (continued)	Yes	No	N/A
36	Is the Audit Committee informed by the External Auditors on an an annual basis as to their quality control procedures and compliance with applicable UK ethics guidance?			
37	Does the Audit Committee consider the External Auditor's Audit Strategy before they commence work, and make suggestions regarding risk and problem areas the audit could address in the short and long term?			
38	Do the External Auditors inform the Audit Committee of key developments and issues at key stages of the audit?			
39	Where relevant, does the Audit Committee review the audit fees?			
40	Does the Audit Committee consider the management letter and other relevant reports (e.g. the NAO's Value for Money work), and the management's response, and monitor the progress made on the recommendations?			
Rela	tionship between Internal Audit and External Auditors			
41	Does the Audit Committee consider whether there are areas where joint working between Internal Audit and the External Auditors would be beneficial?			
42	Does the Audit Committee seek confirmation from Internal Audit and the External Auditors on the effectiveness of the relationship?			
Frau	ıd			
43	Does the Audit Committee consider whether effective anti- fraud and corruption policies and procedures are in place and operating effectively?			
44	Does the Audit Committee consider whether there is a code of conduct and its distribution to employees?			
45	Does the Audit Committee consider whether management arrangements for whistle-blowing are satisfactory?			

Inter	ternal Control			No	N/A
46	govei	the Audit Committee consider whether corporate mance is embedded throughout the organisation, rather than ed as a compliance exercise?			
47	interr	the Audit Committee consider whether the system of al reporting gives early warning of control failures and ging risks?			
48	State	the Audit Committee consider whether the Governance ment is sufficiently comprehensive and meaningful, and vidence that underpins it?			
49	inter	the Audit Committee satisfy itself that the system of nal control has operated effectively throughout the rting period?			
50	incluc	the Audit Committee consider whether financial control, ling the structure of delegations, enables the organisation to ve its objectives and achieve good value for money?			
51	proce	the Audit Committee monitor whether the organisation's dures for identifying and managing business risk have d for the relevant legislation and regulation?			
Fina	ncial I	Reporting			
52		the Audit Committee review the first draft of the annual unts before the External Auditors start work on them?			
53		re the Accounting Officer signs off the Annual Report Financial Statements, does the Audit Committee ider:			
	a.	that the accounting policies in place comply with relevant requirements, particularly the Treasury's Financial Reporting Manual and Accounts Direction;			
	b.	that there has been a robust process in preparing the accounts and annual report;			

Fina	ancial	Yes	No	N/A	
	C.	whether the accounts and annual report have been subjected to sufficient review by management and by the Accounting Officer and/or Board;			
	d.	that when new or novel accounting treatments arise, whether appropriate advice on accounting treatment has been taken;			
	e.	whether there is an appropriate anti-fraud policy in place, and whether losses are suitably recorded;			
	f.	whether suitable processes are in place to ensure accurate financial records are kept;			
	g.	whether suitable processes are in place to ensure regularity and propriety is achieved; and			
	h.	whether issues raised by the External Auditors have been given appropriate attention.			
54	Com	re the accounts have been qualified, does the Audit mittee consider the action taken by the Board to deal the causes of the qualification?			
55	finar the c	s the Audit Committee satisfy itself that the annual ncial statements represent fairly the financial position of organisation, regardless of the pressures on executive agement?			
56	Repr	re the Accounting Officer signs off the Letter of resentation, does the Audit Committee review it and give cular attention to non-standard issues of representation?			

Conclusions

Do we achieve **Principle 4: Scope of Work** – Is the scope of the Audit Committee suitably defined, and does it encompass all the assurance needs of the Board and Accounting Officer?

What do we need to do to enhance the Audit Committee?

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

Principle 5: Communication

The Audit Committee should ensure it has effective communication with the Board, the Head of Internal Audit, the External Auditor, and other stakeholders.

Rep	orting	to the Board	Yes	No	N/A
57		the Audit Committee send regular reports or provide oral tes to the Board that they review at their meetings?			
58	Boar	the Audit Committee provide an Annual Report to the d, timed to support preparation of the Governance ment?			
59		the Annual Report of the Audit Committee present the mittee's opinion about:			
	a.	the comprehensiveness of assurances in meeting the Board and Accounting Officers needs;			
	b.	the reliability and integrity of these assurances;			
	C.	whether the assurance available is sufficient to support the Board and Accounting Officer in their decisions taken and their accountability obligations;			
	d.	the implication of these assurances for the overall management of risk;			
	e.	any issues the Audit Committee considers pertinent to the Governance Statement, and any long-term issues the Committee thinks the Board and/or Accounting Officer should give attention to;			
	f.	financial reporting for the year;			
	g.	the quality of both Internal and External Audit and their approach to their responsibilities; and			
	h.	the Audit Committee's view of its own effectiveness, including advice on ways in which it considers it needs to be strengthened or developed.			

Conclusions

Do we achieve **Principle 5: Communication** – Does the Committee engage effectively with Financial and Performance Reporting issues, and with the work of internal and external audit? And does the Audit Committee communicate effectively with the Accounting Officer, the Board and other stakeholders?

What do we need to do to enhance the Audit Committee?

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

Section II The role of the Chair: good practice

The Chair of the Audit Committee has particular responsibility for ensuring that the work of the Audit Committee is effective, that the Committee is appropriately resourced, and that it is maintaining effective communication with stakeholders.

Ager	nda Setting	Yes	No	N/A
60	Is the Board Secretary different from the Audit Committee Secretary?			
61	Does the Chair of the Audit Committee meet with the Committee Secretary before every meeting to discuss and agree the business for the meeting?			
62	Are inputs on Any Other Business formally requested in advance from Committee members and attendees?			
63	Are outline agendas planned one year ahead to cover core activities and specific issues on a cyclical basis?			
64	Does the agenda exclude executive business, so that there is no overlap with the work of the Board whilst linking to the main elements of the organisation's business?			
65	Are the meetings set for a length of time which allows all business to be conducted, yet not so long that the meeting becomes ineffective?			
66	Does the Chair encourage full and open discussion and invite questions at the Audit Committee meetings?			
Com	munication			
67	Does the Chair of the Audit Committee have open lines of communication with the Board, Head of Internal Audit, and the External Auditors?			
68	Does the Chair encourage all Committee members to have regular interface with the organisation and its activities to help them understand the organisation, its objectives, and business needs and priorities?			
69	Do reports to the Audit Committee communicate relevant information at the right frequency, time, and in a format that is effective?			
70	Does the Audit Committee issue guidelines concerning the format and content of the papers to be presented to the Committee?			

Mon	itoring Actions	Yes	No	N/A
71	Does the Chair or the Secretariat ensure that all action points from Committee meetings are appropriately acted upon?			
72	Does the Chair or the Secretariat ensure that members who have missed a meeting are appropriately briefed on the business conducted in their absence?			
73	Is a report on matters arising made and minuted at the Audit Committee's next meeting?			
Арр	raisal			
74	Does the Chair ensure that the Committee members are provided with an appropriate appraisal of their performance as a Committee member?			
75	Does the Audit Committee Chair seek appraisal of their personal performance from the Accounting Officer or Chair of the Board?			
76	Are Audit Committee meetings well attended, with records of attendance maintained and reviewed annually by the Board?			
Арр	ointments			
77	Is the Chair involved in the appointment of new Committee members, including providing advice on the skills and experience required of the new individual?			

Conclusions

Do we meet **Good Practice: the Role of the Chair** – Is the Committee appropriately resourced, work planned in advance as far as possible, and effective communication with stakeholders maintained?

What do we need to do to enhance the Audit Committee?

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

Section III

Committee support: good practice

The Audit Committee should be provided with appropriate Secretariat support to enable it to be effective. This is more than a minute-taking function – it involves providing proactive support for the work of the Committee, and helping its members to be effective in their role.

Does the Audit Committee Secretariat:			No	N/A
78	Commission papers as necessary to support agenda items?			
79	Circulate meeting documents to all Committee members, Internal Audit and External Auditors in good time before each meeting, to allow members time to study and understand the information e.g. at least one week before the meeting?			
80	Arrange for Executives/senior management to be available as necessary to discuss specific agenda items with the Audit Committee during meetings?			
81	Keep records of meetings and minutes after they have been approved by the Audit Chair and circulate them to Committee members, Head of Internal Audit, External Auditors, Board, and the Accounting Officer on a timely basis e.g. within one week of the meeting?			
82	Ask for confirmation that the minutes are a true and fair representation of a summary of the business taken by the Audit Committee?			
83	Ensure that the minutes clearly state all agreed actions, the responsible owner, when they will be done by and any advice given from any stakeholders?			

s the <i>l</i>	Yes	No	N/A	
Arra	nge the Chair's bilateral meetings with:			
a.	the Accounting Officer, the Head of Internal Audit, Director of the External Auditors;			
b.	the Chair of the Board of sponsored NDPBs.			
relev	ant background information about developments in the			
	Ensu mee Supp to the Arra a. b. Keep relev orga Main due t	Director of the External Auditors;	Ensure action points are being taken forward between meetings? □ Support the Chair in the preparation of Audit Committee reports to the Board? □ Arrange the Chair's bilateral meetings with: □ a. the Accounting Officer, the Head of Internal Audit, Director of the External Auditors; □ b. the Chair of the Board of sponsored NDPBs. □ Keep the Chair and members in touch with developments and relevant background information about developments in the organisation? □ Maintain a record of when members' terms of appointment are due for renewal or termination? □ Ensure that appropriate appointment processes are initiated □	Ensure action points are being taken forward between meetings? □ Support the Chair in the preparation of Audit Committee reports to the Board? □ Arrange the Chair's bilateral meetings with: □ a. the Accounting Officer, the Head of Internal Audit, Director of the External Auditors; □ b. the Chair of the Board of sponsored NDPBs. □ Keep the Chair and members in touch with developments and relevant background information about developments in the organisation? □ Maintain a record of when members' terms of appointment are due for renewal or termination? □ Ensure that appropriate appointment processes are initiated □

Conclusions

Do we meet Good Practice: Support for the Committee – Does the Committee receive appropriate support

from its secretariat?

What do we need to do to enhance the Audit Committee?

- 1 none of the good practice questions.
- 2 some of the good practice questions.
- 3 most, if not all of the good practice questions.

2016-12-07 Audit and Governance Committee Meeting Page 163 of 167

Where to find out more

The National Audit Office website is www.nao.org.uk

Links to other websites <u>www.hm-treasury.gov.uk/audit committee handbook.htm</u> <u>www.hm-treasury.gov.uk/d/mpm_annex3.1.pdf</u>

If you would like to know more about the NAO's work in this area please email **Z5-FMGP@nao.gsi.gov.uk**

www.nao.org.uk/financial-management

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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	17				
Paper number	AGC (07/12/2016) 522				
Meeting date	7 December 2016				
Author	Morounke Akingbola, Head of Finance				
Output:					
For information or decision?	Decision				
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the plan.				
Resource implications	None				
Implementation date	N/A				
Organisational risk	🛛 Low	☐ Medium	□ High		
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information				
Annexes	N/A				

Audit & Governance Committee Forward Plan

AGC Items Date:	21 Mar 2017	13 Jun 2017	3 Oct 2017	5 Dec 2017
Following Authority Date:	10 May 2017	28 Jun 2017	15 Nov 2017	Jan 2018
Meeting 'Theme/s'	Finance and Resources	Annual Reports, Information Governance, People	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity
Reporting Officers	Director of Finance & Resources	Director of Finance & Resources	Director of Strategy & Corporate Affairs	Director of Compliance and Information
High Level Risk Register	Yes	Yes	Yes	Yes
Information for Quality (IfQ) Prog	Yes			Yes
Annual Report & Accounts (inc Annual Governance Statement)		Yes – For approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report	Audit Planning Report	Audit Planning Report
Information Assurance & Security		Yes		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Results, annual opinion approve draft plan	Update	Update	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes		Yes		

AGC Items Date:	21 Mar 2017	13 Jun 2017	3 Oct 2017	5 Dec 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
Legal Risks	Yes			
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				